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FAMILY PLANNING (A BURKE, SECTION EDITOR)

Update on Permanent Contraception for Women

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Abstract

Purpose of Review

We completed this review to update readers on the current literature and controversies surrounding different approaches to permanent female contraception.

Recent Findings

Permanent contraception continues to be a popular method of pregnancy prevention. The withdrawal of the Essure® hysteroscopic approach to permanent contraception from the US market and the increased use of salpingectomy to decrease risk of ovarian cancer have changed options available to women. Current studies support allowing adult women who desire no future pregnancies to access permanent contraception regardless of age, parity, or marital status. Permanent contraception may offer particular benefit to women with complex medical issues, and those who decline hormonal contraception or intrauterine devices. We also discuss the development of new methods of permanent contraception, including the FemBloc® system and polidocanol foam.

Summary

Permanent contraception remains an important option for women who have completed desired family size as it results in long-term, non-hormonal prevention of pregnancy. Women should be thoroughly counseled on the different methods of permanent contraception as well as the risks and benefits.

Keywords Female sterilization · Permanent contraception · Tubal ligation · Salpingectomy · Hysteroscopic sterilization · Essure®

Introduction

Approximately 19% of women around the world use permanent contraception to prevent unwanted pregnancies [1]. Permanent contraception is currently the second most common form of family planning (25.1% or 9.4 million women) in the USA after oral contraceptive pills (OCPs) (25.9% or 9.7 million women) [2].

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While women have a variety of contraception options to choose from adverse side effects, social influence, access, or other pregnancy, or health-related goals may strongly influence the method an individual woman ultimately selects. Over the last two decades, increasing numbers of women have accepted use of highly effective long-acting reversible contraception (LARC) (currently 11.6% or 4.4 million US women) [2]. While the protection against pregnancy provided by LARC methods rival that of permanent contraception, and offers the option of resuming fertility, many women object to intrauterine devices or implants that affect menstrual bleeding or require periodic surveillance or replacement. Similarly, women sometimes cite adverse mood changes as a reason for discontinuing or otherwise avoiding hormonal contraception. Although inconsistent research methodology makes it difficult to draw conclusions about the association between hormonal contraception and mood [3], a woman's concern about this association should be respected; permanent contraception

provides an excellent alternative to hormonal options for women who are certain they do not desire future fertility. Advances in health care have led to improved survival of patients with medically complex issues that also adversely affect pregnancy and the risk/benefit profile of estrogen-containing contraceptives. The World Health Organization and U.S. Centers for Disease Control have issued guidelines for medical eligibility for contraception use [4••]. Table 1 lists several medical conditions recognized by the WHO as associated with adverse health outcomes in pregnancy (Table 1). Although advances in maternal-fetal medicine have improved outcomes for women with complex medical comorbidities with desired pregnancies, these require a considerable investment of time and resources. Although no medical conditions absolutely restrict a woman's eligibility for permanent contraception, conditions that place a woman at high surgical risk (e.g., morbid obesity, severe cardiovascular disease) require consideration in counseling.

Table 1 Medical conditions for which unintended pregnancy may increase risk of adverse maternal health outcome

Bariatric surgery within 2 years
Breast cancer
Cardiovascular disease
Hypertension
Ischemic heart disease
Peripartum cardiomyopathy
Valvular heart disease
Stroke
Diabetes mellitus with: vascular involvement concomitant vascular disease or duration greater than 20 years
Epilepsy
Gynecological cancer
Uterine/endometrial
Ovarian
Malignant gestational trophoblastic neoplasia
HIV/AIDS
Liver disease
Malignant liver tumors
Schistosomiasis with liver fibrosis
Severe cirrhosis
Sickle cell disease
Solid organ transplantation within 2 years
Systemic lupus erythematosus
History of venous thromboembolism or thrombophilia
Tuberculosis

Adapted from World Health Organization (WHO). Medical Eligibility Criteria for Contraceptive Use. Geneva: WHO; 2015. Available at: http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/. Accessed on August 1, 2018

Current approaches to permanent contraception for women involve surgical procedures to occlude the fallopian tubes, or to remove them completely. Most procedures are performed laparoscopically, although laparotomy remains an important approach immediately postpartum and at the time of cesarean delivery. Recently, many clinicians have begun recommending complete bilateral salpingectomy to provide an additional health benefit of reduced risk of ovarian cancer. Hysteroscopic approaches to permanent contraception provide an alternative to abdominal surgery. However, Essure®, the only hysteroscopic method available in the USA, was withdrawn from the market at the end of 2018.

Permanent contraception for men provides an excellent option for women in stable partnerships seeking long-term contraception. Since vasectomy does not require women to undergo any surgical procedure, and can be performed as a simple clinic procedure, vasectomy represents the safest approach and should always be presented in counseling. Still, many women see female permanent contraception as a personal expression of reproductive choice and autonomy. Improved options to make female permanent contraception less invasive and more accessible for women are under development. This chapter reviews the present and future of permanent contraception for women.

Suffice-to-say, permanent contraception provides lifelong, hormone-free protection against pregnancy for any woman who has completed her desired number of pregnancies. For some women, that number may be zero. For family completers with contraindications or sensitivities to reversible methods, permanent contraception offers great benefit and few risks.

Terminology

While sterilization has been historically used to describe procedures related to intentional permanent prevention of pregnancy in both men and women, providers have started to reconsider the term. We prefer the term permanent contraception (PC). This term not only aligns these procedures with other methods of pregnancy prevention, including LARC, but also avoids the negative connotation associated with sterilization, including the history of involuntary or coercive practices [5].

Moreover, most permanent contraception procedures do not result in sterility. Women with healthy ovaries can undergo ovarian stimulation procedures and oocyte recovery. As long as a woman retains her uterus, she can undergo standard embryo transfer procedures after oocyte recovery. If she does not have a healthy uterus, surrogacy provides a path to fertility. Admittedly, these techniques are expensive and carry additional risks, including reduced rates of

successful pregnancy and increased risks of delivery complications. A woman undergoing a permanent contraception procedure must be thoroughly counseled and carefully consider her decision.

The term "tubal ligation" refers to procedures performed via laparotomy or laparoscopy that interrupt the fallopian tubes by excision or occlusion. Tubal ligation can be performed at the time of cesarean delivery, immediately postpartum or as an "interval" procedure. "Interval" tubal ligation refers to any procedure not performed in the immediate postpartum time frame, including tubal ligations performed on women who have never been pregnant. "Interval" tubal ligations are typically performed via laparoscopy using clips, rings, or electrosurgical techniques.

How Effective Are Permanent Contraception Procedures?

The large prospective CREST (Collaborative Review of Sterilization) study published in 1996 provides the most comprehensive evaluation of female permanent contraception [6]. This study followed 10,685 women who underwent permanent contraception procedures for up to 14 years. The CREST results demonstrated high efficacy for all methods of permanent contraception (with a cumulative 10-year probability of pregnancy of 18.5 per 1000 procedures, or 1.3%), with variation in efficacy noted by method as well as age, race, and ethnicity. Higher rates of post-procedure pregnancy were noted in women undergoing the procedure at a younger age (e.g., under 35 years) and those procedures utilizing the Hulka-Clemens clip. CREST data also indicated that postpartum partial salpingectomy was associated with lower failure rates compared to interval tubal ligation procedures performed via laparoscopy. While the CREST study continues to be a landmark study of permanent contraception, many of the methods studied and techniques (e.g., direct vision laparoscopy) are no longer used in the USA, and this limits the generalizability of these data. For example, silicone bands are rarely used in the USA, yet comprised 31% of the procedures studied. The setting of the CREST data, large teaching institutions where house staff completed most of the operations may also have affected outcomes and generalizable to current practice. The study also predates the increasing familiarity with video laparoscopy or newer devices (such as the LigaSure® electrocautery device) over the last two decades. To address the limitations of the CREST study, a 2016 Cochrane review summarized available clinical data and concluded that the 1-year, failure rates for all methods seem similar and low (< 5/1000) [7]. However, a major weakness of the Cochrane review and data collected from clinical trials is the lack of data on effectiveness past 1 year. In CREST, pregnancies were reported during each year of follow-up. While recanalization of surgically occluded tubes may infrequently occur, fecundability in the population of women undergoing permanent contraception provides a more likely explanation for reports of late failure. Clearly, we could benefit from better long-term prospective data, Clinicians should counsel women that permanent contraception procedures are highly effective, but that pregnancy can occur even years after a procedure. For this reason, we recommend testing to rule-out an intrauterine or ectopic gestation whenever a woman experiences pregnancy symptoms (e.g., amenorrhea, breast tenderness, nausea) following a permanent contraception procedure.

Methods of Female Permanent Contraception

Laparotomy and Minilaparotomy

Minilaparotomy presents an acceptable route of PC for women immediately postpartum, and allows access to interval PC procedures in more rural settings or health care facilities that lack access to laparoscopic equipment. Following vaginal delivery, a 2–3-cm infraumbilical minilaparatomy incision provides access to the fallopian tubes for postpartum permanent contraception procedures. The postpartum uterus remains accessible through this approach at least 48 h following delivery. Low transverse or midline incisions for cesarean delivery provide excellent exposure. In many low-resource settings, surgeons use suprapubic minilaparotomy incisions and Collin-Buxton forceps to elevate the uterus and position the tubes in the incision. Traditionally, PC procedures via minilaparotomy have been performed using the Pomeroy, modified Pomeroy, or Parkland methods of suture ligation [8, 9]. These methods are performed by suture ligating and removing the mid-isthmic segment of the fallopian tube, bilaterally. More recently, some surgeons have used mechanical devices developed for laparoscopy for laparotomy approaches. We do not recommend these for postpartum procedures, as studies suggest decreased efficacy, possibly due to the large tube size and extensive vascularity in this setting [10, 11].

Laparoscopic Approaches

In most practice settings, laparoscopic approaches have replaced minilaparotomy for interval permanent contraceptive procedures. Advantages include smaller incisions and faster surgical recovery. Although single puncture techniques that utilize a scope equipped with an operating channel to occlude the tube via a 10–12-mm infraumbilical port remain in use in some practice settings, duel puncture procedures using small 5-mm laparoscopes and instruments have become more common. Laparoscopic approaches to permanent contraception

include mechanical devices (such as the silicone band or titanium occlusive clips), electrocoagulation, and tubal excision (including partial or complete salpingectomy).

The ability to perform laparoscopic permanent contraceptive procedures may be limited by access to laparoscopic equipment, intraabdominal adhesions, obesity, or medical conditions (such as high-risk cardiovascular disease) that present relative or absolute contraindications to general anesthesia. Most anesthesiologists rely on the American Society of Anesthesiologist (ASA) classification to assess risk associated with surgery. Any patient with more than mild systemic disease (ASA II) should undergo preoperative consultation with an anesthesiologist to better define risk prior to elective surgery [12].

Laparoscopic approaches to permanent contraceptive procedures have been thoroughly discussed in previous reviews [13, 14, 15]. As this review focuses on advances in PC within the last 5 years, we will elaborate on the increasing body of literature exploring salpingectomy for PC.

Salpingectomy

Salpingectomy involves the complete removal of the intraperitoneal portions of the fallopian tube, with particular emphasis on removing the fimbria and ampulla. Salpingectomy can be performed at the time of laparotomy (e.g., cesarean delivery) or by laparoscopy. In 2001, Piek et al. reported that close examination of tubal segments removed from patients predisposed to ovarian cancer undergoing risk-reducing bilateral salpingo-oophorectomy showed dysplastic lesions consistent with high-grade serous ovarian cancer in the fallopian tube, specifically in the fimbria [16•]. As ovarian cancer is the leading cause of death due to gynecological malignancy, and the fifth most common cause of female cancer death in the USA [17], both patients and gynecologists have become invested in research evaluating whether salpingectomy could reduce the risk of developing ovarian cancer in average risk women. Over the last two decades, several histopathologic studies have supported the hypothesis that some ovarian epithelial cancer, in particular serous tumors, may originate in the distal fallopian tube [18, 19, 20]. Though a decreased incidence of ovarian cancer in women with a history of simple tubal ligation has been well-documented [21], this new research has started a paradigm shift toward opportunistic bilateral salpingectomy at the time of hysterectomy or for permanent contraception [22•]. Although we currently do not have good epidemiologic data comparing risk reduction with salpingectomy to standard tubal occlusion techniques, a 2017 review documented ovarian cancer risk reduction of 13 to 41% with standard bilateral tubal ligation compared with a 42 to 78% decrease for bilateral salpingectomy [23]. The benefit appears strongest with serous tumors [24]. Though additional data are needed to support routine salpingectomy as a preferred option, current evidence indicates that salpingectomy is as effective, if not more effective, in reducing the risk of ovarian cancer compared to tubal ligation.

Some physicians have expressed concern that salpingectomy, especially at the time of cesarean delivery, may not be safe. However, a retrospective cohort study of 10,741 women noted an increase in the proportion of salpingectomy permanent contraception procedures from 0.4 to 35.5% of all PC operations from 2011 to 2016. Within this study, PC via salpingectomy performed at the time of cesarean delivery increased from 0.1 to 9.2%. The authors noted no difference in median blood loss between occlusive techniques and salpingectomy at the time of cesarean [25•]. A 2016 retrospective case series found the average surgical time was 59.13 and 71.44 min in the bilateral tubal ligation and salpingectomy cohorts, respectively, but noted similar median blood loss and complication rates [26]. However, the retrospective design of both studies represents a major weakness. A 2018 randomized controlled non-inferiority trial of 44 women undergoing planned cesarean delivery including a permanent contraception procedure found a mean difference of 30 s between salpingectomy done using an electrosurgical (LigaSure® (Medtronic)) device and standard tubal ligation using suture (5.6 vs. 6.1 min, respectively) [27]. However, since the comparison used an additional expensive surgical instrument not required for the cesarean, the results are not generalizable to practice settings where standard clamp and ligate techniques are used for salpingectomy. A 2018 retrospective case study of 122 women undergoing cesarean delivery with planned sterilization procedure found that 18.9% of those patients desiring complete salpingectomy could not have the procedure completed bilaterally due to adhesions, engorged vasculature, or other unspecified reasons [28].

An additional concern for salpingectomy is the effect on ovarian reserve, and the impact on premature menopause. A 2017 review of 48 studies evaluating ovarian reserve after salpingectomy for all indications did not document a difference in response to ovarian stimulation for IVF procedures, but did suggest a trend toward lower anti-Müllerian hormone and higher early follicular FSH levels [29]. However, many of the procedures studied occurred in the setting of tubal disease (e.g., hydrosalpinx, adhesions, endometriosis) where dissection might compromise blood supply. The long-term outcomes associated with simple prophylactic salpingectomy, including the effect on onset of menopause, remain unknown.

As noted above, some surgeons use electrocautery devices, such as the LigaSure® device (Medtronic), for salpingectomy at the time of cesarean [27]. However, such devices add significant cost to the procedure ($925 average retail price in 2009) and may not be available at all facilities [30]. More

studies are needed to compare the safety and efficacy of salpingectomy with electrocautery compared to more traditional suture techniques.

Hysteroscopic Tubal Occlusion (Essure®)

Hysteroscopic approaches to permanent contraception avoid the need for surgical entry into the peritoneal cavity. Although technically a surgical procedure, the risks of hysteroscopy are lower than those associated with abdominal surgical procedures, and the need for anesthesia reduced. An office-based approach to permanent contraception for women should improve access to the procedure and reduce inconvenience and cost.

The Essure® system (Bayer Healthcare) is a hysteroscopic technique that involves placing a small (4 cm), flexible nickel/titanium alloy coil-containing polyethylene into the intramural portion of the fallopian tube from the endometrial cavity. The U.S. F.D.A. approved Essure® in November 2002, and more than 750,000 women worldwide have received the microinserts [31].

Over time, the polyethylene fibers degrade and cause a fibrotic reaction leading to a collagen scar restricted to this portion of the tube that prevents sperm from reaching the egg [32]. The nickel/titanium alloy coil remains permanently in place. These materials have a long history in medicine, with well-established safety in a number of applications including vascular stents. Most Essure® procedures are done in outpatient settings under local anesthesia (e.g., paracervical block) or moderate sedation without the need for general anesthesia [33]. Hysteroscopic placement of the microinserts requires surgical training and experience. Failure of bilateral placement occurs in about 10% of attempts [34••].

A related procedure hysteroscopic procedure, Adiana®, approved in 2009, used radio-frequency ablation to cause damage to the intramural tube, followed by placement of a polyethylene plug that stimulated collagen deposition [13, 35]. Adiana® was voluntarily withdrawn from the market in 2012 for financial reasons that resulted in part from a patent infringement lawsuit filed by Conceptus, the company that developed Essure®. Since clinicians may encounter women who received the Adiana® procedure, it is important to note that market withdrawal of the product was not related to safety concerns.

Unlike other mechanical or physical tubal occlusion procedures that immediately block the tubes, the contraceptive effect of Essure® requires several weeks to develop. For this reason, the product label requires a confirmation test to document tubal occlusion 3 months after placement of the microinserts. Confirmation with hysterosalpingography provides the gold standard to confirm bilateral tubal occlusion, although contrast ultrasound is approved in some regions. The Essure® procedure is not considered complete until after verification of bilateral tubal occlusion, and women must use an effective method of contraception until completion of this step. Although the ability to avoid general anesthesia and convenience of an outpatient office-based procedure offer many advantages, some women find this delay and need for a confirmation unacceptable, and this factors into their decision to proceed with laparoscopic surgery. At the same time, many clinicians recommended the procedure for women at higher risk for complications of laparoscopic surgery, including obese women, women suspected to have pelvic adhesions, and other women with contraindications to general anesthesia.

Although the initial phase 3 studies noncomparator studies supported a lower failure rate with Essure® compared to laparoscopic tubal ligation, subsequent studies that factored in placement-related problems and failure to return for occlusion verification comparable or higher typical use efficacy under real world conditions [36]. A 2017 retrospective cohort study of 3497 women that evaluated outcomes following laparoscopic and hysteroscopic PC procedures identified few serious complications and no differences in complications or failure between the approaches [33]. The authors identified no cases of laparotomy, blood transfusion, or life-threatening events, but documented an increased risk of reoperation at 1 year with the hysteroscopic approach compared to laparoscopy (unadjusted odds ratio, 6.2; 95% CI 2.8–14.0). However, women undergoing hysteroscopic sterilization were significantly older and at higher BMI and three times more likely to have undergone a cesarean delivery. The failed Essure placement rate was 9%, and most of the reoperations in the hysteroscopic group were unilateral salpingectomies.

The problems with failed microinsert placement attempts and lack of follow-up for HSG confirmation of tubal occlusion gradually contributed to reduced enthusiasm for the approach among clinicians. At the same time, reports of numerous complications including chronic pain, menstrual irregularities, headache, with serious complications including pregnancy loss, perforation and death led to multiple lawsuits, and an 2016 FDA review that resulted in inclusion of a "black box" in the label for Essure® warning of potential complications [37]. Following this, US sales fell by approximately 70% and Bayer Healthcare discontinued marketing Essure® outside of the USA [38]. In April 2018, the FDA applied additional restrictions that included providing mandatory detailed consent information reviewing potential risks prior to the procedure [39]. The FDA also required Bayer to conduct a detailed postmarketing study comparing outcomes between women receiving hysteroscopic and laparoscopic sterilization. Results of this open-label, nonrandomized, prospective cohort study of 2800 women are expected in 2023 [40]. However, on July 20, 2018, Bayer announced that Essure® would no longer be sold or distributed in the USA after December 31, 2018 [41].

The removal of Essure® from the US market limits choice for women. While some complaints related to Essure® have potential biologic plausibility (e.g., increased uterine cramping in setting of device perforation), other reported symptoms seem less likely to be directly related to Essure® coil placement, such as back, joint, chest, leg, breast, neck, spine, or hip pain; gastrointestinal symptoms of nausea, vomiting, gas, constipation, or diarrhea; mental health concerns, headaches, or migraines; anemia, autoimmune disorders, generalized allergies, or sensitivities; and chronic fatigue could be related to the device. Advocates point at the market removal of Essure® by Bayer as an admission of flaws with the product, but in public statements Bayer remains committed to the safety profile and states the removal was driven by business decisions reflecting declining sales.

Women who have received Essure® need to know that there is no reason to question the safety of the device. Those who have not undergone a confirmation HSG exam should be encouraged to do so. Although some clinicians advocate removal of the devices, we recommend careful consideration of options with the decision for surgery guided by clear evidence of potential benefit and not for vague or non-gynecologic symptoms. In many cases, the explanation for gynecologic symptoms relates to the withdrawal of hormonal contraceptives that reduce dysmenorrhea and menstrual blood loss.

Who Are Appropriate Candidates for Female Permanent Contraception?

In the 1960s, the "120 rule" was endorsed by the American College of Obstetricians and Gynecologist (ACOG) as a means of assessing a woman's candidacy for permanent contraception [42]. This rule dictated that a woman would be candidate for a permanent contraception procedure if her age multiplied by the number of her children was greater than 120. Luckily, the "120 rule" was abolished by the 1970s. While permanent contraception procedures continue to be an appropriate and popular choice for women who have achieved their desired number of children, many physicians continue to feel conflicted and deny young and/or nulliparous women permanent contraception for fear of regret. A 1999 study evaluating rates of regret for women younger than 30 years old prior to tubal ligation found significantly increased rates of regret in women younger than 30 years old compared to women older than 30 [43]. Some experts argue that the methodology for assessing regret is flawed and the results often misleading [42, 44]. We encourage clinicians to thoroughly assess their own biases about the role of women and motherhood and avoid paternalism by denying nulliparous and women < 30 years of age access to permanent contraception procedures. While expensive and inconvenient, assisted reproductive techniques such as IVF and tubal surgery offer a pathway to fertility after a permanent contraception procedure. Adoption represents an alternative path to parenthood. In 2017, ACOG released a committee opinion stating that is was "ethically permissible to perform a requested sterilization in nulliparous women and young women without children." [45].

Other Preoperative Counseling Considerations

Obesity

The obesity epidemic continues to affect women's health and medical decision-making in the USA. According to The National Health and Nutrition Examination Survey (NHANES), a cross-sectional survey conducted from 2007 to 2016, approximately 41.1% of female participants qualified as obese with body mass index (BMI) greater than or equal to 30 kg/m2 [46]. Women with class 3 obesity (BMI $\geq$ 40 kg/m^2) have higher rates of unwanted or mistimed pregnancies (aOR = 1.96 and 1.67, CI, 1.15–3.32 and 1.04–2.29 respectively) compared to normal BMI women [47]. Obese women are more likely to choose permanent contraception (aOR = 1.96, CI 1.45–2.66) compared to their normal BMI counterparts [48].

Socioeconomic Status

Women requesting permanent contraception should receive unbiased counseling that stresses the differences between permanent and reversible long- and short-acting methods. Only women who never wish to ever become pregnancy should consent to a permanent contraception procedure. A recent study evaluating data from the National Survey of Family Growth found that the prevalence of desire for sterilization reversal rose from 18% in 1995 to 25% in 2006–2010, with desire greatest among women of low educational achievement (less than high school) [49]. We believe that providers should keep these data in mind, and specifically address regret when counseling all women. However, women with low socioeconomic status deserve the same access to permanent contraception as other women. Most clinicians have cared for women with unintended pregnancies occurring after a requested permanent contraception procedure was not performed. An unwanted birth or abortion should not be the prescription to prevent permanent contraception regret.

How Do State/Federal Laws Affect Access?

Despite being a popular method of fertility control, permanent female contraception has a complex history, which includes association with the Eugenics movement of the

twentieth century and forced sterilization in vulnerable populations. Though forced sterilization seems like an issue of the past, as recently as 2013 the California Department of Corrections and Rehabilitation was investigated due to complaints that inmates were exposed to coercive counseling practices and some underwent permanent contraception procedures without proper consent between 2006 and 2011 [50]. This investigation resulted in the passage of SB 1135, which prohibits sterilization of all incarcerated individuals in California [51]. Like incarcerated women and women of color, under the Eugenics movement, women with cognitive and physical disabilities were also targeted for forced sterilization procedures. While access to highly reliable permanent contraception is viewed as empowering for many women, it is important that providers understand and acknowledge the inherent distrust of the health care establishment and permanent contraception procedures that some women may have due to the history of forced sterilization [52].

In an attempt to protect vulnerable populations, who are often insured for permanent contraception through federally funded health insurance (Medicaid), the Department of Health, Education, and Welfare developed protective regulations and a standardized consent form for publicly funded permanent contraception procedures in 1976, mandating a 30-day interval between signing the consent form and the actual procedure [53]. This mandatory waiting period does not exist for privately insured patients. However, this mandatory waiting period has been questioned by health care experts and ethicists, with experts noting the burden the waiting period may put on some women with little value added [54, 55]. Explaining this history of cohesive practices in female permanent contraception to patients during counseling may help alleviate some frustration that patients feels when informed of the mandatory waiting period.

New Methods in Development

While current methods of permanent contraception are highly effective, safe, and provide noncontraceptive benefits (such as reduction in ovarian cancer risk) to patients, development of novel approached to permanent contraception could reduce the financial and logistical barriers faced by some women desiring long-term, non-hormonal contraception.

One method currently under investigation is FemBloc® (Femsys Inc.), a catheter-based delivery system placed into the uterus in an office setting, which deploys a degradable biopolymer liquid into the fallopian tubes, causing scarring that leads to tubal occlusion. While no studies of this approach have been published, the manufacturer's website suggests that like Essure®, this process requires a confirmatory test of occlusion via ultrasound 3 months after the initial procedure. The FemBloc® is currently undergoing clinical trials (https://www.clinicaltrials.gov/ct2/show/NCT03433911).

Transcervical polidocanol foam has been investigated in nonhuman primates. Polidocanol (hydroxyl-polyethocydodecane) is a synthetic long-chain fatty acid alcohol approved by the U.S. FDA for the treatment of varicose veins [56]. This agent, when administered transcervically in baboons, caused scarring that obliterated the lumen of the oviduct, resulting in pregnancy prevention [57, 58, 59]. This approach has not entered human clinical trials.

In addition to new surgical techniques and devices for permanent contraception, novel anesthesia approaches could improve access to permanent contraception procedures. A 2018 review of anesthesia techniques used during laparoscopic permanent contraception procedures found similar rates of complications, operating times, and postoperative pain levels when comparing general anesthesia to local anesthesia with conscious sedation [60].

Conclusion

Permanent contraception continues to be an important and highly utilized form of fertility regulation in the USA as well as around the world. With the withdrawal of the Essure® hysteroscopic method of permanent contraception from the market in 2018, women seeking permanent contraception have fewer options. Increasing access to safe and effective permanent contraception for women from various socioeconomic, geographic, and health backgrounds will require new investment from foundations, government, and industry.

Compliance with Ethical Standards

Conflict of Interest Katie Alton and Jeffrey Jensen declare no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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