The prepped vaginal canal may be a sterile conduit for ventral hernia mesh insertion: a prospective comparative study

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Abstract

Background   Although still experimental, natural orifice translumenal endoscopic surgery (NOTES) aims to use the natural orifices for intraabdominal surgery. Pure transvaginal umbilical hernia repair has been reported. However, mesh protection devices were used to minimize mesh contamination during mesh insertion. The authors believe that before widespread implementation of this technique, more foundational research is indicated to establish the sterility of hernia mesh insertion through this route. This prospective study aimed to compare transvaginal ventral hernia mesh insertion sterility with laparoscopic trocar-site insertion sterility to establish baseline data to help promote the safety of NOTES tranvaginal hernia repair.

Methods   This was a prospective descriptive study (Canadian Task Force classification 2A). With institutional review board approval, 10 patients undergoing laparoscopic surgery for benign gynecologic disease were enrolled in the study. Atrium Prolite mesh (polypropylene monofilament) was inserted into the vagina before and after standard surgical preparation with 10 % povidone–iodine. As a control, mesh also was inserted through a prepped laparoscopic port site. The mesh was cultured for bacterial, fungal, and viral contamination. All patients received standard infection prophylaxis that included preoperative intravenous cefazolin and metronidazole.

Results   The unprepped vaginal canal was cultured and demonstrated normal multiorganism vaginal flora in all 10 cases. Of the 10 skin incision mesh samples, 3 (30 %) grew bacteria, including *Staphylococcus lugdunensis*, a potentially pathogenic organism. In contrast, none of the prepped vaginal mesh specimens yielded any growth of microorganisms or potential pathogens.

Conclusions   This study showed that a surgically prepped vaginal canal can be a sterile conduit for insertion of polypropylene mesh for transvaginal ventral hernia repair without the use of additional mesh protection. Surprisingly, the prepped vaginal conduit in our patients was more sterile than a prepped skin incision.

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Although still experimental, natural orifice translumenal endoscopic surgery (NOTES) remains an attractive advance in minimally invasive surgery. The potential benefits include less postoperative pain, fewer wound complications, better cosmesis, faster patient recovery, and quicker return to normal function [1–3] than with traditional laparoscopic surgery. For example, patients undergoing transvaginal NOTES cholecystectomy require less analgesia than patients undergoing traditional laparoscopic cholecystectomy [3]. Multiple feasibility studies have been reported in recent literature.

Transvaginal ventral and umbilical hernia repairs have been reported. Jacobsen et al. [4] demonstrated the technical feasibility of transvaginal incisional hernia repair

using biologic mesh. The procedure also has been performed using standard laparoscopic instruments in porcine models. Additionally, a "hybrid NOTES" has been described, in which one laparoscopic port is used for initial visualization, retraction, and assistance with dissection [5].

Recently, Roberts et al. [6] showed the feasibility of a pure transvaginal umbilical hernia repair with synthetic mesh. For sterile insertion of the mesh, the authors placed the mesh in a protective bag device.

The sterility of ventral and umbilical synthetic hernia mesh inserted tranvaginally has not been reported to date. It is imperative to evaluate, for the safety of the patients, the ability to insert the mesh in a sterile manner without risk of infection. Sterile insertion of mesh through the vaginal canal has multiple implications. Women could safely undergo transvaginal hernia or diastasis repair. Mesh could be inserted without protective devices, and traditional synthetic mesh could be used.

In porcine models, synthetic mesh has been inserted into sterilely lavaged vaginas with low intraabdominal contamination and few septic complications [5]. Another series of porcine models showed significant postsurgical mesh contamination, although this model included a gastrotomy for mesh fixation [7].

This prospective study aimed to compare the sterility of ventral hernia mesh insertion through a prepped vagina with the sterility of mesh insertion through prepped laparoscopic skin sites. To date, there is a paucity of literature establishing the safety and sterility of this route of insertion without the aid of protective insertion devices. By demonstrating equivalence of sterility, transvaginal NOTES can be shown to improve overall outcomes in patients undergoing minimally invasive ventral or umbilical hernia repair with synthetic mesh.

Methods

Institutional review board (IRB) approval was obtained before enrollment of study participants. This prospective comparative study (Canadian Task Force classification 2A) was conducted at the Mount Sinai Hospital from January 2011 to March 2011. The study recruited 10 women ages 32–68 years who already were undergoing laparoscopic or robot-assisted laparoscopic procedures for benign gynecologic disease. Informed consent was obtained from the recruits during the preoperative office visit.

Surgical preparation

All the patients were given cefazolin 1 g and metronidazole 500 mg within 30 min after the initial skin incision. All surgical preparations used standard 10 % providone-iodine

(Betadine, Aplicare, Meriden, Connecticut) and were performed by the same surgeon in the same operative suite.

Atrium Prolite mesh (Marquet, NH, USA) was divided into three equal pieces at the time of surgery (Fig. 1). Separate pieces were inserted into the vagina before and after standard surgical preparation. As a control, mesh was inserted directly through a bare surgically prepped laparoscopic skin incision (PSI) (Fig. 2).

Microbiology

After sampling, the mesh specimens were placed in sterile 15-ml conical tubes to which sterile isotonic saline was added for cover. These specimens were transported immediately to the microbiology laboratory. At their receipt, sterile isotonic saline was added to adjust the volume to 10 ml if required (Fig 3). These specimens were vortexed and plated quantitatively using a sterile calibrated

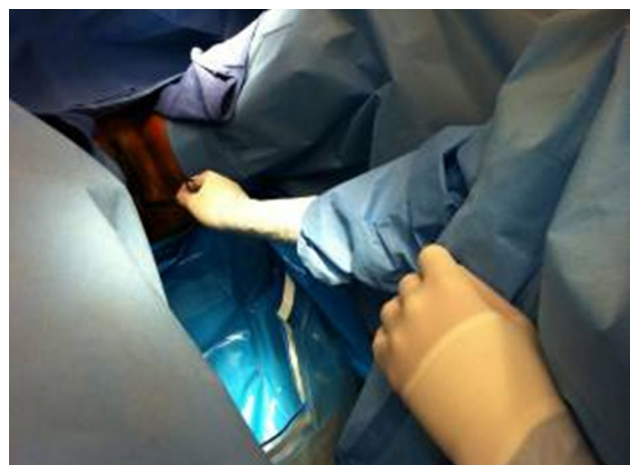Fig. 1 Division of hernia mesh into three equal portions

Fig. 2 Insertion of mesh into a sterilely PVC

loop onto media appropriate for the isolation of aerobic and anaerobic bacteria, fungi, and mycobacteria according to standard laboratory protocols (Fig. 4). These media were incubated under conditions appropriate for the isolation of these microorganisms. From each vortexed suspension, 1 ml was added to Hanks medium and inoculated into separate culture tubes containing rhesus monkey kidney, MRC-5, and A-549 cells lines for the isolation of any viral agents that might have been present in the specimens.

Fig. 3 Isolation of mesh samples

Fig. 4 Incubation and speciation of microbial isolates

After incubation, resulting colonies were quantified and identified using the Vitek 2 automated identification system (bioMerieux, Inc., Durham, NC, USA) or by routine microbiologic methods. The culture results were listed as normal vaginal flora (NVF) (lactobacilli, coagulase-negative staphylococci, *Corynebacterium* spp., and/or *Streptococcus viridans*) or identified in terms of genus and/or genus and species for other microorganisms.

Results

The IRB approved a 10-case study. Consequently, 10 patients were recruited and underwent laparoscopic gynecologic surgery, with specimens obtained through PVC (PVC), PSI, and unprepped vaginal canal (UVC). The patient demographics are summarized in Table 1. The patients ranged in age from 32 to 68 years (median 38 years).

The most common indication for surgery was uterine fibroids. Additionally, the most common procedure performed was robot-assisted laparoscopic myomectomy (RALM), consisting of four procedures followed by laparoscopic supracervical hysterectomy consisting of three procedures. The duration of surgery ranged from 57 to 299 min.

The results of the microbiology analysis are summarized in Table 2. The mesh incubated after insertion through the UVC all grew normal vaginal flora. The innocuous strains included lactobacilli, coagulase-negative staphylococci, *Corynebacterium* spp., and *S. viridans*. Pathogenic organisms isolated included group B streptococci, *Enterococcus* spp., and *Gardnerella vaginalis*.

Microbiologic analysis of all 10 mesh samples inserted through PVCs yielded no organisms. This included incubation samples for bacteria, viruses, and mycobacteria. The PSI samples from three patients had bacterial contamination of the mesh. These included coagulase-negative staphylococci, *Corynebacterium* spp., and *Staphylococcus lugdunensis*. No samples in the study grew mycobacteria or viruses.

Discussion

The current standard of care for laparoscopic ventral and umbilical hernia repair involves the insertion of synthetic mesh through surgically prepped laparoscopic sites [7, 8]. However, before this study, no studies had compared mesh contamination between surgically prepped laparoscopic sites and a surgically PVC. Before larger studies can be performed demonstrating the efficacy of pure transvaginal ventral hernia repair, the safety of the procedure, particularly

Table 1 Patient demographics

Patient	Age (years)	BMI (kg/m²)	PMHx	STI	Indication for surgery	Procedure	Duration of surgery (min)
1	32	32	Asthma	No	Fibroid	RALM	129
2	34	22	Asthma/hypothyroid	No	Stage 3 prolapse	Laparoscopic sacrohysteropexy/ posterior repair/IUD insertion	164
3	32	18	None	No	Fibroid	Hysteroscopic myomectomy/ laparoscopic salpingectomy/LOA	90
4	62	30	HTN	No	Procidentia	Laparoscopic SCH/AP repair/TVT	299
5	37	27	None	No	Fibroid	RALM	149
6	41	21	Asthma	No	Pelvic pain/fibroid	RALM	139
7	68	27	Hypothyroid	No	PMB/fibroid	Laparoscopic SCH	77
8	39	23	None	No	Fibroid	RALM	83
9	32	21	IBS	No	Endometriosis	Laparoscopic cystectomy/resection of endometriosis	92
10	39	24	None	No	Fibroid	Laparoscopic SCH	57

PMHx past medical history, *STI* sexually-transmitted infection, *RALM* robot-assisted laparoscopic myomectomy, *IUD* intrauterine device, *LOA* lysis of adhesions, *HTN* hypertension; *SCH* supracervical hysterectomy, *AP* anterior repair, *TVT* tension-free vaginal tape, *PMB* post-menopausal bleeding, *IBS* irritable bowel syndrome

Table 2 Microbiology results

Pre-prep,; Post-prep,; *NVF* normal vaginal flora, *CFU* colony-forming unit; *NG* no growth

Patient no.	Pre-vaginal prep mesh	Post-vaginal prep mesh	Incision mesh
1	NVF, 400 CFU/ml *Enterococcus* spp.	NG	NG
2	NVF	NG	NG
3	NVF, 13,000 CFU/ml Group B. streptococci	NG	100 CFU/ml *Corynebacterium* spp.
4	NVF, >100,000 CFU/ml *Gardnerella vaginalis*	NG	NG
5	NVF	NG	NG
6	NVF	NG	200 CFU/ml coagulation-negative staphylococci
7	NVF, >100,000 CFU/ml Gr. B. streptococci	NG	NG
8	NVF, 40,000 CFU/ml *Enterococcus* spp.	NG	NG
9	NVF, 1,000 CFU/ml *Enterococcus* spp.	NG	NG
10	NVF, 27,000 CFU/ml *Candida* spp. not albicans, 7,000 CFU/ml *Enterococcus* spp.	NG	1,000 CFU/ml *Staphylococcus lugdunensis*, 2,800 CFU/ml *S. epidermidis*, 500 CFU/ml *Corynebacterium* spp.

the sterility of transvaginal mesh insertion, needs to be confirmed in larger prospective studies.

This study showed that the insertion of ventral and umbilical hernia mesh through a sterilely PVC can be performed without risk of mesh contamination. For the women of this study, the PVC proved to be a more sterile route of insertion than the prepped skin incision in the same patients. The major implication is that a PVC can serve as a sterile conduit for the insertion of synthetic mesh during hernia repair. Also, the sterility of the PVC allows for the insertion of other possible intraabdominal prostheses.

The bacterial flora of the vaginal canal can vary among individual women, with this variation extending to the timing of the menstrual cycle. Lactobacilli are the primary vaginal flora in a healthy individual. However, other normal organisms include coagulase-negative staphylococci, *Corynebacterium* spp. and *Streptococcus viridans* [5, 9]. Pathogenic species include *G. vaginalis*, as well as *Enterococcus* spp. from fecal contamination.

The small size of the sample was the major weakness of this study. Studies with larger samples will serve to confirm the findings of this study and to move transvaginal ventral

and umbilical hernia repair beyond the realm of experimental technique. Additionally, the comparisons were not randomized, although each patient contributed three mesh preparations to the study arms.

Furthermore, the timing of the prep and sample swab varied between the vaginal samples and the PSI samples. The PVC samples were taken immediately after the betadine prep, whereas the PSI samples were taken toward the end of the case. It is conceivable that PVC samples acquired later in the case may have shown higher levels of contamination after more surgical traffic had occurred in the area. However, it is unlikely that the dramatic difference in contamination rates were the result of timing, especially given the consistency of both the surgeon and the prep/draping techniques.

Despite the weaknesses of this study, the results demonstrate that a properly PVC is as sterile or more sterile than a traditionally PSI in the abdomen. The potential applications of this study would allow for expansion of transvaginal NOTES usage to procedures that use other synthetic implants. These implants also could be inserted into the abdominal cavity without the aid of protective devices, thereby reducing surgical cost and procedural complexity.

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