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Instruments and Techniques

Single-Field Sterile-Scrub, Preparation, and Dwell for Laparoscopic Hysterectomy

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ABSTRACT Type VII laparoscopic hysterectomy is classified as a "clean-contaminated" procedure because the surgery involves contact with both the abdominal and vaginal fields. Because the vulva has traditionally been perceived as a separate but contaminated field, operating room guidelines have evolved to require that surgeons gloved and gowned at the abdominal field either avoid contact with the urethral catheter, the uterine manipulator, and the introitus or change their gloves and even re-gown after any contact with those fields. In the belief that the perception of the vaginal field as contaminated stems from inadequate preoperative preparation instructions, we have developed a rigorous abdomino-perineo-vaginal field preparation technique to improve surgical efficiency and prevent surgical site infections. This thorough scrub, preparation, and dwell technique enables the entire abdomino-perineo-vaginal field to be safely treated as a single sterile field while maintaining a low rate of surgical site infection, and should be further investigated in randomized studies. Journal of Minimally Invasive Gynecology (2012) 19, 220–224 © 2012 AAGL. All rights reserved.

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Because abdominal hysterectomy includes contact with the vaginal recesses, it is considered "clean-contaminated." Type VII total laparoscopic hysterectomy, an abdominal hysterectomy in which all surgical dissections, ligations, and sutures are completed through the sheath [1], has also been classified as a clean-contaminated procedure. However, potential for contamination is greater because total laparoscopic hysterectomy begins with placement of uterine manipulators and urethral catheters, is continued through trocars in the abdominal field, may involve manipulation of the urethral catheter or uterine manipulators, and ends with colpotomy, which is then sutured closed [2]. Guidelines established by the Association of periOperative Registered Nurses (AORN) for the surgical preparation of areas classified as contaminated have historically been limited, and do not address the new issue of managing the interchanging use of the vaginal and abdominal fields during laparoscopic surgery [3].

When queried during laparoscopic surgical courses, physician attendees regularly report having diverse or no institutional standards for preoperative sterile preparation and subsequent management of the 2 surgical fields. Furthermore, they report having frequently observed visibly inadequate vaginal apical preoperative preparation in their patients (personal observation, K.A.O.). In the belief that a more thorough exocervical and vaginal preparation could be performed that would safely allow the vulva and vaginal interior to be safely treated as a unified sterile field along with the abdomen, 2 of the authors (K.A.O., B.E.C.) have revised their operating room preparation standards to include

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a meticulous unified scrub and preparation of the abdomen, upper thighs, vulva, vaginal interior, cervix, and anus, with final instillation of 60 mL povidone-iodine solution into the vagina after the preparation as the "dwell." After this preparation, the surgeon can move freely from abdomen to perineum and back without changing gloves or re-gowning during procedures. In our practice, this combined single-field sterile preparation has been used in all patients undergoing any laparoscopic hysterectomy. This retrospective descriptive article explains the single-field preparation technique and reports on surgical site infections (SSIs) from this series of unselected consecutive patients who underwent any radical or total laparoscopic hysterectomy, or any concomitant gynecological or general surgical procedure.

Patients and Methods

All patients undergoing laparoscopic hysterectomy and concomitant procedures from September 1996 through March 2011 were included. Throughout the series, Surgical Care Improvement Project (SCIP) guidelines for prophylactic antibiotic therapy were followed [4]. Pubic hair was left intact or minimally clipped but not shaved. Beginning in 2003, all patients received cefazolin, and those undergoing concomitant hysterectomy and appendectomy received cefoxitin. Levaquin and metronidazole were added when bowel resection was performed or perforation was evidenced. Patients in whom surgery lasted more than 3 hours or resulted in blood loss greater than 1500 mL were given an additional dose of antibiotic.

Investigational review board permission and oversight for this project has been maintained at Sequoia Hospital in Redwood City, California. Data collected included demographic variables, indications for surgery, duration of surgery, estimated blood loss, and duration of hospital stay. Surgical site infections including superficial incisional, deep facial incisional, and organ space were recorded for the first 90 days in accordance with established guidelines of the Centers for Disease Control and Prevention [5,6]. Continuous variables were tested for normality using the Shapiro-Wilk test. Because assumptions of normality were not met for continuous variables, data were analyzed using the nonparametric Wilcoxon rank-sum test, and are reported as median and quartile. Binary data were analyzed using the Pearson χ^2 test. For all tests, significance was set at $p < .05$ (2-sided).

Operative Technique

For the single-field preparation, a kit was used (No. 4468; Cardinal Health, Inc., Dublin, Ohio), which contains 2 cotton-tipped applicators, 6 foam sponges, 3 foam sponge sticks, 3 ounce povidone-iodine scrub, and 90 mL povidone-iodine solution. An additional 60 mL povidone-iodine solution is added to the preparation kit, along with a bulb-tip syringe.

In patients allergic to external iodine preparations, the same preparation is performed using diluted 4% chlorhexidine gluconate. The standard preparation starts by cleaning the debris from the apex of the umbilicus using cotton-tipped applicators. Then each foam sponge is dipped in the scrub solution to vigorously scrub, in sequence, the abdomen, perineum, top third of the thighs, and vulva, and then the vaginal interior up to the cervix; the sponges are discarded after swabbing the anus. The staff is careful to swab the apical vagina and cervix. This scrub is repeated with 5 more foam sponges. The external prepared area is then dried using a sterile towel.

Then 3 sponge sticks soaked in iodine solution are used to paint, in sequence, the abdomen, perineum, top third of the thighs, vulva, vaginal interior up to the cervix, and posteriorly to the anus. Although the anus is not touched during the procedure, it is included in the prepped area because it is adjacent. Last, with the patient in a slight Trendelenberg position, a bulb-tipped syringe is used to inject 60 mL povidone-iodine solution into the vaginal cavity [7]. This leaves the iodine indwelling in the vaginal canal and on the cervix. It was consistently observed that the 60 cc volume of the povidone iodine "dwell" disappears over the course of the operation, much of it spilling out during instillation, but also later during use of the uterine manipulator. By the time of colpotomy, the solution is absent. In reliance on this combined-field, thorough scrub, preparation, and dwell technique, the surgeon inserts and may repeatedly maneuver the uterine manipulator, the urethral catheter [8], performs a vaginal morcellation, uses the 5-mm laparoscope for cystoscopy, and immediately reuses it in the abdominal field [9] without re-gowning or changing gloves [10]. However, any incidental contact with the anus during the procedure would require a change of glove.

Results

Of 1337 patients in whom the described single-field preparation technique was used before undergoing simple or radical laparoscopic hysterectomy, 24 patients (1.8%) experienced SSIs, all in the deep organ space. There were no superficial or deeper incisional infections as defined in guidelines of the Centers for Disease Control and Prevention [6]. Five of 24 patients (0.4% of the total) required a repeat operation. Fourteen patients had pelvic cellulitis as diagnosed by vaginal cuff induration and tenderness, but no sonographic evidence of abscess. Three patients had pain with pelvic fullness. Subsequent computed tomography revealed evidence of abscess that had resolved with antibiotic therapy. Six patients had abscesses that required repeat operation in 3 or computed tomography–assisted drainage in 3. One patient had persistent pain but no radiologic findings, and underwent laparoscopic resection of a culture-negative granuloma.

Patient demographic data (Table 1) were stratified by the presence or absence of SSIs, and demonstrated no differences in baseline characteristics except age: women with SSI were younger than those without SSI (median, 46 vs.

Table 1

Patient demographic data stratified by presence of SSI[a]

Variable	Overall (n = 1337)	No SSI (n = 1311)	SSI (n = 26)	p Value[b]
Age, yr	49 (21, 89)	50 (21, 89)	46 (35, 62)	.047
Parity	1 (0, 7)	1 (0, 6)	1 (0, 3)	.73
Height, inch	65 (57, 72)	65 (57, 72)	65 (62, 67)	.67
Weight, lb	156 (98, 356)	156 (98, 356)	150 (126, 194)	.54
BMI	26.2 (17.6, 64.0)	26.2 (17.6, 64.0)	25.2 (21.3, 35.5)	.43

BMI = body mass index; SSI = surgical site infection.
[a] Data are given as median (25th, 75th percentile).
[b] Wilcoxon rank-sum test.

50 years; p = .047). Patients with SSI were stratified by need for repeat operation (Table 2), required in 5 of 24 patients. There was no difference in SSI rates according to final postoperative pathologic diagnosis (Table 3).

Surgical data and hospital stay were listed for patients stratified by presence of infectious complications (Table 4). There were no differences in median (range) duration of surgery (skin-to-skin operative time) at 116 (34–353) minutes, estimated blood loss at 75 (0–1500) mL, and length of hospital stay at 1 (1–6) day. In patients with infectious complications, duration of surgery was longer than in those without infection (152 vs. 115 minutes; p = .01).

Discussion

For total abdominal hysterectomy or vaginal hysterectomy, Surgical Care Improvement Project and AORN standards have defined the sterile preparations for the single surgical field that is prepared and operated on. However, with a type VII laparoscopic hysterectomy, surgeons must repeatedly contact the vaginal and abdominal fields. The surgeon typically inserts the urethral catheter after draping, then inserts a uterine manipulator and may need to subsequently maneuver it during the course of the surgery. The surgeon may need to morcellate a large uterus through the vagina [10] or perform cystosufflation [8] or laparoscopic cystoscopy [9], both of which require manipulation of the urethral catheter, and then suture the vagina laparoscopically. Traditionally, surgeons have avoided contact with the vaginal field or changed their gloves and even re-gowned after every contact, under the assumption that the perineal and vaginal fields are not sterile [3].

Table 2

Surgical site infections in 1337 patients, stratified according to repeat operation[a]

Variable	No repeat operation	Repeat operation	Total infectious complications
Pelvic cellulitis	14 (1.1)	0	14 (1.1)
Fluid collection, granuloma	2 (0.2)	1 (0.1)	3 (0.2)
Pelvic abscess	3 (0.2)	4 (0.3)	7 (0.5)
Diverticulitis	1 (0.1)	0	1 (0.1)
Clostridium difficile	1 (0.1)	0	1 (0.1)
Total	21 (1.6)	5 (0.4)	26 (1.9)

[a] Values are given as No. (%).

In a 1997 meta-analysis of vaginal antisepsis for hysterectomy, Eason [11] wrote, "Infectious complications of hysterectomy remain common despite the use of prophylactic antibiotics. Most are caused by contamination of the surgical site by vaginal bacteria, which are not controlled by current methods of pre-operative antisepsis." The AORN "Recommended Practices for Preoperative Patient Skin Antisepsis" do not provide specific standards for preoperative sterile vaginal and cervical cleansing for laparoscopic hysterectomy with respect to sterilizing both abdominal and perineovaginal fields for one surgery [3].

Since 1977, the effectiveness of an iodophore soap and solution as preoperative vaginal preparation for surgery has been confirmed for laparotomy and vaginal surgery [12,13]. We used povidone-iodine in the present 15-year retrospective review. Both povidone-iodine and chlorhexidine kill 99% of bacteria in the vagina [13]. Culligan et al [14] have demonstrated that chlorhexidine may be more effective than povidone-iodine in decreasing early (30-minute) but not later bacterial colony counts in the operative field in vaginal hysterectomy. Chlorhexidine cleansing of the vagina seems to be safe [14], with less than 1% allergic reaction [15]. In a retrospective review of 256 patients undergoing gynecologic surgery, Levin et al [16] reported that chlorhexidine 2% seemed to reduce the rate of SSIs, from 15% to 5%, compared with povidone-iodine 10% scrub and paint. However, each of these preparations also contained 65% to 70% alcohol, and the method of vaginal preparation was not specified in that report. Dariouche et al [15] used chlorhexidine 2%–alcohol 70% applicators vs. povidone-iodine 10% scrub and paint, and reported SSIs with follow-up over 30 days, finding no difference in infection rates (1/42 vs. 0/40) among the 82 patients undergoing gynecologic surgery and no difference in deep organ space infections in 4.4% of 849 patients undergoing any type of surgery. Those authors did not mention whether the applicators were used in the vagina or if some other method of vaginal cleansing was used.

Table 3

Final pathologic diagnoses stratified by presence of SSI[a]

Variable	Overall	No SSI	SSI	p Value[b]
Pathologic diagnosis	1337 (100)	1311 (98.1)	26 (1.9)	.50
Adhesions	8 (0.4)	7 (0.5)	1 (12.5)	
Endometriosis	72 (5.4)	69 (5.3)	3 (4.2)	
Ovarian/tubal carcinoma	56 (4.2)	54 (4.1)	2 (3.6)	
Cervical/vaginal carcinoma	31 (2.3)	30 (2.3)	1 (3.2)	
Adenomyosis	191 (14.3)	186 (14.2)	5 (2.6)	
Leiomyoma	490 (36.6)	481 (36.7)	9 (1.8)	
Benign ovarian tumor	274 (20.5)	271 (20.7)	3 (1.1)	
Uterine hyperplasia/carcinoma/sarcoma	198 (14.8)	196 (15.0)	2 (1.0)	
Abscess	1 (0.1)	1 (0.1)	0	
Cervical dysplasia	12 (0.9)	12 (0.9)	0	
Choriocarcinoma	1 (0.1)	1 (0.1)	0	
Metastatic breast or colon carcinoma	3 (0.2)	3 (0.2)	0	

SSI = surgical site infection.
[a] Values are given as No. (%).
[b] Pearson χ^2 test.

To prevent the frequent post-preparation observation of undisturbed white vaginal fluid at the vaginal apex that many gynecologists have reported, our team instituted a standard of ensuring that the apex was repeatedly swabbed and that 60 mL of paint was instilled with the patient in the Trendelenburg position. It is possible that the friction from the required vaginal scrubbing with antimicrobial agents during the cleansing process is more important in removing bacterial organisms than the specific agent used [12,17]. Culligan et al [14] also used such cleansing process with each of the antibacterial agents, using a "vigorous 2 minute scrub in and around the vagina using disposable sponges," followed by a "paint," and application of either povidone-iodine or chlorhexidine, depending on which bactericide the patient was randomized to receive; however, neither Dariouche et al [15] nor Levin et al [16] reported their technique for sterile preparation of the vagina.

Laparoscopic hysterectomy results in a lower rate of SSI compared to open abdominal hysterectomy [18]. In their series of 310 patients undergoing laparoscopy-assisted vaginal hysterectomy, Chang et al [19] reported a rate of SSI of 2.7%. Donnez et al [20] reported a commendably low rate of 0.76% for infectious complications in their series of 1577 laparoscopy-assisted vaginal or total laparoscopic hysterectomies; however, their preparation standards were not discussed.

Recognizing the vast number of variables that may contribute to SSI, we report these historical comparators only to confirm that our SSI rate of 1.8% after the single-field preparation and subsequent unified-field technique remains within reported norms. Interpretations of this report are limited in that a single surgeon (K.A.O.) oversaw the preparations and sterile-field management of all surgical procedures, which may not be applicable to larger groups or multiple practitioners. Unlike some multicenter reports, the long-term follow-up in this single-surgeon report is highly reliable. Operating room staff may vary their interpretations of this preparation technique, and resultant SSIs may also vary. In addition, bias increasing our apparent infection rate may be introduced by assuming that the 2 instances of sterile pelvic fluid aspiration, the case of clostridium difficile, the case of diverticulitis, and the 1 repeat operation at

Table 4

Surgical and hospital stay data stratified by presence of SSI[a]

Variable	Overall (n = 1337)	No SSI (n = 1311)	SSI (n = 26)	p Value[b]
Duration of surgery, min	116 (34, 353)	115 (34, 353)	152 (92, 240)	.01
Estimated blood loss, mL	75 (0, 1500)	75 (0, 1500)	100 (25, 400)	.25
Length of hospital stay, day	1 (1, 6)	1 (1, 6)	1 (1, 2)	.61

SSI = surgical site infection.
[a] Data are given as median (25th, 75th percentile).
[b] Wilcoxon rank-sum test.

6 weeks to excise a suture granuloma were in fact deep organ site infections as the CDC guidelines were not specific about these cases. Without these cases, our SSI rate was 1.6%.

The diagnosis of pelvic cellulitis may be overestimated because there is no culture evidence or other objective diagnostic tests for this entity.

Preoperative preparation technique represents a modifiable element of health care delivery that, as demonstrated herein, may increase surgeon efficiency while maintaining a low rate of postoperative infections. After the thorough preoperative vaginal preparation described, the abdominal, vulvar, and vaginal fields may safely be treated as a single sterile field during a total laparoscopic hysterectomy procedure, with an acceptably low SSI rate. A randomized prospective study is needed to further validate this technique.

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