Primary Care Procedures in Women's Health

An International Guide for the Primary Care Setting

Cathryn B. Heath
Sandra M. Sulik
Editors

Second Edition

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In memory of my mom, who provided constant faithful support and encouragement; and to my family, Jeff, Maryann, Julie, Read, Tammy, Abbie, Joe, Lydia, and Lisa, who have always believed in me. Special thanks to Ferne for her photo help, to my nurses and my many patients who graciously allowed picture taking during their procedures. My thanks to Cathy for her friendship, support, and energy throughout this process. Thanks to all our contributing authors for sharing their expertise and wisdom.
SMS
Special thanks to my wonderful husband John and my dear friend Sandy. To my family, friends, new and old colleagues, staff, and patients: How lucky I am to be surrounded by such wonderful people! To Brendan, Austin, and Claire who have provided strength, encouragement, wisdom, and patience. Thank you to all who contributed their time writing and rewriting chapters and to our colleagues at Springer Nature for assisting us with this journey.
CBH

Preface

Despite the common perception that medicine is becoming specialty driven, there are many reasons for primary care providers to offer women's health procedures in an office setting. Women feel more comfortable having procedures done by clinicians whom they already know and trust. Continuity of care is still valued by patients, who trust their primary care providers to work with them as collaborators in the decision-making process. Women have found that their options for care have become limited, not by their own decision but by the lack of training of their provider. In rural areas, the barriers of time, expense, and travel often prevent many women from obtaining necessary care; yet many of the procedures that these women are requesting are relatively easy to learn. Women who then refer friends and family by word of mouth share positive experiences.

This book is designed to assist not only the clinician performing the procedures covered, but also the office staff with setting up the equipment tray prior to performing the procedure and with preparing office documents and coding information needed to complete the procedure. Most procedures covered can be done with a minimum investment in equipment and require minimal training. Some of the procedures either require or are best performed after a training course; however, even in these cases, this book will serve as a solid aid and review to the practitioner in performing the procedures within the office setting. The book can be used as a quick reference guide to re-familiarize the practitioner with the steps to a given procedure.

The book begins with basic chapters that are applicable to all procedures. Each chapter thereafter outlines one women's health procedure and contains an overview of background information, indications, contraindications, complications, equipment needed, procedure steps, an office note, patient instructions, and a patient handout. Typical case studies and case study outcomes serve as illustrations of typical women found in practices who have needed each procedure. The "tricks and helpful hints" section draws on the years of experience of providers who have performed each procedure many times and have overcome common difficulties often encountered by newcomers to the procedure. A setup picture of equipment is included to assist office staff in gathering the appropriate materials prior to starting

the procedure. Algorithms assisting the provider with the steps to take at decision points of each procedure are also included to serve as a quick guide. References and additional resources are provided for further education, learning, and equipment needs. Key words and questions for learners are available to spark a discussion related to a specific procedure while teaching the procedure. Illustrations, images, and photos further enrich the chapters.

We have elected to start our procedure book with the most common of procedures found in women's health – these include pelvic examinations and Pap smear collection – and its content extends to some of the more complicated office procedures, such as manual vacuum abortions and loop electrical excision procedure (LEEP). There are sections on basic women's health, contraceptive, diagnostic, and therapeutic procedures. A primary care physician (family physicians and a pediatrician) experienced with performing the procedure has written the chapter content. Also included are specific chapters on coding and billing, authored by a physician who oversees a large student health center. A separate chapter is included on the medico-legal aspects of performing women's health procedures in an office setting. This chapter outlines the necessary legal and regulatory considerations to address before adding many of these procedures to an office practice. We have also included a chapter on population health in this edition.

Many procedures have become a "lost art." For example, as fewer patients choose diaphragms as a method of contraception, fewer clinicians are trained in fitting and inserting them. A number of these common women's health procedures are not routinely taught in residency or training programs, and, hence, many practitioners do not offer them in their offices. Some are trained during residency but have not performed the procedure for some time and need a review prior to performing the procedure. This book will serve as a quick refresher for those procedures for which the clinician may have had previous training but may not have performed for a while.

The old standard of "see one, teach one, do one" gets more difficult as procedures become more complex and require more training before they can be performed. A number of excellent procedures courses are offered by the American Academy of Family Physicians, American College of Obstetrics and Gynecology, and the American Society of Colposcopy and Cervical Pathology. Suppliers of medical equipment also offer training courses. Often, a training package is offered as part of the purchase of more expensive pieces of equipment. Finding a local experienced physician to precept and mentor a less experienced clinician in the initial few procedures is another way to become skilled in performing most of these procedures after a training course has been taken. Proctoring or precepted experience is crucial, especially for complex procedures, not only to reduce medico-legal liability but also to ensure patient safety.

Having the patient schedule a separate appointment to have a procedure performed allows the patient time to read the information provided about the upcoming procedure, ask appropriate questions, and prepare herself for the actual procedure. This allows for the proper amount of time to be scheduled for the procedure to be done; for the inexperienced clinician, additional time should be scheduled.

Scheduling new procedures at the end of an office session allows more time. As the practitioner's confidence grows, scheduling times can be adjusted. Scheduling an office session dedicated to just procedures can also be helpful.

A well-trained staff is the clinician's best asset. A lunchtime training session can be very helpful for teaching the staff proper sterilization of instruments, sterile and nonsterile equipment setup, and how best to assist with the procedure itself. Appropriate equipment setups can greatly ease the procedure. Proper Occupational Safety and Health Administration (OSHA) guidelines must also be followed. For most women's health procedures, it is wise to have an assistant in the room with the provider, to assist as well as to comfort and chaperone the patient. A written consent should be done prior to most procedures.

It is important to understand the appropriate billing of your services in order to be properly compensated for your work. Both CPT® codes developed by the American Medical Association and the ICD10 (International Classification of Diseases, 10th Revision, Center for Disease Control and Prevention) codes are provided as suggested codes for each procedure. There may be other more appropriate codes; therefore, each procedure should be coded based on the procedures done or services rendered. Some minor procedures, such as cervical polyp removal, do not have a specific CPT® code. In those circumstances, the CPT® manual recommends that the clinician code the appropriate-level office visit. As covered in our billing and coding chapter, certain insurance plans reimburse differently for some of the contraception devices, and insurance reimbursement varies across the county. It is important that the provider be aware of these differences as these procedures are offered to the patient in the office. Prior authorization is sometimes necessary as well. Some devices (levonorgestrel intrauterine system or etonorgestrel implantables) may need to be ordered through the patient's insurance company and delivered to the office before insertion.

It is our hope that this book will act as a manual for women's health procedures for all providers, including family physicians, gynecologists, general internists, residents, nurse practitioners, nurse midwives, and physician's assistants. There are presently no other texts specifically written for providers and staff of women's health services. It is our hope that this book will allow the clinician to become competent, efficient, and comfortable in performing each procedure in the office on a regular basis.

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Chapter 1
Introduction: The Case for Procedures in Primary Care

Cathryn B. Heath and Sandra M. Sulik

Case Studies

Dr. Jerri Neilsen had a problem. She needed to do a procedure that she had never performed on anyone. There were no specialists available to do it. The nearest specialist was a continent away. What did she do? According to her first-hand account in *Ice Bound: A Doctor's Incredible Battle for Survival at the South Pole*, she received instructions by computer and by satellite telephone on how to do a Fine Needle Aspiration (FNA). She and her assistant, who was an emergency medical technician (EMT), practiced the aspiration technique on some fruit, and then they both did an FNA of a breast mass – on Dr. Jerri Neilsen [1].

One of the authors and editors of this book (CBH) was taking care of one of her patients in New Jersey, a state with more specialist physicians per capita than any state in the United States. A woman requested an intrauterine device (IUD) placement, a procedure that the author had not done in several years. She told the patient that she had not done this procedure in quite some time and offered to send her to another physician. The patient's response was that she preferred her own primary care physician do the procedure, and the patient suggested that the author "just read the book and then go ahead." The procedure was successful and was the first of many IUD placements within this physician's practice in New Jersey.

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A patient came in to see one of the other authors and editors of this book (SMS) with symptoms of pressure in her vagina which worsened upon standing. With many health problems, the patient was considered at high risk for major morbidity and mortality from surgery. She came to the author's office for a pessary fitting, as there were few physicians in town who fit pessaries. SMS successfully treated the woman's symptoms with a pessary, which avoided major surgery and relieved her urinary incontinence. The grateful woman used the pessary successfully for many years.

Location of Practice

These cases exemplify the necessity for women's health procedures being done by primary care physicians such as family physicians, internists, pediatricians, and obstetricians/gynecologists and by primary care practitioners such as midwives, advanced nurse practitioners, and physician's assistants. Although obviously an extreme case, Dr. Neilsen's case typified a situation in which a woman has difficulty finding a physician to do a basic procedure, a concern common with many women who reside in rural areas. Currently, a significant healthcare disparity exists for women who reside in rural areas. Over 20% of the population of the United States resides in rural areas with rates as low as 26.5 primary care providers/100,000 patients in Mississippi and the rates in Georgia and Texas being only slightly higher (31/100,000 and 33.61/100,000, respectively) [2]. Primary care providers in this study included physicians, physician assistants, and advanced practice nurses.

The scope of practice of rural physicians has by necessity been broad, although the rate of surgical procedures reported by rural physicians in Canada was similar to those who practice in a more urban setting [3]. In a study of Canadian physicians, younger male physicians were more likely than middle-aged to older physicians to do procedures, except for women's health procedures, which were more likely to be done by women physicians [4]. In a survey of Wisconsin family physicians, Eliason and colleagues noted that 40% of family physicians reported doing skin surgery, flexible sigmoidoscopy, breast cyst aspiration, joint arthrocentesis, and Norplant® (Population Council, New York, NY, and Washington, DC) insertion. Female physicians performed more women's health procedures than other procedures in any setting [4].

In many instances, access to a specialist for routine procedures is difficult, and, thus, many generalist providers are doing procedures that in more suburban and urban regions are considered reserved for specialists. In a study of colonoscopy in rural communities, family physicians performed colonoscopies on patients with symptoms as well as on patients for screening. Family physicians successfully reached the cecum in 96% of the cases, with an average time of 15.9 min, finding neoplastic polyps in 22% of the patients and cancer in 2.5% of the patients [5].

Continuity of Care: "The Medical Home"

Patients prefer seeing the same provider and consider seeing the same provider every time they have a health problem as very important [6]. Patients prefer, in many cases, to have procedures done by a practitioner whom they know and trust. For instance, in a study conducted at an inner city clinic, 70% of patients thought it appropriate for their family physicians to do medical abortions. Forty-seven percent thought it appropriate for their family physicians to do first-trimester surgical abortions. Of the women who would personally consider an abortion, 73% preferred to have it done by their family physician, 22% preferred to go to a freestanding abortion clinic, and 5% had no preference [7]. In a survey done by the Kaiser Family Foundation, 54% of obstetricians/gynecologists stated that they would be very or somewhat likely to prescribe mifepristone for medication abortions. Fifty percent of family physicians, nurse practitioners, and physician's assistants reported interest in prescribing mifepristone. At the time of the survey, only 5% of family physicians currently performed surgical abortions [8].

In 2017, the rate of clinical procedures performed by family physicians at their practice revealed that 31% performed endometrial sampling, 74% performed skin procedures including biopsy and cryotherapy, and 12% performed colposcopy, among a variety of other procedures [9].

Many patients expect their generalist providers to perform common procedures, especially those done in an outpatient setting. Most patients appreciate continuity and find that receiving care (including procedures) from one provider improved the physician–patient relationship [10].

Procedure Training

A number of procedures have become a lost art, making it difficult for patients to access providers who feel comfortable performing these procedures. Physicians in the past have relied on learning procedures in medical school or residency; yet newer, more advanced procedures can only be offered in a postgraduate setting for most practicing physicians.

In medical school, family medicine clerkships provide some basis for learning common women's health procedures, such as obtaining a Pap smear. In a procedure knowledge survey, Pap smear was the only women's health procedure that students felt competent of being able to perform independently [11]. In Canada, 91% of physicians reported learning procedures in medical school or in a family medicine residency, whereas only 12.6% learned procedures in clinical practice settings, followed by 6.4% who reported learning procedures in formal skills training. Those in rural practice learned a relatively greater proportion of procedural skills through formal skills training [12].

While the general guidelines for women's health procedure skills within a family medicine residency [13] have mandatory procedures (endometrial biopsy, Pap smears, wet mount, and KOH prep), some less common procedures are no longer considered mandatory but are "recommended" (breast cyst aspiration, diaphragm fitting, IUD insertion and removal). Bartholin cyst or abscess treatment and colposcopy are considered "elective." There are some significant barriers to teaching and performing office-based procedures, which need to be overcome by residency practices, including assuring adequate volume to be able to teach the procedure, that the appropriate faculty are available, and that there is enough given time in the schedule to be able to perform the procedure [14].

The American Board of Internal Medicine requires as part of its core competency that all internal medicine residents perform Pap smears and endocervical cultures safely and competently [15].

Lack of experience may subvert the physician's confidence about incorporating procedures into his/her office setting. Sempowski and colleagues did a cross-sectional survey of Canadian family physicians' provision of minor office procedures and found that of the 108 family physicians and general practitioners in Kingston, Ontario, only 35.4% reported performing endometrial biopsies. The most common reason for not performing a specific procedure was the "lack of up-to-date skills" [16].

Insurance Coverage

The good news is that many insurance plans across the United States are covering contraceptive procedures more commonly than ever before. Due to the Patient Protection and Affordable Care Act, the United States now mandates that insurances cover the cost of preventive care and contraceptives. However, there are still many women who do not currently have healthcare coverage.

Conclusion

Whatever the rationale, women's health procedures are in demand, especially in a primary care setting, and are rewarding for both physician and patient alike. No matter where the location of the practice or what type of patient or provider may be involved, generalist providers can offer these procedures as part of their daily practice. All of these procedures are easy to learn, most require minimal equipment, and they offer services that improve women's health and the range of options for the care that all patients wish to receive from their provider.

Questions

- What are the advantages and disadvantages to primary care providers learning procedures?
- Which procedures are the easiest and hardest to implement within an office setting?
- What are some of the potential barriers to providing outpatient women's health procedures?

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Chapter 2
Coding, Billing, and Reimbursement for Procedures

Cathryn B. Heath

Introduction

Coding, billing, and reimbursement are an integral part of the procedures performed in today's modern medical office. Gone are the days when one could learn a procedure and then just expect payment for services rendered. Performing the actual procedure is only part of the process. At times, billing and coding can be even more complicated and time-consuming than actually performing the procedure itself. Appropriate billing with concomitant reimbursement is very satisfying and can gradually change the emphasis and tenor of a clinician's practice. It is crucial that, prior to instituting a new office procedure, the clinician and the billing staff review the proper billing and coding to ensure that payment will occur.

Procedure Coding

As seen in the various procedure chapters in this book, included within each chapter are appropriate codes that must be compatible with the procedures discussed and shown. If a clinician is seeing a patient for diagnoses other than just the procedure, each diagnosis and procedure needs to be coded separately. For instance, if a patient is being seen for a gynecologic exam and requests that her intrauterine device (IUD) be removed, the clinician would code the appropriate health maintenance code for the exam, use a -25 modifier, and then code for the IUD removal [1]. If the patient

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prefers to return another day for the IUD removal, one would only code for the actual procedure on the IUD removal visit.

Many procedures have global codes. Thus, if a procedure such as a Bartholin's gland excision requires a second visit for a recheck, the recheck is considered part of the original global procedure code and would not be billed as a second office visit. Similarly, if there are sutures being removed for a procedure done in the office, the suture removal should be covered in the global fee. There are some exceptions to the rule: for example, one can bill separately for a visit to review and discuss treatment options of colposcopy pathology.

Coding compatibility with the procedure is essential to ensure payment. Medicare's website (http://www.cms.gov) is an excellent place to start [2]. Healthcare Common Procedure Coding System ("HCPCS") has two levels. Level I coding is used to code for the procedure itself, associated with the appropriate ICD-10 code. There are stipulations for which ICD-10 (International Classification of Diseases, 10th Revision, Centers for Disease Control and Prevention) codes will be covered by private payers and CMS for a specific procedure. Level II HCPCS allows for coding for products and supplies.

It is imperative to have someone in your financial office who is prepared to review rejected claims, particularly for procedures, and who can pursue the reasons for rejection. As billing improves, rejected claims decrease in number. Coding also can be improved and facilitated by using specific coding software, websites, or standardized forms, some of which may even be accessed by either an electronic medical record or a handheld electronic device. There are many coding and billing software packages available in the market that will help promote effective coding.

Documentation of Procedures

All procedures need appropriate notes written by the clinician. Size and location of excised lesions should be documented, as reimbursement is determined by size, location, number of lesions removed, and the pathology of the lesion (benign versus malignant). Billing should be submitted based not only on the size of the lesion but also on the size of the margins. For instance, if a 1 cm lesion is removed using a margin of 0.2 cm on each side, the size would be considered 1.4 cm [3]. Follow-up should be clearly stated in order to document whether a subsequent visit should be considered part of the procedure.

Coding and billing for skin procedures is further complicated by the specific pathologic diagnosis of the lesion itself. For instance, coding for removal of a benign versus malignant lesion may be difficult until the biopsy results have returned to the office, which may be anywhere from 10 to 14 days after the date the actual procedure is performed. However, removal of a malignancy is generally reimbursed at an average of two to three times the amount of the removal of a benign lesion. Thus, in some instances in which the CPT® (AMA, Chicago, IL) code may be dra-

matically changed by the pathology results, it may be advisable to hold billing the particular procedure until the pathology report returns and is reviewed.

One can also attempt to bill for an unsuccessful procedure, though the likelihood of being reimbursed is much less [4]. Coding needs to be specific; for instance, if a procedure fails due to anatomic reasons, a -52 code is used as a failed procedure. If the procedure fails due to concern over a patient's well-being, as she has had severe pain or vasovagal symptom, it is considered a discontinued procedure and is coded as a -53. The payer will need to know the extent of what was done; attaching a copy of the office note to the claim will usually suffice. Some insurances do pay for an attempted procedure, while others do not.

Insurance Company Coverage

Medical procedures are highly scrutinized by insurance companies due to the expense of the procedure itself. Some insurance require prior authorization for procedures, which may include submitting prior office notes, labs, or radiology reports to substantiate the need for the actual procedure [5]. This varies nationally by region and by the policy negotiated by the patient's employer. The Patient Protection and Affordable Care Act, signed into law in 2010, currently requires that contraceptives be covered by insurance companies, including long-acting reversible contraceptives (LARCs). Medicaid coverage of LARCs is variable. It is best to check with the insurance company prior to performing the procedure.

The list of billable procedures may not be standardized, even by commercial insurance vendors. It is vital to obtain the region's billable procedure list from each one of the insurance companies that are accepted by an office. If a given procedure is not present on the billable list, the clinician may need to negotiate with the insurance company for inclusion of that particular procedure.

Durable Medical Goods

Durable goods, such as IUDs, may be stocked by an office if they are used on a frequent basis. It is always best to check with a patient's insurance company prior to performing a procedure and, if possible, to arrange with that insurance company to assist with the provision of a device. If a patient cannot or will not wait for that to occur, it is always important to have the patient sign an Advance Beneficiary Notice ("ABN") stating that she is willing to pay for the procedure and the durable goods prior to performing the procedure. If the office is providing the device, the clinician needs to bill the specific HCPCS or "J code" associated with the device as well as billing the code for the procedure itself. Not to do so will mean that the office will absorb the cost of a very expensive device. Many offices order the device when the patient comes in for a consultative visit prior to the procedure. The IUD is then sent

to the office in the patient's name; when it is received, the patient is called so that insertion can be scheduled. In this case, the provider will bill the procedure code but not bill for the device. There are organizations that will assist women advocating with their insurance to get one, such as the National Women's Law Center "Cover her" project [6].

Charity Care Procedures

Charity care services also may be available for procedures such as IUD insertion or implantable devices. For instance, the Arch Foundation was established as a not-for-profit institution to help low-income women who have no insurance coverage for the levonorgestrel intrauterine systems manufactured by Bayer. Primary Care residencies who participate in charity care programs for teaching learners how to insert or implant contraceptive devices may in some cases be able to access devices from manufacturers. Physician preceptors who oversee learners must be present for the entire procedure in order to bill for the procedure.

Cosmetic Surgery Billing

Most cosmetic surgery is not covered by insurance companies and is considered an "out-of-pocket" expense for the patient. Most clinicians who provide cosmetic surgery will stipulate that the patient pays prior to the actual procedure being performed. It is best to do a consultation prior to the procedure and to clearly provide the price of each procedure both verbally and in writing. Having the patient sign an ABN prior to the procedure is helpful.

Summary

Appropriate coding and billing improves women's access to important health procedures, as practitioners are more likely to continue doing procedures for which they can be paid. Due to the coding specificity, tracking payment and improving the process of payment are relatively easy tasks for any clinician's practice. Familiarizing oneself and one's billing staff with coding for procedures by type of procedure and by type of payment by specific insurance company will increase the likelihood of payment, thus rewarding the clinician for providing services that are requested by the patient or necessary for good clinical care.

Questions for Learners

- What are the pros and cons of stocking devices within an office setting?
- How would you streamline the authorization process?

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Additional Resource

Websites

http://www.archfoundation.com/.
The Arch Foundation: http://www.archfoundation.com.
https://larcprogram.ucsf.edu/coding.

Chapter 3
Legal Aspects of Office-Based Women's Health Procedures

David E. Kolva

Introduction

As primary care practitioners face increasing liability risk in this litigious society, careful planning and timely consultation with your competent legal advisor are critically important to reduce your exposure to lawsuits or misconduct sanctions. The conviction of former Michigan State University, US Olympic Committee, and US Gymnastics national team physician Dr. Larry Jassar on several hundred sexual assault charges in 2018 has sent shock waves throughout the medicolegal policy-making world. There will be future far-reaching investigations (and litigation) into the failures of these institutions to protect young female athletes from predation and abuse. The facts will help shape how to correctly respond to accusations in the future. It is imperative that all practitioners who provide health care to females go beyond the institutional written policies and fully adopt a "culture of safety" to avoid invasions of patient privacy or physical boundary violations.

Since the regulation of medical practice is largely an individual state activity, and laws vary widely by locality, this chapter is not intended to provide personal legal advice. When your practice makes decisions about new policies or procedures, they should be clearly recorded in a practice policy and procedure manual. A user-friendly manual, in print or electronic form, will standardize policy and procedure throughout a medical practice and facilitate training of new employees. The clinician leader of the practice must be the role model for establishing a safe culture to protect and respect every female patient.

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Office Physical Plant Concerns

Local zoning laws regulate the use of the office building premises for provision of medical services. If your existing practice location is in complete compliance with local zoning law requirements, none of the procedures described in this book should require additional special permits or variances since they fall into the category of usual medical diagnostic and therapeutic services for licensed physicians.

If you are adding colposcopy or electrosurgery services to your practice, you should consult with an electrician to evaluate your electrical service requirements. Equipment manufacturers will provide the detailed specifications to ensure safe operation.

The decision whether to purchase or lease your new equipment has important tax implications. Consultation with your accountant is mandatory before any large practice expense. For example, the cost of a new colposcopy suite may easily surpass 15,000 dollars. The cost of necessary physical plant electrical, plumbing, and storage improvements should be budgeted carefully. Remember to review your office/business property insurance policy to include the new equipment and leasehold improvements.

O.S.H.A. Concerns

In 2001, the federal Occupational Safety and Health Administration (OSHA) substantially revised the 1991 compliance standards for employers to prevent employees' exposure to bloodborne pathogens [1]. Your practice must have an exposure control plan to reflect these standards, and it must be "reviewed and updated" at least once a year. The employer is responsible for staff training and compliance as well as proper documentation of these activities. Practitioners and assistants who perform these women's health procedures should have serological documented immunity to hepatitis B. The practice must have a written protocol that clearly outlines proper handling, storage, and disposal of "sharps" (needles and blades), toxic chemicals (acetic acid, Lugol's and Monsel's solutions), and regulated medical waste. Personal protective equipment and emergency eyewash stations must be provided by the employer.

The practice must create engineering controls that allow for the proper ventilation of waste nitrous oxide gas from certain cryosurgical instruments if this equipment is used for cryosurgery of cervical or vulvar lesions. Similarly, a smoke evacuation system should be available for electrosurgical procedures to minimize aerosolized tissue inhalation.

Promotion of Services

If the practitioner is providing outpatient women's health procedures for patients outside of the practice's enrolled panel on a referral basis from other practitioners, then state and federal "anti-kickback" laws prevail. These laws, Anti-Kickback

Statute (42 U.S §1320a-7b(b)) and Physician Self-Referral Law (Stark) (42 U.S.C. § 1395nn), prohibit self-referrals, fee-splitting arrangements, and other types of activity between business entities [2]. You must consult an attorney who is knowledgeable with this technical area of the law before promoting or advertising your services to patients outside of your group practice.

Individual States regulate the scope and content of advertisement of physician's services. Fraudulent or misleading advertisement is considered professional misconduct in most states and may negate your malpractice insurance coverage for these services if results are guaranteed or falsely solicited [3].

Credentialing Concerns

While surgery performed in facilities licensed under state Public Health Laws (such as hospitals or ambulatory surgery centers) is subject to regulatory standards established under such law, procedures performed by primary care practitioners in private offices are not subjected to the same standards. The practitioner's authority to perform office-based procedures is derived from the license to practice medicine issued by the states. States are increasingly establishing clinical guidelines for office-based surgery [4]. The practitioner should become familiar with his state's guidelines for definitions of standards of care and quality (see http://lawatlas.org/datasets/office-based-surgery-laws accessed June 6, 2018). These guidelines can serve as a good resource template for creating your office policy concerning staff education and training for individual procedures.

One of the most important rules of risk management is that the practitioner must be able to prove competency in the performance of these outpatient procedures. Procedure-specific competence should include education, training, experience, and evaluations of performance. Proof of competence should include documentation of procedures performed during postgraduate residency programs and/or proof of satisfactory completion of approved didactic courses offered as continuing medical education (CME). The American Academy of Family Physicians offers a Continuing Medical Education syllabus in colposcopy and outlines methods to facilitate credentialing [5]. Your practice should have a system to record the ongoing number of procedures performed by each practitioner and have a formal "re-evaluation of competency" policy in place.

The practitioner must research the terms of coverage of the practice's professional malpractice policy to make sure that the planned procedures are covered under the existing policy. Unlicensed personnel should not be assigned duties or responsibilities that require professional licensure [4]. The practice should have a formal "in-service" instruction program for office assistants involved in these procedures and document successful completion in the personnel record. This program should also address the knowledge needs of telephone-triage or advice nurses who are most likely to receive telephone calls for postoperative care concerns from patients.

Informed Consent

Informed consent is a process of communication with a competent patient about the planned procedure in sufficient detail to allow a decision whether to proceed with the intervention [6]. The key legal components of informed consent have evolved over the last 50 years in the United States. Not only is this process an ethical obligation, it is now a legal duty of professional conduct as described in statutes and case law in all 50 states. Informed consent is also a key component of the "shared decision-making" process that is replacing the "paternalistic" practice of medicine [7].

For the procedures described in this book, informed consent must include the following components:

1. Information on the patient's pathology or current medical condition.
2. Other scientifically valid treatment options.
3. Rationale for the chosen procedure.
4. Anticipated beneficial outcomes of the procedure.
5. Potential harmful complications or consequences of the procedure.
6. Consequences of *not* having the procedure (informed refusal).

There can be no deliberate or willful misrepresentation of facts in these discussions with patients. In addition, the discussion must be in a language that is understandable to the patient in terms of education level and native tongue. Certified medical interpreters should be provided for patients whose native language is discordant with the practitioner. Many studies have shown a higher medicolegal risk when using family members as "ad hoc" interpreters [8].

The Americans with Disabilities Act requires the provider of medical services to provide appropriate means for hearing-impaired patients to function in the medical environment. Because informed consent discussions are of the highest importance, only medically certified interpreters should be hired by the practice to serve in this function with hearing-impaired patients. The cost of this service must be absorbed by the practice and not billed to the patient.

The informed consent discussion should be performed by the practitioner in the office setting. This discussion should be recorded in the patient's medical record, with care to mention the use of any drawings or audiovisual aids [9]. Many practices have preprinted informational brochures that are part of the informed consent discussion. The patient's signature authorizes the procedure *only at the successful conclusion of the informed consent process*. If the patient refuses to have the intervention after this discussion, this refusal should be documented with a discussion of the repercussions fully acknowledged by the patient.

The increasingly popular usage of electronic medical records (EMR) has allowed groups to create standardized electronic consent systems and forms. The use of these new standardized systems has improved the documentation accuracy of the informed consent process [10]. New practice models for primary care introduce more complex rules concerning informed consent and release of information

procedures, treatment and warm hand-off protocols, documentation and electronic record keeping, agreements with other providers, and billing [11].

Rights of Minors

While primary care physicians provide the majority of health care to adolescents, there is "significant evidence that both physicians and adolescents are uninformed of adolescent's legal rights to confidential reproductive health care" [12]. The Guttmacher Institute (https://www.guttmacher.org/state-policy/explore/overview-minors-consent-law) sponsors an online reference source that is updated monthly to provide information on key issues affecting these rights indexed by each individual state [13]. The practitioner AND the office staff must be knowledgeable about their own state's law concerning consent and confidentiality when treating minors. In general, the law recognizes special conditions where the minor child may consent to diagnostic and treatment activities without parental approval or knowledge in matters concerning sexually transmitted infections (STIs), contraception, and reproductive (pregnancy) health including abortion [14]. When the practitioner consents to perform these gynecological procedures on minors, there are practical clinical concerns that may arise in the office with regard to billing, scheduling, telephone calls, and medical records privacy. The practice's policy and procedure manual should anticipate these potential breaches and detail the proper method of handling each issue. If your practice participates in the federal Title X Family Planning Program or the State Children Health Insurance Program (SCHIP), you must be knowledgeable about the confidentiality and consent rules for these programs. The major specialty organizations have all published policy statements regarding health care for adolescents [15]. These comprehensive guides should require reading by practitioners who perform these gynecological procedures.

Use of Chaperones

There is no *uniform* national legal requirement mandating the use of a chaperone during female pelvic examinations or procedures. Even though all medicolegal risk managers recommend the routine use of chaperones, there is wide variation in this practice between American physicians [16] and their European counterparts [17]. The American Medical Association has addressed this deficiency by publishing a Policy Compendium stating, from the standpoint of ethics and prudence, the protocol of having chaperones available on a consistent basis for patient examinations is recommended [18]. A recent study showed that the characteristics of physicians convicted of sexual misconduct involved a combination

of five factors: male physicians (100%), older than the age of 39 (92%), who were not board certified (70%), and practicing in nonacademic settings (94%) where they always examined patients alone (85%) [19].

In April 2006, the Federation of State Medical Boards adopted a policy that defines physician sexual misconduct and provides recommendations for physician education [20]. When reviewing the definitions of sexual impropriety and sexual violation in this publication, it is clear that most false accusations or misunderstandings can be avoided with the proper use of a *medically trained* chaperone *always* when performing these women's health procedures. The practice policy and procedure manual should state this clearly. It is also a good investment to avoid the emotionally wrenching experience of a false sexual misconduct charge. For most of the procedures described in this book, a chaperone is the beneficial "second pair" of hands to assist the operator in the completion of the procedure. Most experts recommend that the chaperone be the same sex as the patient; thus, a male physician should have a female chaperone for a female patient.

Patient Preprocedure Preparation Concerns

Solutions to prevent health-care errors were unveiled in May 2007 by the World Health Organization's (WHO) Collaborating Centre for Patient Safety Solutions. Two of the solutions deal with office-based procedures: patient identification and performance of correct procedure at the correct body site. Your practice should adopt the "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" as standard office policy [21]. It is the responsibility of the practitioner to verify the adequacy of the informed consent process and double-check the patient's identity and planned procedure. The office should have an adequate privacy area to allow for patient disrobing and gowning.

Procedure-Specific Legal Concerns: Cervical Cytology and Pap Smears

Your office should have an established policy for the review of all laboratory reports before the reports are filed into the medical record [22]. The primary care provider must review and acknowledge ALL Pap smear cytology reports. Your office notification system must be fool-proof and have built-in reminders for follow-up of patients with abnormal Pap smear results until diagnostic resolution. Patient risk factors contributing to inadequate follow-up include low-income group, ethnic minority, and low health literacy [23]. Clinical errors occurring that led to Pap smear litigation include failure to notify patients of their abnormal test result, missing or inconsistent follow-up patterns, failure to investigate persistent bleeding following a Pap smear, and failure to biopsy an abnormal cervix given a normal Pap smear

result [24]. Thankfully, the increased utilization of electronic medical records with built-in laboratory results management programs will improve the follow-up process [25]. The practitioner *must* be knowledgeable about the positive and negative predictive values of the Pap smear results to give adequate informed consent.

Procedure-Specific Legal Concerns: Pessary

New self-positioning pessaries are effective, easy to use, and have few complications [26]. The most serious complications from pessary use are attributable to neglected devices in patients lost to follow-up [27]. These rare complications include urosepsis, impaction, vesicovaginal fistulae, and incarceration of cervix and small bowel.

Procedure-Specific Legal Concerns: Contraceptives

When the practitioner discusses the contraceptive needs of the patient, the six key components of the previously discussed informed consent process must be addressed. Elements of the patient's current medical condition that are important in choosing the proper contraceptive method include age, emotional maturity, health literacy, parity, number of sexual partners, cardiac risk profile including hypertension and diabetes, migraines, coagulopathy, history of cancers, history of pelvic inflammatory disease or sexually transmitted infections, HIV and hepatitis B status, tobacco use, street drug or alcohol use, access to medical care follow-up, family history, and latex allergy. The practitioner must also have published information available to compare the relative effectiveness rates of each method [28]. This information should be included in table form on the practice's informed consent forms.

Procedure-Specific Legal Concerns: Diaphragms

"Items that come in contact with mucous membranes or non-intact skin are defined by the CDC as semi-critical. These medical devices should be free of all microorganisms, although small numbers of bacterial spores may be present." Diaphragm fitting rings and pessary fitting kits are considered to be "semi-critical" items for disinfection following use [29]. The manufacturer's recommendations for cleaning and disinfecting must be followed, and this procedure must be part of the practice's OSHA blood-borne pathogens exposure control plan.

Effectiveness of the diaphragm for pregnancy prevention is very dependent on proper inspection of the device prior to use, correct initial fitting on a suitable patient, proper insertion, duration of use post-coitus, and storage of the device [30].

Patient education during the fitting/insertion office visit is critical. The most significant complication of diaphragm use is toxic shock syndrome.

Procedure-Specific Legal Concerns: Long-Acting Reversible Contraception (LARC), IUDs and Implants

The *intrauterine device (IUD)* and the *birth control implant* are long-acting reversible contraception methods. The thought process of a generation of physicians was forever changed by the Dalkon Shield litigation history during the 1970s. It was the largest "defective product" tort case in history and has reduced IUD usage in the United States to the lowest level of any industrialized nation in the world [31]. The new approved IUDs for use in the United States have eliminated the design flaws that plagued the Dalkon Shield. Proper patient selection and post-insertion education and follow-up are important factors to reduce complications and to enhance effectiveness [32]. Contraindications and adverse effects should be included on the informed consent forms. Documentation of absence of pregnancy before insertion is legally critical. The most serious complication of the IUD insertion procedure is uterine perforation with a reported rate of 1 per 1000 insertions for copper IUDs and 2.2 per 1000 insertions for hormone-releasing IUD [33].

Procedure-Specific Legal Concerns: Colposcopy and Loop Electrocautery Excision Procedure (LEEP)

The process of informed consent is of the utmost importance when discussing abnormal Pap smear results with patients and determining who should undergo further procedures. Some patients consider an abnormal Pap smear to automatically indicate cancer and wonder why they are not being managed more aggressively. Even the majority of college educated women do not know the role of HPV in cervical neoplasia [34]. An overlooked communication problem is the confusion between the abbreviations "HPV" and "HIV" and "HSV" when talking with patients. Please be careful!

Recent publications contain excellent consensus statements that summarize the 2012 American Society for Colposcopy and Cervical Pathology Guidelines for evidence-based management of abnormal cervical cytology [35]. These protocol algorithms should be referenced in your informed consent discussion and documentation. The highest medicolegal risk in the performance of a colposcopy is an inadequate examination with inappropriate follow-up. Your office notification system must be foolproof and have built-in reminders for follow-up of patients with abnormal colposcopic findings until diagnostic resolution. A telephone call to a patient before a scheduled recheck appointment has been shown to improve compliance with follow-up. Mail reminders have NOT been found to be helpful to improve compliance but are legally important for documentation purposes.

Even though colposcopy is regarded as a core procedural technique for family physicians, the skill and comfort level of the individual practitioner must be assessed with a verifiable credentialing process and ongoing quality assurance process. The practice should tabulate the clinical and pathologic situations where referral to a gynecology specialist is required since "failure to diagnose cancer" is still a leading cause of malpractice actions against primary care practitioners [36].

Loop Electrosurgical Excision Procedure (LEEP) of the cervix has been shown to be an effective office technique that may obviate the need for cold knife conization surgery in the treatment of CIN 2 and CIN 3 [37]. The informed consent discussion must include the reason for selection of the cervix ablation procedure, including risks of incomplete excision, cervical stenosis, and incompetent cervix in subsequent pregnancy [38]. Your practice must have an adequate reminder system for post-procedure follow-up of pathology reports and patient recall.

Procedure-Specific Legal Concerns: Endometrial Biopsy

In an effort to reduce the number of operative dilatation and curettage (D&C) procedures in the diagnostic evaluation of dysfunctional uterine bleeding, several excellent outpatient endometrial biopsy instruments were developed. When coupled with transvaginal ultrasound, saline sonohysterography, and/or hysteroscopy in patients with a low risk for endometrial cancer, the combined results had accuracy rates comparable to formal D&C [39]. During your informed consent discussion with patients with unexplained uterine bleeding, the risk assessment for uterine cancer must be categorized based on age, menopause status, nulliparity, body-mass index, insulin resistance syndromes (such as polycystic ovary syndrome), family history, hormone replacement therapy, and tamoxifen use. Documentation of absence of pregnancy before endometrial biopsy is legally critical. A nondiagnostic tissue sample in patients with persistent bleeding requires referral for operative D&C. Again, remember that "failure to diagnose cancer" is a still leading cause of malpractice actions against primary care practitioners.

The main complication of endometrial biopsy is uterine perforation, although the reported rates are extremely rare.

Procedure-Specific Legal Concerns: Elective Termination of Pregnancy in the United States

There is probably no other medical procedure that provokes as much worldwide divisive emotional and ethical debate as the elective termination of pregnancy. Since the US Supreme Court upheld the constitutionality of the federal Partial-Birth Abortion Ban Act of 2003 in April 2007 (*Gonzales v. Carhart)*, it is imperative for women's health-care practitioners to know their own state's laws and terminology

regarding the elective termination of pregnancy. Two excellent Internet sites contain up-to-date information on the status of state laws governing elective termination of pregnancy: the Guttmacher Institute [40] (www.guttmacher.org) and the National Abortion Federation (https://prochoice.org/health-care-professionals/educational-resources/). These sites contain information on Medicaid abortion funding, mandatory counseling and waiting periods, parental involvement in minor's abortions, and mandatory reporting to state health department requirements.

"Pregnancy termination and miscarriage treatment use overlapping sets of skills and procedures" [41]. It is critical for the practitioner to perform a thorough history, physical examination, and determination of gestational age for all pregnant patients. All the elements of the informed consent process need to be well documented. The risk of the planned procedure on future fertility must be discussed and documented. Postprocedure contraception needs should also be answered. The practitioner's office staff and after-hours call groups should be comfortable providing advice and care for any postprocedure complications to avoid any charge of patient abandonment.

The most common complications of elective termination procedures include uterine perforation, infection, hemorrhage, hematometra, retained products, and pain.

Questions for Learners

- In what way do chaperones during examinations affect a busy office?
- What are the pitfalls of informed consent?

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Chapter 4
Population Health in Women's Healthcare

Cathryn B. Heath

Introduction

Population health is defined as the health outcomes of a group of individuals, including the distribution of such outcomes within the group [1]. Groups of individuals can include geographic regions such as communities, or other groups such as employees, ethnic groups, or disabled persons. The determinants include medical care systems, the social environment, and the physical environment, all of which have a biologic impact on individuals within the group. It also includes the resource allocations involved in linking determinants to outcomes. There are three major components to Population Health, namely, health outcomes, policies and interventions, and patterns of health determinants. Population management utilizes interventions on individuals and organizations to improve morbidity patterns.

Health Outcomes

Determining health outcomes requires a collection of data to support study of an office. The electronic medical record (EMR) can be a particularly rich source of data, although is not a necessity for data collection. One of the important tasks related to population health is creating registries; this is particularly applicable for procedures that are done with lengthy time intervals, such as the current recommendations for cervical cancer screening. A registry is a list of patients who by their age,

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sex, or disease are eligible for screening. Registries track patients eligible for a particular procedure due to their age, sex, and/or disease ("denominator"), and those who have had the procedure ("numerator"), thus creating a percentage of patients who have had the intervention. Many insurance companies who request these reports also require reporting on those patients who would be eligible for a procedure by age and gender but are ineligible for the procedure ("exclusion") due to mitigating factors. A breast cancer survivor would be excluded from breast cancer *screening* as she has breast cancer *surveillance*. Breast cancer survivors are excluded from breast cancer screening rates. Criteria for numerators, denominators, and exclusions are available in a variety of sources, including the National Quality Forum (NQF) and the Centers for Medicare and Medicaid Services (CMS). All reporting for measures are required to be consistent with the standards set for each measure by the Centers for Medicare and Medicaid Services (CMS) or by the standards set nationally by organizations such as the National Quality Forum. National percentiles for each quality measure then allow a practice to compare their rate of screening to similar practices nationwide.

Advanced registries track additional information, such as the date when a patient is due for a screening or procedure, which provider is associated with the patient, and the results of the procedure. Many components of a registry can be automated within an electronic health record and can create a percentage rate of a screening measure that is reportable to the practice and to outside interested parties. Practices then use these registries to create policies and interventions which improve the healthcare of the patient.

One of the major obstacles to creating registries within an Electronic Medical Record (EMR) is making sure that the data that is being followed is present within extractable data fields for aggregation purposes. For many EMRs, if the data is present in free text by having been typed into a blank field, it may not be extractable. Making sure that the data is "in observation terms," i.e. in extractable data fields (as opposed to free text), is important. The more automated the process, the more likely the data will reflect true results as opposed to results that reflect poor data collection.

Registries can be kept on paper or in electronic spreadsheets, if a practice does not use an EMR or their EMR is not capable of creating registry reports. A "tickler" file is a common reminder system that creates a "next due" date that is then reviewed on a regular basis by office staff. Common tickler files have been created on index card, or even postcards which are then mailed as reminders to patients to return for a given test. Registries can track patients with specific diseases (abnormal pap smears), patients who are due for routine screening (Pap smear), or patients who may be due for review of their contraceptives, particularly those with long-acting reversible contraceptives (LARCs), such as intrauterine devices or subdermal implantable contraceptives. Analysis of data from registries helps drive the improvement process by measuring changes in outcomes due to a change in policies within an office setting or on a national basis. Wu reports on the low use rate of highly effective contraceptives such as LARCs where she noted that although still half of all pregnancies in the United States were unintended, the rate of LARC use was still comparatively low at 14% [2].

Policies and Interventions

Policies within an office can create structure and accountability for staff and providers alike. Agreement on the given guidelines is a first step to developing office policies for clinical practice.Once determined, assigning responsibility for tasks outlined within the policy lessens confusion of who is responsible for the tasks, improves efficiency, and allows all staff work to the "top of their license," a term meaning tasks can be allotted by levels of expertise. Creating an efficient workflow centered on a specific preventive service can then lead to a discussion on how to create an atmosphere for shared workload. Shared workload improves health outcomes by sharing responsibility for the care of the patient to the entire office. This is considered the essence of the Quadruple Aim in Medicine – improve quality, decrease cost, improve patient satisfaction, and decrease office burnout [3].

Reviewing data then creates opportunities to improve office procedures. There are many ways that this is done; common methodologies for this are "plan-do-study-act" (PDSA) or "Define-Measure-Analyze-Improve-Control" (DMAIC) to use data to create process improvement. Processes are then changed and restudied to ascertain whether the outcomes are better. Small changes can gradually improve health outcomes of the patients over time. For instance, a team at West Virginia State University studied their rate of patients who came for a colonoscopy and were found to have a high "poor prep" for the study. After reviewing the workflow and making changes within their EMR to create standard instructions which were reviewed with the patient, they decreased their rate of poor preps from 19% to 4% [4].

Similarly, for outpatient procedures, analyzing the actual specific procedure steps can then optimize how that procedure is performed. Studying the rate of outcomes (successful procedures without incident and with incident of poor outcomes) can lead toward an improved procedure process. When there is a negative outcome to a procedure, a "root cause analysis" (RCA)is a process of collaborating among all parties to review the occurrence and take steps to avoid the occurrences in the future. RCAs review the process instead of placing blame on specific people involved.

Patterns of Social Determinants

Social determinants of health include all the conditions under which people are born, grow, live, work, and age. Factors that influence health outcomes include access to medical care, access to nutritious foods, access to clean water and functioning utilities, education and health literacy, ethnicity and cultural orientation, family and other social supports, gender, housing and transportation, linguistic and communication capabilities, neighborhood safety, occupation and job security, exposure to violence and adverse factors in the home environment, sexual identification, social status, socioeconomic status, and spiritual/religious values. The

clinician needs to be able to address social determinants of health in order to promote good health outcomes for individuals and populations.

Assessing social determinants of health and breaking down barriers when possible help meet the needs of individual patients and also help improve health of a population.

Using population-based cancer registries to examine incidence and mortality data helps identify disparities based on race and ethnicity. Cote et al. found that while the overall cancer incidence rates have been declining in the United States, endometrial cancer rates have continued to increase. While the incidence rates have increased for all racial/ethnic groups, non-Hispanic black women have a significantly higher incidence of aggressive endometrial cancers as well as higher mortality rates [5]. Population health requires attention to an entire population. In this manner, we are tasked with optimizing medicine and healthcare resources for the benefit of all.

As national guidelines change for preventive screening, it is important to neither over- nor under-screen for preventive services. Analysis of screening data can identify current utilization rates, identify discrepancies from the norms, and help address changes in polices to improve screening rates. Some factors which may determine rates of screening procedures include variance by socioeconomic status of the patient, race of the patient, and even gender of the provider. A study by Ince-Cushman found that the rate of cervical cancer screening done by women physicians was much higher than the rate of those done by male physicians, although the rate of mammography screening was similar for both male and female physicians [6]. Current rates then need to be analyzed with proposals on how to increase the rates for patients in need. For instance, a simple reminder that a patient may have a Pap smear done in a family medicine office may improve the rate of that specific procedure, as many women may not understand that they can receive such services there. Other factors that may make it difficult for women to receive services are the requirement for a woman to make two appointments for preventive healthcare, one for a preventive health examination and another for cervical cancer screening. This may be difficult for women who are not paid if they take time off of work; combining the visit into one service would improve compliance. If a woman does not have insurance, an office needs to be able to give a patient the current rate for the procedure and other low or no-cost alternatives, such as planned parenthood or family planning.

Language can be a barrier as well; providing translation services is a requirement of ambulatory practices.

Another overlooked social determinant for women is the patient's weight; many providers are reluctant to do cervical cancer screening on women who are morbidly obese (body mass index (BMI) 40–49.9) or the super morbidly obese (BMI greater than 50). Similarly, biases regarding cervical cancer screening on patients who are having sex with women or patients who have specific occupations such as being in a religious order may impact current rates of screening.

Discussions of specific procedures and patients' reluctance or avoidance to have them might reveal prior undisclosed incidences of sexual assault, which need to be addressed in an empathic manner. Certain populations such as the developmentally disabled woman might need special accommodations in order to accomplish needed

screening procedures. In one office, we have a population of developmentally disabled adult women who require anesthesia to have simple dental work done; arranging a cervical cancer screening to occur along with the dental screening while under anesthesia optimizes the rate of a successful Pap smear.

Summary

Population health as a methodology for improving the health of women has great relevance to procedural training. It is a necessary process to improve the actual procedures as well as to improve the processes by which we care for the health of women individually and collectively.

Questions for Learners

- What are the possible sources of data available within your current setting to study population health?
- What other social determinants can affect the rate of screening in a population?

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Chapter 5
Empathic Pelvic Examination

Rhina Acevedo

Introduction

The pelvic examination is an important and basic procedure for women's healthcare providers. It is an integral part of the evaluation of common gynecologic and abdominal complaints including but not limited to lower abdominal pain, pelvic pain, vaginal discharge, vaginal bleeding, and irregular menses. The American College of Obstetricians and Gynecologists (ACOG) recommends a routine annual health assessment visit beginning at the age of 21 years, which includes a screening pelvic exam [1]. The USPSTF, the American College of Physicians, and the American Academy of Family Physicians do not recommend screening pelvic examinations in asymptomatic women [2, 3]. The USPSTF and American Cancer Society (ACS) recommend that women begin cervical cancer screening at the age of 21 years and obtain a Pap smear every 3 years between 21 and 29 years of age. After the age of 30 years, women may choose to do co-testing of pap with HPV every 5 years or continue screening every 3 years [3, 4, 5].

Women with a past history of abnormal Pap smears, with a history of breast or ovarian cancer, at risk for sexually transmitted infections, and who cannot remember to have pelvic examinations unless they have them every year are candidates to continue yearly screening. There is currently no evidence to continue yearly pelvic examinations or Pap smears after the age of 65 years. Women over 65 years of age with normal Pap test results in the previous 10 years should discontinue screening. If a woman has a history of CIN2 or greater, screening should continue until 20 years of negative screening is obtained [4]. Consideration needs to be made for personal history, including recent change in male sexual partners or multiple male

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partners. The US Preventative Services Task Force found insufficient evidence to suggest routine screening examinations past the age of 65 years [5]. Medicare presently does not pay for yearly routine screening pelvic examinations. Woman under the age of 21 years need pelvic examinations only if symptomatic with vaginal discharge or pelvic pain. Screening for sexually transmitted diseases may be done by the patient by inserting vaginal swabs or with a urine specimen.

Although the Pap smear has been a mainstay for the evaluation of cancer of the cervix, there is no recommended screening for ovarian cancer. Three cohort studies assessed the diagnostic accuracy of the pelvic examination for detecting ovarian cancer in asymptomatic women. The studies together found that 96.7%–100% of abnormal pelvic examinations did not identify ovarian cancer [2].

See Algorithm 5.1 for the decision tree on the necessity of performing a pelvic exam.

Case Study

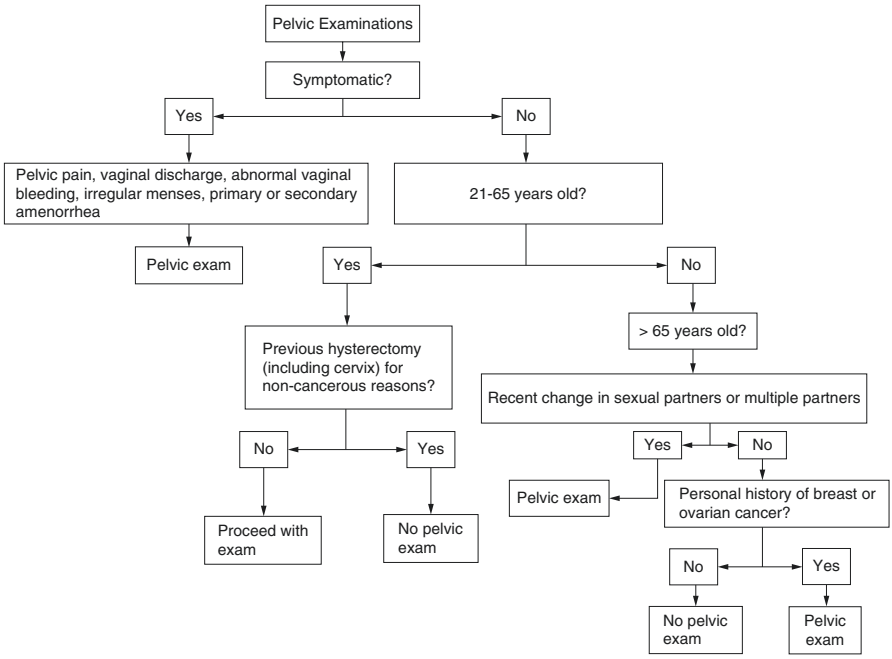
A 21-year-old G0P0 woman presents to your office for her first annual gynecological evaluation. She has become sexually active in the last 2 years. She denies any current complaints. She reports that her menses are regular. She is not currently using any contraceptive method. She is very nervous about her gynecologic examination.

Diagnosis (Algorithm 5.1)

Routine annual women's health examination.

Indications (Algorithm 5.1)

- Routine annual women's health exam
- Lower abdominal or pelvic pain
- Menstrual irregularities including
  - Primary amenorrhea (no menses by age 16)
  - Secondary amenorrhea
  - Menorrhagia (heavy bleeding)
  - Menometrorrhagia (irregular heavy bleeding)



Algorithm 5.1 Decision tree on the necessity of performing a pelvic exam

- Vaginal discharge
- Postcoital bleeding
- Dyspareunia
- Dysmenorrhea
- Pregnancy
- Vaginal bleeding in pregnancy
- Postmenopausal bleeding
- Sexual assault
- Vaginal warts

Contraindications

- Patient refusal
- Placenta previa (contraindication to digital vaginal exam)

Equipment (Fig. 5.1)

- Appropriate-sized gown
- Sheet
- Light source
- Nonsterile nonlatex gloves
- Water-based lubricating gel
- Large vaginal swabs
- Speculum: comes in different sizes and forms, from metal to plastic, Pedersen and Graves
- If clinically appropriate
  - Pap smear (Fig. 5.3a)
    (a) For fixed glass slide specimens – glass slide, wooden cervical spatula, and endocervical brush; or endocervical broom, cell fixation spray
    (b) For liquid Pap – plastic spatula and endocervical brush or endocervical broom, liquid Pap smear jar (preferred)
  - Wet mount
    (a) Cotton swab, small test tube, saline, pH paper, glass slide
  - Additional cultures – for gonorrhea and chlamydia cultures, HPV, and Group B Streptococcus

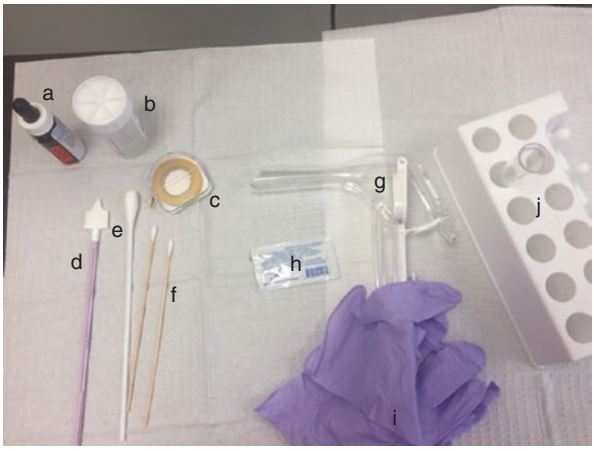


Fig. 5.1 Setup for pelvic examination: (a) saline for vaginitis specimens, (b) Pap smear jar for Pap specimen, (c) pH paper, (d) endocervical broom, (e) large vaginal swabs, (f) cotton-tipped applicators for pH and saline specimen for vaginitis, (g) small disposable Pederson speculum, (h) water-based lubricant, (i) nonsterile latex-free gloves, and (j) plastic test tube for vaginitis specimen. Light source is not shown in photo

Procedure

1. Take history before the patient changes into the gown. Using appropriate language and/or drawings, describe the pelvic examination to the patient. Answer any questions the patient may have regarding the upcoming procedure. Let the patient know that although the exam may be uncomfortable, it should not be painful and that every effort will be made to minimize her discomfort.
2. Offer a chaperone: ask if the patient wishes to have another person present in the room at the time of the examination. Chaperones may be a requirement in some states and should be the same sex as the patient.
3. Step out of the room so that the patient may change into a gown, instructing her to take off her clothing, including underwear.
4. Ask the patient to lie down on the table. Do the rest of the examination, leaving the pelvic examination for last. Have her lie down on the table, placing the stirrups in the appropriate positions, extending and externally rotating the stirrups.
5. Ask the patient to place her heels in the stirrups and to slide down so that her perineum reaches the edge of the examination table. Be sure to use the drape or sheet across her abdomen and pelvic area.
6. Put on nonsterile gloves on both hands.
7. Ask the patient to relax her legs, and let her knees fall to the sides as much as possible (Fig. 5.2). Describe to the patient each part of the procedure that you are about to perform.
8. Examine the labia for the presence of any lesions (warts, ulcerations, or abnormal moles). Also examine the patient for the presence of a cystocele or rectocele.
9. If you are using a self-lit speculum, place the light source in the appropriate segment of the handle. If you are using a gooseneck lamp as a light source, position to provide appropriate lighting for visualization inside the vagina without burning the patient's thigh.
10. Apply warm water and/or warm lubricant gel to the blades of the speculum. Introduce the tip of the speculum at a 45- to 90-degree angle to the introitus, and apply downward and posterior pressure until approximately three-fourths of the speculum's blades have been introduced. Introducing the speculum slowly allows the tissue to accommodate the speculum.
11. Rotate the speculum so that the blades are at a perpendicular position in relation to the vaginal canal, and open the blades (Fig. 5.3a).
12. Reposition as needed in order to bring the cervix into full visualization between the blades of the speculum.
13. Inspect the vaginal walls for the presence of any lesions (i.e., warts and ulcers). Also note for presence or lack of moisture or rugae indicating atrophy.
14. Clean any cervical mucus from the cervix with the large cotton tipped swab prior to obtaining either Pap smear or gonorrhea and chlamydia DNA probes.
15. Obtain clinically appropriate vaginal/cervical/endocervical samples and Pap smear, if indicated (Fig. 5.3b). Obtain culture specimens prior to obtaining Pap

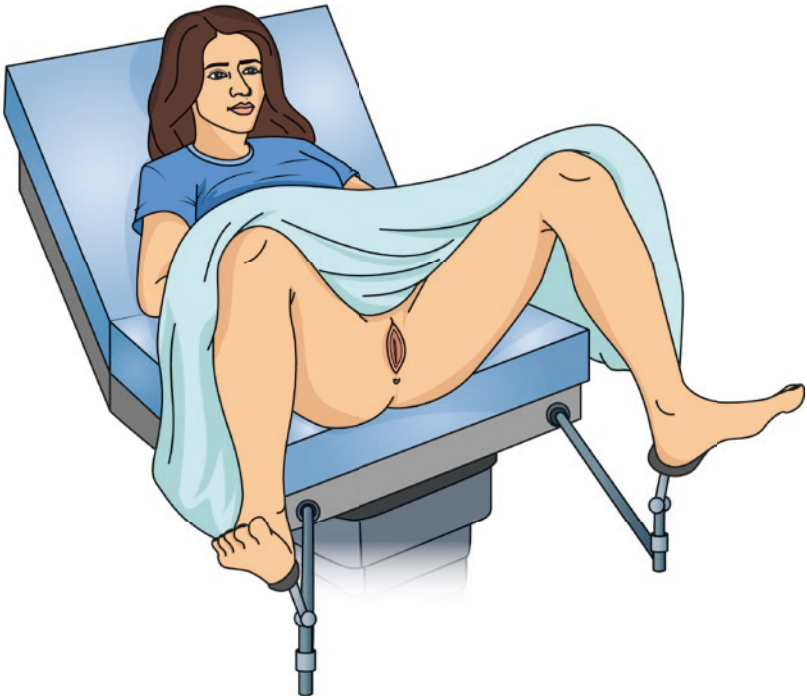


Fig. 5.2 Dorsal lithotomy position and pelvic exam position

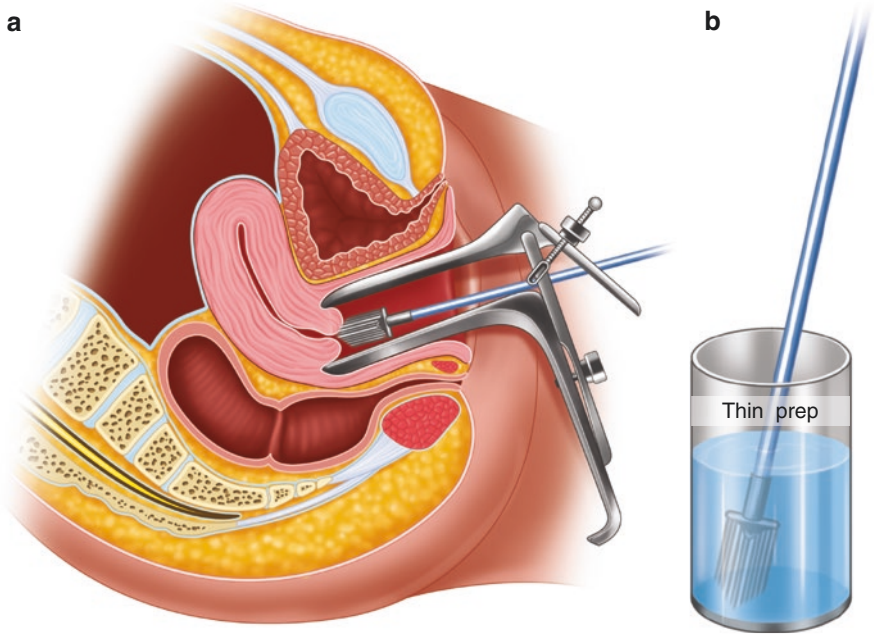


Fig. 5.3 (**a**) Speculum examination. (**b**) Liquid Pap smear

smear specimens. Many times, the use of the endocervical brush to obtain an endocervical sample can produce some bleeding, which could affect the evaluation of other samples such as a wet mount or gonorrhea/chlamydia DNA probes.
16. Withdraw the speculum from the vaginal canal, being careful not to release the cervix quickly (do not "pop" the cervix).
17. Perform a bimanual examination by introducing the index and middle finger of the dominant hand into the vaginal canal. The examiner then places the non-dominant hand over the patient's lower abdomen. With the finger located inside the vagina, locate the cervix and apply upward pressure to the body of the uterus. Sweep the external hand down the midline of the lower abdomen to palpate the size of the uterus in order to measure uterine size.
18. Move internally placed fingers laterally to the adnexae on each side by applying upward pressure while applying downward pressure on the external hand to locate the ovaries.
19. If indicated, perform a rectovaginal examination, withdrawing the internal vaginal fingers, changing gloves, and relubricating and then placing one finger inside the vaginal canal and one finger of the same hand into the rectum. Palpate the rectovaginal wall for thickening or herniations, and ovarian enlargement or pain.
20. Help the woman into a seated position by sliding back up the table first, and then removing feet from the stirrups. Offer tissues for cleaning the lubricant and sanitary pads for any bleeding. Allow her to change prior to going over any results. Let her know when she can expect to be contacted about her results.

Complications and Risks

Although there is a small risk of trauma to the adjacent tissue, it is usually not necessary to obtain a written consent form for the performance of a pelvic examination.

Tricks and Helpful Hints

- Specula come in various sizes and configurations:
  - Pedersen: It has narrow blades and is considered the speculum of choice. Usually, a medium-sized Pedersen speculum will suffice for women of any size.
  - Graves: It has wider blades, which are more useful in multiparous women or women with redundant vaginal walls.
  - Smaller sized specula are more appropriate for women who have never been sexually active. Consider using a pediatric speculum; have one available for use if necessary.
  - Larger specula may be useful in patients with a cystocele or rectocele. It may be necessary to use vaginal wall retractors (see Chap. 5).

  - It is best to start with the smallest speculum that will allow full visualization of the cervix and to change to a larger size if needed.

- Have the patient take a deep breath to relax the perineal muscles while you are inserting the speculum.
- If you are having difficulty finding the cervix, withdraw the speculum from the vaginal canal and perform a digital examination to identify the presence and location of the cervix. Alternatively, withdraw the speculum approximately half way down the vagina, being careful not to pinch the patient as the blades close slightly. Apply downward pressure on the entire speculum toward the rectum. Open speculum blades partially to view the vaginal tissue. If more tissue is found superiorly, aim the speculum tip downward. Conversely, if more tissue is found inferiorly, aim the speculum tip upward.
- Inserting the speculum slowly allows the woman's perineal tissues to accommodate to the blades. This is especially important in women who are postmenopausal or nulliparous or women with vaginal infections.
- Be aware of your patient's cultural needs. Different ethnic groups may hold to different beliefs and health practices than those of the clinician. When appropriate, ask the patient about any other health beliefs or health maintenance practices in which she may participate. Be respectful, listen with an open mind, and welcome the opportunity to learn about these differences. Being judgmental may be detrimental toward building trust between the patient and the clinician. If the clinician is concerned that a belief may be harmful, present the reservations in an open dialog and negotiate a solution that is acceptable to all.
- Some women may find it more comfortable to have a "stirrup-free" pelvic examination. To use this technique, have the woman slide herself down to the edge of the exam table, placing her feet on the corners of the withdrawn extension of the table. She then externally rotates her knees. This technique was found to decrease both physical discomfort and the sense of vulnerability [6].
- If the male partner insists on being present, make sure that there is some time during the examination that the clinician and the patient are alone. Be sure to ask the patient if she has been harmed in any way. Posting discrete notices about safe houses for abuse in discrete places (usually restrooms) may be helpful.

Procedure Note

(Provider to fill in blanks/circle applicable choice when given multiple choices and customize as necessary.)

Patient placed in a dorsal lithotomy position. External genitalia examined without lesions or abnormalities. Speculum inserted without difficulty; cervix visualized; Pap smear (done/not done due to _____). Bimanual examination performed with uterus noted to be in _____ (anteverted, retroverted) position. Approximately _____ cm in size. Adnexae without masses or tenderness. Rectal examination (performed, not performed) with no noted lesions.

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
99387 99397	New Patient Preventive Medicine Services Established Patient Preventive Medicine Service
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 10th Revision, Clinical Modification, Centers for Disease Control and Prevention)	
Z01.419	Encounter for gynecological examination (general) (routine) without abnormal findings.
Z01.411	Encounter for gynecological examination (general) (routine) with abnormal findings

Postprocedure Patient Instructions

The patient may experience some vaginal spotting; she is to be instructed to call if it does not resolve spontaneously within 2 days. She should be told to call the office with heavy vaginal bleeding (more than one pad per hour), vaginal discharge, or pain. She needs to be told how to expect the results of any Pap smears or cultures and how soon to expect the results.

Case Study Outcome

Breast and pelvic examinations were performed. A Pap smear was obtained and sent to the laboratory. Contraception options were discussed with the patient and prescribed. One week later, results revealed normal cytology and cultures. The patient was advised to return to office in 1 year and told their own suggested interval for pelvic examinations.

Postprocedure Patient Handout

(Provider to customize as necessary.)
You have had a pelvic examination today and may experience some vaginal spotting for 1 or 2 days, which will resolve spontaneously. Please call the office if you have heavy bleeding, vaginal discharge, or abdominal or pelvic pain. You will be notified of the results of your Pap smear and/or cultures within the next 2 weeks. If you have not heard from this office by then, please call us.

Questions for Learners

- Name some common concerns from patients about the pelvic examination. How can we as clinicians be sensitive to our patients' concerns?

- Considering recent news events concerning the possible inappropriate behavior of clinicians during examinations, what are the best practices concerning sensitive examinations?

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Additional Resources

Articles

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Websites

1. http://www.asccp.org/asccp-guidelines.
2. https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/cervical-cancer-screening.

Videos

1. https://www.bing.com/videos/search?q=gynecological+pelvic+exam+instructional+videos&view=detail&mid=E01223FF57B0284A6DBDE01223FF57B0284A6DBD&FORM=VIRE (Note: primarily for assisting procedure; but shows preparation or room, handling of specimens and support of patient).
2. https://www.bing.com/videos/search?q=Gynecologist+Examination+Video+Pelvic+Exam&&view=detail&mid=A379DEA67E64CDF3885BA379DEA67E64CDF3885B&&FORM=VRDGAR (Note: Pelvic exam found between 26:00-39:00 minutes).

Chapter 6
Difficult Exams: Cystocele, Rectocele, Stenotic Cervix/Cervical Dilatation, Nonsexually Active Women, and Elderly Women

Rhina Acevedo

Introduction

There are various anatomical conditions that can affect the performance of the pelvic exam and may lead to modifications of your pelvic examination techniques. These conditions include examinations of women who are not sexually active, women with cystoceles or rectoceles, women with atrophic vaginitis, and women with cervical stenosis.

Women who have never been sexually active may have greater anxiety about their first pelvic examination; these patients would benefit from more time, explanation, and support during their examinations. Indications for examination of women who have never had vaginal intercourse are limited to those with pelvic pain, discharge, or women above the age of 21 [1]. Most examinations are possible; however, if the examination becomes too painful, the provider should discontinue the examination and consider referral for an examination under anesthesia or, alternatively, using a pelvic ultrasound. For nonemergent situations (i.e., Pap smear), a woman without prior sexual contact may benefit from first using tampons during her menses prior to her first pelvic examination as tampon use may have the woman experience the physical sensation of having something placed inside her vagina. Using the smallest speculum will also improve their comfort during the exam, as well as using lubricant liberally.

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There are acquired and congenital changes of the pelvic structures that may also add difficulty in performing the pelvic exam. These include cystoceles, rectoceles, atrophic vaginitis, and cervical stenosis.

Rectoceles and cystoceles result from weakened pelvic support structures. Weakness can occur due to childbirth, pelvic trauma, and the aging process. A rectocele is produced when the weakened pelvic structure allows the rectum to bulge into the vaginal canal. The patient may report the presence of a sensation of heaviness in the vagina and constipation and may need to splint the vagina with her fingers in order to evacuate stool during a bowel movement [2]. Cystoceles occur when the pubovesical cervical fascia is weakened, allowing the descent of the bladder into the vaginal canal. Patients often have a sensation of fullness or pressure, stress incontinence, urinary urgency, or a feeling of incomplete voiding. A cystocele is best observed with the patient in the dorsal lithotomy position. With the posterior wall of the vagina depressed (manually or with the use of a retractor), the patient is then asked to Valsalva or cough to visualize the degree of cystocele that is present [2]. A cystocele that presents only on Valsalva or upright posture is considered grade 1. A grade 2 cystocele occurs when the cystocele is present at the introitus. Grade 3 is a cystocele that protrudes halfway beyond the introitus; and if it occurs with an everted vaginal cuff or cervix, it is called a "procidentia," complete pelvic floor collapse, or grade 4 cystocele. Alternatively, pelvic organ prolapse quantification (POPQ) measures nine sites in centimeters between the vagina and perineal body to the hymen [2].

Cervical stenosis can be either acquired or congenital. It commonly occurs in the region of the internal os. Acquired cervical stenosis can result from radiation therapy, previous infection, cancer, atrophic changes, and surgical interventions. Cone biopsy and cautery of the cervix, electrocautery, and cryotherapy can all lead to cervical stenosis [4]. Presenting symptoms vary depending on the patient's hormonal status (pre- or postmenopausal) and degree of obstruction present. Premenopausal women with cervical stenosis may present with complaints of dysmenorrhea, pelvic pain, abnormal uterine bleeding, amenorrhea, or infertility. Postmenopausal women are predominantly asymptomatic but eventually may develop hydrometra (collection of clear fluid in the uterine cavity), hematometra (collection of blood in the uterine cavity), or pyometra (collection of exudate within the uterine cavity). The diagnosis of cervical stenosis is based on the inability to pass a 1- to 2-mm cervical dilator through the cervical os into the endocervical canal. The treatment for complete cervical stenosis is cervical dilatation (can be performed under ultrasound guidance). It is important to rule out the presence of endometrial carcinoma and endocervical carcinoma in patients with complete cervical stenosis [3].

Vaginal atrophy is the result of estrogen deficiency. This commonly occurs in postmenopausal women, but it may also occur in premenopausal women who have a relative estrogen deficiency. Premenopausal atrophy due to estrogen deficiency can occur in the immediate postpartum period, during lactation, or with use of low-dose estrogen contraceptives, progesterone-only contraceptives, and estrogen block-

ers such as Danazol (Sanofi-Synthelabo, Bridgewater, NJ) (Danocrine®) and tamoxifen. Patients with atrophic vaginitis may present with complaints of vaginal itching, vaginal soreness, spotting, urinary incontinence, dysuria, or dyspareunia [4]. On exam, the vaginal tissues appear pale and dry and have decreased distensibility and decreased vaginal rugae. The tissue may be friable and have areas of stenosis. Patients may also have adhesions of the vaginal wall, either externally or internally.

Case Study

A 65-year-old woman, G5P5005, presents to your office for her annual well woman examination and Pap smear. Her last pap smear with HPV co-testing was 5 years ago. There is no history of prior abnormal pap. The patient has had no vaginal bleeding since her last menses 12 years ago. She also reports some vaginal dryness and itching. As you introduce the speculum into the vaginal canal, the patient reports discomfort. As you examine the vagina, you notice that her vaginal walls are devoid of rugae and appear thin. When attempting to obtain an endocervical sample, it is impossible to insert the brush into the tightly closed cervical os.

Diagnosis (Algorithms 6.1 and 6.2)

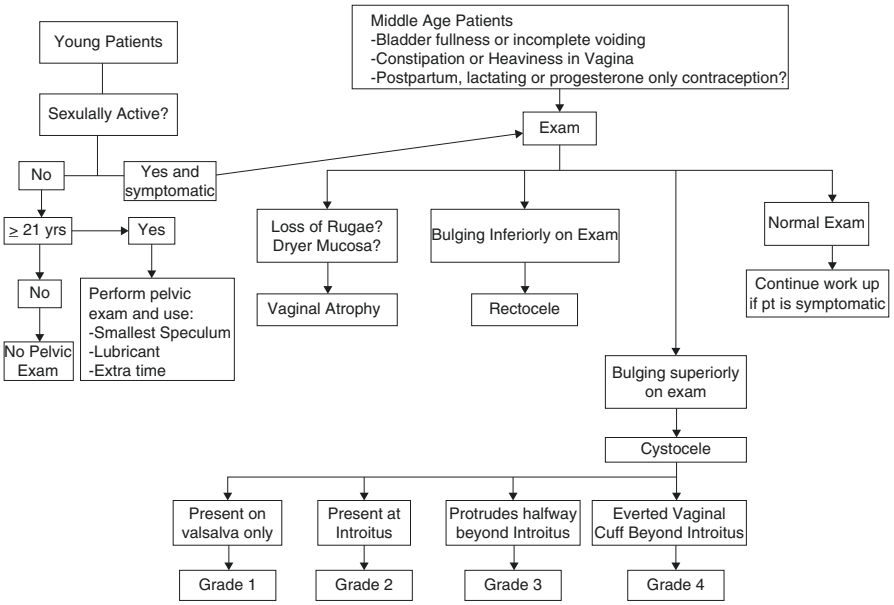
- Atrophic vaginitis
- Cervical stenosis

Differential Diagnosis (Algorithms 6.1 and 6.2)

- Female sexual dysfunction
- Infectious vaginitis
- Vaginal neoplasia (most commonly squamous cell)
- Status postcervical cone or cryotherapy (differential for cervical stenosis).
- Estrogen deficiency due to post-menopausal state

Indications (Algorithms 6.1 and 6.2)

- Routine women's health examination
- Lower abdominal and/or pelvic pain
- Irregular menses



Algorithm 6.1 Decision tree for pelvic examinations of adolescent and middle-age women.

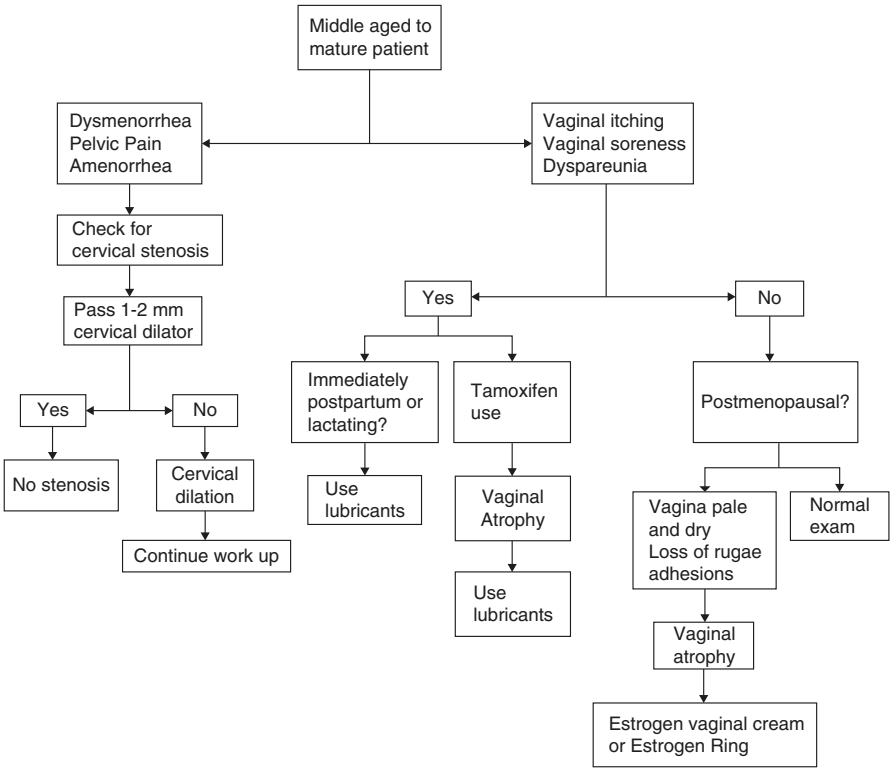
- Postcoital bleeding
- Dyspareunia
- Pregnancy
- Postmenopausal bleeding
- Sexual assault

Contraindications

- Patient refusal
- Placenta previa (contraindication to digital vaginal examination) (Fig. 6.1)

Equipment (Fig. 6.1)

- Gown (appropriately sized for patient)
- Sheet
- Light source
- Vaginal cotton swabs
- Nonsterile latex-free gloves
- Lubricating gel



Algorithm 6.2 Decision tree for abnormal pelvic exams of middle-aged to mature women.

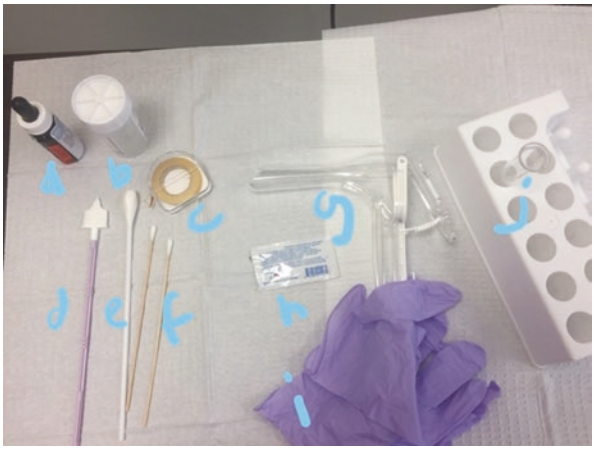


Fig. 6.1 Setup for pelvic examination: (a) saline for vaginitis specimens, (b) Pap smear jar for pap specimen, (c) pH paper, (d) endocervical broom, (e) large vaginal swabs, (f) cotton-tipped applicators for pH and saline specimen for vaginitis, (g) small disposable pederson speculum, (h) water-based lubricant, (i) nonsterile latex-free gloves, and (j) plastic test tube for vaginitis specimen. Light source is not in photo

- Speculum (Fig. 6.2): Metal or plastic – Various sizes and shapes available, including Graves ("duck-billed") or Pederson ("straight"); each speculum comes in small (pediatric), medium, large, and extra large sizes.
- Vaginal wall retractors: may be separate from speculum or incorporated into speculum
- Wet mount specimen
  - Cotton swab
  - KOH
  - Small test tube with saline
  - pH paper
  - Glass slide with cover
  - Microscope
- Additional cultures as necessary
  - Gonorrhea and chlamydia
  - HSV (herpes virus)
- Pap smear equipment
  - Glass slide method (rarely used)
    (a) One glass slide
    (b) Fixation spray or jar with alcohol
    (c) Wooden cervical spatula and endocervical brush OR
    (d) Cervical broom
  - Liquid cell medium
    (a) Plastic cervical spatula and endocervical brush OR
    (b) Cervical broom

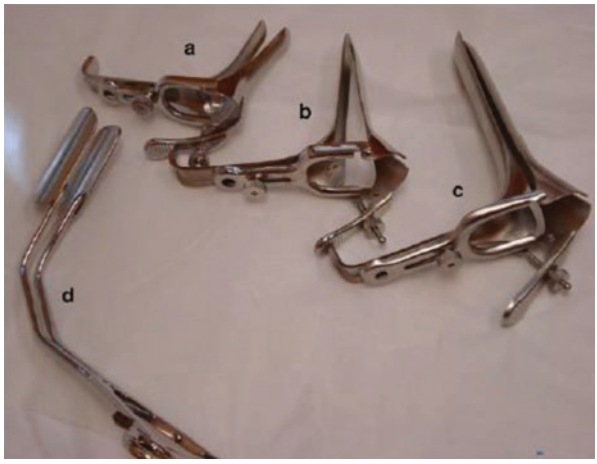


Fig. 6.2 Small Pederson speculum (**a**), medium Pederson speculum (**b**), large Graves speculum (**c**), with separate vaginal wall retractor/spreader (**d**)

Procedure

Proceed with the steps described in Chap. 5 in the Procedures section, with the following variations:

1. Examine the labia for the presence of any lesions (warts, ulcerations).
2. Separate the labia and inspect the introitus for any masses or bulges.
3. Ask the patient to Valsalva and watch the area for any bulges on the superior (cystocele) (Fig. 6.3) or inferior (rectocele) (Fig. 6.4) aspect of the vaginal canal.

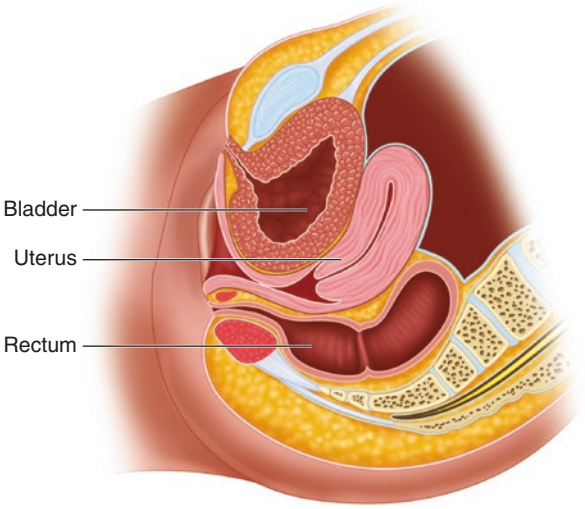


Fig. 6.3 Visualization of cystocele with patient in dorsal lithotomy position

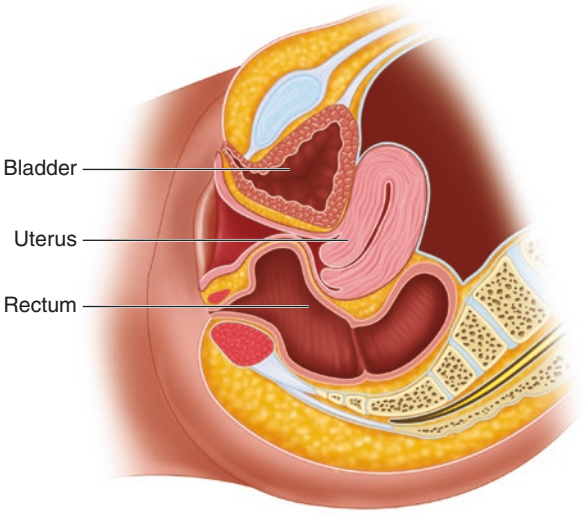


Fig. 6.4 Rectocele with patient in dorsal lithotomy position

4. Place the index finger into the vaginal canal and apply downward pressure to displace the introitus, which will allow the examiner to visualize a cystocele or a rectocele.
5. Position the light source in order to optimize visualization of the vaginal canal.
6. Apply a small amount of warm lubricant gel to the blades of the speculum or wet the metal speculum with warm water. Use the smallest speculum available that will permit visualization of the vaginal walls and cervix.
7. Introduce the tip of the speculum at an angle to the vaginal canal entry and apply slow downward and posterior pressure until approximately three-fourths of the speculum blades have been introduced. Allow time to have the patient's vaginal tissue accommodate to the procedure.
8. Rotate the speculum so that the blades are perpendicular to the vaginal canal and open the blades. Reposition as needed in order to bring the cervix into full visualization between the blades of the speculum.
9. Inspect the vaginal walls for the presence of any lesions. Also note the presence or absence of rugae and vaginal moisture.
10. Obtain clinically appropriate vaginal/cervical/endocervical samples.
11. Carefully withdraw the speculum from the vaginal canal.
12. Perform a bimanual examination. For women with a small introitus, one finger may be all that is necessary for the intravaginal portion of the bimanual examination.
13. Perform a recto-vaginal examination, with the middle finger being introduced into the rectum and the index finger into the vagina if necessary.

Complications and Risks

There is a small risk of trauma to the adjacent tissue.

Tricks and Helpful Hints

- Do not assume that postmenopausal women are not sexually active.
- Use a well-lubricated speculum when performing an examination of a woman with possible atrophic vaginitis. Consider using a Pedersen instead of a Graves speculum.
- A speculum with a wider blade (such as a medium- or large-sized Graves) will provide better support of superior and posterior structures and will allow for better visualization of the cervix.
- For vaginal walls that persistently protrude into the field of vision, consider the following:
  - Use vaginal wall retractors with the speculum (must use medium or large Graves with retractors).
  - If vaginal wall retractors are unavailable, make a retractor out of a clean latex glove by cutting the thumb portion from the glove and then cutting the tip off

the thumb portion of the glove (Fig. 6.5). Introduce the speculum blades into the rubber cylinder created (Fig. 6.6), and lubricate both the speculum and the cylinder prior to introducing it into the vagina.
  - Use a condom in the same fashion as the latex glove.

- For cervical stenosis:
  - Use an endometrial cell sampler to relieve mild cervical strictures. Then retry using the endocervical brush or broom.
  - Use cervical dilators.
  - Use intravaginal estrogen cream, one applicatorful, to vagina nightly for 2–4 weeks and then obtain the specimen.
  - Use laminaria.
  - Use misoprostol 200 mg orally or intravaginally 4 h prior to the exam.

Fig. 6.5 Cutting latex glove finger for vaginal retractor

Fig. 6.6 Glove finger used as a vaginal retractor

- In women who have never been sexually active, the clinician may opt to insert only one finger intravaginally during the bimanual examination.
- In extreme cases of tenderness or pain with examination, discontinue the exam and consider doing under general anesthesia.
- In extreme cases of tenderness or pain, consider gently questioning women about previous sexual abuse. In some cases, pelvic examinations may need to be done after desensitization programs or under general anesthesia.
- Be sure to question women alone about their needs for a chaperone. Chaperones in general should be health professionals, but they can be family members or partners if that is the preference of the patient. However, be sure to discuss this in private with the patient prior to agreeing to any nonprofessional chaperone, as abusive partners may insist on being present.

Procedure Note

(Provider to fill in blanks/circle applicable choice when given multiple choices and customize as necessary.)

Patient was placed in the dorsal lithotomy position. Upon examination, _____ (cystocele, rectocele, vaginal atrophy, cervical stenosis) was noted. Careful speculum examination (with, without) vaginal retractors occurred; cervix was visualized, and Pap smear was obtained. Patient tolerated procedure well and a note will be mailed to her with her results.

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
99,387 99,397	New Patient Preventive Medicine Services Established Patient Preventive Medicine Service
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 10th Revision, Clinical Modification, Centers for Disease Control and Prevention)	
Z01.419	Encounter for gynecological examination (general)(routine) without abnormal findings.
Z01.411	Encounter for gynecological examination (general) (routine) with abnormal findings
N81.1 N81.11	Cystocele Cystocele, midline
N81.12	Cystocele, lateral
N81.6	Rectocele
N88.2	Stricture and stenosis of cervix uteri
N95.2	Postmenopausal atrophic vaginitis

Postprocedure Patient Instructions

The patient should be advised of any findings on exam and how she will be notified of the results. She should also be advised that she may experience some scant vaginal spotting which is usually self-limited. If the patient begins to experience significant vaginal symptoms of heavy bleeding, discharge or pelvic pain, she should return to the office for evaluation.

Case Study Outcomes

Vaginal examination revealed the presence of a cystocele and atrophic vaginitis. The patient was treated with estrogen vaginal cream. Upon re-evaluation 1 month later, the patient reported significant improvement of symptoms.

Postprocedure Patient Handout

(Provider to fill in blanks/circle applicable choice when given multiple choices and customize as necessary.)

You have just had a pelvic examination. This examination showed that you have (provider to circle diagnosis):

- A cystocele is a protrusion of the bladder into the vagina that happens due to the relaxation of the pelvic structures. Many women who have cystoceles have no symptoms at all. Some women notice urgency of urination, stress incontinence (losing urine with laughing, coughing, or sneezing), or a sense that their bladder is just not emptying. Some women also experience only a vague sense of fullness of the bladder. If these symptoms are becoming bothersome to you, please make an appointment to discuss treatment options, such as pessary fitting or surgery.
- A rectocele occurs when the rectal mucosa protrudes into the vaginal wall. Many women with rectoceles have no symptoms, but some experience symptoms of heaviness in the vagina, constipation, or the need to provide support to their vagina to have a bowel movement. If these symptoms are becoming bothersome to you, please make an appointment to discuss treatment options, such as pessary fitting or surgery.
- Vaginal atrophy occurs when there is a lack of estrogen lubricating the vaginal walls, either from medications such as tamoxifen or progesterone-only birth control, menopause, breastfeeding, or hysterectomy with removal of both ovaries. Most women have no symptoms, but some may experience painful intercourse,

vaginal itching or soreness, burning on urination, urinary incontinence, or vaginal spotting. If these symptoms are becoming bothersome to you, please make an appointment to discuss treatment options, such as hormone replacement, if indicated.

- Cervical stenosis occurs when there is a lack of estrogen lubricating the cervix or when there is a surgical procedure or radiation that has caused the cervical opening to become small. Symptoms of cervical stenosis for women who still are getting their periods include dysmenorrhea (painful periods), pelvic pain, abnormal uterine bleeding, amenorrhea (no period), or infertility. Postmenopausal women usually have no symptoms but can experience abdominal cramping or pain from collections of blood or fluid in the uterus. This is very rare. If you are experiencing any of these symptoms, please make an appointment with your provider to discuss treatment options.

Questions for Learners

- Under what circumstances would one elect to perform a vaginal examination on a woman older than 65?
- Under what circumstances would one elect to perform a vaginal examination on a woman who had never had vaginal intercourse?

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Chapter 7
Sexual Assault Victim Examination

Beverly A. Poelstra

Introduction

The term "sexual assault" means any nonconsensual sexual act proscribed by Federal, tribal, or State law, including when the victim lacks capacity to consent. Rape is considered an act requiring forced penetration of the mouth, genitals, or anus by the offender where the force is either physical or psychological [2]. According to the 2015 National Intimate Partner and Sexual Violence Survey, one in five American women is a victim of sexual assault [3]. In 2017, there were 393,580 reported victims of rape, attempted rape, or sexual assault in the United States, at a rate of 1.4 per 1000. The rate of reporting sexual assault increased from 23% in 2016 to 43% in 2017 [4], perhaps reflecting an increased empowerment of people who have been victimized of nonconsensual sex.

When a victim of rape presents to the Emergency Department or private office for examination, one of the most important issues is to take steps to collect and preserve all forensic evidence to ensure that there are few impediments to prosecution. It is important to be complete and thorough in the exam and evidence gathering, while at the same time being sensitive to the fact that the victim has likely already endured a lengthy process prior to arriving for her physical examination. To that end, the number of examiners and interviews should be kept to a minimum with as much history as possible being obtained from law enforcement personnel, social workers, and family members. The use of the team approach toward evaluation and treatment is effective in minimizing the trauma of the emergency department setting [5]. With that background, a

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more focused interview can be obtained from the victim using as many of the victim's own words as possible in recording the history. The interview process need not be duplicated, except as it pertains to specific evidence that needs to be collected for a more in-depth, directed physical exam or specimen collection. Offering to have a support person present (who is not suspected of the abuse) may be reassuring to victims of all ages [6].

Having another professional (nurse, aide) assist during the exam and evidence collection is very helpful, not only to serve as a witness but also to provide materials and label evidence promptly as it is collected, minimizing disruption and misplaced specimens. This will also expedite the process by allowing the examiner to continue wearing gloves during the entire examination without having to change them for record-keeping. Specially trained nurses in the Sexual Assault Nurse Examiner (SANE) program help coordinate all the team members and minimize further trauma to the victim [6]. For a more extensive resource on the examination of sexual assault victims, the US Department of Justice publishes "A National Protocol for Sexual Assault Medical Forensic Examinations Adult/Adolescents," which is a comprehensive guide on this examination.

Case Study

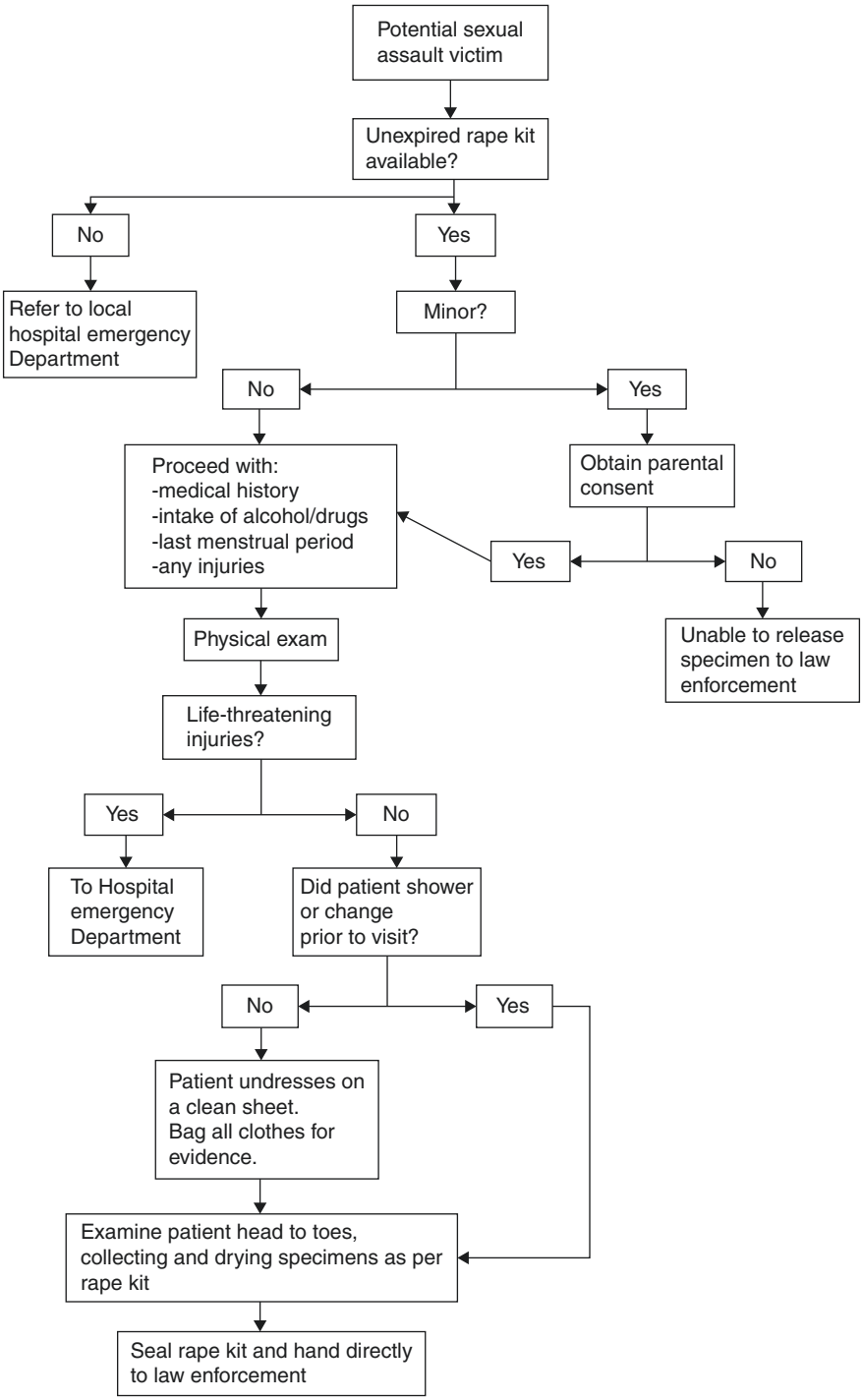
A 22-year-old woman was at a party with her friends where alcohol was being served. She recalls drinking two beers within a time span of 3 h but denies taking any drugs. She remembers dancing with several young men, but she now has a headache, her clothing is disheveled, and she is experiencing vaginal spotting. She suspects that she may have been a victim of unwanted sexual advances, but her memory is fuzzy for the event. She is presently on oral contraceptives; her last menstrual period was 1 week ago.

Indications (Algorithm 7.1)

Suspected rape

Contraindications

Unwilling or uncooperative patient



Algorithm 7.1 Decision tree for sexual assault victim

Equipment

- Speculum
- Lubricant
- Light source
- Rape kit: as determined by local law enforcement agencies (This includes envelopes, swabs, and slides for evidence collection, as well as forms with routine questions and diagrams.)
- GC/*Chlamydia* test kit with swabs, depending on local custom
- Venipuncture materials: needle, vacutainer collection tubes, alcohol prep, gloves, and gauze
- Urine collection container with cleansing wipes
- Rapid pregnancy test kit
- Pencil for labeling specimens on glass slides
- Pen for recording findings and labeling envelopes and paper bags
- Nonsterile latex-free exam gloves
- Clean sheet for patient to stand on while collecting clothing for evidence
- Hospital gown for patient to wear during exam and clean sheet for cover-up.
- Water for dampening swabs to collect evidence
- Paper bags in various sizes to collect clothing
- Extra clothing for victim, preferably "street clothes" as opposed to hospital gown

Optional Equipment

- UV light colposcope with video capabilities to record the evidence as collected

Procedure (Algorithm 7.1)

1. Consent must be obtained from the victim or a parent/legal guardian (in the case of a minor) in order to release the specimens to law enforcement authorities.
2. Medical history, noting the following:
    - Any complaints of injuries related to the alleged sexual abuse. The rape kit forms are very thorough in assessing and recording the circumstances of the sexual assault and which body parts of the victim came in contact with which body parts of the perpetrator.
    - The date and time of alcohol or drug intake, if applicable.
    - Last menstrual period (LMP), prior pregnancies, sexual partners, and birth control.
    - Past medical history, current medications, and allergies.

3. Observe and record the general appearance and demeanor of the victim, noting any obvious injuries. Any potential life-threatening injuries should be attended to first, including transfer to a local Emergency Department if deemed necessary by the provider.
4. Wearing nonsterile gloves, lay out a clean white sheet on the floor.
5. Have the patient undress on the sheet, which will prevent any contamination of clothing and secure any fibers or evidence that may be on clothing, lodged in the patient's hair, or under fingernails.
6. Have the patient completely disrobe while standing on the sheet and package each piece of clothing individually in a paper bag, which should then be sealed. If the victim has showered and changed clothing after the sexual assault has occurred, this step may be unnecessary. Provide patient with a hospital/office gown and a sheet.
7. A complete physical exam should be performed with special attention directed to the oral cavity, skin around and near the breasts, and the perineal area.
8. *Important*: Check expiration date on rape kit prior to proceeding.
9. Using the rape kit (Fig. 7.1) as a guide, proceed from head to toe gathering specimens as appropriate and placing them in the appropriately labeled envelopes (Fig. 7.2). Thoroughly dry all specimens prior to packaging to avoid the destruction of samples by mold growth. Avoid use of a hair dryer or other heat source, as this may degrade specimens.
10. Obtain cervical swabs to be sent to the local laboratory for gonorrhea and chlamydia by the preferred local detection method, if indicated.
11. In order to minimize further trauma to the patient, plucked specimens of the victim's scalp hair and pubic hair can be obtained either at this step or at any follow-up visit under less stressful circumstances. Combed specimens should be obtained at the time of exam.
12. Seal the rape kit with the stickers provided and sign off each sticker with time and date and initials of the examiner (Fig. 7.3). The kit must be handed directly to a law enforcement officer in order to preserve the chain of evidence (Fig. 7.1). Sign each page (usually 15–20 pages, not including duplicates) and hand over

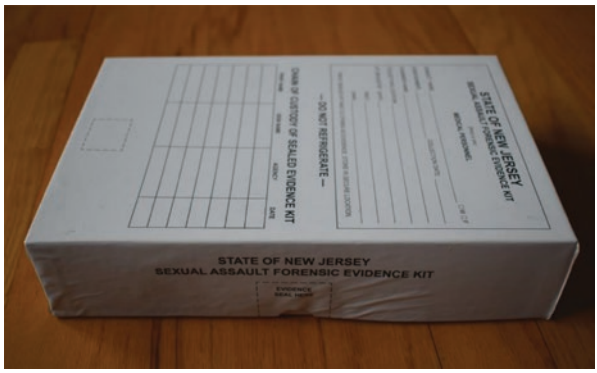


Fig. 7.1 Sample of an intact unopened rape kit (Sirchie®, Youngsville, NC). Note the chain of custody

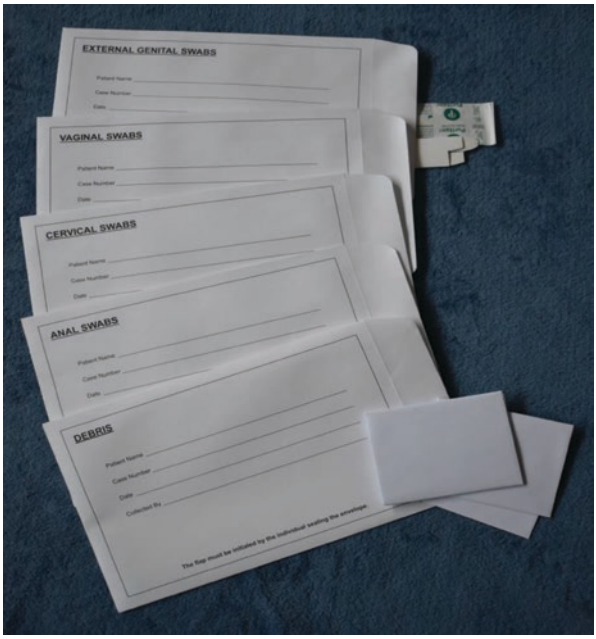


Fig. 7.2 Rape kit contents

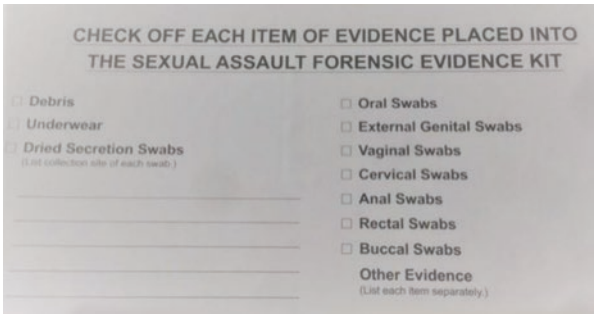


Fig. 7.3 Rape kit box with all necessary forms and packaging materials for samples collected. External portion of the box with check-off list of sent contents

the originals to the officer, keeping copies for the chart and sexual abuse management (SAM) clinic.

13. Blood and urine specimens should be labeled and delivered to the lab. The prosecutor will obtain these results later.
14. Perform serum toxicology screens – alcohol, drug screen if indicated – noting time of alcohol ingestion obtained in history, if known. These specimens are sent to the local hospital laboratory. Specimens may also be sent for Hepatitis B, Hepatitis C, and HIV.
15. Results of the rapid pregnancy test and/or quantitative β-HCG results should be obtained and recorded if the patient is a female of childbearing age.
16. Offer pregnancy prophylaxis, if indicated.

17. Sexually transmitted disease and nonoccupational postexposure HIV prophylaxis (nPEP) should be provided empirically based on CDC guidelines.Arrange a follow-up appointment in 2 weeks to review labs, review medication side effects, and address emotional needs concerning the assault. Local support groups are often invaluable for handling the emotional aftermath.

Tricks and Helpful Hints

- UV light has been used in the past to highlight areas of semen on skin and in hair; however, studies have recently shown that this yields confusing results, as many common items (such as K-Y jelly and powder) will fluoresce. Local authorities may dictate whether this step is performed, but it is no longer recommended.
- It is *very important* to check the date on the seal of the rape kit before proceeding to determine that it has not expired. Otherwise, all evidence collected may be considered invalid and the case may not be able to be prosecuted. However, in the absence of an alternative, the kit may still be used to collect specimens to be used in patient care.
- Many of the "date-rape" drugs do not have metabolites that can be detected on routine toxicology screens. However, some drugs may be possible to detect if special instructions are given to the laboratory. Check with local law enforcement as some specimens can be sent to the state lab for testing of metabolites. The length of time from drug ingestion to collection of the specimen also plays a role in the likelihood of detection.
- It is the patient's preference to make the decision regarding her own about pregnancy prophylaxis, even if that patient is a minor.
- Special handling and special consent may be needed for HIV serology and for nonoccupational postexposure prophylaxis (nPEP) to be initiated.
- If the patient prefers, a support person may be present during the exam.
- When an assessment is made, it is important to note that although the physical exam may be normal, this does not exclude the possibility that a sexual assault did indeed occur. This should be discussed with the patient and with the authorities and documented in the chart.
- In some areas of the country, a colposcope may be used to aid in recording details in the vaginal examination, including bruising or bleeding consistent with trauma.

Procedure Note Provider to Customize as Needed

The rape kit provides a very elaborate and thorough form for recording various aspects of the history and physical exam. An additional note for the hospital or office record may make a reference to these documents and should summarize the major findings.

For example:

CC: A 22-yo female c/o alleged sexual assault 12 h prior to admission. Patient consumed one beer at 1:00 am. Patient has voided and brushed her teeth but has not showered, douched, or defecated since the event. She changed her clothing prior to going to police station. No other injuries. LMP 9/13/07 G1P0010 sexually active, one partner, on oral contraceptives. No significant past medical history. No other meds, no known allergies.

PE: Small abrasion of left labia minora with no active bleeding; exam otherwise normal. (See rape kit sheets.)

A/P: Alleged sexual assault. STD and pregnancy prophylaxis offered. Hepatitis, HIV, GC/chlamydia pending. Patient to f/u with Sexual Abuse Management (SAM) Clinic.

ICD 10-CM-Diagnostic Codes (International Classification of Diseases, Tenth Revision, Clinical Modification, Centers for Disease Control and Prevention)	
Z04.41	Examination for alleged rape or sexual assault

Postprocedure Patient Instructions

Follow-up is to be arranged with the local sexual abuse management team or equivalent where counseling can be provided; follow-up on pregnancy prophylaxis and infectious diseases can take place. Appropriate follow-up should also be made to manage any injuries that may be related to the sexual assault.

Case Study Outcome

The patient has been evaluated by the clinician in the emergency room for rape. She has elected to be treated for sexually transmitted infections. She decided to follow-up with her primary care clinician and is planning on going to the next meeting of the support group for women who have been sexually abused.

Postprocedure Patient Handout

(Provider to customize as necessary.)

You have just been evaluated for sexual assault (rape). It is important to remember that what happened is not your fault. *No one* "deserves this" or was "asking for it." Rape is a crime. You have a right to report this to the police, and you have the right to be treated fairly during the justice process.

Many people experience a widely varying set of emotions, including rage, depression, anxiety, and fear. This is normal. In addition, it is very common for loved ones to have similar reactions. It is important not to "take the law into your own hands," as these actions will likely end in more hardship to you and to your loved ones. Allow the law to do its job. Law enforcers are specialists and are there to assist you in bringing the perpetrator to justice.

Some women prefer private counseling with a psychologist or mental health social worker. Many people find support groups quite helpful. These local support groups often have trained therapists and other women who have gone through similar circumstances. Talking with people who have also experienced rape often helps people understand their own feelings and emotions. There are also national groups to help support women through the crisis of rape:

- National Coalition Against Sexual Assault: 1-717-728-9764.
- Rape, Abuse and Incest National Network: 1-800-656-HOPE.

It is also important to follow up on the medical issues surrounding sexual assault. This can be done by a local sexual abuse management team or at your primary care physician's office.

If you are on birth control and are taking it regularly, the likelihood of pregnancy is low. If you wish to be treated for prevention of pregnancy, you may be given a series of pills to take. It is important to take them as directed. If you are concerned about the possibility of infection, you may be treated for gonorrhea, chlamydia, and syphilis. If you are concerned about contracting HIV, understand the risk of this is less than 1%. However, if you elect to be treated, be sure to take the medication as directed.

Questions for Learners

- Considering the high rate of sexual assault on college campuses, what steps can be taken to better support victims' rights?
- In what circumstances might a clinician prefer to refer a patient for sexual assault evaluation?

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Chapter 8
Pap Smear and HPV Testing

De Ann Cummings

Introduction

The Pap smear for cervical cancer screening was first introduced in the 1940s. Since then, the incidence of cervical cancer in the USA has decreased from 14/100,000 to 7.4/100,000 in 2018 [1]. Despite this decline, cervical cancer continues to be the third most common gynecologic malignancy in the USA and the second most common gynecologic cancer worldwide. This underscores the need for continued vigilance.

Pathology of Pap smear specimens shows that 95–100% of squamous cell cervical cancers and 75–95% of high-grade CIN lesions have detectable HPV-DNA [2]. This observation has led to new options for prevention, screening, and management of cervical cancer and its precursors. Vaccines against HPV types 16, 18, 31, 33, 45, 52, and 58 have been introduced to reduce HPV infection. HPV DNA testing is now being utilized in the management of the abnormal Pap smear and cervical dysplasia as well as for primary screening.

HPV testing has a sensitivity of 94.6% and a specificity of 94.1% for the detection of high-grade cervical disease. In comparison, the Pap smear has a sensitivity of 55.4% and a specificity of 96.8%. The combination of Pap smear and HPV testing has been approved by the FDA for screening women over age 30 every 5 years. Combination screening improves the sensitivity but decreases the specificity [9].

Liquid-based cytology (ThinPrep®, SurePath™) as an alternative to the conventional Pap smear was introduced in 1996 to improve the sensitivity of the Pap smear (40–80%). Instead of applying the cervical specimen to a slide, the specimen (collected in the same fashion) is instead inserted into a vial of fluid which is later spun in the lab to remove excess material. With the SurePath™ method, the brush is detached and sent in the specimen container along with the sample. One meta-analysis

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found that liquid-based technology is as good or even better than a conventional Pap smear for the detection of high-grade cervical disease [3]. Another benefit of liquid-based cytology is the ability to obtain reflex HPV DNA testing from the same Pap test. Comparison between the two methods of liquid-based cytology shows that SurePath™ may have a higher specimen adequacy rate (therefore decreasing the number of unsatisfactory Pap smear results) [4]. Other studies have shown that the SurePath™ system may handle adverse limiting factors such as blood better than the ThinPrep® system [5].

New guidelines for the interpretation of the Pap smear results have been published and provide different options for following minor cytological abnormalities based on age [8]. New recommendations for management after colposcopy can be found in Chap. 23 on "Colposcopy".

Case Study

A healthy 32-year-old G2P2 presents for her yearly physical exam. She has had a negative Pap smear every 3 years since she started screening at age 21. She has not been exposed to diethylstilbestrol and is not immunocompromised (low risk). She is otherwise healthy and has had the same partner for the past 5 years.

Diagnosis

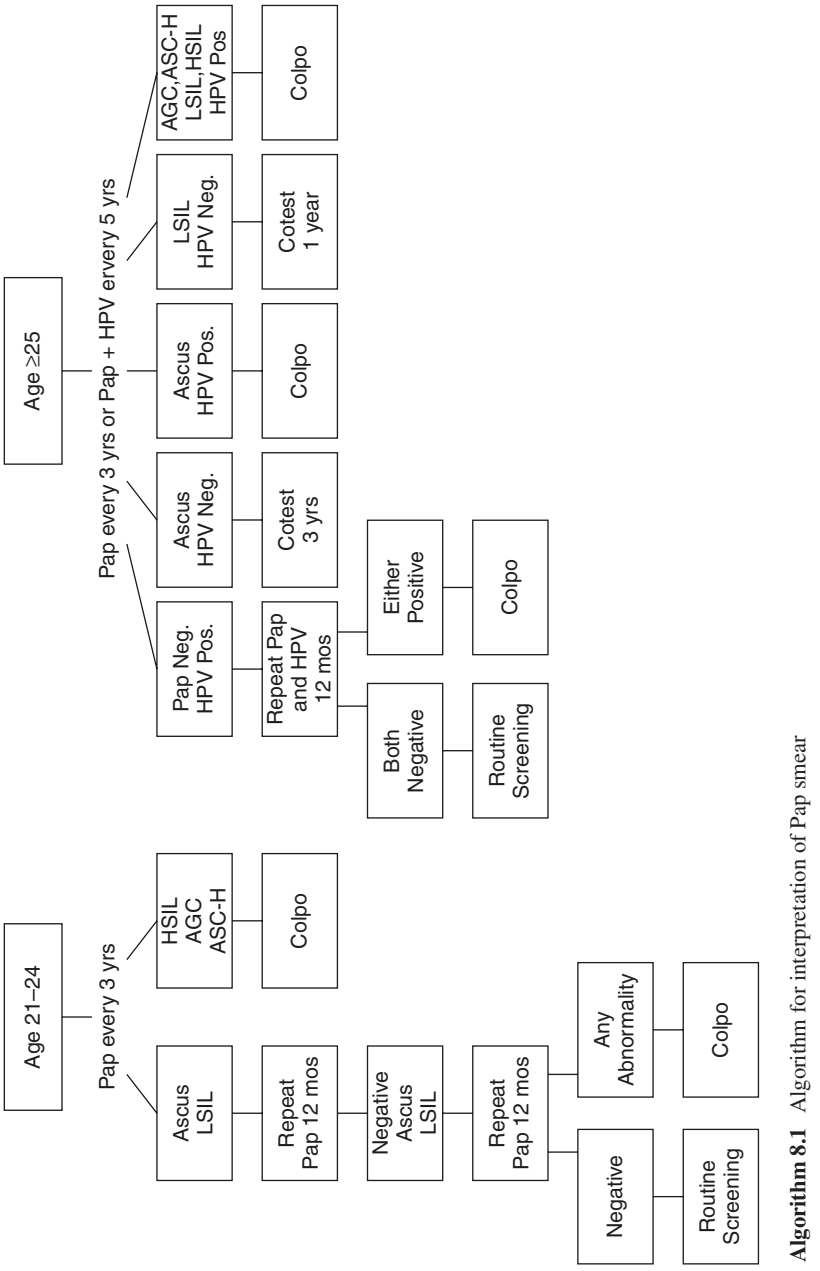
Normal exam

Differential Diagnosis (Algorithms 8.1)

- Cervical dysplasia
- Human papillomavirus

Indications [2, 6, 7, 9]

- *Adolescents*: Recommendations from the American College of Obstetricians and Gynecologists (ACOG), American Society of Colposcopists and Cervical Pathologists (ASCCP), US Preventive Services Task Force (USPSTF), and the American Cancer Society (ACS), all state that *screening should begin at age 21.*



Algorithm 8.1 Algorithm for interpretation of Pap smear

- *Women Aged 21–29*: All guidelines (ACOG, ASCCP, ASC, and USPSTF) recommend regular screening for cervical cancer with a *Pap smear only every 3 years*.
- *Women Ages 30–64:* Three options
  - *Pap smear every 3 years*
  - *Pap smear and high-risk HPV testing every 5 years*
  - *High-risk HPV testing alone every 3 years (USPSTF recommends every 5 years)*
- *Women Ages 65 and older:*
  - All guidelines agree that *screening is not indicated* for women 65 and older who have had regular cervical cancer screening and have no history of cervical cancer or high-grade dysplasia.
- *Women with history of hysterectomy:*
  - All guidelines agree that *screening is not indicated* for women who have undergone hysterectomy with removal of the cervix for reasons other than cervical cancer.

Contraindications

Uncooperative patient

Equipment (Fig. 8.1)

- Exam table equipped to place patient in lithotomy position
- Vaginal speculum (metal or plastic)
- Light source
- Nonsterile latex-free gloves
- Large cotton swabs
- Pap broom (Cytobroom) *or* extended tip spatula plus endocervical brush
- Liquid transport medium *or* conventional Pap smear slide plus fixative
- HPV collection kit (if using Pap smear slide plus fixative)

Procedure

1. Place patient in dorsal lithotomy position.
2. Insert speculum to visualize the entire transformation zone.

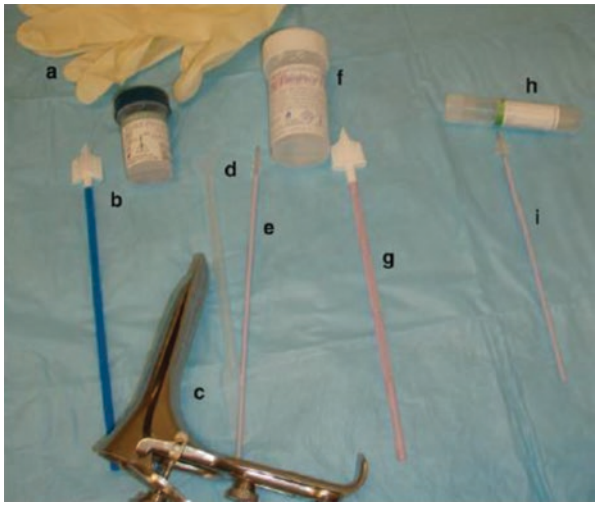


Fig. 8.1 Equipment setup with Pap smear tools: (**a**) gloves; (**b**) SurePath™ (TriPath, Burlington, NC) Pap jar with detachable broom; (**c**) Graves speculum; (**d**) spatula; (**e**) endocervical brush; (**f**) ThinPrep® (Hologic, Bedford, MA) Pap jar with cervical broom; (**g**) cervical broom; (**h**) HPV specimen container; (**i**) HPV collection brush

3. If sexually transmitted infection (STI) testing is indicated, then perform prior to performing Pap smear.
4. Look for warts, lesions, erosions, or leukoplakia on the cervix.
5. Obtain a Pap smear either with a broom device or spatula plus endocervical brush:
   - Must obtain sample from both endocervix and ectocervix.
   - If using broom, rotate 360 degrees, making sure that the long bristles in the center extend into the cervical os and rotate at least three times.
   - If using the spatula, take an ectocervical sample first by rotating the spatula (long end into the os) and rotating the shorter end 360 degrees around the ectocervix. Then insert the endocervical brush and rotate 360 degrees.
6. Avoid using a swab on the cervix prior to Pap unless there is a large amount of blood or discharge.
7. For conventional Pap, smear specimen onto a prelabeled slide by sliding down the slide, turning the cytobroom over, and sliding down the slide again, and then apply fixative immediately. Both ectocervical and endocervical samples can go on the same slide (Fig. 8.2).
8. For liquid-based cytology, place collection device in the liquid transport medium and vigorously twirl the device in the liquid (Fig. 8.3).
9. HPV testing can be done with the liquid transport medium, or a separate testing brush can be used. For the latter, insert the brush two-thirds of the way into the

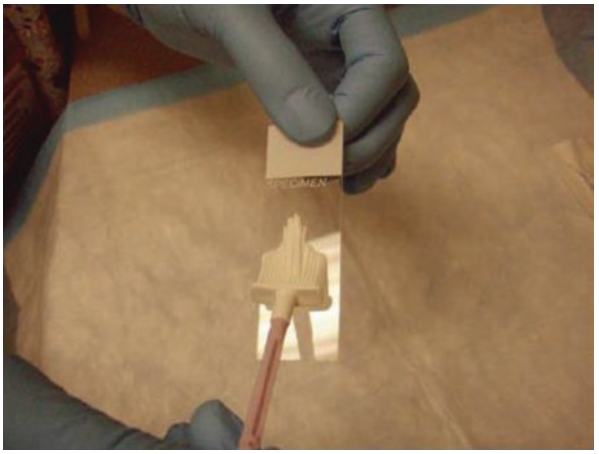


Fig. 8.2 Conventional Pap smear collection onto a glass slide

Fig. 8.3 Swish the broom in the liquid cytology jar

cervical os so that part of the brush is on the ectocervix and part is in the endocervix and rotate 360 degrees. Place brush into the transportation device and break off the stem.

10. Upon removal of the speculum, observe the vaginal walls and vulva for any lesions.

Complications and Risks

False-positive result with unnecessary additional tests.

Tricks and Helpful Hints

- Difficult to visualize the cervix:
  - Move patient down on the table so that her pelvis is just at the edge.
  - Have patient press down on her lower abdomen to raise the cervix into view.
  - Try a larger or longer speculum.
  - If using a plastic speculum, try metal speculum.
  - If vaginal wall blocks view, try placing a condom with a small hole in the end over the blades of the speculum.
- Stenotic cervical os:
  - Have patient use estrogen cream intravaginally for 3 weeks prior to a Pap smear.
  - Use endocervical brush.
- No endocervical cells on previous Paps: Use endocervical brush.
- Excessive cervical discharge or bleeding: Use a large cotton swab to clear away exudate or blood, consider using liquid-based cytology, if using conventional Pap slide then consider having the patient return for Pap later when bleeding or discharge has resolved.

Interpretation of Results [8] (Algorithms 8.1)

- Unsatisfactory: Pap must be repeated.
- Negative pap smear but HPV positive: Repeat Pap and HPV in 12 months if either repeat test is positive refer for colposcopy.

- ASC-US (atypical squamous cells of undetermined significance). 5–17% will be diagnosed with CIN 2 or greater.
  - Age >24 years – Reflex HPV typing
    (a) If high-risk HPV positive, refer for colposcopy.
    (b) If high-risk HPV negative, return to routine screening.
  - Age 21–24 years – Repeat Pap at 12 months
    (a) If Pap ASC-H, AGUS, or HSIL, refer for colposcopy.
    (b) If Pap normal, LSIL, or ASCUS, repeat Pap again at 12 months. If pap again shows any abnormality, refer for colposcopy.
  - HPV testing should not be done in women <25 years
  - Pregnant women – Defer to 6–8 weeks postpartum
- ASC-H (atypical squamous cells, cannot rule out high-grade disease). 24–94% will be diagnosed with CIN 2 or greater.
  - Refer for colposcopy in all ages and all pregnant women.
- AGC-NOS (atypical glandular cells, not otherwise specified). 9–38% will be diagnosed with CIN 2, AIS, or greater. 3–17% will have invasive cancer.
  - Refer for colposcopy with endocervical sampling and endometrial biopsy
  - If atypical endometrial cells on Pap, perform endometrial biopsy prior to colposcopy.
- AGC favor neoplasia or AIS (adenocarcinoma in situ). 27–96% will be diagnosed with CIN 2 or greater.
  - Refer all patients for colposcopy with endocervical sampling.
  - Endometrial biopsy if indicated. (See previous discussion in this section.)
  - If testing negative for neoplasia, refer for diagnostic excisional procedure.
  - Following with repeat Pap smears is unacceptable.
- LSIL (low-grade intraepithelial lesion). 12–16% will be diagnosed with CIN 2 or greater.
  - Age >24 years.
    (a) Test for high-risk HPV.
    (b) If HPV negative, repeat Pap and HPV tests in 12 months. If both are negative, return to routine screening. If either test is abnormal, refer for colposcopy.
    (c) If HPV positive, refer for colposcopy.
  - Age 21–24 years
    (a) Repeat Pap in 12 months (no HPV testing)

(b) If Pap negative, ASC-US, or LSIL, repeat Pap again at 12 months. If repeat Pap is abnormal, refer for colposcopy. If repeat Pap is normal, return to routine screening.
(c) If Pap HSIL, ASC-H, or AGUS, refer for colposcopy.

- HSIL (high-grade intraepithelial lesion). 70–75% will be diagnosed with CIN 2 or greater.
  - Refer all patients for colposcopy regardless of age or pregnancy.
    (a) In women <25 if colposcopy negative for CIN 2 or 3, close observation is recommended instead of diagnostic excisional procedure.
    (b) In women <25 with limited CIN 2, close observation may be an option.
    (c) In women 25 or greater, if colposcopy is negative, consider diagnostic excisional procedure.
    (d) In women 25 or greater, if colposcopy shows CIN 2 or 3, excisional procedure is preferred.
- Endometrial cells
  - If premenopausal, no further action is required.
  - If postmenopausal, perform endometrial biopsy.

Procedure Note

(Provider to fill-in blanks/circle applicable choice when given multiple choices and customize as needed.)

The patient was placed in the dorsal lithotomy position and a speculum was inserted. The cervix was well visualized. Pap smear was obtained using _____ (insert collection device) and _____ (insert either conventional Pap processing or liquid based cytology). No cervical, vaginal, or vulvar lesions were seen.

Coding

Pap and Physical

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)
99,395 (age 18–39), 99,396 (age 40–64), 99,397 (age 65 or greater)

Medicare Pap and Pelvic Codes
G0101 and Q0091
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 10th Revision, Clinical Modification, Centers for Disease Control and Prevention)
Z12.4 for any Pap done

Postprocedure Patient Instructions

Instruct the patient that her Pap results will be mailed to or called into her. Reassure her that spotting can be normal after a Pap smear.

Case Study Outcome

The patient is at low risk for cervical cancer and has a history of consistent Pap smears. She may decrease her Pap frequency to every 3 years or get HPV testing and Pap smear every 5 years or get HPV testing alone every 3–5 years.

Patient Handout

(Provider to customize as needed.)

What is a Pap smear?

- It is a test in which cells are taken from the cervix and examined under a microscope to look for signs of cancer or precancer.

How is the Pap smear done?

- An instrument called a speculum is inserted into the vagina in order to see the cervix. A brush is then rotated over the cervix to collect a sample.

How often do I need to have a Pap smear?

- If you are less than 30, you should have a Pap smear every 3 years.
- If you are 30 or over and have had regular Pap smears, you may be able to get a Pap smear every 3 years or Pap with HPV testing every 5 years depending on your risk factors for cancer.

When should I start getting Pap smears?

- Women should begin getting Pap smears at age 21.

When can I stop getting Pap smears?

- If you have had regular Pap smears and are not at high risk for cervical cancer, you can stop Pap smears at age 65.

What are the risk factors for cervical cancer?

- Almost all cervical cancers are caused by the HPV virus, which is sexually transmitted.
- Risk factors include multiple sexual partners, early age of the first sexual intercourse, personal history of HPV infection, partner with HPV infection, previous abnormal Pap smear, illnesses that suppress the immune system, and smoking.

If I have had a hysterectomy, do I still need to get Pap smears?

- You do not need to get Pap smears unless you have a history of cervical cancer or still have your cervix.

What is HPV?

- HPV stands for Human Papilloma Virus. It is the virus that causes genital warts. Certain types can also cause precancer and cancer of the cervix. HPV is transferred from person to person through sex.

What can I do to keep from getting HPV?

- Practice safe sex, using condoms
- There is now a vaccine for HPV approved for girls and boys between ages 9 and 26 that protects against the most common types of the virus that cause cancer. The vaccine is recommended for all 9–26-year-old people, whether they have had HPV infections or not.

Should I be tested for HPV?

- Your doctor may recommend HPV testing as part of a screening program.
- A test for HPV is also often done to monitor abnormal Pap smears.

Is there a treatment for HPV?

- There is no medicine that will get rid of the virus. Most of the time your body's immune system will fight off the virus over time. If there are severe changes in the cells on your Pap smear, the abnormal cells can be surgically removed or frozen.

What can I expect after a Pap smear?

- Some women have a small amount of spotting after a Pap smear; consider wearing a sanitary pad for the next 24 h.
- Expect either a phone call or a letter from your provider describing the results of your Pap smear and when you should return to the office for your next Pap or HPV testing.

Questions for Learners

- Under what circumstances would one refrain from performing a Pap smear during a vaginal examination?
- What different types of clinicians provide Pap smears?
- Is a bimanual examination necessary for routine Pap smears?

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Additional Resources

Articles

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Websites

www.ahrq.gov.
www.asccp.org.
www.cancer.gov.
www.cancer.org.

Chapter 9
Vaginal Discharge

Barbara Jo McGarry

Introduction

The most common identified pathological causes of vaginal discharge are vulvovaginal candidiasis (VVC) in 20–25% cases, bacterial vaginosis (BV) in 40–50% cases, and trichomoniasis in 15–20% cases [9]. While VVC and BV are not sexually transmitted,*Trichomonas vaginalis* is a sexually transmitted protozoan. Allergic reactions, atrophic vaginitis, vaginal irritants, and inflammatory conditions are non-infectious causes which can occur but are much less common.

Vulvovaginal Candidiasis

- The vaginal discharge is classically thick, white, and of a cottage cheese consistency.
- The vaginal mucosa is generally erythematous.
- Patients complain of itching and/or burning.
- Generally, there is no odor.
- Vaginal pH <4.5.
- KOH wet mount shows buds and hyphae.
- Risk factors: diabetes, antibiotic use, corticosteroid use, and immune compromise.
- Organisms: *Candida albicans* and other *Candida* species (less common).

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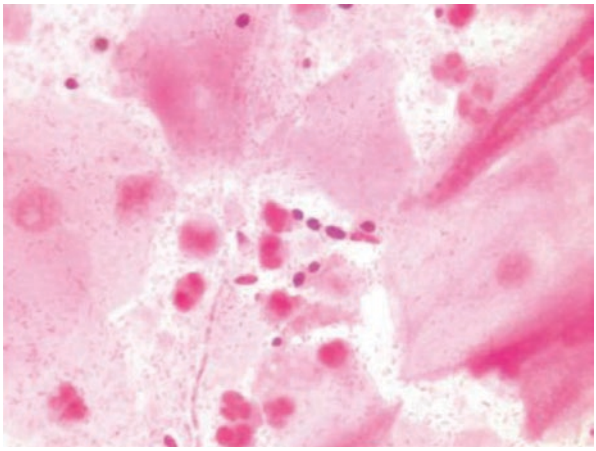


Fig. 9.1 Budding yeast and hyphae on a Gram-stained specimen

Microscopic examination of the discharge associated with VVC (Fig. 9.1) will show hyphae and buds when discharge is combined with 10% KOH solution.

Bacterial Vaginosis

- The hallmark complaint is discharge with a fishy odor [1].
- The discharge is generally thin and white-gray.
- The vaginal mucosa is either normal or may be mildly inflamed.
- Vaginal pH > 4.5.
- Clue cells noted on saline wet mount (Fig. 9.2).
- Generally patients do not complain of vaginal itching or burning.
- Risk factors: smoking, douching, low socioeconomic status, new or multiple sex partners, unprotected intercourse, and women who have sex with women [9].
- Organisms: Polymicrobial anaerobes: *Gardnerella vaginalis*, *Prevotella*, *Mobiluncus*, *Ureaplasma*, and *Mycoplasma* [10].

Diagnosis of BV is done using Amsel's Criteria. Three of the following four criteria are required to make a diagnosis:

- A thin nonclumping, homogeneous gray-white discharge.
- A vaginal pH greater than 4.5.
- More than 20% of cells are clue cells (Fig. 9.2) that are present on a saline wet mount (most reliable single indicator of BV).
- A positive whiff test (presence of fishy amine odor with addition of KOH to the discharge) [3].

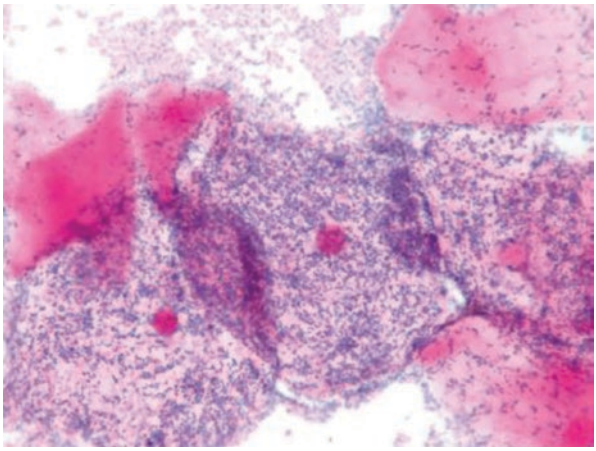


Fig. 9.2 Clue cells on vaginal smear on a Gram-stained specimen. These cells appear clear on a nonstained specimen

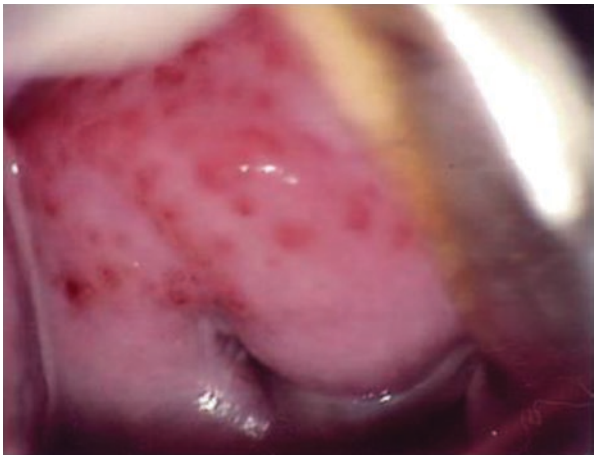


Fig. 9.3 Strawberry cervix

Trichomoniasis

- Discharge is classically frothy, green, or yellow [2].
- Foul odor – may be fishy smelling.
- Itching and burning may be present.
- Strawberry cervix seen in 10% women (Fig. 9.3).
- Vaginal pH >5.4.
- Saline wet mount shows pear-shaped motile organisms.
- Risk factors: low socioeconomic status, multiple sex partners, unprotected intercourse, smoking, and drug use [9].

- Organism: *Trichomonas vaginalis*.
- Nucleic acid amplification tests are highly sensitive and specific for *T. vaginalis* and recommended. NAAT detects three to five times more *T. vaginalis* than wet mount microscopy [10].

In trichomoniasis (Fig. 9.4), saline wet mount will show motile pear-shaped organisms.

Healthy women have varying amounts of normal vaginal discharge during their menstrual cycles. A Gram stain will demonstrate smooth squamous epithelial cells and lactobacillus (Fig. 9.5).

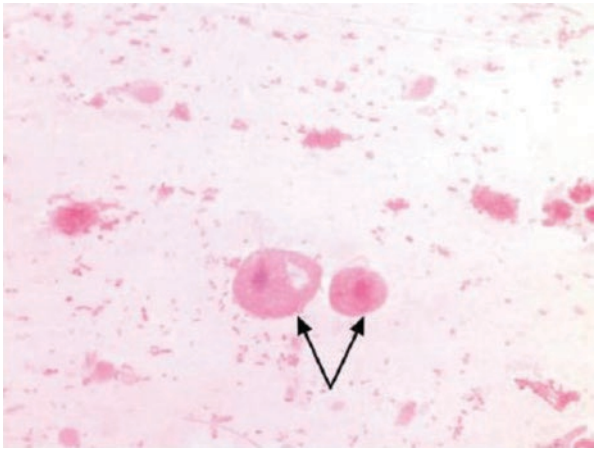


Fig. 9.4 Trichomonads on vaginal smear on a Gram-stained specimen

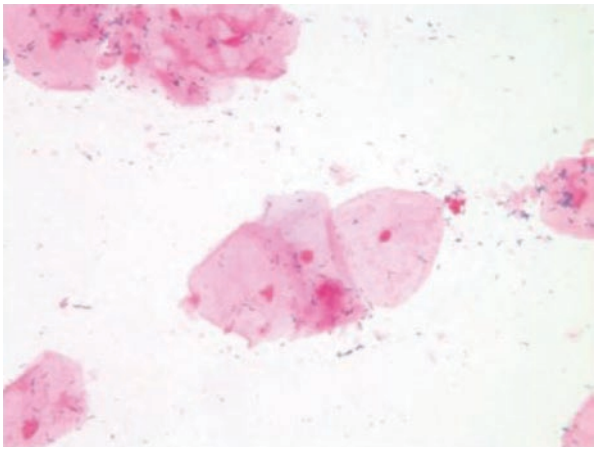


Fig. 9.5 Gram stain of normal vaginal discharge

Commercially Available Tests

There are several commercial kits available to assist in the diagnosis of vaginitis.

The Affirm™ VPIII Microbial Identification Test (Becton, Dickinson, & Co., Sparks, MD) is a DNA probe test intended for use in the detection and identification of *Candida* species, *Gardnerella vaginalis*, and *Trichomonas vaginalis* in vaginal fluid specimens from patients with symptoms of vaginitis/vaginosis [4]. The results are available in 45 minutes, and the sensitivity and specificity are 63% and 99.9%, respectively [10]. A speculum exam without water or lubricant should be performed to obtain the sample of vaginal fluid from the posterior vagina and the lateral walls of the vagina. The sample is then processed in the office if the equipment is purchased or alternatively sent to the lab for testing.

The APTIMA *Trichomonas vaginalis* assay (Hologic Gen-Probe, San Diego, CA) detects *T. vaginalis* RNA with a sensitivity of 95.3–100% and specificity of 95.2–100% [10]. The urine and vaginal swabs have up to 100% concordance.

For identification of bacterial vaginosis, the OSOM BV Blue test (Sekisui Diagnostics, Framingham, MA) detects vaginal sialidase activity and has sensitivities of 92%–100% and specificities of 92%–98% compared with Gram stain [11].

Treatment

Candidal Vaginitis

Oral Regimen:Fluconazole (Diflucan) 150 mg po × 1 dose
Over the Counter (OTC) Intravaginal regimens:

- Clotrimazole 1% cream 5 g intravaginally nightly × 7–14 days or
- Clotrimazole 2% cream 5 g intravaginally nightly × 3 days
- Miconazole 2% vaginal cream 5 g nightly × 7 days or
- Miconazole 4% vaginal cream 5 g nightly × 3 days or
- Miconazole 100 mg vaginal suppository nightly × 7 days or
- Miconazole 200 mg vaginal suppository nightly × 3 days or
- Miconazole 1200 mg vaginal suppository nightly × 1
- Tioconazole 6.5% ointment 5 g intravaginally in a single dose

Prescription Intravaginal Regimens:

- Butoconazole 2% cream 5 g as a single dose
- Terconazole 0.4% cream 5 g vaginal suppository nightly × 7 days

- Terconazole 0.8% cream 5 g vaginal suppository nightly × 3 days
- Terconazole 80 mg vaginal suppository nightly × 3 days.

Recurrent VVC: Fluconazole 150 or 200 or 300 mg every 3 days for 7 days

Non-albicans Candida *Species*

- Optimal treatment regimen is unknown. Longer duration of therapy helpful.
- Topical or oral treatment with a nonfluconazole azole drug for 7–14 days.
- May respond to boric acid 600 mg intravaginally daily for 14 days [8].

Bacterial Vaginosis

- Metronidazole 500 mg PO BID for 7 days; efficacy 86% at 5–7 days; 78% at 4 weeks [6]
- Metronidazole 0.75% gel 5 g vaginally BID for 5 days; efficacy 81% at 5–7 days; 71% at 4 weeks
- Clindamycin 2% cream 5 g vaginally nightly for 7 days; efficacy 85% at 5–7 days; 82% at 4 weeks
- Alternative regimens:

  (a) Clindamycin 300 mg PO BID for 7 days
  (b) Clindamycin 100 mg ovules inserted into the vagina nightly ×3 days
  (c) Tinidazole 2 g orally once daily for 2 days
  (d) Tinidazole 1 g orally once daily for 5 days

Recurrent BV: Repeat any of the regimens, or 2 gm metronidazole with 150 mg fluconazole monthly has been shown to be effective.

The following treatments are recommended by the CDC 2015 STI guidelines:

Trichomoniasis

- 2 g metronidazole orally (po) at once or tindazole (Tindamax) 2 g po × 1 dose.
- Alternative regimens: Metronidazole 500 mg po twice daily (BID) × 7 days.
- Recurrent infection: Avoid single-dose therapy; treat with metronidazole 500 mg po twice daily for 7 days. If this fails, treatment should be 2 gm of metronidazole or tindazole for 7 days [7].

- There is little evidence the following work and therefore should be avoided: intravaginal betadine (povidone-iodine), clotrimazole, acetic acid, furazolidone, gentian violet, nonoxynol-9, and potassium permanganate.

Case Studies

Case A

A 32-year-old G3P3 who comes in complaining of a 2-week history of foul-smelling vaginal discharge. She describes the discharge as whitish and profuse. She feels the need to wear a panty liner at times. She denies having any vaginal sores or bumps. She does not find her vagina to be particularly itchy or sore. She emphatically insists that her only sexual partner is her husband of 12 years. She is otherwise well and has no chronic medical problems and does not take any medications. Her LMP was 2 weeks ago and was normal. She denies any other associated symptoms.

Case B

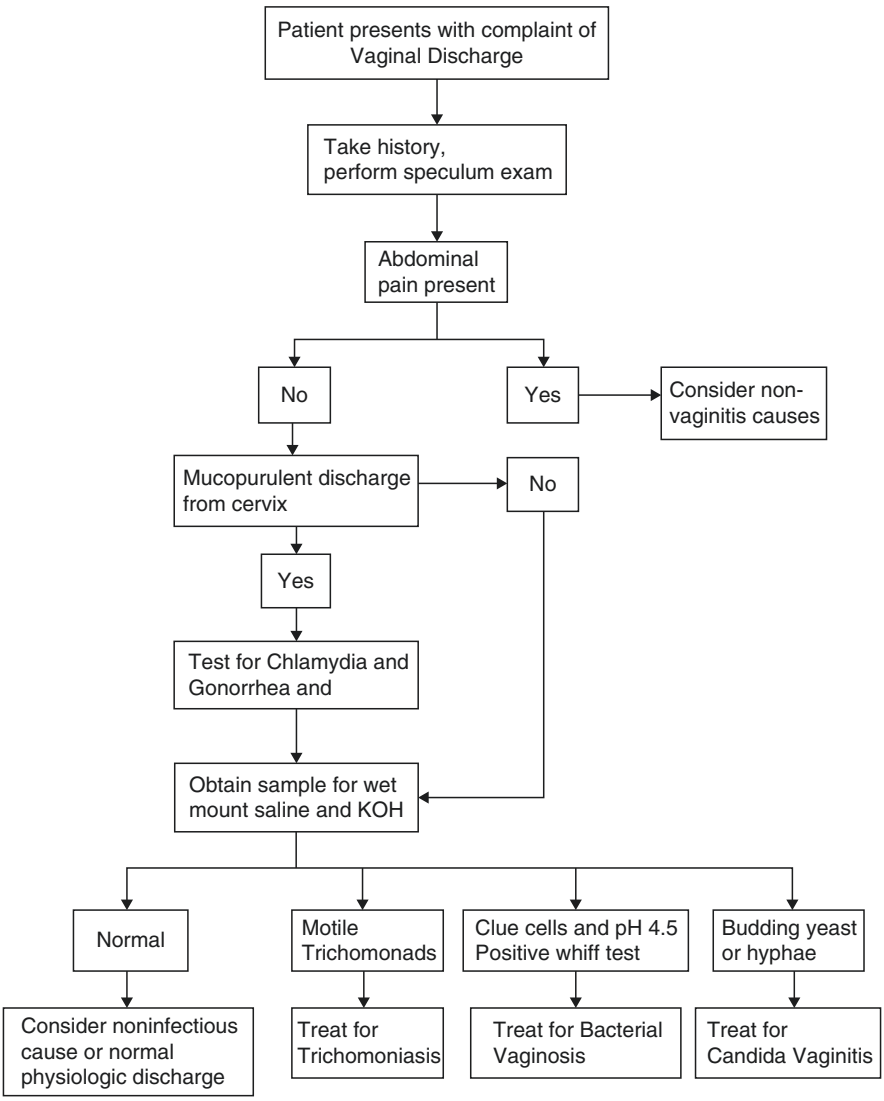
A 29-year-old woman complaining of multiple episodes of vaginal discharge and itching. She has used multiple over-the-counter preparations to try and help her symptoms. She has found these products moderately helpful in the past, but this time, she feels that the usual creams are not helping. She describes the discharge as thick and white. She finds her vaginal area to be very itchy. She has had two sexual partners in the past year but insists that she always uses condoms for protection. She denies any other associated symptoms.

Case C

This is an 18-year-old woman who comes in for an emergency visit to your office for an itchy vaginal discharge that began 4 days ago. She is very concerned about “this smelly, constant discharge.” She also complains of itching and burning in her vaginal area. She is healthy and is on no medications. She has had several sexual partners in the past year. She denies any other associated symptoms.

Diagnosis (Algorithm 9.1)

Vaginal discharge



Algorithm 9.1 Decision tree for diagnosis of vaginitis

Differential Diagnosis (Algorithm 9.1)

- Vulvovaginal candidiasis
- Bacterial vaginosis
- Trichomoniasis
- Gonorrheal cervicitis
- Chlamydial cervicitis
- Noninfectious causes of vaginitis:
- Atrophic vaginitis
- Irritant/chemical vaginitis
- Normal physiologic discharge

Indications (Algorithm 9.1)

- Vaginal discharge
- Vaginal irritation
- Vaginal odor

Contraindications

None.

Always use sensitive exam techniques, but especially in women who have never had penetrative intercourse, postmenopausal females, and sexually assaulted females. Consider avoiding the speculum exam if it is not tolerated, and do vaginal swab.

Equipment (Fig. 9.6)

- Vaginal speculum
- Nonsterile gloves
- Cotton swab applicators
- Test tube with saline
- Microscope with 10× and 40× magnification
- 10% KOH solution
- Microscope glass slides and cover slips

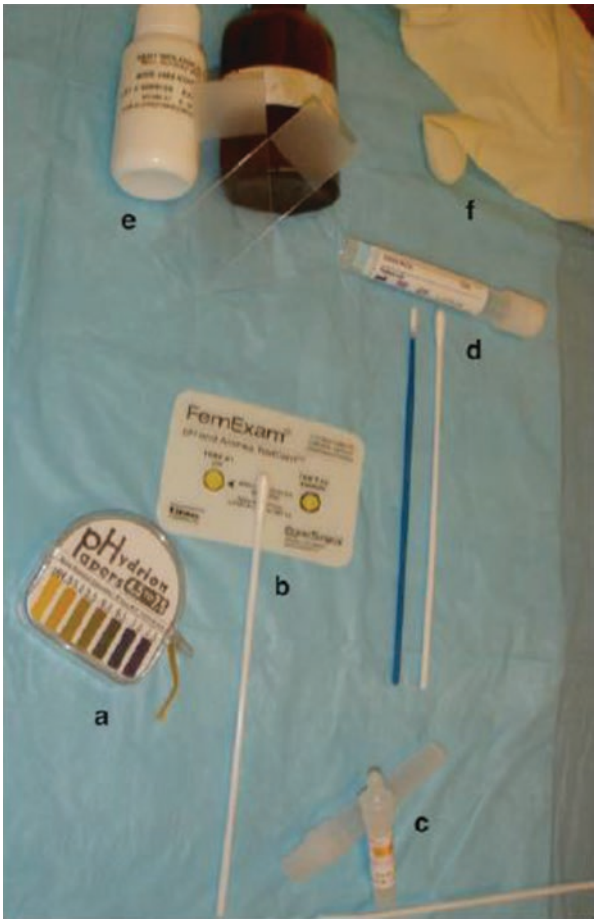


Fig. 9.6 Nonsterile equipment setup for vaginal discharge: (**a**) pH paper (Hydrion™ Papers, Micro Essential Labs, Brooklyn, NY); (**b**) FemExam® (CooperSurgical, Trumbull, CT) specimen card with swab [5]; (**c**) Affirm® (Becton, Dickinson, & Co, Franklin Lakes, NJ) specimen collection container, KOH, swab; (**d**) Gonorrhea/ Chlamydia collection container with swabs; (**e**) saline and KOH for microscopic evaluations with glass slides; (**f**) gloves

- Nitrazine paper – narrow range pH paper
- Gonorrhea and chlamydia antigen culture tubes
- Commercial kits (optional):
  - BD Affirm™ VPIII Microbial Identification Test
  - APTIMA
  - OSOM BV, OSOM Trichomonas Test

Procedure (Algorithm 9.1)

1. Place the patient in the dorsal lithotomy position after noting any abdominal or pelvic tenderness on abdominal examination.
2. Carefully note any irritation of the labia. Note any discharge, smell, open sores, or masses.

3. Insert speculum into vagina.
4. Note quality, color, and character of discharge. Also note erythema or open sores in vagina or on cervix. Note whether the discharge is primarily coming from the cervical os or whether it is diffusely in the vagina.
5. Use cotton swab to take sample of discharge from lateral vaginal walls. Consider whether it is useful to do a chlamydia and gonorrhea culture. If the discharge is primarily coming from the os, and if the patient has had unprotected intercourse, consider doing a culture.
6. Place a cotton swab into test tube that contains a few drops of saline solution. Cap the test tube.
7. Use a cotton swab to take another sample of discharge from lateral vaginal walls, and then use nitrazine paper to determine pH of the discharge sample. Normal vaginal pH is 3.8–4.5. Bacterial vaginosis (BV), trichomoniasis, and atrophic vaginitis often increase the vaginal pH above 4.5. Obtain cultures for gonorrhea and chlamydia, if indicated. Remove speculum and perform a bimanual pelvic exam. If there are symptoms of pain or if the patient is at risk for sexually transmitted infections, send the cultures for gonorrhea and chlamydia.
8. Take test tube to your office laboratory while your patient is changing.
9. Perform the whiff test. Add several drops of potassium hydroxide (KOH) to a sample of the vaginal discharge. Using gloved hands, hold the slide within 4–6 inches of your nose and inhale through your nose. A strong fishy odor from the mixture suggests bacterial vaginosis or *Trichomonas vaginalis*.
10. Make the KOH slide by placing a sample of the vaginal discharge on the slide and mix with a few drops of the 10% KOH solution. The KOH destroys bacteria and cells from the vagina, leaving yeast hyphae and spores (if present) that indicate a yeast infection. Place cover slip on the slide, and then view under a microscope.
11. Make the wet mount slide by placing a sample of the vaginal discharge on a slide and mix with saline solution. Place cover slip on the slide. The prepared slide is then examined under a microscope for bacteria, yeast cells, trichomonads, white blood cells that indicate an infection, or clue cells that indicate bacterial vaginosis (BV). These are best seen by 40× magnification.

Complications and Risks

- Pain and tenderness during exam
- Extreme anxiety (consider whether patient has been victimized)

Tricks and Helpful Hints

- Women with some forms of vaginal discharge, especially candidal vaginitis, may actually have very little lubrication. Consider using extra time when inserting the speculum.

- Many women have more than one sexually transmitted infection (STI) at the same time. Consider doing cultures on those who are at risk for STIs.
- Women with trichomoniasis should be instructed to avoid intercourse with sex partner until partner is treated.
- Women should be counseled to avoid alcohol when taking metronidazole.
- Clindamycin vaginal cream is oil-based and can weaken latex condoms or diaphragms during use of the cream and for 5 days after use.
- VVC is usually not sexually transmitted; therefore, male partners do not need treatment.
- All vaginal creams/suppositories used for VVC can weaken latex condoms and diaphragms.
- pH may be elevated (more alkaline) due to menstrual blood and semen [12]
- Assays sent to laboratories for evaluation may not be covered by all insurance companies and can be very expensive. Consider reviewing the patient's insurance coverage prior to sending.

Interpretation of Results

See Algorithm 9.1 for a decision tree for diagnosis of vaginitis.

Procedure Note

(Provider to fill in blanks/circle applicable choice when given multiple choices and customize as needed.)

On speculum examination of the vagina and cervix, samples of vaginal discharge were obtained with cotton-tipped applicators. The whiff test was performed. The sample was examined with KOH slide and with a saline wet mount preparation. Microscopy revealed clue cells, trichomonads, or yeast and hyphae. Nitrazine paper revealed the pH to be ___.

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
87210	Smear, primary source with interpretation; wet mount for infectious agents using KOH or saline
Medicare Codes	
Q0111	(HCPCS code) Wet mounts, including preparations of vaginal, cervical, or skin specimens for saline slide

Q0112	For the slide with KOH
ICD 10-CM-Diagnostic Codes	
N76.0	Vaginitis NOS
B37.3	Candidal vaginitis
N76.0	Bacterial vaginosis
A59.01	Trichomonas vaginitis
N95.2	Atrophic vaginitis
N89.8	Vaginal discharge
R10.2	Vulvar pain
R10.2	Vaginal pain

Case Study Outcome

Case A

The nitrazine paper showed a pH of 5.0. The KOH slide did not show any buds or hyphae. The whiff test released a strong fishy odor. The saline wet mount showed many clue cells. The diagnosis of bacterial vaginosis was made, and the patient was treated with metronidazole 500 mg PO twice daily for 7 days. She was advised to abstain from alcohol during the time of treatment to avoid nausea, vomiting, and abdominal pain.

Case B

The nitrazine paper showed a pH of 3.5. The KOH slide showed many buds and hyphae. The whiff test did not produce any strong odors. The saline wet mount showed some white blood cells, but no clue cells. The diagnosis of candidal vaginitis was made, and the patient was treated with diflucan 150 mg orally one time.

Case C

The nitrazine paper showed a pH of 5.4. The KOH slide did not show any buds or hyphae. The whiff test did not produce any strong odors. The saline wet mount showed many motile pear-shaped organisms. The diagnosis was trichomoniasis, and the patient was treated with 2 g of metronidazole orally at once. She was advised that trichomoniasis is a sexually transmitted infection, and so her sexual partner should be treated at the same time. She was advised to abstain from alcohol during the time of treatment to avoid nausea, vomiting, and abdominal pain.

Postprocedure Patient Handout

(Provider to customize as needed.)

Candida

You have an infection of *Candida albicans*, commonly known as yeast. Yeast is *not* a sexually transmitted infection (STI); you did *not* catch it from anyone, and your partner does not need to be treated. It is caused by a change in the pH of the vagina, which is usually acidic and keeps yeast from growing. A variety of antibiotics, diabetes, pregnancy, and your menstrual period may change the pH and make it more likely for yeast to grow. In addition, there are some preventable measures that may help in avoiding another infection. Wearing cotton underwear, wiping front to back after urination, and avoiding douching may help. The medications are safe to use while pregnant and nursing.

Occasionally, women have chronic yeast infections. If you have not improved after the course of medication given to you, please return to your clinician.

Bacterial Vaginosis

You have bacterial vaginosis, also known as *Gardnerella vaginalis*. It is the most common vaginal infection. It is caused by an overgrowth of the anaerobic bacteria that are commonly present in the vagina. BV is *not* a STI; you did *not* catch it from anyone, and your partner does not need to be treated. The infection can cause a thin vaginal discharge and sometimes a distinct fishy odor. It can be treated with oral pills or vaginal creams or gels. While it is safe to take the medication in pregnancy, there is less information about using the medication while nursing. If you are nursing, please discuss with your clinician.

If you are taking metronidazole by mouth, be sure not to drink alcohol while on the medication and for 24 hours after you take the last dose of medication. If you are using the clindamycin vaginal cream or ovules, be aware that the cream may cause condoms to break. Use another form of birth control while on the cream and for 3 days afterward.

Some women may experience a yeast infection at the same time or after the treatment of bacterial vaginosis. If so, you may need treatment with an antifungal medication after the treatment of the BV. If you have any questions, please call your clinician.

Trichomonas Vaginalis

You have an infection of *T. vaginalis* ("trich" or "tric"). Trich is a protozoal organism that is sexually transmitted. Trich causes a thin, watery yellow-greenish discharge that can have fishy odor. It can cause itching of the vagina and vulva ("lips") and burning during urination. It can also be present with very few symptoms for a very long time.

You and your partner should be treated for Trich at the same time to avoid passing the infection back to each other. It is important to avoid drinking alcohol while you are on the medication and for 24 hours afterward. Trich infections can be avoided by having your partner use condoms. Treatment is safe in pregnancy. Please let your clinician know if you are nursing.

Trich can be present with other vaginal infections and other STIs. Please make an appointment with your clinician to discuss screening for other STIs if you have not done so during your visit today or if other symptoms occur after treatment. Please make a follow-up visit in 3 months for retesting.

Questions for Learners

- What are the circumstances where it would be advisable to send cultures for gonorrhea and chlamydia?
- If the microscopic examination, nitrazine, and whiff tests are nondiagnostic, what further testing should be suggested?

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Chapter 10
Cervical Polyp Removal

Ryan Planer

Introduction

Cervical polyps are pedunculated red masses which vary in size from several millimeters to centimeters (Fig. 10.1). They are usually found in the endocervical canal and protrude from the cervical os. Occasionally, polyps protruding from the cervical os are endometrial in origin. Cervical polyps are often single but can be multiple; they are the most common cervical lesion and occur in 2–5% of women [1]. They are usually bright red, spongy in nature, and friable. Management of cervical polyps in the primary care setting may be accomplished through either

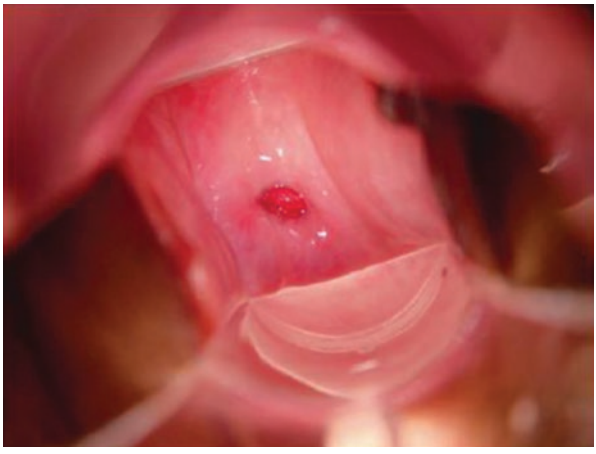

Fig. 10.1 Endocervical polyp

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expectant management or polypectomy, with close considerations of the patient's risk factors. The clinician must review factors such as patient's symptoms, pregnancy, or menopausal status.

Most often asymptomatic, polyps are commonly found on the routine women's health exam. They can also be detected on colposcopy, seen as filling defects on hysterosalpingogram, and seen on abdominal and transvaginal ultrasound. Women with polyps can also present with intermenstrual spotting, post-coital bleeding, persistent leukorrhea, postmenopausal bleeding, or heavy menses (i.e., symptomatic polyp). The cause of polyps is unknown, although they may be a secondary reaction to cervical inflammation or hormonal stimulation and are thus seen more often with increasing age, inflammation, trauma, and pregnancy. Cervical polyps are most frequently seen in parous, perimenopausal, and postmenopausal women in the second through fifth decades of life [1, 2]. Symptomatic polyps tend to be more common in premenopausal women. More pathological conditions are associated with symptomatic polyps and tend to occur more commonly in the postmenopausal age group. While malignant potential is rare, if symptomatic in the postmenopausal woman, uterine dilatation and curettage (D&C) should be considered as part of the evaluation [2].

Asymptomatic Cervical Polyp

In the asymptomatic premenopausal female, a cervical polyp may be treated as a normal variant, and expectant management may be utilized to minimize procedure risk, return visits, and overall healthcare expenditure. A shift in the management of asymptomatic cervical polyps over the last three decades is well supported in the literature, although currently there are no practice guidelines from professional societies. Large research studies (*n* of 898–5488) demonstrate that asymptomatic cervical polyps in a premenopausal patient with normal cytology reported no cases of malignancy or significant pathology [3]. Important discussion with the patient about individualized risks, prior Pap smear results, and proper consent with documentation are prudent in either expectant management or polypectomy.

Symptomatic Cervical Polyp

Symptomatic polyps most often present with complaints of intermenstrual spotting, postcoital bleeding, persistent leukorrhea, postmenopausal bleeding, or heavy menses. Several studies have noted an association of endocervical polyps and endometrial polyps, with one study showing that 25% of women with cervical polyps had endometrical polyps as well [4–6]. Combination oral contraceptives reduce the incidence of cervical polyps in this population from 25% to 8.3%. Postmenopausal women with polyps had a 56.8% incidence of cervix-related endometrial polyps [4].

Because of this association between endometrial and cervical polyps, some advocate that removal of cervical polyps should be done with hysteroscopy which would allow for evaluation of the endometrial cavity. This would help clarify the initial diagnosis as well as allow for precise visualization of the polyp peduncle and treat concurrent asymptomatic intrauterine pathology [4].

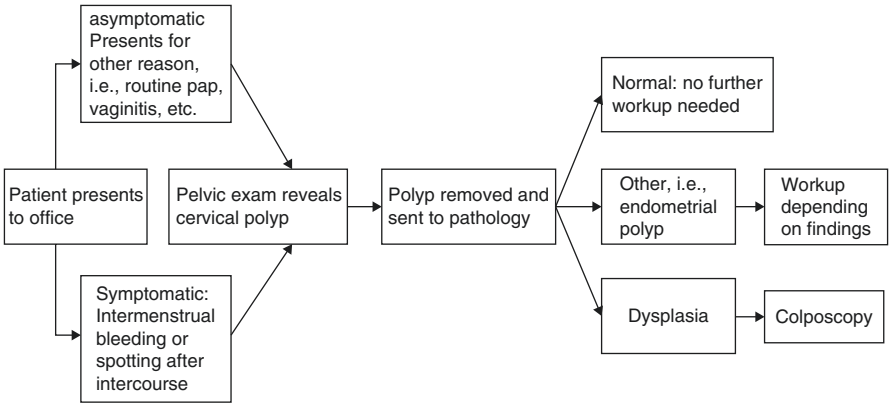
Histologically, cervical polyps are composed of endocervical epithelium with a fibrovascular stalk. Most are benign, some will show squamous metaplasia or squamous dysplasia, and malignancy is very rare [7]. All polyps should be sent to pathology for evaluation.

Pregnancy

The removal of cervical polyps during pregnancy has been shown to increase the risks of chorioamnionitis, spontaneous abortion, and preterm delivery [8, 9]. Polypectomy during pregnancy is reserved for clinical situations in which there is a high suspicion of possible malignancy. The provider may also consider removal at the time of delivery, and if a concern for malignancy, provide for close coordination with obstetrical and oncological colleagues [9] (Algorithm 10.1).

Case Study

A 45-year-old female presents to your office for her annual exam and is also due for a Pap smear. Review of systems reveals regular menses, with occasional spotting after intercourse. No other spotting noted. On pelvic exam, a pedunculated red mass at the endocervical os is found.



Algorithm 10.1 Decision tree for endometrial polyp removal

Diagnosis

Cervical Polyp

Differential Diagnosis

- Cervical polyp
- Condyloma
- Nabothian cyst
- Prolapsed myoma
- Cervical malignancy
- Squamous papilloma
- Sarcoma
- Retained products of conception

Indications for Polyp Removal

- Intermenstrual spotting or bleeding
- Spotting after intercourse
- Removal to prevent future irritation, bleeding, or discharge

Contraindications

- Pregnancy – delay removal until postpartum, unless significant bleeding exists
- Inability to visualize the base of the polyp
- Bleeding or coagulation disorder

Complications

- Bleeding/spotting
- Recurrence
- Infection (rare)

Equipment (Fig. 10.2)

- Vaginal speculum
- Nonsterile gloves

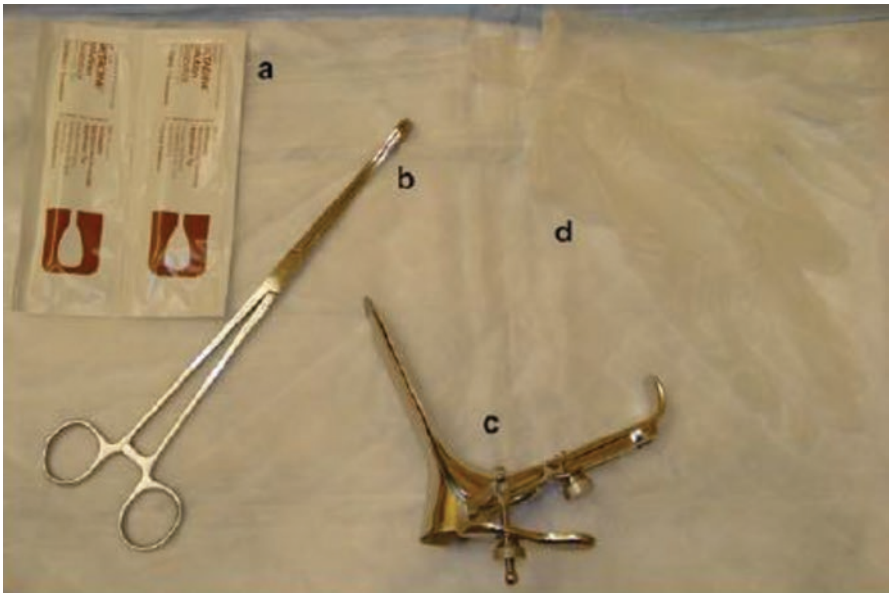


Fig. 10.2 Nonsterile equipment for endocervical polyp removal: (**a**) Betadine® Solution Swabsticks (Purdue Pharma, Stamford, CT); (**b**) Ring forceps; (**c**) Pederson speculum; (**d**) Gloves

- Long Kelly or ring forceps
- Monsel's solution or silver nitrate sticks
- Topical anesthetic
- Formalin container
- Optional equipment (Fig. 10.3):
  - Endocervical curette (ECC)
  - Tischler biopsy forceps
  - Colposcope

Procedure

1. Insert speculum into the vagina and identify polyp.
2. Place long Kelly or ring forceps as close to the base of the polyp as possible and clamp.
3. Twist the polyp in one direction until it easily breaks off.
4. An ECC curette can be used to curette the base of the endocervical canal in order to remove any polyp remnants. An endocervical brush can also be used.
5. Send specimen to pathology for review.
6. Silver nitrate or Monsel's solution can be used to treat any bleeding.

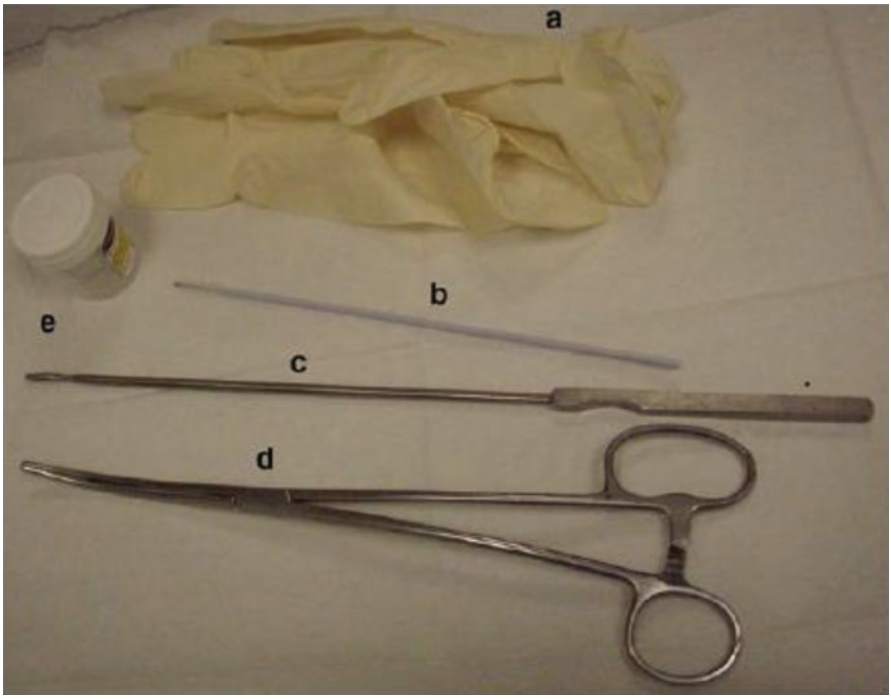


Fig. 10.3 Optional Equipment for endocervical polyp removal: (**a**) Nonlatex, nonsterile gloves; (**b**) Endocervical brush; (**c**) Endocervical curette; (**d**) Long kelly forceps; (**e**) Cytology fixative jar

Helpful Hints

Use the colposcope to identify the base of the polyp, and then remove the polyp using a Tischler biopsy forceps.

Interpretation of Results

- Report usually indicates benign tissue.
- If dysplasia noted on polyp, consider colposcopy.
- Any abnormal finding (i.e., sarcoma) requires additional therapy.

Procedure Note

The patient was placed in the lithotomy position, a speculum was inserted into the vagina, and the cervix was identified. The polyp was identified. A long Kelly was placed at the base of the polyp, and the polyp was removed in its entirety by gentle

twisting. An ECC curette was used to remove any polyp fragments in the endocervical canal. The specimen was sent to pathology. The patient tolerated the procedure without difficulty.

Coding

There is no separate CPT code for cervical polyp removal.

57500	Cervix uteri biopsy
57505	Endocervical curettage
58100	Endometrial sampling with or without endocervical sampling, without cervical dilation, any method

ICD 10-CM Diagnostic Codes

N84.1	Polyp of cervix uteri
N85.0	Endometrial hyperplasia
D26.0	Benign neoplasm of the cervix uteri
A63.0	Condyloma acuminatum

Postprocedure Patient Instruction

The patient should be told to avoid douching or intercourse until all bleeding/spotting has resolved. Any excessive bleeding should be reported immediately and the patient re-evaluated. Pathology is usually benign and no further treatment usually necessary. Routine follow-up with an annual exam is recommended.

Case Study Outcome

The polyp was easily removed with minimal bleeding. Pathology revealed normal benign epithelium.

Patient Handout

Cervical Polyp Removal

Cervical polyps are small pieces of tissue that are found within the canal of your cervix. While these are usually benign tissue pieces, the sample is always sent to the pathologist for review to ensure that no cancer or other abnormality is present.

Today your clinician removed a cervical polyp from your cervix. You should expect to have some minimal spotting/bleeding. This should not be heavier than a normal period.

If you experience heavier bleeding, please call your physician/clinician right away.

Cramping is usually transient, but if it persists, please take 3 ibuprofen 200 mg tablets every 6 hours as needed or acetaminophen 650 mg every 4–6 hours as needed.

You should avoid intercourse, douching, or tampon use for several days.

Your clinician/physician will inform you of the results of the polyp when they receive the information from the pathologist.

Please call the office if you have any problems or questions.

Questions for Learners

- Should lack of payment from insurance companies affect a clinician's decision to remove an endocervical polyp?
- When would it be appropriate to leave a polyp in place?

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Chapter 11
Barrier Contraception

Jennifer W. McCaul

Introduction

The use of barrier methods as the primary mode of contraception has declined over several decades due to the increasing number and relative effectiveness of other available methods. Barrier methods still have a place in providing contraception for certain carefully selected women. Unlike other forms of contraception, many barrier methods may also provide some degree of protection against sexually transmitted infections. The use of barrier methods is generally female controlled, although may require partner cooperation. Many barriers are widely available without a prescription. They are not hormonally based, making them safe for many patients in whom the use of a hormonal contraceptive would be contraindicated or undesired. Barrier methods available today include male (external) and female (internal) condoms, the contraceptive sponge, diaphragms, and cervical caps.

Case Study

Kara is a 26-year-old nulliparous patient in a monogamous longstanding relationship. She presents to your office today for her Pap smear and physical exam and asks you about changing her birth control method. She and her partner have been using condoms but would like a method that allows a little more spontaneity. She intends on having children in the next 1–2 years. In the past, she gained a great deal of weight on Depo-Provera and does not want to use this method again. She is a

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smoker and wants to avoid oral contraceptives because she has heard about the risks. Her aunt told her about her diaphragm and she asks if this method is still available?

The Male Condom

Some version of the male (external) condom has been used to prevent pregnancy since the beginning of recorded history. Early versions were made of silk and animal tissues. Currently external condoms are available in latex (most common), polyurethane, polyisoprene, silicone, and lambskin. Widely available without a prescription and with few contraindications, condoms provide the most consistent protection against transmission of sexually transmitted infections of all barrier methods.

If used properly, condoms can be quite effective, with perfect use failure rates of 2%. However, they require commitment, forethought, and consistent and well-timed use, resulting in a typical use failure rate of 18% [1]. There is no evidence that condoms lubricated with non-oxynol-9 spermicide are more effective, and due to potential adverse effects of N-9 such as increased rate of HIV transmission, these condoms are no longer recommended [2].

Latex condoms are available in multiple sizes, textures, and colors and tend to be inexpensive. They must be used with water-based lubricants only, as the latex condom will become permeable within seconds of contact with oil-based lubricants. Sexually transmitted infection (STI) prevention is most effective for diseases that are transmitted in bodily fluids (HIV, chlamydia, gonorrhea, trichomoniasis) as they have not been proven to be as effective for those infections spread by skin contact (herpes and HPV) [3]. If not stored properly in a dark, cool, dry place, or if stored for more than 5 years, the latex can deteriorate and effectiveness decreases. Patients using latex condoms may complain of decreased sensitivity, a side effect which may be utilized therapeutically to address premature ejaculation in males.

Nonlatex condoms offer alternatives for those who have latex allergies or other issues that prevent their consistent use. Polyurethane condoms transmit more body heat and can be used with oil-based lubricants. While possibly less effective than latex, due to higher breakage rates [4], all but lambskin condoms offer some protection against STI transmission. Lambskin condoms have small pores on the surface that can allow passage of viral particles such as HIV, HSV, and hepatitis B [4].

Condoms need to be applied to the erect penis, prior to penetration, allowing space for semen by pinching ½ inch at tip while it is rolled on (Fig. 11.1). Avoiding the presence of air bubbles under the condom and wearing throughout intercourse prevents leakage and increases effectiveness. Proper removal occurs after ejaculation but while the penis is still erect, using care to hold the rim of the condom to prevent spillage.

Fig. 11.1 Male condom; pinch air out of condom after application

Indications for Use of Male Condom

- Patient desires nonhormonal contraception that provides protection against sexually transmitted infections.
- Both partners are willing to use the device properly with every act of coitus and store the device as directed prior to use.

Contraindications to Use of Male Condom

- Allergy to components in the condom (latex for latex condoms or lanolin for lambskin)
- Improper size, application process, or removal of condom
- Inability to store device in a cool, dry, dark place

Complications and Risks

- Irritation due to latex, lubricant, or spermicide.
- Slippage, breakage, or leakage of the condom.
- Increased risk of urinary tract infections (UTIs) due to alteration of normal vaginal flora with spermicide-coated condoms [5].
- Men may have decreased sensation or loss of erection.
- Errors in use may result in leakage, slippage, or breakage.

Procedure and Initiation of Method

1. Condoms are widely available in stores, online and through clinics, and do not require a prescription.
2. Patients choosing this method should be properly educated on selecting the correct size and type of condom; proper storage, utilization, and disposal of the condom; and safe lubricants to use with the selected type of condom. Models are available to demonstrate proper application.
3. Educate patients about the availability of emergency contraception (EC) in the event of condom failure and consider providing a prescription for EC if required in your patients using condoms as the primary method. STI testing should also be considered in this setting.

Tips and Helpful Hints

- Ensure that the patient is aware that they still have a risk for contracting sexually transmitted diseases and recommend routine screening.
- Encourage the patient to make condom application part of foreplay and involve both partners in the process of application if issues of erectile function and lack of spontaneity are barriers to use.
- Provide patients with a list of safely used lubricants if latex condoms are chosen as a primary contraceptive method.

Female Condom (Fig. 11.2)

The female condom has undergone several changes to address concerns regarding the initial version. Originally composed of polyurethane and available as Reality®, the new version is named FC2 and is the only female (or internal) condom available in the USA. Composed of nitrile polymer, it is a seamless soft sheath, closed at the

Fig. 11.2 Female condom (Courtesy of Mayer Laboratories, Inc.)

proximal end. Flexible rings at both ends act to anchor the proximal end into the vagina and to keep the outer end in place on the perineum.

FC2 is coated with a silicone-based lubricant but can be used with both water- and oil-based lubricants. FC2 should not be used with a male condom, as friction between the devices increases risk of displacement. Nitrile is less likely to degrade than latex and withstands storage well.

The FC2 acts as a physical barrier to skin contact and semen that can be inserted up to 8 hours prior to intercourse. It is the only barrier method that provides protection against pregnancy and a probable barrier to HIV and sexually transmitted infections and is completely female controlled. However, there is no current data to directly support that the FC2 is as effective as latex external condoms at preventing transmission of STIs [6]. Any recommendations for use to prevent STI transmission are based on prior data regarding the effectiveness of polyurethane male condoms.

Unlike male condoms, the penis does not need to be erect to initiate use.

The male partner may find it less constricting and the female partner may find the outer ring can increase enjoyment by stimulating the clitoris during intercourse.

Contraceptive effectiveness is estimated as comparable to the latex male condom, with a 5% annual pregnancy rate with perfect use and up to 21% rate with typical use [1]. Failure can occur due to device breakage; displacement, where the device slips completely into or out of the vagina during intercourse; or misdirection, if the penis is accidentally inserted next to rather than within the sheath [7]. The same events are thought to result in potentially less protection against STIs due to increased exposure to semen.

Indications for Use of Female Condom

- The patient desires a barrier method of contraception providing a degree of protection against STIs and allowing autonomous control.
- Allergy to latex or inability to use or tolerate external/male condoms.
- Willingness and ability to insert and use a new FC2 for each act of intercourse.

Contraindications to Use of Female Condom

- Allergy to nitrile
- Inability to insert the device properly due to pelvic anatomy or physical limitations

Complications and Risks

- Difficulty in inserting the FC2 properly.
- Slippage, breakage, displacement of device, or misdirection of penis during intercourse due to poor insertion of FC2.
- Rings may cause discomfort for either partner during intercourse.
- Noise can occur during intercourse (however this has been improved by the change to nitrile composition of the FC2).

Procedure and Initiation of Method

1. Female condoms can be purchased without a prescription; however, they can be prescribed for patients with many insurances to decrease the cost of the device to that of a prescription co-payment. In general, FC2 are more expensive when purchased over the counter than male condoms.
2. Insertion must occur prior to penetration and is accomplished by folding the internal ring and inserting it to the posterior fornix. FC2 do not need to be fitted to patients prior to use. Positions for insertion can include laying down or with one leg raised on a chair.
3. A new FC2 must be used for each act of coitus.
4. After intercourse, the outer ring must be twisted to close the sheath to contain semen prior to standing or removing. Remove by placing gentle traction on the twisted FC2.
5. FC2 must be thrown out, not flushed down the toilet.
6. Educate patients about the availability of emergency contraception and consider providing a prescription for EC in patients who choose condoms as the primary contraceptive method.

Tricks and Helpful Hints

- Many insurances will cover FC2 as a monthly prescription benefit.
- Male partners may find it more comfortable and less constricting than male condoms, and erect penis is not required for application.
- A female partner may find external ring increases enjoyment by stimulating the clitoris.
- If a mishap occurs, ensure that the patient is screened for STIs and considers the use of EC.

The Contraceptive Sponge and Other Spermicidal Agents

The contraceptive sponge is a soft, round, porous polyurethane device that is saturated with nonoxynol-9 spermicide and is inserted into the vagina prior to intercourse (Fig. 11.3).

Currently, the Today sponge, produced by Mayer Laboratories, Inc. is the only vaginal contraceptive sponge available on the US market. Today sponge's dimpled side fits around the cervix and works by blocking the sperm path, absorbing sperm into the sponge, and through its spermicidal activity. There is a loop on the other side of the device to facilitate removal. The Today sponge is effective immediately on insertion and protection lasts for a full 24 hours.

In addition to the contraceptive sponge, spermicides are available in many delivery methods, including gels, creams, films, and foams. In general, the use of spermicide alone is considered less effective for pregnancy prevention than when combined with a barrier. When used alone, the failure rate in nulliparous patients

Fig. 11.3 Contraceptive sponge

with perfect use of the sponge is 9% but up to 20% in parous women. For nulliparous women, typical use failure rate is 12% but 24% in parous women [8]. However, it should be noted that studies are very inconsistent and reported contraceptive failure rates for spermicides vary widely. Nonoxynol-9 is a surfactant that destroys the sperm cell membrane [8]. It is not a microbicidal substance. There is a risk of genital tissue irritation with the use of nonoxynol-9, which may facilitate transmission of HIV. This risk increases with duration of exposure and frequency of repeated use. For this reason, its use is not recommended in sex workers or others at high risk of HIV transmission [9].

Indications for Use of the Contraceptive Sponge

- Desire for nonhormonal contraception that is female controlled, in a patient with inability to use other available methods or who prefers not to.
- Patient who does not require STI protection.
- Need for 24 hours of uninterrupted protection without reapplication.
- Use in nulliparous patients has proven more effective.

Contraindications to Use of the Contraceptive Sponge

- High risk of exposure to HIV, HIV positivity, or current use of antiretroviral therapy
- Interrupted vaginal epithelium
- Allergy to spermicide ingredients
- History of toxic shock syndrome (TSS) in the past
- Need for protection against STIs
- Inability to properly insert the sponge
- Recurrent UTIs
- Vaginal bleeding – including menses or delivery in the last 6 weeks.

Complications and Risks

- There is a risk of developing TSS, and it is imperative that the device not be left in the vagina for more than 30 hours.
- Increased risk of HIV transmission with the use of nonoxynol-9.
- Relatively high risk of pregnancy with spermicide alone.
- Risk of urinary tract infections with nonoxynol-9 use.

Procedure and Initiation of Method

1. The Today sponge is available over the counter without a prescription. The sponge does not require fitting; it is available only in one size.
2. When inserting the sponge, wash hands and wet the sponge thoroughly with clean water.
3. Squeeze the sponge to activate foaming.
4. Insert the sponge deep inside the vagina with the dimple toward the cervix and the loop facing into the vagina (Fig. 11.4). It is effective immediately on insertion but must be in place before intercourse occurs.
5. The device should be left in place for 6 hours after the last episode of intercourse, up to a maximum of 30 hours. It provides 24 hours of protection without reinsertion for repeated acts of coitus. Remove by pulling down on loop.

Helpful Hints

- Ensure the sponge user is aware of symptoms/signs of TSS.
- Careful selection of patients for this method is crucial, taking into consideration risk of STI transmission and acceptability of unplanned pregnancy – due to high failure rates when used alone.

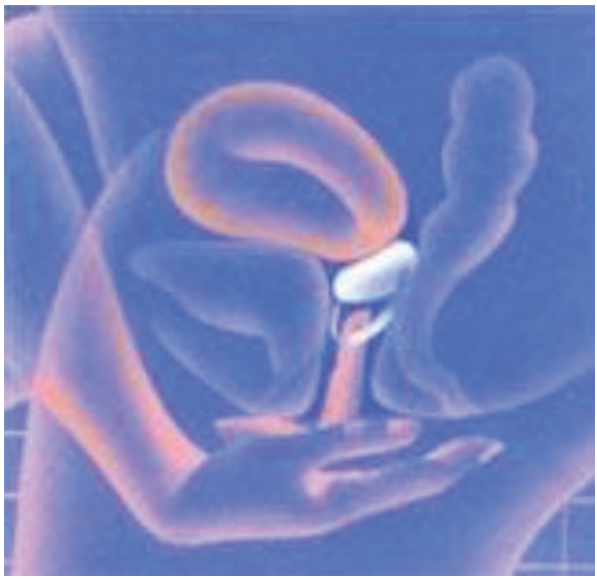

Fig. 11.4 Sponge placement

Contraceptive Diaphragm

The diaphragm is a silicone flexible dome that fits over the cervix and into the vaginal fornices during intercourse, providing a physical barrier to sperm. Inserted up to 2 hours prior to intercourse, it must be left in place for at least 6 hours and up to 24 hours after. The options currently available for patients choosing a diaphragm include the provider-fitted traditional version (Milex) (Fig. 11.5) or the newer single-size contraceptive barrier device (SILCS) called Caya® (Fig. 11.6), a product that requires a prescription and a vaginal examination but not a traditional size fitting. Janssen Pharmaceuticals ceased production of the popular Ortho All-Flex diaphragm in 2013, leaving the Milex Wide Seal as the only available fitted diaphragm.

The traditional diaphragm type must be properly fitted to each patient by their provider and refitted as necessary due to weight change or reproductive events. Effectiveness of the diaphragm is very user dependent, and estimated effectiveness rates range widely from 70% to 96%, assuming "perfect use" and spermicide use with the diaphragm [1].

The Milex Wide-Seal diaphragm is available in arcing spring and coil spring versions. Both types are silicone-based and have a thin skirt of silicone around the base of the rim to improve the seal and help hold spermicide. They are supplied by Cooper Surgical and select other medical suppliers and come in a variety of sizes ranging from 60 to 95 mm. Both types can be ordered through the provider who orders it directly from the supplier. Neither type of diaphragm can be obtained at the pharmacy.

The Milex arcing spring-type diaphragm folds into a half moon shape for insertion along a single plane and does not require an introducer. The arcing spring diaphragm's firm rim makes it the best choice for women with decreased pelvic support. Due to single plane folding, if the axis rotates while inserted, some women may find it difficult to remove.

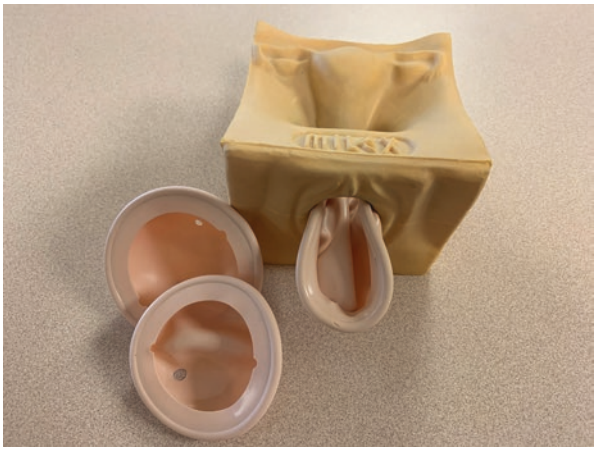

Fig. 11.5 Milex Wide-Seal silicone diaphragm

Fig. 11.6 Caya® diaphragm (Photo – image courtesy of KESSEL MEDintim)

The coil spring version of the Milex Wide-Seal diaphragm, the Omniflex, has a rim which is more flexible than the arcing spring, allowing for folding anywhere along the rim. It can be used with or without an introducer for insertion. It is better suited to women without pelvic muscle relaxation.

In September 2014, the Caya® was FDA approved for use in the USA. The Caya® is a silicone-based contoured-shaped diaphragm with a nylon rim. It has grip dimples to ease insertion and a dome for easy removal. It is designed to fit most women who would normally wear between a 65 mm and 80 mm diaphragm. Single-use disposable test fit devices are available from the distributor, HPSRx Enterprises Inc., to allow the patient to test use prior to ordering. The device is available supplied through the provider's office by purchasing from supplier, specialty pharmacies, and several commercial pharmacies with a prescription. If patient has already been fitted with a diaphragm in the 65–80 mm size range, there is no fitting required. Those with no prior diaphragm use may benefit from a test fit visit to ensure they are able to use the device comfortably. Caya® has a 6-month typical use failure rates of 9.6–12.5%, which is similar to the Milex diaphragm [10].

The diaphragm is filled with spermicidal jelly or cream to increase effectiveness. One small study has shown that women who use the diaphragm without spermicide are slightly more likely to become pregnant, but due to the low power of the study, this finding was not significant [11]. If repeated acts of intercourse take place during 24 hours of use, the diaphragm is left in place (Fig. 11.7) and additional spermicide is added. Acid-buffering gel has been explored as a spermicidal alternative with standard diaphragms and was found to have about the same effectiveness [12]. It has

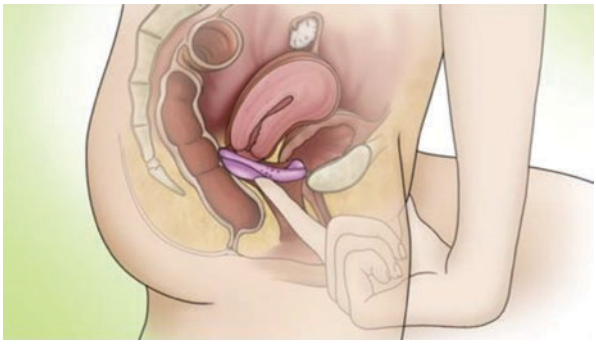

Fig. 11.7 Caya diaphragm in vaginal vault (Image courtesy of KESSEL MEDintim)

also been used in the treatment of bacterial vaginosis. Effectiveness is thought to be due to a physical barrier function of the gel and to the decreased sperm motility in lower pH environments [13].

Some studies show modest protection provided against transmission of STIs, mainly due to physical protection of the cervix which is thought to be more susceptible to infections. Other studies do not show benefit and cite there are multiple confounding factors such as the fact that diaphragm users may be at lower risk in general [13]. Frequent use of nonoxynol-9 spermicides may be associated with increased risk of HIV transmission due to the formation of small cervical and vaginal erosions or irritation from the spermicide [12].

Adolescents may not be good candidates for diaphragms because of the level of maturity required for their use and the decreased level of protection from sexually transmitted diseases and unplanned pregnancy.

Indications for Diaphragm Placement

- Patient desires a nonhormonal, immediately reversible, female-controlled method of birth control.
- Comfortable with insertion and removal of the device and is willing to reliably use the device with every act of coitus.
- Safe for use while breastfeeding.
- Safe for women with a latex allergy history.

Contraindications to Contraceptive Diaphragm

- Significant pelvic organ prolapse, including cystocele, rectocele, or uterine prolapse (however, arching spring diaphragms may be helpful for women with mild pelvic relaxation).
- Frequent urinary tract infections.

- Allergy to spermicide or silicone.
- Vaginal or cervical lacerations or significant friability.
- History of toxic shock syndrome.
- Inability to insert or use properly.
- History of HIV or high risk of HIV transmission.
- Inability to clean, store, or transport device to location of use.
- Inability to be refit Milex after pregnancy, weight gain >10 lbs. or abortion.
- Caya® is not recommended if size required is >85 mm or <60 mm.

Complications and Risks, Contraceptive Diaphragm

- Unintended pregnancy (not as effective as other types of contraception).
- Frequent urinary tract infection.
- Toxic shock syndrome (risk is 2.4 cases per 100,000 women, particularly when left in place more than 24 hours) [1].
- Improper fitting resulting in failure of the method.
- Cervical or vaginal lacerations, ulcerations, or abrasions.
- Dislodgement during intercourse.
- Vaginal discharge or odor can develop if left in place too long.
- Female or male partner awareness of device or pain with device.
- Penile abrasions.
- Requires resizing postpartum, post abortion, or with any change in weight of 10 pounds.

Equipment List, Diaphragm

- Diaphragm fitting kit or fitting ring kit (sterilized) if using Milex products
- Test fit device if using Caya®
- Nonsterile gloves
- Vaginal speculum
- Spermicidal jelly
- Vaginal lubricating gel for fitting

Procedure Steps, Diaphragm Fitting

1. Patient should be known to have normal cervical cytology prior to proceeding.
2. Patient should be at least 6 weeks postpartum or 2 weeks postabortion.
3. Have patient empty bladder and place in the dorsal lithotomy position.

4. Insert vaginal speculum and examine cervix and vaginal vault for any lacerations, abrasions, polyps, or signs of infection which would contraindicate placement.
5. To estimate size of diaphragm needed, insert the index and middle fingers into the vaginal vault so that the middle finger is placed at the posterior fornix.
6. Place the thumb of the same hand against the symphysis pubis (Fig. 11.8).
7. Keeping the thumb against the index finger, remove the entire measuring hand, and measure the distance from the tip of the thumb to the tip of the middle finger. This distance represents the estimated necessary diaphragm size (Fig. 11.9).
8. Choose the estimated-size diaphragm from the fitting kit and insert it into the vaginal vault by folding it in half spring and directing it posteriorly while separating the vulva with the other hand. Most women fit a 70 mm size.
9. Palpate edges of diaphragm to ensure that it fits snugly behind the pubic symphysis, covers cervix entirely, and reaches the posterior fornix (Fig. 11.10)**.** If necessary, choose a larger or smaller size to meet these criteria and try again.
10. Instruct the patient to feel for proper placement of the diaphragm in the vagina and to remove it by hooking the index finger behind the anterior rim and pulling straight down.
11. Provide or order the diaphragm from CooperSurgical for patients if using Milex. If using Caya, patient measures 65–80 mm on exam, and test fitting is successful, write a prescription for the device.
12. Clean Milex fitting set between fittings by autoclaving and discard the Caya test fit device.

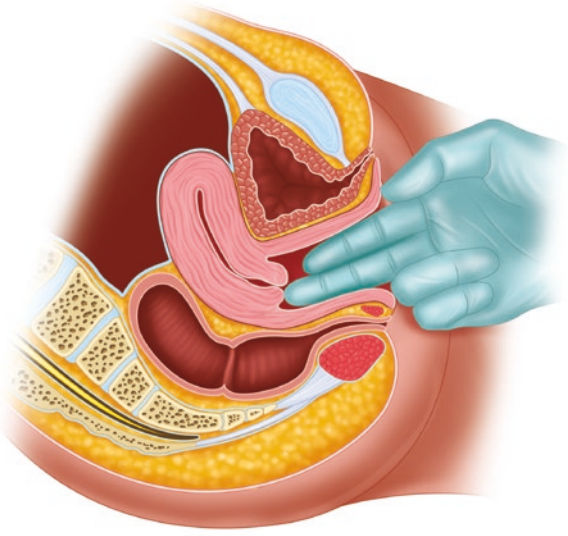

Fig. 11.8 Estimating diaphragm size by measuring distance from the posterior fornix to pubic symphysis

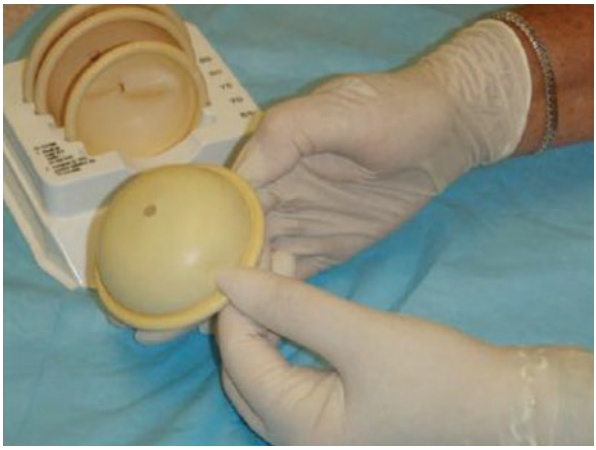

Fig. 11.9 Estimating diaphragm size for fitting

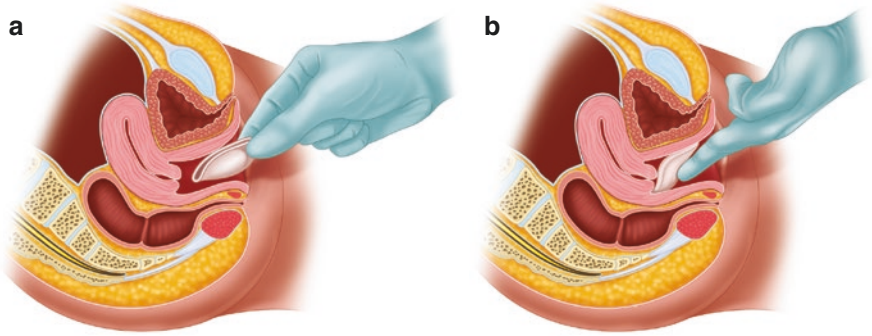

Fig. 11.10 Proper position of the diaphragm in vaginal vault

Tricks and Helpful Hints, Diaphragm

- Have the patient perform a Valsalva maneuver and walk around the exam room after fitting to make sure there is no discomfort and the diaphragm does not dislodge.
- Ensure that the patient is comfortable with insertion and removal of the device on their own while they are in your office and demonstrate proper application of one tablespoon of spermicide into the dome and around the rim of the device.
- Patient should be able to feel their cervix through the membrane of the diaphragm if properly placed.
- Patient should be instructed to urinate before insertion and again after intercourse to avoid urinary tract infection.
- If UTIs occur, consider changing diaphragm type, size, or switch to cervical cap [14].

- Provide a prescription for, or inform patient of availability of emergency contraception given higher failure rate of barrier devices.
- Milex and Caya diaphragms should be replaced in 2 years.

Cervical Cap

First approved by the FDA in 1988, the cervical cap is smaller than a diaphragm and more thimble-shaped with a deeper well (Fig. 11.11**).** Many types of caps are in production worldwide, but only the silicone FemCap is FDA approved for use in the USA. The second-generation FemCap device had several upgrades to the first and was released in 2003. The device is available today through the office of a provider who stocks them or with a prescription through the FemCap website or designated specialty pharmacies.

Cervical caps are sized by a provider based on exam and patient history. They are available in three sizes, namely, small (22 mm), medium (26 mm), and large (30 mm). Requiring less spermicide than a diaphragm, the cap is placed more tightly around the cervix. The FemCap dome covers the cervix, and the brim fits into the vaginal fornices to collect semen [15]. There is a strap to facilitate removal. Like the diaphragm, it must be left in place for 6 hours after intercourse. Additional spermicidal gel should be inserted for subsequent episodes of intercourse in that time. The FemCap is approved for continuous use up to 48 hours in the USA.

Indications for Cervical Cap Placement

- Nonhormonal, immediately reversible, female-controlled method of birth control.
- Comfortable with insertion and removal of the device and willing to use the device with every act of coitus.

Fig. 11.11 FemCap cervical cap

- Cervical caps are most appropriately chosen for nulliparous patients due to the higher rate of failure in women with vaginal birth prior to fitting. Failure rates in parous women approach 17% at 6 months, approximately twice that of the nulliparous groups.
- Cervical caps are less likely to be associated with an increased frequency of urinary tract infections.
- The size of a cervical cap is unaffected by weight changes [16].

Contraindications to the Cervical Cap

- History of toxic shock syndrome
- Immediate postpartum (<6 weeks) or postabortion (<2 weeks) use
- Anatomic barriers, such as cervical polyps
- Abnormal cervical cell cytology
- Patient inability to insert or use properly
  - Patient inability to clean, store, or transport device to location of use
  - Should not be used during menses due to theoretical risk of endometriosis
  - Presence of sexually transmitted disease, history of HIV, or high risk for HIV exposure

Complications and Risks, Cervical Cap

- Unintended pregnancy (not as effective) – particularly parous patients.
- Toxic shock syndrome (risk is 2.4 cases per 100,000 women, particularly when left in place more than 24 hours) [1].
- Cervical or vaginal lacerations, ulcerations, or abrasions.
- Dislodgement during intercourse.
- Vaginal discharge or odor can develop if left in place too long.
- Female or male partner awareness of device or pain with device.
- Penile abrasions.

Equipment List, Cervical Cap

- Cervical caps in three sizes to be provided to the patients
- Vaginal speculum
- Nonsterile gloves
- Spermicidal jelly
- Informational materials and video for patient review

Table 11.1 Cervical cap fitting

Cervical cap size	Patient characteristics
22 mm	Patient has never been pregnant
26 mm	Patient has been pregnant but no vaginal delivery
30 mm	Patient has had a vaginal delivery

1. The patient should have known normal cervical cytology before proceeding and be at least 2 weeks postabortion or 6 weeks post birth.
2. Have patient empty their bladder.
3. Place patient in the dorsal lithotomy position and insert the vaginal speculum.
4. Examine the cervix for lacerations, polyps, or other structural abnormalities.
5. Perform pelvic exam to check cervical size [Table 11.1].
6. Choose cervical cap size based on exam and obstetrical history using the above chart.
7. Allow patient to insert her own FemCap based on manufacturer instructions.
8. Check placement by digital exam to ensure cervix is completely covered and that the cap is not dislodged easily by movement or with a Valsalva maneuver (Fig. 11.12**).**
9. Ensure the patient can remove the FemCap on her own.
10. Instruct patient on how to use one-half to three-fourths teaspoon spermicide in the groove facing the vaginal vault prior to use.

Tricks and Helpful Hints, Cervical Cap

- Consider a prescription for emergency contraception given higher failure rate of barrier devices.

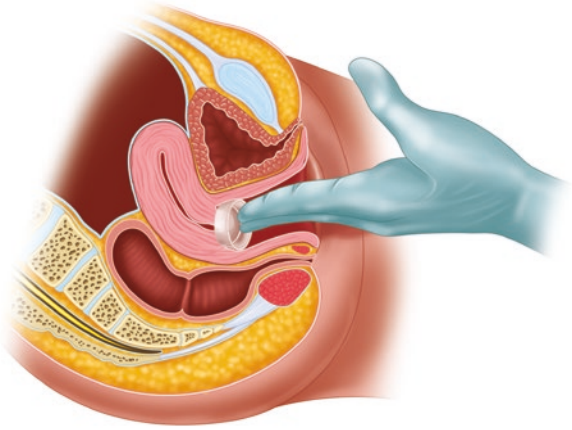

Fig. 11.12 Proper cervical cap placement on the cervix

- Women with a long, short, or anterior cervix may not be amenable to fitting with a cervical cap and will need to use another method.
- The FemCap should always be inserted prior to any sexual arousal.
- Removal can be facilitated by squatting and bearing down.

Procedure Note

Diaphragm

The patient was placed in the dorsal lithotomy position. Vaginal speculum was inserted, and the cervix and vagina were visually inspected and found to be normal. Diaphragm size was estimated by manual exam measurement. Fitting diaphragm was inserted to ensure proper size selection and #_____ was prescribed. Patient was instructed about insertion, care, use, and removal and demonstrated the ability to independently insert and remove the diaphragm. The patient tolerated the procedure well.

Cervical Cap

The patient was placed in the dorsal lithotomy position. Vaginal speculum was inserted, and the cervix and vagina were visually inspected and found to be normal. Manual vaginal examination was performed to estimate the size of the cervix. The patient's FemCap size was selected based on obstetrical history and examination and a size #_____ was selected. The patient viewed the instructional materials and was able to adequately insert her own FemCap with the provided instructions. FemCap placement was checked by manual exam and size found to be appropriate. Patient demonstrated the ability to independently remove the device. Patient tolerated the procedure well.

Coding

Diaphragm

CPT Diaphragm or cervical cap fitting with instructions	57170
HCPCS code for Supply of Diaphragm	A4266
Procedure ICD-10 for insertion of diaphragm	Z30.018

Cervical Cap

CPT fitting diaphragm or cervical cap for contraception	57170
Procedure ICD-10 for cervical cap fitting	Z30.018
HCPCS code for supply of cervical cap	A4261

Postprocedure Patient Instructions

Diaphragm

Ensure that the patient receives proper training regarding the insertion and removal of the device while in the office.

Patient should insert the device 2 hours prior to intercourse.

Patient can insert up to 6 hours prior to intercourse, but if so, an applicator of spermicide should be added at the time of intercourse.

Device should be left in place for a minimum of 6 hours after intercourse but can stay in place up to 24 hours.

The patient should check for dislodgement after intercourse and reposition if it occurs with insertion of an additional applicator of spermicide.

If additional episodes of intercourse take place the device should be left in place and an additional applicator of spermicide should be inserted prior.

Instruct patient to inspect diaphragm for holes or tears prior to each use by holding up to the light.

Diaphragm should be cleaned after each use with mild soap and water, wiped dry, and kept in its case avoiding extremes of temperature during storage.

Cervical Cap

Patient should return in 2 weeks for a follow-up visit with the cap in place to ensure correct usage.

Pap smear must be performed within 3 months of initiation of use and treated as indicated. If cytology is normal, the patient can resume yearly exams.

Instruct patient not to use during menstruation.

Instruct patient to check position after intercourse to ensure it has not dislodged.

FemCap should be washed with antibacterial hand soap and water, dried, and stored in its container.

The FemCap should be replaced yearly or sooner if worn or damaged.

Case Study Outcome

After discussing the specifics of the diaphragm barrier method, Kara was willing to try it. She felt that the risk of pregnancy was acceptable and was willing to use emergency contraception in the event of device failure. Kara was examined and found to be approximately 65 mm. Review of her gynecological and obstetrical history revealed no contraindications to diaphragm usage. She was tested for fit and appropriateness with the Caya test kit and was able to independently place and remove it. The patient was instructed in its use and care and provided with a prescription and a follow-up appointment.

Questions for Learners

- Considering the decrease in male condom use, what measures could be taken from a public health standpoint to increase their use?
- Providers who are skilled at fitting diaphragms are becoming less prevalent. What are some of the barriers that need to be overcome to offer this form of contraceptive? Should diaphragms and cervical caps still be offered as a reliable contraceptive device?

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Additional Resources

Caya: www.hpsrx.com
FC2: https://fc2.us.com
FemCap: www.femcap.com
Milex: www.coopersurgical.com

Chapter 12
Copper Intrauterine Device

Elizabeth H. McNany

Introduction

Globally, intrauterine devices account for 14.3% of reversible contraception in women of reproductive age, and in some countries, it accounts for 40% of the contraception used by women [1]. In the United States, the use of long-acting reversible contraception has been increasing significantly in the last decade, and with this, the IUD use now accounts for 14.3% of contraception used [2]. Historically there were issues with infection and infertility with the Dalkon Shield in the 1970s, but the newer IUDs are safe and effective forms of birth control when used in appropriate patients. There are five IUDs currently in use in the United States, the copper T 380A (in place for up to 10 years, and some advocate 12 years) [3], and four levonorgestrel intrauterine systems that range in length of use from 3 to 5 years and vary in dose of levonorgestrel. Determining which type of IUD is most appropriate for a patient depends on the characteristics, patient preference, and medical conditions of the patient. Both types are effective forms of birth control with the rate of unintentional pregnancy with typical use of the copper T 380A is 0.8% and a rate of 0.2%–0.9% with the levonorgestrel systems [3, 4].

Shared decision-making is essential with any discussion of contraceptive choice, including IUDs. A detailed history should be obtained, and the patient must have a thorough understanding of the benefits and risks of the copper IUD.

It is important that a woman have a clear understanding of possible adverse events with the insertion and use of an IUD. She needs to know the possible side effects and when to seek medical attention. This should be emphasized by the clinician, and a patient handout should be given to the patient for reference.

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Historically, there has been great concern about ectopic pregnancy and IUD use. A meta-analysis showed that the use of an IUD does not increase the risk of ectopic pregnancy in a woman because the IUD generally prevents pregnancy effectively. If a woman gets pregnant with an IUD in place, however, she is more likely to have an ectopic pregnancy than a woman without an IUD [5].

Case Study

A 27-year-old patient, presents to the office requesting an IUD. She has been on oral contraceptives for the past 10 years. She is not good about taking them regularly and would like something more permanent. She has had a stable partner for the past 10 years, and they do not wish to have a child within the next few years. Her periods are regular, she has never had a sexually transmitted infection, and her Paps are normal. She is interested in a copper IUD, as she prefers a nonhormonal method.

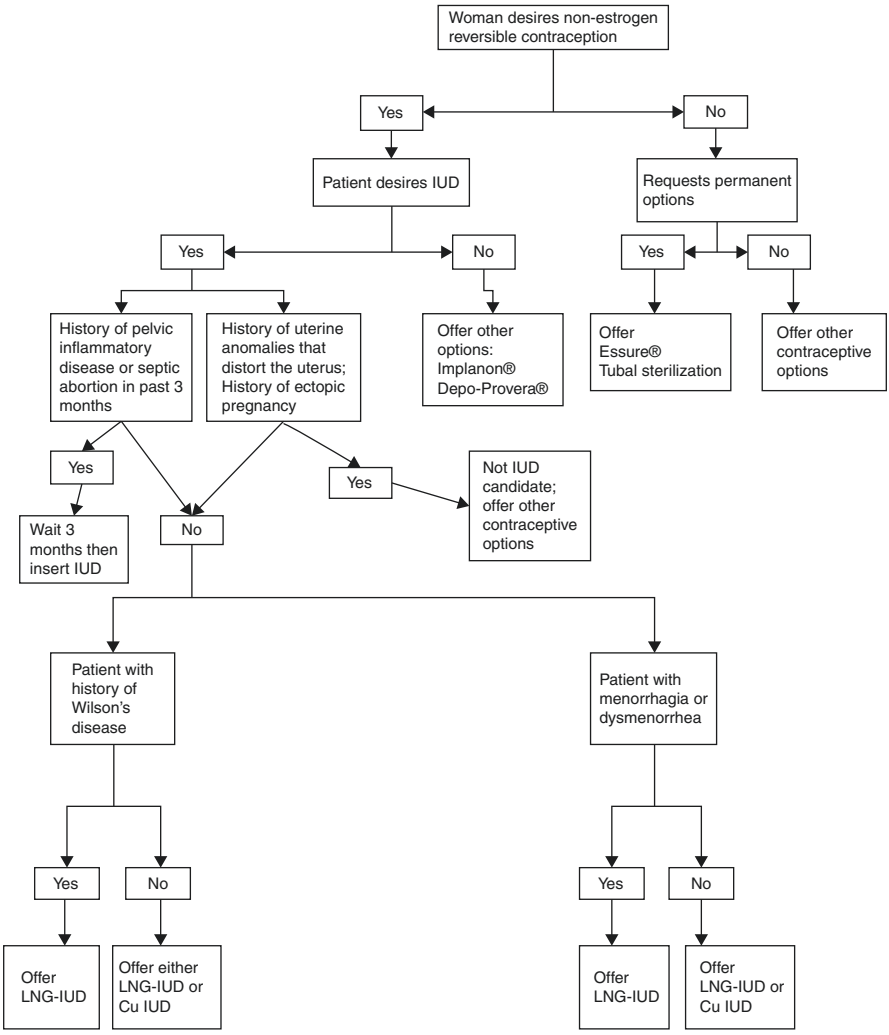
Indications (Algorithm 12.1) [6]

- Women who desire long-term reversible contraception.
- Failure of a previous birth control method due to noncompliance.
- Previous uncomplicated use of IUD.
- Contraindications to hormonal contraception.
- Emergency contraception within 5 days of intercourse for a woman who meets other criteria.
- Women with the following medical conditions:
  - Breastfeeding.
  - Breast cancer.
  - Clotting disorder.
  - Poorly controlled diabetes mellitus or hypertension.

Contraindications [7–10] (Algorithm 12.1)

Absolute Contraindications

- Current intended pregnancy
- Abnormalities of the uterus resulting in distortion of the uterine cavity
- Acute pelvic inflammatory disease, or current behavior suggesting a high risk for pelvic inflammatory disease
- Postpartum endometritis or postabortal endometritis in the past 3 months



Algorithm 12.1 Decision tree for determining a nonhormonal contraception method. IUD intrauterine device, LNG-IUD levonorgestrel IUD, Cu IUD copper IUD. Cu IUD Duramed Pharmaceuticals, Cincinnati, OH; LNG-IUD Bayer Pharmaceuticals Inc., Wayne, NJ; Implanon®, NV Organon, Schering Corporation, Kenilworth, NJ; Essured®, Conceptus Inc, San Carles, CO; Depo-Provera®

- Known or suspected uterine or cervical malignancy
- Genital bleeding of unknown etiology
- Mucopurulent cervicitis (until resolved)
- Wilson's disease
- Allergy to any component of Paragard®
- A previously placed IUD that has not been removed.

Relative Contraindications *(Algorithm 12.1)*

- Excessively heavy periods or marked dysmenorrhea.
- Small uterine cavity (higher risk of expulsion if uterus <6 cm).

Equipment (Fig. 12.1)

- Paragard® T 380A (Duramed Pharmaceuticals, Cincinnati, OH).
- Speculum.
- Basin with cotton balls moistened with antiseptic solution.
- Cervical tenaculum.
- Uterine sound.
- Sterile gloves.
- Nonsterile gloves.
- Sterile towel for tray top.
- Long suture scissors.
- Topical anesthetic (Hurricane®, Beutlich LP Pharmaceuticals, Waukegan, IL).
- Ring forceps.

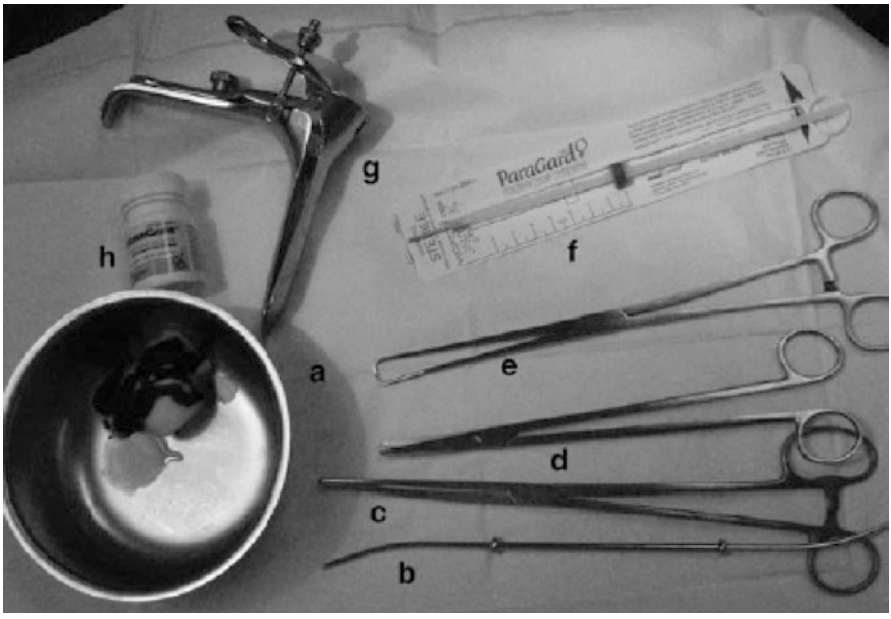


Fig. 12.1 Equipment setup for copper IUD. (a) Metal basin with cotton balls soaked in iodine; (b) sterile uterine sound; (c) sterile long Kelly forceps; (d) long scissors; (e) sterile cervical tenaculum; (f) sterile Paragard® (Duramed Pharmaceuticals, Cincinnati, OH) IUD Contraceptive; (g) sterile Graves speculum; (h) topical cervical anesthetic (Hurricane®, Beutlich LP Pharmaceuticals, Waukegan, IL)

Procedure

1. Prior to placement:
   - Discuss thoroughly with the patient the risks, benefits, and expectations for follow-up after placement and obtain signed consent.
   - Document negative pregnancy test.
   - Screen patients based on CDC recommendations who have not undergone routine screening for sexually transmitted infection (STI). If the patient requires screening due to increased risk of STIs or previous lack of screening, IUD insertion should not be delayed. STI screening and IUD insertion should occur at the same visit. Placement of IUD should not be delayed for results of screen. Treatment of a positive screen can occur without the removal of the IUD. The American College of Obstetricians and Gynecologists (ACOG) does not recommend screening the low-risk patient [9].
   - Recommend NSAID use 1 hour prior to placement.
2. Perform a bimanual exam to check for the position of the uterus.
3. Insert a warm vaginal speculum (large enough to easily visualize the cervix).
4. Clean the cervix with antiseptic solution.
5. Apply a topical anesthetic to the cervix (if tenaculum is going to be used).
6. Remove nonsterile gloves and put on sterile gloves. *The next four steps should be done using sterile technique.* Use sterile uterine sound to determine the depth of the uterus. Uterus should be between 6 and 9 cm to continue with the placement of IUD. Stabilize cervix, if needed, by the application of single-tooth tenaculum to the anterior lip of the cervix.
7. Have assistant place contents of IUD package on a sterile towel. Alternatively, do this step prior to changing into sterile gloves, making sure the contents of the package drop onto the sterile towel in a manner that maintains the sterile field.
   - Insert the solid white inserter rod so that it just touches the tip of the vertical arm of the IUD (Fig. 12.2). Fold the horizontal arms down and place inside the tube. (Do not do this step more than 5 min prior to placement.) Insert the arms no further than necessary to ensure retention.
   - Adjust the blue flange on the inserter rod to the depth of the uterus as determined by sounding, measuring from the top of the folded IUD to the blue flange. Be sure that the horizontal arms of the T of the IUD are parallel to the horizontal orientation of the long axis of the blue flange (Fig. 12.3). If needed, use the tenaculum to stabilize the cervix and insert the IUD through the cervical canal into the uterus up to the blue flange (Fig. 12.4). Ask an assistant to hold the tenaculum in place (if using) and hold the solid white rod steady in the nondominant hand. Using the dominant hand, pull back on the clear insertion tube 1–2 cm. The solid colored rod should *not* move (Fig. 12.5).

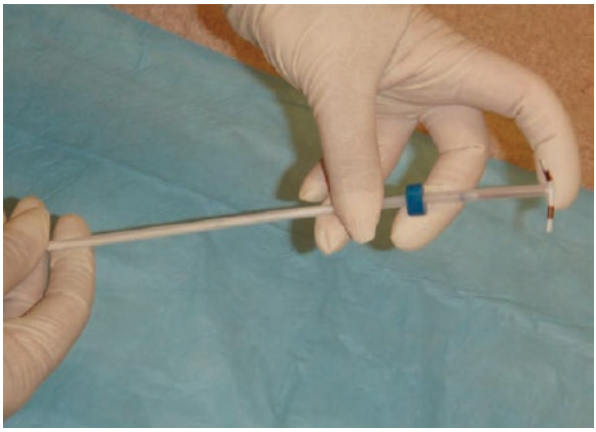


Fig. 12.2 Insert the white rod into the insertion tube and move up to the tip of the IUD. Keep a finger on the IUD to prevent it from falling out of the insertion tube

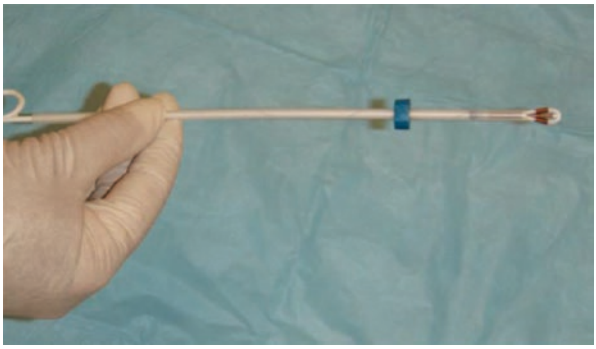


Fig. 12.3 Fold down the arms into the insertion tube just enough to hold in place. Adjust the blue flange to the measured uterine length

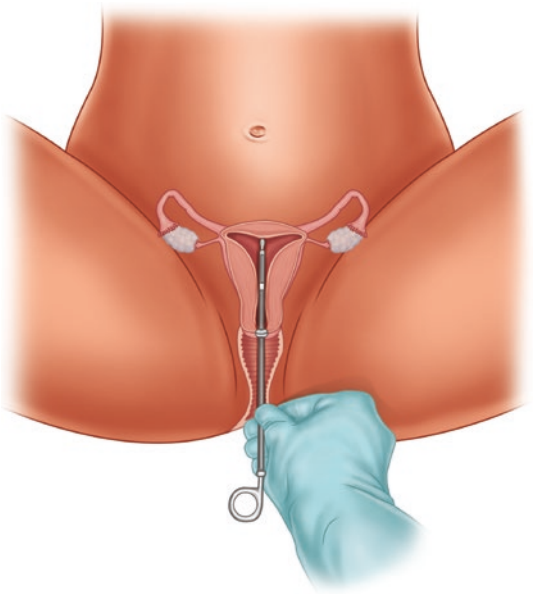


Fig. 12.4 Insert the IUD into the uterus until it meets the fundus (measured by the blue flange)

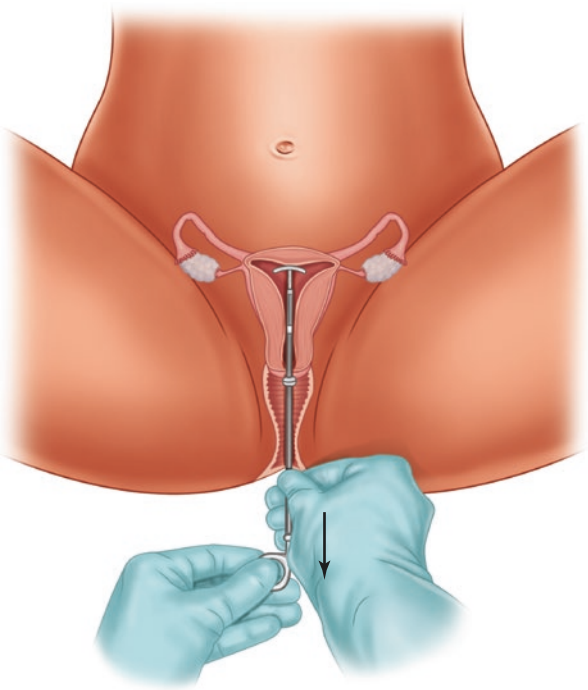


Fig. 12.5 Holding the white rod steady, pull the insertion tube toward the clinician. Once the IUD is released, push the insertion tube back up to the blue flange to anchor the IUD in the fundus of the uterus. Then, remove the rod and insertion tube

8. Once the IUD is released, gently push the tube inserter toward the fundus until slight resistance is felt to assure high placement of the IUD.
    - Hold the insertion tube steady and withdraw the solid white rod.
    - Slowly and gently withdraw the insertion device, leaving only threads protruding from the cervix.
9. Cut the threads protruding from the cervical os to 3–5 cm in length (Fig. 12.6) and document length in records.
    - It is best to leave threads longer because they can be shortened at the follow-up visit if necessary.
10. Instruct the patient on how to check for strings after each menstrual period and prior to intercourse.
11. Be sure to give the patient the handout provided by the company that gives information about when to contact a healthcare provider.
12. Schedule a follow-up appointment with the patient after the first menstrual period to assess placement.
13. If there is any concern about whether IUD is properly placed, an ultrasound can be done to assess placement (this is rarely needed).

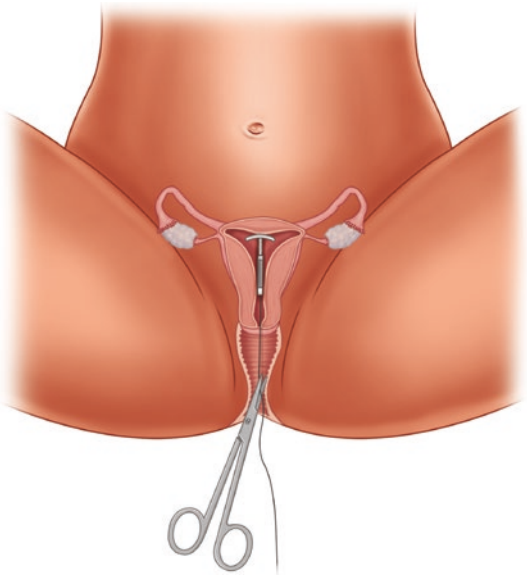


Fig. 12.6 Cut the strings 3–5 cm from the os and give the strings to the patient so she knows what they feel like on self-examination

Complications and Risks

- Cramping and bleeding:
  - This leads to 11.9% of the removal requests in the first year [9]. The cramping can be treated with nonsteroidal anti-inflammatory drugs (NSAIDs), but if bleeding symptoms persist for more than three to four cycles, consider prescribing a short course of estrogen or oral contraceptive pills. If the bleeding persists, removal can be considered.
- Expulsion:
  - Most common in the first year at a rate of 5.7% [9].
  - Typically occurs during menses. Emphasize importance of checking for the strings on a regular basis [5, 9].
  - If the location of the device is uncertain, an ultrasound can determine the location of the IUD.
  - When the IUD is inserted later in the mestrual cycle, the expulsion rates are lower.
  - Uterine cavity less than 6 cm can increase the risk of expulsion, perforation, and bleeding while greater than 9 cm increases the risk of expulsion.
- Pelvic inflammatory disease (PID):
  - Risk immediately after IUD placement is 0.5% [10]. Women who are at low risk for STIs have little risk of PID with IUD use after the initial 20 days post-

insertion There is no indication of prophylactic antibiotics at the time of insertion to reduce PID. A meta-analysis confirmed that prior antibiotic use conferred little benefit [11].

- Uterine perforation.
  - Uterine perforation is rare (occurring in 0.1–0.3%). It must be corrected surgically with the removal of the IUD and repair of the uterus [9]. Proper technique and uterine sounding are important to help prevent this from occurring.
- Pregnancy.
  - If pregnancy is confirmed and the IUD is in place, the IUD should be removed as soon as possible. There is a higher rate of ectopic pregnancy in patients who become pregnant while using an IUD. However, pregnancy is rare due to its high rate of effectiveness.

Tricks and Helpful Hints

- Advance a large cotton-tipped applicator (Scopette®, Birchwood Laboratories, Eden Prairie, MN) in with the uterine sound. The applicator's cotton swab will stop at the cervix; continue to advance the sound to the fundus of the uterus. Then remove the applicator and the sound simultaneously with the same hand. The distance from the top of the cotton applicator to the top of the sound is a clear indication of the uterine depth.
- Show the device through the packaging to the patient prior to insertion in order to reassure her of the small size and configuration of the device.
- If the IUD is contaminated or dropped, call the manufacturer, who will replace it free of charge.

Procedure Note

(Provider to customize as needed.)

Complications, risks, and benefits of IUD discussed.Consent signed by patient and provider. Pregnancy test performed and patient is not pregnant. Bimanual examination performed; speculum applied, and cervix visualized without difficulty. Cervix washed with antiseptic three times. Tenaculum placed under local anesthetic. Uterus sounded to 6–9 cm size. IUD inserted without difficulty. Strings cut to appropriate length. Strings given to patient to feel, and instructions given on how to check for the strings. Patient tolerated procedure well.

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
58,300	Insertion of IUD
J7300	Charge for cost of copper IUD
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 10th Revision, Clinical Modification, Centers for Disease Control and Prevention)	
Z30.430	Encounter for insertion of intrauterine contraceptive device
Z30.431	Encounter for routine checking of intrauterine contraceptive device

Postprocedure Patient Instructions [10, 14]

- Educate the patient on how to check for strings after each menstrual period and prior to intercourse.
- Be sure to give the patient the handout provided by the company that gives information about when to contact a healthcare provider. Emphasize the following major concerns:
  - The patient must check for the threads of the IUD after each menstrual period. If not palpable, she should contact her healthcare provider.
  - Remind the patient to report any of the following: excessive pain, malodorous discharge, excessive bleeding, fever, prolonged pelvic discomfort or pain during intercourse, genital lesions, suspicion of STIs, missed period, or any other concerns she may have.
- Schedule a follow-up appointment with the patient after the first menstrual period to assess placement.

Case Study Outcome

The patient had an IUD inserted without difficulty in her provider's office. She was delighted to discontinue her oral contraceptive pills and reported no difficulty with her IUD.

Postprocedure Patient Handout

(Provider to customize as needed.)

- Check for the threads from the IUD after each menstrual period, and if you cannot feel them, contact your provider immediately.
- You may have increased bleeding during your periods and spotting between periods during the first 2–3 months after placement. Typically, these symptoms improve with time, but if they persist, contact your provider.

- You may have cramping associated with the placement of the IUD, but if the pain is severe, let your provider know.
- When to contact your provider:
  - If you think you are pregnant.
  - If you cannot feel the threads from the device or the length has changed.
  - If you have severe menstrual bleeding.
  - If you have pelvic pain during sex.
  - If you have unusual vaginal discharge or genital sores.
  - If you have unexplained fever.
  - If you may have been exposed to STIs.
  - If you or your partner becomes HIV positive.
  - Continued cramping pain, particularly within the first month after insertion.

Questions for Learners

- What are the pros and cons of hormone-based IUDs versus copper IUDs?
- What are some of the advantages to the use of copper IUDs?

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Additional Resources

Website

Supplier: Duramed Pharmaceuticals: www.paragard.com.

Chapter 13
Levonorgestrel Intrauterine System Insertion

Komal G. Bhatt

Introduction

The levonorgestrel-releasing intrauterine system (LNG IUS) is one of the most effective, safe, and convenient reversible contraceptive methods. The number of women choosing an intrauterine device (IUD) for contraception is increasing in the United States due to the fact that the LNG IUS can be used in women irrespective of age or parity and is one of the least expensive and most effective methods of long-acting reversible long-term contraception(LARC). LARC such as LNG IUS, Copper IUDs, and etonorgestrel subdermal implants have had a resurgence of interest due to their ease of use, with user effective rates being the same as method effective rates. Current rates of LARC use within the United States have reached 8.0% of women who are of childbearing age [1]. Women aged 25–33 have the highest rate of usage of LARC, and parous women have a higher percentage rate of LARC use. Current rates of LARC use have increased fivefold from 2005 to 2015 [1]. Five-year continuation rates (not including Skyla) of LNG IUS is similar to copper IUDs [2].

LNG IUS insertion is a relatively simple procedure that can be performed in the office setting by trained providers. The LNG IUS consists of a polyethylene T-shaped device with hormone reservoir, which releases small amounts of levonorgestrel at a constant rate into the uterine cavity over time. Mirena® was the first LNG IUS introduced in the United States. There have been some additional LNG IUS added into the marketplace within the last several years.

Currently there are four Food and Drug Administration (FDA)-approved LNG IUS available in the United States: LNG-20 (Mirena®), LNG-19.5 (Kyleena®), LNG-18.6 (Liletta®), and LNG-13.5 (Skyla®). Mirena® and Liletta® contain a total of 52 mg of levonorgestrel and release 20 mcg/day and 18.6 mcg/day, respectively.

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https://doi.org/10.1007/978-3-030-28884-6_13

Kyleena® contains a total of 19.5 mg of levonorgestrel and releases 17.5 mcg/day; Skyla® contains a total of 13.5 mg of levonorgestrel and releases 14 mcg/day of levonorgestrel (see Fig. 13.2).

All LNG IUS have similar mechanisms of action including thickening of the endocervical mucus and suppressing the endometrial lining of the uterus. They also cause a foreign body reaction in the uterine cavity and may have effects on tubal motility. Taken together, these changes impair sperm survival and effectiveness. Tubal washing studies demonstrate that LNG IUS are not an abortifacient; rather, its contraceptive action is prevention of conception [3].

Mirena® and Kyleena® are approved for 5 years of use, with recent FDA approval of Liletta® for six years and Skyla® for 3 years. Mirena® is the only IUD which is FDA approved for treatment of menorrhagia, and more recent studies have suggested Mirena may have extended use up to 7 years although not FDA approved to date for the extended use [4]. All LNG IUS have similar side effect profile and comparable efficacy rates (>99%). Bleeding pattern changes including decreased menstrual bleeding and amenorrhea are less severe with LNG IUS with lower hormone concentration [3].

Mirena®, Kyleena®, and Skyla® have a similar inserter design and use the same technique for insertion. All three are nonreloadable. The newer single-handed Liletta®inserter with a double slider mechanism is slightly different from the other LNG IUS in terms of the design and technique. Liletta®'s inserter tube is 2 cm longer than the other LNG IUS and has the capacity to be reloaded. Kyleena® and Skyla® are smaller in size (28X30 mm) with narrow inserters, which allows easier insertion.

Although the current standard recommends waiting until 6 weeks postpartum prior to insertion of the LNG IUS, there are some who are advocating for insertion within 48 hours postpartum [5]. Although the risk of expulsion is slightly higher than those inserted at 6 weeks postpartum, the rate of insertion was higher immediately postpartum, and the continued use at 1 year was higher among women who had immediate postpartum insertion [6].

The cost of IUDs ranges between $800 and $1000 in 2019; cost has been a major limiting factor for both providers and patients. Some insurance companies have a buy and bill policy for LNG IUS, which limit some providers due to the high cost of stocking LNG IUS in the office. Other insurances allow the patient or provider to order the LNG IUS on an individual basis. Most private insurance companies cover one type of LNG IUS, with an additional standard fee for the insertion. Liletta® was developed to be a low-cost option available to public health clinics.

Case Study

A 26-year-old woman, who is now G2P1011, returns to your office 6 months after her delivery. She is breastfeeding twice a day and wants to discuss a contraceptive method that she can use for 2–3 years. She took oral contraceptives for a short time in the past and discontinued them due to headaches and stomach symptoms. She has used condoms periodically and is not satisfied with that method. She has been

together with the father of the baby for 3 years, and they do not have any partners outside this relationship. Her Pap smear was normal. She has no history of CIN or HPV, and screening for other infections during pregnancy was negative.

Diagnosis

A 26-year-old woman wants reversible contraception. Her risk factors and history suggest that she is not at high risk for exposure to sexually transmitted infections. She would like to avoid pregnancy for 2 or more years. The side-effect profile, cost, and efficacy of LNG IUS make it an excellent option for this patient.

Indications (Algorithm 13.1)

- Long-term reversible contraception
- Monogamous
- Prefers continuous contraception

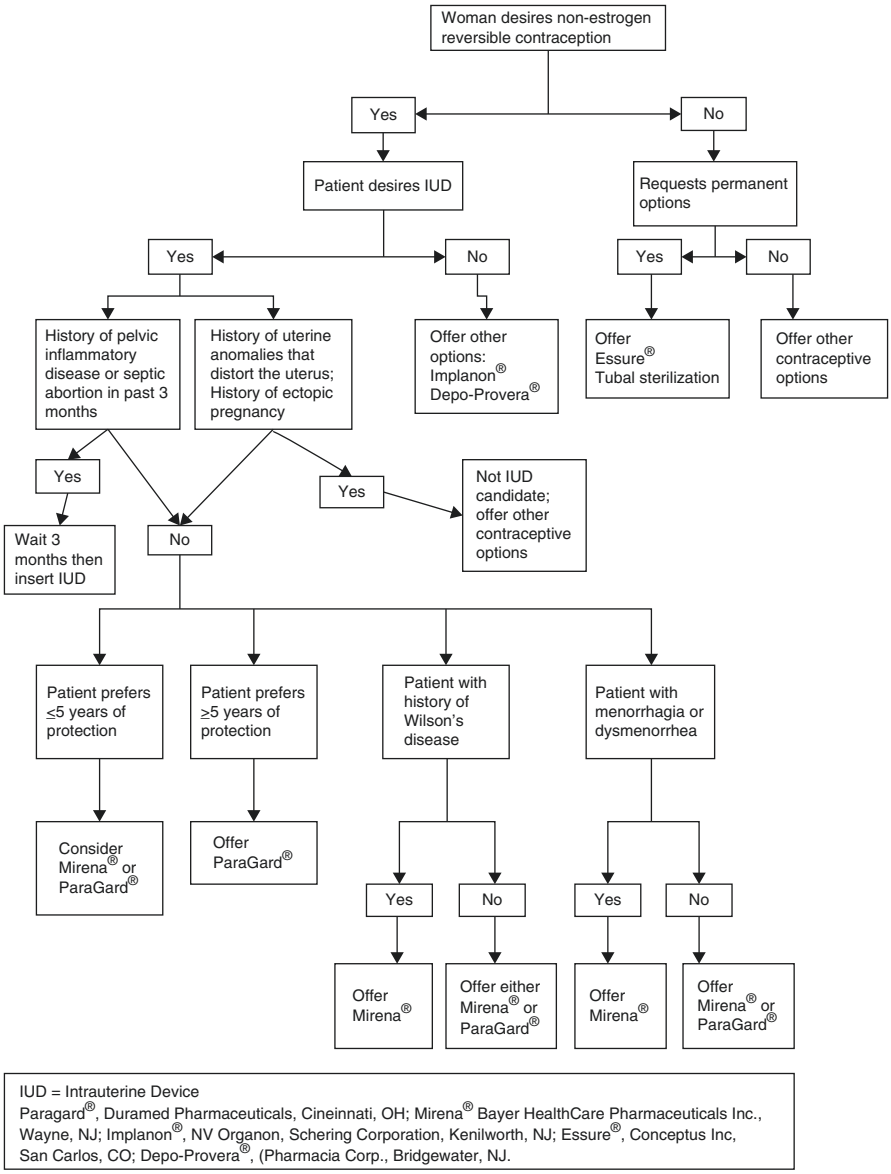
Contraindications (Algorithm 13.1, [6])

Relative Contraindications

- Current sexually transmitted infection (STI) or cervicitis
- Cervical cancer

Absolute Contraindications

- Pregnancy
- Abnormal uterine anatomy(some patients with fibroids may be candidates)
- History of pelvic inflammatory disease (PID) within 3 months
- Endometritis within 3 months
- Uterine cavity less than 6 cm or greater than 9 cm depth (associated with higher expulsion rates)
- Suspected or known breast or uterine neoplasia or any progestin-sensitive cancer
- Uterine bleeding of unknown etiology
- Sensitivity to prior exposure to systemic levonorgestrel
- Acute liver disease or tumors (benign or malignant)
- Acute venous thromboembolism
- Advanced HIV/AIDS



Algorithm 13.1 Candidates for IUD placement

Time of Insertion

- LNG IUS can be inserted at any time during menstrual cycle if reasonably certain that there is no pregnancy. If inserted in the first 7 days of menstrual cycle, then no backup contraception is needed. If switching from other forms of hor-

monal contraception such as oral contraceptive pills, NuvaRing, patch, or the subdermal implant, discontinue use of prior method 7 days after IUD insertion. LNG IUS can be used immediately after child birth, first trimester, and at least 4 weeks after second trimester abortions. Insertion can be delayed up to 4 weeks postpartum for women who are breastfeeding to reduce the theoretical risk of reduce milk production. LNG IUS is not approved for the use of emergency contraception [2–5].

Equipment (Fig. 13.1)

- Levonorgestrel intrauterine system (Fig. 13.2)
- Nonsterile exam gloves
- Sterile gloves
- Urine pregnancy test
- Speculum
- Light source
- Iodine/povidine solution

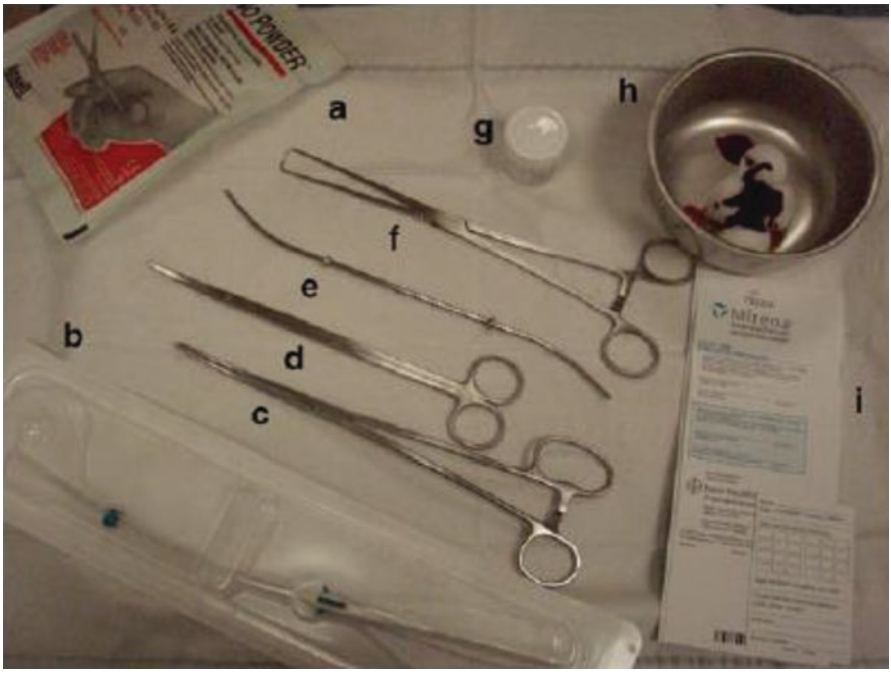


Fig. 13.1 Sterile tray for Levonorgestrel IntraUterine System insertion: (**a**) Sterile nonlatex gloves; (**b**) LNG IUS in sterile package; (**c**) Long Kelly forceps; (**d**) Long scissors; (**e**) Sterile uterine sound; (**f**) Sterile cervical tenaculum; (**g**) Specimen jar (if needed for Pap); (**h**) Metal basin with sterile cotton balls soaked in iodine; (**i**) Mirena® permit and patient card

- Tenaculum
- Uterine sound
- Ring forceps
- Gauze
- Large cotton swabs (with a long shaft for use in speculum). Scopettes®(Birchwood Labs, Eden Prairie, MN)
- Long-handled scissors
- Instruments and anesthesia for paracervical block

Insertion Procedure (Figs. 13.3, 13.4, 13.5, 13.6, 13.7, 13.8, 13.9, 13.10, 13.11, and 13.12)

1. Patients should receive the LNG IUS manufacturer's patient education to review before the procedure. Pamphlets and a video are available. Review the patient's cervical cancer screening with her. Review the patient's STI risk and any screening for STIs and Pap done preprocedure. Review risks, benefits, and side effects with the patient. Ask if she has any questions about LNG IUS use.
2. Confirm that the patient is not pregnant with a urine pregnancy test. Sign the consent form and ask the patient to sign the consent form with a witness present.
3. Place the patient in the dorsal lithotomy position. Perform a bimanual exam to estimate the uterine size and to confirm the position and direction of the uterine cavity.
4. Place a speculum and visualize the cervix.
5. Replace your exam gloves with a new pair of sterile gloves.

Fig. 13.2 Different LNG Intrauterine Systems available in the United States

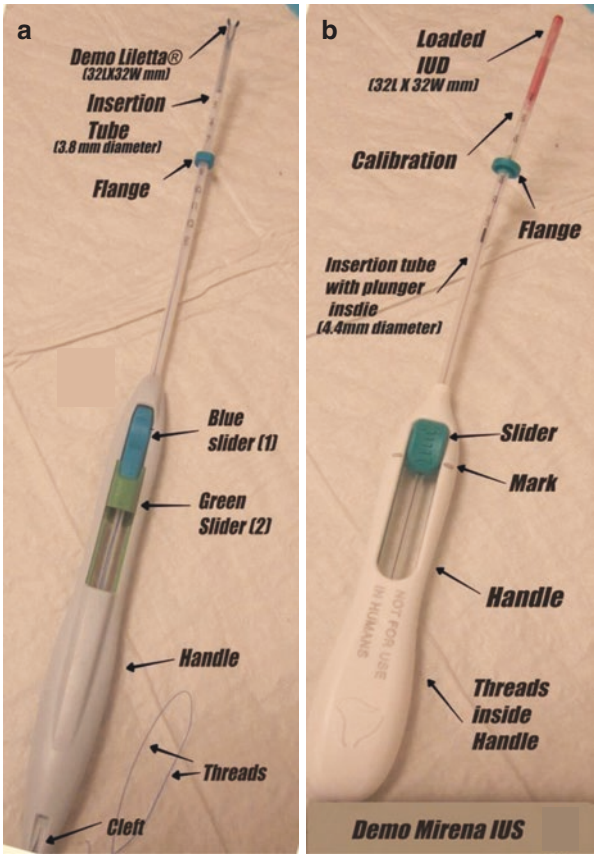


Fig. 13.3 Terminology for (**a**) Liletta® and (**b**) Mirena® IUD insertion system

6. Swab the cervix with antiseptic. Use large swabs or gauze folded in the ring forceps, and paint the cervix with the iodine solution to sterilize the outer cervix.
7. Grasp the anterior lip of the cervix with the tenaculum about 1.5 cm from the os. Close the tenaculum slowly until one tooth is engaged.
8. Gently pull on the tenaculum to straighten the endometrial cavity before sounding the uterus. Maintain this traction when inserting the sound. Determine the endometrial cavity size with the uterine sound.
9. Open the IUS package and maintain the IUS in a sterile state (Fig. 13.4).
10. Remove the LNG IUS from the package by grasping the handle below the slider/s. Do not attempt to remove the IUS by pulling on inserter tube (Fig. 13.4).
11. Push the slider on the inserter to the limit away from you. Confirm that the arms of the IUS are horizontal (Figs. 13.5 and 13.6).

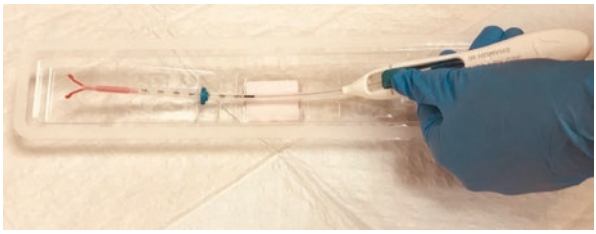


Fig. 13.4 Remove IUS from sterile packaging using a sterile technique

Fig. 13.5 Advance slider to the furthest away position

12. Set the marker/flange on the inserter to the uterine depth measured with the uterine sound (Fig. 13.7).
13. Insert the IUS into the uterine cavity. Stop when the flange is 1.5–2 cm away from the cervix (Fig. 13.14).
14. Pull the slider 1 cm to allow the arms of the IUS to open. There is a mark on the inserter indicating that it has been pulled 1 cm back (Figs. 13.8 and 13.9). Allow 10–15 seconds so IUS arms fully open.
15. Advance the whole inserter until the flange is at the os. This will place the open arms at the top of the uterine fundus (Fig. 13.10).
16. Pull the slider all the way to the limit toward you, releasing IUD in uterus (Fig. 13.11).

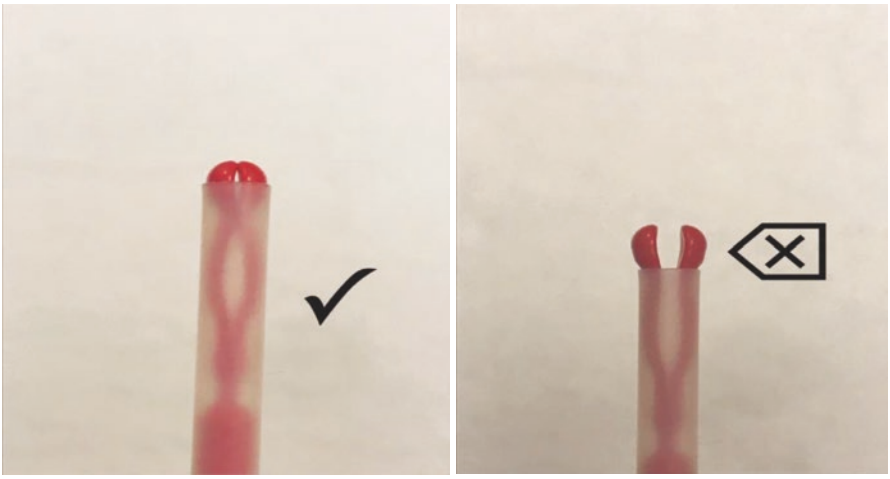


Fig. 13.6 Horizontal arm tips fold superiorly into the insertion tube

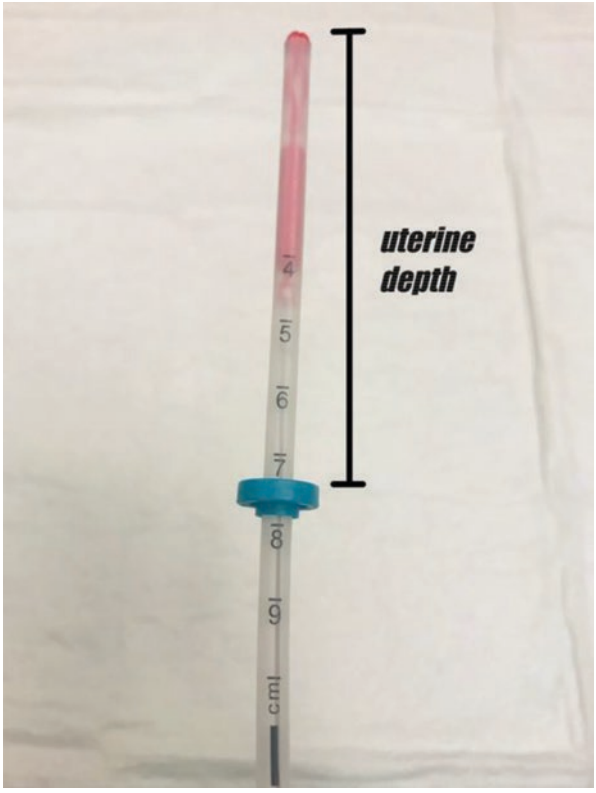


Fig. 13.7 Adjust flange to the depth of uterine sound

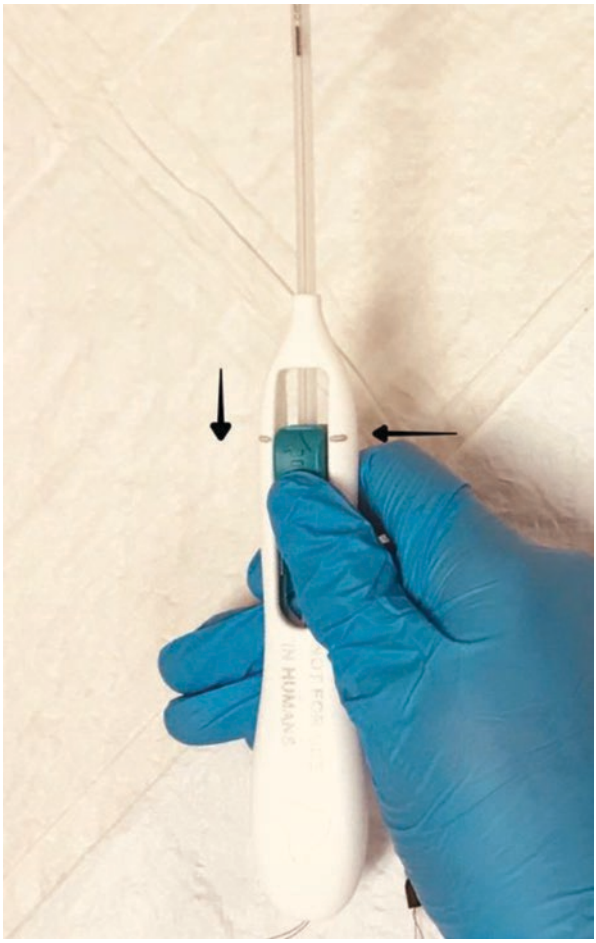


Fig. 13.8 Close-up of mark on handle

17. Remove the IUD inserter.
18. Trim the strings with the scissor so that 2–3 cm will remain (Fig. 13.12).
19. Remove the tenaculum and inspect for bleeding. Apply gentle pressure with a swab to achieve hemostasis.

Liletta Insertion

1. Follow steps 1–10 above.
2. For Liletta®, push your thumb on the blue slider keeping green slider steady as shown in figure (Fig. 13.5).
3. For loading Liletta® IUD in the inserter tube, pull the strings at the base of the inserter until the LNG IUS system is drawn into the inserter. Lock the strings into the handle of the inserter (Figs. 13.13).

Fig. 13.9 Extend arms horizontally by pressing the slider to mark on handle

Fig. 13.10 Advance the handle so that flange touches endocervical os

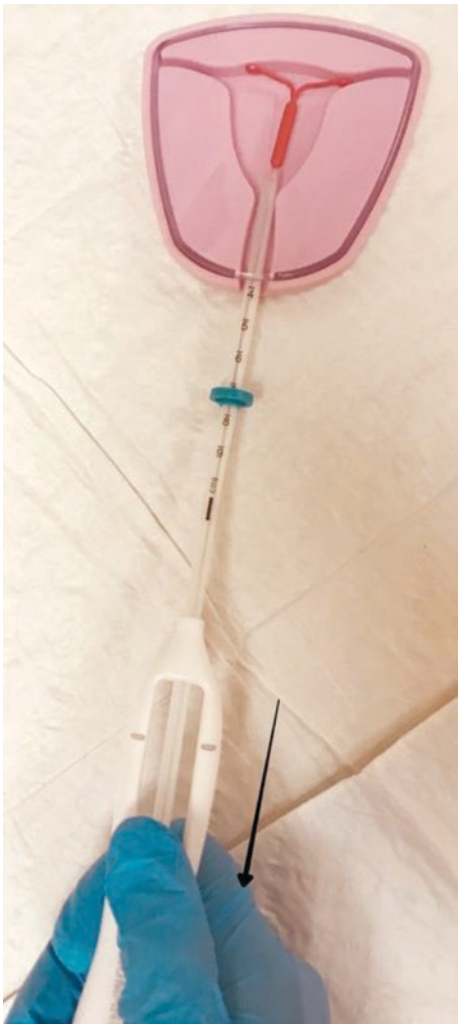


Fig. 13.11 Push slider toward the inserter, releasing IUD in the uterine cavity

4. Insert the IUD into the uterine cavity. Stop when the flange is 1.5–2 cm away from the cervix. For Liletta®, maintain forward pressure on blue slider while inserting IUD (Fig. 13.14).
5. Pull the slider 1 cm to allow the arms of the IUD to open. There is a mark on the inserter indicating that it has been pulled 1 cm back (Figs. 13.8 and 13.9). For Liletta®, move the blue slider toward the green slider so that both sliders merge (Figs. 13.15 and 13.9). Allow10–15 seconds so IUD arms fully open.
6. Advance the whole inserter until the flange is at the os. This will place the open arms at the top of the uterine fundus (Fig. 13.10).
7. Pull the slider all the way to the limit toward you, releasing IUD in uterus (Fig. 13.11). For Liletta®, pull both the sliders (green and blue) toward you to release IUD and confirm that this has released the strings (Fig. 13.16).

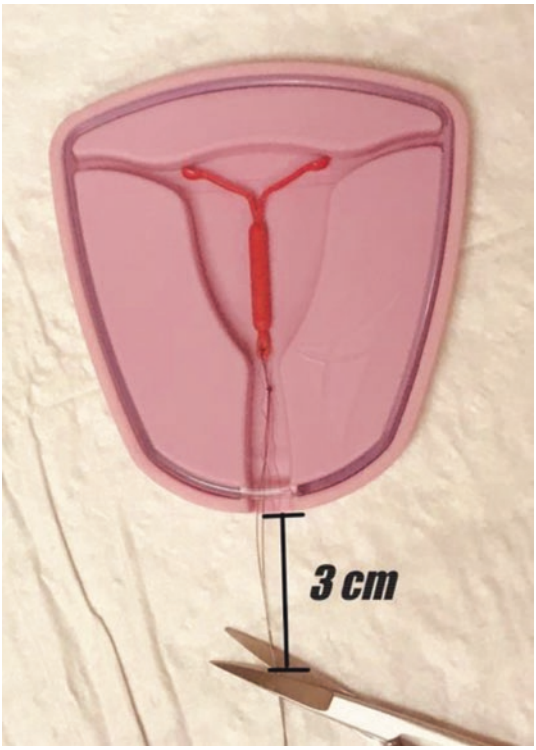


Fig. 13.12 Cut string 2–3 cm beyond os

Fig. 13.13 For Liletta®, lock strings into place maintaining forward pressure on the blue slider to load IUD

Fig. 13.14 Insert system to within 1–2 cm of flange marker

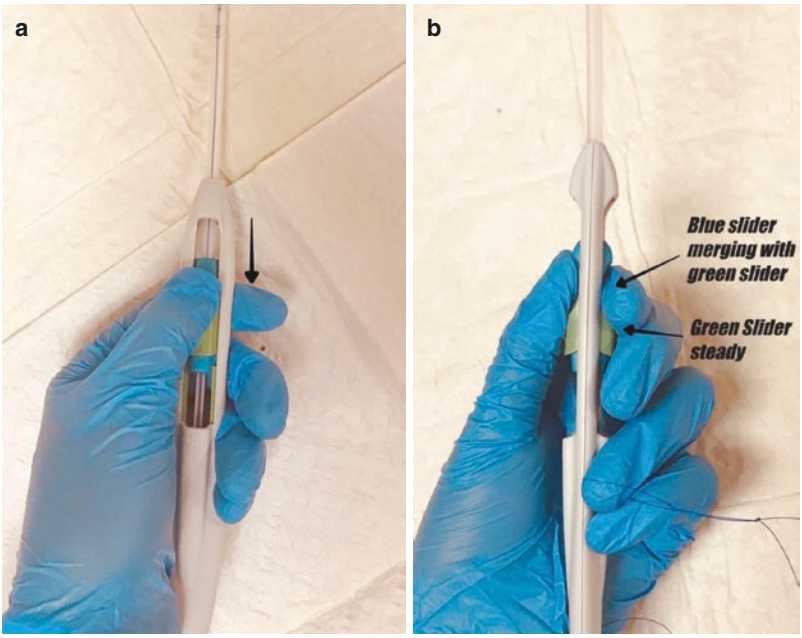


Fig. 13.15 Releasing arms in the uterine cavity (Liletta®)

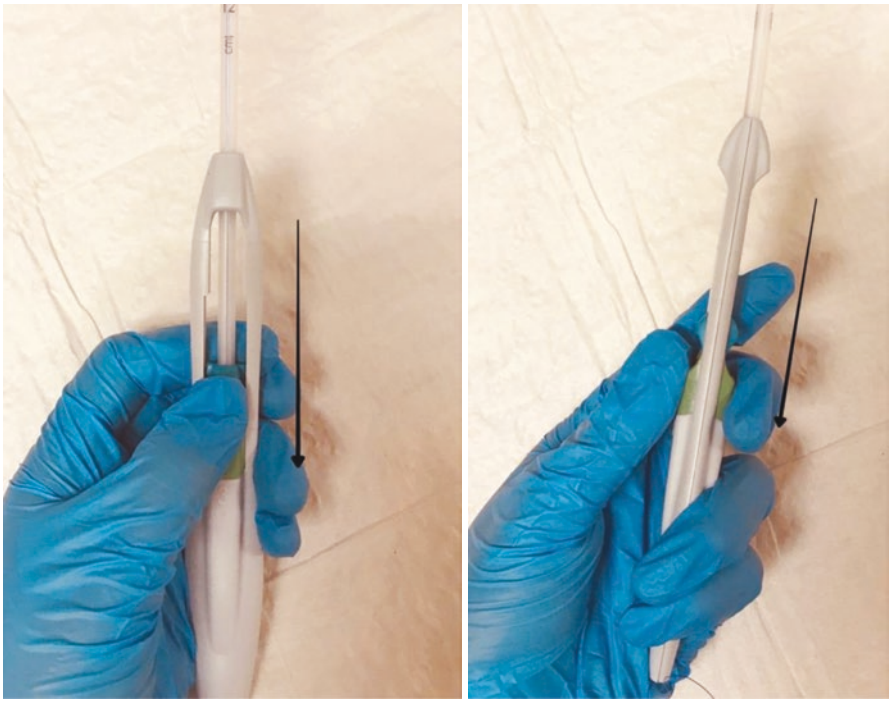


Fig. 13.16 Push slider toward the inserter, allowing strings to release

8. Remove the IUD inserter.
9. Trim the strings with the scissors so that 2–3 cm will remain (Fig. 13.12).
10. Remove the tenaculum and inspect for bleeding. Apply gentle pressure with a swab to achieve hemostasis.

Complications and Risks

- Uterine perforation(rare)
- Infection (risk of salpingitis is 1/1000.)
- Pain during placement
- Bleeding and cramping(common up to a week post procedure)
- Spotting and irregular bleeding during the first 6 months
- Eventual amenorrhea

Tricks and Helpful Hints

- Show patients a nonsterile IUS and let them hold it when counseling them. Seeing how small and flexible an IUD is may reduce patient fear.
- Have the patient take 400–800 mg ibuprofen or 440–500 mg naproxen an hour before IUS insertion. This may reduce postprocedure cramping.

- Some providers prefer to do IUS insertions when patients are menstruating.This may be inconvenient but somewhat helpful with nulliparous and adolescent women with a narrower cervical canal.
- Before gripping the cervix with the tenaculum, you may want to pause the procedure and use lidocaine or Hurricane to anesthetize the anterior cervix or to perform a paracervical block. A 1% lidocaine paracervical block decreases pain during IUS insertions [7].
- If the uterus is retroverted, placing the tenaculum on the lower lip of the cervix and maintaining traction will help straighten the endometrial cavity.
- When maintaining traction on the tenaculum, you may need to monitor the speculum to ensure that it is not displaced.
- When advancing the sound, use torque to advance the tip. Put a very gentle bend in the sound and twist the tip from side to side to advance it. This is safer than pushing the tip in. If you meet resistance at the level of 3–4 cm, consider that you may be at the endocervix or at the fold near where the cervix joins the uterine body. Check to see if more traction is needed to straighten the uterus. In case of suspected cervical stenosis, the use of a dilator would be beneficial to overcome resistance [8].
- Marking the maximum advance of the sound visually is difficult. Insert the long end of a swab adjacent to the sound and align the tip of this with the exocervix. Then, pull the sound and the swab out together. The tip should line up with the sound mark that corresponds to the uterine depth.
- Rinse the cut end of the IUD string and allow the patient to hold it so she can see what it feels like on her fingertip. This may facilitate finding the strings when the IUD is in place.
- Complete the reminder card from the LNG IUS package insert and give it to the patient.

Procedure Note

(Provider to fill in blanks/circle applicable choice when given multiple choices and customize as needed.)

- *Recent Pap shows no dysplasia and cultures show no signs of sexually transmitted infections.*
- *Patient has no history of recent STIs.*
- *Patient understands the risk of bleeding, infection, pain/cramping, and the patient knows alternatives. She consented to IUD placement in writing after having opportunity to ask questions.*
- *Bimanual exam performed.*
- *Speculum placed; cervix normal looking and midline.*

- *Cervix visualized and swabbed three times with Betadine.*
- *Tenaculum clamped onto anterior lip of cervix; uterus sounded to _____cm.*
- *Levonorgestrel IUS placed without complications per package insert.*
- *Arms deployed in a high fundal position.*
- *String trimmed and string palpation described to patient. Bimanual exam after placement demonstrates no/minimal uterine tenderness.*

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
58,300	IUD insertion
58,301	IUD removal
HCPCS codes (healthcare common procedure coding system, level II)	
J7298	Mirena, LNG-20 system
J7297 J7296 J7301	Liletta, LNG −18.6 system Kyleena, LNG-19.5 system Skyla, LNG-13.5 system
ICD10-CM-diagnostic codes (international classification of diseases, tenth revision, clinical modification, Centers for Disease Control and Prevention)	
Z30.430	IUD insertion
Z30.431 Z30.432 Z97.5	IUD surveillance IUD removal Presence of IUD

Postprocedure Patient Instructions

Instruct patient to return in 4–6 weeks for IUS string check. If the IUS is inserted after the first 7 days of menstrual cycle, then a backup method (condoms or spermicide) should be used for 1 week postinsertion. Tell the patient to check IUS string after each period. Instruct the patient to use ibuprofen after the insertion, as needed for cramping and to call office if she develops purulent discharge, fever, chills, nausea, vomiting, or excessive bleeding.

Case Study Outcome

The patient selected the levonorgestrel intrauterine system, which was inserted without difficulty in the office. She tolerated the procedure well and remarked at her follow-up visit that she was very satisfied with her selection.

Postprocedure Patient Handout

(Provider to fill in blanks/circle applicable choice when given multiple choices.)

You have just had a Levonorgestrel Intrauterine System (LNG IUS) inserted on_____ (insert date). This contraceptive system is effective for ___ (insert years). Your Levonorgestrel Intrauterine System should be removed prior to_____ (insert date/years from date of insertion).

Please remember to check for the LNG IUS string afte every period.

Most women have no side effects from the LNG IUS, but common side effects include:

- Uterine cramping, which usually goes away within the first 3 months. Consider taking two 600 mg ibuprofen for pain up to every 6 h as needed.
- Change in bleeding pattern, including spotting and between-period bleeding. Most women eventually have little or no period.
- Acne, breast tenderness, weight gain, and back pain occur rarely (less than 3.5% of the time).

Please call your clinician's office if:

- You develop a smelly discharge or have a fever.
- Develop severe abdominal pain not relieved by ibuprofen.
- If the bleeding becomes excessive (more than one pad per hour or more than ten pads per day).
- You are interested in getting pregnant and wish for your provider to remove the LNG IUS. Please be aware that fertility returns immediately upon removal.

Please make a follow-up appointment in the office in 1 month.

Questions for Learners

- Some women have difficult IUD insertions. What are some techniques or medications that are currently studied to reduce pain during IUD insertions?
- How can you improve the adherence rate for LNG IUS?
- How would you counsel a patient to choose between LNG IUS vs. copper IUD?

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Chapter 14
Intrauterine Device Removal

Cathryn B. Heath

Introduction

One of the many benefits of utilizing intrauterine contraception is the typical ease with which the device can be inserted and removed. Following patient counseling, once the patient and provider have together formulated a decision to remove the device, retrieval of the apparatus can often be accomplished in a short office visit.

There are currently five options for intrauterine contraception available for use in the United States. The T380A intrauterine copper contraceptive (Paragard®, CooperSurgical, Inc., Trumbull, CT) is licensed for use up to 10 years [1]. The hormonal intrauterine devices available in 2018 in the United States include Mirena [2] and Kyleena [3] (Bayer, Whippany, NJ), which are licensed for 5 years of use; Liletta [4] (Allergan), which is licensed for up to 6 years of use; and Skyla [5] (Bayer), which is licensed for up to 3 years of use. Patients seek to have their intrauterine device (IUD) removed when they desire pregnancy or they have reached the maximum recommended time for utilization of the apparatus. Adverse reactions that most often prompt women to present for removal of their IUD include pelvic cramping and abnormal vaginal bleeding [5, 6]. Other less common reasons for removal include concerns such as partner discomfort with intercourse, and the inability of the patient to self-palpate IUD strings. Although there is some evidence that a small percentage of women remove the IUD themselves, this is considered inadvisable.

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https://doi.org/10.1007/978-3-030-28884-6_14

Case Study

A 27-year-old female, gravida 2 para 1011, presents to the office concerned that she has not been able to feel her IUD strings over the past few weeks since her last period ended. Prior to her last menstrual cycle, she had been able to palpate her strings since placement of the device 15 months earlier, and she had always been able to do so without difficulty. The patient had experienced minimally increased bleeding and cramping with menses in the first few months following placement of the IUD; however, these symptoms resolved, and she has had no other concerns with her contraception until now. The patient and her husband have unprotected sex regularly, and they remain mutually monogamous.

Review of systems reveals continued regular menses, with no spotting in between periods and no symptoms suggestive of pregnancy. On pelvic exam, a normal appearing cervix is identified, without evidence of IUD strings passing through the external os, with no abnormalities identified on bimanual exam. A urine pregnancy test is negative.

If in fact her IUD is still in place, the patient does not want to have the device removed. She and her husband have been in the process of discussing when they would plan to have their next child.

Arrangements were made to have a pelvic ultrasound performed for confirmation of IUD presence (Figs. 14.1 and 14.2). The IUD was noted to be in a satisfactory intrauterine position. The patient felt comfortable not being able to check her strings monthly since her periods continued to be very regular.

Diagnosis and Indications

- Patient adverse reaction:
  - Pelvic pain

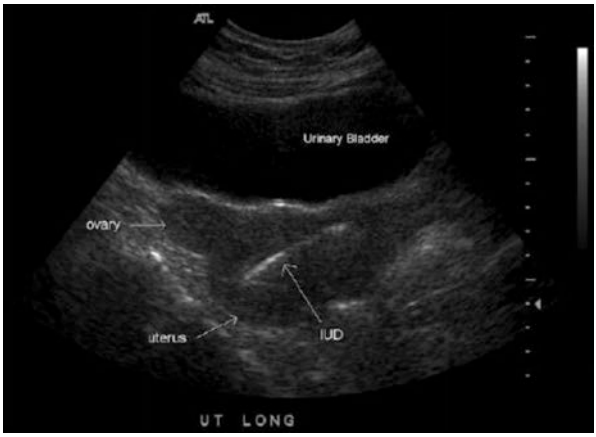


Fig. 14.1 Longitudinal view of intrauterine device in uterus

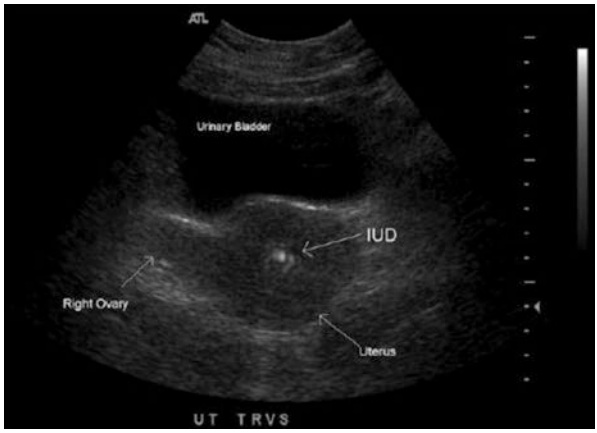


Fig. 14.2 Cross-sectional view of IUD in the uterus

  - Back pain
  - Dysmenorrhea
  - Meno- or menometrorrhagia
  - Partial IUD expulsion
- Pregnancy
- Patient desires pregnancy
- Patient has reached the maximum recommended time for use
- Patient has reached menopause
- Patient dissatisfaction
- Partner discomfort with intercourse
- Inability to palpate IUD strings

Contraindications

IUD removal in the presence of pregnancy should be performed by an experienced clinician following appropriate patient counseling and review of informed consent. In the case of a rare IUD migration, adhesion to the myometrium, the IUD should be removed by an experienced clinician.

Equipment (Fig. 14.3)

Equipment for Straightforward IUD Removal

- Vaginal speculum

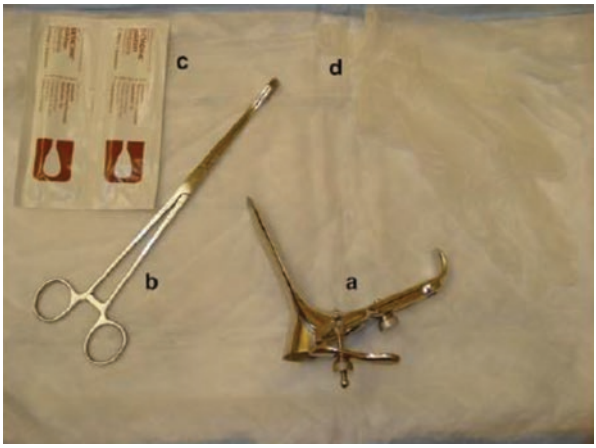


Fig. 14.3 Setup for IUD removal: (**a**) Pederson speculum; (**b**) ring forceps; (**c**) Betadine® Solution Swabsticks (Purdue Pharma, Stamford, CT); (**d**) gloves

- Nonsterile gloves
- Ring forceps

Equipment for Potentially Complicated IUD Removal Including Evaluation of Absent Strings

- Vaginal speculum
- Nonsterile gloves
- Cytobrush, cytobroom, or two sterile cotton swabs
- Antiseptic solution
- Single-toothed tenaculum
- Alligator clamp or IUD hook
- Endocervical speculum
- Ring forceps
- Uterine sound

Optional Equipment

- Colposcope
- Monsel's solution
- Silver nitrate sticks
- Topical anesthetic
- Ultrasound

Procedure

When IUD Strings Are Visualized [6]

1. Perform pregnancy test.
2. Perform a bimanual examination to determine the size and position of the uterus.
3. Insert a speculum into the vagina to bring the cervix into view.
4. Grasp the IUD strings with ring forceps and gently apply steady traction (Fig. 14.4).
5. Encourage the patient to take a deep breath and exhale slowly, allowing for enhanced relaxation of the pelvic floor musculature as the IUD is withdrawn through the cervix (Fig. 14.5).

When IUD Strings Are Absent (Algorithm 14.1)

1. Perform a pregnancy test.
2. Perform a bimanual examination to determine the size and position of the uterus.
3. Insert a speculum into the vagina to bring the cervix into view. Cleanse the cervix with antiseptic solution prior to instrumentation.
4. Grasp the anterior lip of the cervix with a single-toothed tenaculum in order to maintain gentle traction to facilitate instrumentation.
5. Insert a cytobrush into the os, twirling as it is withdrawn, in the hopes of snagging the strings to permit removal of the device.

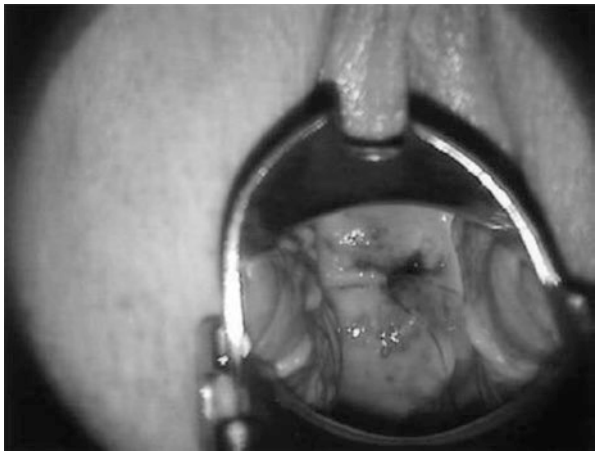


Fig. 14.4 Vaginal view of IUD string prior to removal

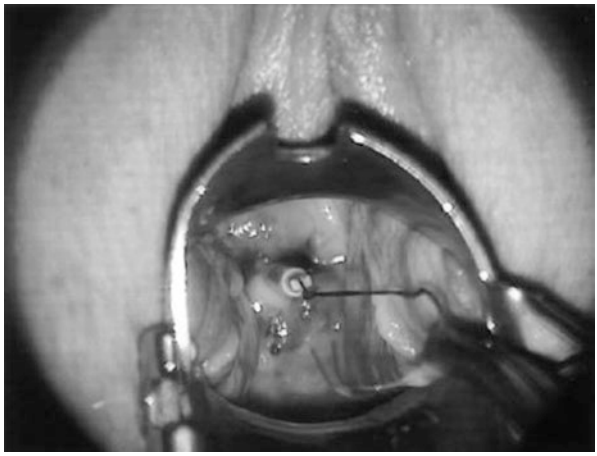


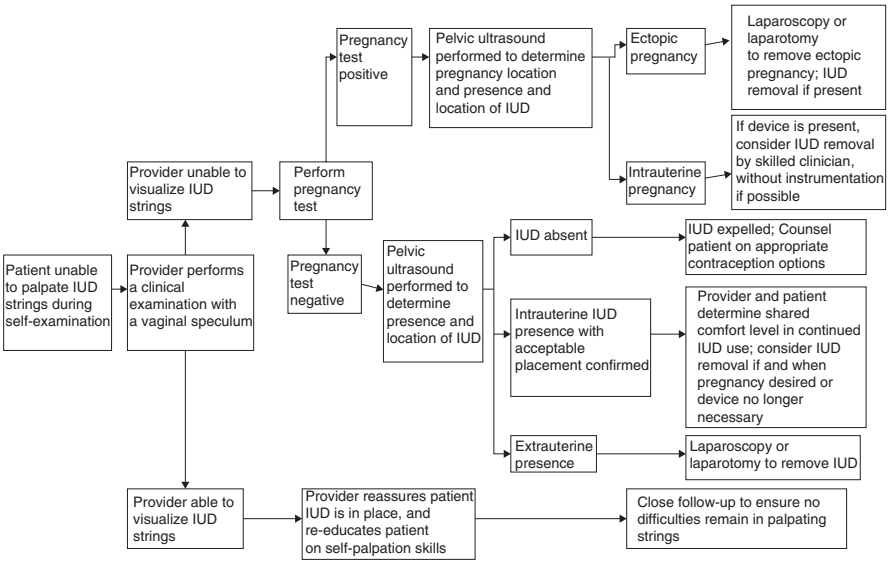
Fig. 14.5 Vaginal view of IUD during removal

- Alternatively, two sterile cotton swabs may be inserted, and then twirled as they are withdrawn, in an attempt to snag the strings.
- The cervix may be dilated with a uterine sound, and an endocervical speculum is inserted to facilitate visualization of the strings; an alligator clamp may then be passed to attempt grasping the strings.

6. Visualization of the uterus with an ultrasound may aid in more difficult removals.
7. When retrieval has been attempted unsuccessfully, the patient may then require having the IUD removal performed with hysteroscopy in the operating room under anesthesia.

Tricks and Helpful Hints

- Advising a woman to take NSAIDs such as ibuprofen or naproxen prior to her appointment may help limit discomfort experienced during and following the procedure.
- Although less commonly utilized, specially designed instruments for IUD removal are commercially available, including the IUD hook and IUD extractor.
- It may be necessary to apply a single-toothed tenaculum to the anterior lip of the cervix in order to stabilize the cervix and uterus prior to instrumentation. Once the tenaculum has been removed, pressure can be applied to the puncture sites with a large swab to control any oozing of blood; silver nitrate or Monsel's solution can be used to treat any excessive bleeding.



Algorithm 14.1 Decision tree for absent IUD strings. Note that some IUDs available outside the United States do not have strings

Interpretation of Results

See the Algorithm 14.1, which illustrates possible options for proceeding when IUD strings are absent [7].

Procedure Note

(Clinician to customize as needed.)

The patient was placed in the lithotomy position, a speculum was inserted into the vagina, and the cervix was identified. The IUD strings were noted to be passing through the external os. The strings were grasped with a ring forceps, and gentle traction was applied. The IUD was retrieved without incident. The patient tolerated the procedure without difficulty.

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
58301	Removal of intrauterine device
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 10th Revision, Clinical Modification, Centers for Disease Control and Prevention)	
Z30.432	Encounter for removal of an intrauterine device
Z30.433	Encounter for removal and reinsertion of an intrauterine device
Z 32.02	Pregnancy test-negative

Postprocedure Patient Instructions

The patient should be advised that she may experience mild cramping and minimal vaginal spotting and/or discharge in the first 12–24 h following removal. Although no further follow-up is usually necessary, any excessive bleeding should be reported immediately and the patient re-evaluated. Couples should be reminded of the subsequent rapid return to fertility once the apparatus has been removed [8].

Case Study Outcome

The patient presented to the office 4 months later for removal of her IUD, as she and her husband had decided that they were now emotionally and financially prepared to conceive again. The patient's periods had remained regular, although she continued not to be able to feel her IUD strings following menstruation. Upon repeat examination, the IUD strings could still not be visualized. Attempts were made at retrieval utilizing a cytobrush and then sterile swabs, though these were both unsuccessful. Following administration of a paracervical block, the cervix was dilated with the passing of a uterine sound. Another attempt at retrieval was then made utilizing an alligator clamp, with successful identification of the strings and subsequent removal of the IUD.

Postprocedure Patient Handout

(Provider to customize as needed.)

- Today your clinician removed your intrauterine device. You may expect minimal vaginal spotting or discharge and possibly mild abdominal cramping. You should not experience bleeding heavier than a normal period.

- If you experience heavier bleeding, foul smelling vaginal discharge, persistent abdominal pain, or fevers, please call your clinician right away.
- Abdominal cramping is usually temporary. You may wish to take three ibuprofen 200 mg tablets every 6 h or two acetaminophen 325 mg tablets every 4–6 h, as needed.
- As a reminder, immediately following removal of your intrauterine device (IUD), you are now able to get pregnant if you have vaginal sex without the use of a condom or other barrier method. In fact, the majority of women trying to conceive are able to successfully become pregnant in the first year after removal of their IUD.
- Please call the office if you have any problems or questions.

Questions for Learners

- What are the complications with removal that should be discussed prior to removal?
- Is it necessary to remove an Intrauterine Device in a postmenopausal woman?
- Considering the current medical system within the United States, what are the pros and cons of using a contraceptive that requires clinician removal, which includes the cost of removal as well as the loss of personal autonomy?

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Additional Resources

Web Sites

https://www.paragard.com/
http://www.skyla-us.com/index.php
https://www.liletta.com/
https://www.mirena-us.com
https://www.kyleena-us.com

Chapter 15
Fertility Awareness Method/Natural Family Planning

Dawn Brink-Cymerman

Introduction

Natural family planning (NFP) is one of the oldest practiced methods of birth control. Also known by the names periodic abstinence, rhythm method, and fertility awareness method, it can be used for either pregnancy prevention or planning and is acceptable to all major religious groups. Although it is not a popular method of birth control, there are couples who still choose to practice natural family planning and may request the assistance and support of their health care provider. In motivated patients with appropriate instruction, NFP may be an effective method of preventing or spacing pregnancies. Eighty-five percent of women will get pregnant within a year of having intercourse without contraception. With perfect use, 2–5% of women who have been instructed and use the symptothermal or the ovulation method will become pregnant [1]. However, perfect use is uncommon and many women do not use NFP appropriately or choose not to continue using this method [2].

There are several methods of NFP, including the calendar method, the lactational amenorrhea method, the basal temperature method, the cervical mucus method, the Creighton method, the symptothermal method, and the standard days method/two-day Method.

The calendar method is the original natural method and is based solely on calculation of the days of a woman's cycle. This method is based on the theory that a woman ovulates approximately 14 days prior to menses. Most women have variations of one to several days in their cycle; therefore, predicting the day of menses is difficult. This is even more difficult in women with irregular cycles. Although the calendar method may be appropriate for women with regular cycles, additional means of assessing ovulation may be necessary for women with irregular cycles.

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https://doi.org/10.1007/978-3-030-28884-6_15

The lactational amenorrhea method (LAM) can be used by breastfeeding women in the postpartum period. This method should only be considered by women who are exclusively breastfeeding eight to ten times per day and at least one time during the night. This assures prolactin levels remain high enough to suppress ovulation [3]. LAM should not be used after the initial 6 months postpartum as fertility can return prior to the onset of menses.

The basal temperature method is based on the change in the early morning basal temperature at the time of ovulation when the cycle comes under the influence of progesterone. Intercourse is avoided from the onset of menses through the ovulation period. This lengthy period of abstinence is unacceptable to some couples. The basal body temperature rises under the influence of progesterone, with most ovulatory cycles having a lower temperature in the first half of the cycle and a higher temperature with the onset of ovulation. At the time of ovulation, the temperature usually rises by 0.4 °F and remains elevated until menses. Patients should be instructed that their fertile period lasts until the temperature is elevated for at least 3 days.

The cervical mucus method (also called ovulation method) is a method that instructs a woman to check her cervical mucus pattern on a daily basis to determine the time of ovulation. She learns to recognize patterns of mucus by sensations on the vulva and visual inspection and avoids intercourse during the ovulation period. Probabilities of pregnancy are 3.1% in the first year with perfect use and 86.4% during imperfect use. It is crucial that couples who choose this method follow some very important rules, which include no intercourse during mucus days, no intercourse during times of stress, and no intercourse within 3 days after the peak of fecundity [1].

The different types of mucus are based on glucose composition. Changes in cervical mucus occur at the beginning and end of the fertile period even in irregular cycles. Secretions should be observed by how they look, by touch, and by feel. Women chart their mucus changes in order to be aware of their fertile period. There is variation in mucus composition woman to woman, but each individual has a pattern that remains fairly stable. Ultrasound studies have confirmed that these symptoms accurately identify the timing of ovulation [4]. The World Health Organization (WHO) is interested in finding birth control methods that are inexpensive but effective for use in third-world countries. A study supported by WHO found that 93% of women were able to determine the state of the cervical mucus regardless of educational level and cultural influences [5].

The Creighton model of birth control is a modification of the cervical mucus method and was developed at the Pope Paul VI Institute by Dr. Thomas Hilgers in 1980. It was intended as a natural procreativity education method that allowed a couple to know when their fertile periods occurred. When a couple uses this method, they meet with an instructor over a period of approximately 1 year in order to accurately learn to recognize the changes in cervical mucus and body changes

that indicate fertility. The vulvar mucus is observed, and intercourse is avoided during the 3 days prior to until 2 days after the peak vulvar mucus [6]. Proponents of the method quote studies that state the failure rate is less than 1% per year; however, some couples who became pregnant during the study were deliberately not counted as failures as investigators believed the couples intended pregnancy [7].

The symptothermal method is a combination of monitoring symptoms that indicate fertility, using the basal body temperature to assess for ovulation and using calendar calculations to assess peak fertility. In this method, women assess cervical mucus and observe symptoms of fertility, such as midcycle cramping and breast tenderness, to help determine the period prior to ovulation that they may engage in intercourse. Women also use calendar calculations to monitor fertile periods and also monitor basal body temperatures to indicate when ovulation has occurred and that they have passed through the fertile period of the menstrual cycle. By combining these methods, couples may avoid the prolonged periods of abstinence required by other NFP; however, a higher level of instruction is necessary for its appropriate use. Monitoring cervical mucus and observing symptoms of fertility such as midcycle cramping and breast tenderness aid a woman in determining the time prior to ovulation during which she may engage in intercourse without risking pregnancy. By combining symptom observation and basal body temperature monitoring, couples can avoid the prolonged period of abstinence recommended with the use of the basal body temperature method alone.

The standard days method [8] is based on the probability of pregnancy and the timing of ovulation. Studies have shown that a woman's fertile period is approximately 6 days: 5 days before ovulation and for 24 hours after ovulation. After 24 hours, there is decreased probability of pregnancy. Thus, the fertile window in a woman's cycle is 6 days. Data have also shown that ovulation occurs in the middle of the cycle when the cycles last between 26 and 32 days. Couples avoid intercourse on days 8–19 of every cycle to avoid pregnancy. With correct use, the failure rate is approximately 4% with actual rates that approach 9% [9].The standard days method may be used for multiple years in those who were successful in the first year [10]. CycleBeads® (Cycle Technologies, Inc., Washington, DC) are a color-coded string of beads to help women keep track of their cycles. To use the beads, a rubber ring is moved over the beads each day of the cycle to track where she is in the cycle. The colors of the beads indicate fertile and nonfertile days.

There are several systematic reviews that have looked at the efficacy and pregnancy rates of the various methods. Perfect use pregnancy rates reported in Urritia et al. ranged between 0 and 12.1%, with typical use pregnancy rates between 3 and 33% [11].

There are now multiple websites, downloadable apps, and electronic hormone fertility monitors (EHRM) available. Some of these methodologies may be expensive, requiring one to use test strips which may become cost prohibitive for the average consumer.

Case Study

A 22-year-old woman and her partner present at the office to discuss birth control. They have not been sexually active prior to this time and are planning to be married in 3 months. They would like to put off pregnancy for 1–2 years yet and would like to have a method that is consistent with their religious beliefs. In their premarital counseling sessions, there was discussion of natural family planning methods.

Diagnosis (Algorithm 15.1)

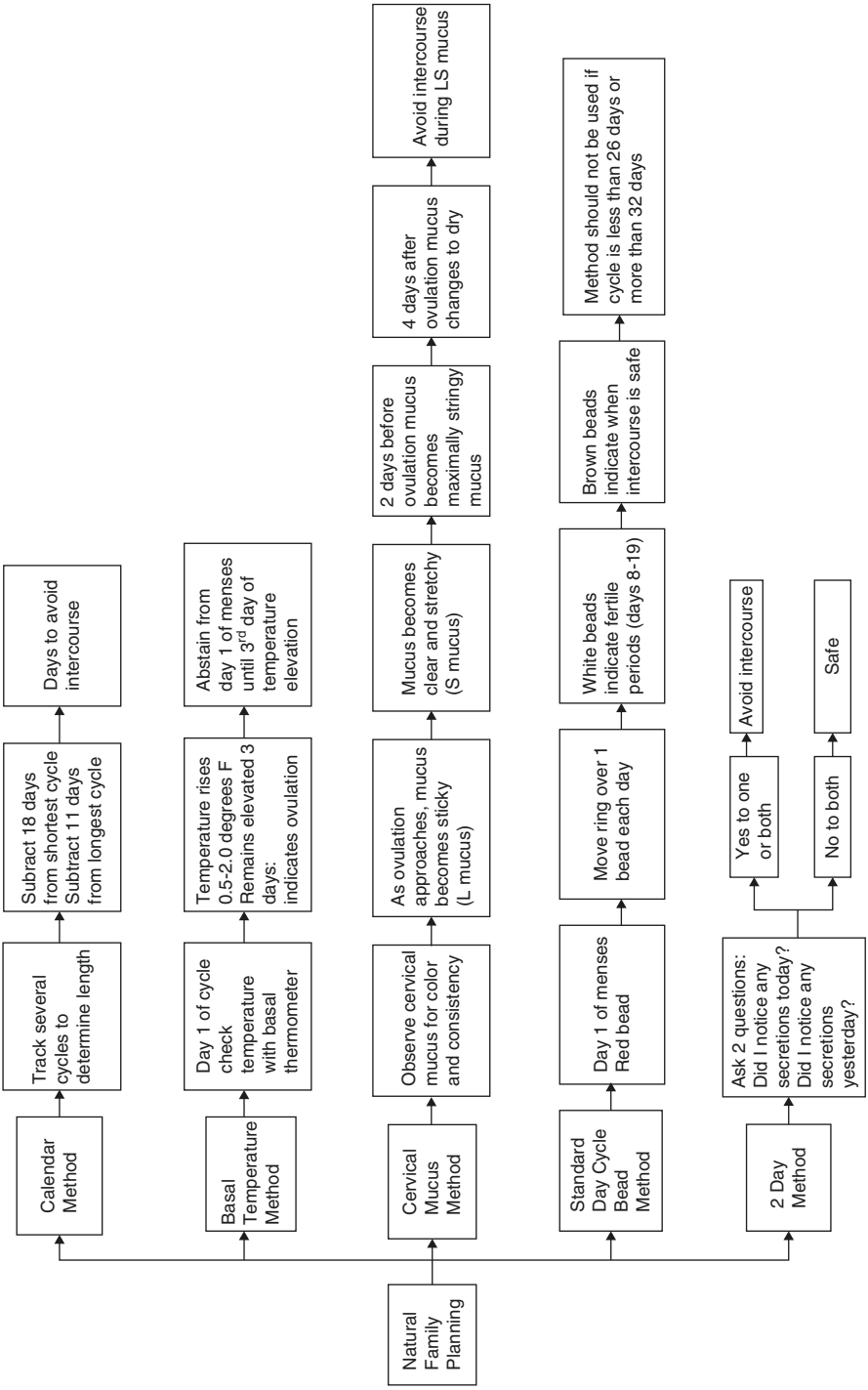
Request for natural family planning methods.

Indications (Algorithm 15.1)

- Women who prefer nonhormonal contraceptive method due to religious or financial reasons.
- Women who have contraindications due to concomitant diseases or side effects to hormonal birth control
- Women requesting immediately reversible contraception
- Women who wish an increased awareness of their own body's hormonal cycles, including fertility and infertility

Contraindications, Complications, and Risks (Algorithm 15.1)

- High failure rate in couples who are not highly motivated
- Requires periods of abstinence from intercourse
- Less effective for women with irregular menstrual cycles
- No protection against sexually transmitted infections
- Interference in charting the correct temperature can be caused by illness, alcohol use, travel, or interrupted sleep (at least 3 h of sleep must occur). These events should be noted on the chart.
- Monitoring of cervical mucus may be inaccurate if a vaginal infection is present, with use of douches, vaginal creams, or gels, or if there is an illness or use of medication.



Algorithm 15.1 Decision tree for choosing a method of family planning

Equipment

- Basal body temperature thermometer (Fig. 15.1)
- Chart for temperature and recording consistency of cervical mucus
- Mucus and menstrual bleeding (Fig. 15.2).

Procedure and Patient Instructions (Algorithm 15.1)

Calendar Method

1. Track several menstrual cycles to determine length. (Cycle determination is based on the first day of menses as day 1 of cycle.)
2. Subtract 18 days from the shortest cycle.
3. Subtract 11 days from the longest cycle.
4. This determines the range of days to avoid intercourse.

Example

- Month 1 cycle 30 days.
- Month 2 cycle 28 days.
- Month 3 cycle 32 days.
- Month 4 cycle 28 days.
- Woman subtracts 28–18 = 10.
- Woman subtracts 32–11 = 21.
- Patient would avoid intercourse between days 10 and 21.

Basal Temperature Method

1. Day 1 of cycle (menses) begins charting basal body temperature with a basal thermometer marked to detect small fluctuations in body temperature.

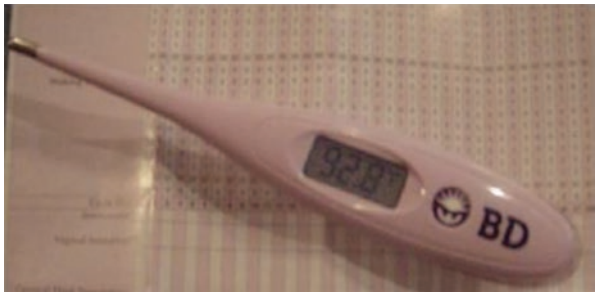
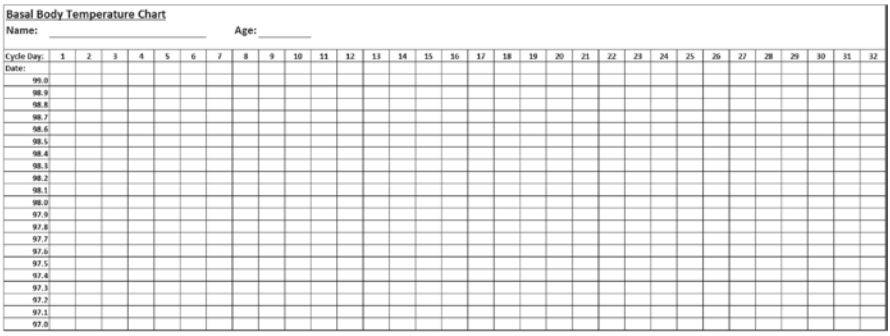


Fig. 15.1 Sample digital basal body temperature thermometer (Becton Dickinson & Co., Franklin Lakes, NJ)


Basal Body Temperature Chart

Name: _____ Age: _____

Cycle Day:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
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Take your temperature before getting out of bed. Record the temperature by placing a mark in the box that correlates to your temperature for the day of cycle. A lasting elevation in temperature indicates ovulation occurred two or three days prior. Cycle day one is the first day of menses.

Fig. 15.2 Basal body temperature and cervical mucus chart

2. Temperature must be checked prior to getting out of bed at the same time each morning.
3. A rise in temperature of 0.5–2.0 °F that remains elevated for 3 days indicates ovulation. Ovulation actually occurs just prior to the temperature elevation.
4. A true postovulatory rise lasts 10 days.
5. The period of abstinence should be from the first day of menses through the third day of temperature elevation to completely cover the fertile period.
6. Interference in charting the correct temperature can be caused by illness, alcohol use, travel, or interrupted sleep (at least 3 h of sleep must occur). These events should be noted on the chart.

Cervical Mucus Method

1. Women should be instructed to observe their cervical mucus:
   Observe the mucus for color and consistency on undergarments or toilet paper. Highly fertile secretions are wet, slippery, clear, and stretchy. Ovulation can occur the day before, during, or after the day of the clear stretchy mucus.
2. At the end of menses: G mucus forms a plug in the cervix causing the woman to be dry or without cervical mucus discharge.
3. As ovulation approaches, G mucus decreases and L mucus increases. L mucus has a sticky, cloudy nature.
4. With increasing estrogen: S mucus increases and peaks on the day of peak estrogen during the cycle. The combination of S and L mucus causes clear, stretchy mucus that aids the survival of sperm and transport through the female genital tract.
5. Two days prior to ovulation, the stringy sensation is at a maximum.
6. Two hours prior to ovulation, the slippery sensation or wetness is at its most noticeable.

7. Four days after ovulation, the mucus pattern reverts back to dry or unchanging as the G mucus again develops under the influence of progesterone.

Monitoring of cervical mucus may be inaccurate if there is vaginal infection; use of douches, vaginal creams, or gels; illness; or use of medication.

The Standard Day (CycleBead® Method, Cycle Technologies, Inc., Washington, DC) (Fig. 15.3)

1. Women are considered fertile on days 8–19 of their cycle.
2. Women start on the first day of their menstrual cycle with the red bead.
3. Move the ring over one bead each day.
4. White beads indicate fertile periods.
5. Brown beads indicate nonfertile periods when intercourse is safe.
6. The dark brown bead indicates a cycle shorter than 26 days, and this method should not be used.
7. If the menses does not start by the end of the brown beads, the cycle is longer than 32 days, and this method should not be used.

2 Day Method

- Uses cervical secretions to determine fertility.
- Patient asks herself two questions:
  - "Did I notice any secretions today?"
  - "Did I notice any secretions yesterday?"

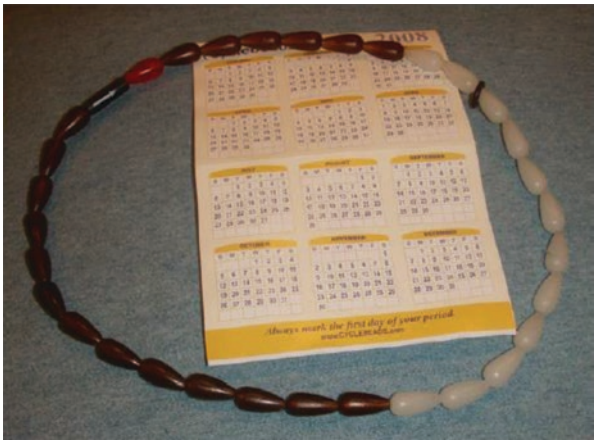

Fig. 15.3 CycleBeads® (Cycle Technologies, Inc., Washington, DC)

- If the patient noticed secretions, either day she is potentially fertile and should avoid intercourse.
- If the answer is no to both questions, then the probability of pregnancy is low and intercourse is safe.

Fertility rates are similar to the standard day method.

Procedure Note

(Provider to customize as needed.)

The patient and her partner were counseled on the different methods of Natural Family Planning and made aware of the advantages and disadvantages of each, including the risk of pregnancy. The patient was instructed to chart her menstrual bleeding and symptoms throughout the month and to bring the chart with her to future visits so that the chart could be evaluated with the patient to aid in understanding of cyclic periods of fertility. The patient and partner will decide whether or not they want to include basal temperature monitoring as a part of their daily monitoring. They are encouraged to hire a natural family planning coach to give further instruction and training in the method they choose.

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
Preventive Medicine Counseling:	
99401–15 min	
99402–30 min	
99403–45 min	
99404–60 min	
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 9th Revision, Clinical Modification, Centers for Disease Control and Prevention)	
Z30.02	Counseling and instruction in Natural Family Planning to avoid pregnancy

Case Study Outcome

After 1 year of use of natural family planning, the couple continues to be satisfied with their choice of birth planning method. The patient has discontinued the use of basal temperature as her comfort level with the use of cervical mucus to

determine that fertility has increased. She also considers it an added benefit that she has increased understanding of her fertility cycles and will be able to use that information to her advantage when she does desire pregnancy.

Question for Learners

- Discuss the approach you would use with a couple interested in fertility awareness-based methods.

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Web Sites

An in-depth explanation of the method and assistance in finding an instructor can be found at the web site: www.CreightonModel.com.
Couple to Couple League: htpp://www.ccli.org/.
http://www.familyplanning.net
http://www.popepaulvi.com
http://www.irh.org
http://www.fertaware.com
http://www.woomb.org

Chapter 16
Etonogestrel Subdermal Contraceptive Implant: Insertion and Removal

Jeffrey P. Levine and Joshua A. Mleczko

Introduction

The progestin-only, etonogestrel implant, Nexplanon®, is a sterile 4-cm × 2-mm single flexible rod that is implanted subdermally in a woman's upper arm and can provide up to 3 years of continuous highly effective contraception. Each rod contains 68 mg of the progestin etonogestrel and 15 mg of barium sulfate, encased in an ethylene vinyl acetate copolymer core and rate-controlling membrane [1]. It is supplied in a sterile, preloaded disposable applicator that prevents noninsertion, greatly facilitates proper insertion in a superficial plane, reduces the risk of infection via contamination of the sterile rod, and allows insertion without the need for incision and concomitant risk of scarring.

Nexplanon® (FDA-approved 2011) replaced the original etonogestrel subdermal contraceptive implant, Implanon® (FDA-approved 2006), due to cases of incorrect insertions with the Implanon® applicator device. The changes from Implanon® to Nexplanon® include:

1. Barium sulfate has been added to make Nexplanon® a radiopaque implant, thus rendering it visible on X-ray and CT scan to facilitate localization. Nexplanon® is not contraindicated in patients with allergy to sulfa-containing compounds.
2. The applicator has been redesigned, which requires a different insertion procedure than the Implanon®. The Nexplanon® implant is securely retained inside the needle to prevent it from inadvertently falling out prior to insertion, as the

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applicator is more ergonomically designed to facilitate single-handed subdermal insertions in a superficial plane, reducing the risk of deeper insertions into muscles, blood vessels, or nerves.

The Implanon® and Nexplanon® rods look identical and contain the exact same amount of etonogestrel and ethylene vinyl acetate (EVA) copolymer. In a 3-year clinical trial, Nexplanon® and Implanon® yielded comparable exposure to etonogestrel. Thus, the same pharmacokinetic, efficacy, and side effect data from earlier clinical trials utilizing Implanon® apply to Nexplanon®.

Etonogestrel Implant (EI) is indicated for women of reproductive age seeking safe, convenient, highly effective, continuous, long-acting (up to 3 years), and rapidly reversible contraception. Once inserted, the etonogestrel implant offers excellent patient convenience since its effectiveness is not user-dependent [2]. The implant can be removed at any time, with a rapid return to fertility. In particular, EI is a consideration for patients who do not want or cannot/should not use estrogen-containing contraceptives (e.g., uncontrolled hypertensive patients, smokers >35 years old), and those willing to tolerate irregular menses, possibly for the full duration of use [3]. Nexplanon® does not protect against sexually transmitted infections (STIs). While the etonogestrel implant was not initially evaluated in patients >130% of their ideal body weight, several postmarketing studies have not shown decreased efficacy with an increased body mass index (BMI) [4]. Thus, there is no weight or BMI limit for EI use.

The etonogestrel implant is the most highly effective reversible contraceptive method, with a contraceptive failure rate of only 0.05% for both perfect and typical use, comparable to IUDs (0.2–0.8%) and female sterilization (0.5%) [5]. However, efficacy depends on proper insertion. Expulsion may also occur if the full length of the needle is not inserted when placing the implant. Failure to insert the implant completely and correctly can lead to unintended pregnancy. Too deep an insertion can hinder removal, and failure to remove the implant within the recommended time period can also result in an unintended pregnancy.

Potential complications related to etonogestrel implant insertion and removal procedures include pain, paresthesia, bleeding, hematoma, scarring, infections, and migration of the implant. These complications are usually the result of deep intramuscular, fascial, or intravascular insertions and prolonged traumatic removal attempts. Incomplete insertions or infections may also lead to expulsion. To reduce the risk of these complications:

1. The Nexplanon® implant is supplied in a sterile, preloaded disposable applicator that prevents noninsertion, greatly facilitates proper subdermal insertion in a superficial plane, reduces the risk of infection via contamination of the sterile rod, and allows insertion without the need for incision and concomitant risk of scarring.
2. All physicians and advanced practice clinicians should participate in the FDA-mandated 2-hr live Nexplanon® Clinical Training Program to certify their ability to properly insert, localize and remove the etonogestrel implant prior to performing these procedures on patients (www.nexplanontraining.com) [6].

Unexpected changes to menstrual bleeding patterns are the most common side effect of hormonal contraceptives and the most common reason for patient discontinuation. Nexplanon® is no exception. Bleeding irregularities are the most common adverse events contributing to the discontinuation of EI use in clinical trials (11%) [7]. However, the typical bleeding changes that occur with etonogestrel implant use differ from other hormonal contraceptive methods. After the initial 3 months of EI use, approximately 50% of women will revert back to their previous menstrual patterns prior to insertion, 20% will have decreased menses or amenorrhea, while 30% will have irregular bleeding such as bleeding in between menses. These bleeding patterns may persist throughout the potential 3 years of implant use. Less common reasons for discontinuation (<3%) include emotional lability, weight gain, headache, acne, and depression, but none of these side effects were found to be significantly increased in clinical trials of Implanon®. Advising patients about the potential bleeding changes and other possible side effects related to EI use is an essential part of the shared decision-making process regarding any contraceptive, including Nexplanon® [2].

Patients, who are considering EI as their contraceptive method, should undergo a focused history to assess for any potential contraindications. However, a physical exam (including gynecologic exam), Pap smear, or lab testing is unnecessary [8]. The clinician should document the counseling and patient consent process and provide a copy of the patient labeling to the patient for reference [1]. A procedure consent form is included in each Nexplanon® package.

Nexplanon® can be inserted at *any time* provided the clinician is reasonably certain that the woman is not pregnant [9] (Table 16.1).

However, if EI is inserted >5 days after menses started, patients should use a backup method or abstain for at least 7 days following insertion [9].

Following EI insertion, patients should receive verbal and written instructions advising them to call or to return the office at any time to discuss side effects or other problems/concerns or if they want to change to another contraceptive method. They should also be informed verbally and in writing when their implant needs to be removed.

No routine follow-up visit is required for EI. However, during other routine visits, it is advisable to assess the patient's satisfaction with her contraceptive implant and

Table 16.1 How to be reasonably certain that a woman is not pregnant [9]

A healthcare provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:
Is ≤ 7 days after the start of normal menses.
Has not had sexual intercourse since the start of the last normal menses.
Has been correctly and consistently using a reliable method of contraception.
Is ≤ 7 days after spontaneous or induced abortion.
Is within 4 weeks postpartum.
Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and < 6 months postpartum.

whether she has any concerns about it. Clinicians should also assess any changes in patient's health status, including medications that would change EI's appropriateness for safe and effective continued use.

Nexplanon® must be removed within 3 years of insertion. Before beginning the removal procedure, determine whether the patient wants to continue contraception with another implant, which can be inserted in the same location, immediately upon removal of the current implant. If the patient does not want to continue using the contraceptive implant and does not wish to become pregnant, alternative methods of contraception should be discussed and initiated. It should be emphasized to the patient that her fertility will rapidly return following removal, and she should assume she can become pregnant immediately after removal.

A meta-analysis of six open studies and seven comparative trials found that etonogestrel implant insertions (average time: 1.1 min) and removals (average time: 2.6 min) are relatively short procedures [10]. The authors also concluded that "complications with insertion and removal are rare in the hands of medical professionals familiar with the techniques." Indeed, infection, expulsion, and local reactions are rare, especially when insertion is properly performed using the preloaded applicator.

This chapter describes the recommended Nexplanon® insertion and removal techniques. However, all clinicians should participate in the FDA-mandated 2-hr live Nexplanon® Clinical Training Program to certify their ability to properly insert, localize, and remove the etonogestrel implant prior to performing these procedures on patients (www.nexplanontraining.com) [6]. In addition, they should review the insertion and removal instructions and package insert information prior to each related patient visit [1].

Case Study

A 35-year-old female, G3P3003, comes to your office for a routine gynecological exam. She is in a monogamous relationship with her husband, with no history of STIs. They use condoms as their only method of contraception, but she admits that they are not consistent with using them. She has smoked cigarettes (~1 ppd) for the past 12 years and is not ready to quit. She has three daughters and at this time does not want any more children. However, she is not ready to commit to sterilization, and she does not like the idea of having a foreign body in her uterus (intrauterine device-IUD). She has no complaints and denies any chronic medical problems. Her physical exam is completely normal.

Indications

- Any women desiring reversible contraception
- Smoking women over age 35 who desire reversible contraception
- Women who desire contraception but cannot utilize estrogen

Contraindications

Etonogestrel implant should not be used in women who have:

- Known or suspected pregnancy
- Current or past history of thrombotic disease*
- Hepatic tumors, active liver disease
- Undiagnosed abnormal genital bleeding
- Known, suspected, or history of breast cancer
- Hypersensitivity to any of the components of Nexplanon®

*While the Nexplanon® package insert lists the current and past history of thrombotic disease as a contraindication, evidence documented in the CDC 2016 US Medical Eligibility Criteria show that the benefit of the etonogestrel implant in preventing unintended pregnancy generally significantly outweighs any actual or theoretical risk of venous thromboembolism (VTE) [11]. Clinicians should refer to the CDC 2016 US MEC to assess eligibility for various contraceptive methods in patients with chronic medical conditions. Clinicians can locate these criteria on the US Medical Eligibility Criteria (US MEC) for Contraceptive Use webpage at: https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/summary.html or download the "CDC Contraception 2016" Application for point of care access.

Insertion

Insertion Equipment (Fig. 16.1)

Before beginning, assemble everything needed for the insertion procedure. In addition to the sterile packing containing the Nexplanon® applicator, you will need:

- Sterile gloves (Nonsterile gloves acceptable if utilizing appropriate "no-touch" technique)
- Sterile surgical drape
- Antiseptic solution, such as iodine-containing swabs
- Local anesthetic (preferably 1% lidocaine), epinephrine is not needed
- Needles (preferably an 18-gauge to draw up lidocaine; a 1.5-in. 25-gauge to inject)
- Syringe (preferably 3cc)
- Sterile gauze (4× 4 cm)
- Adhesive bandage or Steri-Strips™
- 4" Pressure bandage (i.e., cotton roll-Kerlix, Ace wrap, compression bandage-Coflex)
- A sterile marker with tape measure (optional)

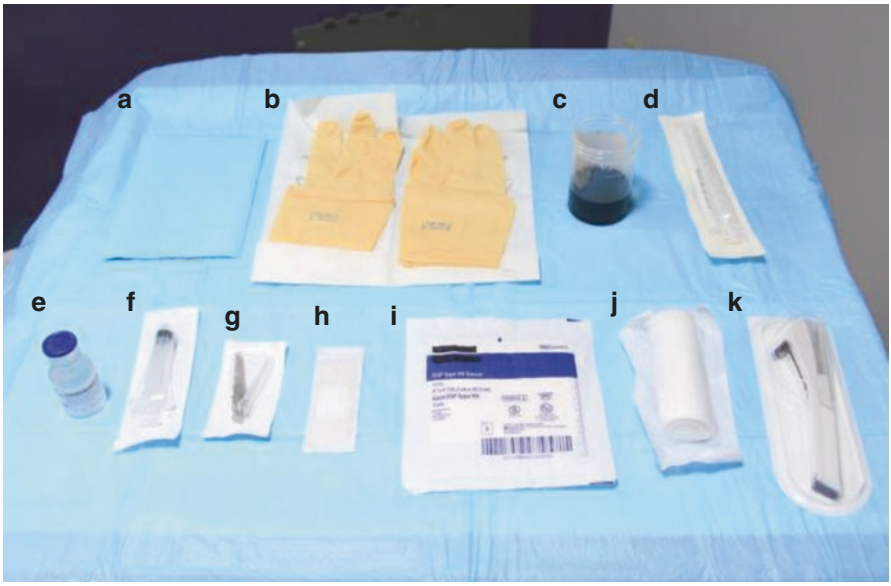

Fig. 16.1 Equipment list for insertion of Nexplanon®: (**a**) sterile drape; (**b**) sterile gloves; (**c**) antiseptic solution (i.e., povidone-iodine); (**d**) skin marking pen with paper ruler; (**e**) anesthetic (i.e., 1% lidocaine); (**f**) 3 cc syringe; (**g**) 25-gauge 1.5″ needle; (**h**) sterile bandage; (**i**) 4 × 4 cm cotton gauze; (**j**) 4″ cotton bandage roll for arm; (**k**) Nexplanon® in applicator

Insertion Procedure

1. Schedule patient at the appropriate time for insertion
2. Obtain consent and perform urine pregnancy test.
3. Place patient in supine position on the exam table with her nondominant arm rotated externally so that her elbow is flexed and her wrist is parallel to her ear, alongside her head.
4. Identify the insertion site at the inner side of the upper, nondominant arm approximately 8–10 cm proximal to the medial epicondyle of the humerus and at least 3–5 cm posterior to the sulcus between the bicep and the tricep muscles. If it is not possible to insert at this location, the implant should be inserted as far posterior to the sulcus as possible. There have been a few documented cases in which the implant was inserted too deeply and into the neurovascular bundle within the sulcus/groove described above (Fig. 16.2a).
5. Use a sterile marker to make a dot where the implant will be inserted and then another about 5 cm proximal to the first, which serves as a direction guide (Fig. 16.2b)
6. Use antiseptic solution to clean the insertion site and then anesthetize the area, preferably with 1% lidocaine along the insertion track prior to the insertion (1–2 mL should be sufficient) (Fig. 16.3)

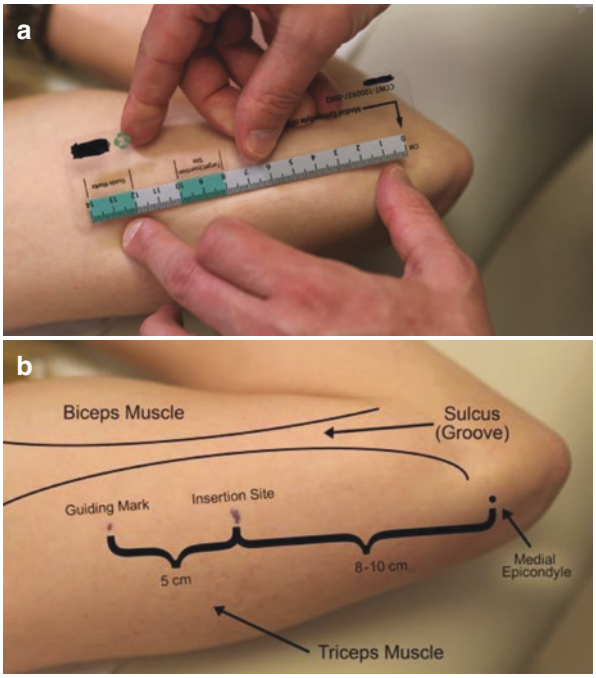

Fig. 16.2 (**a**, **b**) Identify insertion site, which is at the inner side of the nondominant upper arm about 8–10 cm (3–4 inches) proximal to the medial epicondyle of the humerus and 3–5 cm posterior to the sulcus (groove) between the biceps and triceps muscles and the large blood vessels and nerves that lie there in the neurovascular bundle deeper in the subcutaneous tissue. When following these directions, it is expected that the implant will be inserted subdermally just under the skin over the triceps muscle. Use a sterile marker to make a dot where the implant will be inserted and then another about 5 cm proximal to the first, which serves as a direction guide

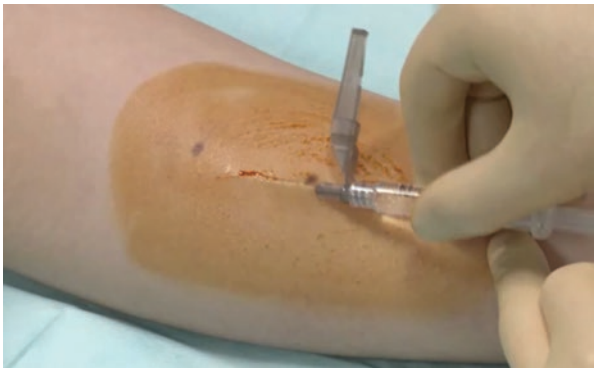

Fig. 16.3 Clean the insertion site with an antiseptic solution, and inject about 2 mL of 1% lidocaine or similar anesthetic (epinephrine is not necessary) along the planned insertion tunnel

7. Remove the applicator from its sterile packaging without removing the shield. It is helpful to grip the applicator with your thumb and forefinger of your dominant hand on the textured surface found on either side, adjacent to the insertion slider. When ready, remove needle shield to expose needle containing the implant. You should be able to see the white implant (Fig. 16.4). **Do not move the purple slider until the needle is in the correct position under the skin. It is best to sit during the rest of the procedure to visualize insertion fully and to ensure proper superficial insertion**.
8. Applying counter-traction to the skin around the site, insert only the tip of the needle with the beveled side up at a slight (<30°) angle. (Fig. 16.5a)
9. Next, lower the applicator until it is horizontal and parallel to the skin (Fig. 16.5b)
10. "Tent" the skin by lifting it with the tip of the needle, while still maintaining the needle in the subdermal connective tissue. In this position, gently and fully insert the entire needle, keeping it parallel to the skin surface in the superficial layer between the dermis and subdermal fat tissue. (Fig. 16.6) Be sure that the entire length of the needle is buried in the subcutaneous layer before continuing. If the needle punctures through the other side of the skin during insertion, gently pull back and redirect in desired direction.
11. While keeping the applicator in the correct position, pull back on the purple insertion slider until it stops at the end of its track. There will be two audible clicks (one when the applicator is engaged and the other when it the needle is fully retracted). When this procedure is performed as described, the rod will be left in the correct position. (Fig. 16.7a, b)
12. Remove the applicator. Palpate the patient's arm immediately after insertion to verify the presence of both ends of the rod (Fig. 16.8).
13. Cover the site with a small adhesive bandage (Fig. 16.9).
14. Then have the patient palpate the rod as well (Fig. 16.10).
15. Once the presence of the rod has been confirmed, apply a pressure bandage with sterile gauze to reduce the risk of bruising (Fig. 16.11).

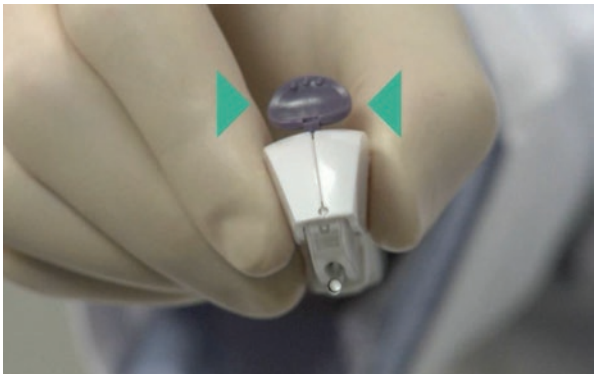

Fig. 16.4 Remove the sterile preloaded disposable Nexplanon® applicator carrying the implant from the blister package. Hold the applicator just above the needle at the textured surface area and remove the transparent protection cap by sliding horizontally away from the needle. Confirm presence of the white implant inside the needle

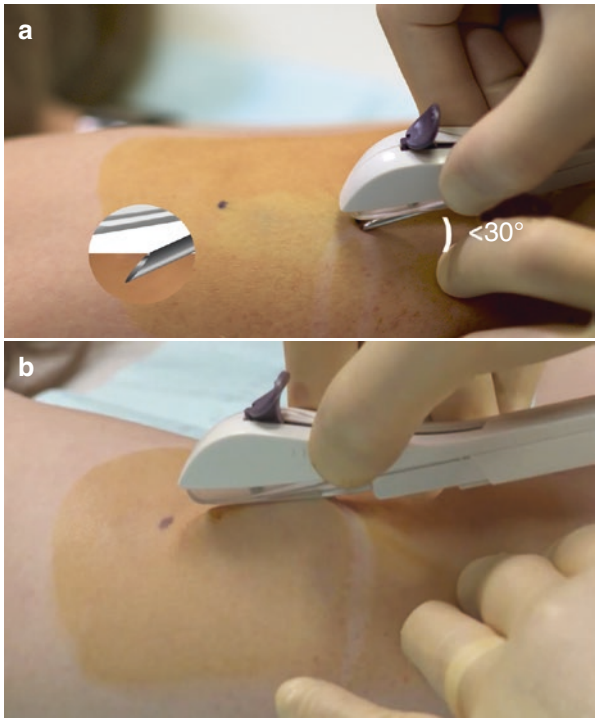

Fig. 16.5 (**a**) Stretch skin around the insertion site with fingers. Puncture the skin with the tip of the needle slightly angled less than 30°. (**b**) Lower the applicator to the horizontal position

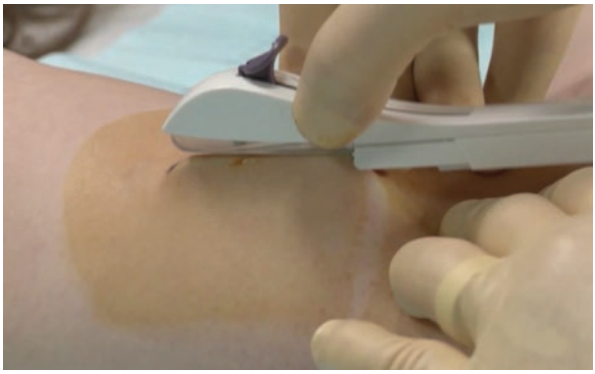

Fig. 16.6 While lifting (tenting) the skin with the tip of the needle, slide the needle to its full length. During the entire insertion procedure, you should be able to see the insertion site and the movement of the needle. You may feel slight resistance but **do not exert excessive force. If the needle is not inserted to its full length, the implant will not be inserted properly**

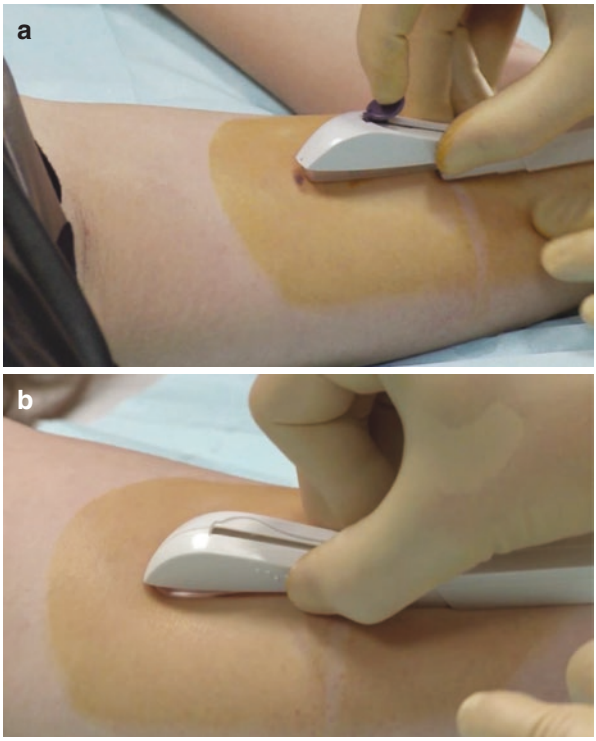

Fig. 16.7 (**a**, **b**) While keeping the applicator in the same position and the needle inserted to its full length, unlock the purple slider by pushing it slightly down. Move the slider fully back until it stops, leaving the implant now its final subdermal position and locking the needle inside the body of the applicator. **If the applicator is not kept in the same position during the procedure or if the slider is not completely moved back, the needle will not be fully retracted and the implant will not be inserted properly**

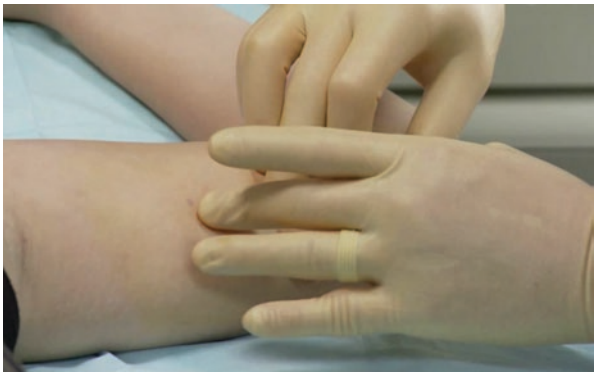

Fig. 16.8 Remove the applicator. Immediately after insertion, confirm the presence of the 4-cm implant by palpation

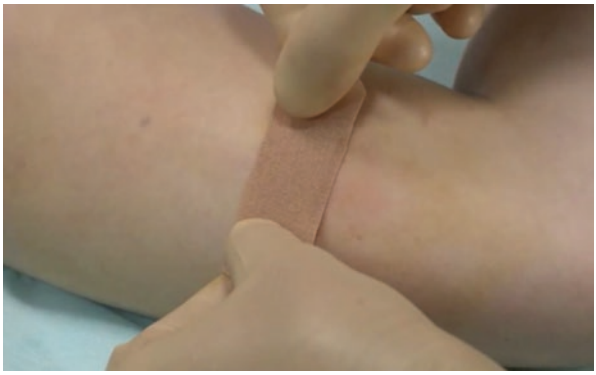

Fig. 16.9 Apply a small adhesive bandage over the insertion site

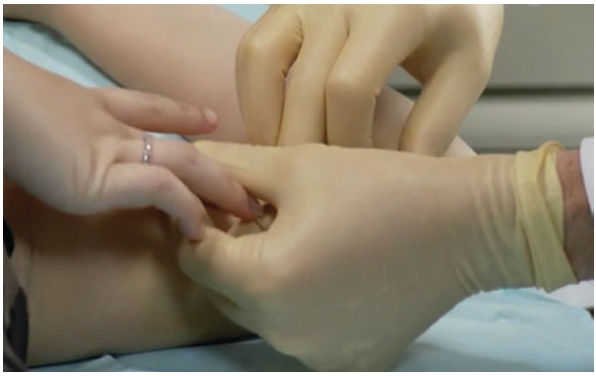

Fig. 16.10 Then have the patient palpate the rod as well

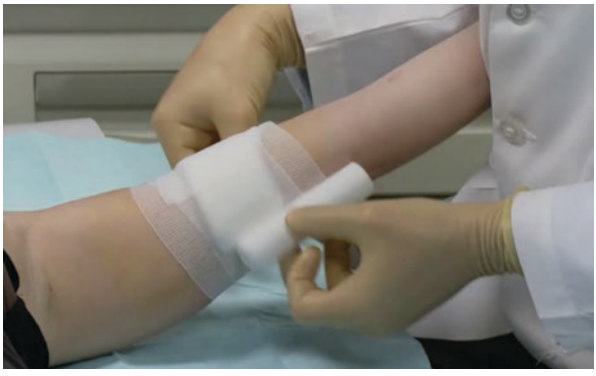

Fig. 16.11 Apply a pressure bandage with sterile gauze to minimize bruising

16. Instruct the patient to keep the top bandage on for 24 hours and the small bandage on for 3–5 days. Use acetaminophen or NSAIDs if analgesics are needed.
17. Provide the patient with the completed User Card and affix the completed Patient Chart Label to the patient's records.
18. Dispose of the applicator in accordance with CDC guidelines for hazardous waste.

Procedure Note

(Provider to fill in blanks/circle applicable choice and customize as needed.)
Insertion
Age: _____ G: _____ P: _____ LMP: _____; Urine Pregnancy: +/−
BP_____ Pulse _____ Weight _____
Current Contraceptive Method: _____
Date of Last Delivery/Termination: _____; Breastfeeding: Y/N

Informed Consent for Nexplanon® insertion (consent form provided with each device) has been signed and all questions answered. Patient has no contraindications to this method. She desires long-term protection against pregnancy. Patient has no pregnancy or risk of pregnancy at the time of insertion. Patient counseled about potential benefits, risks, side effects, and complications. Patient has no allergy to lidocaine, betadine, or tape.
Plans for backup contraception if needed:_____
Nexplanon® Lot #: _____ Expiration date: _____

The ventromedial surface of _____ arm was cleansed with antiseptic solution and a sterile field created. Lidocaine 1% _____ mL with/without epinephrine was injected intradermally into the planned insertion site, 8–10 cm proximal to the medial epicondyle of the humerus and 3–5 cm posterior to the sulcus between the bicep and tricep muscles. The implant was inserted according to the Nexplanon® system protocol. Both provider and patient were able to palpate the implant at the end of the procedure. Steri-Strips™ (3 M, St. Paul, MN) and compression dressing applied to insertion site.
Complications:None/_____
Postinsertion
Patient aware of the need for backup method for 1 week if not inserted cycle day less than day 5. Patient Labeling/Education booklet (provided with each device) given to client.
Follow-up appointment: _____
Patient advised to call ASAP if any symptoms/signs of infection.
Patient aware Nexplanon® must be removed on or before (mm/yyyy):_____
Signature/Title: _____Date:_____

Case Study Outcome

Given the patient's desire for long-term, reversible, nondaily or nonintrauterine contraception, and the fact that she is a 35-year-old 1 ppd smoker, she was recommended Nexplanon® or Depo-Provera®. The Nexplanon® was inserted without difficulty. The patient returned the following year after Nexplanon® insertion for a recheck visit. She reports some occasional spotting but no other complaints. She is extremely satisfied with the method and has not smoked in over 3 months.

Removal

Removal Equipment (Fig. 16.12)

The following equipment is needed for implant removal:

- Sterile gloves
- Sterile surgical drape
- Antiseptic solution, such as iodine-containing swabs
- Local anesthetic (preferably 1% lidocaine), epinephrine is not needed

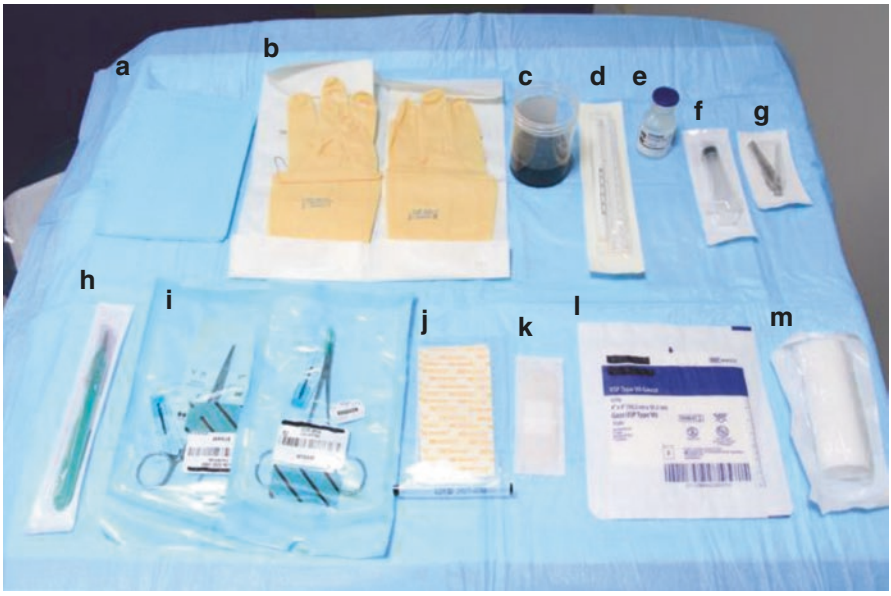

Fig. 16.12 Equipment list for removal of Nexplanon®: (**a**) sterile drape; (**b**) sterile gloves; (**c**) antiseptic solution (i.e., povidone-iodine); (**d**) skin marking pen with paper ruler; (**e**) anesthetic (i.e., 1% lidocaine); (**f**) 3 cc syringe; (**g**) 25-gauge 1.5″ needle; (**h**) #11 sterile scalpel; (**i**) straight and curved mosquito clamps; (**j**) skin closure (i.e., Steri-Strips™); (**k**) sterile bandage; (**l**) 4 × 4 cm cotton gauze; (**m**) 4″ cotton bandage roll for arm

- Needles (preferably an 18-gauge to draw up lidocaine; a 1.5-in. 25-gauge to inject)
- Syringe (preferably 3 cc)
- #11 sterile scalpel
- Mosquito clamps (straight and curved)
- Sterile gauze (4 × 4 cm)
- Skin closure (i.e., Steri-Strips™; 3M, St. Paul, MN)
- 4" Pressure bandage (i.e., cotton roll-Kerlix, Ace wrap, compression bandage-Coflex)
- A sterile marker (optional)

Removal Procedure

1. Check the patient's User Card or the Patient Chart Label to confirm which arm contains the implant and then locate the rod by palpation.
2. Clean the site where the incision will be made and apply antiseptic solution.
3. Locate the implant by palpation and mark the distal end (end closest to the elbow) with a sterile marker. The incision for implant removal is performed at the same site/end as the insertion. (Fig. 16.13a, b)
4. Anesthetize the arm with no more than 0.5–1 mL of 1% lidocaine at the marked site where the incision will be made. Be sure to inject the local anesthesia under the implant to keep it close to the skin surface.

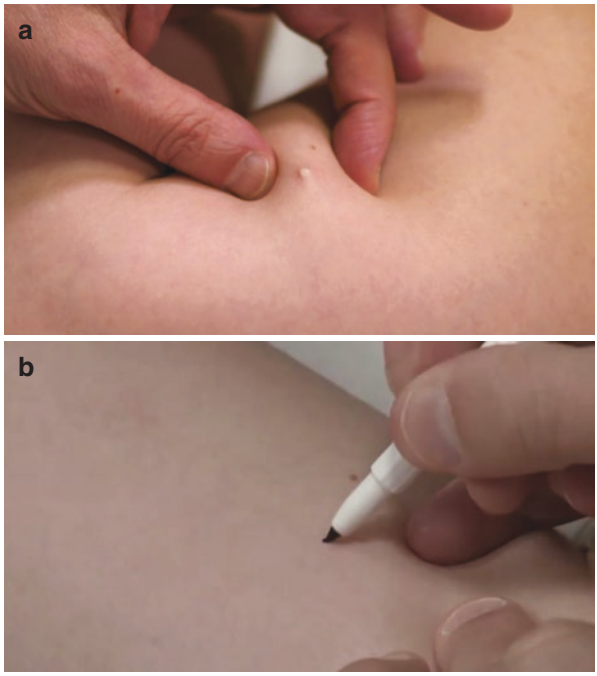

Fig. 16.13 (**a**, **b**) Locate the implant by palpation and mark the distal end (end closest to the elbow)

5. Push down the proximal end of the implant to stabilize it; a bulge may appear, indicating the distal end of implant. If the distal end does not easily pop up, removal of the implant may be more challenging and should only be performed by a provider experienced with difficult and deep removals. In this instance, refer to a provider experienced with difficult removals or call 1-877-888-4231 for more information about Centers of Experience. At the end of the implant closest to the elbow, make a 2–3 mm longitudinal incision with a #11 sterile scalpel blade, being careful to not bisect the tip of the implant. (Fig. 16.14a, b)
6. Gently push the implant toward the incision until you can see the tip. (Fig. 16.15) Use a straight or curved mosquito clamp to grasp the distal tip, and pull the implant out gently. If the tip is still not visible, but is able to be grasped, it may be necessary to dissect the fibrous tissue around it utilizing sterile gauze, the #11

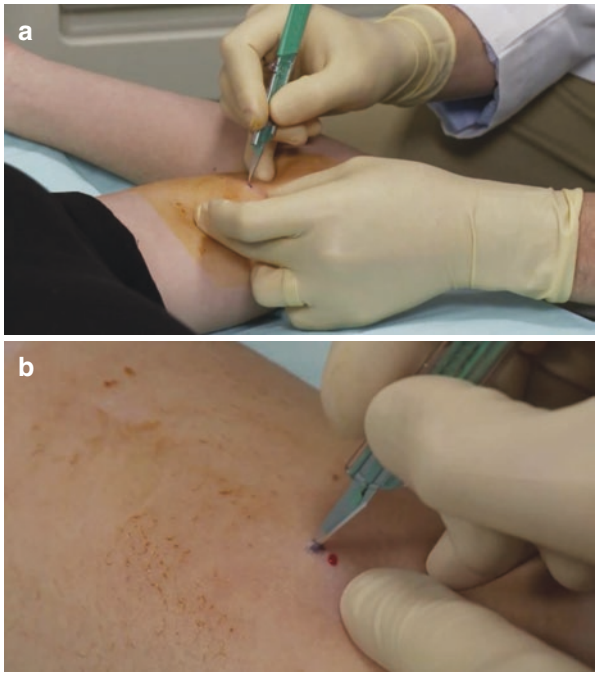

Fig. 16.14 (**a**, **b**) Push down the proximal end of the implant to stabilize it. Starting from the distal tip of the implant, make a longitudinal incision of 2 mm toward the elbow

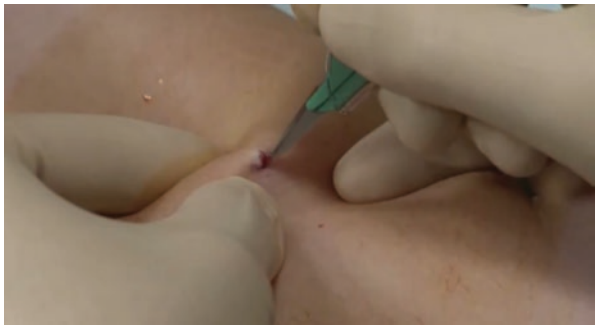

Fig. 16.15 Gently push the implant toward the incision until the tip is visible. If the implant is encapsulated, dissect the fibrous tissue sheath surrounding it

blade tip, or a curved mosquito clamp (Fig. 16.16a). If the tip does not become visible at the incision site, insert forceps (preferably mosquito clamps with curved ends up) superficially into the incision. Gently grasp the distal end of the implant and flip your forceps to your other hand. (Fig. 16.16b)With a second pair of forceps, carefully remove the surrounding tissue and grasp the implant. The implant should now be removed gently. Again, if there is difficulty with removal, stop the removal and refer to a provider experienced with difficult removals or call 1-877-888-4231.

7. Measure the rod to be sure that all of it (4 cm) has been removed. (Fig. 16.17)
8. Approximate the incision edges with closure strips (Fig. 16.18)

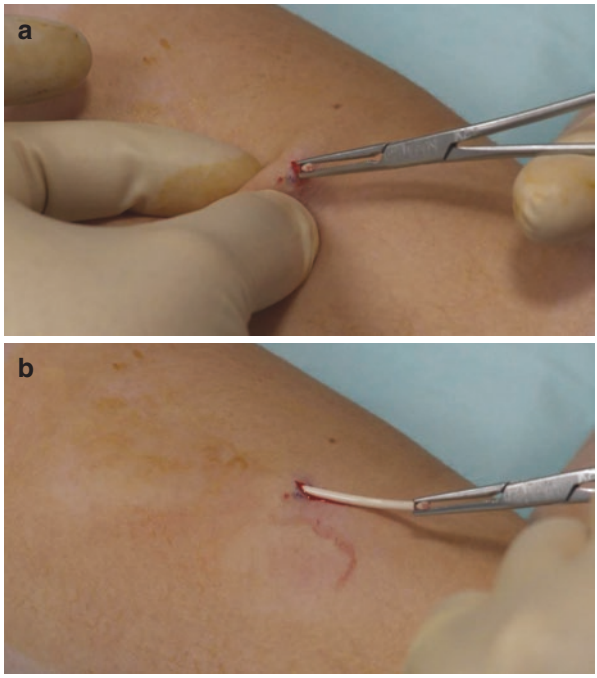

Fig. 16.16 (**a**, **b**) Grasp the implant with a curved or straight mosquito clamp, and gently remove it

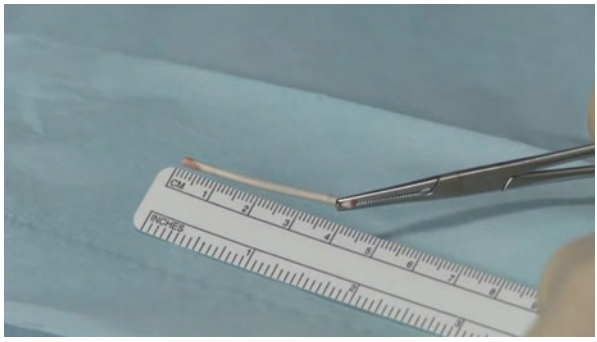

Fig. 16.17 Confirm that the entire 4 cm implant has been removed by measuring its length

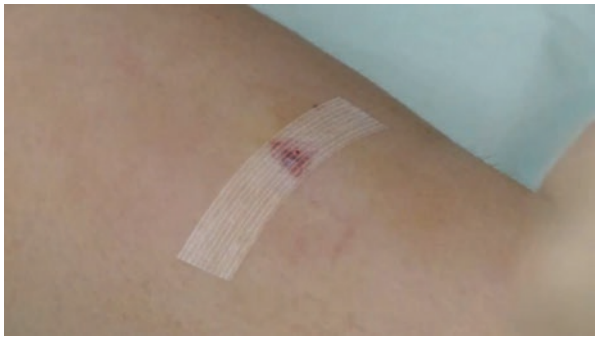

Fig. 16.18 Close the incision with wound closure strips

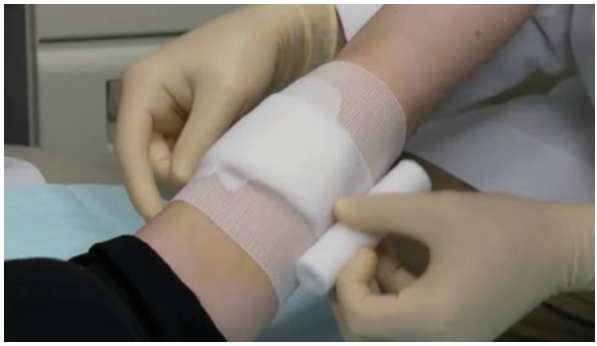

Fig. 16.19 Apply a pressure bandage with sterile gauze to minimize bruising

9. Apply a pressure bandage with sterile gauze to reduce the risk of bruising. (Fig. 16.19)
10. Instruct the patient to keep the top bandage on for 24 hours, and the Steri-Strips™ on for 3–5 days or until they fall off on their own. Use acetaminophen or NSAIDs if analgesics are needed.

Complications and Risks

Implantation Site

- Failure to insert the implant: Undetected failure to insert rod, 1% occurrence, may lead to unintended pregnancy.
- Pain
- Redness
- Paresthesias
- Bleeding
- Hematoma
- Scarring
- Infection

Removal

- Difficult removal: Deep insertion may lead to difficult or impossible removals, which require a surgical procedure in the operating room. Deep insertion may cause nerve or vascular damage or migration of the rod.
- Breakage of implant during removal: May necessitate surgical removal.

Causes for Discontinuation

- Bleeding (most common: accounts for 11% discontinuation rate)
- Emotional lability (<3%)
- Depression (<3%)
- Weight gain (<3%)
- Headache (<3%)
- Acne (<3%)

Localization

As mentioned above, Nexplanon® differs from its predecessor in that barium sulfate was added to make it radio-opaque. The implant should be palpated immediately after insertion by both the clinician and the patient. This is to both ensure that the Nexplanon® was inserted correctly and to teach the patient how to quickly localize it quickly. If the 4-cm rod is not palpable after insertion, during use or before removal, its presence should be verified using two-dimensional x-ray. MRI, CT, and ultrasound can also be used to locate the implant. The axilla should be investigated first if the implant is unable to be palpated at any time during use or before removal. Standard removal or other advanced techniques may be necessary to remove Nexplanon®. Ultrasound can also be used to conduct difficult removals. If no rod is visible on imaging, contact the manufacturer at 1-877-467-5266 for specific instructions on obtaining an etonogestrel level (not available in the United States).1

Tricks and Helpful Hints

Insertion

- Nexplanon® insertion can be performed without sterile gloves utilizing appropriate no-touch techniques.
- At the time of insertion, it is important to confirm that the patient is not pregnant and does not have allergies to etonogestrel or the antiseptic or anesthetic.

- Do not move the purple slider until the needle is in correct position under the skin. It is best to sit during the rest of the procedure to visualize insertion fully and to ensure proper superficial insertion.
- If the needle punctures through the other side of the skin during insertion, gently pull back and redirect in the desired direction.
- **If the applicator is not kept in the same position during the procedure or if the slider is not completely moved back, the needle will not be fully retracted and the implant will not be inserted properly**
- The implant should be palpated immediately after insertion by both the clinician and the patient. If the 4-cm rod is not palpable after insertion, during use or before removal, its presence should be verified using two-dimensional X-ray. MRI, CT, and ultrasound can also be used to locate the implant.

Removal

- Nexplanon® removals should not be performed without sterile gloves.
- Injecting more lidocaine may interfere with localizing the distal rod tip
- If the patient has chosen to continue Nexplanon®, the preferred method is to insert a new rod in the same location, using the same incision. However, you will need to anesthetize the insertion track with an additional 1–2 mL of lidocaine

Procedure Note

(Provider to fill in blanks/circle applicable choice and customize as needed.)
Removal
Age:_____ BP_____ Pulse _____ Weight _____
Consent for Nexplanon® removal has been signed and all questions answered.
Reason for contraceptive implant removal: _____
Plans for contraception after removal: _____
Nexplanon® Lot #: _____ Expiration date: _____

The ventromedial surface of _____ arm was cleansed with antiseptic solution and a sterile field created. Lidocaine 1% _____ mL with/without epinephrine was injected intradermally into the planned removal site. The implant was removed completely according to the Nexplanon® system protocol. Patient was shown removed implant. Steri-Strips™ and compression dressing applied to insertion site.
Removal Time: _____
Complications:None/_____
Post-removal

*Contraceptive method prescribed:*_____
Follow-up appointment: _____
Patient advised to call ASAP if any symptoms/signs of infection.
*Signature/Title:*_____*Date:*_____

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
11981	Insertion of non-biodegradable drug delivery implant
11982	Removal of non-biodegradable drug delivery implant
11983	Removal with reinsertion of non-biodegradable drug delivery implant
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 10th Revision, Clinical Modification, Centers for Disease Control and Prevention)	
Z30.01	Encounter for initial prescription of implantable subdermal contraceptive
Z30.46	Encounter for surveillance of implantable subdermal contraceptive

Postprocedure Patient Instructions

Patient labeling/education booklet is provided with each device.

Insertion

- Inform the patient of the need for backup method for 1 week if not inserted cycle day less than day 5 of menses.
- Advise the patient to call ASAP if any symptoms/signs of infection.
- Ensure that the patient is aware that the Nexplanon® must be removed on or before 3 years from the insertion date.
- Counsel patient to expect changes in their bleeding patterns that may be unpredictable and include changes in bleeding frequency, duration, and/or amenorrhea. Patients with persistent bleeding should be seen to rule out pregnancy or pathologic conditions.

Removal

- Advise the patient to call if any symptoms/signs of infection.
- Discuss other contraception needs or preconception counseling.

Case Study Outcome

Given the patient's desire for long-term, reversible, nondaily, or nonintrauterine contraception, and the fact that she is a 35-year-old 1 ppd. smoker, she was recommended Nexplanon® or Depo-Provera®. The Nexplanon® was inserted without difficulty. The patient returned the following year after Nexplanon® insertion for a recheck visit. She reports some occasional spotting but no other complaints. She is extremely satisfied with the method and has not smoked in over 3 months.

Patient Handout

The contraceptive implant (Nexplanon®) is a very effective, convenient, and safe form of contraception. A small operation under local anesthetic is needed to insert the implant under the skin. Each implant lasts 3 years.

What Is Nexplanon®?

Nexplanon® is a contraceptive implant, a small flexible rod that is inserted under the skin. It contains a progestin hormone. Nexplanon® lasts for up to 3 years. It is 99% effective.

How Does the Nexplanon® Work?

The progestin hormone in the implant is released slowly into the bloodstream at a steady rate. The progestin works mainly by stopping ovulation (the release of the egg from the ovary). It also thickens the mucus made by the cervix which forms a "mucus plug" in the cervix. This stops sperm getting through to the uterus (womb) to fertilize an egg. It also makes the lining of the uterus thinner. This means that if an egg was to fertilize, it is not likely to be able to attach to the uterus.

How Effective Is Nexplanon®?

Nexplanon® is more than 99% effective. This means that less than 1 woman in 100 who uses this method of contraception will become pregnant each year. (Compare this to when no contraception is used. More than 80 in 100 sexually active women who do not use contraception become pregnant within 1 year.)

What Are the Potential Advantages of Using Nexplanon®?

- You do not have to remember to take a pill every day.
- You only have to think about contraception every 3 years.
- It does not interfere with sex.
- It can be used when breastfeeding.
- Period pain is usually less than usual.
- It stops ovulation and thickens cervical mucus.
- It can be used by some women who cannot take pills that contain estrogen.
- It may help protect against Pelvic Inflammatory Disease (PID). (The mucus plug in the cervix may help to prevent bacteria from traveling into the uterus.)

What Are the Potential Disadvantages of Using Nexplanon®?

The release of progestin will usually cause changes to the pattern of periods. During the first year, it is common to have irregular bleeding. Sometimes, periods are heavier and longer than before. They usually settle back into a regular pattern after the first year but may remain irregular. In some women, the periods become infrequent and light or even stop altogether.

Some women worry about irregular or changed periods, but it does not mean anything is wrong and is of no consequence. However, unpredictable or irregular periods can be a nuisance.

Who Cannot Use Nexplanon®?

Your healthcare provider will discuss any current and past illnesses. Some illnesses may mean that you cannot use progestin-based contraceptives such as Nexplanon®. However, the number of women this affects is small.

Are There Any Potential Side Effects with Nexplanon®?

Some women report side effects such as mood changes, breast discomfort, fluid retention, weight gain, headaches, and increase in acne. These are uncommon, and, if they do occur, they tend to develop in the first few months only, and often resolve after 3–6 months if the implant remains. The area around the implant may be bruised and sore for a few days. You can apply an ice pack to the area and/or take some ibuprofen or acetaminophen to help the discomfort.

How Is the Implant Put Under the Skin?

- It is put in the inner side of the upper arm.
- It is usually first inserted within 5 days of a period starting. (This ensures that you are not pregnant.) It is effective from then on.
- An injection of local anesthetic is used to numb the skin. A small cut is made and the implant is placed under the skin. The wound is dressed and will soon heal just like any other small cut.
- The area around the implant may be bruised and sore for a few days, but this soon goes away.

When Is the Implant Taken Out?

The implant is usually removed at the end of 3 years but may be removed sooner by patient request.

A replacement rod can be reinserted at the time of removal if so desired.

Once removed, the rod loses its effect immediately and another form of contraception should be used if pregnancy is not desired.

Further Information

Your healthcare provider and pharmacist are good sources of information if you have any questions. You may also call: (1-877-467-5266) or visit www.nexplanon.com

Questions for Learners

- Why would some women choose Nexplanon® over other long-acting contraceptives?
- What are some of the logistic issues regarding training and continued skills in subdermal implants?

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Web Sites

Information about insertion and removal of Nexplanon® is available from the manufacturer by contacting Merck at 1-877-467-5266 or www.nexplanon.com.

Nexplanon Questions and Answers: When should I call my healthcare provider? http://www.nexplanon.com/questions.

Chapter 17
Pessary

Catherine I. Keating

Introduction

A pessary is a device that allows for nonsurgical treatment of pelvic organ prolapse (POP) and/or stress urinary incontinence (SUI). One of the oldest known medical devices, the pessary dates back to Hippocrates' pessary design: a pomegranate soaked in vinegar. Other historical pessaries include other fruits, items of bronze, cotton wool, linen, wax-coated cork and wood, and rubber [1]. Today, the pessary is generally made of medical-grade silicone in many different styles. Recent innovations have even resulted in 3-D printing of a custom-designed pessary, although this is not commonplace [2]. There are two main types of pessaries: space filling and support. Examples of space-filling pessaries are Cube, Inflatoball, and Donut. Support pessaries include Ring and Shaatz.

Indications for pessary use include uterine or vaginal prolapse, cystocele, rectocele, enterocele, and stress urinary incontinence. Less common indications include incompetent cervix and the correction of a retroverted or incarcerated uterus. For the surgeon, the pessary can be used for preoperative selection of patients with SUI, as correction of incontinence with the pessary can predict successful operative correction of incontinence. A pessary can also allow for healing of prolapsed pelvic mucosa prior to surgery. The pessary was originally indicated for pregnant women, those wishing to have more children, or those who had contraindications to surgery. Today, however, a pessary is an excellent option for anyone who prefers nonsurgical treatment of their condition [3]. A woman's lifetime risk of undergoing surgery for urinary incontinence and/or prolapse by age 80 is 11.1% [4]. Despite the common use of surgery, a prospective study by Abdool et al. showed similar outcomes at 1 year in urinary, bowel, sexual function and quality of life parameters between

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women treated with surgical repair versus those treated with pessary placement for pelvic organ prolapse [5].

One-third of premenopausal women and up to 45% of postmenopausal women experience POP and/or SUI [6]. While these symptoms are more common in parous women, nulliparity does not provide absolute protection against prolapse or SUI [7]. Different pessary styles are appropriate for different degrees, or stages, of prolapse. The Pelvic Organ Prolapse Quantification (POP-Q) defines Stage 1 as descent of the uterine cervix to above 2 cm from the hymen, Stage 2 as descent to within 1 cm of the hymen, either externally or internally, and Stage 3 as descent beyond 2 cm below the hymen (Fig. 17.1) [8]. Reported successful use of pessaries ranges from 33.9% to 89% [9–12]. Although pessaries can successfully be used to treat most stages of prolapse, complete organ prolapse most often needs surgical repair. Studies have not shown an association between prolapse stage and outcome of a pessary trial [12, 13].

One study found that improvement in prolapse symptoms was limited to women with anterior vaginal wall prolapse [10]. Patient characteristics associated with continued successful pessary use for POP are age greater than 65 years and being considered a high surgical risk [14]. Unsuccessful pessary fittings and use are related to previous reconstructive surgery for prolapse or hysterectomy, obesity, increased parity, severe posterior vaginal wall prolapse, short vaginal length, and wide introitus [11, 12, 15, 16]. One study demonstrated that weight was not a negative or positive predictor of successful fitting and use [11]. Another study among women with pelvic floor dysfunction showed that pessary satisfaction was associated with improvements in sexual function and body image [17]. Women who use vaginal estrogen had higher incidence of continued pessary use and lower incidence of vaginal discharge than women who did not [18].

One complication of treating prolapse with a pessary is the unmasking of underlying urinary incontinence. One study showed that during treatment with a pessary for prolapse, 21% of patients developed de novo stress incontinence, 6% urge incontinence, and 4% developed difficulty with voiding. Despite these findings,

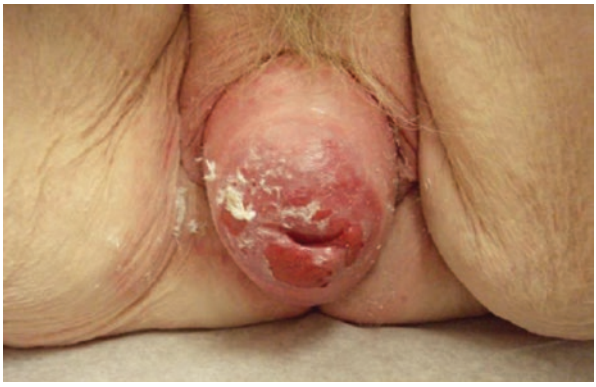


Fig. 17.1 Fourth-degree uterine prolapse

67% of treated patients reported improvement in prolapse or incontinence symptoms with pessary use [13]. If a woman with POP develops stress incontinence once fitted with a pessary, switching to an incontinence pessary may be helpful [19].

Pessary treatment for stress urinary incontinence occurs by compressing the urethra against the upper posterior portion of the symphysis pubis and elevating the bladder neck. This results in an increase in outflow resistance and corrects the angle between the bladder and the urethra [20]. Women who have undergone prior incontinence surgery have a higher failure rate of pessary use for their incontinence [9].

Pessary use should be individualized based on the patient's symptoms (Table 17.1) (Figs. 17.2, 17.3, 17.4, and 17.5). Women who are incontinent during daily activities can wear the pessary continually. For others who experience incontinence only

Table 17.1 Pessary style choices based on symptom

First- and second-degree uterine prolapse	Ring, Donut, Milex® Inflatoball, Milex® Regula
Mild prolapse with cystocele	Ring with support, Shaatz
Third-degree uterine prolapse	Cube, Donut, Milex® Inflatoball, Gellhorn
Third-degree uterine prolapse with cystocele	Gehrung
Prolapse s/p hysterectomy	Ring with support
Mild cystocele	Ring with support, Dish with support, Hodge with support, Donut, Gehrung
Moderate cystocele	Gellhorn, Gehrung
Rectocele and enterocele	Gellhorn, Donut, Milex® Inflatoball, Cube, Gehrung
Stress incontinence	Incontinence Ring, Incontinence Dish
Incontinence during exercise	Ring, Ring with knob, Cube, Hodge, Inflatoball
Incontinence and cystocele	Hodge, Hodge with support

Data from Weber and Richter [7]; Viera and Larkins-Pettigrew [20]; http://milexproducts.com
Milex®, CooperSurgical, Trumbull, CT

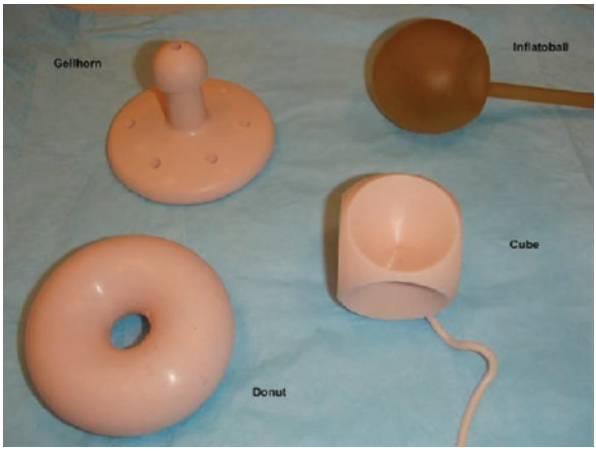


Fig. 17.2 Space-filling pessaries (pelvic organ prolapse)

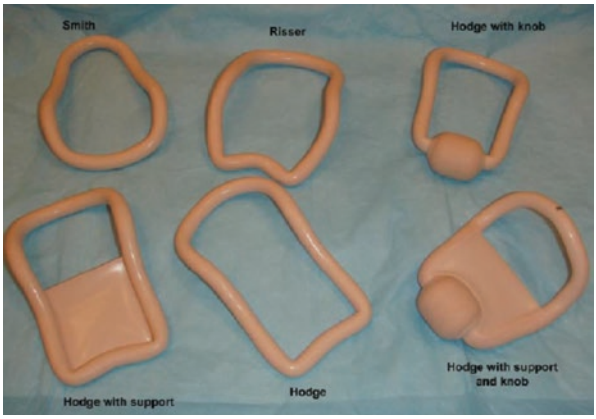


Fig. 17.3 Support pessaries (pelvic organ prolapse)

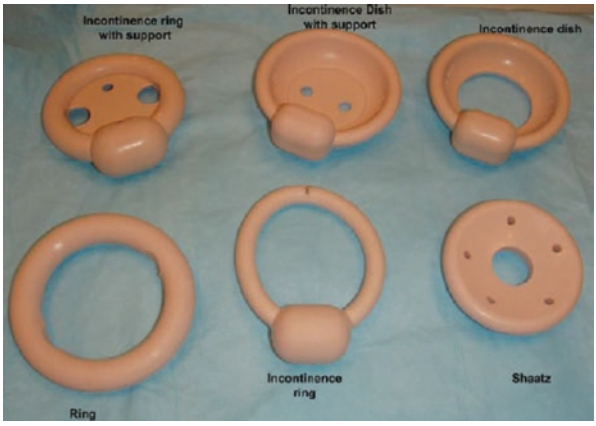


Fig. 17.4 Incontinence pessaries

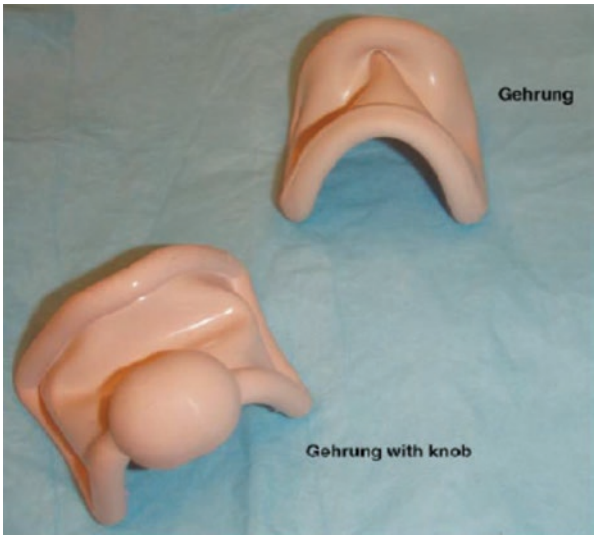


Fig. 17.5 Saddle pessaries

during vigorous activities, the pessary can be worn as needed. One small study showed 5 of 14 subjects achieved complete continence during vigorous exercise [21]. A recent review showed a randomized controlled study of the use of pessaries which compared effectiveness between Gellhorn and Ring pessaries. No significant differences in effectiveness (60%) were found between the two groups [22, 23]. For patients with pelvic organ prolapse, if the pessary fails to remain in place, a stiffer pessary such as a Shaatz or Gellhorn may be used. Cube pessaries may be better for severe prolapse but need close follow-up because of the higher risk of erosions [24]. It is important for women to follow up with their health care providers once fitted with any pessary. Major complications are more likely to occur in women who are lost to follow-up.

Case Study

Case A

A 36-year-old female with a past medical history significant for two vaginal deliveries following uncomplicated pregnancies presents to your office for a routine physical examination. After the last pregnancy, she noticed that she occasionally leaked urine when she laughed, coughed, or while she was running. She failed to mention her symptoms at a postpartum checkup because she thought they were normal, but a year later, she is still troubled with the problem and would like to know about treatment options. She performs Kegel exercises only intermittently. Today, pelvic exam is completely within normal limits.

Case B

A 72-year-old female with a history of a cystocele presents for evaluation. Previously, she has been able to tolerate her symptoms of stress incontinence; however, today, she is interested in available treatment options. On exam, patient has a grade I cystocele and slight atrophy of vaginal mucosa consistent with chronic estrogen deficiency.

Diagnosis (Algorithm 17.1)

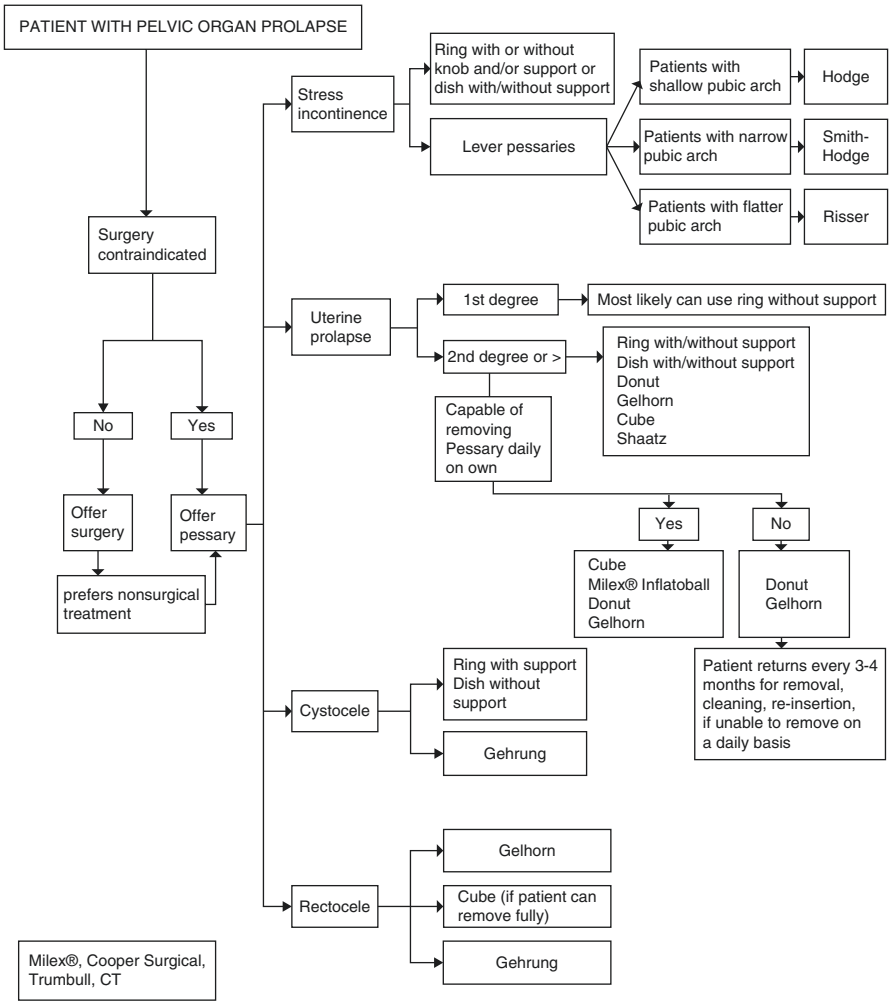
- Stress incontinence
- Pelvic organ prolapse

Differential Diagnosis (Algorithm 17.1)

Urge incontinence

Indications (Algorithm 17.1)

- Pelvic organ prolapse
- Vaginal vault prolapse



Algorithm 17.1 Decision tree for a patient with pelvic organ prolapse

- Cystocele
- Rectocele
- Enterocele
- Uterine prolapse
- Stress urinary incontinence
- Preoperative evaluation for stress incontinence
- Preoperative preparation for eroded prolapsed tissue

Contraindications

- Noncompliance
- Vaginal erosions
- Active vaginal or pelvic infections
- Silicon or latex allergy

Equipment (Figs. 17.6 and 17.7)

- Pessary fitting kit or actual pessaries for fitting (Table 17.1)
- Water-based lubricant

Fig. 17.6 Milex pessary fitting kit with incontinence dish with support, ring with support, Gellhorn, cube and donut pessaries and Milex Trimo-san Vaginal Jelly (CooperSurgical, Trumball, CT)

Fig. 17.7 Cube (**a**) pessary setup with gloves (**b**) and Aqua-Gel® Lubricating Gel (Parker Laboratories, Fairfield, NJ) (**c**)

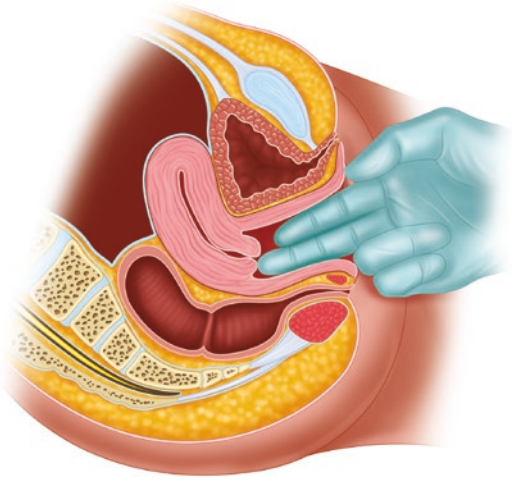


Fig. 17.8 Estimate the pessary size

Procedure

1. Patient preparation
   (a) For pelvic organ prolapse, have the patient empty her bladder.
   (b) For incontinence, fit the patient with full bladder.
2. Place the patient in the lithotomy position.
3. Replace any prolapsed tissue.
4. Perform a bimanual exam to estimate pessary size (Fig. 17.8).
5. Lubricate the tip of pessary and introitus with water-based lubricant.
6. Insert the pessary into the vagina in a downward fashion, avoiding the urethra.
7. Position the pessary properly (Figs. 17.9, 17.10, 17.11, 17.12, 17.13, 17.14, 17.15, and 17.16). The examiner's fingers should pass easily between the pessary and vaginal wall.

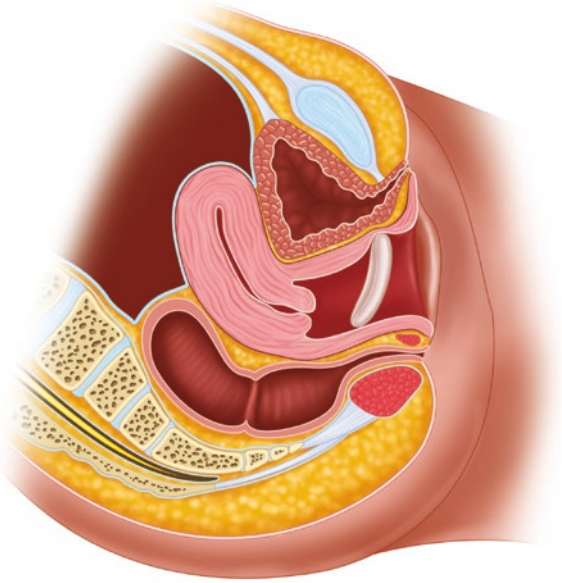


Fig. 17.9 Proper position of incontinence Ring pessary

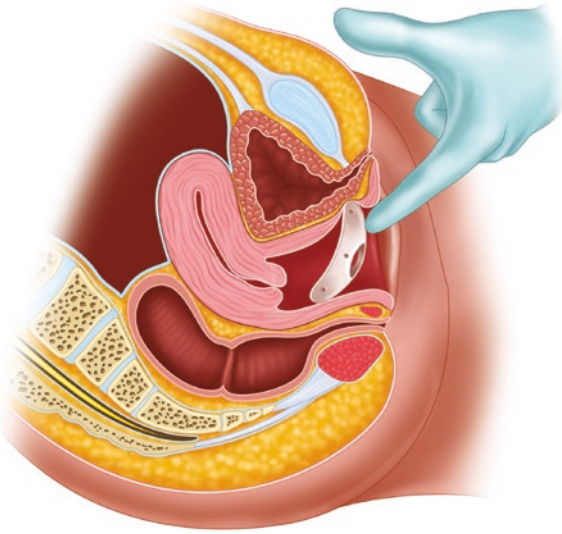


Fig. 17.10 Placement of a Shaatz pessary

(a) Have the patient stand, walk, and Valsalva.
(b) If painful or uncomfortable, try the next smallest size.
(c) If it falls out or starts to slip out, try the next largest size. The largest pessary that the patient can comfortably wear is generally the most effective.

8. The patient needs to void effectively before leaving the office to ensure there is no urethral obstruction.

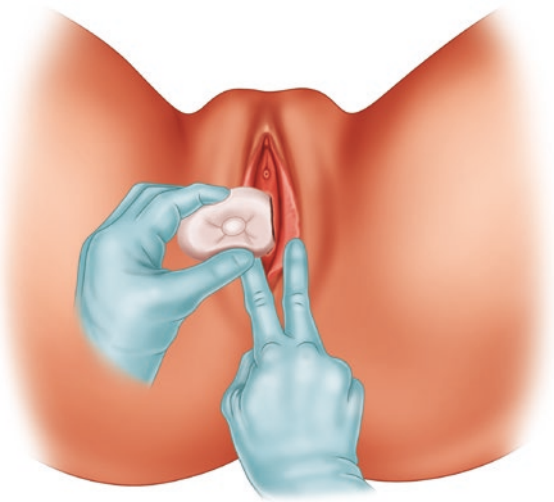


Fig. 17.11 Insertion of a Donut pessary

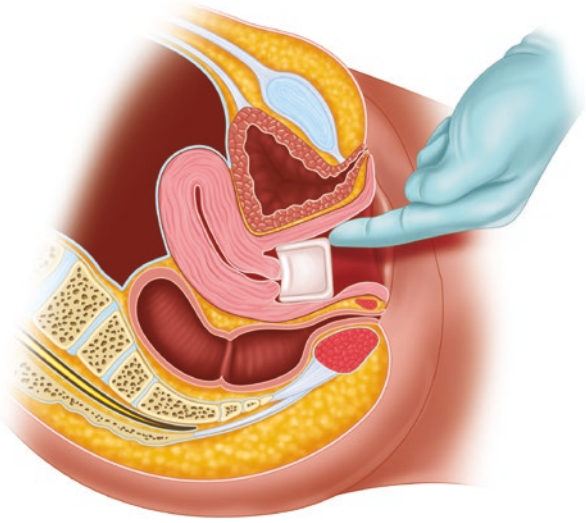


Fig. 17.12 Proper position of the Milex® Regula pessary (CooperSurgical, Trumbull, CT)

9. Schedule follow-up visit within 1 week.
   (a) Remove pessary and inspect vagina for irritation, erosion, or allergic reaction.
10. For those unable to remove their own pessary, schedule routine removal and cleaning visits from 1 to 6 months depending on doctor and patient preference.

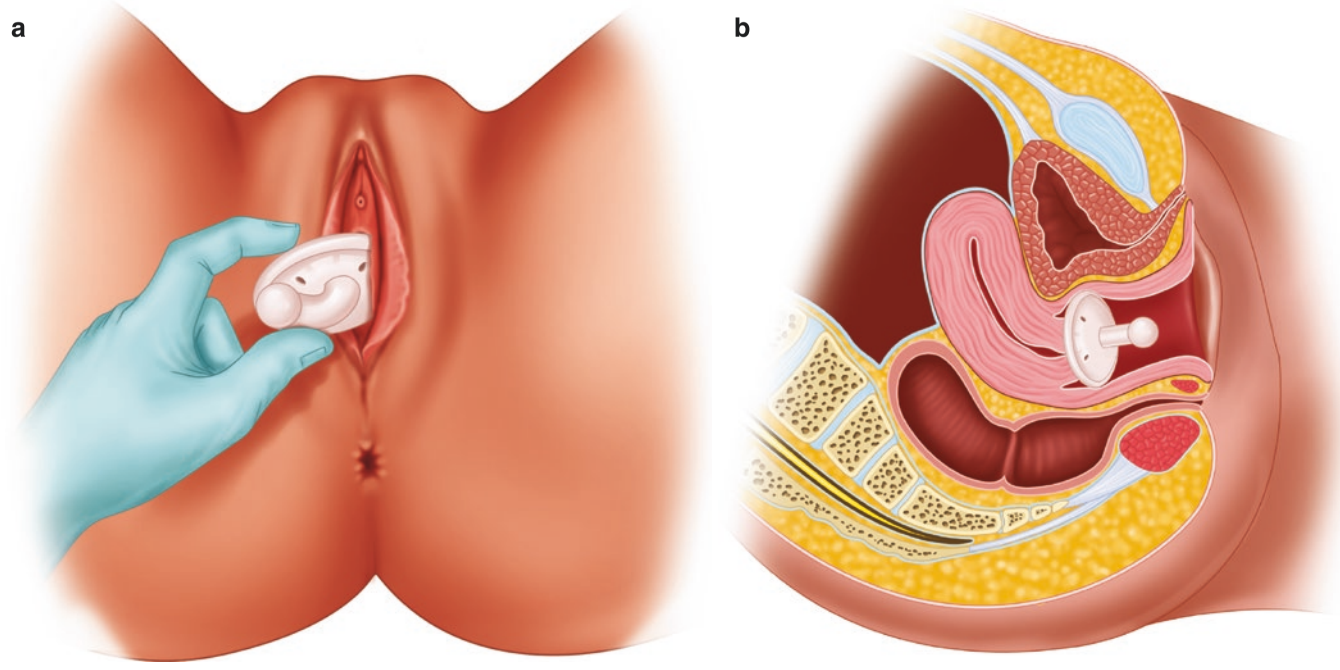


Fig. 17.13 (**a**) Gellhorn knob is folded on its side for easier insertion. (**b**) Proper position of inserted Gellhorn pessary

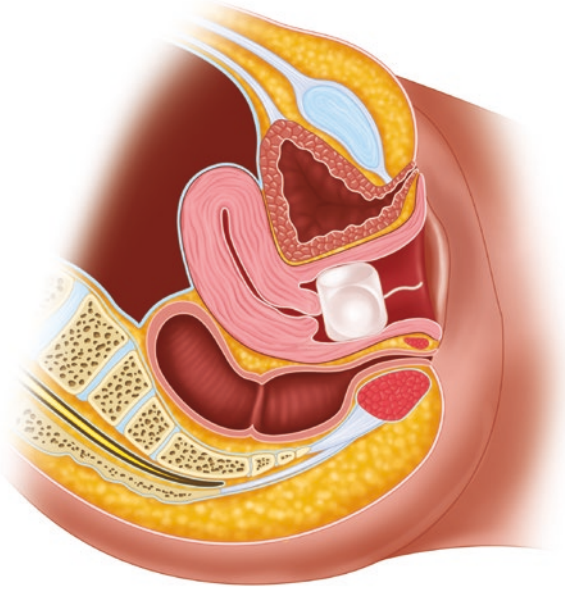


Fig. 17.14 Cube pessary in proper placement

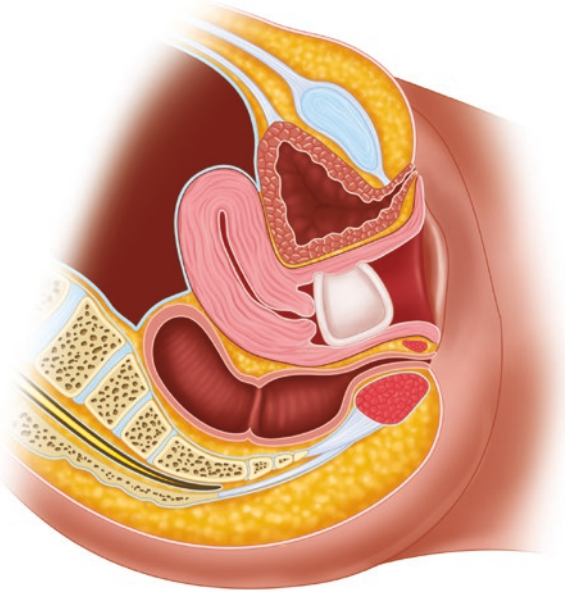


Fig. 17.15 Gehrung pessary placement

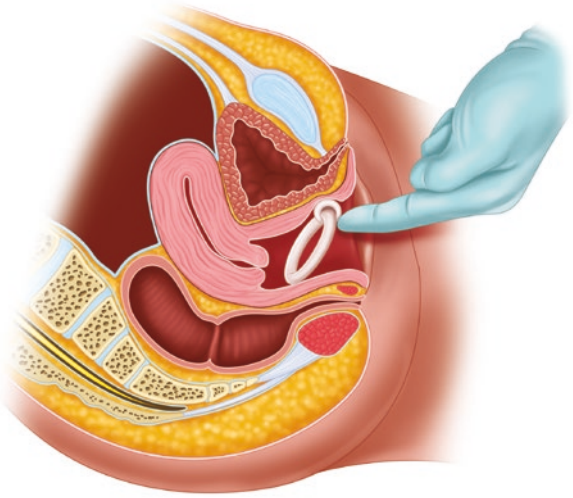


Fig. 17.16
Incontinence ring with knob in proper position

Complications and Risks

- Vaginal irritation/erosions/bleeding
- Vaginal discharge and odor
- Discomfort
- Infections:
  - Bacterial vaginosis
  - Actinomycosis
  - Urosepsis
- Rectovaginal fistula
- Incarceration
- Dislodgment
- Urinary tract or bowel obstruction
- Hydronephrosis
- Cervical/uterine herniation/entrapment
- Latex allergy

Tricks and Helpful Hints

- For patients with atrophic vaginal tissue, pretreat for 1–2 weeks with estrogen cream (1/2 applicator full at night prior to bedtime).
- Advise patients that usually many fittings are necessary to get the right size and shape pessary.

- If the patient is not going to remove the pessary daily, then use an acidic vaginal gel, such as Milex® Trimo-san (CooperSurgical, Trumbull, CT), three times a week (may be ordered with the pessary) to prevent odor and discharge.
- For patients who use a diaphragm, their diaphragm size does not correlate with their correct pessary size. (Patients may use a diaphragm to help with incontinence or prolapse.)
- If one size is too large and the next smaller size is too small, try a different style pessary.
- In some patients with long-term pessary use, it may be necessary to switch to a smaller pessary over time.
- The Milex® Regula (CooperSurgical, Trumbull, CT) can be tried when expulsion of the pessary is a problem.
- The Milex® Inflatoball (CooperSurgical, Trumbull, CT) is a good choice for someone who needs a space-filling pessary but has a very narrow introitus and is capable of removing the pessary on a daily basis.
- The Cube can be difficult to remove and needs to be removed daily.

Procedure Note

(Provider to customize as needed.)

Risks and benefits of pessary use were reviewed with the patient. Patient was placed in the lithotomy position. (Prolapsed tissue was inspected and replaced.) Bimanual exam was performed to estimate pessary size. Chosen pessary was lubricated and gently inserted into the vagina. Fit was ensured as pessary filled vagina and one finger passed easily around it. (If too loose, larger size was tried. If uncomfortable or too tight, smaller size was tried.) Patient was asked to stand, ambulate, and Valsalva with the pessary in place to ensure fit. Patient voided without difficulty with pessary in place. Follow-up appointment was given.

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
Pessary fitting	57160
Pessary, rubber	A4561
Pessar, nonrubber	A4562
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 10th Revision, Clinical Modification, Centers for Disease Control and Prevention)	
Incontinence:	
Stress urinary	N39.3
Urge and stress	N39.46

Incompetent cervix	N88.3
Prolapse:	
Cystocele	N81.10
Uterovaginal, incomplete	N81.2
Uterovaginal, complete	N81.3
Uterovaginal, unspecified	N81.4
Uterus prolapse	
First degree	N81.2
Second degree	N81.2
Third degree	N81.3
Unspecified	N81.4
Posterior vaginal wall prolapse	N81.6
Vaginal vault prolapse post hysterectomy	N99.3

Postprocedure Patient Instructions

Have the patient call if pessary becomes dislodged, falls out, or is uncomfortable or if the patient is having difficulty voiding or having a bowel movement with the pessary in place.

Follow up in 1–2 weeks for confirmation of fitting and vaginal exam to look for irritation, pressure sores, or allergic reaction.

Case Study Outcome

Case A

A size 3 Cube pessary was successfully inserted into the vagina and positioned. The patient tolerated the pessary well and was able to walk and Valsalva without it falling out. She voided while at the office and was able to demonstrate removing the pessary. She understands the importance of taking the pessary out on a daily basis. She returns in 1 week for follow-up.

Case B

The patient is asked to use estrogen cream nightly for the next week. Upon returning the following week, the vaginal mucosa appears less atrophied. Attempts are made to fit a dish with support, but these prove uncomfortable. Next, the Gehrung is fitted with the patient experiencing no loss of the pessary with walking or a Valsalva

maneuver. She also voids without difficulty. She is given a tube of Milex® Trimo-san and returns in 1 week for follow-up.

Postprocedure Patient Handout

(Provider to fill in blanks/circle applicable choice when given multiple choices and customize as needed.)

A pessary is a silicone or latex device placed inside your vagina. It can be used to help support your uterus (which can hang down from its original position), vagina (which can lose the firm support to its walls), bladder (which can push down into your vagina), or rectum (which can push up into your vagina). A pessary can also be used to help prevent the leakage of urine, which happens during coughing, sneezing, straining, or exercise. This is called stress incontinence.

Today you were fitted with a _____ pessary. Ideally, your pessary should be removed and cleaned every _____ day(s). It is important to follow your doctor's directions in caring for your pessary so it will last as long as possible. Remove and clean your pessary as instructed by your doctor today. You can use a mild soap and water to clean it. If you are not going to wear it, make sure to dry it completely and store it in a safe place. Your pessary can be worn even during your period, although it is very important to remove your pessary daily during your menses. Some women will leave their pessaries in for several days; however, if you do this, you may experience more discharge and odor.

Your doctor might have told you today that you do not need to remove your pessary yourself. If this is the case, your doctor will remove and check it for you at your follow-up appointment.

You will need to return for follow-up within 1 week to make sure the pessary fits well and is not causing any irritation in your vagina. Please call the doctor before your appointment if you experience any of the following: vaginal bleeding, vaginal pain, difficulty urinating, or having a bowel movement. Also, call if your pessary is falling out or falls out. After your first follow-up appointment, your doctor will schedule less frequent regular visits.

Many styles of pessaries can be worn during intercourse. Your doctor should have told you today if you can wear your pessary during intercourse.

You may have an increase in vaginal secretions/discharge or odor while using a pessary. Using Milex® Trimo-san cream or gel three times a week may be helpful in decreasing the discharge and odor.

Please call the office if you have any problems or questions.

Questions for Learners

What are possible surgical risk factors that would cause a physician and a patient to opt for a pessary instead of surgery?

With the wide choices of pessaries that are available, how does a clinician choose which ones to offer for fitting?

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Additional Resources

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Miscellaneous

Trimo-San vaginal cream or gel – Milex products, available over the counter.
Milex pessary fitting kit (Cooper Surgical, Trumbull, CT) 1-800-243-2974; http:\\www.coopersurgical.com\.
or
Monarch Medical Products 1-866-241-1625, http:\\www.monarchmedicalproducts.com.

Chapter 18
Bartholin Gland Cysts and Abscesses

Janice E. Daugherty

Introduction

Bartholin gland cysts are caused when trauma or inflammation obstructs the duct of the Bartholin gland, which normally secretes mucus near the hymenal ring [1]. Often asymptomatic, intermittent obstruction of the duct can cause the cyst to fluctuate in size. If secondarily infected, the cyst can become an abscess.

Visual inspection of the vulva will show a soft, compressible mass at approximately 4 o'clock or 8 o'clock on either side of the hymenal ring (Figs. 18.1 and 18.2). If not infected, Bartholin gland cysts are usually nontender. Abscesses are usually tender to palpation and may cause discomfort when walking or sitting. Abscesses may rupture spontaneously and may have associated cellulitis. In addition to a drainage procedure with re-creation of a gland orifice, local heat to the area can provide relief of discomfort and enhance healing.

Bartholin gland cysts or abscesses are distinct from other vulvar masses in their location and cystic texture on palpation. Solid or vascular vulvar masses generally would not lie in the same anatomic position as a Bartholin gland cyst or abscess [2]. Bartholin glands are most active during the reproductive years, so masses occurring before puberty or beyond the menopausal period are not likely to be Bartholin cysts.

The Word catheter, placed inside the Bartholin gland cyst, is a small, originally latex, now silicone device with a balloon that allows it to function as a self-retaining drain [3]. It can remain in place within the cyst from several days to up to 4 weeks to allow a new gland opening to epithelialize [4, 5]. Alternatively, women may need a marsupialization procedure if the cyst or abscess is recurrent. Studies have shown no significant difference in recurrence rates between Word catheter and

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C. B. Heath, S. M. Sulik (eds.), *Primary Care Procedures in Women's Health*,
https://doi.org/10.1007/978-3-030-28884-6_18

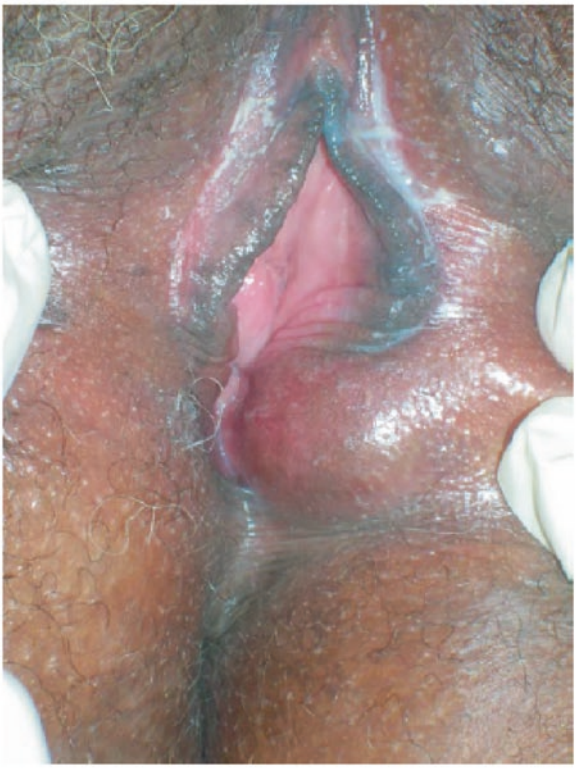


Fig. 18.1
Photograph of
Bartholin gland cyst

marsupialization [6, 7] but significantly lower costs with Word catheter placement. Quality of life was found to be good during treatment with the Word catheter [7, 8].

Case Study

A 21-year-old woman presents for her annual health maintenance examination and states that she has for 6 months noted a swelling on the right side of her vulva near the vaginal opening. She is concerned because it gets larger at times, and she has had pain when she sits or has intercourse.

Diagnosis (Algorithm 18.1)

Bartholin gland cyst or abscess

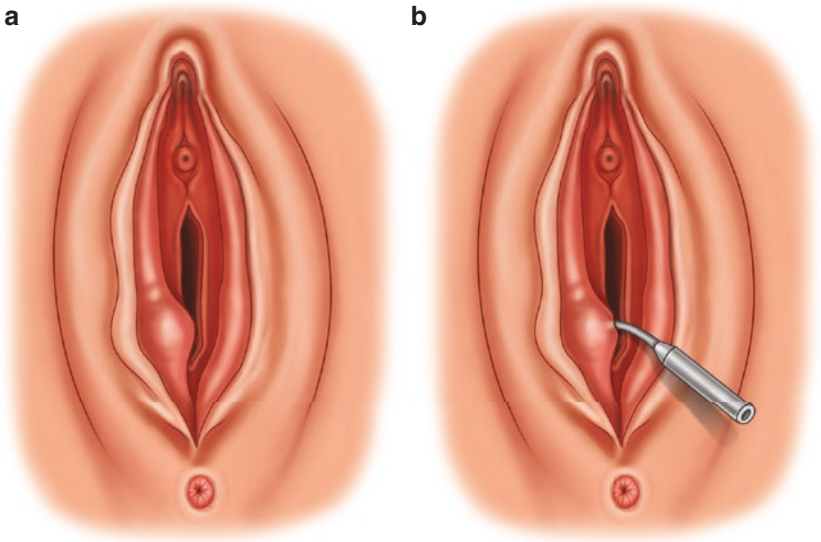


Fig. 18.2 (**a**) Drawing of the Bartholin gland with cyst. (**b**) Word catheter in place within the Bartholin cyst

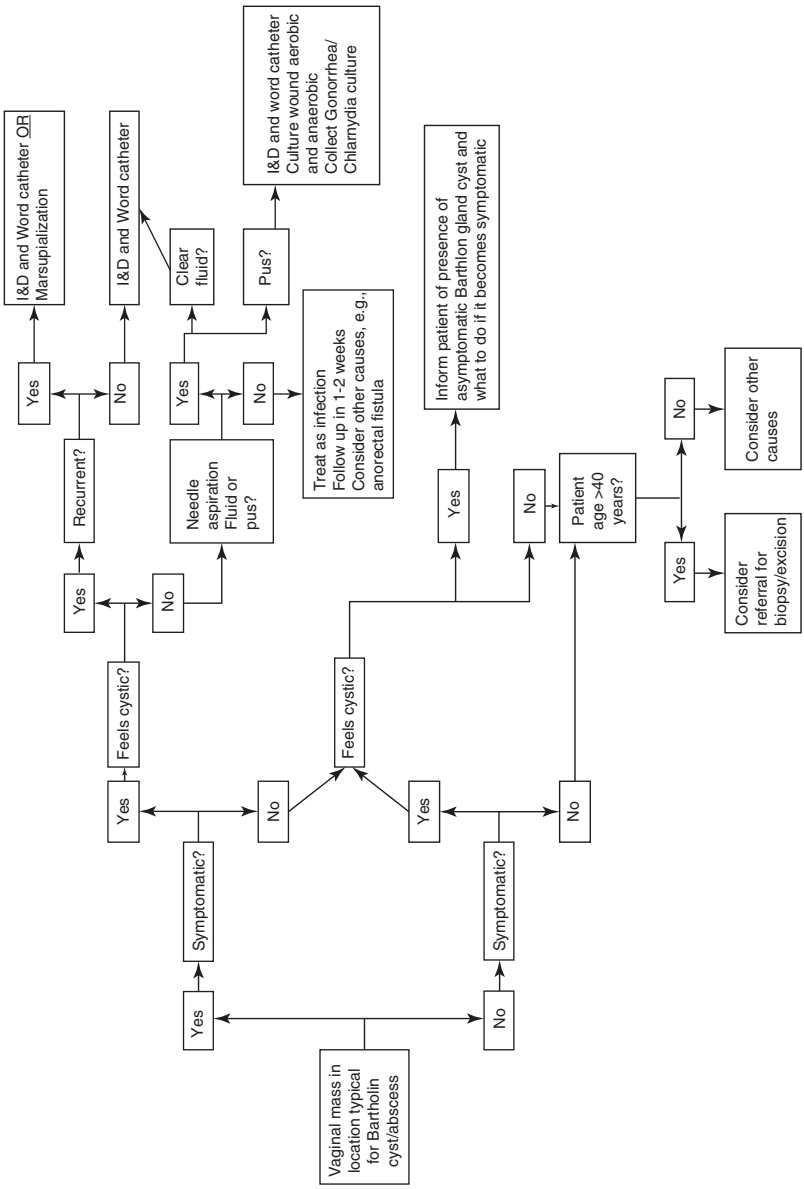
Differential Diagnosis

- Hematoma
- Sebaceous cyst
- Hemangioma
- Lipoma
- Malignant neoplasm: primary or metastatic carcinoma
- Sarcoma

Indications (Algorithm 18.1)

Symptomatic cyst or abscess

- The purpose of the procedure is not only to drain the cyst fluid but also to re-establish a gland opening in good anatomical position.
- The procedure of first choice is usually incision and drainage of cyst or abscess with insertion of Word catheter.
- If prior drainage procedures have repeatedly failed, or follow-up is unlikely to occur, marsupialization of the cyst may be the primary management [1, 9].



Algorithm 18.1 Decision tree for vaginal mass near the hymenal ring

Contraindications

- Bleeding disorders, systemic anticoagulation
- Sensitivity to latex, unless silicone Word catheter is available

Equipment (Fig. 18.3)

- Word catheter
- Antiseptic solution
- No. 11 or 15 scalpel
- 1% lidocaine
- 22- or 25-gauge 1-in. needle for catheter inflation
- 30-gauge 1-in. needle for infiltration anesthesia
- 3- or 5-cc syringe
- Hemostat: curved mosquito
- Silver nitrate stick

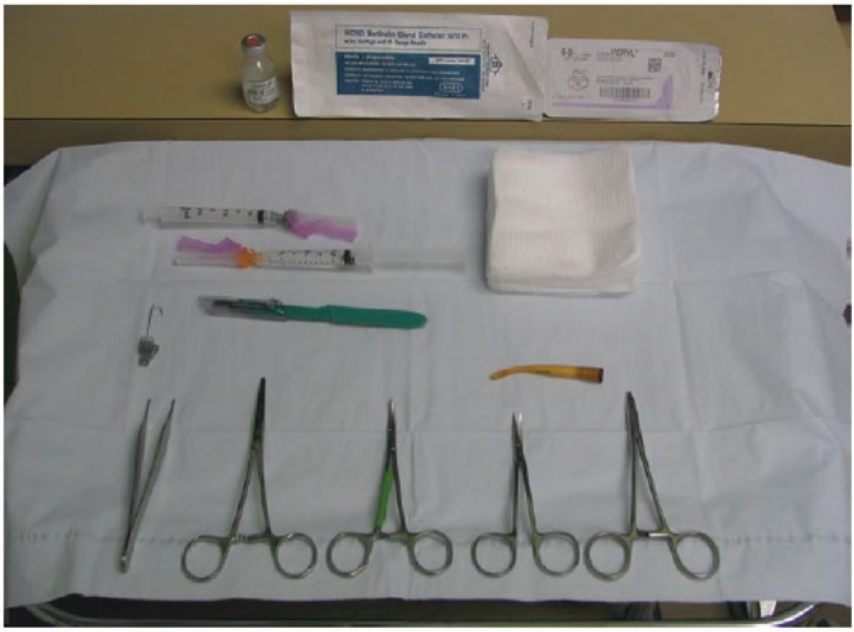


Fig. 18.3 Sterile setup tray for Word catheter insertion: (**a**) 1% lidocaine anesthetic; (**b**) syringe with 3 cc of 1% lidocaine; (**c**) needle driver; (**d**) hemostats; (**e**) scissors; (**f**) pickups; (**g**) scalpel; (**h**) 4 × 4 inch gauze; (**i**) Word catheter; (**j**) 3 cc syringe with water; (**k**) add extra needle 1½" for a hook

- 4 × 4 sterile gauze pads
- Pickups with teeth
- Needle holder: small
- 3-0 or 4-0 absorbable suture on small cutting needle
- Scissors
- Eye protection
- Mask
- Gloves

Procedure

Procedure for Incision and Drainage with Word Catheter Placement

1. Remove Word catheter from the package. Attach a 22- or 25-gauge 1″ needle to a 3-cc syringe filled with tap water.
2. Carefully insert the needle into the center of the wider end of the catheter and test the balloon by filling it with approximately 3 cc of water (Fig. 18.4).

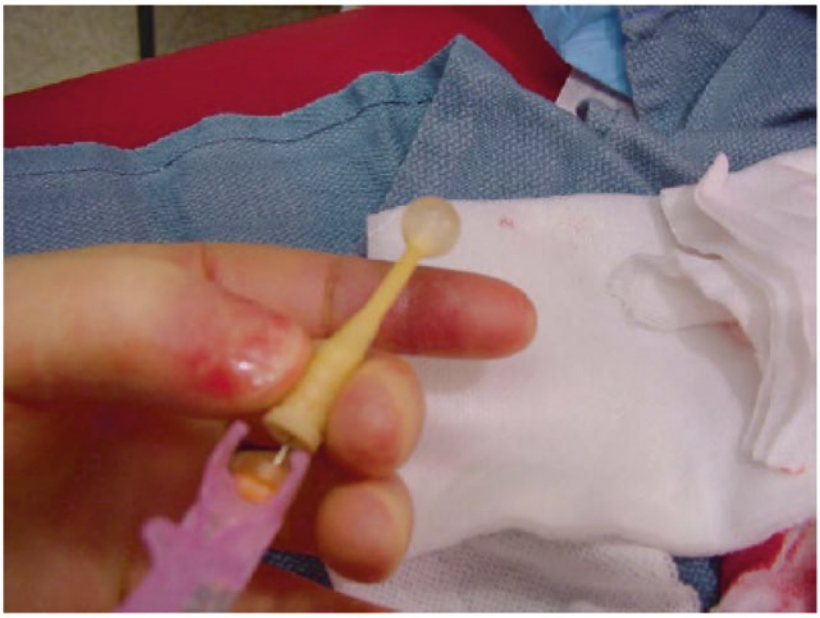


Fig. 18.4 Testing Word catheter balloon system

3. Aspirate the water from the catheter and leave the catheter in place on the needle.
    - The syringe will serve as a handle to make the catheter easier to insert into the cyst, and fewer punctures mean less likelihood that the water will leak out.
4. Place patient in lithotomy position.
5. Have an assistant place traction on the vulvar skin to provide good exposure to the area.
6. Infiltrate the area over the cyst, just inside the hymenal ring, with local anesthetic in an area about 1.5 cm across.
7. Cleanse the area with antiseptic solution.
8. Stabilize the cyst with either your fingers or a needle-hook into the cyst (Fig. 18.5).
9. Make a stab incision approximately 1.5 cm deep and 0.5 cm long into the cyst (Fig. 18.6).
10. Insert a hemostat and spread the tips within the cyst or abscess to break up any loculation.
11. Insert the Word catheter into the cyst (Fig. 18.7) and fill the bulb with 2–3 cc of water. Remove the needle from the catheter (Fig. 18.8).

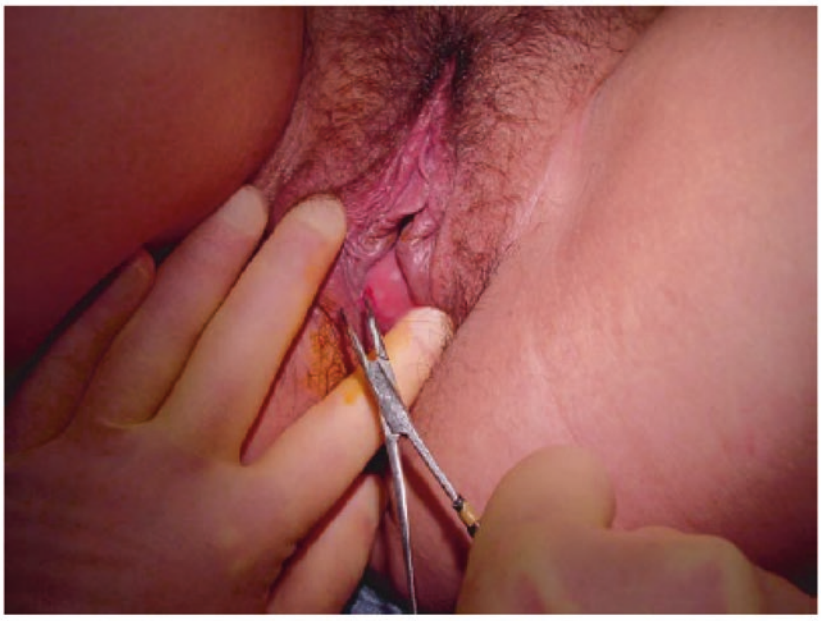


Fig. 18.5 Stabilization of Bartholin cyst prior to incision and drainage

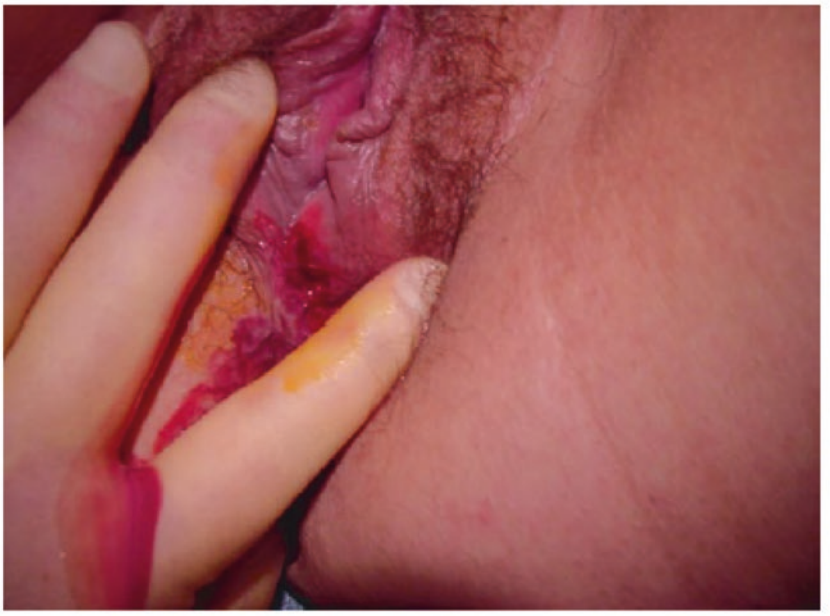


Fig. 18.6 Incision has been made into Bartholin cyst prior to insertion of Word catheter

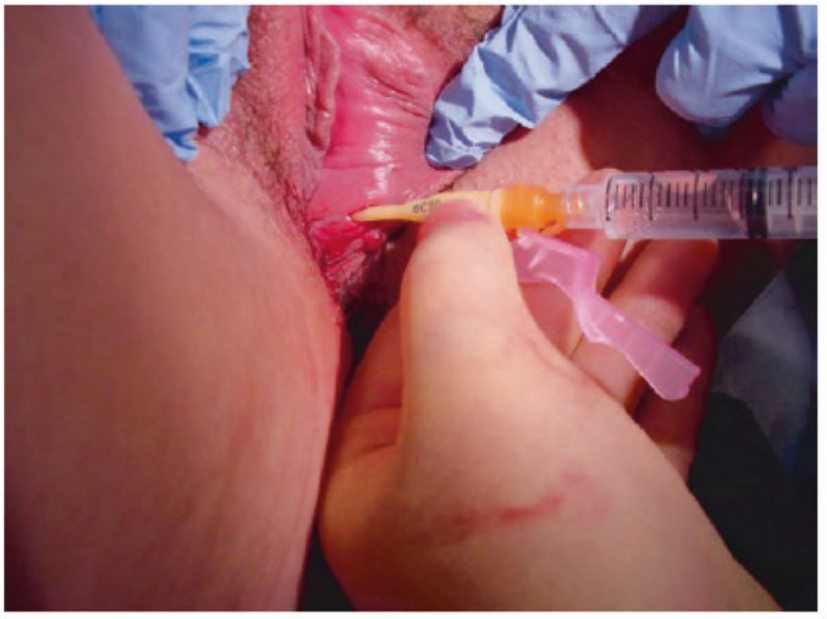


Fig. 18.7 Insertion of Word catheter

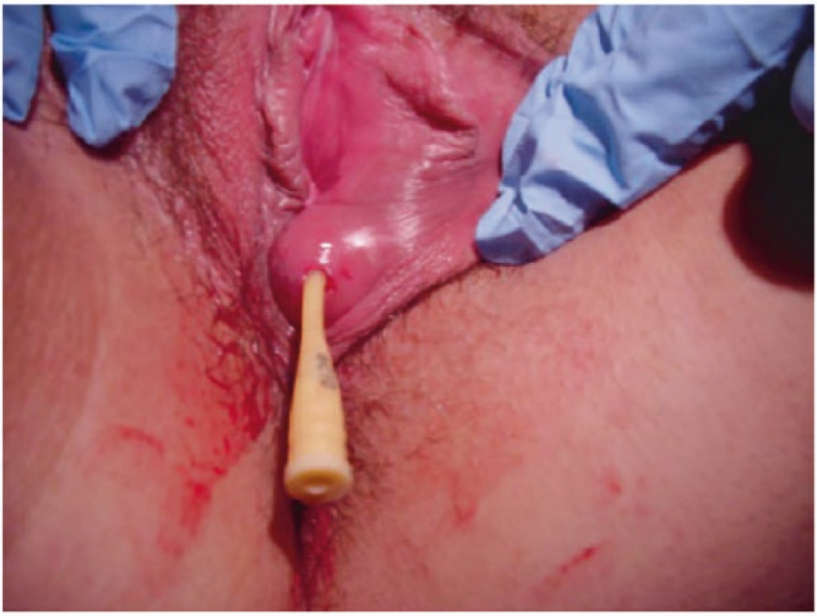


Fig. 18.8 Word catheter in place after insertion

12. If desired, place a small absorbable suture next to the incision, tie a knot, and then tie the suture around the catheter. Do not place a suture through the catheter.
13. Push the external end of the Word catheter up through the hymenal ring into the vagina. Instruct the patient that she can push it back up when it slips out.

Procedure for Marsupialization

1. Place the patient in lithotomy position.
2. Have an assistant place traction on the vulvar skin to provide good exposure to the area.
3. Infiltrate the area over the cyst, just inside the hymenal ring, with local anesthetic in an area about 2.5 cm across.
4. Cleanse the area with antiseptic solution.
5. Stabilize the cyst with either your fingers or a needle-hook into the cyst (Fig. 18.9a).
6. Excise an ellipse of mucosa and its underlying cyst wall approximately 1–1.5 cm in diameter (Fig. 18.9b, c).

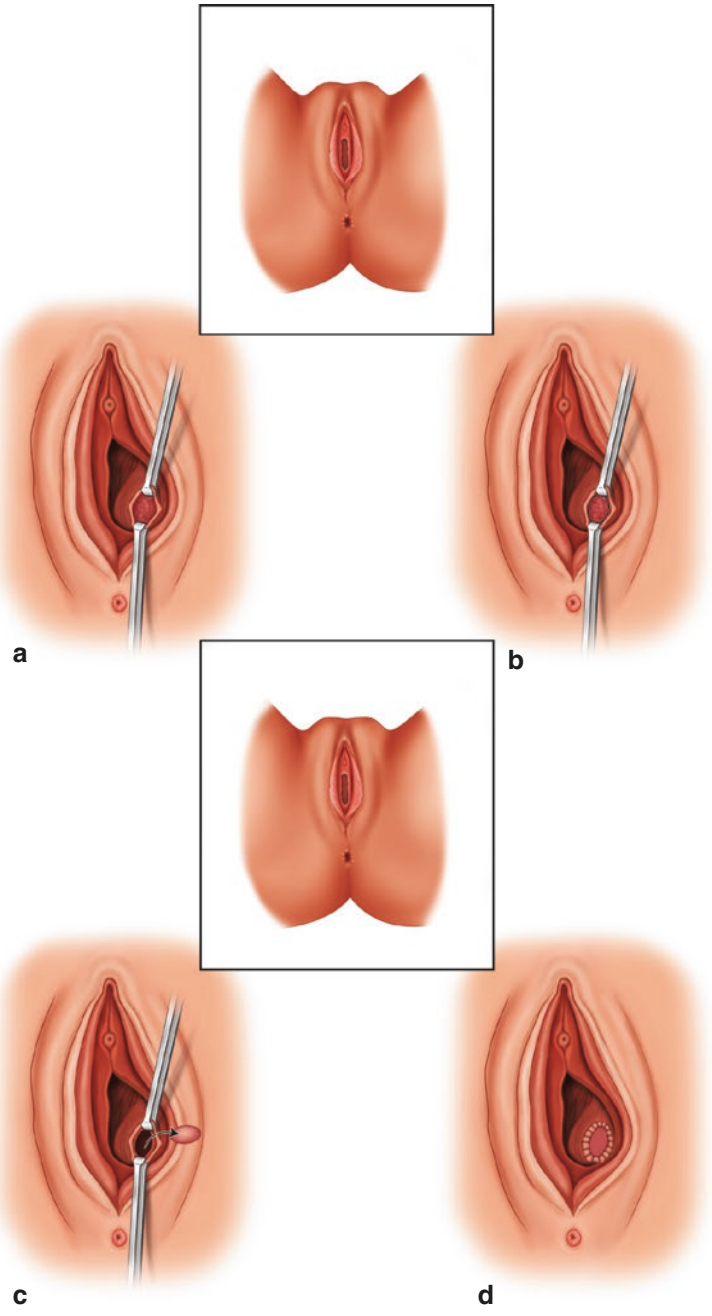


Fig. 18.9 (**a**–**d**) Bartholin cyst marsupialization. (**a**) Stabilization of the Bartholin cyst. (**b**) An elliptical incision is made on the center of the cyst. (**c**) Excise an ellipse of mucosa and its underlying cyst wall approximately 1–1.5 cm in diameter. (**d**) Suture the vulvar mucosa to the cyst wall around the circumference of the incision, using either running or simple interrupted absorbable sutures

7. Insert a hemostat and spread the tips within the cyst or abscess to break up any loculation.
8. Suture the vulvar mucosa to the cyst wall around the circumference of the incision, using either running or simple interrupted absorbable sutures (Fig. 18.9d).

Complications and Risks

- Bleeding at the site
- Infection
- Reactions to local anesthetic
- Reactions to latex unless silicone Word catheter is used

Tricks and Helpful Hints

- Having an assistant to help with maintaining exposure to the area will make the procedure much easier.
- As the original Word catheter is made of latex, its balloon is subject to weakness and rupture brought on by age and environmental exposure to petroleum products. Use of the silicone Word catheter will avoid problems associated with latex. At this time of this writing, however, the latex version was still available for purchase online.
- Do not inflate the catheter with air: it will leak out too soon. Sterile water is not necessary for filling the catheter, as the vulva is not sterile.
- Take care when inserting the needle into the catheter not to pierce the side or end of the catheter.
- Stabilize the cyst wall by using a curved hemostat or make a needle-hook by using a hemostat to bend a 25-gauge 1½[2] needle attached to a small locking syringe. The syringe serves as a handle for the hook, which can be placed into the cyst to stabilize it, facilitate exposure, and make it less likely for the skin and the cyst wall to "eclipse" the incision, which makes proper insertion of the Word catheter difficult (see Fig. 18.10).
- An alternative to a Word catheter is to fashion a Jacobi ring from rubber tubing (some use rubber tubing from a butterfly blood collection kit) threaded with an absorbable suture which is then laced through the cyst. It is then tied off and left in place for one month. It is removed by cutting the visible suture and pulling out the threaded ring [10].
- A portable warm soak can be made by folding a washcloth in quarters and then once again to make a rectangle approximately the size of a sanitary pad (Fig. 18.11). Place the washcloth in a sandwich-sized zipper-lock plastic bag, add enough water to soak the cloth, and seal the bag. Heat the bag and cloth in the microwave for a few seconds until it is warm but not hot to the touch. The woman can place this in her underclothing to provide moist heat without wetting her clothing. She can reheat the cloth as necessary without opening the bag.

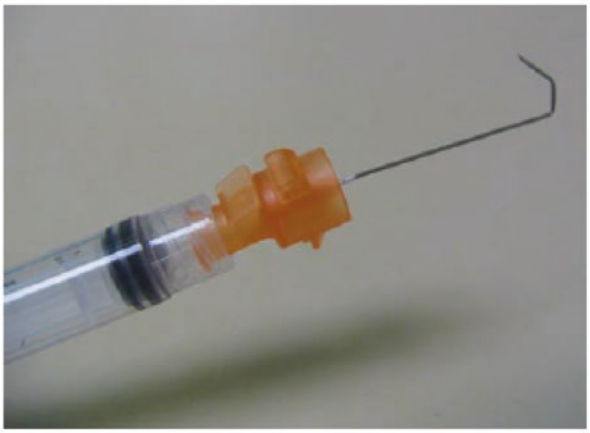


Fig. 18.10 Make a needle-hook by using a hemostat to bend a 25-gauge needle attached to a small Luer-tip syringe. The syringe serves as a handle for the hook, which can be placed into the cyst to stabilize it, facilitate exposure, and make it less likely for the skin and the cyst wall to "eclipse" the incision, making proper insertion of the Word catheter difficult

Fig. 18.11 Moist washcloth in a plastic sandwich bag can be microwaved and reused as a heat pack

Procedure Note

(Provider to customize as needed.)

Incision and Drainage with Word Catheter Placement

The procedure was discussed with the patient, including benefits of draining cyst fluid/pus and establishing a new gland opening, as well as the likely relief of discomfort. Risks including bleeding, infection, early dislodging of the catheter, and possible recurrence of the cyst/abscess were discussed, as were alternative treatments for this condition. The patient states no known allergy to latex, iodine, or local anesthetics. Aftercare instructions were discussed. The patient signed a consent form for this procedure.

The patient was placed in the lithotomy position. The cyst was identified and palpated near the hymenal ring. Local anesthesia was achieved with 1–2 cc of 1% lidocaine by local infiltration. The area was cleansed with povidone–iodine and manually stabilized, and an incision was made into the cyst. A Word catheter that had been previously tested was placed into the cyst cavity and filled with water to allow retention of the balloon. (A retention suture of 4-0 absorbable suture was placed around the catheter.)

The patient tolerated the procedure well, and aftercare instructions were repeated. She is to return to the office in 2 weeks for follow-up.

Marsupialization of Bartholin Gland Cyst

The procedure was discussed with the patient, including benefits of draining cyst fluid/pus and establishing a new gland opening, as well as the likely relief of discomfort. Risks including bleeding, infection, and possible recurrence of the cyst/abscess were discussed, as were alternative treatments for this condition. The patient states no known allergy to iodine or local anesthetics. Aftercare instructions were discussed. The patient signed a consent form for this procedure.

The patient was placed in the lithotomy position. The cyst was identified and palpated near the hymenal ring. Local anesthesia was achieved with 1–2 cc of 1% plain lidocaine by local infiltration. The area was cleansed with povidone–iodine and manually stabilized, and an ellipse of mucosa and cyst wall was removed. The edge of the mucosa was sutured to the cyst wall in a circumferential fashion with running absorbable suture.

The patient tolerated the procedure well, and aftercare instructions were repeated. She is to return to the office in 2 weeks for follow-up.

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)

Incision and Drainage with Word Catheter Placement	
Procedure:	56420
Supplies:	99070
Marsupialization of Bartholin Gland Cyst	56440
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 10th Revision, Clinical Modification, Centers for Disease Control and Prevention)	
Bartholin gland cyst	N75.0
Bartholin gland abscess	N75.1

Postprocedure Patient Instructions

Incision and Drainage with Word Catheter Placement

- It is best if the catheter can remain in place for 2–4 weeks.
- If using Word catheter, the patient may want to tuck the end of the catheter back into the vagina when it comes out with straining, etc.
- Otherwise, the woman may resume her normal activities immediately after the procedure.
- Antibiotics are not necessary unless there is cellulitis, or systemic signs of infection associated with an abscess.
- Instruct the patient to report any heavy bleeding, apply moist heat as much as possible during the first few days after the procedure, and return for follow-up as scheduled.
- Keeping the abscess open is adequate to allow healing in most cases.

Marsupialization of Bartholin Gland Cyst

- Warm moist soaks will help ease the discomfort and speed healing

Case Study Outcome

At her follow-up visit 2 weeks after the procedure, the patient had good resolution of her symptoms and the tract around the Word catheter was well-healed. The balloon was deflated with a needle, and the catheter was removed. She was wished well and requested to follow-up as needed.

Postprocedure Patient Handout

(Provider to fill in blanks/circle applicable choice when given multiple choices and to customize as needed.)

What Is a Bartholin Gland Cyst or Abscess?

The Bartholin glands are small mucus-producing glands on either side of the vaginal opening. If a gland opening becomes blocked due to irritation or infection, the mucus can accumulate and form a cyst. If this fluid becomes infected, it can form an abscess.

How Is a Bartholin Gland Cyst or Abscess Treated?

The purpose of treatment is to drain the fluid and create a new opening for the gland. If the fluid is drained without creating a new opening, the cyst or abscess is more likely to come back. The usual treatment for Bartholin cysts is to drain the fluid and insert a small soft tube, called a Word catheter, which has a balloon that helps keep it in place within the cyst for about 2 weeks. Leaving the tube in place allows the body to heal with a new opening for the gland. The Word catheter procedure can be done in the office with local anesthesia.

What Can I Do at Home to Feel Better?

Applying a warm pack to the area can help with the swelling and discomfort. Sometimes an abscess will drain on its own, and moist heat can help it heal more quickly. Getting extra rest will also help your body heal more quickly.

Acetaminophen 650 mg taken every 4 hours or ibuprofen 400 mg every 4–6 hours will help with your discomfort.

If you have a Word catheter in place, it is OK to have sexual intercourse, and you can bathe normally with the catheter in place.

What if the Cyst or Abscess Comes Back?

If a cyst or abscess has come back more than once after the Word catheter procedure, your healthcare practitioner may recommend a procedure that makes a larger opening in the cyst. This procedure can usually be done in the office.

When Should I Call My Healthcare Practitioner?

If you have:

- Discomfort that is increasing rather than decreasing
- Fever or chills
- Any questions or concerns

Remember to keep your appointment for follow-up in 2 weeks.
Your appointment date and time is _____.

Questions for Learners

- In what instances would one choose to do a marsupialization in place of using a Word catheter?
- What are the pros and cons of doing an incision and drainage over performing another type of procedure?

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10. Omole F, Kelsey R, Phillips K, Cunningham K. Bartholin Duct Cyst and Gland Abscess: Office Management. Am Fam Phys 2019;99(12):760–6.

Additional Resources

Websites

http://www.operationalmedicine.org/Videos/Bartholin1.mpg: a video of the procedure of Word catheter insertion.

Equipment Companies

Artisan Medical 1-866-930-3390 www.artisanmed.com.
Cook Medical 1-800-457-4500 www.cookmedical.com.
CooperSurgical, 1-800-243-2974, www.coopersurgical.com.

Chapter 19
Endometrial Biopsy

Kristen McNamara

Introduction

The endometrial biopsy is a safe, simple office procedure that can be used to diagnose most abnormal uterine bleeding in women. The most common indication for the procedure is postmenopausal bleeding or dysfunctional uterine bleeding in younger women. Other uses include the workup of an atypical glandular cell (AGC) Pap in women over 35, evaluation of endometrial cells on a Pap in postmenopausal women, evaluation of women at higher risk for endometrial cancer prior to instituting hormone replacement therapy (HRT), evaluation of women bleeding on tamoxifen therapy, and, infrequently, as an evaluation for infertility. In most cases, office endometrial biopsy has replaced dilatation and curettage (D&C) due to its ease of performance in the outpatient setting. This also allows for the evaluation of bleeding women who are poor candidates for general anesthesia.

Endometrial biopsy has a high overall accuracy when an adequate specimen is obtained. The overall sensitivity for detecting carcinoma is 99.6% in postmenopausal women and 91% in perimenopausal women. Endometrial sampling with a Pipelle® (Unimar, Wilton, CT) also detects atypical hyperplasia with a sensitivity of 81% and a specificity of 98% [1–3]. Some practitioners also use uterine ultrasound to assess endometrial lining thickness prior to the endometrial biopsy.

While no anesthesia is required for most endometrial biopsies, it is recommended that the patient takes a dose of a nonsteroidal anti-inflammatory drug (NSAID) such as ibuprofen prior to the procedure to decrease discomfort and cramping. In addition, use of local anesthesia with 1% lidocaine via a paracervical block and/or intramyometrially has been shown to decrease pain as well. Use of a paracervical block

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can also decrease the risk of vasovagal events postprocedure [4]. Topical anesthesia can be used locally on the cervix for some reduction of discomfort caused by placement of the tenaculum [5].

Performing an endometrial biopsy on a woman with a stenotic os is difficult technically for clinicians and uncomfortable for the patient. Nulliparous, breastfeeding, postmenopausal women or women using progestogen-only contraceptives are at greatest risk for cervical stenosis. Treatment for cervical stenosis prior to performing the endometrial biopsy may involve insertion of a laminaria several hours to 1 day prior to the procedure, use of misoprostol intravaginally or orally the day prior to the procedure, or premedication with estrogen cream vaginally for 2 weeks prior to the procedure.

Case Study

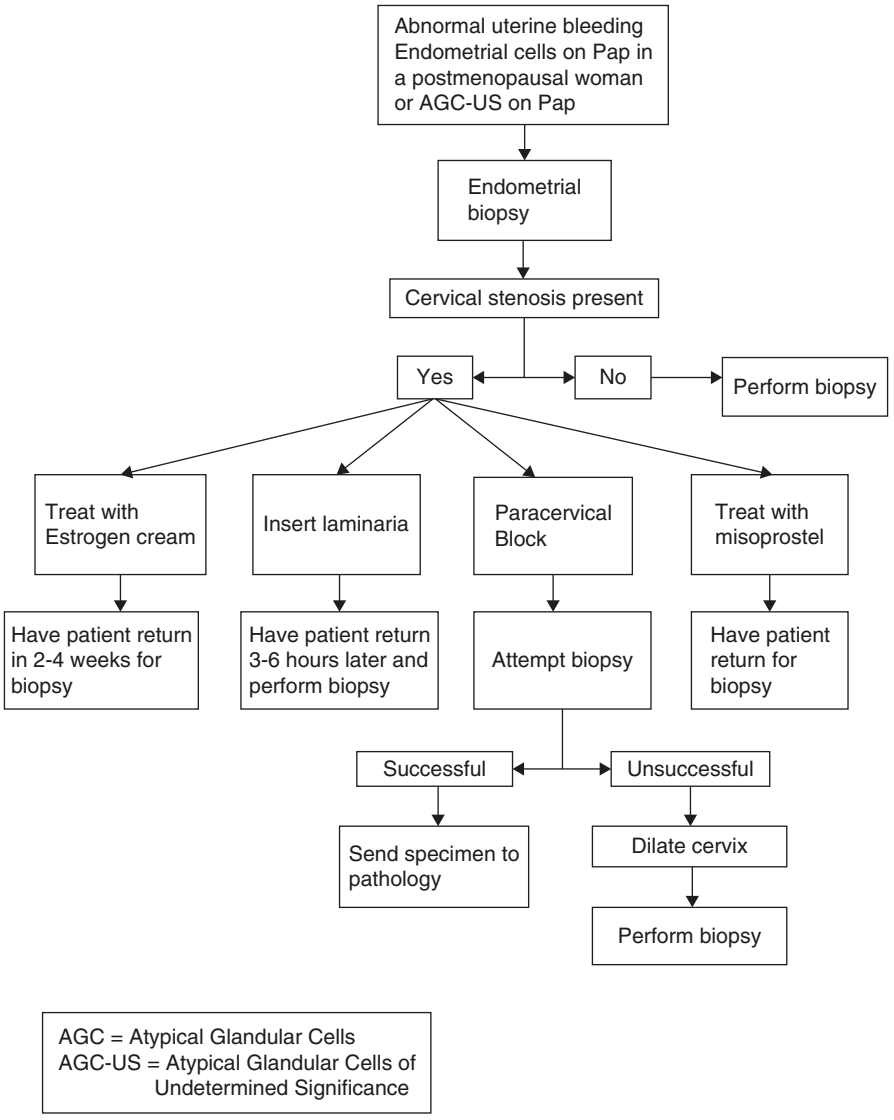
A 56-year-old postmenopausal female, LMP at age 54, presents to the office complaining of 2 days of vaginal bleeding last week that spontaneously resolved. She has not had any menses or vaginal bleeding in 2 years, and the episode was accompanied by abdominal cramping. She used two pads on the first day of bleeding and one pad on the second day of bleeding. The bleeding spontaneously resolved, and she is currently feeling well. A pelvic exam is essentially unremarkable, and she has no other health problems. She is on no medications. Her Pap smear is current and is normal.

Diagnosis (Algorithm 18.1)

Postmenopausal vaginal bleeding; rule out endometrial malignancy.

Indications (Algorithm 18.1)

- Postmenopausal vaginal bleeding
- Dysfunctional uterine bleeding over age 45
- AGC-US (atypical glandular cells of uncertain significance) Pap in a woman over 35
- Evaluation of endometrial thickness > 5 mm in a postmenopausal woman
- Endometrial cells on Pap in a postmenopausal woman
- Endometrial dating in an infertility evaluation (used infrequently)
- Evaluation of endometrium prior to the onset of HRT use in high-risk women
- Evaluation of bleeding in women on tamoxifen
- Dysfunctional uterine bleeding under age 45 that hasn't responded to standard treatments



Algorithm 18.1 Decision tree for endometrial biopsy procedure

Contraindications

- Pregnancy
- Known cervical cancer

Relative Contraindications

- Acute cervicitis/pelvic infection
- Active uterine bleeding (may be difficult to obtain a core sample of endometrium adequate for analysis)
- Cervical stenosis
- Difficulty passing cannula secondary to cervical stenosis, large leiomyomas, marked uterine flexion, patient sensitivity

Equipment (Fig. 19.1)

- Antiseptic solution
- Tenaculum
- Hurricaine® gel (Beutlich LP Pharmaceuticals, Waukegan, IL) (topical anesthetic)
- Vaginal speculum

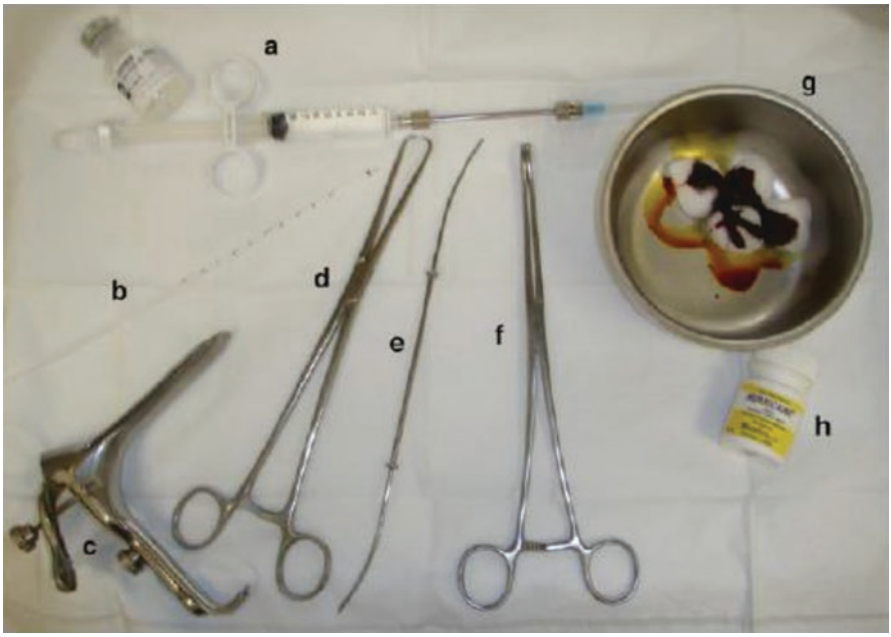


Fig. 19.1 Equipment setup for endometrial biopsy: (**a**) 1% lidocaine with epinephrine anesthetic in 10 cc syringe with needle extender; (**b**) Endometrial sampler, sterile; (**c**) Sterile speculum; (**d**) Sterile cervical tenaculum; (**e**) Sterile uterine sound; (**f**) Sterile long-looped forceps; (**g**) Metal basin with betadine-soaked cotton swabs; (**h**) Hurricaine® gel (Beutlich LP Pharmaceuticals, Waukegan, IL) for topical anesthesia

- Formalin sample bottle with labels
- Endometrial biopsy sampler [Pipelle® (Unimar, Wilton, CT), Endocell™ Endometrial Sampler (Wallach Surgical Devices, Orange, CT), or endometrial aspirator]

Optional Equipment

- Uterine sound (endometrial sampler can be used to sound the uterus)
- 1% lidocaine with epinephrine
- Needle extender
- 10 cc syringe

Procedure

1. Obtain informed consent for the procedure, and obtain urine pregnancy test if the patient is not postmenopausal.
2. Place the patient in dorsal lithotomy position.
3. Perform a bimanual examination to determine the position and size of the uterus
4. Insert vaginal speculum and visualize the cervix.
5. Cleanse the cervix with the antiseptic solution.
6. Sound the uterus (determine depth of the uterus to avoid perforation) and document the depth (usually 6–9 cm). This may be done using a uterine sound or the biopsy sampler itself inserted through the cervical os.
7. If there is difficulty inserting the sound, the cervical canal may be straightened and the cervix stabilized using a tenaculum. Hurricaine® anesthetic should be applied to the cervix prior to placing the tenaculum. The "teeth" of the tenaculum should be placed on the cervix horizontally, at 11 o'clock and 1 o'clock positions, approximately 1 cm from os (Fig. 19.2).
8. Insert the sampler through the cervical os. If resistance is encountered, use gentle pressure. If there is still resistance, terminate the procedure and follow steps below for stenotic cervical os (Fig. 19.3a).
9. Stabilize the sheath with one hand and draw the piston completely back in one continuous motion. This creates a vacuum, or negative pressure, within the uterus (Fig. 19.3b).
10. Rotate the sheath between the thumb and index finger and move it in and out between the fundus and the internal os three or four times until the sampler is full. These actions pass the sampler opening through a helical arc against the uterine walls. The negative pressure vacuum draws the endometrial tissue into the sampler. The tissue can be visualized in the lumen of the sampler (Fig. 19.3c).
11. Withdraw the device (with piston still drawn back).

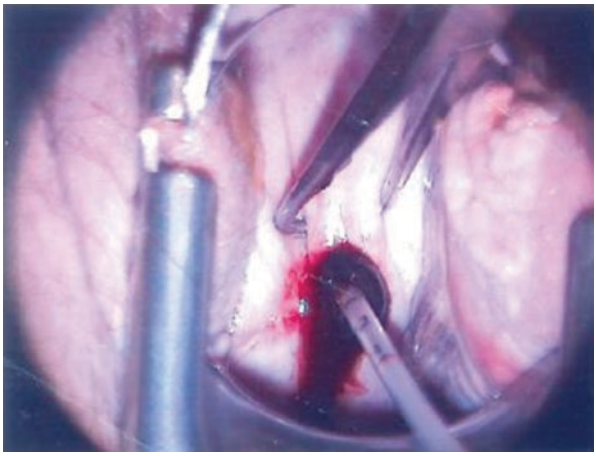


Fig. 19.2 Proper placement of tenaculum and insertion of endometrial sampler

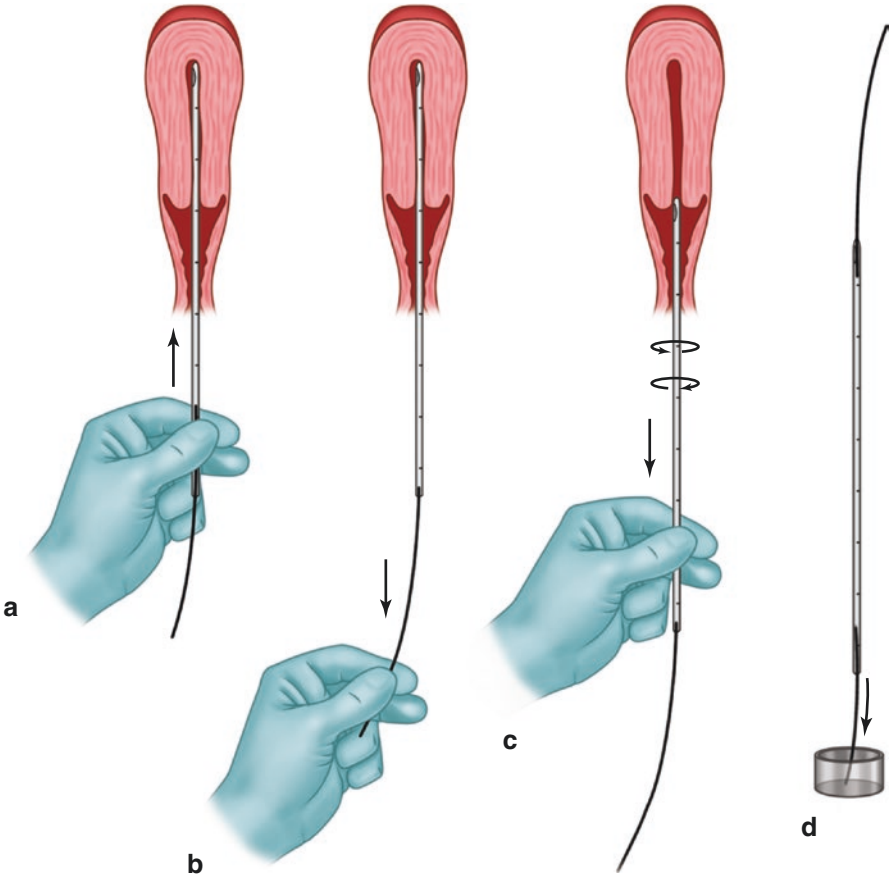


Fig. 19.3 (**a**) Endometrial sampler is inserted to the fundus of the uterus. (**b**) The sampler is stabilized and the piston is pulled entirely back to the stopper. (**c**) The endometrial sampler is moved in and out and rotated clockwise and counterclockwise to obtain the uterine sample. (**d**) The sample is placed in the formalin container to send to pathology

12. Expel the sample into the formalin by advancing the piston back into the sheath. Do not put the tip of the sampler directly into the formalin in the container. Some clinicians use the sampler to repeat the procedure to obtain a second sample (Fig. 19.3d).
13. Some clinicians cut the tip of the sampler and send it with the specimen.
14. Remove the tenaculum, if applied.
15. Remove the speculum from the vagina and send the specimen to pathology.

Complications and Risks

- Missed lesion in biopsy sample (5–15% false-negative rate)
- Uterine perforation (0.1–1.0%)
- Infection (0.4%)
- Excessive uterine bleeding
- Cramping (common and brief)
- Vasovagal syncope (10% of patients)

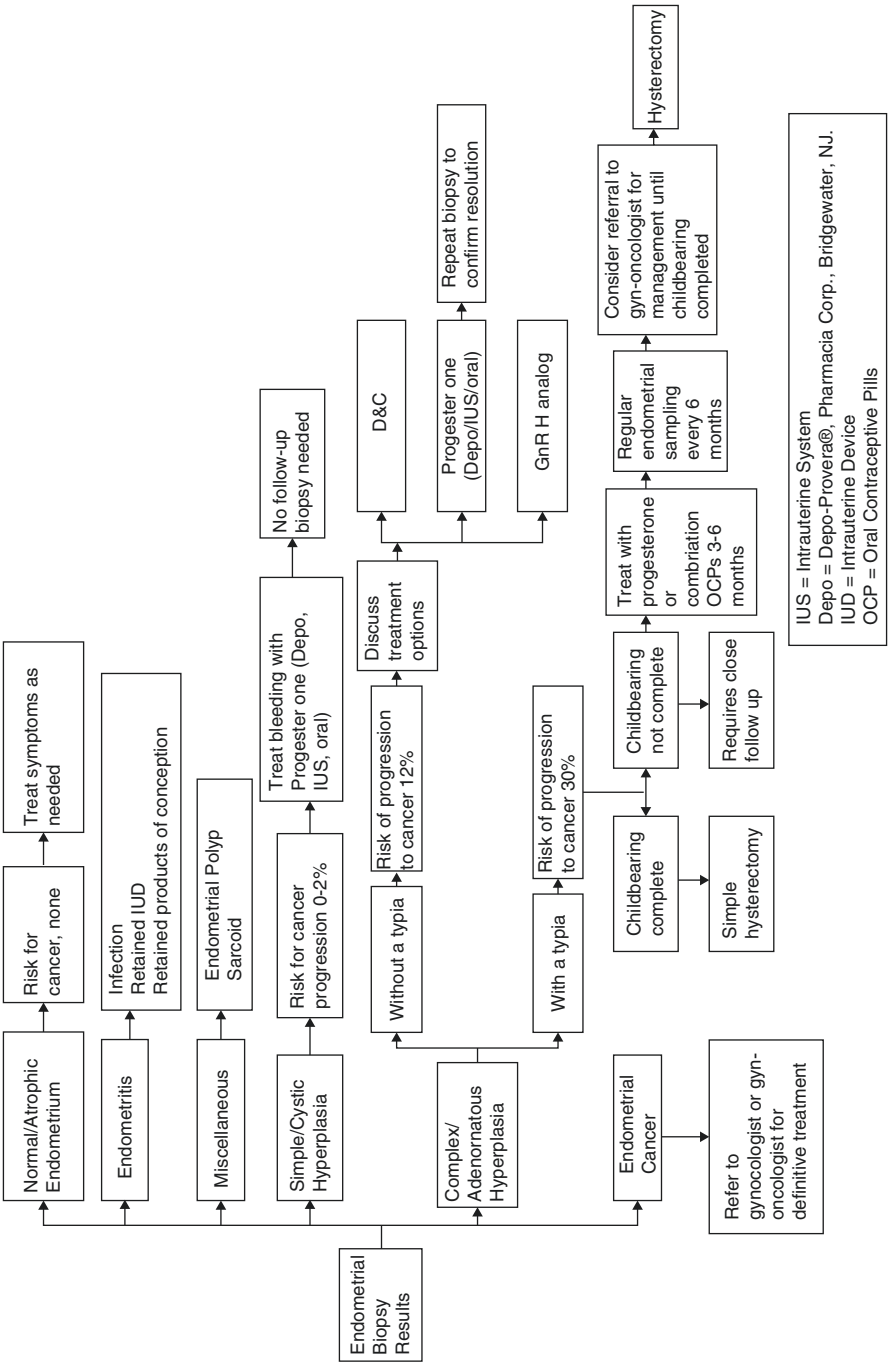
Tricks and Helpful Hints (Algorithm 18.1)

- Storing the sampling device in the freezer stiffens the plastic enough that a tenaculum may be unnecessary.
- For cervical stenosis:
  - Pretreat postmenopausal women or women who have not had vaginal deliveries with estrogen cream one half-full applicator into the vagina every other night for 2–4 weeks prior to the procedure.
  - Insert laminaria into the cervical os 1 day prior to procedure or in the morning and have the patient return later in the day for the procedure.
  - Have the patient insert 200 μg of misoprostol into her vagina or take orally the day prior to procedure. (This may cause some mild cramping.)
- For uncomfortable patients:
  - Two to 3 days prior to the procedure, have the patient begin taking ibuprofen or other NSAID to decrease the discomfort felt during the procedure.
  - A paracervical block done just prior to the procedure can decrease the pain during the endometrial biopsy.
  - To perform a paracervical block:
    (a) Use 5–10 cc of 1% or 2% lidocaine with epinephrine.
    (b) Place a needle extender onto the syringe with a 26-gauge needle.
    (c) Stabilize the cervix by placing a tenaculum, as described previously.

(d) Inject submucosally 1–2 cc of lidocaine into the cervix at the 12, 3, 6, and 9 o'clock positions (can use 2:00, 4:00, 8:00, and 10:00 positions if preferred.)
(e) Proceed with the biopsy as described previously.
(f) If also injecting intramyometrially, inject 5 cc of lidocaine through the cervical os using an angiocatheter or spinal needle, leave needle in place for approximately 10–15 min before withdrawing and starting the procedure [6, 7].

Interpretation of Results [8, 9] (Algorithm 18.2)

- *Insufficient Tissue*: Follow-up will depend on the reason biopsy was done. If need to repeat, consider mid-cycle sample rather than at the end of menses.
- *Proliferative or secretory endometrium*: Normal findings, no follow-up required, and confirms ovulation.
- *Atrophic endometrium*: No treatment needed.
- *Hyperplasia*:
  - Simple (cystic)
    (a) 0–2% progress to cancer
    (b) If bleeding persists, treat with progesterone.
    (c) No follow-up biopsy is needed.
  - Complex (adenomatous) *without* atypia
    (a) 12% progress to cancer – close follow-up is required.
    (b) Treatment with progesterone and follow-up biopsy to confirm resolution is necessary.
  - Complex (adenomatous) *with* atypia
    (a) 30% progress to cancer
    (b) If childbearing *not* completed:
      - Progesterone treatment for 3–6 months
      - Regular endometrial sampling every 6 months
    (c) If childbearing completed, simple hysterectomy is recommended.
- *Carcinoma*: Refer to gynecology oncology for staging and hysterectomy.
- *Endometritis*: Multiple causes
  - Acute: infection, necrosing endometrial polyp
  - Chronic: infection, sarcoidosis, radiation effects, carcinoma, retained IUD, retained products of conception (postmiscarriage or termination)



Algorithm 18.2 Decision tree for endometrial biopsy results

Procedure Note

(Provider to customize as needed.)

Preoperative Diagnosis:

Postoperative Diagnosis:

Indications:

Procedure Details: Urine pregnancy test is done and negative. The risks (including infection, bleeding, pain, and uterine perforation) and benefits of the procedure were explained to the patient, and written consent was obtained.

The patient was placed in the dorsal lithotomy position. Bimanual exam showed the uterus to be in the anteverted position. A speculum was inserted, and the cervix prepped with iodine solution. Endocervical curettage was not performed.

A sharp tenaculum was applied to the anterior lip of the cervix for stabilization. A sterile uterine sound was used to sound the uterus to a depth of 7 cm. A pipelle was used to sample the endometrium. The sample was sent for pathologic examination.

Condition: Stable

Complications: None

Plan: The patient was advised to call for any fever or for prolonged or severe pain or bleeding. She was advised to use OTC analgesics for pain. We will call her with the pathology results.

After the patient gave informed consent, she was placed in the dorsal lithotomy position. Bimanual exam was performed, revealing a mobile anteverted uterus. A speculum was inserted, and the cervix was visualized. Cervix was cleaned with an iodine solution. There was difficulty sounding the uterus with the endometrial sampler. Hurricaine® gel was applied, and a tenaculum was placed in the 11:00–1:00 position. The uterus was sounded to ___ cm using the endometrial sampler. The sampler piston was drawn back, and multiple passes were made in the uterine cavity to obtain a sample. Two endometrial samples were placed in a sterile container of formalin. The tenaculum was removed, and the patient had no bleeding from the os or the tenaculum site. The speculum was removed. The patient tolerated the procedure well, and the sample was sent to pathology.

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
58100	Endometrial sampling (with or without endocervical sampling, without cervical dilatation, any method)
57800	Dilation of cervical canal, instrumental
59200	Insertion of cervical dilator, laminaria
ICD 10-CM-Diagnostic Codes	
C54.1	Cancer uterus

D28.2	Benign neoplasm, uterus
D07.0	Cancer in situ, uterus
N85.00	Endometrial hyperplasia
R10.2	Pelvic pain
N93.8	Dysfunctional uterine bleeding
N93.9	Abnormal uterine bleeding
N92.4	Premenopausal menorrhagia
N95.0	Postmenopausal bleeding
R87.628	Atypical glandular cells
Z79.890	Postmenopausal HRT
Z85.42	Personal cancer uterus

Postprocedure Patient Instructions

- The patient may experience dizziness/syncope after the procedure: Have the patient sit up slowly on the exam table postprocedure.
- Mild cramping is expected: The patient may take ibuprofen.
- Vaginal bleeding/spotting is a common postprocedure. The patient can resume sexual activity after her bleeding has stopped.
- Postprocedure infection is uncommon. Instruct the patient to call the office if a fever, foul smelling vaginal discharge, or abdominal pain develops.
- Have patient return in 1 week to discuss results of the biopsy.

Case Study Outcome

The patient's biopsy showed secretory endometrium. She was reassured that she did not have cancer or precancerous cells. She will continue to be monitored by her physician.

Patient Handout

(Provider to customize as needed.)

An endometrial biopsy evaluates the tissue inside of the uterus and is used to check for cancerous or precancerous cells. This procedure involves passing a small tube into your uterus and removing part of the endometrium (lining) of your uterus. Your clinician may be doing this test to evaluate any abnormal vaginal bleeding, check on the lining of the uterus if you are on hormones, or check for endometrial cancer.

The endometrial biopsy can be uncomfortable, and we recommend you start taking ibuprofen, three 200 mg tablets three times daily, with food for 2 days prior to the procedure. This will help alleviate the discomfort during the procedure.

The procedure takes less than 10 min, and after the procedure, the sample from your uterus will be sent for microscopic evaluation by a pathologist. You will return to the office in 1 week to discuss those results.

After the procedure, you may have some mild cramping. If this happens, you may take ibuprofen, three 200-mg tablets three times a day with food. Some vaginal bleeding or spotting is common after your procedure. If you have heavy vaginal bleeding, more than one pad every 2 h, please call your clinician. Infection following this procedure is also uncommon. If you develop fever, foul smelling vaginal discharge, or lower abdominal pain, please contact the office.

Question for Learners

- What are some of the various treatments for hyperplasia?

References

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Chapter 20
Breast Cyst Aspiration

Cathryn B. Heath

Introduction

A breast mass is a common presenting symptom in a primary care office setting, at times accompanied by symptoms of pain and tenderness. It is also frequently found on a well-woman examination and is a concern to both clinician and patient due to the fear of malignancy. Most breast masses are caused by fibrocystic changes of the breast, but these must be differentiated from breast cancer. Over half of the women in the United States will have fibrocystic changes sometime during their reproductive life; these changes are most common between the ages of 30 and 50 [1]. Seven percent of women in the Western world will have palpable breast cysts [2]. Fibrocystic changes consist of two different forms: fibroadenomas, which are solid, and cysts, which are liquid-filled sacs. Most fibrocystic changes fluctuate with hormonal cycles, worsening just prior to menses and improving after the initiation of menses. If a mass is noted by the clinician or the patient, consideration of returning after the patient's menses for a reevaluation may be appropriate. If the mass is still present, a diagnostic mammogram and sonogram should be ordered. If the breast cyst is complex and shows a thickened cyst wall, intramural tumor, or multiple septae or is eccentric on ultrasound, it has a higher likelihood of being malignant [3]. If the palpable mass is solid on ultrasound or mammogram, then the patient should be referred for evaluation and definitive biopsy. A breast mass must be evaluated even if the mammogram is read as normal, as breast cancer can present in a similar fashion.

Breast cysts are often uncomfortable, and patients may prefer drainage by aspiration for relief of symptoms. Breast cyst aspiration is a very easy office procedure

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that can be performed with minimal risks or complications. If the mass is not completely resolved with aspiration, referral to a breast surgeon or interventional radiologist for further evaluation is recommended. Follow-up in 2 weeks is recommended, as many breast cysts recur. Fluid that is gray-green in color is not usually sent for cytology, as it is considered benign [3, 4].

Case Study

A 36-year-old female presents to the office for her routine gynecologic evaluation. She is a G2P2 whose last menses were 1 week ago. She has a past history of fibrocystic breast changes. Her family history is positive for breast cancer in her mother at the age of 55. During the examination, a 2 × 2 cm mass is palpated in the upper outer quadrant of the left breast. She has been doing regular breast examinations and does not remember feeling this particular mass within the last 3 months. The mammogram shows a mass; and ultrasound shows it is a unilocular (simple) cyst. She is uncomfortable due to its size and is requesting an aspiration.

Diagnosis (Algorithm 20.1)

Unilocular breast cyst.

Indications (Algorithm 20.1)

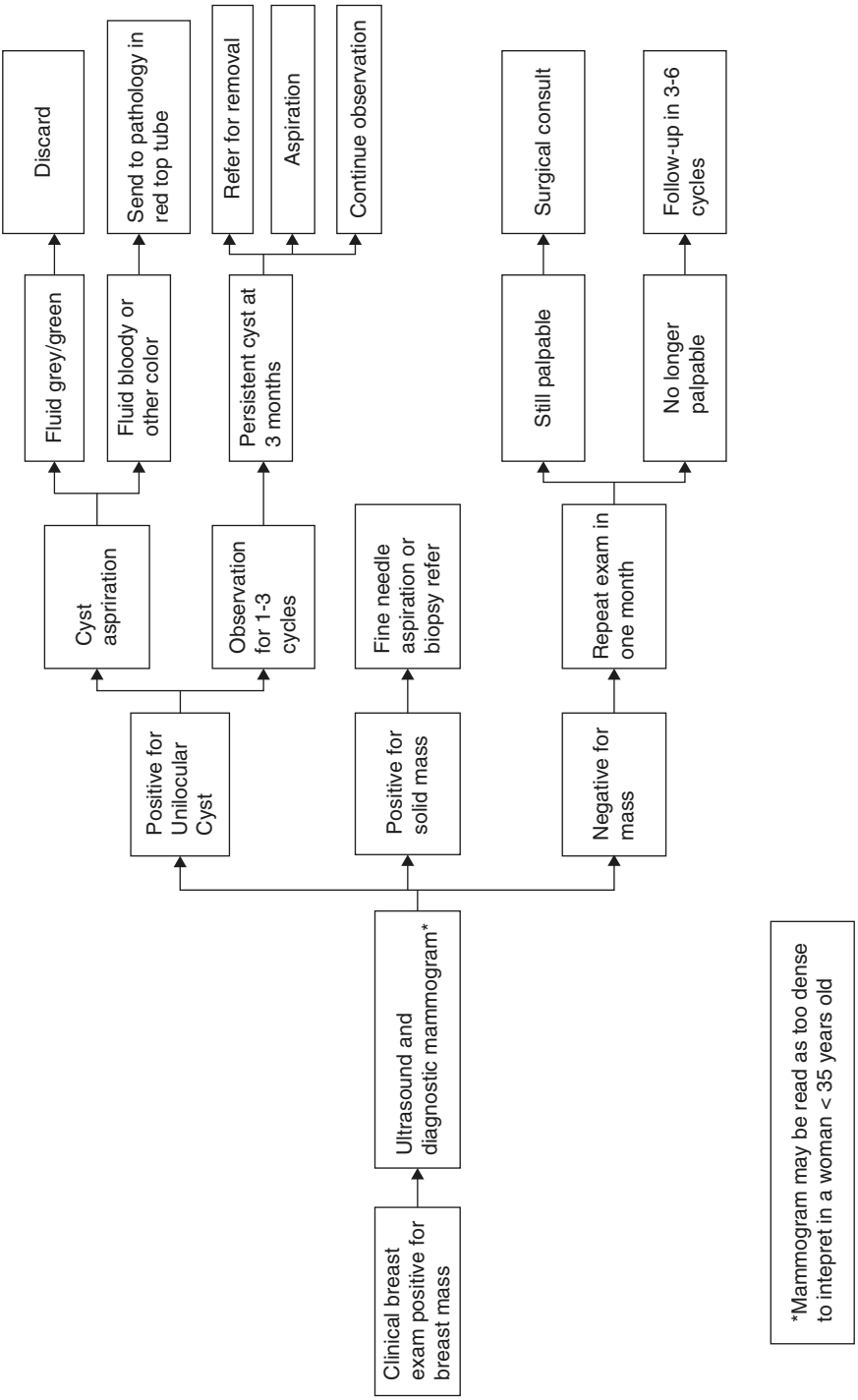
Uncomfortable breast mass documented to be cystic by ultrasound.

Contraindications

- Previous history of breast cancer
- Mass lying too close to the chest wall
- Ultrasound shows noncystic lesion or a complex cyst

Equipment (Fig. 20.1)

- A 5–10 cc syringe (Fig. 20.2a) or butterfly needle with tubing attached to a syringe (Fig. 20.2b)
- 23 G or 25 G needle or butterfly with tubing (Fig. 20.2a, b)



Algorithm 20.1 Decision tree for breast mass aspiration and/or FNA

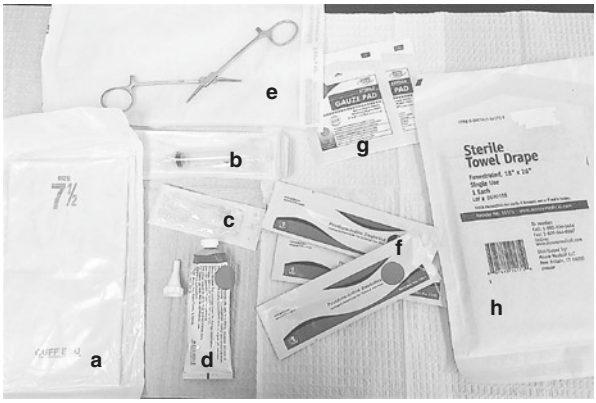


Fig. 20.1 Tray setup for breast cyst aspiration. (**a**) Sterile gloves; (**b**) 5 cc Luer lock syringe (**c**) 23 gauge 1.5 in. needle; (**d**) topical anesthetic cream; (**e**) straight hemostat; (**f**) povidone-iodine swabsticks; (**g**) 2 × 2 in. gauze pads; (**h**) fenestrated sterile drape

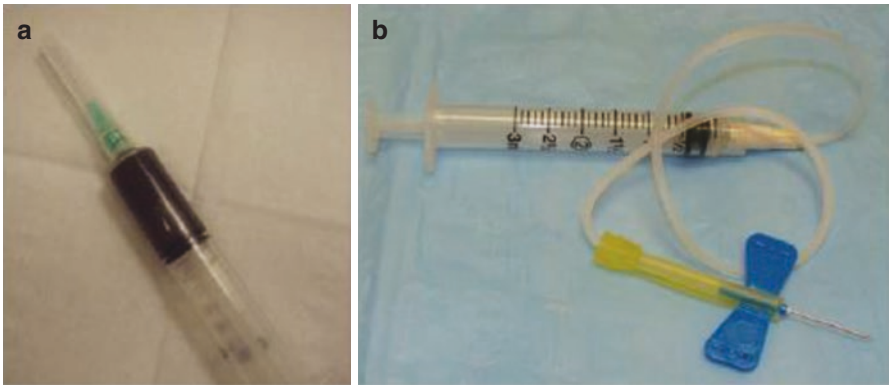


Fig. 20.2 (**a**) Syringe and needle, this one with gray-green fluid from breast cyst. (**b**) Butterfly with tubing

- Hemostat
- Antiseptic solution, such as povidone-iodine swabsticks
- Ultrasound, if available
- Surface anesthetic cream, spray freezant (i.e., ethyl glycol)
- Bandage
- 2 × 2 gauze pads (for use for pressure under bandage if needed)
- Gloves

Procedure

Breast Cyst Aspiration

1. Clean the area with antiseptic solution three times in an outward circular fashion.

2. Apply topical anesthesia or ethyl chloride. If applying EMLA™, you must wait for 40 min prior to doing the procedure. Local anesthesia may be used instead but may distort architecture.
3. "Juice" the syringe (slide it back and forth a couple of times to ease aspiration later) and then leave 0.1–0.2 cc of air to the syringe prior to insertion. Put needle on the end of the syringe.
4. Using gloves on both hands, grasp breast mass in the nondominant hand, cupping the mass within fingertips and applying some tension to remove it from the chest wall (Fig. 20.3). Alternatively, some practitioners capture the lesion between the second and third finger of the nondominant hand and pin the lesion above one of the patient's ribs (Fig. 20.4).
5. If ultrasound is available, ask an assistant to place the ultrasound lateral to the lesion, aiming toward the lesion.
6. Hold the syringe like a pencil during insertion, keeping the needle bevel up.
7. After insertion into the lesion, apply suction. This can be accomplished by placing the thumb under the plunger or inching one's fingers up the syringe to the plunger. Alternatively, you can have an associate withdraw the plunger to create the suction. With a pistol grip syringe holder, the syringe is held by the handle, with suction being applied after insertion by pulling back on the handle (Fig. 20.5).
8. Milk the mass (gently squeeze; Fig. 20.5) until it is totally gone. If there is too much fluid for the selected syringe, use the hemostat to twist the needle off the syringe, remove the fluid, and reinsert syringe onto needle again. It is not necessary to remove the needle from the patient.
9. When the mass is gone, stop applying suction and remove the needle. There is usually minimal bleeding involved. Apply pressure with the 2 × 2 gauze and then apply the bandage, if needed.

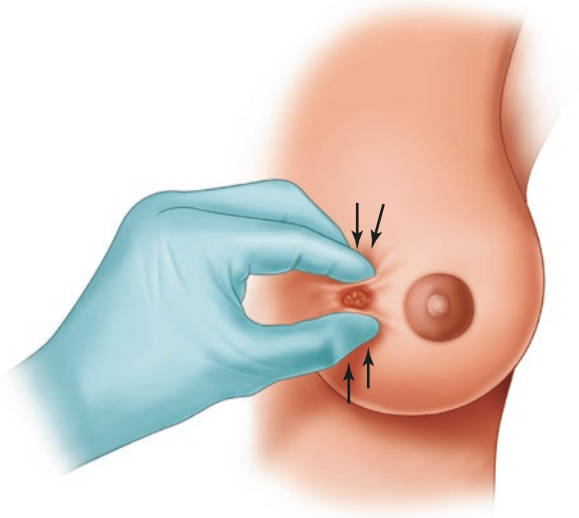


Fig. 20.3 Cupping lesion between the first and the second finger of the nondominant hand

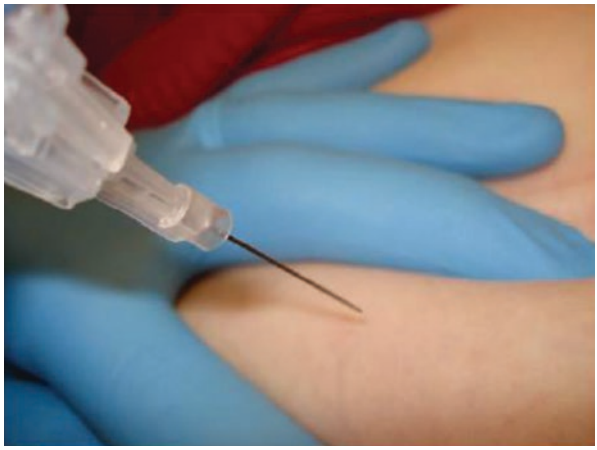


Fig. 20.4 Breast mass localization with the nondominant hand

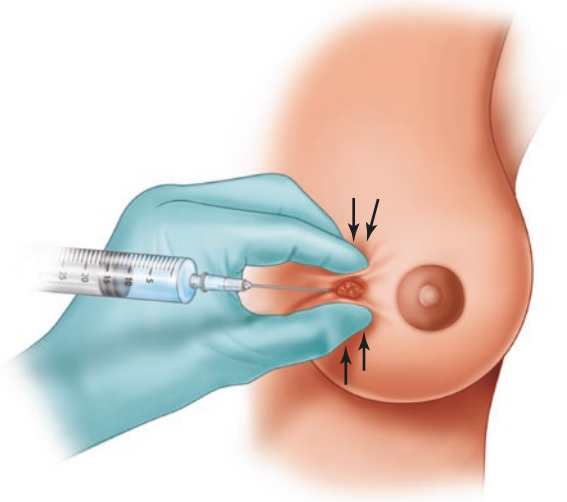


Fig. 20.5 Aspiration and "milking" of breast cyst

10. If the fluid is a clear, yellow, or grayish-green color (Fig. 20.2a), it is not necessary to send to the lab. If there is any blood or if the fluid is any other color, put the fluid into the red top tube for transport [3, 4]. Use as many red top tubes as necessary to send fluid.
11. If available, use the ultrasound to document that the cyst is gone.
12. Document whether the mass is entirely gone or still present. If still present, refer for further workup [4]

If the mass is solid and nothing is coming through the needle, follow the steps for fine needle aspiration.

Complications and Risks

- Pneumothorax (rare)
- Bleeding (rare)
- Infection
- Further workup if mass is not totally gone with aspiration

Tricks and Helpful Hints

- *Do not* let go of the mass or allow your associate to hold the mass while attempting to aspirate. This increases the likelihood of inadvertently causing a needle stick to yourself or your assistant.
- "Juice" the syringe by sliding the barrel up and down several times within the syringe prior to using on the patient. This facilitates easier withdrawal of the plunger during the aspiration.
- If possible, avoid the use of injectable anesthesia, as it distorts the skin above the mass and may make the mass more difficult to palpate. If necessary for patient comfort, consider using ethyl chloride or EMLA™.

Interpretation of Results (Algorithm 20.1)

- Gray-green fluid from a breast cyst is considered benign and can be discarded.
- Any bloody fluid should be sent to pathology for evaluation.
- Any solid lesion should be referred for surgical or interventional radiology consultation.

Procedure Note

(Provider to fill in blanks/circle applicable choice when given multiple choices and customize as needed.)

Breast Cyst Aspiration

Risks, benefits, and complications of breast mass evaluation discussed alternative providers of the procedure discussed; consent signed. Patient placed in supine position; mass localized. (Topical anesthetic applied.) Area prepped and draped in a

sterile fashion. Mass located and held with nondominant hand; breast mass aspirated with a 25 gauge needle on a 10 cc syringe. _____ccs of fluid obtained with complete resolution of breast cyst. Bandage applied. Patient tolerated procedure well.

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
88170	Breast mass evaluation and recommendations for breast cancer screening
19000	Aspiration and drainage of one breast cyst
19001	Aspiration and drainage of breast cyst – each additional
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 10th Revision, Clinical Modification, Centers for Disease Control and Prevention)	
N60	Benign mammary dysplasia N60.0 Solitary cyst of the breast N60.01 solitary cyst of the right breast N60.02 Solitary cyst of the left breast N 60.09 solitary cyst of unspecified breast N60.1 Diffuse cystic mastopathy N 60.11 diffuse cystic mastopathy of the right breast N 60.12 diffuse cystic mastopathy of the left breast N 60.19 diffuse cystic mastopathy of unspecified breast

Case Study Outcome

Breast cyst successfully aspirated in the office under local anesthesia. Gray-green fluid obtained and mass completely resolved. No recurrence when reexamined in 1 month.

Patient Handout

(Provider to customize as needed.)

Breast cyst aspiration is an office procedure that involves putting a needle into the cyst and removing all the fluid. If you choose to have this done, plan on taking three 200 mg ibuprofen 1 hour before coming to the office. The area will be cleaned

with an antibacterial disinfectant. The clinician will insert a needle to remove the fluid. After the procedure is done, a bandage will be applied.

Call your clinician's office if you are experiencing any warmth, swelling, bleeding, or shortness of breath after the procedure. Please make a follow-up appointment in 2 weeks to reevaluate your mass and discuss the results.

Questions for Learners

- Should the term be "fibrocystic disease" or "fibrocystic changes"?
- If a solid mass is found on exam and with mammogram and ultrasound workup, what are the next recommended steps?

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Additional Resources

Articles

Lucas JH, Cone DL. Breast cyst aspiration. Am Fam Physician. 2003;68(10):1983–6.
Marchant DJ. Benign breast disease. Obstet Gynecol Clin N Am. 2002;29(1):1–20.

Equipment

Cameco pistol syringe holder syringe: http://www.belpro.ca/cameco.htm.
Tao pencil grip syringe holder: http://www.taoaspirator.com/.

Chapter 21
Vulvar Skin Punch Biopsy

Matthew L. Picone

Introduction

Vulvar lesions consist of a wide array of benign, premalignant, and malignant lesions that involve the vulva (Fig. 21.1). The decision to biopsy is determined by many factors including the time course of the lesion, uncertainty of diagnosis, symmetry of the lesion, irregularity of the borders, bleeding tendencies of the lesion, family history of vulvar malignancy, and patient concerns. All of these factors independently play a role in the decision to biopsy.

Cancer of the vulva is statistically the fourth most common gynecologic malignancy (following cancer of the endometrium, ovary, and cervix) and comprises 5% of malignancies of the female genital tract [1]. Vulvar carcinoma presents most commonly in the postmenopausal female. Risk factors include cigarette smoking, history of lichen sclerosis or any vulvar dystrophy, cervical cancer, immunodeficiency syndromes, and human papillomavirus (HPV).

As always, a thorough history (before patient undresses) and complete gynecologic exam are necessary to make the diagnosis and to determine the appropriate treatment plan. Hygiene habits and personal care products used (including detergents, fabric softeners, soaps, feminine hygiene sprays, sanitary napkins, and habits of douching) should be evaluated. Soaps, shaving products, hair removal techniques, and spermicides are all irritants that cause a number of dermatoses in the vulvar area. Hormonal status can be determined based on the physical exam of the vulva to assess for hypoestrogenism. A discussion of the potential "home cures" that the patient has tried should be explored, as these remedies can often make visual diagnosis difficult. Finally, patient concerns for cancer should be elicited.

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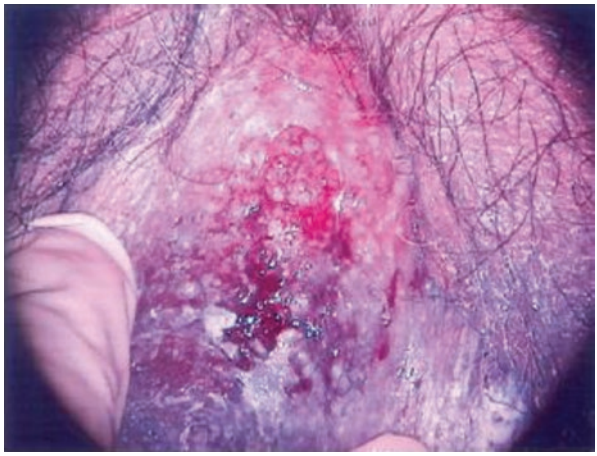


Fig. 21.1 Paget's skin lesion of the vulva

Often asymptomatic, vulvar lesions present in a variety of ways to the physician. Pruritis is usually the most common symptom complaint. Physicians are often the first to see these lesions and bring them to the patient's attention.

Case Study

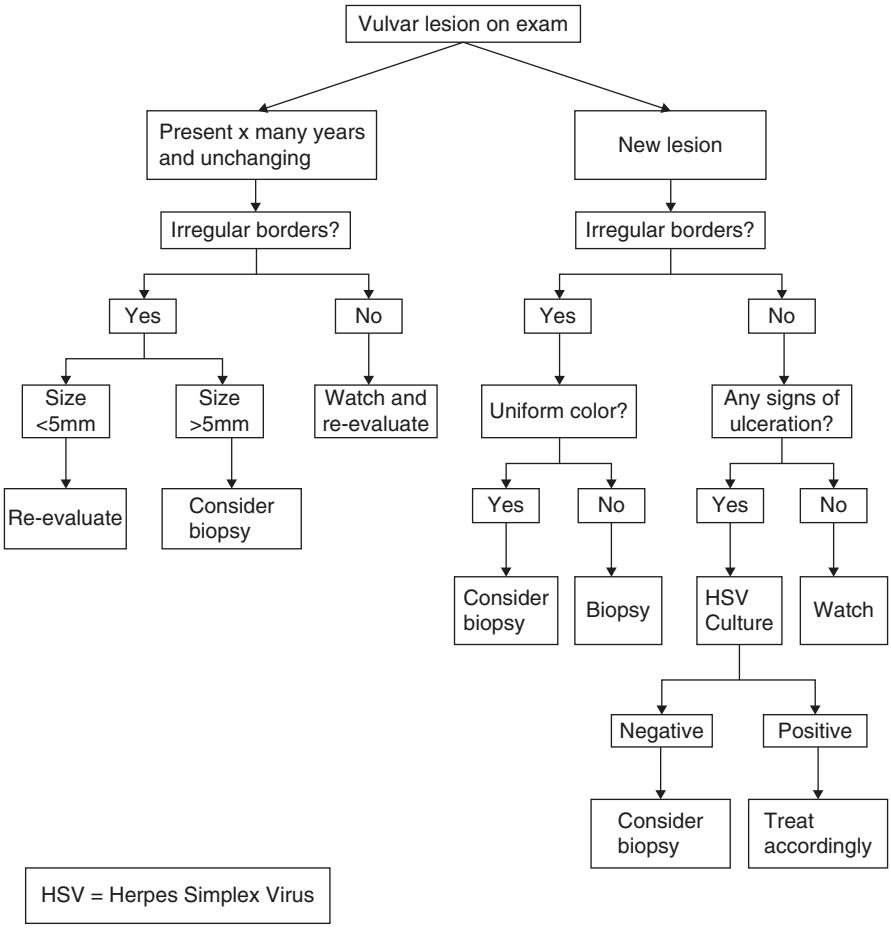
A 65-year-old presents to your office for her annual physical exam and Pap smear. Review of systems reveals that the patient has been postmenopausal for the past 13 years with no history of hormone replacement therapy. During the physical exam, an irregularly shaped, nonulcerated, raised, flesh-toned plaque measuring approximately 1.5 × 1.5 cm in diameter is noted. Patient was unaware that the lesion was present. Biopsy was suggested based upon the uncertainty of diagnosis.

Diagnosis

Vulvar lesion, Not Otherwise Specified (NOS).

Differential Diagnosis [2, 3] (Algorithm 20.1)

- Vulvar intraepithelial neoplasia
- Cancer: most common is squamous cell carcinoma
- Condyloma Acumulata: genital warts
- Lichen sclerosis



Algorithm 20.1 Decision tree for vulvar skin lesion

- Vestibular papillae
- Acrochordon: skin tags
- Cysts: bartholin, pilonidal, dermoid, and mucus cysts
- Molluscum contagiosum: immunosuppressed disorders
- Hyperkeratosis or lichen simplex: white patches
- Vitiligo: depigmenting autoimmune disorder
- Acanthosis nigricans: pigmented macules/plaques
- Junctional nevi: common
- Seborrheic keratosis
- Dermatofibroma
- Extramammary breast: found along the nipple line
- Fox-Fordyce disease

- Kaposi's sarcoma: immunodeficiency syndromes
- Dysplastic nevi
- Melanoma: family history sometimes present
- Dermatitis: chemical or allergic
- Psoriasis
- Infection

Indications

Diagnostic.

Contraindications

- Bleeding or coagulation disorders
- Uncooperative patient

Equipment (Fig. 21.2)

Nonsterile tray for anesthesia:

- Nonsterile gloves
- 4 × 4 inch gauze pads
- 3-cc syringe filled with 1% lidocaine with epinephrine and 25–27-gauge needle
- Labeled formalin container(s) for the number of biopsies

Sterile tray for the procedure:

- Sterile gloves
- Desired punch biopsy instrument (2–6 mm)
- Scalpel with blade if preferred
- Needle holder for suturing if needed
- Desired size of suture usually 4-0 or 5-0 nylon
- Iris scissors
- Small-gauge needle

Procedure

1. Sign consent for the procedure.

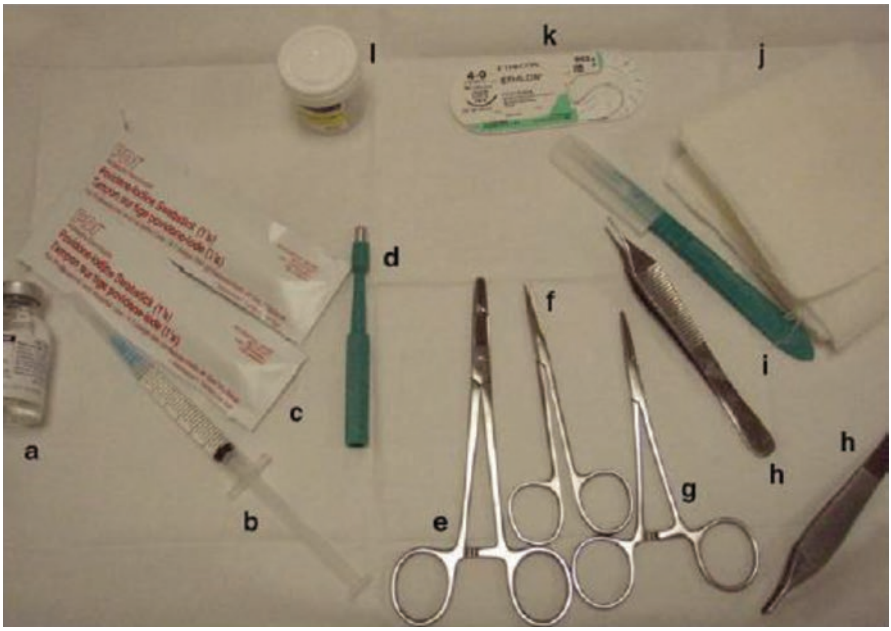


Fig. 21.2 Equipment tray for vulvar skin biopsy. (**a**) Lidocaine; (**b**) 1% lidocaine in 5 cc syringe; (**c**) PDI® povidone-iodine swabsticks (Orangeburg, NY); (**d**) punch biopsy; (**e**) needle driver/holder; (**f**) fine scissors; (**g**) hemostat; (**h**) needle nose pick-ups; (**i**) scalpel; (**j**) gauze; (**k**) Ethilon™ 4–0 Nylon Absorbable Suture. (Ethicon Inc., West Somerville, NJ); (**l**) formalin specimen container

2. Clean the skin with povidine–iodine solution after determining the selection of site.
3. Pick the site for biopsy at the center of the lesion and not at the periphery – be sure to include 1–2 mm of normal skin for analysis [4] (Fig. 21.3).
4. Use generous local anesthesia to surround the lesion. Allow 3–5 min for anesthesia to be fully absorbed.
5. Identify the lines of least skin tension (the lines vertical to the vulva).
6. Stretch the skin around the site perpendicular to the skin lines with the opposite hand (Fig. 21.4a).
7. Hold the punch biopsy vertical to the skin and rotate downward between the first and second fingers in a clockwise and counterclockwise fashion, penetrating the dermis and subcutaneous tissues.
8. Lift the lesion with a small-gauge needle and cut the base with iris scissors, and place in formalin. Properly label the specimen and send to pathology with identification of biopsy, any pertinent history, and presumed diagnosis (Fig. 21.4b).
9. Place sutures perpendicular to the tension lines for the vulva that were identified earlier using 4-5.0 nylon suture.

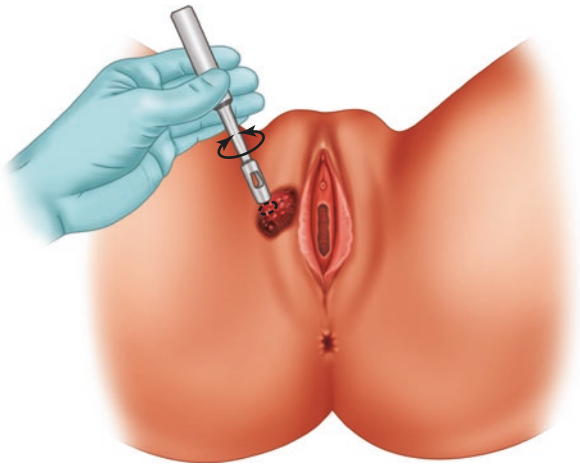


Fig. 21.3 Identify the vulvar lesion and perform biopsy in the center of the lesion

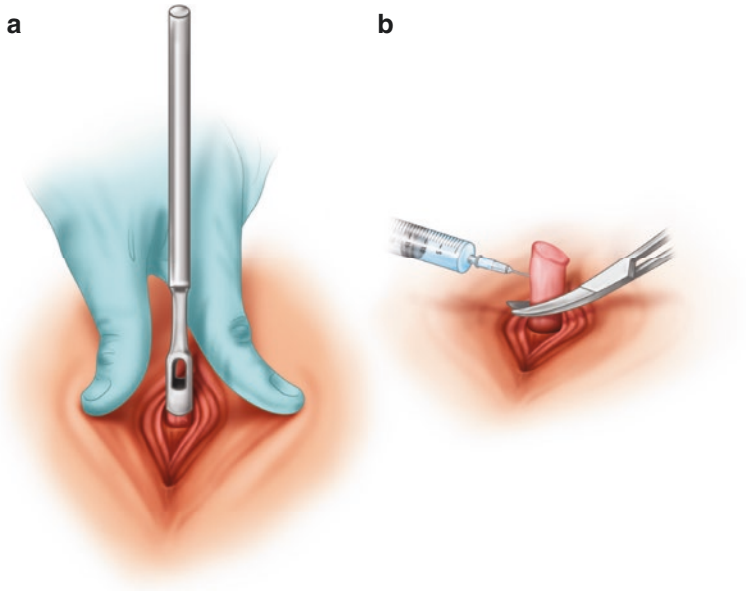


Fig. 21.4 (**a**) Stretch the skin at the biopsy site perpendicular to the skin lines with the non-dominant hand. (**b**) Lift the punch biopsy with a needle and cut the base to avoid crushing the tissue

10. Apply antibiotic ointment and a bandage.
11. If preferred, the entire lesion can be removed. Follow the steps previously delineated. Once the area is anesthetized, make a fusiform incision with the scalpel that encompasses the entire lesion. The blade should be pressed firmly to penetrate the entire thickness of the dermis.

12. Grasp the corner of the incision with a pair of forceps and cut the lesion free with the scalpel or iris scissors.
13. Close the incision as above.

Complications and Risks

- Bleeding
- Recurrence
- Scarring/Keloids
- Infection: rare
- Pain

Tricks and Helpful Hints

- Use a small-gauge needle instead of forceps to avoid crushing the lesion and interfering with pathology interpretation.
- If 6 mm punch is required, it may be better to perform a fusiform incisional removal.
- Consider delaying submission for payment until pathology returns, as payment is based on pathology results.
- Consider applying EMLA® cream, a eutectic mixture of lidocaine 2.5%, and prilocaine 2.5% one hour prior to procedure to decrease pain as an alternative or an adjunct to intradermal local anesthesia

Interpretation of Results

Treatment is determined by the final pathology. If cancerous, then referral to specialist is indicated. See Algorithm 20.1.

Procedure Note

(Provider to customize as needed.)

The patient was placed in the lithotomy position. The area was cleansed, and sterile technique was utilized. After local anesthesia was administered, a 4 mm punch biopsy to the region of concern was performed. The lesion was placed in formalin and sent to pathology. Hemostasis and closure of the wound was obtained by placing two 5-0 interrupted sutures. The patient tolerated the procedure well and will return in 10 days for pathology report and suture removal.

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
56605	Biopsy of vulva or perineum [one lesion]
56606	Biopsy of each additional vulvar or perineal lesion
ICD-10 CM 10th Revision (International Classification of Diseases, 10th Revision, Clinical Modification, Center for Disease Control and Prevention)	
N 90.0	Mild vulvar dysplasia
N 90.1	Moderate vulvar dysplasia
N 90.3	Vulvar dysplasia
N 90.4	Leukoplakia of the vulva
N 90.5	Atrophy of the vulva
N90.9	Noninflammatory lesion of vulva
N90.3	Vulvar dysplasia moderate
D 07.1	Vulvar intraepithelial neoplasia (VIN) III
L98.9	Skin tag
D28.0	Benign vulvar neoplasm
A63.0	Condyloma acumulata

Postprocedure Patient Instructions

- Instruct the patient to keep the bandage in place for the next 24–36 hours followed by air drying the area and keeping it clean and dry until the follow-up appointment.
- Have the patient call the office for signs of infection, pain, redness, fever, discharge, or wound opening.
- Tell the patient to return to the office in 10 days for suture removal and pathology report.

Case Study Outcome

The biopsy was successfully obtained and sutures were removed 10 days post biopsy with excellent approximation of the site. Pathology report revealed a vulvar intraepithelial neoplasm (VIN) 3. The patient was referred to a specialist for complete excision. She will follow up 2 months after surgery has been performed.

Patient Handout

(Provider to customize as needed.)

A vulvar biopsy is a procedure done to take a small piece of an abnormal area that is found on the vulva, which many call "the lips." The procedure is done in the office to help determine or clarify what type of growth is present.

You may want to take Tylenol (650 mg) or Ibuprofen (600 mg) 1 hour prior to the visit for some mild discomfort that may occur. There will be a local anesthesia given to the area before a biopsy is performed; this may cause mild pain and possibly burning. After the area is numb, you may experience nothing at all or a pressure sensation.

After the procedure is performed, the lesion will be sent out to a lab that will help us determine the cause of the abnormal growth. At the follow-up visit, we will have the report and will discuss any future treatment plans.

There is a small risk for bleeding, infection, and possibly excessive scar formation or discoloration that persists at the biopsy site. You should call the office if signs of infection should occur, such as redness, swelling, increased pain, or discharges from the biopsy site.

Questions for Learners

- Under what circumstances would you choose to biopsy a lesion of the vulva as opposed to watchful waiting?
- What common skin diseases can occur in the vulva?

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Chapter 22
Treatment of Genital Warts

Cathryn B. Heath

Introduction

Genital warts caused by Human Papilloma Virus (HPV) are the most common sexually transmitted disease in the United States. Prevalence of genital infection with any HPV type was 42.5% among United States adults aged 18–59 years during 2013–2014 [1]. High-risk genital HPV prevalence was 22.7% in the total population, with 20.4% among women [1]. An increased prevalence in progression to cervical cancer has been correlated with cigarette smoking, earlier onset of sexual activity, multiple sex partners, immunosuppression (HIV or high-dose steroid use), lack of cervical cancer screening, cigarette smoking, three or more pregnancies, and long-term use of contraceptives [2]. There are currently 150 known types of HPV virus.

Genital warts are soft, moist, fleshy colored lesions on the genital area. Warts can also be flat, cauliflower-like, papular or rounded, keratotic with a thick horny surface, multiple or single lesions on the labia, vulva, vagina, cervix, penis, scrotum, glans, urethra, perianal area, oropharynx, or rectum. There is a broad spectrum of disease presentation ranging from asymptomatic external lesions to invasive carcinoma. Lesions may appear within weeks or months of initial contact. Two-thirds of individuals who have had sexual contact with a partner with genital warts will develop lesions within 3 months. In the anogenital area, warts, dysplasia, and carcinoma are all indistinguishable. There should be a higher index of suspicion for advanced lesions in patients older than 40, immunocompromised patients, women with lesions refractory to treatment, and patients with any large atypical appearing lesions. A biopsy should be performed whenever the clinician is unsure of the diagnosis or when lesions do not respond to treatment.

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The expression of anogenital warts varies considerably, although most individuals have a subclinical infection that is cleared spontaneously by the host immune response. Anogenital HPV types are divided based on their oncogenic response into low- and high-risk types. Almost all cervical cancers and 50–80% of vulvar, vaginal, and anal carcinomas are due to high-risk types of HPV. Over 90% of genital warts, however, are due to the low-risk oncogenic types 6 and 11 and do not become cancerous. However, individuals who have one type of HPV may harbor other types of HPV and other types of sexually transmitted infections (STIs); therefore, it is important to perform a Pap smear and STI screening on all women with genital warts.

Genital warts develop anywhere in the anogenital tract or oropharynx. Many warts are asymptomatic and are found only on physical examination; however, symptoms may include burning, anogenital pruritis, vaginal discharge, bleeding, and, rarely, dyspareunia. The vulva is the most common site for genital warts in women. Most warts are visible with the naked eye, but a magnifying glass or colposcope can aid in identifying additional or smaller lesions.

Prevention

In 2006, the HPV vaccine Gardasil® (Merck & Co., Inc., Whitehouse Station, NJ) became available to immunize women against HPV types 6, 11, 16, and 18. Types 6 and 11 are responsible for most anogenital warts, and types 16 and 18 account for over 80% of cervical cancer types worldwide. In the phase III trial of this medication, the rate of vulvar, vaginal, and anogenital lesions of the vaccinated population decreased by a rate of 34%, while the rate of cervical lesions decreased by 20% [3]. Vaccination has been approved in women and men aged 9–26 years and is considered most effective prior to exposure to the HPV virus. The vaccine requires a series of two immunizations if given from 9 to 14 years of age, with an interval of 6–12 months between the immunizations. Immunizations initiated after 14 years of age require three immunizations, and are given at the interval of 2 months after initial vaccine and then 6 months after first vaccination [4]. Gardasil-9 (Merck) covers 9 subtypes of HPV virus, including 6, 11, 16, 18, 31, 45, 52, and 58. Within 6 years of vaccine introduction, there was a 64% decrease in 4vHPV type prevalence among females aged 14–19 years and a 34% decrease among those aged 20–24 years [5].

Treatments

A variety of treatments exist for anogenital warts, both patient-administered (podofilox, 5% imiquimod cream, and 15% sinecatechins) and provider-administered (podophyllin resin, trichloroacetic acid (TCA), cryotherapy, laser vaporization, or

intralesional interferon [6]). Patient preference and affordability are important in choosing a regimen for each patient. There are no treatments that are 100% effective, recurrence is common, and up to 70% of patients have been treated more than once for their warts. A number of therapies are contraindicated in pregnancy, and therefore the patient's pregnancy status and method of contraception must also be considered.

The patient-administered therapies allow for privacy of treatment, which helps reduce the psychological discomfort and stress associated with this condition. Available treatments have been 0.5% podofilox (Condolox® Gel, Corona, CA) and 5% imiquimod cream (Aldara™, 3 M Company, St. Paul, MN) and sinecatechin (Veregen®, MediGene, Germany). For women who prefer treatment in an office setting, podofilox is an antimitotic agent that works by arresting the formation of the mitotic spindle in metaphase, preventing cell division. Podophyllin resin (10–25%, less stable formulation than podofilox) is available in tincture of benzoin. With podofilox and podophyllin resin, the surface area treated must not exceed 10 cm^2 and no more than 0.5 cc should be used at any one application [7]. Clearance rates vary from 45% to 88%, with recurrences common. Podofilox and podophyllin resin should not be used during pregnancy and cannot be used in the vagina or rectum.

Five percent topical imiquimod (Aldara®) cream is a local immune modulator that induces interferon and cytokine release, stimulating both innate and cell-mediated immune responses. The cream is applied to the individual lesions three times per week for up to 12–16 weeks. A small amount of cream is used at each treatment, and a single sachet packet can cover most areas effectively. Local erythema and some swelling are the most common side effects and are reported in over 50% of patients. Clearance rates range from 72% to 84% in women with higher clearance rates reported in women compared to men. Up to 81% of patients report at least a reduction in the wart area if not completely resolved. Recurrence rates are reported from 5% to 19%, which is less than rates reported by cytodestructive methods. Imiquimod is category B and is safe for use in pregnancy, although its safety has not been firmly established.

Veregan, an ointment derived from a water extract of green tea, was approved by the Federal Drug Administration (FDA) in late 2007 for use on external and perianal warts. Sinecatechins ointment (Veregen®) is composed of eight catechins, which may act to inhibit proinflammatory enzymes and proteases found in HPV. It is approved for immunocompetent patients above the age of 18. In the phase III trials of the medication, 56.8% of women cleared the virus versus 34.1% of the placebo patients. Men had a clearance rate of 60.1% versus 40.5% who cleared with placebo [8]. The most common side effects of the ointment were redness (70%), itching (69%), burning (67%), pain (56%), and erosions/ulcerations (49%) [9]. Sexual contact needs to be avoided while undergoing treatment. In addition, sinecatechin ointment was found to weaken condoms and diaphragms; use of these contraceptives with Veregen® is not recommended. Sinecatechin ointment is pregnancy category C.

The provider-administered treatment modalities depend on expertise and equipment availability of the provider. Chemical agents that can be applied in the provider office include podofilox, podophyllin resin, and trichloroacetic acid (TCA). Bichloroacetic acid is no longer available.

TCA is used in concentrations of 80–90% and can be used on both skin and mucosal surfaces. They are not systemically absorbed and can be used during pregnancy. Application causes burning and this is reduced by applying petroleum jelly to the surrounding skin before application of the acid. Multiple applications are usually necessary and clearance rates approach 80%. Recurrence rates are similar to other treatment modalities.

Cryotherapy can be used to treat genital warts. Both nitrous oxide and liquid nitrogen may be used. The freeze-thaw cycle with cryotherapy causes cell lysis and is cytodestructive. The ice ball should extend 2–3 mm past external lesions. Both nitrous oxide and liquid nitrogen can be used for anogenital and vulvar warts; however, cryotherapy of the cervix should be done only with nitrous oxide as liquid nitrogen is not cold enough to produce adequate freezing of the area. With weekly treatments until clear, approximately 90% resolve with recurrence rates up to 40%. Cryotherapy may be used safely during pregnancy.

Surgical removal of condyloma can be accomplished with scissors, scalpel, electrocautery, or loop excision. These methods are appropriate as first-line therapy for large or obstructing lesions. Excision with scissors or a scalpel is best for smaller lesions or when a biopsy is needed to rule out cancer or dysplasia. Clearance rates approach 70% with recurrence often at the surgical margins. Large condyloma are very vascular and may require a surgical setting where bleeding can be easily controlled and better anesthesia can be used.

Laser vaporization can also be used for treatment although this requires extensive expertise of the provider and costly equipment. Clearance rates approach 87% with recurrence rates also at the margins of approximately 50%. Laser is especially effective in the vagina and for extensive eternal genital and perianal warts. Intralesional interferon has also been used with success rates up to 60%; however, it is costly, is painful, and has multiple systemic side effects.

Due to the extensive recurrence rates with individual treatment modalities, combination therapies have been proposed, but there are no established guidelines for their use.

Case Study

A 25-year-old G0P0 presents for a well woman's examination. During the course of the history, she relates that she has been sexually active with one partner having just started a relationship within the last 3 months. She wants to be checked for sexually transmitted diseases and notes that she has noticed some "bumps" on her genital area in the last month. On physical examination, five lesions are found scattered on the patient's introitus. She was never immunized for HPV.

Differential Diagnosis (Algorithm 21.1)

- Microglandular papillomatosis (normal papillary tissue in the vestibule of the female single base for each projection versus multiple projections with papilloma)
- Hymenal remnants
- Condyloma lata
- Bowenoid papulosis
- Buschke-Lowenstein tumors
- Nevi
- Seborrheic keratosis
- Molluscum contageosum
- Cancer

Indications (Algorithm 21.1)

- Noted lesions present on examination
- Symptomatic lesions
- Patient desire for treatment
- Lesions that obstruct the vaginal opening

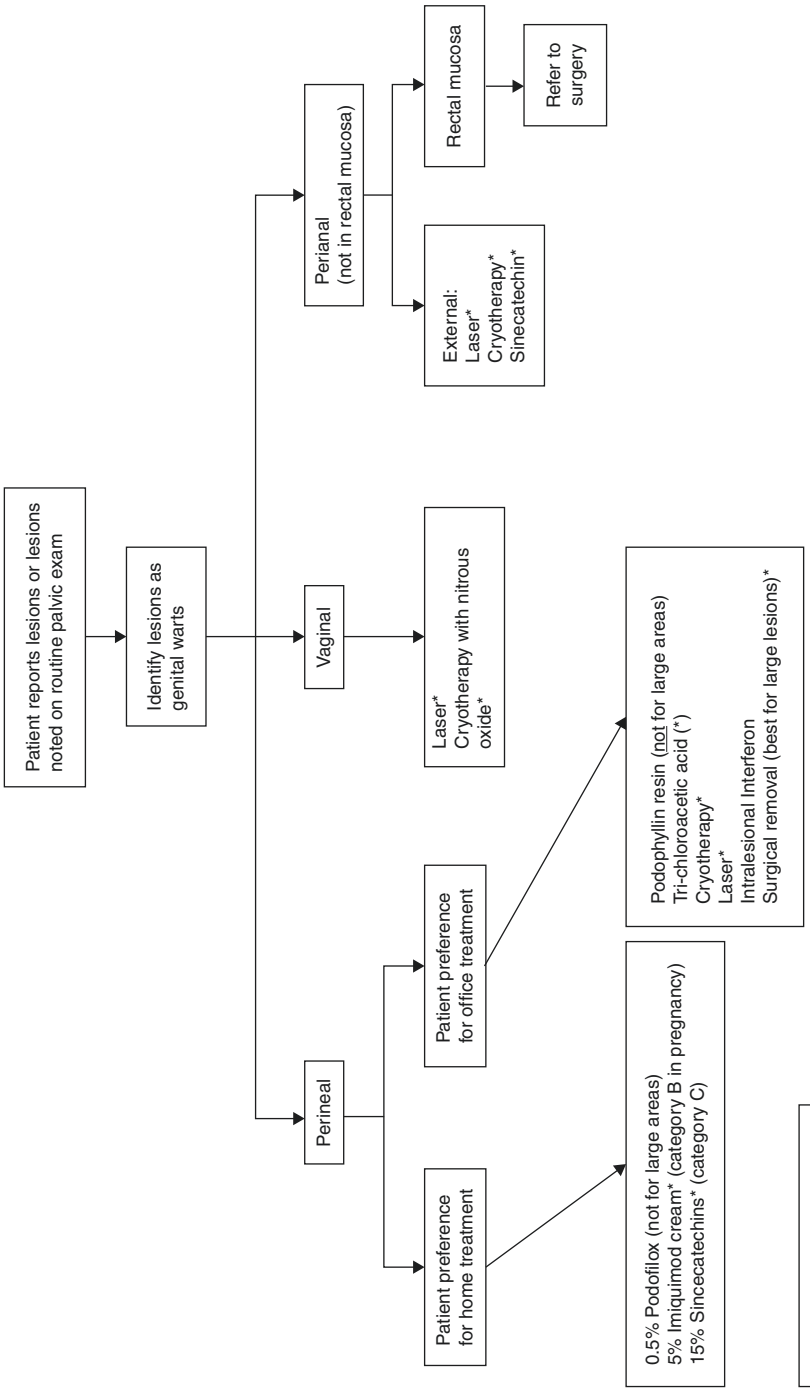
Contraindications (Algorithm 21.1)

- Some methods should not be used during pregnancy (podophyllotoxin, podophyllum resin, or imiquimod).
- Some methods are not for use with vaginal lesions (podophyllox, podophyllin).
- Lesions in rectal mucosa or in urethra should be referred to a specialist.

Equipment

Equipment is variable depending on method chosen:

- Cryotherapy: liquid nitrogen or nitrous oxide, water-based gel, cryoprobe, cotton-tipped applicator, or handheld cryogen
- Podophyllin: 10–25% podophyllin resin, pregnancy test, cotton-tipped applicator, and petroleum jelly
- TCA: TCA, cotton-tipped applicator, talc or baking soda, petroleum jelly
- Surgical excision: EMLA® (AstraZenaca, London, UK) or 1% xylocaine, iris scissors, scapel, electrocautery, or aluminum chloride solution



Algorithm 21.1 Decision tree for treatment of genital warts based on location

Procedure

Patient-Directed Methods (Suggest First Time Use in Office)

Podophyllotoxin 0.5 mg Solution or Gel

1. Gently wash and dry application area.
2. Apply with cotton swab or on finger directly on the lesion.
3. Apply twice daily for 3 days to each lesion; then do not apply for 4 days. Repeat this cycle up to four times.
4. Patient should wash hands after application.

Imiquimod 3.75% or 5% Cream

1. Gently wash and dry application area.
2. Rub cream on each lesion until cream is no longer visible.
3. Wash hands before and after application.
4. Remove all cream by washing the area 6–10 h posttreatment.
5. When applying 5% cream, apply a thin layer over each lesion on alternate days, either according to a Monday, Wednesday, Friday regimen or a Tuesday, Thursday, Saturday regimen.
6. May be repeated for a total of four cycles.
7. When using imiquimod 3.75% cream, may apply daily for up to 8 weeks.

Sinecatechins 15% Ointment

1. Is approved for external genital and perianal warts in immunocompetent women and men 18 years or older.
2. Ointment should be applied after bathing or showering.
3. Hands should be washed prior to and after application.
4. Up to 250 mg per application applied topically three times a day (TID).
5. Itching and burning frequently occur; continuation of application until side effects are intolerable or until warts disappear is recommended.
6. Applied up to 16 weeks or until complete clearance of warts.
7. Medication to be refrigerated or kept up to 77 °F.

Physician-Directed Methods

Cryotherapy

1. Place patient in dorsal lithotomy position.

2. Cotton-tipped application or Cryoprobe method or Cryogun (Fig. 22.1).

Cotton-tipped application:

- Apply liquid nitrogen on lesion with large cotton-tipped applicator until ice ball extends 3 mm beyond perimeter of lesion.
- May need to exchange applicators, as liquid nitrogen will evaporate in less than 15 s.

Cryoprobe method or Cryogun (Fig. 22.1):

- Apply water-based gel solution to tip of cryoprobe.
- Put cryoprobe on wart and apply freezant until ice ball covers wart and 2–3 mm beyond wart, approximately 20 seconds.
- Consider "freeze–thaw–freeze" method on recalcitrant lesions.
- Consider application of podophyllum resin after treatment.
- Patients may return every 1–2 weeks for repeat treatment.

Podophyllum Resin: 10–25% Podophyllin

- Pregnancy test should be done prior to start of treatment.
- Apply petroleum jelly around each lesion to protect skin.
- Apply podophyllin with a small cotton-tipped applicator.
- Air dry.

Fig. 22.1 Setup for cryotherapy (e.g., Ultrafreeze™ Liquid Nitrogen Cryosurgical System, Wallach Surgical Devices, Orange, CT)

- Use no more than 0.5 ml of podophyllin in a 10 cm^2 area.
- Instruct patient to wash off in 1–4 h.
- May be reapplied weekly until lesion is gone.

TCA (Trichloroacetic Acid) (Fig. 22.2)

- Apply petroleum jelly around each lesion to protect skin.
- Apply TCA with small cotton-tipped applicator; need to apply with care as TCA is runny and can easily destroy surrounding tissue.
- Allow to air-dry. A whitish frost should appear on lesion after application.
- Apply talc or baking soda to absorb any remaining acid.
- May be reapplied weekly up to 6 weeks.

Laser Treatment

- Carbon dioxide laser can be used.
- Suggest local anesthetic, such as xylocaine 1% (injected) or topical EMLA® cream, be used prior to procedure.
- Surgeon to use mask during application as HPV virus is present in flume of smoke created by laser.

Surgical Removal

- Anesthetize patient with xylocaine 1% subcutaneously, or EMLA® cream to be applied topically 45 min prior to procedure.
- May use electrocautery or scalpel.

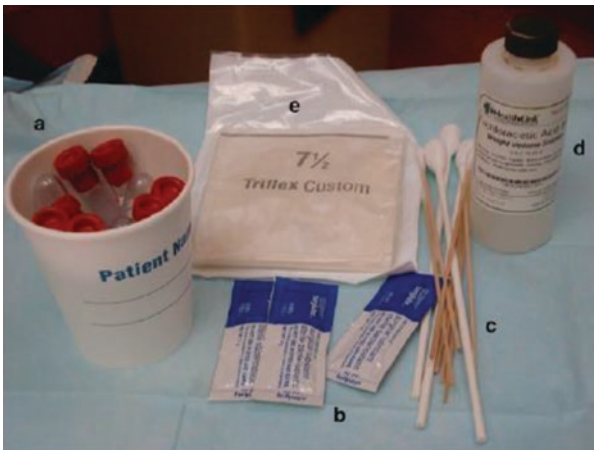


Fig. 22.2 Setup for trichloroacetic acid. (**a**) Small test tubes for acid solution; (**b**) Surgilube® (Fougera, Melville, NY) lubricant for protecting surrounding skin; (**c**) cotton-tipped applicators; (**d**) trichloroacetic acid (e.g., HealthLink®, Jacksonville, FL); (**e**) surgical nonlatex gloves

- Alternatively may use tangential scissors technique by cutting off exophytic lesion.
- May need electrocautery or aluminum chloride solution to create hemostasis.

Complications and Risks

- Erythema and pain at treatment site
- Blistering (uncommon)
- Severe side effects from absorption of podophyllin include:
  - Nausea
  - Vomiting
  - Renal failure
  - Fetal death

Tricks and Helpful Hints (Algorithm 21.1)

- Recommend patient takes a nonsteroidal anti-inflammatory drug (NSAID) 1 h prior to appointment time.
- Vaginal lesions: use laser, cryotherapy with cotton applicator only or TCA.
- Pregnancy: use cryotherapy, TCA, or surgical removal.
  - Important to minimize exposure of neonate to HPV lesions that may cause laryngopapillomatosis (risk 0.04%).
- Anal warts: use cryotherapy, TCA, or surgical removal.
  - If there are anal warts, check patient by anoscopy for rectal mucosal warts.
  - Do *not* treat warts in the rectal mucosa; these are best treated by a surgeon.
- Genital or anal lesions in prepubescent girls may be associated with sexual abuse.
- Persons with immunodeficiency may have particularly difficult warts to treat; Imiquimod may be most effective.
- Patients should be warned to be vigilant for the next 3 months and check for recurrence of warts.
- While most subtypes of external warts are low risk, patients should have a current Pap smear or one should be obtained at the time of treatment.
- For imiquimod: treatment can be stopped for several days and then restarted if a significant erythematous reaction occurs.
- For any self-applied creams or ointments: If a woman wishes to use tampons, it is recommended that she do so prior to application of antiviral topical medications.

- Cryoprobes should be avoided in the vagina and rectum as there is a higher risk of fistula formation in these areas secondary to the greater depth of freezing.
- For podoflox: Redness and itching may occur after use.
- Patients who have performed oral sex on a male partner are at risk for oropharyngeal warts, and need a thorough examination of the oropharynx. Consider referral to an Otolaryngologist for complete laryngeal evaluation.

Procedure Note (Depends on Treatment Used)

(Provider to fill in blanks/circle applicable choice when given multiple choices and customize as needed.)

Patient placed in dorsal lithotomy position. Petroleum jelly applied/Local anesthetic applied. _____method was used to treat _____number of condylomata. Patient instructed to wash off podophyllin/TCA within 6 h of treatment. Patient tolerated procedure well. Follow-up appointment for retreatment was made.

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
Per lesion: same coding is used for all treatments	
56501	Destruction vulvar lesions 1–5
17111 56515	Destruction vulvar lesion 6 or more
11420	Excision diameter of 0.5 cm or less
ICD 9-CM-Diagnostic Codes (International Classification of Diseases, 9th Revision, Clinical Modification, Center for Disease Control and Prevention)	
A63.0 O98.319	Genital warts due to HPV Genital warts complicating pregnancy

Postprocedure Patient Instructions

Patients should be instructed to wash off the podophyllin or TCA within 6 h of treatment. Some burning or swelling may be experienced and can be relieved with additional NSAIDs and a warm bath. They should be encouraged to have male partners use condoms while being treated for their genital warts. Partners should also be seen in a physician's office.

Case Study Outcome

Patient treated in the office with cryotherapy. Subsequent follow-up revealed no lesions.

Postprocedure Patient Handout

(Provider to customize as needed.)

You have just been treated for genital warts. Warts are caused by a highly infective virus. It is important that you refrain from having sexual relations until these lesions are gone as they commonly spread to sexual partners. Even skin-to-skin contact with the wart without actually having sex will spread external genital warts. It is especially important to avoid pregnancy while undergoing treatment for genital warts. Your partner should see a physician and be checked for genital warts as well.

A nonsteroidal antiinflammatory (ibuprofen or naproxen) can help with the pain of treatment 1 h prior to the treatment and the evening after the treatment. If you have been treated by a liquid, cream, or gel, be sure to follow the instructions regarding the timing for removal of the compound. If you have severe pain or swelling, be sure to wash the medication off immediately. Most lesions need to be rechecked by a physician. If your doctor treated you with cryotherapy or trichloroactetic acid (TCA), please make a follow-up appointment within 1–2 weeks for a recheck.

Questions for Learners

- Considering the efficacy of the HPV vaccination, what are some tactics that health providers can use to improve the acceptance of the vaccine?
- How do providers choose between a variety of treatments available for HPV?
- Since pap smears are not done for routine gynecologic care prior to age 21, what measures can a provider use to screen for the presence of genital warts?

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Chapter 23
Colposcopy

Stephen D. Hoag and Laurie Turenne-Kolpan

Introduction

Colposcopy is a procedure used to evaluate the abnormal Pap smear as well as to visualize abnormalities noted anywhere along the lower female reproductive tract. The colposcope is an illuminating instrument that enables the provider to examine the vulva, vagina, cervix, and anus under magnified view. The goal of colposcopy is to identify areas of abnormal epithelium and perform directed biopsies, which will allow for a histological evaluation of abnormal cytological results. This article will focus on colposcopy of the cervix and its guidelines.

The procedure is simple and can be performed in the outpatient office; however, recognition of the normal versus abnormal cervix requires a certain level of expertise. Practitioners performing colposcopy should be adequately trained. Such training can be found from a number of sources such as courses offered by the American Society for Colposcopy and Cervical Pathology (ASCCP), the American Academy of Family Physicians (AAFP), and the National Procedures Institute (NPI).

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Case Study

A 26-year-old female presents to your office for her annual exam and Papanicolaou (Pap) smear. She is sexually active and using oral contraceptives. She has never had a Pap smear and has no history of any sexually transmitted disease. She smokes one pack of cigarettes per day. Her exam is normal. Pap smear results return as low-grade squamous intraepithelial lesion (LSIL).

Diagnosis

Abnormal Pap Smear with LSIL.

Indications: See ASCCP Updated Consensus Guidelines

- Atypical squamous cell of undetermined significance (ASC-US) with HPV positive for high-risk types.
- Two or more ASC-US Pap smear results.
- Atypical squamous cells cannot rule out high-grade lesion (ASC–H).
- Low-grade squamous intraepithelial lesion (LSIL) with positive high-risk HPV.
- High-grade squamous intraepithelial lesion (HSIL).
- Atypical glandular cells of undetermined significance (AGC-US).
- History of intrauterine DES exposure.
- Suspicious lesion seen or palpated on exam.
- Leukoplakia.

Contraindications

- Pregnancy is only a contraindication for endocervical curettage (ECC); biopsies are performed for suspicion of cancer only.
- Heavy menses.
- Uncooperative patient.
- Active cervicitis.

Equipment (Fig. 23.1)

- Vaginal speculum (metal or plastic)
- Small and large cotton-tipped applicators

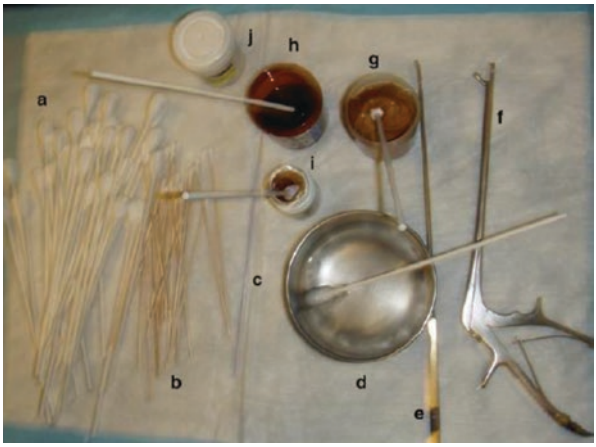


Fig. 23.1 Setup tray for colposcopy: (**a**) large cotton swab applicators; (**b**) small cotton swab applicators; (**c**) endocervical brush; (**d**) basin with acetic acid; (**e**) sterile endocervical curette; (**f**) sterile Kevorkian punch biopsy; (**g**) Monsel's solution; (**h**) Lugol's solution; (**i**) topical anesthetic; (**j**) Formalin specimen container

- 3–5% acetic acid (vinegar)
- Lugol's solution
- Specimen containers
- Kogan endocervical speculum
- Endocervical curette with or without basket
- Tischler or Kevorkian biopsy forceps
- Cervical hook
- Monsel's solution
- Silver nitrate sticks
- Toothpicks
- Papanicolaou smear supplies

Optional Equipment

Cytobrush with a straw, ring forceps, or long kelly, nonstick gauze pads cut into small squares to collect the specimen.

Procedure

1. Check a urine pregnancy test prior to procedure, and obtain surgical consent.
2. Place the patient in the dorsal lithotomy position.
3. Insert the speculum into the vagina and visualize the cervix under medium magnification (12–15×). Ensure the entire cervix can be visualized.
4. Wipe off excess mucus with large cotton swab and identify landmarks. The squamocolumnar junction is the area of delineation between squamous and columnar epithelium (Fig. 23.2). The active transformation zone is the area where prior

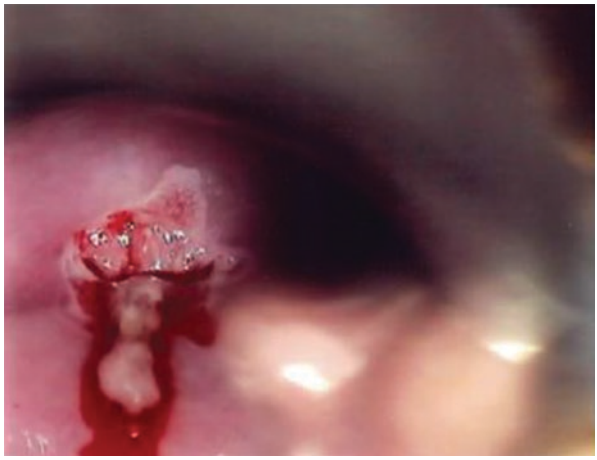


Fig. 23.2 Colposcopic view of squamocolumnar junction

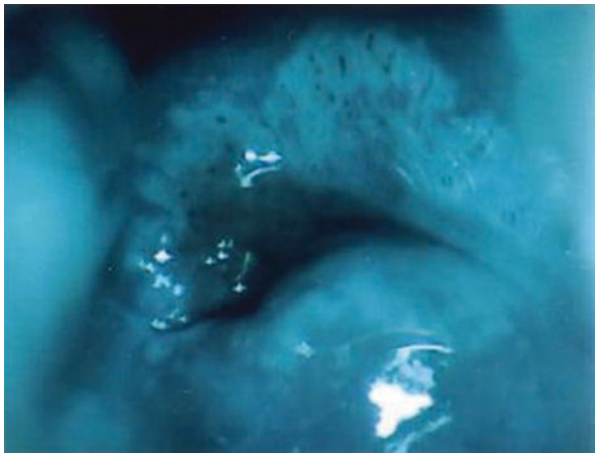


Fig. 23.3 Higher magnification view of cervix with green filter

columnar epithelium has been changed or is in the process of changing into squamous epithelium, and thus is the area where dysplasia is most likely to occur. Gland openings, crypts, or nabothian cysts are usually seen in this area. An adequate colposcopy requires that the entire transformation zone and squamocolumnar junction be seen.

5. Perform Pap smear if desired. Recent evidence shows this practice is rarely useful even if the first cytology was obtained by a conventional smear [1, 2].
6. Use the green filter and higher magnification (25–40×) to identify any abnormal vessels (Fig. 23.3).

   - Normal saline can be used with the green filter if preferred.
   - Abnormal vascular patterns include the presence of mosaicism, which is caused by vessels lying along the superficial area of the cervix forming a pattern similar to mosaic tiles (Fig. 23.4), punctation which is caused by vessels

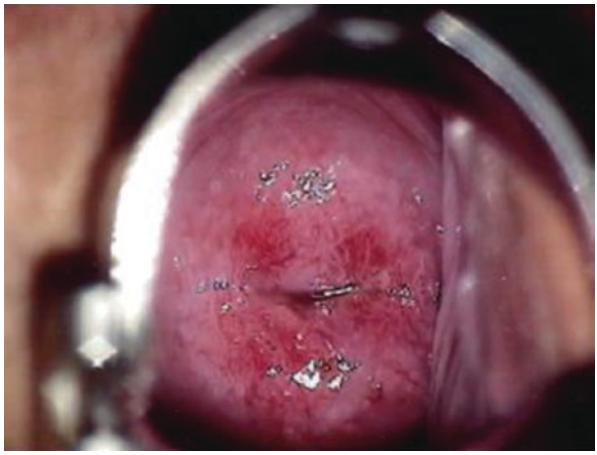


Fig. 23.4 Cervix with mosaic tile pattern

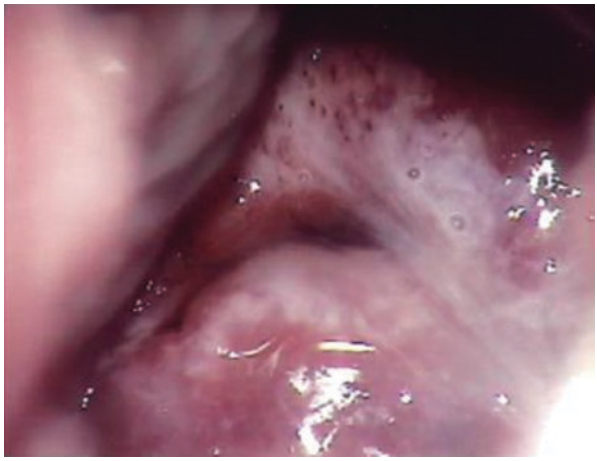


Fig. 23.5 Cervix with coarse punctation

lying perpendicular to the cervical surface and creates an appearance of the cervix being dotted with a red marker (Fig. 23.5), and atypical vessels, which are evidence of the presence of a blood vessel lying on top of the cervical surface (Fig. 23.6). The presence of larger or more coarse vessels in any of these vascular patterns is associated with higher-grade dysplasia.

7. Return to white light, medium magnification, and apply 3–5% acetic acid with large cotton swabs or cotton balls (Fig. 23.7)
   - These need to be held against cervix for at least 1 minute (min). Acetic acid may cause minor stinging, which will quickly abate.
   - Identify any areas of whitened epithelium (acetowhite). Look for all borders of the lesion.

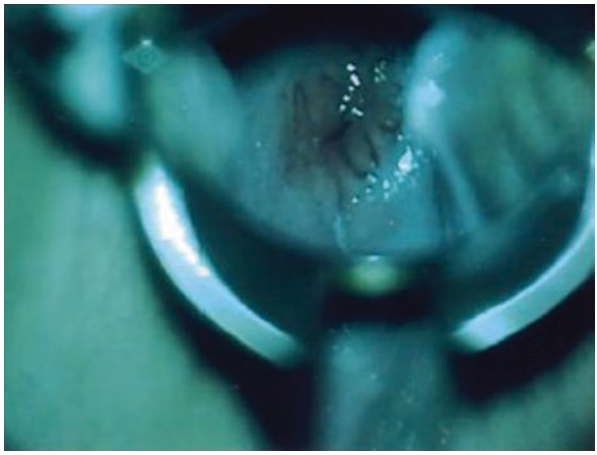


Fig. 23.6 Cervix with green filter showing superficial horizontal abnormal blood vessels

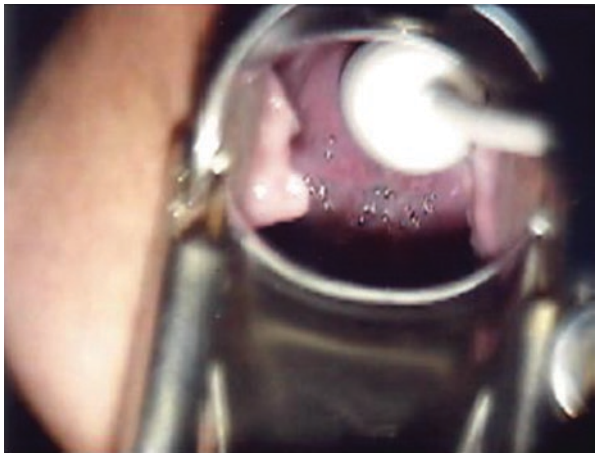


Fig. 23.7 Application of acetic acid under medium magnification

- Identify which areas are the most densely white. High-grade dysplasia is typically associated with thick, well-demarcated areas of acetowhite. The acetowhite reaction will fade quickly (especially in low-grade disease) and more acetic acid may need to be applied (Fig. 23.8).

8. If the entire squamocolumnar junction is not seen or if an acetowhite area enters into the cervical canal, place the Kogan speculum into the cervical os and open slowly and gently.
    - If you are still unable to see the entire squamocolumnar junction or acetowhite area, or if you cannot get the Kogan speculum through the os, the colposcopy is considered unsatisfactory.
    - Remove the endocervical speculum.

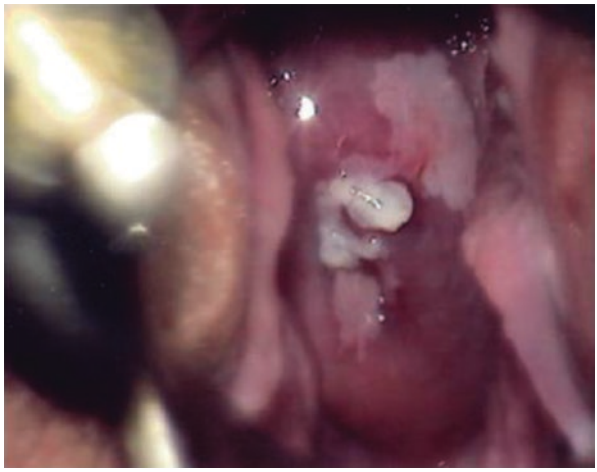


Fig. 23.8 Thick, well-demarcated lesions with acetowhite reaction indicating potential high-grade lesion

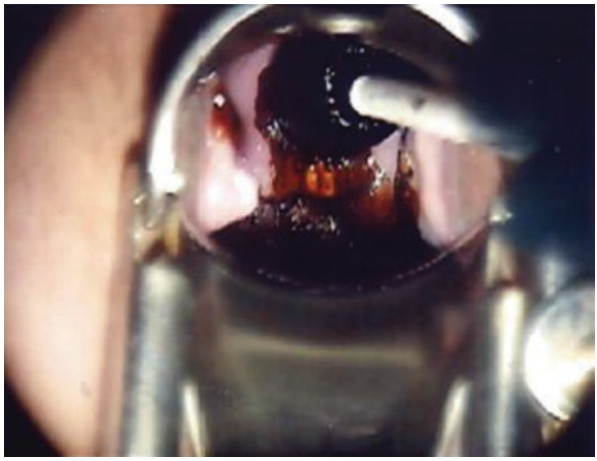


Fig. 23.9 Application of Lugol's solution to cervix with large cotton-tipped applicator

9. Apply Lugol's solution if desired (Fig. 23.9).
    - Abnormal epithelium has low levels of glycogen and does not take up iodine well; therefore, abnormal areas will remain light (mustard yellow in color) or "Lugol's Negative." Normal epithelium remains a deep dark brown stain.
    - Be aware that glandular and columnar epithelium will also not take up Lugol's solution.
10. Perform the Endocervical Curettage (ECC) by inserting the curette through the external os, and, with firm pressure, scrape the sides of the canal using downward strokes around the entire canal (360° × two rotations) (Fig. 23.10).
11. Place the specimen from the curette into a formalin container. This can be facilitated by using a small square of nonstick gauze to wipe the curette, and then

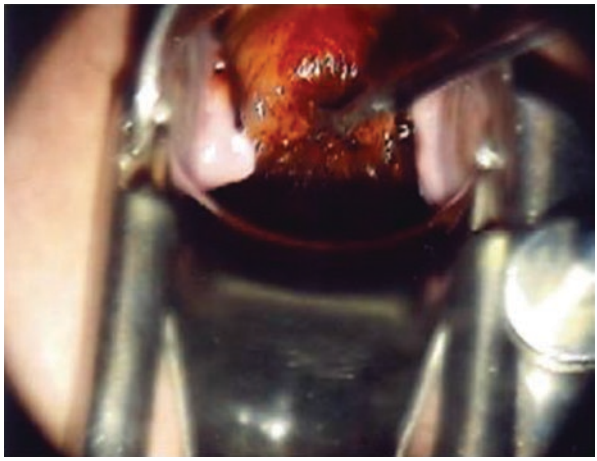


Fig. 23.10 Endocervical curettage performed after application of Lugol's solution

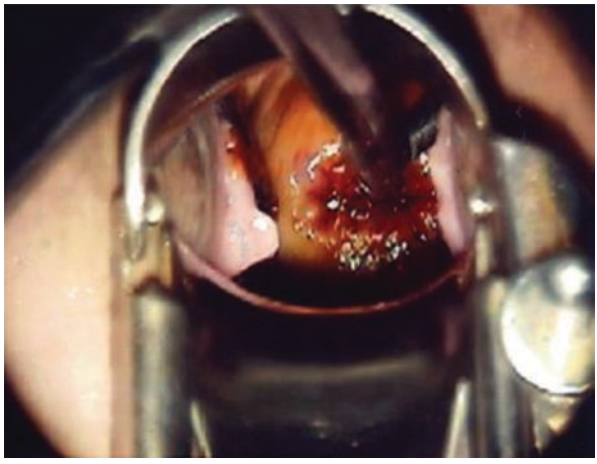


Fig. 23.11 Cervical biopsy with Tischler forceps

place the gauze in the container. If additional sample is seen at the os, it can be grasped with a ring forceps or a long Kelly forceps.

- Alternatively, a cytobrush can be used to obtain any residual sample from the os, and the tip of the brush can be cut off into the container.

12. Use the Tischler forceps to biopsy the most abnormal areas of the cervix. Start with the abnormal area most posterior on the cervix so as to avoid bleeding into the next area for biopsy (Fig. 23.11).

    - Recent evidence has shown that even in the hands of the most expert colposcopists, taking more than one biopsy increases the sensitivity of detecting CIN 3 [3]. Therefore, it is recommended that liberal biopsies be taken of the abnormal cervix. It is *not currently recommended*, however, that random biopsies be taken of the normal cervix.

13. Place biopsies in a formalin jar. A toothpick or broken stem of a wooden cotton-tipped applicator can be used to remove the biopsy from the forceps. Do not place the forceps directly into the formalin.
    - Although all biopsies can be sent in the same specimen container, the more common approach is to use a separate container for each specimen, allowing the provider to compare the histology results obtained with the visual abnormality seen.
14. Remove excess blood/clot from the vagina.
    - Apply pressure to all bleeding sites with large cotton-tipped applicators.
    - Apply Monsel's solution to all bleeding areas by using firm pressure over the bleeding site. Silver nitrate sticks may also be used (occasionally will stain the cervix).
    - Visualize the cervix under medium magnification to ensure hemostasis.
15. Remove the speculum and have the patient return to a sitting position slowly. Rapid sitting can cause a vasovagal response.

Complications and Risks

1. Discomfort
2. Bleeding
3. Infection
4. Missed disease

Tricks and Helpful Hints

- An alternate way of performing the ECC is to use intensive cytobrushing. A cytobrush is inserted through a straw and into the os. It is rotated 360° five times and then removed through the straw. The purpose of the straw is to prevent contamination of the endocervical sample with ectocervical disease. A recent study has shown this method to be more sensitive and less painful than the traditional ECC [4].
- Some colposcopists prefer to perform the ECC after the biopsies as this is the most uncomfortable part of the procedure. The concern with this method is contamination of the endocervical specimen with ectocervical disease. Care must be taken to avoid this.
- If a colposcopy is unsatisfactory because the os is stenotic, the patient may be given intravaginal estrogen 2 g inserted nightly for 2 weeks, or 200–400 μg of misoprostel inserted intravaginally 6 hours (h) before the procedure. The colposcopy is repeated. Either of these techniques has been shown to open the os, often enough to allow for an adequate exam.

Interpretation of Results

There are multiple different pathways for diagnosis and treatment that ultimately depend on the patient's age, dysplasia history, and childbearing goals. Refer to the ASCCP Consensus Guidelines (www.asccp.org) for detailed algorithms. It is also important to relate the histological results with the colposcopic and cytological results. If significant discrepancies are present, further evaluation needs to be done. This can initially be accomplished by having the pathologist review the slides from both the Pap smear and histological samples obtained at colposcopy. If the discrepancy is not resolved, the patient warrants referral to a provider who can perform a diagnostic excisional procedure (Loop Electrode Excisional Procedure or cold knife cone biopsy).

Unsatisfactory Colposcopy

The colposcopy is considered unsatisfactory if the cervix cannot be fully visualized, the entire squamocolumnar junction cannot be fully visualized, or the limits of the lesion cannot be seen. If the initial cytology was HSIL, or histology is shown to be CIN-2 or CIN-3, the patient should undergo a diagnostic excisional procedure. If the cytology was less severe than HSIL and the colposcopy and histology were normal, the patient may be followed up either by a Pap at 6 and 12 months, HPV testing at 1 year (preferred method), or repeat Pap and colposcopy at 1 year [5].

Normal Colposcopy

See ASCCP guidelines

CIN 1

See ASCCP guidelines.

CIN 2/3

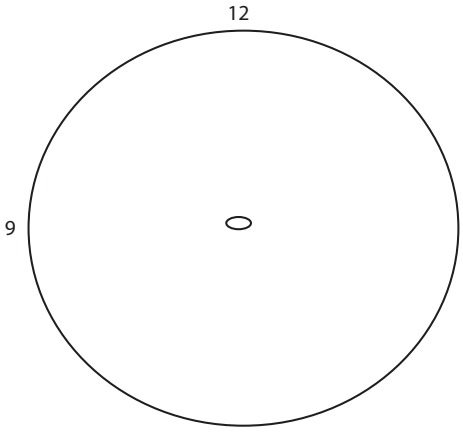
Treatment is required for most cases of CIN 2 and 3, although this may depend on age, dysplasia history and pregnancy history, and future plans. This can be performed by either ablative (cryotherapy, laser ablation, cold coagulation, or electrofulguration) or excisional (LEEP, cold knife cone, or laser excision) methods and should include treatment of the entire transformation zone. If the patient has disease within the canal, an excisional procedure is required. Most current guidelines do

allow for an option to observe CIN 2 and 3 in young patients with a combination of cytology and colposcopy performed at 6-month intervals. If both are normal for two consecutive exams, the patient may return to normal screening [6]. See ASCCP Updated Consensus Guidelines.

Procedure Note

(Provider to fill in blanks/circle applicable choice when given multiple choices and to customize as needed.)

Name:_____ Date:_____
Chart #: _____
Dae of Birth:_____ Contraception:
_____ HCG_____
G____ P____ A——— Pap Smear History:
_____
Reason for Colposcopy:
–
_____
_____
_____
_Smoking: _____
Colposcopic Exam () Satisfactory () Unsatisfactory
TZ = Transformation zone
Go = Gland openings
NC = Nabothian cysts
CO = Condylomy
WE = White epithelium
MO = Mosaic punctation
LK = Leukoplakia
AV = Atypical vessels
X = Biopsy site
X = Biopsy site
SCJ SEEN: (X)Y N **6**
ECC DONE: (X)Y N



Impression:
_____
Disposition:
_____
Suggest subsequent examination and/or follow-up: _____
_____
Physician's Signature

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
57452	Colposcopy of the upper vagina and cervix
57454	Colposcopy with biopsy(ies) and ECC
57455	Colposcopy with biopsy(ies)
57456	Colposcopy with ECC
57450	Colposcopy of the entire vagina and cervix
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 9th Revision, Clinical Modification, Center for Disease Control and Prevention)	
R87.89	Abnormal Pap Smear of cervix and cervical HPV
R87.619	Abnormal Pap Smear, glandular
N87.9	Dysplasia, cervix, unspecified
N87.0	Dysplasia, cervix, mild (CIN 1)
N87.1	Dysplasia, cervix, moderate (CIN 2)
D06.9	Dysplasia, cervix, severe (CIN 3)

Postprocedure Patient Instructions

Explain to the patient that menstrual-like cramps are common and can be treated with ibuprofen 600 mg every 6 h as needed. Spotting will occur, but bleeding should not persist beyond a week and should not be heavier than a menstrual period. If Monsel's solution or iodine was used, inform the patient that her vaginal discharge may be brown or black over the next several days. The patient should be instructed not to put anything in the vagina until all bleeding has resolved for 24 h to reduce the likelihood of infection. She should be counseled on the signs of infection and should be told to call for any abdominal pain beyond cramping and for fevers, shaking chills, and foul-smelling vaginal discharge. A follow-up visit should be scheduled with the patient to review her results and make a definitive treatment plan.

Case Study Outcome

The patient was found to have CIN 2 (moderate dysplasia) on biopsy. She was referred for a LEEP procedure.

Patient Handout

(Provider to customize as needed.)

A colposcopy is a procedure by which your doctor can examine your vulva, vagina, and cervix more closely to evaluate for any possible abnormalities. Most patients are requested to have a colposcopy for further evaluation of an abnormal Pap smear. The procedure is done similarly to a Pap smear in that a speculum is placed into the vagina while you lie on the exam table. The provider will then use a colposcope, which is an instrument that shines light on the cervix and magnifies the view. A vinegar solution, and perhaps an iodine solution, will be applied to your cervix to better identify any areas of potential concern. If such areas are noted, your doctor will take a biopsy, which is the removal of a small amount of tissue, and this will be examined in a lab. If you are not pregnant at the time of your colposcopy, a scraping of the inside of your cervix will also be performed and sent to the lab.

The cervix does not have the same kind of nerve endings as your skin, so while you may feel some pinching with a biopsy, it will not be severe. More likely you will feel menstrual-like cramps. These can be reduced by taking three tablets (600 mg) of over-the-counter ibuprofen 1 hour (h) prior to the procedure. Do NOT take this if you are pregnant or allergic to aspirin, ibuprofen, or naproxen.

We ask that you do not douche, do not use tampons or vaginal medications, and do not have sexual intercourse for 24 h prior to your procedure.

After the procedure, you may have some brownish/black vaginal discharge from the medicines used to stop any bleeding. You may also have some spotting for 1–3 days and some menstrual-like cramps. These should improve with additional doses of ibuprofen. Do not put anything in the vagina (douches, tampons, etc.) and do not have intercourse until all spotting has stopped for 24 h.

Risks to the procedure are very minimal, but please call us if you have heavy vaginal bleeding (more than your normal menstrual period), significant abdominal pain, fevers, chills, or foul-smelling vaginal discharge.

Questions for Learners

- How can clinicians gain skills in colposcopy?
- In what ways can a clinician assure that their skills in colposcopy are kept up to standard practice?

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5. Dresang L. Colposcopy: an evidence-based update. J Am Board Fam Pract. 2005;18(5):383–92.
6. Massad S, Einstein M, Huh W, Katki H, Kinney W, Schiffman M, Solomon D, Wentzensen N, Lawson H. 2012 updated consensus guidelines for the management of abnormal cervical cancer screening tests and cancer precursors. J Low Genit Tract Dis. 2013;17(5):s1–s27.

Additional Resources

Articles

Wright T, Massad S, Dunton C, Spitzer M, Wilkinson E, Solomon D. 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests. Am J Obstet Gynecol. 2007;197(4):346–55.

Wright T, Cox T, Massad L, Twiggs L, Wilkinson E. 2001 consensus guidelines for the management of women with cervical cytological abnormalities. JAMA. 2002;287:2120–9.

Wright T, Cox T, Massad L, Carlson J, Twiggs L, Wilkinson E. 2001 consensus guidelines on the management of women with cervical intraepithelial neoplasia. Am J Obstet Gynecol. 2003;189(1):295–304.

Aggarwal R, Suneja A, Agarwal N, Mirshra K. Role of misoprostol in overcoming an unsatisfactory colposcopy: a randomized double-blind placebo-controlled clinical trial. Gynecol Obstet Investig. 2006;62(2):115–20.

Books

Apgar B, Brotzman G, Spitzer M. Colposcopy principles and practice: an integrated textbook and atlas. Philadelphia: W.B. Saunders; 2002.

Website

www.asccp.org.

Chapter 24
Cervical Cryotherapy

Laurie Turenne-Kolpan

Introduction

Cryotherapy is an ablative technique that has been used to treat all grades of cervical dysplasia for more than 50 years. In low resource settings it is a preferred method of many primary care providers because of its cost-effectiveness, safety, and ease in performance. While excisional procedures are associated with a small increase in the risk of preterm labor and low birth weight, ablative procedures like cryotherapy have not been associated with these effects in pregnancy, making this a potentially attractive procedure for reproductive-aged women [3]. Cryotherapy causes destruction of cells by producing a rapid freezing of tissue followed by a slow thaw. This causes intracellular ice crystals to form, followed by expansion of intracellular material, leading to rupture of the cells [1]. The depth of freezing is directly proportional to the length of ice ball formation around the side of the probe, so that an ice ball 7-mm thick around the probe will yield a depth of freezing equal to 7 mm. It is important to note that the temperature of the tissue in the distal 2 mm of the ice ball is insufficient to cause cell death, so the level of actual tissue destruction is generally 2 mm less than the thickness of the ice ball [2].

Treatment in properly selected patients with cryotherapy for Cervical Intraepithelial Neoplasia 1 (CIN) and CIN 2 can be as high as 95% effective; however, for larger CIN 2 (>2 cm) and CIN 3 lesions, the effectiveness may be significantly reduced. This is not due to the severity of the lesion but to the depth of dysplasia that occurs with more severe lesions. Cervical crypts have a depth up to 7 mm. Most mild and moderate dysplasia will be confined to an area above 5 mm, making cryotherapy a good choice for treatment. Crypt involvement, however, is a characteristic of high-grade lesions such as CIN 3; therefore, treatment of these lesions using cryotherapy should be limited to small lesions 1 cm or less in size [2].

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Cryotherapy is indicated for treatment of both low-grade and small high-grade biopsy-proven squamous dysplasia. As this therapy does not allow for tissue exam, it is essential that the colposcopy performed is adequate and that the histology does not differ more than 1 degree of severity from the cytology on the Pap smear. Other criteria for use of cryotherapy of the cervix include that the probe tip must cover the entire lesion and transformation zone, that endocervical sampling was performed and was negative for dysplasia, and that the patient is reliable for follow-up [2]. If these conditions are not met, a diagnostic excisional procedure must be performed [2, 4]. Because the majority of cases of CIN 1 will spontaneously regress, the consensus guidelines set forth by the American Society for Colposcopy and Cervical Pathology (ASCCP) recommend observation without treatment. If the patient continues to have CIN 1 after 2 years, treatment versus further observation can be offered at that point [4]. Treatment failures do occur; however, in properly selected patients, similar success rates have been shown with cryotherapy, laser ablation, fulguration, cold coagulation, LEEP, laser conization, and cold knife conization [3].

Studies comparing the flat and shallow conical probe tips show no difference in effectiveness for eradicating CIN, but they do show a slight increase in posttreatment migration of the squamocolumnar junction into the canal with the conical tip [5]. Nipple-tipped probes should be avoided however as they can cause cervical stenosis post procedure [2].

Cryotherapy may also be used to treat external genital warts; however, a different freezing regimen is employed.

Case Study

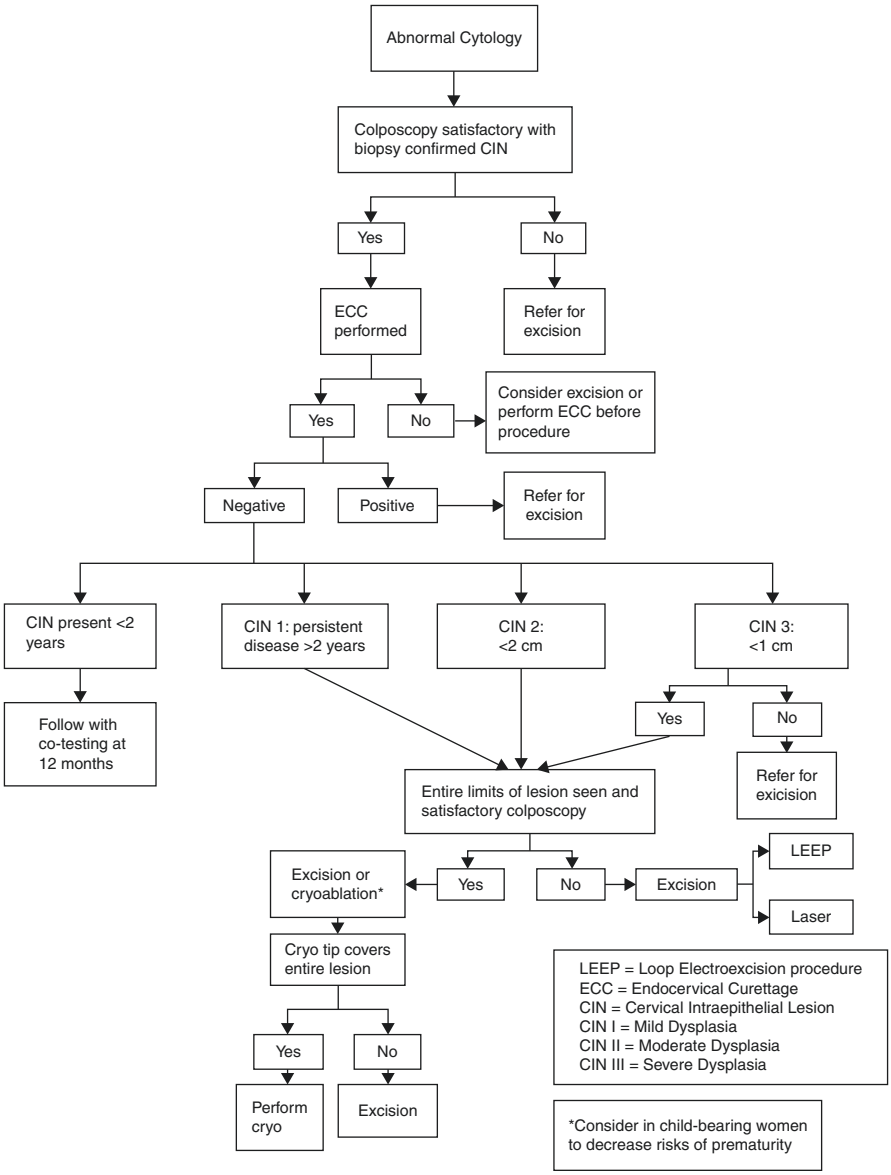
A 27-year-old G2P2 had a colposcopy performed in your office for a Pap smear result of Low-Grade Intraepithelial Lesion (LSIL). The histology report returns as CIN 1, and an Endocervical Curettage (ECC) shows benign endocervical cells. You review her chart and see that her colposcopy was adequate and showed an acetowhite lesion approximately 1 cm in length at the 12 o'clock position. This is her third colposcopy, and prior histology reports have also revealed CIN 1. She does not smoke and is on oral contraceptives. At this point, she is requesting definitive treatment.

Diagnosis

Persistent low-grade dysplasia.

Indications (Algorithm 24.1)

- Persistent low-grade squamous intraepithelial lesion 3 cm or less.



Algorithm 24.1 Decision tree for treatment of an abnormal pap smear with cryotherapy

- Moderate dysplasia with a small lesion confirmed by adequate colposcopy 2 cm or less.
- External genital warts (see Chap. 21 on genital warts).

Contraindications (Algorithm 24.1)

- Large lesions that are not covered completely by the probe tip
- Inadequate colposcopy
- Positive endocervical curettage
- Histology that differs more than 1° from the cytology of the Pap smear
- Lesions that extend more than 5 mm into the canal
- Current heavy menses or within 1 week of expected menses (relative)
- Pregnancy
- Active cervicitis
- High-grade lesions with a noncompliant patient
- Invasive lesions

Equipment (Fig. 24.1)

- Nitrous oxide 20-lb tank
- Flexible tubing from the tank to probe
- Probe tips either flat or slightly coned. Sizes include 19 and 25 mm
- Vaginal speculum
- Water-soluble lubricant
- Colposcope (Some clinicians repeat the colposcopic exam at the time of the cyrotherapy procedure.)
- 5% acetic acid

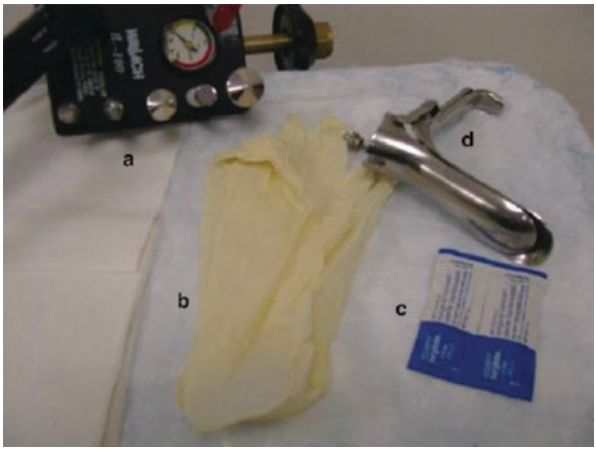


Fig. 24.1 Equipment tray for cervical cryotherapy: (**a**) Cryo tips with cryo tank and attachments (Wallach LL100 Cryosurgical System, Wallach Surgical Devices, Orange, CT); (**b**) gloves; (**c**) water-based lubricant Surgilube® (Fougera, Melville, NY); (**d**) speculum

Optional Equipment

- Vaginal sidewall retractors
- Condom or glove finger for retraction of vaginal wall

Procedure

1. Check urine pregnancy test prior to procedure.
2. Ensure the tank pressure is adequate and open the valve on the tank (Fig. 24.2). (The needle will be in the green zone on the pressure gauge.)
3. Place the patient in the dorsal lithotomy position.
4. Insert the speculum into vagina.
5. Apply 5% acetic acid to identify the location and size of the lesion, with or without magnification from a colposcope.
6. Select the appropriate probe size.
7. Apply water-soluble lubricant to the tip of the probe to achieve an even freeze.
8. Apply the probe over the cervix, ensuring the entire lesion and transformation zone are completely covered.
9. Pull the trigger on the probe gun. The probe should adhere within a few seconds. Pull back slightly on the gun so the cervix is slightly forward, decreasing the likelihood of freezing the vaginal sidewalls (Fig. 24.3).

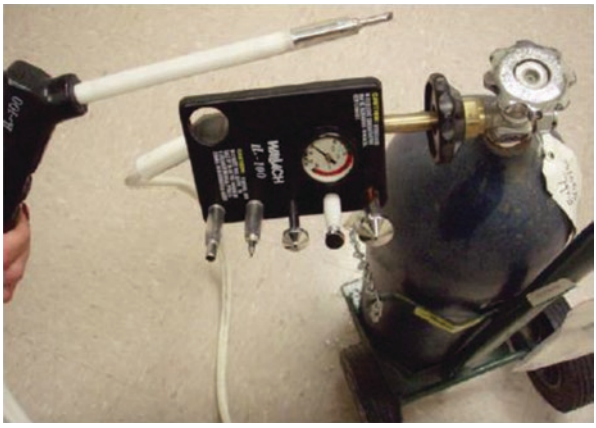


Fig. 24.2 Cryo tank with probe (Wallach LL100 Cryosurgical System, Wallach Surgical Devices, Orange, CT)

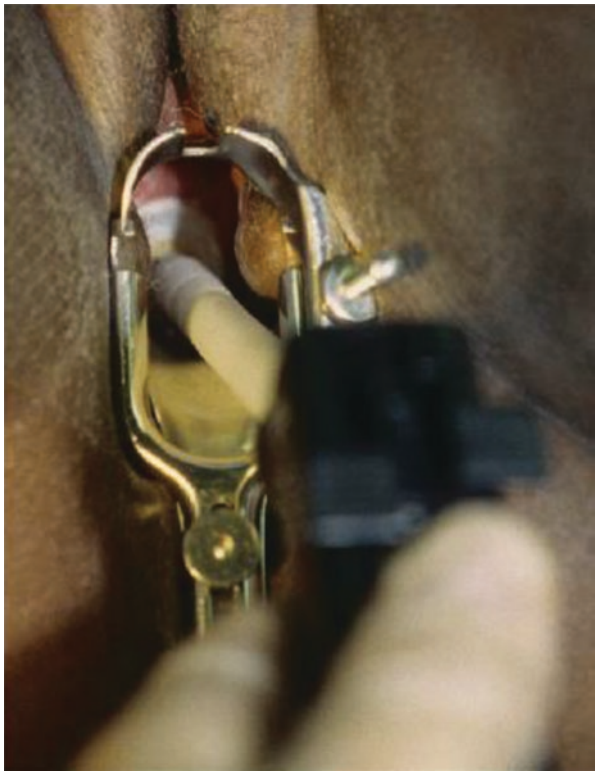


Fig. 24.3 Place probe onto the cervix after lubricant has been applied to the probe tip and pull trigger on the probe gun

10. Continue freezing until a 7–10 mm ice ball is noted around the entire probe, with a minimum freeze time of 3 minutes.
11. Defrost the probe by releasing the trigger or pushing the defrost button, depending on your unit. The probe will detach shortly. *Do not pull on the probe until it is visibly defrosted to avoid pain and cervical laceration.*
12. Wait for the cervix to completely thaw, evidenced by a return of its pink color. A minimum of 5 minutes should be given.
13. Repeat the freeze–thaw cycle. Once the probe is disengaged the second time, the speculum can be removed.
14. Have the patient return to a sitting position slowly to avoid vasovagal symptoms.
15. Close the value on the tank and discharge the remaining freezant.

Complications and Risks

- Treatment failure.
- Cervical stenosis.

- Difficulty with subsequent colposcopic exams as a result of the squamocolumnar junction retreating into the canal.
- Skip lesions (lesions further in the cervical canal behind the stenosis).
- Pelvic cramping typically lasts no more than a few days.
- Freezing of the vaginal wall.
- Profuse watery discharge, often malodorous lasting 2–4 weeks.
  - This occurs as a result of necrotic tissue and exudate being sloughed from the treatment site.
- Bleeding and infection: very rare.

Tricks and Helpful Hints

- The optimal time to perform this procedure is 1 week after the start of the menstrual cycle. If a patient starts her cycle shortly after the procedure is performed, the subsequent edema of the cervix can cause stenosis of the os, retained menses, and significant pain and cramping. If this happens, the cervix can be probed with a cotton swab or cervical dilator, which will usually initiate the flow (2).
- Do not use "nipple-tipped" probes as they increase the rates of cervical stenosis and subsequent inadequate colposcopic exams.
- If vaginal side walls collapse into the canal and obscure full cervical visualization, the finger from a glove or a condom with the tip cut can be placed over the speculum blades, or vaginal sidewall retractors can be used to displace the redundant tissue and protect it from accidental freezing.
- Having the patient take 600 mg of ibuprofen 30–45 minutes prior to the procedure and every 6 hours as needed over the next few days can reduce cramping.

Procedure Note

(Provider to fill in blanks/circle applicable choice when given multiple choices and to customize as needed.)

Date of Birth:_____contraception_____HCG_____

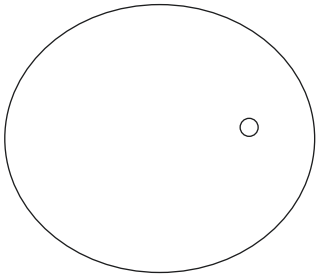
G_____P_____A___Pap Smear History_____

Reason for Cryotherapy:

_____

_____*Smoking*_____

Time Out completed.
(Final Verification of patient/procedure/site)



Colposcopy performed () yes () no
Finding:_____
Cryotherapy:
A_____cm flat/conical tipped probe was applied over the cervix with full coverage of the transformation zone and squamous lesion. The cervix was frozen yielding a _____mm ice ball. A full thaw was completed. The cervix was frozen a second time yielding a _____ mm ice ball. The speculum was removed and the patient slowly returned to a sitting position.
Complications:_____
Impression:_____
Suggest subsequent examination and/or follow-up:_____
Amnio Cerv prescribed intravagionally nightly for 14 days ()yes ()no

_____
Physician's Signature

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
57511	Cryocautery of the cervix, initial, or repeat
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 10th Revision, Clinical Modification, Center for Disease Control and Prevention)	
N87.0	Mild cervical dysplasia(CIN 1)
N87.1	Moderate cervical dysplasia (CIN 2)
N87.9 D06	Dysplasia of the cervix uteri, unspecified Carcinoma in situ of cervix uteri

Postprocedure Patient Instructions

The patient should be advised of the watery discharge that will ensue and persist for 2–4 weeks. This discharge is often malodorous as it is a result of the sloughing of the dead cervical tissue. Cramping is common and should be relieved with ibuprofen, 600 mg every 6 hours. A small percentage will need stronger pain management. These patients should be reexamined to rule out an infection or retained menstrual flow prior to prescribing additional medication. The patient may have a small amount of spotting, but should not have significant bleeding. Infection is uncommon and can be greatly reduced by having nothing inserted in the vagina for 3 weeks following the procedure. Patients should call for any fevers, shaking chills, or pain unrelieved by nonsteroidals. Follow-up is essential after cryotherapy as failure of treatment does happen.

Follow-up testing after cervical cryotherapy is essential to ensure treatment was adequate. The ASCCP guidelines recommend that women undergo co-testing with HPV and cervical cytology at 12 and 24 months postprocedure. If any test is abnormal, colposcopy should be performed. If all results are negative, it is recommended the patient have repeat contesting in 3 years, and then she may return to routine screening [4].

Case Study Outcome

The patient had cervical cryotherapy performed without complications. Co-testing with Pap and HPV were done at 12 and 24 months were both negative. She was co-tested again in 3 years and both testes were negative. She resumed regular testing consistent with her age and risk group thereafter.

Patient Handout

(Provider to customize as needed.)

Cryotherapy is a method of treatment for cervical dysplasia (abnormal cells on your cervix that are precancerous) that involves destroying abnormal tissue in the cervix by freezing it. This is performed right in our office. The best time to have the procedure done is the week after your period has started, and this can be done even if you are still having a small amount of spotting.

The procedure starts like a Pap smear, with you lying on your back and your feet on the footrests (stirrups). A speculum will be placed in the vagina to visualize the cervix. A metal probe is placed on your cervix and gets very cold, allowing for the freezing. It is normal to hear a hissing sound as the procedure begins, and

then you may feel some cramping similar to menstrual cramps. There is generally no pain beyond the cramps. Taking three 200 mg ibuprofen tablets (total 600 mg) 30 minutes prior to the procedure will help minimize this. You may also feel a little warm and flushed. This goes away within a few minutes after the procedure ends. The freezing will take about 3 minutes, and then the cervix will be allowed to thaw for about 5 minutes. This process is repeated once.

Cryotherapy is generally very safe and effective. The possible complications include the cramping, infection, and narrowing of the cervical canal, which can very rarely be significant enough to cause difficulties letting menstrual flow out. This can be repaired. Finally, while cryotherapy is 85–95% effective in treating cervical abnormalities, failures can and do occur. Therefore, it is very important to continue to get regular follow-up Pap smears as directed by your clinician.

After cryotherapy, you can expect a profuse watery vaginal discharge that may have an odor and can last for 2–4 weeks. To decrease the risk of infection, we recommend that nothing be placed in the vagina (douching, tampons, etc.) and that you abstain from intercourse for 3 weeks. Typically, cramping may last for 1–2 days and can be minimized with ibuprofen, up to three 200 mg tablets (total of 600 mg) taken every 6–8 hours as needed with food.

Please call us if you have any fever, bleeding heavier than a period, or abdominal pain not relieved with ibuprofen.

Questions for Learners:

1. Who is a good candidate for treatment of cervical dysplasia using cryotherapy?
2. What are the main side effects and complications a woman can have after undergoing cervical cryotherapy?

References

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2. Pfenninger J, Fowler G. Procedures for primary care. St. Louis: Mosby; 2011.
3. Apgar B, Kaufman A, Bettcher C, Parker-Featherstone E. Gynecologic procedures: colposcopy, treatment of cervical intraepithelial neoplasia, and endometrial assessment. Am Fam Physician. 2013;87(12):836–42.
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Chapter 25
LEEP: Loop Electrosurgical Excision Procedure

Stephen D. Hoag

Introduction

Loop Electrosurgical Excision Procedure (LEEP) uses alternating electrical current to remove abnormal cervical tissue, which provides a specimen for pathological review. Historically, physicians have used high-frequency current for lesion removal as early as the 1940s. The introduction of the large loop with an insulated cross bar in 1989 by Prendeville revolutionized the treatment of cervical dysplasia. Other methods, such as cryotherapy and laser vaporization evaporated tissue, did not allow for pathological review. LEEP confers the advantage over cryotherapy and laser by providing tissue for histopathological review, thus allowing for prediction of recurrence of disease [1].

LEEP and Loop Electrosurgery remain the most common terms for this procedure although Diathermy Loop Treatment, Loop Excision of the Transformation Zone (LETZ), and Large Loop Excision of the Transformation Zone (LLETZ) are other terms noted in the literature.

LEEP uses low-voltage high-frequency alternating current to produce an uninterrupted sine wave. As the loop is introduced into the tissue, an arc of current occurs causing the tissue cells to be rapidly heated and to explode into steam. The steam envelope allows for a continuous arc, thus allowing for a clean cut through the tissue and producing minimal thermal artifact. Once the tissue has been removed, the coagulation mode can be used with a ball electrode to fulgurate the tissue and cause hemostasis. With the more modern units, the coagulation and cut modes can be combined into a blend mode that produces less bleeding while minimizing the thermal artifact. The current is dispersed through a grounding pad with a large surface area to prevent burns.

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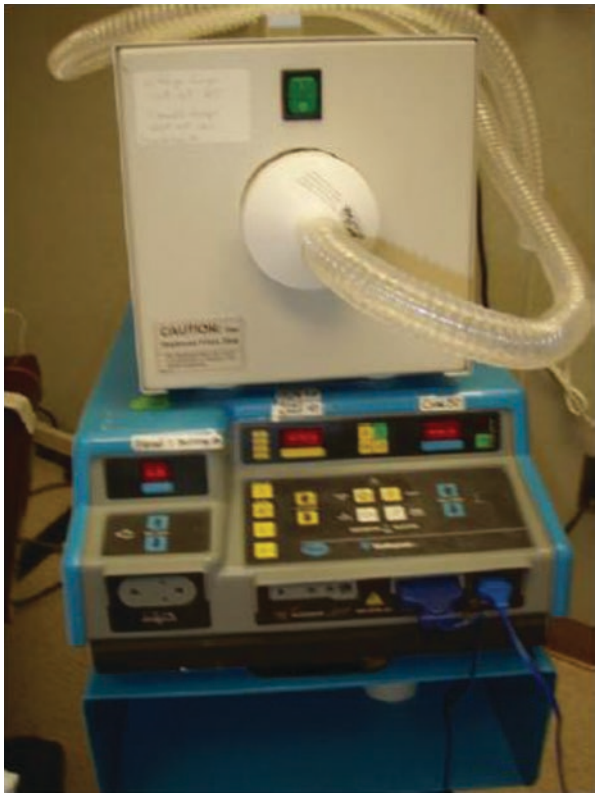

Fig. 25.1 Smoke evacuator and LEEP electrical generator

The type of generator used for the LEEP procedure (Fig. 25.1) is similar to any electrosurgical generator used in either urological or laparoscopic surgery. The alternating current output ranges from 100 to 4000 kHz and comes with a variety of features. These features may include isolated circuitry and Return Electrode Monitoring (REM). Isolated circuitry helps prevent alternate site burns by automatically deactivating the electrical surgical generator if any current transmitted through the active electrode is not returned through the patient electrode. The REM emits a warning sound and/or light if the return circuit is interrupted. Most generators will allow for combining of the cut and coagulation modes into a blend mode. Blend 1 provides 75% cut with 25% coagulation, which helps decrease bleeding during the procedure. Higher blend modes, while available, can increase the amount of thermal artifact in the tissue and make pathological diagnosis of the margins more difficult [2].

Most loops have an insulated cross bar and shaft to prevent thermal injuries. The ball electrodes (Fig. 25.2) range in sizes from 3 to 5 mm, and both the ball electrodes and the loops are connected to a probe with a monopolar output. (The grounding electrode is usually an adhesive gel pad, or a solid "antenna" may be used.) The grounding pad should be applied near the operative site, usually the upper thigh or buttocks. The pad wire should be connected to the generator and tested prior to the procedure to ensure the system is functioning properly.

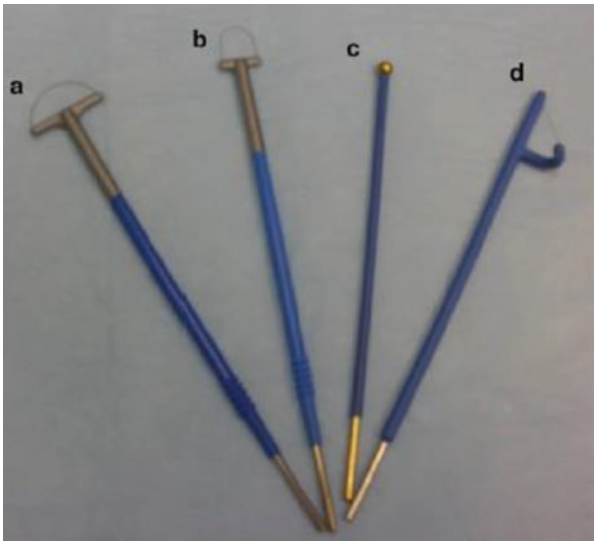

Fig. 25.2 Samples of loops and ball cautery tools. (**a**) 0.8 × 2.0 cm loop; (**b**) 1.0 × 1.0 cm loop; (**c**) ball electrode; (**d**) Fischer cone loop

A smoke evacuator is essential to remove the smoke plume during the procedure in order to provide adequate visualization. The smoke evacuator will filter any airborne particles and coexisting microorganisms into the plume and out of the air in the procedure room. Generally, the smoke evacuator is turned on prior to the generator and is a separate unit; however, there are a number of manufacturers that combine the smoke evacuator with the generator so that both turn on at the same time.

An insulated speculum is recommended for this procedure, and most have an attachment site for the smoke evacuator. This helps prevent secondary burns from the speculum to the vagina or vulvar areas. Special coated vaginal/lateral wall retractors are also available. Human papillomavirus has been isolated from laser plumes: thus, clinicians are encouraged to wear micropore or submicron surgical masks during the procedure.

Efficacy and patient acceptance of the LEEP procedure compares positively to other modes of treatment for cervical dysplasia. Studies indicate that LEEP is 91–98% effective in treating cervical intraepithelial lesions compared to 81–95% efficacy for cryotherapy and 83–94% efficacy for laser treatment of the cervix. Most patients report the degree of discomfort with the procedure to be minor, with 85% of patients reporting no discomfort at all [3].

The morbidity associated with the LEEP is related to the volume of tissue removed and the depth of excision into the endocervical canal. This has direct implications in younger women who have not completed childbearing. The overall rate of preterm delivery or spontaneous preterm Premature Rupture of Membranes (pPROM) post-LEEP is directly related to the increased depth of the cervical tissue removed during LEEP, with women who have >1.7 cm removed having a greater than threefold increased risk of pPROM compared to untreated women [4]. Women

who have had LEEP are more likely to deliver preterm overall and to have more low birthweight babies; however, there are no differences in maternal or neonatal outcomes [5].

Posttreatment follow-up for the LEEP patient should include an office visit to discuss the pathology results and discuss a future surveillance plan per the ASCCP updated consensus guidelines. Women with positive margins have a higher incidence of recurrent dysplasia usually within 2 years and a higher incidence of cervical carcinoma for at least 20 years posttreatment [6].

Case Study

A 39-year-old patient returns to your office after receiving a phone call from your nurse stating that you would like to talk with her about her abnormal Pap smear. You inform her that her Pap has returned as High Grade Intraepithelial Lesion (HSIL) and that she needs to have further evaluation with a colposcopy. Colposcopy was performed and biopsies were taken. She returns to your office for her results, which show severe dysplasia at the 4:00 and 6:00 biopsies with a negative Endocervical Curettage (ECC). You discuss the risks and benefits of the LEEP procedure for definitive treatment and she elects to schedule the procedure.

Diagnosis

Severe dysplasia with negative ECC.

Indications (ASCCP Updated Consensus Guidelines)

- Any biopsy-proven CIN lesion with adequate colposcopy
- Diagnostic purposes for inadequate colposcopy
- LEEP preferred over cryotherapy for the following:
  (a) High-grade lesions that encompass greater than 2 quadrants of the cervix
  (b) Large lesions not covered by the cryoprobe
  (c) Irregularly shaped cervix
  (d) Recurrent CIN after previous therapy
  (e) If “See and Treat” at a single visit is necessary (not preferred method)

Contraindications

- Bleeding or coagulopathy
- Less than 12 weeks postpartum
- Clinically apparent invasive carcinoma of the cervix
- Heavy menses (relative)
- Active/severe cervicitis (relative)
- Pregnancy (relative): should be performed only by experienced specialist when carcinoma suspected

Advantages

- Allows for histologic audit of colposcopic diagnosis with histopathologic examination to rule out microinvasion
- Allows for excision of the dysplastic lesion and transformation zone
- Can treat lesions of all sizes involving all four quadrants of the cervix
- Easily learned technique
- Uses inexpensive readily available equipment with relatively low operating costs
- Is office or outpatient procedure
- Can be performed with initial colposcopy ("See and Treat," although this is not the preferred method of treatment)

Equipment (Fig. 25.3)

- Electrical generator
- Smoke evacuator and tubing
- Grounding pad
- Insulated speculum
- Lateral wall spreaders: insulated (optional)
- Loops: range in sizes from 1.0 × 1.0 cm to 2.0 × 1.5 cm
- Ball electrode: sizes range from 3 to 5 mm
- 20% Benzocaine (Hurricaine® gel, Beutlich LP Pharmaceuticals, Waukegan, IL)
- 1% lidocaine with epinephrine: 5–10 cc
- Needle extender
- 25- or 28-gauge needle
- Colposcope

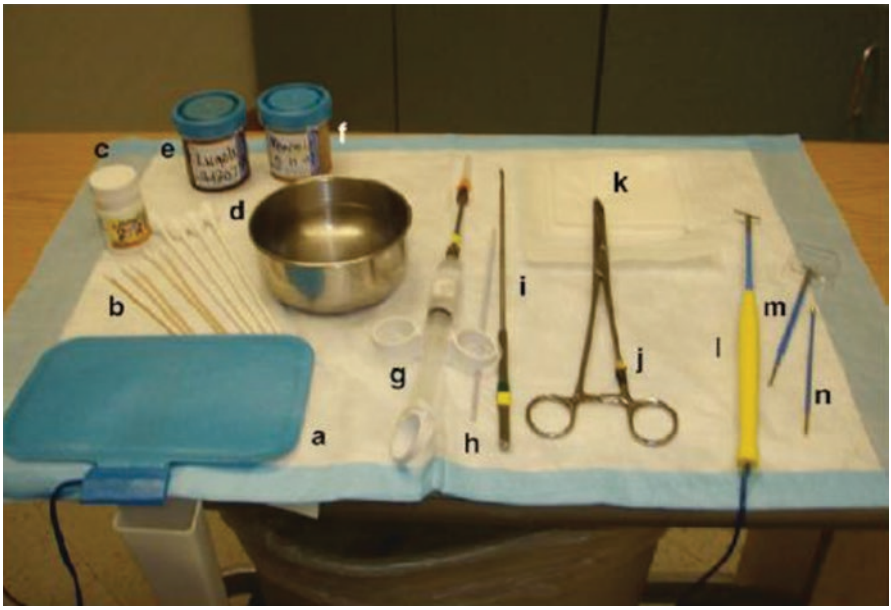

Fig. 25.3 Equipment setup for LEEP. (**a**) Grounding pad; (**b**) large and small cotton swabs; (**c**) Hurricaine® gel (Beutlich LP Pharmaceuticals, Waukegan, IL); (**d**) metal basin with acetic acid; (**e**) Lugol's solution; (**f**) Monsel's solution; (**g**) 10 cc syringe with 1% lidocaine with epinephrine with needle extender; (**h**) endocervical brush; (**i**) sterile endocervical curette; (**j**) sterile long Kelly forceps; (**k**) gauze; (**l**) monopolar probe with 0.8 × 2 cm loop attached; (**m**) 1.0 × 1.0 cm loop; (**n**) ball electrode

- Acetic acid
- Lugol's solution
- Monsel's solution
- Specimen jar
- Endocervical curette (ECC) (optional)
- Large cotton swabs (Scopettes®, Birchwood Laboratories Inc., Eden Prairie, MN)
- Small cotton swabs
- Long Kelly or ring forceps
- Face mask: micropore or submicron surgical face mask

Optional Equipment

- Suture material: chromic or vicryl 3.0 absorbable
- Long-handled needle holder and scissors
- Vasopressin for bleeding

Procedure

1. Obtain informed consent and sign permit.
2. Check pregnancy test.
3. Place patient in lithotomy position; apply grounding pad.
4. Check equipment to make sure all functioning appropriately.
5. Insert insulated speculum and visualize cervix.
   (a) Adequate visualization of the entire cervix is key to a simple procedure.
   (b) Use the vaginal/lateral wall spreaders if necessary to provide adequate visualization.
6. Perform colposcopy and apply Lugol's solution.
7. Anesthetize the cervix.
   (a) Use 20% benzocaine (Hurricaine®) gel prior to lidocaine (Fig. 25.4).
   (b) Inject at 12:00, 3:00, 6:00, and 9:00 positions around the cervix with up to 0.5–1 cc of lidocaine per site locally (Fig. 25.5). (Alternatively, you can inject at 2:00, 4:00, 8:00, and 10:00.)
   (c) Use depth of 1–2 mm only (submucosal).
   (d) Allow several minutes to pass, and check to see if area is anesthetized.
8. Choose appropriate loop, and attach to the monopolar probe.
   (a) Check settings to ensure appropriate for chosen loop.
   (b) Smaller loops require less current (i.e., 1.0 × 1.0 set at approximately 40 MHz, varies machine to machine).
   (c) Check to make sure setting is on Blend 1.
9. Make dummy pass over the cervix with generator on stand-by to ensure adequate removal of the lesion.

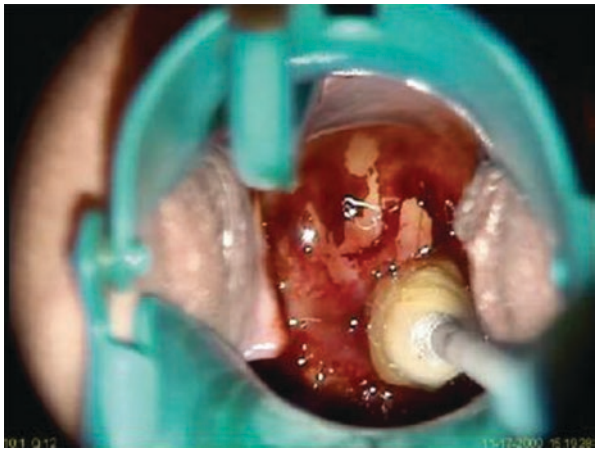

Fig. 25.4 Apply topical benzocaine to the cervix with a large swab prior to injecting the local anesthetic

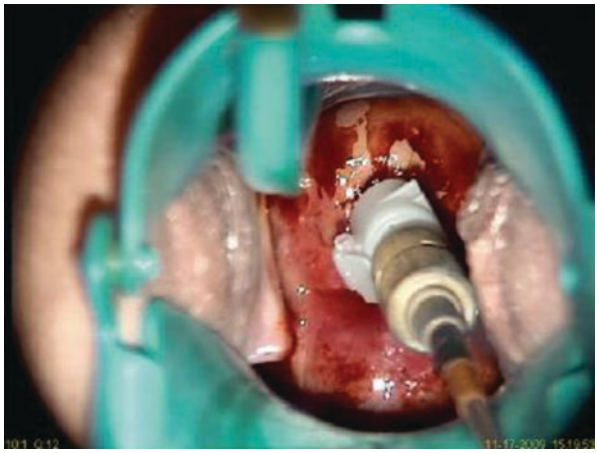

Fig. 25.5 Injection of lidocaine anesthetic at the 12:00 position on the cervix

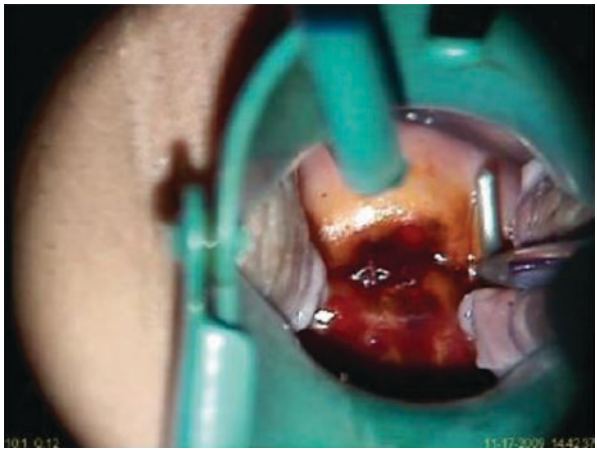

Fig. 25.6 Pass the loop through the tissue in a perpendicular fashion

10. Turn on smoke evacuator and generator, and recheck settings.
11. Pass loop into tissue, and remove the entire transformation zone around lesion (Fig. 25.6).
    (a) If necessary, make additional passes with loop to remove the entire lesion.
    (b) Start the flow of current either by using the index finger to press the cut button on the handheld tool or by using the foot pedal.
    (c) Start excision approximately 5 mm lateral to the lesion, and place loop just at but not touching the cervix. Start the flow of current prior to touching the cervix.
    (d) The cut should be made with a continuous flow of current, passing the loop to a depth of at least 8 mm – maximal crypt involvement of CIN reaches a depth of 5 mm. Stopping the flow of current can increase thermal artifact and may damage the loop.

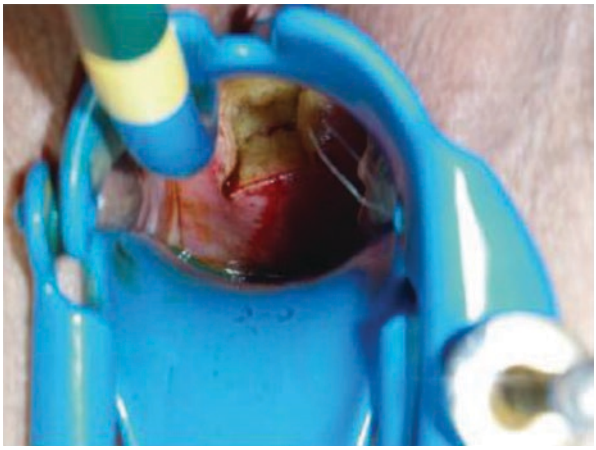

Fig. 25.7 Cervix with excision completed prior to hemostasis with ball cautery

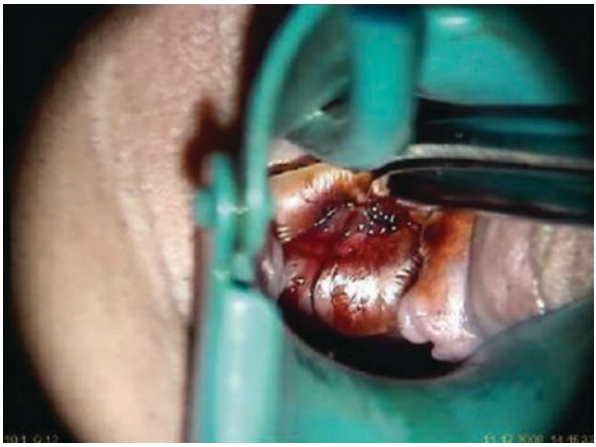

Fig. 25.8 Remove the cut specimen with a long Kelly

(e) Push the loop into the tissue and slowly draw the loop across the transformation zone with equal pressure until 5 mm past the lesion edge, and then remove the loop from the tissue perpendicularly (Fig. 25.7).

12. Remove specimen (Fig. 25.8) with long Kelly, after generator is placed on stand-by.
13. Perform ECC if not done during colposcopy or if desired.
14. Use ball electrode to fulgurate the base of the tissue crater and achieve hemostasis. Press the coagulation button on the handheld tool or with the foot pedal. *Do not fulgurate the cervical os* (Fig. 25.9).
15. Apply Monsel's solution to crater.
16. Remove speculum and grounding pad.
17. Mark specimen as per your pathology department's recommendations and place in sterile container (Fig. 25.10).

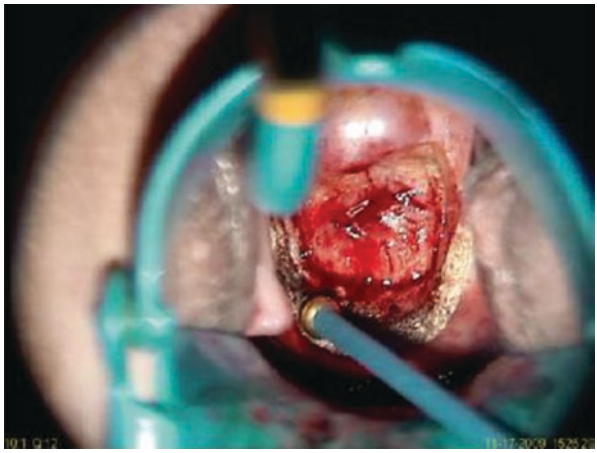

Fig. 25.9 Use the ball electrode to fulgurate the base of the excised cervix to achieve hemostasis

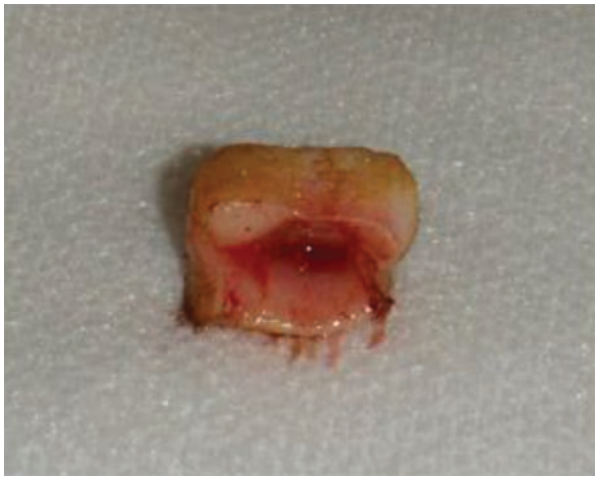

Fig. 25.10 LEEP tissue sample to be sent to pathology

18. LEEP Cone Procedure: looks like a reverse "cowboy hat" when completed

    (a) Can be used when the lesion extends into the cervical canal.
    (b) Anesthetize the cervix in the same fashion, but use an additional 0.5–2 cc of lidocaine into the cervix to a depth of 1 cm at the 12 and 6:00 positions.
    (c) Use a 1.0 × 1.0 or a square loop to excise a 9–10 mm portion of the endocervical canal. If doing this first, the specimen does not need to be marked, but if performing after the LEEP on the ectocervix, mark the endocervical edge of the specimen so that the pathologist can assess if the margins are negative for disease.

(d) The remaining transformation zone is excised in the usual manner as described previously.

19. Have the patient sit up slowly after procedure to ensure vasovagal response does not occur.
20. Observe patient for 15–20 min postprocedure before discharging to home.

Complications and Risks

- Burns to vaginal walls, usually due to poor visualization or operator experience.
- Bleeding: immediate bleeding 0.5–1%, late bleeding 1–8.5%. Perioperative bleeding is uncommon with the use of the blend-mode fulguration and Monsel's. Excessive bleeding can be controlled by use of vasopressin. Rarely, a figure of eight suture is necessary to control the bleeding.
- Posttreatment cervical stenosis: more common with postmenopausal women, women on Depo-Provera® (Pfizer, New York, NY) or Implanon® (Schering Corporation, Kenilworth, NJ), or in breastfeeding women postpartum.
- Consider treatment with estrogen vaginal cream for several weeks post-LEEP.
- Infection: rare.
- Cervical incompetence.
- Positive margins or recurrent disease.

Tricks and Helpful Hints

- When using the lateral wall spreaders, a larger speculum is usually necessary: use a Graves or a long Graves.
- A cartridge system (Campion syringe or dental syringe) can be used for anesthesia. A thumb syringe with a dental extender, a spinal needle, or a Potochy Needle® (CooperSurgical, Trumbull, CT) can also be used.
- Consider adding 8.3% sodium bicarbonate solution 1:1 or 1:4 to decrease pain with the injection.
- Excessive bleeding can be controlled with use of vasopressin: Draw up 1 cc of vasopressin (20 units/cc). Withdraw 40 cc of saline from 100 cc mini bag and inject 1 cc vasopressin into mini bag. Draw up 10 cc of solution and inject directly into the cervix into the area of bleeding.
- Cone LEEP can also be done using a Fischer cone loop.

Interpretation of Results (See ASCCP Website)

- Review pathology report to determine if the entire lesion is removed. Assess margins.
- If margins are positive, closer follow-up is usually necessary.
- If margins are negative, follow-up per ASCCP guidelines [7].

Procedure Note

(Provider to customize as needed.)

The permit was signed, and the pregnancy test was performed and is negative. The patient was placed in the lithotomy position, and the speculum was inserted. The cervix was visualized, and colposcopy was performed. The cervix was anesthetized with ___ cc of 1% lidocaine with epinephrine in the 3:00, 6:00, 9:00, and 12:00 positions infused locally. One pass with the 0.8 × 2.0 cm loop was made to remove the transformation zone in its entirety. Hemostasis with the ball cautery and Monsel's was done. The specimen was marked with suture at the _____ position and sent to pathology. The patient tolerated the procedure well and will follow up in 2 weeks for results.

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
57460	Colposcopy with loop electrosurgical excision or LEEP excision of the cervix
57500	Cervical biopsy
57520	Cervical conization with or without fulguration
57522	Cervical conization using loop technique
57505	Endocervical curettage
99070	Supplies and materials for kits and electrodes: A surgical tray charge is generally allowed for an office LEEP
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 9th Revision, Clinical Modification, Center for Disease Control and Prevention)	
180.9	Cervical cancer
N87.0	CIN 1 (mild dysplasia)
N87.1	CIN 2 (moderate dysplasia)
D06.9	CIN 3 (severe dysplasia,)

Postprocedure Patient Instructions

- Instruct the patient to refrain from intercourse, tampons, or douching for 2–4 weeks postprocedure, until all bleeding has stopped.
- Discharge is common for 2–3 weeks but may last up to 6 weeks.
- The patient should report any excessive bleeding (heavier than a normal period, or soaking a pad per hour) or any malodorous discharge.
- Instruct the patient to make a follow-up appointment to review pathology results within 2–4 weeks.
- Follow-up surveillance as per current 2012 ASCCP guidelines.

Case Study Outcome

The patient returned to your office for her LEEP, which was done without complications. She comes in today for results, and you review with her the pathology results. It contained severe dysplasia with negative margins. She will follow up in 12 months for a repeat Pap smear and high-risk HPV typing.

Postprocedure Patient Handout

You have just had a LEEP (Loop Electrosurgical Excision Procedure). This involves removing small pieces of abnormal cervical tissue that are then sent for pathologic evaluation. Most women tolerate LEEP well, as the procedure generally causes little bleeding. However, in order to make sure that you heal well, we ask that you avoid putting anything in your vagina for the next 2–4 weeks until the bleeding has stopped. This means:

- No douching
- No tampon use
- No vaginal sex

You should call your provider if any of the following occur:

- Increase in bleeding or heavy bleeding (more than a pad per hour)
- Fever, above 101 °F.
- Pelvic pain
- Smelly discharge

Discharge, even dark brown discharge, is common after LEEP.

Please make a follow-up appointment to discuss your results in 2–4 weeks. You will also need to discuss frequency of Pap smears and follow-up plans at this appointment.

Questions for Learners

- When is it appropriate to perform a LEEP procedure?
- When would you not perform LEEP?

References

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Additional Resource

Article

Wright TC, Massad LS, Dunton CJ, Spitzer M, Wilkinson EJ, Solomon D. 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests. Am J Obstet Gynecol. 2007;197:346–55.

Website

www.asccp.org.

Chapter 26
Hysterosalpingography/ Hysterosalpingogram (HSG)

Sandra M. Sulik

Introduction

Hysterosalpingography (HSG) is a dye-based radiologic evaluation of the uterus and fallopian tubes. It is used primarily for the workup of infertility. Other indications include the evaluation of women with a history of recurrent spontaneous abortions, postoperative evaluations for women who have undergone reversal of tubal ligation, and assessment of women prior to undergoing myomectomy. The primary role of the procedure is to evaluate the patency of the fallopian tubes [1]. The optimal time for the study to be performed is day 7–12 of the menstrual cycle. This ensures that there is not a pregnancy present and allows for optimal visualization of the endometrium in the proliferative phase. While the HSG is used to assess the tube patency, it has been known that some women will conceive within months of the test suggesting tubal flushing might play a role in improving fertility. Either oil-based contrast or water-soluble contrast material can be used to perform the test. Several randomized controlled trials have been done comparing the two types of contrast material and infertility rates with some suggesting that the use of the oil-based contrast might have a higher rate of pregnancy success [2]. Magnetic resonance hysterosalpingography (MR-HSG) with injection of gadolinium is also available in some areas. Diagnostic performance of MR-HSG is similar, but there is a decreased pain associated with the MR-HSG [3].

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Case Study

A 34-year-old woman presents to your office with the concern that she is unable to get pregnant. She and her husband have been trying for the past year without success. She has had no other pregnancies, denies history of any sexually transmitted infections, and has regular menses. Her husband has a child from a previous marriage. You discuss the infertility workup and suggest an evaluation with a hysterosalpingogram.

Diagnosis (Algorithm 26.1)

Infertility investigation.

Indications (Algorithm 26.1)

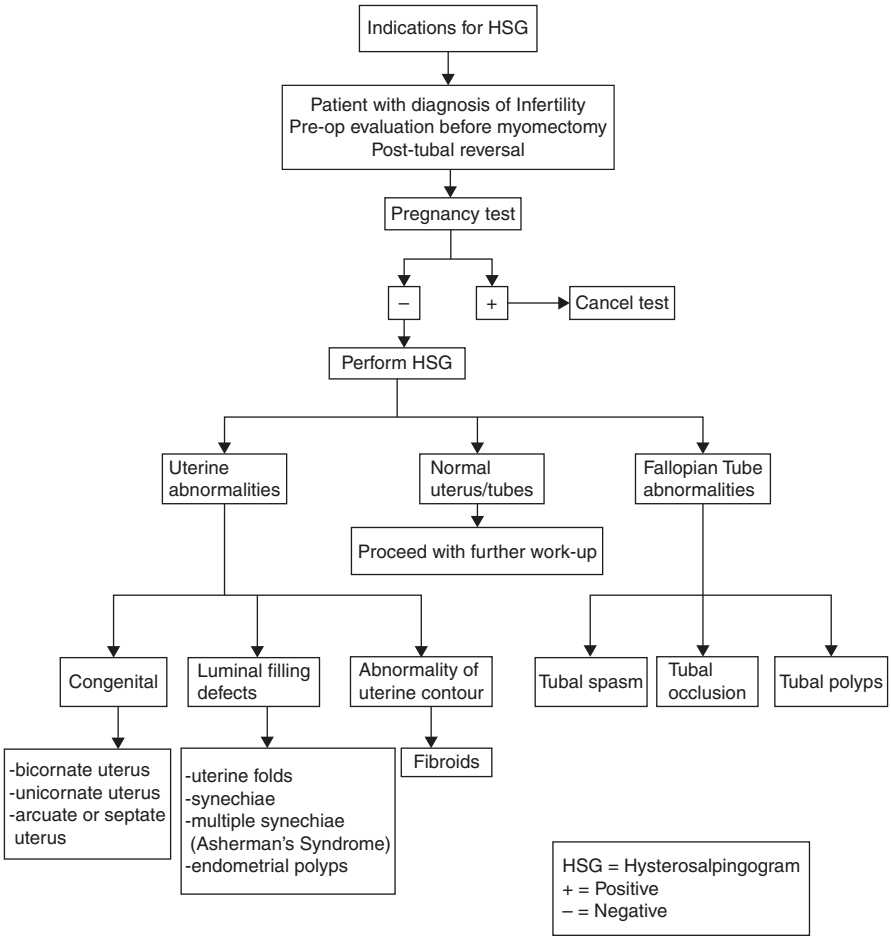
- Infertility
- Recurrent spontaneous abortions
- Preoperative evaluation prior to myomectomy
- Postoperative evaluation following tubal ligation reversal

Contraindications [1] (Algorithm 26.1)

- Pregnancy
- Active pelvic infection
- Active vaginal bleeding
- Allergy to contrast dye

Equipment (Fig. 26.1)

- Radiologic shields for provider, radiologist, and technician
- Sterile tray with the following:
  - Sterile gloves
  - Sterile speculum
  - Small cup for antiseptic solution
  - Antiseptic solution
  - 3 cc syringe to test catheter balloon
  - 10 cc syringe to inject dye



Algorithm 26.1 Indications and interpretations of HSG

- HSG catheter
- Tenaculum
- Contrast medium
- Menstrual pad

Procedure

1. Perform pregnancy test.
   - The patient should be instructed to abstain from unprotected intercourse from the onset of the menses until after the procedure is completed.

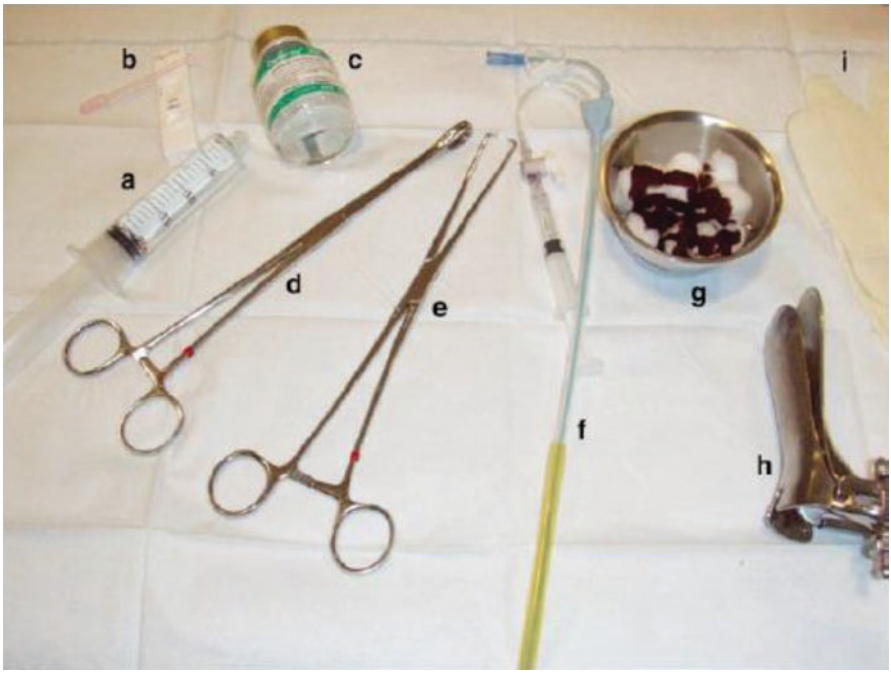


Fig. 26.1 Sterile tray set up for HSG: (**a**) 20 cc syringe filled with contrast dye; (**b**) pregnancy test; (**c**) contrast dye (e.g., Optiray®, Mallinckrodt Inc., St. Louis, MO); (**d**) ring forceps; (**e**) tenaculum; (**f**) hysterosalpingogram catheter, with 3 cc syringe attached; (**g**) metal basin with cotton balls soaked in iodine; (**h**) Graves speculum; (**i**) sterile gloves

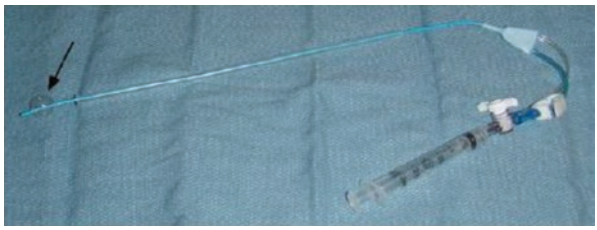


Fig. 26.2 Hysterosalpingogram catheter: check catheter balloon prior to start of the procedure

2. Patient is placed in the lithotomy position, supine on the fluoroscopy table.
3. Check the HSG catheter, and flush the catheter with contrast material prior to insertion (Fig. 26.2).
4. Insert the speculum, visualize the cervix, and clean with antiseptic solution.
    - Insert the HSG catheter through the cervix into the endometrial cavity, and inflate the balloon using 3 cc of air. If necessary, use the tenaculum to help stabilize the cervix to insert the catheter.
5. Turn the stopcock to keep the balloon inflated.

6. Obtain a scout radiograph to check position of the catheter.
7. Inject contrast material slowly into the uterine cavity, until adequate fluoroscopic images are obtained.

   - Watch for spill of contrast medium into the fallopian tubes and then into the intraperitoneal area (Fig. 26.3).
   - Observe for filling defects and contour abnormalities as early filling occurs.
   - The shape of the uterus is best evaluated as the uterus is fully distended (Fig. 26.4).

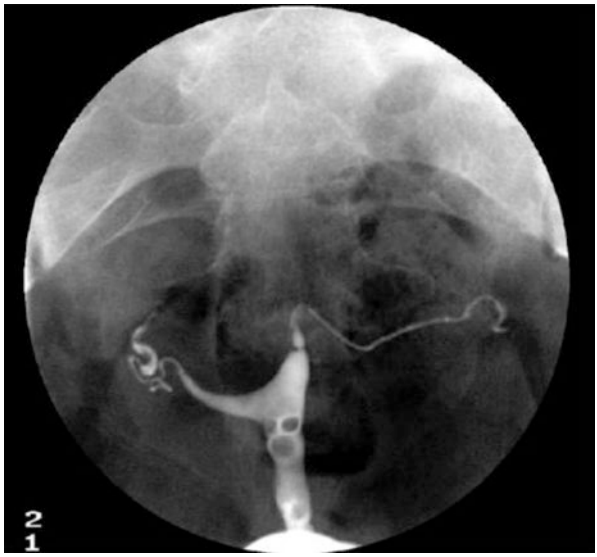


Fig. 26.3 Hysterosalpingogram with contrast spilling from both tubes

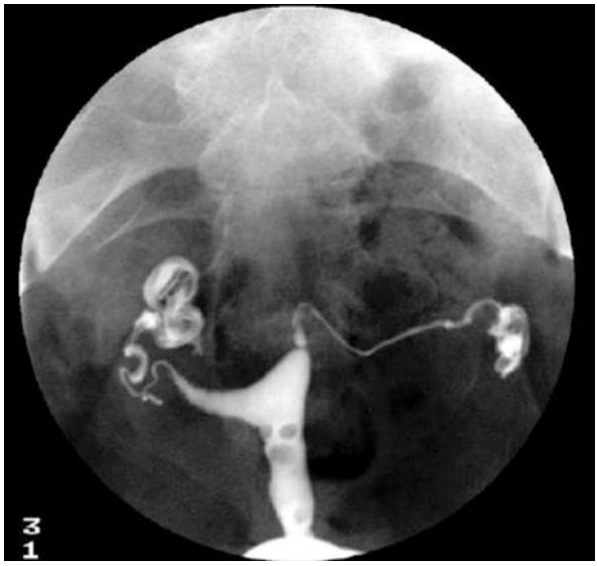


Fig. 26.4 The shape of the uterus is best visualized when fully distended

- Additional spot radiographs may be obtained to evaluate any abnormality that is seen.
- Oblique views of the fallopian tubes may be needed and are obtained by having the patient roll from side to side (Fig. 26.5).
- A radiograph can be obtained once the balloon is deflated to evaluate the lower uterine segment.

8. Once the radiographs are obtained, deflate the balloon and remove the catheter.

Complications and Risks

Spotting.

Rare Complications

- Heavy vaginal bleeding
- Infection
- Reaction to contrast medium
- Perforation of the uterus or fallopian tube
- Potential for irradiation of an early, unsuspected pregnancy
- Severe cramping causing need to terminate the study before completion

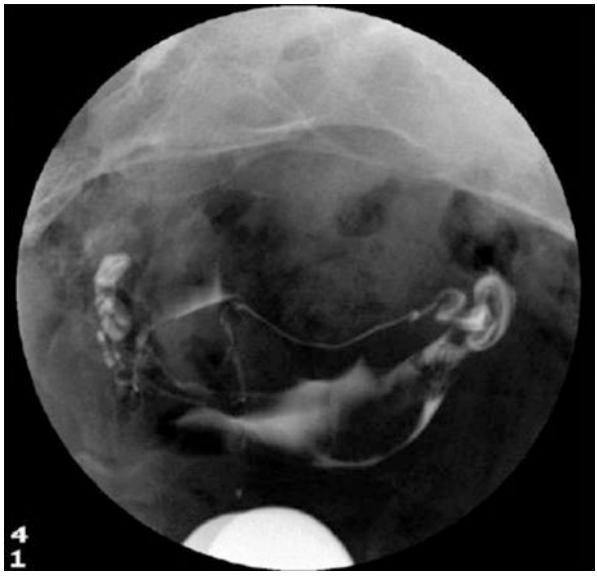


Fig. 26.5 Oblique views obtained by having the patient rotate side to side to asses for spill from both tubes

Tricks and Helpful Hints

- Use an inverted bedpan or a pillow, or have the patient place her hands under her hips, in order to raise the pelvis; this will facilitate insertion of the speculum and better visualization of the cervix.
- If unable to easily pass the catheter, use the tenaculum to straighten the cervical canal.
- Have patient pretreat with a non-steroidal anti-inflammatory drug (NSAID) prior to procedure.
- If cervical stenosis is present, use a small dilator to open the cervical os prior to insertion of the HSG catheter.
- Removing the speculum prior to the dye injection allows for better visualization of the lower uterine segment.
- Excessive injection of dye prevents proper evaluation of the uterine cavity [4].
- Use of intrauterine lidocaine is not effective in reducing pain during the HSG [5].

Interpretation of Results [1, 2, 4, 6] (Algorithm 26.1)

Uterus

- Should look like an inverted triangle with well-defined smooth contours.
- Uterine anomalies – three types:

1. Congenital abnormalities of shape:
   (a) Unicornuate uterus.
   (b) Bicornuate uterus: demonstrates a cleft in the outer contour of the fundus.
   (c) Arcuate or septate: shows a depression of the uterine fundus but a normal outer uterine contour.
2. Luminal filling defects (common):
   (a) Uterine folds: normal variants, parallel the long axis of the uterus and can extend into the uterine horns
   (b) Synechiae (intrauterine adhesions) due to scarring/infection are seen as irregular filling defects; usually linear arising from one of the uterine walls.
   (c) Multiple synechiae = Asherman syndrome.
   (d) Endometrial polyps: well-defined filling defects best seen during the early filling stage. Sonohysterography is the preferred method of imaging endometrial polyps.

3. Abnormalities of uterine dontour:
   (a) Leiomyomas most common, well-defined filling defects; only seen if submucosal. Seen best during early contrast filling of the uterus.
   (b) Large myomas can distort the size of the uterus.

Fallopian Tubes

- Tubes should appear as thin, smooth lines that widen in the ampullary portion.
- Vary in length (approx. 10–12 cm) and tortuosity.
- There should be free spillage of contrast material into the peritoneal cavity.
- Tubal spasm can occur rarely and is difficult to distinguish from tubal occlusion.
- Tubal polyps: Rare; appear as smooth rounded filling defects without tube dilatation or occlusion; less than 1 cm in diameter and can be unilateral or bilateral.

Procedure Note

(Provider to customize as needed.)

Informed consent was obtained. Pregnancy test was done and is negative. The patient was placed in the lithotomy position on the fluoroscopy table, and the speculum was inserted. The cervix was visualized and cleaned with iodine solution. The HSG catheter was gently inserted through the cervix, and the balloon was filled with air. Position of the catheter was confirmed with fluoroscopy. The radiologist was called and, when ready, the dye was instilled via *the catheter into the uterus. Spillage from both tubes was noted; no uterine abnormalities were seen. The study was completed, and the catheter was easily removed. The patient tolerated the procedure well.*

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
58340	Hysterosalpingography
74740	Hysterosalpingography, radiologic supervision, and interpretation
99070	Supplies and materials
ICD10-CM-Diagnostic Codes (International Classification of Diseases, 10th Revision, Clinical Modification, Center for Disease Control and Prevention)	
Q513	Bicornate uterus
N97.1	Infertility, female (626.2 of tubal origin) Infertility, female due to tubal occlusion
N88.3	Incompetence of cervix Incompetence of cervix uteri

Patient Instructions

- The patient should be instructed to take an NSAID, i.e. ibuprofen 800 mg, three times daily for 1–2 days prior to the procedure and the morning of the procedure (at least 30 min prior).
- She should call the provider when her menses are due so that the test can be scheduled at the end of the menstrual cycle, ideally days 7–12 of the cycle.
- She should be instructed to abstain from unprotected intercourse from the start of her menses until the procedure is completed.
- The patient should be told to expect some cramping and flushing with instillation of the dye as well as with insertion of the catheter. Some cramping can continue postprocedure but usually subsides shortly after the procedure is completed.
- The patient should expect sticky vaginal discharge after the procedure for several hours. Some spotting is also normal, but she should report any heavy vaginal bleeding or foul-smelling discharge.

Case Study Outcome

HSG was performed without difficulty, both tubes were patent, and the uterus appeared normal in contour. Results were reviewed with the patient and her husband, and the infertility workup was continued.

Patient Handout

(Provider to customize as needed.)

Your provider has ordered a hystersalpingogram. This is an X-ray test done to look at the shape, size, and location of your uterus, fallopian tubes, and ovaries. Usually, this test is done to determine if the fallopian tubes are open and will allow an egg from your ovary to pass through the tube. This test is done as part of the workup for infertility. The test is also done after sterilization with the Essure®.

Before this test, your provider will perform a pregnancy test. A radiology technician or nurse will assist your provider and radiologist with the procedure. They will ask you for the dates of your last menstrual period and if you have any allergies. Before the test is done, you will be asked to empty your bladder and put on a hospital gown.

Once ready, you will lie down on the X-ray table, and an X-ray of your pelvis will be taken. The speculum will be inserted into your vagina, and your cervix will be cleaned with an antiseptic solution. The catheter will then be threaded through your cervix into your uterus, and a small balloon will be filled with air. This will keep the catheter in the proper position for the test. Once the catheter is in place, the radiologist will be called in, the dye will be injected through the catheter, and the X-ray pictures will be taken. You may be asked to turn onto one or both sides in

order to see both fallopian tubes. When the dye is injected, you may experience a warm flush and some cramping.

When the test is completed, the catheter and the speculum will be removed. You will be given a menstrual pad to wear. You may have some spotting and a sticky discharge for the rest of the day of the test. If you have cramping, you can take ibuprofen.

The radiologist will review the X-rays and will send a report to your provider. Your provider will schedule a follow-up appointment with you to review the test results and discuss a treatment plan.

Question for Learners

- At what point in a fertility workup should HSG be done?

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Additional Resource

Article

Eng CW, Tang PH, Ong CL. Hysterosalpingography: current applications. Singap Med J. 2007;48(4):368–74.

Chapter 27
Medication Abortion Using Mifepristone and Misoprostol

Jennifer Amico and Anna Sliwowska

Introduction

Half of all pregnancies in the United States are unintended, and half of these pregnancies end in elective termination [1]. At current abortion rates, one in four women will have an abortion by the age of 45 [2]. Despite the demand for abortion services, 90% of all counties in the United States have no abortion provider [3]. Furthermore, the majority of women seek abortion services at nonprimary care sites, disrupting continuity of care for those who would prefer to access abortion service from their primary care provider. Over 90% of all abortions occur in the first trimester, when safe, simple, and highly effective abortion services can be provided in the primary care setting [4]. If primary care clinicians were to offer abortion care, they could greatly improve timely access to safe abortion and relevant reproductive health services, particularly in rural and underserved settings [5].

Offering medication abortion in the office setting does not require expensive equipment or specialized procedural training, thus facilitating its incorporation into primary care [6–9]. Medication abortion offers an important alternative to procedure abortion from a patient perspective (see Table 28.1 in Chap. 28 on MVA Abortion.). Patients' reasons for choosing a medication abortion include a desire for privacy, a preference for a more "natural" method, and avoidance of an invasive procedure.

In September 2000, the U.S. Food and Drug Administration (FDA) approved mifepristone (also known as RU486 or Mifeprex®, Danco Laboratories, New York, NY) to be used with misoprostol (a prostaglandin) for medication abortion up to 49 days gestational age. In March 2016, the FDA approved an updated protocol which endorsed use of medication abortion up to 70 days gestational age [9]. This process first involves the administration of mifepristone (a progesterone antagonist),

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which effectively detaches the pregnancy from the endometrial lining and sensitizes the myometrium to prostaglandins. Misoprostol is administered approximately 24–48 hours (h) later and stimulates uterine contractions, thus causing expulsion of the pregnancy tissue (Fig. 27.1).

While the FDA-approved 2016 regimen is widely utilized for medication abortion, other protocols for medication abortion have been studied [10]. These utilize different timing or modes of administration of misoprostol. Though less often used, medication abortion can also be accomplished using methotrexate and misoprostol, or with misoprostol alone [11]. Advantages of using methotrexate include its relatively inexpensive cost and wide availability, and the fact that it can medically treat ectopic pregnancy under certain circumstances. However, given that methotrexate (used with misoprostol) can take a longer period of time for abortion completion (up to 4 weeks), it is not typically the regimen of choice for most US providers and patients.

Many states have laws regulating the provision of abortion services, including mandatory waiting periods, parental consent for minors, physician-only laws, and/or mandatory health department reporting. Some states have also mandated that medication abortion follows only the updated FDA protocol. Clinicians should be familiar with state regulations prior to introducing medication abortion in their practice.

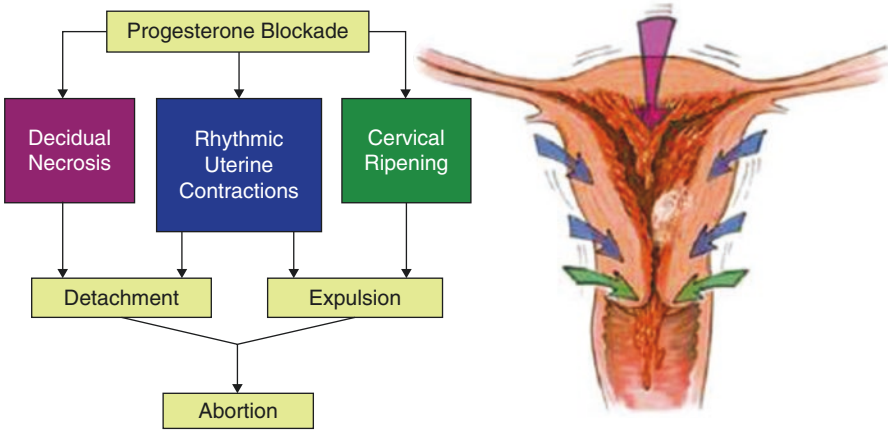


Fig. 27.1 Mifepristone and misoprostol mechanism of action. Mifepristone binds to progesterone receptors, causing decidual necrosis and detachment of the pregnancy from the endometrium. In addition, mifepristone induces uterine contractility and sensitizes the myometrium to prostaglandins. Misoprostol administration then promotes cervical ripening and further uterine contractions. The synergistic action of mifepristone and misoprostol ultimately causes pregnancy detachment and expulsion. (Reprinted with the permission of the National Abortion Federation. Early Options: A Provider's Guide to Medical Abortion. Medical Education Series. "Overview of Medical Abortion: Clinical and Practice Issues." 2005)

Case Study

A 23-year-old nulliparous female presents to your office after missing her menses. Her last menstrual period was 6 weeks ago. She and her partner experienced a condom break a couple of weeks ago, but she did not know about emergency contraception. She is a young graduate student and does not feel ready to be a parent at this time. After pregnancy options and abortion options counseling, she decides to proceed with a medication abortion. Her examination today reveals a 6-week-size, anteverted uterus with no adenexal masses or tenderness. A transvaginal ultrasound reveals an intrauterine pregnancy approximately 6.2 weeks by crown-rump length.

Diagnosis (Algorithm 27.1)

- 6.2-week intrauterine pregnancy
- Desire for elective termination

Differential Diagnosis

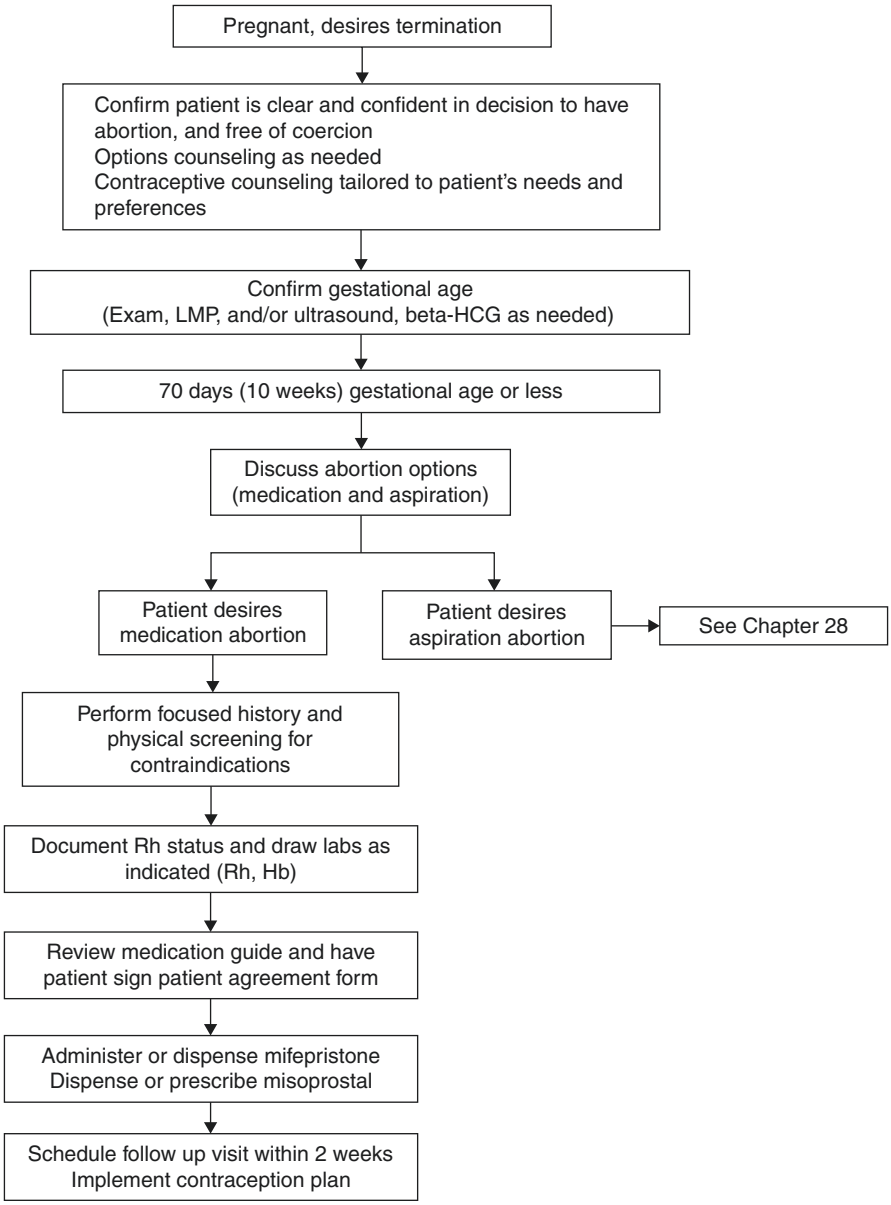
- Normal, intrauterine pregnancy
- Ectopic pregnancy
- Heterotopic pregnancy: concomitant presence of an intrauterine and ectopic pregnancy
- Early pregnancy failure: threatened, incomplete, or complete spontaneous abortion

Indications (Algorithm 27.1)

- Elective procedure
- May also be medically necessary for women with comorbidities in which carrying pregnancy to term poses a threat to health and/or life
- May be used for completion of spontaneous early pregnancy loss (off-label use)

Contraindications (Algorithm 27.1)

- Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass
- Intrauterine device in place (remove prior to treatment)



Algorithm 27.1 Decision tree for abortion options

- Chronic adrenal failure
- Current long-term, systemic corticosteroid therapy
- Allergy to mifepristone, misoprostol, or other prostaglandins
- Inherited porphyria
- Hemorrhagic disorder or current anticoagulant therapy

Special Considerations

- Patients with severe anemia (hemoglobin <10 mg/dl, hematocrit <30%) should be evaluated individually for symptoms and presence of current bleeding in order to determine the safest method of pregnancy termination.
- Any patient with chronic medical conditions (e.g., cardiac disease, hepatic disease, uncontrolled diabetes, uncontrolled seizure disorder, inflammatory bowel disease, renal disease, pulmonary disease) should be evaluated individually to determine the safest method of pregnancy termination.
- Breastfeeding mothers: There is no evidence that mifepristone is harmful to breastfeeding infants. Women should be warned that misoprostol can cause mild side effects such as diarrhea in infants, but they do not necessarily need to stop breastfeeding during this time.

Equipment (Fig. 27.2)

- Danco® Patient Agreement Form and the Mifeprex® Medication Guide (download from website www.earlyoptionpill.com)
- Patient Instructions for Medication Abortion Form (Fig. 27.2)
- Ultrasound – optional (not mandatory per FDA protocol)
- Ultrasound documentation form (if applicable)
- Mifepristone 200 mg pills (must be a registered provider with Danco®; http://www.earlyoptionpill.com)
- Misoprostol 200 mcg tablets (can order in bulk and dispense)
- Urine pregnancy test
- Ability to document Rh status, and other blood work if needed (e.g., hemoglobin)

Procedure (Algorithm 27.1)

1. Confirm the patient is clear and confident about the decision to end the pregnancy, and is free of coercion. If needed, perform pregnancy options counseling. Important points to consider for pregnancy options counseling:
    - Ask open-ended questions in a nonjudgmental manner (e.g., “How do you feel about being pregnant?”).
    - Inquire about the patient’s support network (partner, family, friends, etc.).
    - Discuss all options as necessary: continuing the pregnancy and becoming a parent; continuing the pregnancy and opting for an adoption; ending the pregnancy.

Medication Abortion Instructions

Today you took mifepristone to end your pregnancy. You took 200 milligrams of mifepristone at ____am/pm. You may have some vaginal bleeding after taking this pill.

Any time from 24 to 48 hours after you took the first pill, _____am/pm, you must take another medicine, misoprostol (also called Cytotec). **Choose a time when you have had a good meal and plenty of rest.** Swallow one ibuprofen pill one hour before you take the misoprostol – this will help decrease your cramps. You must take the misoprostol even if you have started to bleed.

Each misoprostol pill is 200 micrograms. **Place 2 misoprostol pills in each cheek (4 pills total).** Leave them in your cheeks for 30 minutes. After 30 minutes, swallow the pills with water.

WHAT TO EXPECT

Cramping and Bleeding: Misoprostol causes cramping and bleeding, often with clots. The cramps and bleeding may be much more than you get with a period. The cramps usually start 2 to 4 hours after you take the pills, and may last for 3 to 5 hours. This heavy bleeding means that the treatment is working. The bleeding often lasts 1 to 2 weeks, and it may stop and start a few times.

You may have a lot of pain or cramps – if so, take pain medicine. You can take ibuprofen (Motrin or Advil) up to 800 milligrams every 8 hours and/or hydrocodone up to 2 pills every 4 to 6 hours. You can also use a heating pad to relieve the pain. You may have nausea, diarrhea, or chills. This should get better in a few hours.

Sadness or very emotional: You may feel very relieved when the abortion is over. You may also feel sad or moody. These feelings are partly from the changes in hormones, now that you are no longer pregnant. Feeling emotional at this time is normal. If you think your emotions are not what they should be, please talk to us.

When will your period come back? You can expect a period in 4 to 8 weeks. It is not the same for everyone.

You **should** call me if:
- Your bleeding soaks through more than 2 maxi pads per hour for 2 hours,
- You do **not** bleed within 24 hours after taking the misoprostol, OR
- You start to feel very ill after the heavy cramping and bleeding is over.

To reach me:
Call my 24-hour number: _____. If you have any questions or think something is going wrong, call this number and I will call you back. It may take me 10 to 15 minutes to return your call. No question is too small. **Please feel free to call me.**

Follow-up:
You will have a visit or phone call with me in 7-14 days to make sure that the abortion is complete.

Birth Control:
If you want to use birth control pills, patch, or ring, I have given you a prescription. You should start these on _____, even if you are still bleeding.

Fig. 27.2 Patient instructions for medication abortion. (Adapted from Reproductive Health Access Project http://www.reproductiveaccess.org/. Accessed Sept 6, 2018)

2. Confirm pregnancy diagnosis and gestational age:

- Assess last menstrual period (LMP) and perform a bimanual to check for consistency between history and examination.
- Obtain a urine pregnancy test or serum β-HCG, as indicated.
- Obtain or perform an ultrasound, as indicated.

A note about ultrasound: While ultrasonography is widely used for gestational age dating, it is not mandatory to perform in an ultrasound for medication abortion per FDA protocol. According to the Mifeprex® Prescribing Information, "the duration of pregnancy may be determined from menstrual history and by clinical examination. Ultrasonographic scan should be used if the duration of pregnancy is uncertain, or if ectopic pregnancy is suspected" [9]. It has been shown that women

seeking abortions can accurately estimate their gestational age and that clinician assessment of gestational age (based on exam and LMP) had a high correlation with sonography [12]. Based upon this evidence, some providers have advocated for an "ultrasound as needed" protocol, such that an ultrasound is performed only under certain circumstances [13, 14]. This approach can greatly improve access to abortion services, particularly in sites where the cost of an ultrasound machine is prohibitive and/or there are no trained ultrasonographers.

Indications for ultrasonography prior to medication abortion:

- Discrepancy between gestational age as assessed by uterine size and LMP
- Uncertain LMP
- Adnexal mass or pain
- Recent use of hormonal contraception
- Provider uncertainty with exam
- History of previous ectopic pregnancy

At Mifepristone Visit

1. Confirm eligibility criteria and conduct other medical screening as indicated (e.g., Pap smear, sexually transmitted infection (STI) testing). The performance of such screening tests in otherwise asymptomatic patients is not mandatory prior to providing medication abortion.
2. Help the patient choose a birth control method if desired. Discuss emergency contraception and provide advance prescriptions if necessary.
3. Confirm Rh type: review blood donor cards and/or old prenatal labs, or send for testing.
4. If the woman is Rh negative, a dose of MICRhoGAM® (50 μg) (Ortho Clinical Diagnostics, Raritan, NJ) should be given just prior to using misoprostol or within 72 h of bleeding. RhoGAM® (300 μg) may be substituted if MICRhoGAM® unavailable.
5. Testing for hemoglobin or hematocrit is not mandatory per the Mifeprex® Medication Guide. Providers may choose to routinely screen for anemia depending on the local prevalence on anemia and/or by individual risk factors and clinical history [9, 15].
6. Review the *Mifeprex® Medication Guide* and have patient review and sign the *Patient Agreement Form* (both required by Danco®, the manufacturer of mifepristone).
7. Counsel the patient on what to do and expect (Fig. 27.2).
8. The patient should pick a convenient time to administer the misoprostol, after mifepristone ingestion. Review *how and when* to administer the misoprostol, depending on which route has been chosen.
9. Advise on the use of pain and/or nausea medications prior to misoprostol administration (e.g., ibuprofen, promethazine).

10. Review when to call: if no bleeding occurs within 24 h, if soaking through two pads an hour for two consecutive hours, and if sustained fever >100.4 °F.
11. Advise that cramping and bleeding may occur a couple of hours (h) after taking the misoprostol, which may peak in 3–5 h. The cramping ranges from mild to intense. Approximately two-thirds of women will complete the abortion process within 4 h. By 24 h, 90% of patients will have successfully completed the abortion.
12. The bleeding is similar to a heavy period with or without clots. The patient should be told that she will see blood and tissue and may recognize fetal parts at 64–70 days gestation.
13. Either administer or dispense mifepristone. Document the time and date and the lot number of the mifepristone.
14. Prior to leaving, the patient should have:
    (a) Misoprostol tablets (record the lot number and expiration date) to self-administer at home
    (b) Prescriptions for pain and/or nausea
    (c) Prescriptions for birth control and, if necessary, emergency contraception.
15. The patient can start self-administered hormonal methods within 5 days of taking mifepristone, even if still bleeding.
16. A follow-up appointment in 2 weeks
17. A 24-h provider contact number
18. The Patient Instruction Form (Fig. 27.2)

At Follow-Up Visit

1. Confirmation of pregnancy termination can be confirmed by:
    - Patient history (a description of cramping and bleeding, passage of pregnancy tissue) *and*
    - Physical examination *or* ultrasound *or* documentation of declining serum β-HCG level (at least 80% decline from baseline over 5–10 days) [15]; Postabortion indications for ultrasonography:
        – History not consistent with successful abortion
        – Patient still feels pregnant
        – Serum β-HCG not declining
        – Provider uncertainty with history
2. If the abortion is incomplete (persistent sac, no evidence of fetal cardiac activity), the patient can be offered repeat misoprostol or an aspiration procedure. An aspiration procedure may need to be involved for problematic bleeding and/or ongoing pregnancy (presence of fetal cardiac activity).
3. Clinicians should inquire about the patient's experience with the abortion process and provide support and reassurance as appropriate.

4. Review the contraceptive plan and initiate the method that day, if possible.

Complications and Risks

Less than 1% of all US abortion patients experience a major complication. The risk of death associated with abortion in the United States is less than 0.6 per 100,000 procedures, which is less than one-tenth the risk associated with childbirth. Complications and risks are:

- Significant bleeding requiring intervention: <1%
- Infection: <1%
- Sepsis: <0.01%
- Incomplete abortion, requiring a uterine aspiration procedure: 0.16–5%

With medication abortion, the most common significant complication is the risk of ongoing pregnancy (1–3%) or incomplete abortion (3–6%), so all patients should be counseled about the importance of the follow-up visit as well as the potential need for a uterine aspiration procedure at the time of medication abortion counseling [10].

A Note about Sepsis: On July 15, 2005, the US Food and Drug Association (FDA) issued a public health advisory regarding four deaths in the United States (all in California) that occurred following vaginal administration of misoprostol and oral mifepristone for medication abortion. *Clostridium sordelli*, a virulent Gram-positive bacteria, was identified as the causative agent in all cases. Other cases of *Clostridium sordelli*-related deaths have involved cases of spontaneous abortion and childbirth. After an extensive investigation, the Centers for Disease Control and Prevention, the FDA, and the National Institute of Allergy and Infectious Diseases concluded that there is no definitive causal relationship between mifepristone and the deaths [16]. Clinicians should be familiar with the signs and symptoms of sepsis and initiate prompt evaluation of women who present with severe abdominal pain, prolonged heavy bleeding, syncope, or abdominal pain or general malaise, with or without fever, that occurs more than 24 h after taking misoprostol [11]. For more information on this topic, please visit the CDC website (http://www.cdc.gov/ncidod/dhqp/id_Csordellii.html).

Tricks and Helpful Hints

- Some patients who otherwise meet medical eligibility may not be appropriate candidates for medication abortion for psychosocial reasons.
- Clinicians should consider the following questions to identify patients who may be unable to carry out instructions or follow-up: Does the patient have a phone, a car, childcare? How far do they live from your office? Is there a language barrier?

Procedure Note

See Fig. 27.3 for the Medication Abortion Charting Form.

(Provider to fill in blanks/circle applicable choice when given multiple choices and customize as needed.)

Chart Review Form
Medication Abortion

	Yes	No	N/A
Options counseling documented			
Adverse effects education documented			
Protocol explanation documented			
Informed consent form: signed, in chart			
Rh status documented Rhogam given, if indicated			
Contraindications ruled out No IUD in place No allergy to prostaglandins No chronic adrenal failure No long-term systemtic corticosteroid use No concurrent anticoagulant therapy No ectopic pregnancy No hemorrhagic disorder			
Iniital beta-HCG level obtained (if indicated)			
Ultrasound dating obtained (if indicated)			
Screening for anemia performed/documented (if indicated)			
Pain medication prescribed			
Follow up visit completed			
Assessment of abortion completed documented by History Beta-HCG level Ultrasound			
Contraception plan documented			

Fig. 27.3 Medication abortion procedure note/charting form. (Adapted from Reproductive Health Access Project http://www.reproductiveaccess.org/. Accessed Sept 6, 2018)

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)		
For the visit	99204 or 99214	Level 4 new or established patient E/M visit
For the ultrasound	76817	Transvaginal ultrasound, pregnant uterus
	76815	Limited ultrasound, pregnant uterus
For medication(s)	J8499	Prescription drug, oral, nonchemo, not otherwise specified
	J3490	Unclassified drug
	90385	MICRhoGAM®, if given in office
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, 10th Revision, Clinical Modification, Center for Disease Control and Prevention) [non-comprehensive]		
Legally induced abortion, without mention of complication, complete		Z33.2

If J codes not accepted by insurance carrier, use 99070 (a cost of materials CPT code) for Mifeprex® or S0190 for Mifeprex®. Note: Each insurance carrier may reimburse for Mifeprex® using a different code. The name of the drug (Mifeprex®), the dosage (200 mg), and the 11-digit National Drug Code (NDC) from the drug package must accompany this claim. In addition, submit a copy of the drug invoice to show the cost of the drug.

Patient Instructions

See Fig. 27.2.

(Provider to fill in blanks/circle applicable choice when given multiple choices and to customize as needed.)

Case Study Outcome

The patient took 200 mg of mifepristone the day of the office visit in your office. She self-administered 800 μg of misoprostol buccally at home approximately 24 h later and experienced bleeding similar to a heavy period 1–2 h later, passing cramps and tissue. She also had cramping that eventually subsided with ibuprofen and a

heating pad. At her follow-up visit, an ultrasound revealed a thick endometrial stripe but no intrauterine pregnancy. She was bleeding lightly and pain-free and reported relief that the process was over. She started her birth control pills within 5 days of taking mifepristone, as you advised.

Questions for Learners

- What are some reasons why a patient may choose a medication abortion over an aspiration abortion?
- What anticipatory guidance would you give a patient who is planning to have a medication abortion?

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Additional Resources

Websites

For educational resources and a clinical curriculum regarding medication abortion, visit The National Abortion Federation: http://www.prochoice.org/education/resources/index.html.

For information regarding abortion training in family medicine residencies, visit The Center for Reproductive Health Education in Family Medicine: www.rhedi.org.

For information regarding state laws on abortion, visit The Center for Reproductive Rights: http://www.reproductiverights.org/ or the Guttmacher Institute: guttmacher.org.

For patient and clinician resources regarding early abortion care (including the methotrexate/misoprostol regimen), visit The Reproductive Health Access Project: http://www.reproductiveaccess.org/.

To obtain the Mifeprex® Medication Guide and Patient Agreement Form, visit: www.earlyoptionpill.com.

Chapter 28
Manual Vacuum Aspiration (MVA) Abortion

Anna Sliwowska and Jennifer Amico

Introduction

Aspiration abortion is a safe procedure that can be performed in the office or in an ambulatory surgical center. It can be accomplished either by using a 60 cc handheld syringe (manual vacuum aspirator) or by using vacuum aspiration with an electric pump. These methods are commonly referred to as a "surgical abortion" and can be performed safely and effectively in an outpatient setting with local anesthesia alone or combined with light to moderate sedation [1]. Aspiration abortion is associated with lower rates of complications than sharp curettage (dilation and curettage), and along with medication-induced abortion are the preferred methodologies of abortions whenever possible [2]. Aspiration abortion performed with a Manual Vacuum Aspirator (MVA) is particularly adaptable for use in the primary care setting because of several features of the MVA: (1) low cost and ability to reuse the manual aspirator; (2) small size and portability of the manual aspirator; (3) its ability to aspirate tissue without extensive fragmentation, allowing for easier identification of early pregnancy tissue; and (4) its ability to work without an electrical source. The MVA is also a quieter device than the electric vacuum, which may reduce patient anxiety. Use of the MVA is clinically indicated for elective abortions up to 12 weeks by uterine size, ultrasound dating, or last menstrual period (LMP). Other uses of the MVA technique include treatment of early pregnancy failure and endometrial biopsy.

After the United States (US) Food and Drug Administration's (FDA) approval of mifepristone for medication abortion in 2000, the number of medication abortions

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performed in the US has steadily increased. Medication abortion offers an important alternative for women seeking early abortion services (see Chap. 26). In order to provide comprehensive abortion options counseling, clinicians should be familiar with the advantages and disadvantages of medication abortion versus aspiration abortion from a patient perspective (see Table 28.1, patient handout).

Clinicians should be familiar with state regulations for first trimester abortion provision prior to introducing MVA in their practice. Regulations may include mandatory waiting periods, parental consent for minors, and/or mandatory health department reporting. Advanced practice clinicians (nurse practitioners, physician assistants) should specifically check if "physician-only" laws apply for abortion provision in their state.

Less than 1% of all US abortion patients experience a major complication. The risk of death associated with a legally induced abortion in the United States is less than 0.65 per 100,000 of reported legal procedures, which is less than one-tenth the risk associated with childbirth [3]. The routine use of antibiotics just prior to or following induced abortions <16 weeks is associated with a 42% reduction in the incidence of postabortal upper genital tract infection, regardless of the woman's preprocedure risk status [4]. All patients undergoing a surgical abortion should receive prophylactic antibiotics using one of the following, single-dose regimens: doxycycline 200 mg by mouth once, azithromycin 500 mg by mouth once, or metronidazole 500 mg by mouth once [5]. It is not clear which antibiotic regimen has the greatest preventive effect.

Case Study

A 42-year-old G3P2002 female presents to your office with complaints of nausea. Her last menstrual period was 8 weeks ago. She stopped using birth control pills a year ago, citing that "I was too old to be on the pill." She and her husband already have two teenagers. She is shocked when her pregnancy test is positive and feels overwhelmed about the thought of having another child. After pregnancy options counseling, she goes home to talk with her husband. The couple returns the next week, having decided to proceed with an aspiration abortion. Her examination reveals an 8-week-size, anteverted uterus. A transvaginal ultrasound reveals an intrauterine pregnancy approximately 8.6 weeks by crown-rump length.

Diagnosis (Algorithm 28.1)

- 8.6-week intrauterine pregnancy
- Desire for elective termination

Table 28.1 Comparison of early abortion options: a patient resource

Abortion pill/medication abortion (mifepristone and misoprostol)	Aspiration abortion (suction or vacuum aspiration)
1. How far along in the pregnancy can I be?	
Up to 10 weeks from the first day of your last period	Up to 12 weeks from the first day of your last period
2. What will happen?	
The abortion happens at home.	The abortion happens in the office
During your appointment, you will get the first abortion pill (mifepristone) which you will take at a time that works best for you.	The actual abortion procedure takes 5–10 minutes
You will likely feel fine after taking mifepristone. You may have some nausea.	Your healthcare provider puts instruments in your vagina and uterus to remove the pregnancy
6–72 hours later, you take four misoprostol pills.	You may have a return visit to your regular healthcare provider or to the office where you had the abortion 1–2 weeks later
The cramping and bleeding starts 1–4 hours after you insert the misoprostol. You will have heavy bleeding and cramps for a few hours.	The abortion happens in the office
3. How painful is it?	
You may have mild to very strong cramps off and on during the abortion. Pain pills help.	You may have mild to very strong cramps during the abortion. Pain pills help
4. How much will I bleed?	
Expect heavy bleeding with clots during the abortion. After that, lighter bleeding may continue off and on for a few weeks.	You may have light bleeding for 1–7 days. Bleeding may continue off and on for a few weeks
5. How much does it cost?	
For both types of abortion, the exact cost depends on where you go.	For both types of abortion, the exact cost depends on where you go
6. Can the abortion fail?	
The pills work 98–99% of the time. If the pills fail, you may try the pills again or have an abortion procedure.	It works 99% of the time. If it fails, you must have a repeat abortion procedure
7. Can I still have children afterward?	
Yes. Neither type of abortion lowers your chances of getting pregnant or staying pregnant in the future.	Yes. Neither type of abortion lowers your chances of getting pregnant or staying pregnant in the future
8. Is it safe?	
Both pills have been used safely for over 10 years. Big problems are rare. Abortion is at least 10 times safer than continuing a pregnancy.	The suction abortion procedure has been done safely for over 40 years. Abortion in the first 12 weeks leads to very few problems. Abortion is at least 10 times safer than continuing a pregnancy
9. What are the advantages?	

(continued)

Table 28.1 (continued)

Abortion pill/medication abortion (mifepristone and misoprostol)	Aspiration abortion (suction or vacuum aspiration)
You won't have shots, anesthesia, or instruments in your body.	It is over in a few minutes. It works 99% of the time
It may feel more natural, like a miscarriage.	You see less bleeding than you would with a pill abortion
Being at home instead of in an office may feel more private.	Medical staff members are with you during the abortion
	It can be done later in the pregnancy than a pill abortion
10. What are the disadvantages?	
It takes 1–2 days to complete the abortion.	A healthcare provider must insert instruments inside the uterus
Bleeding can be very heavy and may last longer than with a suction abortion procedure.	Anesthetics and pain medicines may cause side effects
Cramps can be severe and may last longer than with an abortion procedure.	You have less control over the abortion procedure. You may not be able to choose who is with you
It cannot be done as late in pregnancy as an abortion procedure.	

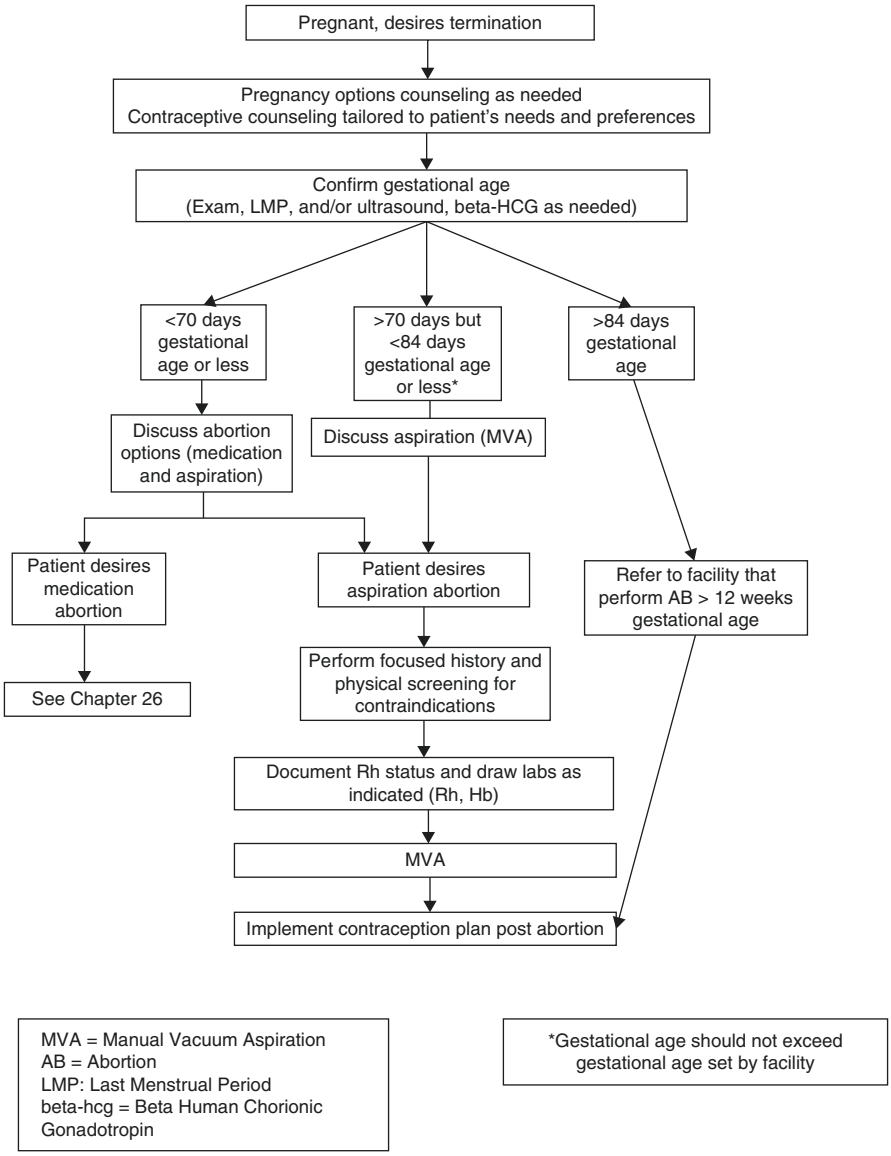
Adapted from the Reproductive Health Access Project: www.reproductiveaccess.org with permission

Differential Diagnosis

- Normal, intrauterine pregnancy
- Ectopic pregnancy
- Heterotopic pregnancy (concomitant presence of an intrauterine and ectopic pregnancy)
- Early pregnancy failure (threatened, incomplete, or complete spontaneous abortion)

Indications (Algorithm 28.1)

- Elective abortion up to 12 weeks
- Treatment for early pregnancy failure up to 12 weeks
- Medical necessity for women with comorbidities in which carrying a pregnancy to term poses a threat to health and/or life
- Endometrial biopsy (instead of using endometrial pipelle)



Algorithm 28.1 Decision tree for women desiring elective termination

Contraindications (Algorithm 28.1)

- Gestational age is greater than the limit set by the clinical site
- Inability to tolerate MVA under local anesthesia and available analgesia
- Known hydatidiform mole

- Hemodynamic instability
- Severe medical illness (e.g., suspected diabetic ketoacidosis, uncontrolled seizure disorder, acute asthmatic attack) for which surgery would be life-threatening

Special Considerations/Contraindications

- Active intrauterine infection: Clinicians should decide whether or not to proceed with the procedure depending on the patient's clinical status. Treatment should be initiated promptly per the Centers for Disease Control (CDC) Sexually Transmitted Diseases Treatment Guidelines [6].
- Mucopurulent cervicitis: The patient should be treated per CDC guidelines for presumptive gonorrhea and chlamydia cervicitis [6]. The patient can still undergo the procedure that day but should complete treatment postprocedure.
- Significant medical comorbidities: Examples include uncontrolled diabetes, cardiovascular or pulmonary disease, seizure disorder, and blood-clotting disorders. Patients should be medically stable prior to the procedure and/or referred to a facility that is able to treat women with such conditions.
- Cervical stenosis: May require cervical ripening agents, special dilation techniques.
- Severe anemia: Defined as hemoglobin <8 mg/dl, hematocrit <24%, and/or symptomatic. Clinicians need to determine whether to proceed or delay the procedure.
- Suspected and/or known ectopic pregnancy: Evaluate, treat, and refer according to local protocol.

Equipment (Fig. 28.1)

Sterile instrument trays containing the following:
Procedure supplies:

- Specula (various sizes)
- Ringed forceps (sponge stick)
- Iodine cups
- Tenaculums
- Vaginal dilators (e.g., Denniston or Pratt)
- 60 cc aspiration syringe (e.g., IPAS MVA Plus®, IPAS, Chapel Hill, NC)
- Flexible cannulas in sizes 6–12 (e.g., IPAS Karman® [IPAS, Chapel Hill, NC], MedGyn® [Medgyn, Lombard, IL], Berkeley® [Berkeley Medevices, Richmond, CA])

For viewing and processing products of conception (POC):

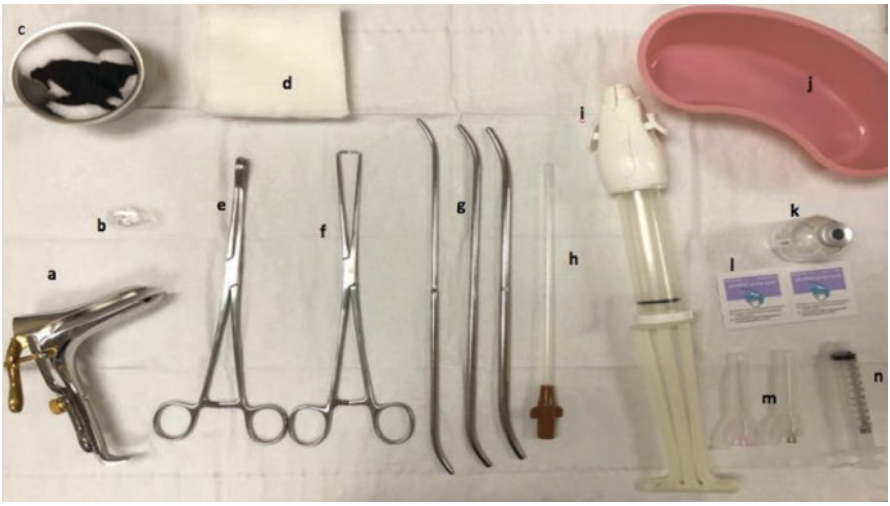


Fig. 28.1 Equipment setup for MVA. *Sterile*: (**a**) speculum; (**b**) surgical lubricant; (**c**) antiseptic-soaked cotton balls in basin; (**d**) sterile gauze sponges; (**e**) ring forceps; (**f**) single-tooth tenaculum; (**g**) cervical dilator set; (**h**) flexible cannula. *Not sterile*: (**i**) manual vacuum aspirator; (**j**) kidney-shaped basin; (**k**) lidocaine; (**l**) alcohol pads; (**m**) 18-gauge and 22-gauge 1.5-inch needles; (**n**) 10-cc syringe

- Light box (available at a photography or craft store)
- Glass pyrex dish (traditional pie size)
- Strainer (kitchen supply)
- Long forceps (to move and pick up POC)
- Pathology specimen jars or disposal cups

Additional supplies:

- Two 10–12 cc syringes
- 22 gauge 1½ in. needles
- Sharps containers
- Nonsterile gloves/Sterile gloves
- Sterile gauze
- Betadine
- Kidney basins
- Autoclave and supplies for cleaning and wrapping equipment

Medications:

- Lidocaine 1% (may dilute 50/50 with Normal Saline)
- RhoGAM® (Ortho Clinical Diagnostics, Raritan, NJ)
- For emergency use:
  - Methergine® (Novartis, Basil, Switzerland) (for excessive bleeding)
  - Misoprostol (for cervical ripening, excessive bleeding)

  - Atropine
  - IV tubing, IV fluid, IVs in various gauges, tape
  - Albuterol inhaler
  - Epinephrine 1:1000

  Ultrasound and supplies (if an ultrasound is on-site):

- Probe covers
- Probe disinfectant
- Ultrasound gel
- Printer paper (if printer available)

  Patient items:

- Drape
- Gown
- Sanitary napkins

  Documents:

- MVA Consent Form (Fig. 28.2)
- MVA Procedure Form (Fig. 28.3)
- MVA After-Care Instructions and Information (Fig. 28.4)
- Relevant birth control education

Procedures

Pre-procedure Steps

1. Perform pregnancy options counseling. Important points to consider:
   - Ask open-ended questions in a nonjudgmental manner, e.g., "How do you feel about being pregnant?"
   - Inquire about the woman's support network (partner, family, friends).
   - Discuss all options as necessary: (1) continuing the pregnancy and becoming a parent; (2) continuing the pregnancy and opting for an adoption; or (3) ending the pregnancy.
   - Assess that the woman's decision, whatever it may be, has not been coerced.
2. Confirm pregnancy diagnosis and gestational age by assessing LMP, performing a bimanual examination, and obtaining an ultrasound. Obtain a urine pregnancy test or serum β-HCG, if indicated.
3. Confirm eligibility criteria and conduct other medical screening as indicated (e.g., Pap smear, STI testing). The performance of such screening tests in otherwise asymptomatic patients is not mandatory prior to performing MVA.

4. Help the woman select an appropriate birth control method. Discuss Emergency Contraception (EC) and provide advance prescriptions of EC if necessary.
5. Providers may choose to routinely screen for anemia depending on the local prevalence of anemia and/or by individual risk factors and clinical history [4].
6. Confirm Rh type (review blood donor cards, old prenatal labs, or send for testing).
7. Review consent form and obtain the patient's signature (Fig. 28.2).

Manual Vacuum Aspiration (MVA) Consent Form

____ I request a Manual Vacuum Aspiration (MVA), a procedure that will empty my uterus. This procedure may be used as a suction abortion or as treatment for a miscarriage, a failed medication abortion or for abnormal uterine bleeding.

____ I understand that if I am pregnant, my three options regarding this pregnancy are parenthood, adoption, and abortion. I understand that if I am pregnant, the MVA will end my pregnancy.

____ I understand that before the MVA, I may have blood tests done to check me for anemia and I will have to document my Rh type by history, blood donor card, prior blood test or a new blood test.
If I am Rh negative, I will be offered a shot of MicRhogam.

____ I understand that I might be offered medication before the MVA, ibuprofen to lessen the cramping. I will have local anesthesia with Lidocaine injected. To the best of my knowledge, I am not allergic to Ibuprofen or Lidocaine.

____ I understand that the possible complications from MVA include: incomplete emptying of my uterus, infection, bleeding, allergic reaction and perforation.

____ I have read this form and have had time to think about it. I have had all my questions answered.

____ I have been given an information sheet explaining how and when to get help should a question or problem arise after the procedure.

____ In the event of an unexpected complication during the MVA, I request and authorize the physician to do whatever is needed to protect my health and welfare.

____ I hereby consent that _____ do the procedure "manual vacuum aspiration" for me.

____ If I had testing for sexually transmitted infections or blood type testing I will be available at this number to receive results:

My Phone: _____ May we leave a confidential message? ___yes ___no

Signature of patient: _____**Date:**_____

Witness: _____ **Date:** _____

Signature of Clinician:_____ **Date:** _____

Fig. 28.2 MVA consent form (adapted from Reproductive Health Access Project: http://www.reproductiveaccess.org/ with permission)

Manual Vacuum Aspiration (MVA) Consent Form

____ I request a Manual Vacuum Aspiration (MVA), a procedure that will empty my uterus. This procedure may be used as a suction abortion or as treatment for a miscarriage, a failed medication abortion or for abnormal uterine bleeding.

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If I am Rh negative, I will be offered a shot of MicRhogam.

____ I understand that I might be offered medication before the MVA, ibuprofen to lessen the cramping. I will have local anesthesia with Lidocaine injected. To the best of my knowledge, I am not allergic to Ibuprofen or Lidocaine.

____ I understand that the possible complications from MVA include: incomplete emptying of my uterus, infection, bleeding, allergic reaction and perforation.

____ I have read this form and have had time to think about it. I have had all my questions answered.

____ I have been given an information sheet explaining how and when to get help should a question or problem arise after the procedure.

____ In the event of an unexpected complication during the MVA, I request and authorize the physician to do whatever is needed to protect my health and welfare.

____ I hereby consent that _____ do the procedure "manual vacuum aspiration" for me.

____ If I had testing for sexually transmitted infections or blood type testing I will be available at this number to receive results:

My Phone: _____ May we leave a confidential message? ___yes ___no

Signature of patient: _____**Date:**_____

Witness: _____ **Date:** _____

Signature of Clinician:_____ **Date:** _____

Fig. 28.2 (continued)

Performing MVA

Throughout the procedure, the "no-touch" technique should be followed such that instrument parts that enter the cervical os are never touched.

Step 1: Prepare the Woman and Prep the Cervix (Fig. 28.5)

- Have the woman empty her bladder.
- Explain the procedure steps to the woman and answer all her remaining questions.

MVA PROCEDURE NOTE

Date:
Name:
DOB:

Physical Examination:
Uterus: Size in weeks (bimanual): _____ AV/Mid / RV Cervix: WNL / CMT, parous/nullip
Vagina: WNL / discharge noted:

Procedure:
- Cervix and vagina swabbed with Betadine.
- Lidocaine 1%, _____cc total injected.
- Tenaculum applied _____ o'clock.
- Cervix progressively dilated to: _____.
- Cannula inserted, size _____.
- Estimated blood loss: _____ cc.
- Additional comments:

Tissue Exam:
- Decidual tissue
- Villi
- Gestational sac
- Tissue appropriate for gestational age

Post-Op Ultrasound if done:
No IUP visualized
Other:

Assessment:
Patient stable, AB complete
- Pad checked for bleeding
  - For complications, see progress notes
- Post-procedure vital signs: B/P____ P____

Plan:
- Expected symptoms discussed; post-procedure instructions given.
- Rhogam if needed:_____
- Doxycycline 100 mg tabs 2 tab _____ Dispensed or ___ 1 gm Zithromax
- Contraception:_____
- Follow up appointment recommended.

Clinician Signature:_____

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Fig. 28.3 MVA preprocedure note and procedure note (adapted from Reproductive Health Access Project: http://www.reproductiveaccess.org/ with permission)

ABORTION PROCEDURE AFTER-CARE

Today you had an abortion procedure. You will probably feel fine when you go home. You can go back to your regular activities as soon as you want to. You can take a shower and wash your hair as soon as you want to. You can eat normally, although you may still feel nauseated for another few days.

Are there things you should not do? Yes. For one week, do not put anything in your vagina. Do not use tampons, do not douche, and do not have sex.

WHAT TO EXPECT Vaginal Bleeding: You can expect to have bleeding for up to 2 weeks. It is common for the bleeding to stop and start for several weeks after the abortion. Some people have no bleeding for 2 or 3 days and then begin to have bleeding like a period. Other people have only spotting for a few days and then no more bleeding at all. If you exercise or have a lot of activity, you may notice the bleeding increases; this is not dangerous.

Cramping: You may have cramps off and on during the week following an abortion. You can use pain medication like Tylenol, Ibuprofen (Motrin or Advil), or Naproxen (Aleve or Naprosyn). You can also use a heating pad, or drink some warm tea.

Sadness or very emotional: You may feel very relieved when the abortion is over. You may also feel sad or moody. These feelings are partly from the changes in hormones, now that you are no longer pregnant. Feeling emotional at this time is normal. If you think your emotions are not what they should be, please talk to us.

When will your period come back? You can expect a period in 4 to 8 weeks. Itis not the same for everyone.

You **should** call me if: Your bleeding soaks through more than 2 maxi pads per hour for more than 2 hours. Your cramps that are getting stronger and are not helped by pain medication. ! If your temperature is higher than 101 degrees (38.3 degrees Celcius).

To reach me:

Call my 24-hour number: _____. If you have any questions or think something is going wrong, call this number and I will call you back. It may take me 10 to 15 minutes to return your call. No question is too small. **Please feel free to call me.**

Follow-up visit: You have an appointment in 1 week, _____ at _____am/pm.

Birth Control:

If you want to use birth control pills, patch, or ring, I have given you a prescription. You should start these on _____, even if you are still bleeding.

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Fig. 28.4 MVA patient instructions (adapted from: Reproductive Health Access Project: http://www.reproductiveaccess.org/ with permission)

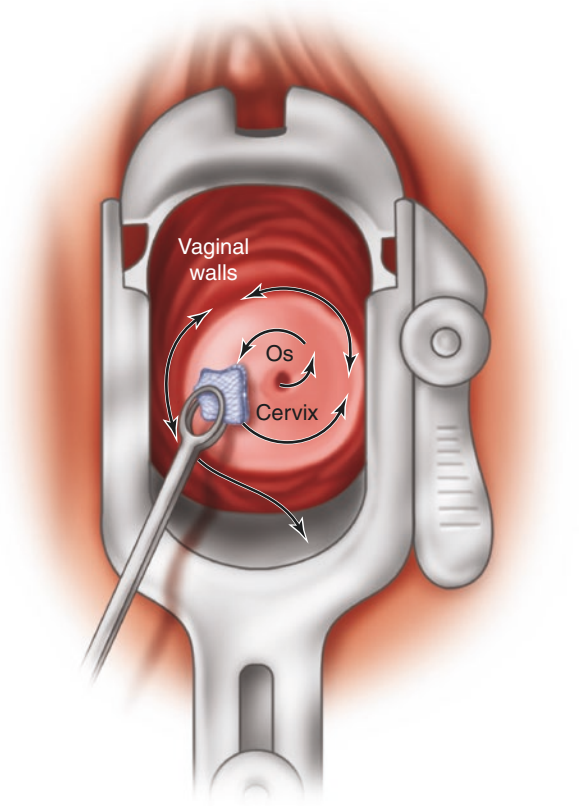

Fig. 28.5 Prepping the cervix (with permission from IPAS, Stephen C. Edgerton, illustrator)

- Help the woman into dorsal lithotomy position on the table.
- Wash hands, put on appropriate barrier equipment; gloves can be sterile or nonsterile.
- Perform a bimanual examination, noting the size, shape, and position of the uterus.
- Insert the speculum so that the entire cervix is well visualized.
- Clean the cervix with an antiseptic-soaked sponge.

Step 2: Administer a Paracervical Block (Fig. 28.6)

- Inject 1–2 cc of local anesthetic at the planned tenaculum site (12:00 for an anteverted uterus, 6:00 for a retroverted uterus).
- Place the tenaculum at the anesthetized site by opening the tenaculum and closing it around a generous amount of cervical tissue, which allows gentle traction to be applied to straighten the uterus.

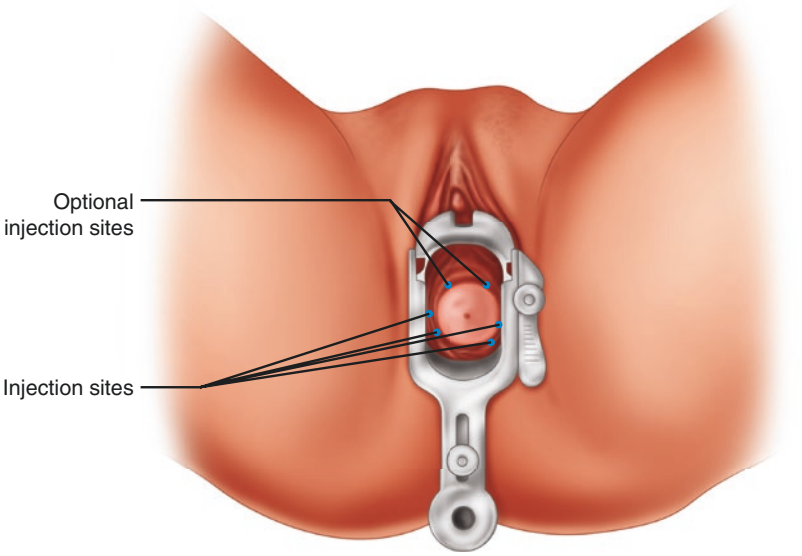

Fig. 28.6 Paracervical block sites (with permission from IPAS, Stephen C. Edgerton, illustrator)

- Using the tenaculum, move the cervix to the side to visualize the "reflection," the site at which smooth cervical tissue meets vaginal tissue.
- Inject 5–10 mL of anesthetic into a depth of at least 1.5 cm at 2–4 points at the "reflection" (2 and 10 o'clock and/or 4 and 8 o'clock). Pull back on the plunger before injecting, to avoid injecting in a blood vessel.

Step 3: Dilate the Cervix (Table 28.2)

Table 28.2 displays the recommended dilation and cannula size needed for corresponding gestational age. During dilation, maintain gentle traction on the tenaculum to pull the uterine axis as straight as possible.

1. Gently insert the first dilator into the cervix so that it is introduced just beyond the internal os. A slight "give" may be felt as the dilator slides from the wider external os past the internal os.
2. Take the dilator out and turn it over to dilate with the other side of the dilator (which is the next size up). Progressively dilate to the appropriate size.

Table 28.2 Suggested dilation and cannula by gestational age

Gestational age (weeks) by ultrasound	Dilator size – measured in circumference (or in diameter; mm)	Cannula size (mm)
5.0–6.4	19 (6)	6
6.5–7.4	21 (7)	7
7.5–8.4	25 (8)	8
8.5–9.4	27 (9)	9
9.5–10.4	31 (10)	10
10.5–11.4	33 (11)	11
11.5–12.4	37 (12)	12

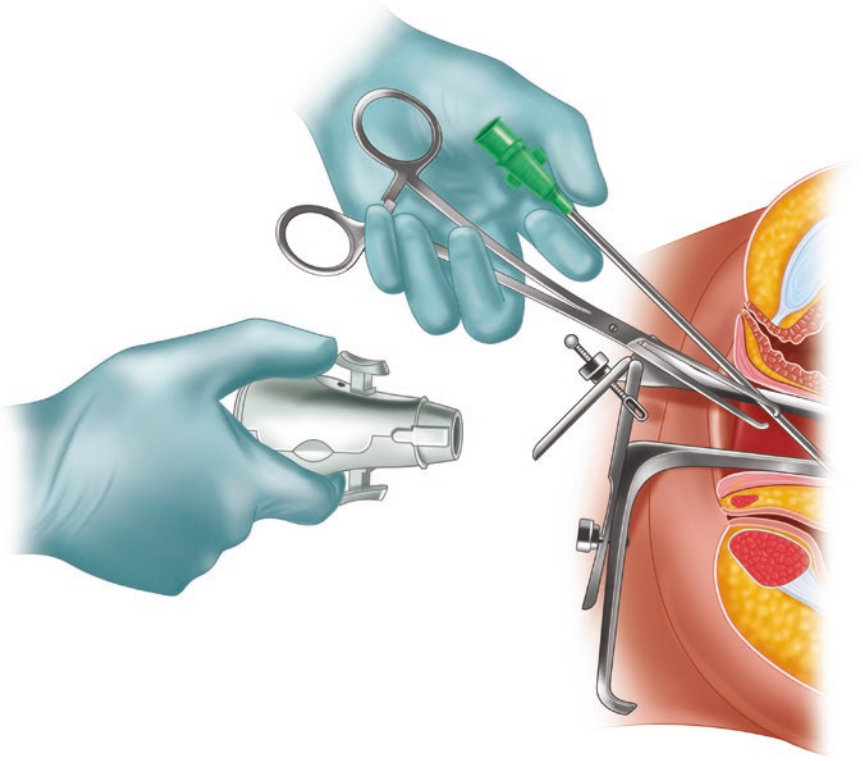

Fig. 28.7 Cannula inserted and attaching aspirator (with permission from IPAS, Stephen C. Edgerton, illustrator)

Step 4: Insert the Cannula and Attach the Syringe (Fig. 28.7)

1. Insert the cannula into the cervix, past the cervical os and into the uterine cavity.
2. Attach a "primed" MVA syringe to the cannula, holding the tenaculum and the end of the cannula in one hand and the aspirator in the other.

Step 5: Evacuate the Uterus

- Release the valve buttons of the MVA aspirator, which will start the suction (Fig. 28.8).
- Gently and slowly rotate the syringe 360°, using an in-and-out motion at the same time. There should be a return of blood and tissue through the cannula and into the syringe (Fig. 28.9).
- Once the aspirator is filled or once no further return of tissue occurs, withdraw the cannula beyond the cervical os until the vacuum is lost (a soft "whoosh" will be heard as the seal is broken).
- Reinsert the cannula just beyond the os at this time. Detach the aspirator from the cannula (Fig. 28.10). Empty the aspirator contents into a kidney basin.
- "Prime" the aspirator and attach it to the cannula. Repeat steps 4 and 5 until evacuation is complete.

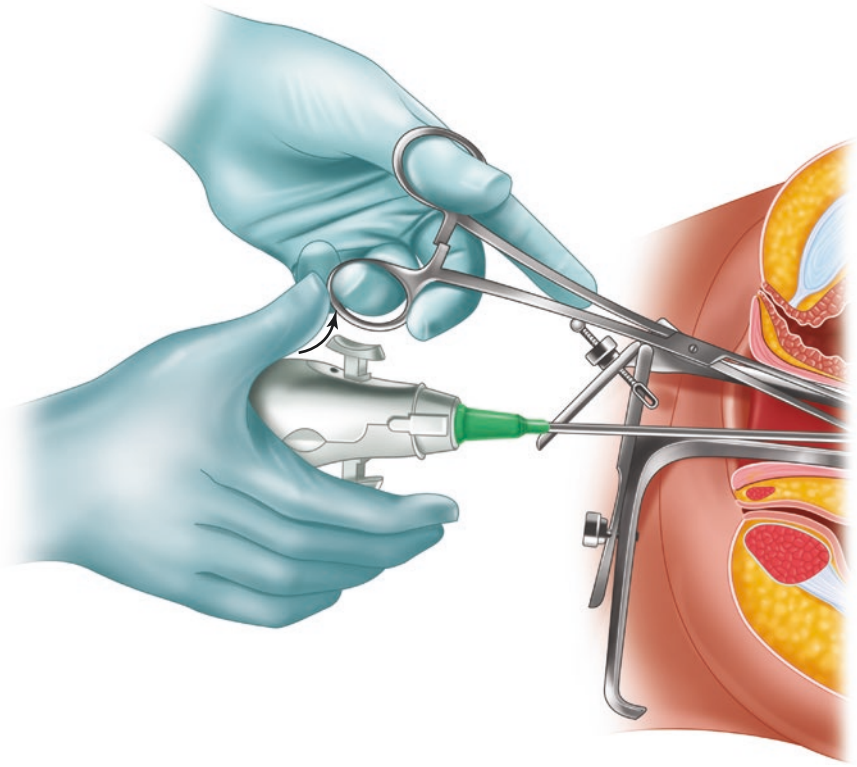

Fig. 28.8 Release the valve buttons of the MVA aspirator, which will start the suction (with permission from IPAS, Stephen C. Edgerton, illustrator)

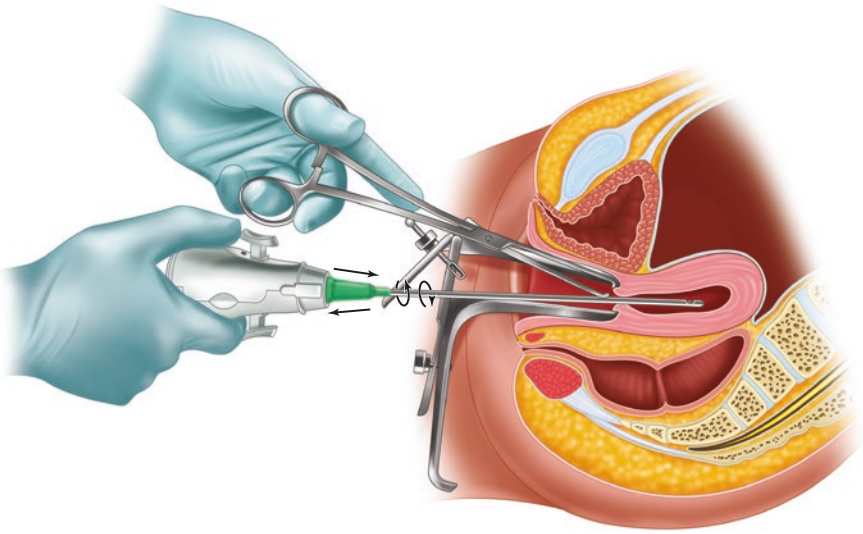

Fig. 28.9 Evacuating uterine contents (with permission from IPAS, Stephen C. Edgerton, illustrator)

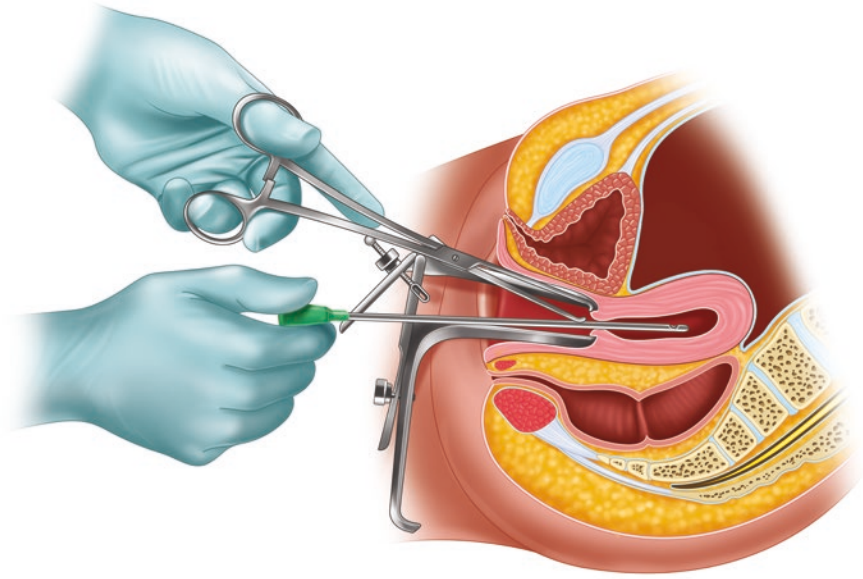

Fig. 28.10 Aspirator detached from cannula. (with permission from IPAS, Stephen C. Edgerton, illustrator)

Step 6: Assess for Complete Uterine Evacuation

The following signs indicate the uterus is completely evacuated:

- A "gritty" sensation is felt as the cannula passes over the uterine wall.
- The uterus "tightens" around the cannula.

Step 7: Complete the Procedure

- Take the cannula and aspirator out of the cervix.
- Take the tenaculum off. This can be facilitated by releasing the clamp and then gently rotating the entire tenaculum clockwise 360°, effectively lifting the "teeth" out of the cervical tissue.
- Use a sponge stick to gently swab any remaining blood out of the vaginal vault.
- Observe for any active bleeding, particularly from the tenaculum site. Apply pressure to any sites of bleeding.
- If an intrauterine device is desired, it can be safely inserted at this time, although patients should be warned of slightly higher expulsion rates [7, 8].
- Remove the speculum.
- Remove barriers and gloves, and wash hands.
- Help the woman into a comfortable position on the table.

Step 8: Inspect the Products of Conception (POC)

- The tissue should be rinsed in a strainer and placed in a clear, glass dish with water to help "float" the tissue.
- For best visualization, the dish should be placed on a light box.
- Identify villi, gestational sac, and decidual tissue (Fig. 28.11). As early as 8–9 weeks, fetal parts may be visible. Fetal parts must be positively identified in pregnancies 10–13 weeks LMP.

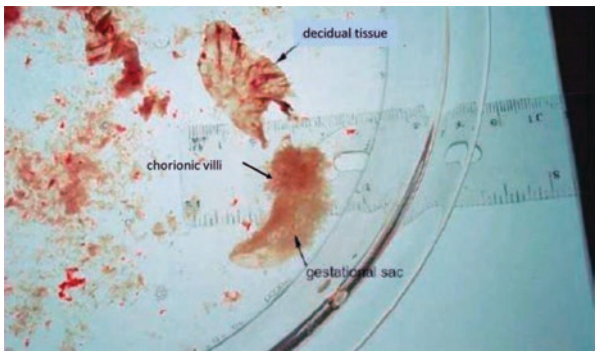

Fig. 28.11 Products of conception: villi/gestational sac and decidual tissue. (Courtesy of Deborah Oyer, MD, Seattle, WA)

- If no POC are visible or are less than expected for gestation age, an ultrasound and/or reaspiration should be considered, as well as reevaluation of the diagnosis. The differential for absent POC or POC less than expected includes: (1) incomplete abortion; (2) spontaneous abortion that already completed; (3) a uterine anomaly that precluded complete aspiration; (4) a failed abortion; or (5) ectopic pregnancy.
- After satisfactory inspection, the POC should be discarded per medical waste guidelines or sent to a pathology laboratory if required by institutional/state regulations.

Complications and Risks

- Significant bleeding (first-trimester rate): 0.1%
- Infection: 0.1–0.5% (with the use of prophylactic antibiotics)
- Hematometra (retained uterine clots): 0.2%
- Need to reaspirate (retained tissue or continuing pregnancy): 0.3–2%
- Perforation: 0.1%

Tricks and Helpful Hints

- Cervical preparation: Cervical priming with misoprostol (a prostaglandin) for first trimester abortion has been shown to increase initial cervical dilation, decrease blood loss, and require less dilation force [9]. The benefits of cervical priming must be weighed against the disadvantages of increased side effects, such as nausea, vomiting, diarrhea, bleeding, and cramping that can occur prior to the procedure. Common protocols for cervical priming include 400 μg (two tablets) of misoprostol taken 1–3 hours (h) prior to the procedure via buccal, oral, or vaginal administration [9]. Potential indications for preprocedure misoprostol cervical preparation may include:
- Pregnancies over 11 weeks in nulliparous women
- Any situation in which the risk of perforation is increased (e.g., stenotic os)
- Pregnancies over 12 weeks
- Performing the paracervical block: To reduce patient anxiety and pain, some clinicians like to ask the patient to cough just as the needle is inserted into the cervix. The cough serves to push the cervix forward toward the needle and most importantly, it is a pain distracter. This technique can also be used when placing the tenaculum.
- Difficult dilation of an extremely anteverted or retroverted uterus: Changing to a shorter blade speculum (e.g., Klopfer, Weisman-Graves, Moore-Graves) allows the provider to pull the cervix closer. It also provides more anterior and posterior space to accommodate the dilators and cannula at a steeper angle to follow the uterine axis.

Procedures

Coding

CPT® Codes (Current Procedural Terminology, AMA, Chicago, IL)	
For the visit	99204 or 99214 (level 4 new or established patient E/M visit)
For the ultrasound	76817 (transvaginal ultrasound, pregnant uterus) or 76815 (limited ultrasound, pregnant uterus)
For the procedure and medications:	
59840	Induced abortion, by dilation and curettage
J2000	Lidocaine
64450	Injection, nerve block
A4550	Surgical tray
99000	Specimen handling
J2210	Methergine®
90385	MICRhoGAM®
90782	Therapeutic injection
ICD 10-CM-Diagnostic Codes (International Classification of Diseases, Tenth Revision, Clinical Modification, Center for Disease Control and Prevention)	
Z33.2	Legally induced abortion, without mention of complication, complete

Postprocedure Patient Instructions

- The woman should be allowed to rest and recover for at least 15 minutes
- Continue to monitor her vitals and symptoms. Uterine cramping and bleeding should continue to subside. Prolonged cramping and excessive bleeding are not normal.
- Rh-negative patients should be given a dose of MICRhoGAM® (50 μg) (Ortho Clinical Diagnostics, Raritan, NJ). RhoGAM® (300 μg) should be given if the patient is 12 weeks or if the 50 μg dose is unavailable.
- The following items should be reviewed carefully with the patient (Fig. 28.4):
- Postprocedure self-care
- Signs and symptoms requiring medical attention
- How to “QuickStart” birth control (begin that day), review correct use, possible side effects
- The woman should be discharged home with the following:
- A follow-up appointment in 1–2 weeks (optional)
- Prescriptions or supplies for ibuprofen or analgesic of choice
- Prescriptions or supplies of birth control to start as soon as possible
- Prescriptions or supplies of a postabortion antibiotic regimen
- A 24-h provider contact number
- The Patient After-Care Instructions and Information Form (Fig. 28.4).

(Provider to fill in blanks/circle applicable choice when given multiple choices.)

Case Study Outcome

The patient underwent an uncomplicated MVA in the office. She had a copper intrauterine device placed immediately after the procedure. The products of conception were consistent with 8.5-week pregnancy. She was discharged home in good condition.

Patient Handout

Pre Procedure Handout Table 28.1
Post Procedure Handout Fig. 28.4

Questions for Learners

What are some reasons why a patient would choose an aspiration abortion over a medication abortion?

What anticipatory guidance would you give a patient who is planning to have an aspiration abortion?

References

1. Westfall JM, Sophocles A, Burggraf H, Ellis S. Manual vacuum aspiration for first trimester abortion. Arch Fam Med. 1998;7(6):559–62.
2. World Health Organization (WHO). Clinical practice handbook for safe abortion. Geneva: WHO; 2014.
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8. Creinin MD, Cwiak CA, Espey E, Jensen JT. Immediate intrauterine device insertion following suction aspiration between 5–12 weeks of gestation increases rates of insertion and utilization compared to scheduled delayed insertion. Contraception. 2009;80:203.
9. Allen RH, Goldberg AB. Cervical dilation before first-trimester surgical abortion (<14 wks gestation). Contraception. 2016;93:277–91.

Additional Resources

Websites

For patient and clinician resources regarding early abortion care, visit The Reproductive Health Access Project: http://www.reproductiveaccess.org/.

For information regarding abortion training in family medicine residencies, visit The Center for Reproductive Health Education in Family Medicine www.rhedi.org.

For educational resources and a clinical curriculum regarding medication abortion, visit The National Abortion Federation: http://www.prochoice.org/education/resources/index.html.

For information regarding state laws on abortion, visit The Center for Reproductive Rights: http://www.reproductiverights.org/ or guttmacher.org.

For information regarding MVA aspirators and supplies: www.ipas.org.

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