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Evidence-based wound classification for vulvar surgery: Implications for risk adjustment

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HIGHLIGHTS

- Wound classification for vulvar procedures (VP) is ambiguous and not well studied.
- VPs showed high surgical site infection (SSI) rate, higher than total abdominal hysterectomy (TAH).
- Radical VPs showed a similar SSI rate with patients undergoing TAH with type IV wound.
- VPs should be categorized as clean-contaminated or contaminated wounds.

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ABSTRACT

Objectives. The correct wound classification for vulvar procedures (VP) is ambiguous according to current definitions, and infection rates are poorly described. We aimed to analyze rates of surgical site infection (SSI) in women who underwent VP to correctly categorize wound classification.

Methods. Patients who underwent VP for dysplasia or carcinoma were collected from the National Surgical Quality Improvement Program database (NSQIP). SSI rates of vulvar cases were compared to patients who underwent abdominal hysterectomy via laparotomy, stratified by the National Academy of Sciences wound classification. Descriptive analyses and trend tests of categorical variables were performed.

Results. Between 2008 and 2016, 2116 and 31,506 patients underwent a VP or TAH, respectively. Among VP, 1345 (63.6%), 364 (17.2%), and 407 (19.2%) women underwent simple vulvectomy, radical vulvectomy, or radical vulvectomy with lymphadenectomy, respectively. The overall rate of SSI for VP was higher than that observed for TAH (5.6% vs. 3.8%; $p < 0.0001$). While patients undergoing TAH displayed a corresponding increase in the rate of SSI with wound type (type I: 3.4%; type II: 3.8%, type III: 6.8%; type IV 10.6%; $p < 0.001$), no such correlation was observed for simple VP (type I: 3.3%, type II: 3.0%; type III: 3.2%; type IV: 0%; $p = 0.40$). On the other hand, a non-significant correlation was observed for radical VP (type I: 4.0%, type II: 10.1%; type III: 14.3%; type IV: 20.0%; $p = 0.08$). The overall rate of SSI in patients undergoing any radical VP was similar to patients undergoing hysterectomy with a type IV wound (10.1% vs 10.6%, $p = 0.87$).

Conclusion. Patients undergoing VP are at high risk of infection. Simple vulvectomy should be classified as a type II and radical vulvectomy as a type III wound. These recommendations are important for proper risk adjustment.

1. Introduction

Surgical site infections (SSI) are associated with significant morbidity, mortality, and increased health care expenditures [1]. Over the last few decades, SSI rates decreased dramatically due to antibiotic prophylaxis and minimally invasive surgical techniques [2,3]. Surgical wounds are traditionally classified into four categories based on the risk of SSI [4]. Assessment of surgical risk and appropriate wound classification has been used to develop protocols to decrease SSI rates [5]. This classification is also an important predictor of postoperative outcomes and a stepwise increase in SSI rates by wound class has been demonstrated in the past [2,6].

Wounds from most operative gynecologic procedures are categorized as clean or clean contaminated and the American college of

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Obstetricians and Gynecologists (ACOG) published guidelines for perioperative antibiotic prophylaxis [7]. ACOG recommends perioperative antibiotic prophylaxis for patients undergoing hysterectomy [7]. Although appropriate wound classification and prophylaxis after certain procedures including hysterectomy have been well studied, little is known for other gynecologic procedures such as vulvectomy. In the latest bulletin, a single dose of cefazolin is recommended for vulvectomy similar to other clean contaminated procedures since vulvar skin is a polymicrobial [7].

Vulvar procedures (VP) are associated with a high risk of infection, as high as 58% for radical vulvectomy [8]. Despite this high SSI risk, wound classification of VP is ambiguous according to current definitions, and infection rates and risk factors for SSI are poorly described. In this study, we aimed to analyze the rate of SSI in women who underwent vulvar surgery. As a reference, these rates were compared to women undergoing total abdominal hysterectomy (TAH), which has a well-studied wound classification based on anatomic location and infection rate.

2. Materials and methods

A retrospective analysis was performed using the American College of Surgeons National Surgical Quality Improvement Program database (NSQIP). Patients who underwent vulvectomy or abdominal hysterectomy between 2008 and 2016 were included. Patients were stratified according to wound classification defined by National Academy of Sciences [4]; clean (type I), clean-contaminated (type II), contaminated (type III) and dirty (type IV). SSI rate was the primary outcome. This study is exempt from IRB review; individual study patients and hospitals were deidentified. The NSQIP database includes outcomes such as SSI up to 30 days after surgery from randomly assigned patients. This information is collected from patients' charts (rather than insurance claims) by trained nurse abstractors. NSQIP defines superficial SSI as infections with purulent drainage, swelling and erythema involving only the skin and/or subcutaneous tissue of the incision. Deep SSI is defined as infections involving the deep soft tissues such as fascial and muscle layers beneath the incision or deep incision that spontaneously dehisces or is opened with fever or localized pain/tenderness. Organ-space SSI includes infections involving any part of the anatomy that was opened or manipulated during an operation excluding the incision, or purulent drainage from a drain [9]. The term “any SSI” was used to define all three types of infections (superficial, deep and organ space). For descriptive analyses, clean and clean contaminated cases, and contaminated, dirty, and deep and organ space infections were combined into single categories where appropriate due to low numbers. CPT codes used for each procedure were as follows: simple vulvectomy 56620 and 56625, radical vulvectomy 56630 and 56633, radical vulvectomy with lymphadenectomy 56631, 56632, 56634, 56637 and 56640. Diagnosis codes were then used to identify patients with invasive cancer (184.1, 184.2, 184.3, 184.4, C51, C51.0, C51.1, C51.2, C51.8, and C51.9) and patients with a diagnosis of dysplasia (233.32, 624.01, 624.02, D07.1, N90.0, N90.1 and N90.3).

Total abdominal hysterectomy cases were defined using CPT code 58150. In this study, only patients who underwent TAH without other concomitant surgeries were selected. Patients who underwent minimally invasive hysterectomy were excluded. Both vulvectomy and hysterectomy cohorts included benign, precancerous and malignant cases.

The SSI rate was the primary outcome. Pearson's chi-square tests compared SSI across groups while a one-sided Cochran-Armitage test for trend was used to assess the association of SSI rate with wound type. Multivariable analysis was performed to analyze the effect of procedure on any SSI after adjusting for age, diabetes and BMI, known risk factors for SSI.

Table 1
Wound classification among patients who underwent a vulvar procedure (VP) or total abdominal hysterectomy (TAH).

	VP, n (%)	TAH, n (%)
Total number of patients	2116	31,506
Number of patients in each wound category		
Clean	86 (4.1)	1818 (5.8)
Clean contaminated	1967 (93.0)	29,281 (92.9)
Contaminated	52 (2.5)	265 (0.8)
Dirty	11 (0.5)	142 (0.5)
SSI rate; any	118 (5.6)	1197 (3.8)
Clean and clean contaminated	113 (5.5)	1164 (3.7)
Contaminated and dirty	5 (7.9)	33 (8.1)

3. Results

Between 2008 and 2016, 2116 and 31,506 patients underwent a VP or TAH, respectively (Table 1). Among VP, 1345 (63.6%), 364 (17.2%), and 407 (19.2%) women underwent simple, radical, or radical vulvectomy with lymphadenectomy, respectively (Table 2). The majority of VP and TAH were classified as clean or clean-contaminated (Table 1). The rate of SSI (both superficial and deep/organ) for any VP was higher than for TAH (5.6% vs 3.8% $p < 0.0001$).When stratified by procedure, the SSI rate was significantly higher for radical VP compared to TAH(10.1% vs. 3.8%, $p < 0.0001$) but not for simple VP (3.0% vs. 3.8%, $p = 0.12$). Patients with vulvar cancer had a higher rate of SSI rate compared to patients with dysplasia (8.9% vs. 2.1% respectively, $p < 0.0001$). On multivariable analysis adjusting for age, body mass index and diabetes, VP was associated with a higher risk of SSI compared to TAH (OR 1.56; 95% CI 1.27–1.93, $p < 0.001$).

Patients undergoing TAH displayed a corresponding increase in the rate of SSI with wound type (type I: 3.4%; type II: 3.8%, type III: 6.8%; type IV 10.6%; $p < 0.001$, Table 3). However, no such correlation was observed for simple VP (type I: 3.3%, type II: 3.0%; type III: 3.2%; type IV: 0%; $p = 0.40$, Table 3). On the other hand, a non-significant correlation was observed for radical VP (type I: 4.0%, type II: 10.1%; type III: 14.3%; type IV: 20.0%; $p = 0.08$, Table 3). Of note, the overall rate of SSI in patients undergoing any radical VP was similar to patients undergoing hysterectomy with a type IV wound (10.1% vs 10.6%, $p = 0.87$), while women who underwent radical vulvectomy with lymphadenectomy showed even higher rate of SSI (13.3%, $p = 0.40$).

4. Discussion

SSI has been shown to increase health care costs, length of hospital stay, and is associated with worse overall survival for some gynecologic cancers [10]. Our results from a national dataset show that in contrast to other surgical procedures, the current wound classification system does not reflect the risk of SSI for simple VP. In contrast, in one NSQIP investigation of 634,426 patients who underwent various surgical procedures, the SSI rates for type I, II, III and IV wounds was 2.6%, 6.7%, 8.6% and 11.8%, respectively [2], similar to the progression of SSI risk we found in patients undergoing TAH (Table 1). It is also important to

Table 2
SSI rates in subgroups of patients with and without invasive cancer and patients who underwent different vulvar procedures.

	n, (%)	SSI rate, n (%)
Indication for procedure		
Dysplasia	1038 (49.1)	22 (2.1)
Invasive cancer	1078 (50.9)	96 (8.9)
Vulvar procedures		
Simple vulvectomy (partial/complete)	1345 (63.6)	40 (3.0)
Radical vulvectomy (partial/complete)	364 (17.2)	24 (6.6)
Radical vulvectomy (partial/complete) with lymphadenectomy	407 (19.2)	54 (13.3)

Table 3
SSI rates among patients who underwent total abdominal hysterectomy (TAH), simple vulvar procedure (VP) or radical VP with each wound type.

Type of wound	TAH $n = 31,506$	Simple VP $n = 1345$	Radical VP $n = 771$
Type 1 (clean)	3.4%	3.3%	4.0%
Type II (clean-contaminated)	3.8%	3.0%	10.1%
Type III (contaminated)	6.8%	3.2%	14.3%
Type IV (dirty)	10.6%	0%	20.0%
p value	<0.001	0.40	0.08

recognize that the overall rate of SSI for VP is significantly higher than hysterectomy performed via laparotomy (a type II incision). Proper risk estimation is critical for equitable state and national reporting, and in order to design countermeasures to improve quality [5]. Appropriate wound classification would also improve hospital reimbursement policies by insurance companies including Medicaid and Medicare. Since SSI is often preventable, it is an important quality metric used by most insurance companies. For instance, Medicaid reimbursement is higher for ruptured appendectomy compared to appendicitis without rupture due to complexity of the surgery and its associated infectious morbidity [11] Hence, procedures with an inherent higher complication risk including SSI have a different reimbursement bundle and with appropriate wound classification, reimbursement for VP can be modified based on its higher intrinsic infection risk. Our findings have implications for public reporting and proper risk adjustment for tertiary care institutions with a high burden of vulvar pathology.

The prevalence of SSI for VP ranges from 5.6% to as high as 58% [8]. Senn et al. investigated the risk factors for wound complications after VP and found that extent of surgery (i.e. local excision, hemivulvectomy, or radical vulvectomy) and inguinofemoral lymphadenectomy were independent risk factors for wound complications including infection [12]. Their results are in agreement with ours. In another NSQIP study, preoperative hypoalbuminemia was associated with wound complications (deep and organ/space SSI, wound dehiscence and graft failure) after surgery for vulvar cancer [13]. Patients with albumin levels <3.5 mg/dl were more likely to have major wound complications with an odds ratio of 2.9 (95% CI: 1.1–7.3, $p = 0.02$).

Implementation of peri-operative measures significantly reduced the SSI rate among women with ovarian or endometrial cancer [3]. However, different strategies are needed to reduce SSI in VP and for proper estimation of SSI risk, such as albumin and size of the resection. The very high rate of SSI in patients undergoing inguinal lymphadenectomy underscores the advantages of performing sentinel lymphadenectomy for appropriate patients [14]. Although prolonged antibiotic use is currently not recommended after any surgical procedure [1,15], it has been shown to be beneficial in rare instances, such as knee revision arthroplasty [13]. Whether prolonged antibiotic use is beneficial after VP would be an interesting area of research.

Our investigation has strengths and limitations. We have chosen TAH as a comparator because it is familiar to all gynecologists, but it is nevertheless an arbitrary reference. While other comparators could be used, we feel our data shows that the rate of SSI for VP is unacceptably high. Unidentified comorbidities such as diabetes and prior radiation are also likely to contribute to SSI. We were unable to collect data on incision size, and used indication for surgery and the type of resection performed as surrogates. Other limitations include the inability to adjust SSI rate for stage of vulvar cancer or the use of sentinel lymph node biopsy. Strengths include the use of a large national database collected by trained nurse abstractors who use predefined and standardized inclusion and exclusion criteria, as well as SSI definitions, which makes our findings generalizable [9,16]. However, NSQIP collects only 30 day morbidity and is concentrated in tertiary institutions due to costs of reporting [9].

In conclusion, patients undergoing radical vulvar procedures, particularly those who undergo inguinal lymphadenectomy, are at very high risk of infection, comparable to the rates observed in women undergoing TAH with type III/IV incisions. Considering the high national SSI rates presented here, the inevitable local inflammatory response associated with vulvar dysplasia and carcinoma, and confusion around whether the vulva is considered clean skin or a contaminated site, simple vulvar procedures should be categorized as clean-contaminated and radical vulvar procedures should be categorized as a contaminated wound.

Author contributions

IM, WAC and SCD conceived the idea, designed the study, analyzed the data and prepared the manuscript. KAB and EBH performed the statistical analysis, participated in data analysis and writing of the manuscript.

Declaration of Competing Interest

All authors declare no conflict of interest.

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