

# Wound complications following vulvar excision for nonmalignant lesions



Glenn P. Boyles, MD; Ashlee M. Weaver, MD; David E. Cohn, MD; Floor J. Backes, MD; Larry J. Copeland, MD; Kristin L. Bixel, MD; Jeffrey M. Fowler, MD; David M. O'Malley, MD; Casey M. Cosgrove, MD

**BACKGROUND:** There is a paucity of literature regarding the outcomes following vulvar excision for nonmalignant lesions. This is a common procedure among gynecologists and gynecologic oncologists, and a body of evidence is warranted to guide clinical care and future research.

**OBJECTIVE:** This study aimed to estimate the rate of wound complications following simple vulvar excision and to identify the risk factors for these outcomes. Our secondary objectives were to determine the rates of (1) positive margins and (2) occult carcinoma in the cases of vulvar dysplasia.

**STUDY DESIGN:** We conducted a single-institution, retrospective cohort study of the patients who underwent simple vulvar excision procedures for suspected premalignant or benign lesions between June 2016 and February 2020. Our primary outcome was the rate of composite wound complications, including wound separation or breakdown, infection, or hematoma. Our secondary outcomes were the incidence of (1) margins positive for residual dysplasia and (2) occult minimally invasive carcinoma. The Fisher exact tests and chi-squared tests were used to compare the categorical variables and logistic regression models and independent student *t* tests were used for continuous variables, as appropriate. Multivariate stepwise selection and multiple logistic regression was performed to evaluate the risk factors for complications and generate the odds ratios.

**RESULTS:** Of the 338 patients included in the study, 143 (42.3%) experienced wound complication. Most of these complications were wound separation or breakdown ( $n=134$ , 39.6%), followed by infection ( $n=22$ , 6.5%), and hematoma ( $n=4$ , 1.2%). On multivariate analysis, the presence of high-grade vulvar dysplasia (adjusted odds ratio, 1.83; 95% confidence interval, 1.06–3.15), longer specimen diameter (adjusted odds ratio, 1.03; 95% confidence interval, 1.01–1.05), and lesion location on the perineum (adjusted odds ratio, 2.25; 95% confidence interval, 1.38–3.66) were independent risk factors. With high-grade vulvar dysplasia, the rate of positive margins was 50.2% (114/227) and that of occult microinvasive carcinoma was 17.2% (39/227). Notably, the primary and secondary outcomes were similar among gynecologic oncologists and gynecologists.

**CONCLUSION:** Wound complications following vulvar excision for nonmalignant lesions are common. Select groups may benefit from anticipatory counseling and future interventional studies to prevent complication. The incidence of positive surgical margins and occult minimally invasive carcinoma is also high, reflecting the challenging nature of treating vulvar disease.

**Key words:** gynecologic surgical procedures, margins, postoperative complication, risk factors, simple partial vulvectomy, vulvar carcinoma, vulvar dysplasia, vulvar surgery, wide local excision

## Introduction

Vulvar dysplasia is a common problem in the United States, with population-level data showing a 4-fold increase from 1973 to 2000.<sup>1</sup> The incidence of invasive vulvar cancer, on the other hand, has risen by a lesser degree of 20% over this time period.<sup>1</sup> Human papilloma virus infection and chronic dermatoses such as

lichen sclerosus are related to vulvar cancer carcinogenesis.<sup>2–4</sup> Along with the continued prevalence of human papilloma virus infection, the aging population in the United States brings the management of vulvar disease closer to the forefront.

Wide local excision (WLE) of the vulva or simple partial vulvectomy

(SPV) are similar procedures performed for suspected premalignant or benign lesions or for early-stage (International Federation of Gynecology and Obstetrics [FIGO]-IA) cancers.<sup>5</sup> The common indications for WLE/SPV include vulvar intraepithelial neoplasia (VIN)—now commonly known as vulvar high-grade squamous intraepithelial lesions

From the Department of Obstetrics and Gynecology, The Ohio State University Wexner Medical Center, Columbus, OH (Dr Boyles); The Ohio State University College of Medicine, Columbus, OH (Dr Weaver); Division of Gynecologic Oncology; The Ohio State University Comprehensive Cancer Center and Arthur G. James Cancer Hospital and Richard M. Solove Research Institute, Columbus, OH (Drs Cohn, Backes, Copeland, Bixel, Fowler, O'Malley, and Cosgrove).

The authors report no conflict of interest.

This study did not receive any funding.

This work was presented in poster format at the 2021 annual meeting of the Society for Gynecologic Oncology, held virtually, March 19–25, 2021.

**Cite this article as:** Boyles GP, Weaver AM, Cohn DE, et al. Wound complications following vulvar excision for nonmalignant

lesions. *Am J Obstet Gynecol Glob Rep* 2021;1:100022.

Corresponding author: Casey M. Cosgrove, MD. [casey.cosgrove@osumc.edu](mailto:casey.cosgrove@osumc.edu)

2666-5778/\$36.00

© 2021 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>)

<http://dx.doi.org/10.1016/j.xagr.2021.100022>

## AJOG Global Reports at a Glance

**Why was this study conducted?**

There is a paucity of literature regarding the outcomes of simple vulvar excision. This study aimed to describe the outcomes following vulvar excision and to identify the risk factors for wound complications. We also aimed to estimate the rate of positive surgical margins and occult carcinoma.

**Key findings**

The overall rate of postoperative wound complications was high (42.3%). The important predictors of wound complications were the presence of vulvar dysplasia, lesion location on the perineum, and incision length. With vulvar dysplasia, the rates of positive surgical margins and occult carcinoma on the final pathology were 50.2% and 17.2%, respectively. The rates were similar among gynecologists and gynecologic oncologists.

**What does this add to what is known?**

Previous literature on vulvar surgery focuses on radical procedures for patients with vulvar cancer.

We add to one existing study on wound complications following vulvar excision for nonmalignant disease; we contribute both descriptive data and identify new predictors for adverse wound outcomes. These results have immediate utility for counseling patients and guiding future interventions within high-risk groups.

The estimated risk of positive surgical margins in the cases of vulvar dysplasia agrees with the prior work. Our estimated risk of the incidence of microinvasive carcinoma within dysplastic lesions is more robust than previous smaller studies.

(HSIL)<sup>6</sup>—and differentiated VIN (dVIN), vulvar low-grade squamous intraepithelial lesions, Paget's disease of the vulva, hidradenitis suppurativa, and various other dermatologic conditions. Obstetrician-gynecologists and gynecologic oncologists routinely perform these surgeries given the variety of indications. However, there is a paucity of information regarding the surgical outcomes. By contrast, radical vulvectomy, which is performed for invasive vulvar cancers has been well-studied, with complications such as wound infection, wound breakdown, and cellulitis extensively documented in the literature.<sup>7</sup> A corresponding body of evidence is needed for simple vulvar excision (WLE/SPV).

Surgeries of the vulva and the associated postoperative complications bear significant ramifications for the quality of life of patients. Wound breakdown and infection are associated with pain and the potential need for reoperation or antibiotics. Even after simple vulvectomy, the patients may experience sexual dysfunction or alterations to body image.<sup>8</sup> Furthermore, patients with VIN require

long-term surveillance. Along with postoperative issues, the recurrence of dysplasia or cancer magnifies the impact of these procedures on patient care. The most well-established risk factor for local vulvar recurrence is margin status, and with this in mind, the published rates of margin positivity range from 49 to 66%.<sup>9–11</sup> This study describes the outcomes of simple vulvar excision at an academic medical center and National Cancer Institute (NCI)-designated Comprehensive Cancer Center from 2016 to 2020. Our primary objectives were to determine the rate of wound complication and to identify the risk factors for these outcomes. Our secondary objectives were, in the cases of vulvar dysplasia, to estimate the rates of (1) positive margins and (2) occult carcinoma.

**Materials and Methods**

This was a single-center retrospective cohort study evaluating the outcomes of WLE/SPV. The surgeries were performed under academic specialists in gynecology (GYN) and gynecologic oncology (GO) between June 1, 2016

and February 28, 2020. All the surgeries took place at the Ohio State University Wexner Medical Center or the James Cancer Hospital and Solove Research Institute. This study was approved by The Ohio State University Office of Responsible Research Practices (approval number 2020H0088).

The surgery logs were manually reviewed by 1 author (G.P.B.) to identify the cases including WLE/SPV. The known vulvar carcinomas were excluded, whereas the cases with benign or premalignant pathology on index biopsy were included (Figure). The cases with foci of carcinoma on final pathology were also included to evaluate the incidence of occult malignancy.

After the eligible patients were determined, 2 authors (G.P.B. and A.M.W.) abstracted information from the electronic medical record into an encrypted database in accordance with the institutional review board protocol. The first 40 subjects were reviewed by the authors independently and compared for consistency. Thereafter, 10% of the dataset was randomly rereviewed by G. P.B.; no material discrepancies were noted. The key variables that were collected included the following: demographics (age, race and ethnicity, marital status, cigarette smoking, body mass index [BMI], American Society of Anesthesiologists classification), medical history (prior vulvar excision; parity; documented comorbidities such as diabetes, cardiovascular disease, etc.), perioperative information (surgeon division, antibiotic use, anesthesia type, and blood loss), specimen-related information (pathologic diagnosis, lesion location and size, margin status), and the presence of postoperative wound complication. Race and ethnicity were listed according to the patients' self-reported information and were included to characterize the baseline differences between the groups. The specimen dimensions (maximum length, width, depth) were recorded and the surface area was calculated, assuming an elliptical excision ( $\text{area} = 0.25 \times \text{p} \times \text{length} [\text{mm}] \times \text{width} [\text{mm}]$ ). The cumulative surface area was recorded for surgeries with >1 specimen.

The primary outcome was the rate of wound complication within 8 weeks after vulvar excision. This time frame was similar to previous studies.<sup>12</sup> Wound complication was defined as wound separation, infection (superficial surgical site infection, cellulitis, or abscess), or hematoma. The complications were recorded as diagnosed by the treating surgeon at follow-up, or occasionally, by an outside provider, with the documentation reviewable in our electronic medical records. The secondary outcomes were the rates of positive surgical margins and those of occult microinvasive disease in the cases including high-grade dysplasia (vulvar HSIL or dVIN).<sup>13</sup>

The demographics and medical comorbidities were compared between the patients who did and did not develop wound complication to evaluate for the baseline differences. The peri- and post-operative variables were then compared between these groups. The missing and

outlier values were excluded from the analyses. The Fisher exact tests and chi-squared tests were used to compare the categorical variables and logistic regression models, and independent student *t* tests were used for continuous variables, as appropriate. Multivariate stepwise regression was applied to select the variables that were most likely to predict wound complication. With these, multiple logistic regression analyses were performed to identify the independent risk factors and generate adjusted odds ratios for the composite outcome. Two-tailed 95% confidence intervals and *P* values were reported with a *P* < .05 denoting statistical significance. The JMP 15.2.0 (SAS Institute, Cary, NC) software was used to perform all statistical analyses.

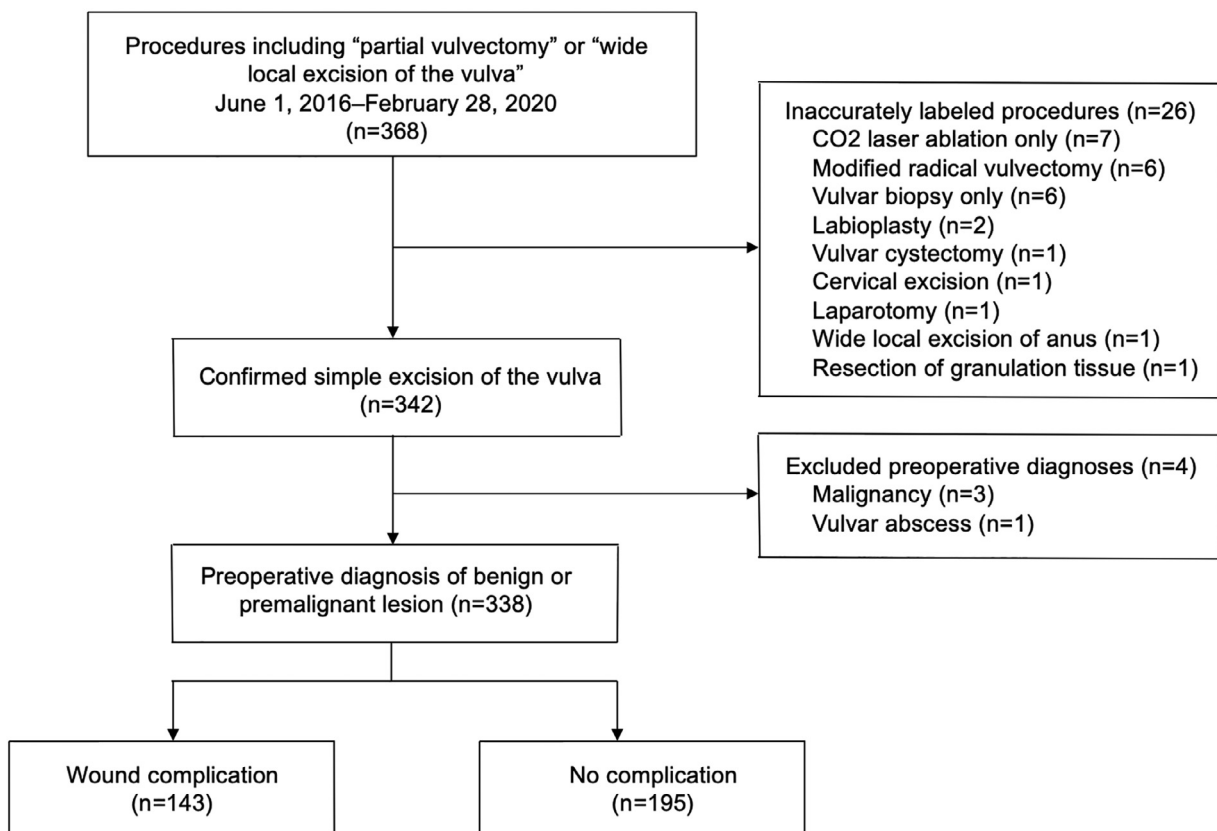
### Results

A total of 368 patients were evaluated for inclusion over the study period. Of

these, 338 were confirmed to have undergone WLE/SPV for suspected benign or premalignant lesions and met the inclusion criteria (Figure). The mean age of our cohort was 51.2 years. Most of them were White (87.3%) and non-Hispanic (98.5%). Most were obese (53.0%), and 29% were morbidly obese (BMI >35 kg/m<sup>2</sup>). Current smokers comprised 37.3% of our cohort, whereas 24.6% were former smokers. Overall, 16% had diabetes, and 48.5% had other forms of cardiovascular disease.

The perioperative factors were examined. Most of the patients were undergoing an initial vulvar excision (70.0%) compared with 30.0% undergoing repeat WLE/SPV (second or more). A total of 225 surgeries were done by GO faculty (66.6%) compared with 113 surgeries by the GYN division (33.4%). A small number (9.5%) of patients received preoperative antibiotics; for them, cefazolin (n=19), cefoxitin

**FIGURE**  
Patient inclusion flowsheet



Boyles. Vulvar excision for nonmalignant lesions. *Am J Obstet Gynecol Glob Rep* 2021.

**TABLE 1**  
Demographic and preoperative characteristics according to the development of wound complication

Variable	Wound complication (n=143)	No complication (n=195)	P value
Age (y)	50.7±14.9	51.5±15.3	.64
BMI (kg/m <sup>2</sup> )			
30–34.9	38 (26.6)	43 (22.1)	.37
35–39.9	30 (21.0)	29 (14.9)	.15
>40	17 (11.9)	22 (11.3)	.86
>30	85 (59.4)	94 (48.2)	.05
Race			
White	131 (91.6)	164 (84.1)	.26
Black	10 (7.0)	26 (13.3)	
Other	2 (1.4)	5 (2.6)	
Ethnicity			
Non-Hispanic	142 (99.3)	191 (98.0)	.40
Hispanic	1 (0.7)	4 (2.1)	
Marital status, married	70 (49.0)	96 (49.2)	1.00
Postmenopausal	78 (54.6)	110 (56.4)	.74
Smoking status			
Current	62 (43.4)	64 (32.8)	.05
Former	37 (25.9)	45 (23.1)	.61
Diabetes	28 (19.6)	27 (13.9)	.18
Cardiovascular disease	72 (50.4)	92 (47.2)	.58
End-organ vascular disease	24 (16.8)	30 (15.4)	.76
Autoimmune disease	12 (8.4)	15 (7.7)	.84
History of vulvar cancer	14 (9.8)	18 (9.2)	.85
Immunosuppressive drugs	13 (9.1)	23 (11.8)	.48

Data are presented as mean±standard deviation or number (percentage).

BMI, body mass index.

Boyles. Vulvar excision for nonmalignant lesions. Am J Obstet Gynecol Glob Rep 2021.

(n=11), ciprofloxacin (n=1), and gentamicin/clindamycin (n=1) were used. Most surgeries involved 1 specimen (71.9%) compared with having multiple excisions (28.1%).

The postoperative outcomes were then evaluated. A total of 143 patients (42.3%) experienced a wound complication. Most of these developed wound separation or breakdown (n=134, 39.6%), followed by infection (n=22, 6.5%), and hematoma (n=4, 1.2%). The need for reoperation (n=1), hospital readmission (n=3), and/or intravenous

antibiotics (n=2) were uncommon. Twenty-two patients were treated with oral antibiotics. The culture data were available for only 5 patients, and the isolates included *Escherichia coli* (n=3), *Streptococcus agalactiae* (n=2), other streptococcal species (n=2), methicillin-resistant *Staphylococcus aureus* (n=1), and other staphylococcal species (n=1). Three infections were polymicrobial. On the final pathology, most of the patients had malignant precursor lesions (high-grade dysplasia; HSIL or differentiated VIN, 67.2%). Overall, 111

of 338 (33%) of the patients had benign lesions, which included vulvar condyloma/VIN 1 (n=16), Paget disease of the vulva (n=16), epidermal inclusion cysts (n=13), keloids (n=9), lichen simplex chronicus (n=4), lichen sclerosus (n=3), angiomyxoma (n=2), hidradenitis suppurativa (n=1), and benign not otherwise specified (n=47). The rate of positive margins among those with high-grade vulvar dysplasia was 50.2% (114/227). Thirty-nine of these patients were found to have foci of invasive carcinoma on a background of dysplasia, making the rate of occult carcinoma 17.2%.

The clinically important variables were compared among those who did experience wound complication vs those who did not. On univariate analysis, those with wound complications were more likely to be current smokers (43.4% vs 32.8%) (odds ratio [OR], 1.57; 95% confidence interval [CI], 1.00–2.47), whereas former smoker status was not significant (25.9% vs 23.1%) (OR, 1.16; 95% CI, 0.70–1.92). Obesity (BMI >30 kg/m<sup>2</sup>) was more common among those with wound complication (59.4% vs 48.2%) (OR, 1.57; 95% CI, 1.02–2.44). No other demographic or preoperative variables were significant ( $P=.15–1.00$ ). Notably, similar proportions of patients had diabetes, cardiovascular disease, or a history of vulvar cancer ( $P=.18–.86$ ) (Table 1). The patients with a final pathology of high-grade vulvar dysplasia were at a greater risk of wound complication than those with benign pathologies (OR, 2.22; 95% CI, 1.37–3.60). Wound complication was also associated with a longer maximum specimen length (median, 32.0 mm vs 29.0 mm;  $P=.02$ ) and lesion location on the perineum (OR, 2.78; 95% CI, 1.77–4.37). However, the cumulative surface area excised and the depths of the specimen were similar between these groups ( $P=.09–.45$ ). Of those with perineal excisions (n=131), there were similar rates of previous vaginal birth(s) among those who developed wound complication (44/75) and those who did not (36/56) (58.7% vs 64.3%;  $P=.51$ ). Preoperative antibiotics did not seem to influence wound



**TABLE 2**  
**Perioperative and pathology-related characteristics according to the development of wound complication**

Variable	Wound complication (n=143)	No complication (n=195)	P value
Repeat vulvectomy (second or more)	43 (30.3)	58 (29.7)	1.00
Surgeon division			
GO	102 (71.3)	123 (63.1)	.13
GYN	41 (28.7)	72 (36.9)	
Preoperative antibiotics	13 (9.1)	19 (9.7)	1.00
≥2 specimens	47 (32.9)	48 (24.6)	.11
Specimen dimensions			
Maximum diameter (mm)	32.0 (24.0–42.0)	29.0 (20.0–40.0)	.02
Maximum depth (mm)	5.0 (4.0–8.0)	5.0 (4.0–8.0)	.45
Cumulative surface area (mm <sup>2</sup> )	566.0 (326.0–1107.0)	424.0 (207.0–828.0)	.09
Final pathology			
Benign	33 (23.1)	78 (40.0)	<.01
HSIL (VIN 2-3) or dVIN	117 (81.8)	110 (56.4)	
Anesthesia type			
General	136 (95.1)	177 (90.8)	.23
MAC	7 (4.9)	16 (8.2)	
Spinal	0 (0)	2 (0)	
Lesion location(s)			
Periclitoral	20 (14.0)	32 (16.4)	.65
Periurethral	2 (1.4)	8 (4.1)	.20
Mons	3 (2.1)	12 (6.2)	.11
Perineum	75 (52.5)	56 (28.7)	<.01
Perianal	24 (16.8)	25 (12.8)	.35
Unilateral labial	67 (46.9)	95 (48.7)	.74
Bilateral labial	32 (22.4)	48 (24.6)	.69

Data are presented as number (percentage) or median (interquartile range).

BMI, body mass index; dVIN, differentiated vulvar intraepithelial neoplasia; GO, gynecologic oncologists; GYN, gynecologists; HSIL, high-grade squamous intraepithelial lesions; MAC, monitored anesthesia care; VIN, vulvar intraepithelial neoplasia.

Boyles. Vulvar excision for nonmalignant lesions. Am J Obstet Gynecol Glob Rep 2021.

complication ( $P=1.00$ ), though <10% of this cohort received prophylaxis (Table 2).

The surgeon type (GO vs GYN) was not associated with a decrease in complications; the composite outcome occurred in 102 of 225 (45.3%) of the GO patients and 41 of 113 (36.3%) GYN patients (OR, 1.45; 95% CI, 0.92–2.31). Individual complications were also similar, with wound separation in 42.7% vs 33.6% ( $P=.13$ ), wound

infection in 7.1% vs 5.3% ( $P=.64$ ), and hematoma in 0.9% vs 1.8% ( $P=.60$ ). Of the patients with high-grade vulvar dysplasia (GO=181, GYN=46), similar proportions from each group had positive surgical margins (49.2% vs 54.3%; OR, 0.83; 95% CI, 0.43–1.59) and microinvasive disease on final pathology (17.7% vs 15.2%; OR, 1.20; 95% CI, 0.49–2.92).

The final model utilizing multivariate stepwise selection included obesity (BMI >30 kg/m<sup>2</sup>); both current and

former smoking status; diabetes; 2 or more specimens per surgery; maximum specimen length; cumulative surface area excised; presence of high-grade dysplasia; and periurethral, periclitoral, and perineal lesion location (Table 3). After controlling for these variables, the presence of high-grade vulvar dysplasia (OR, 1.83; 95% CI, 1.06–3.15), longer specimen diameter (OR, 1.03; 95% CI, 1.01–1.05), and lesion location on the perineum (OR, 2.25; 95% CI, 1.38–3.66) were determined to be independent risk factors for wound complication in our population.

### Comment Principal findings

This retrospective cohort study including 338 patients who underwent WLE/SPV for nonmalignant vulvar lesions determined that the rate of postoperative wound complication is high (42.3%). Wound separation or breakdown is the most common complication (39.6%). The important risk factors for complication are the presence of high-grade vulvar dysplasia, longer incision length, and lesion location on the perineum. Neither the surgeon type (GO vs GYN) nor the receipt of preoperative antibiotics was significant in this cohort, though prospective data is needed. Among those with high-grade vulvar dysplasia, the rate of positive margins was 50.2%, and the incidence of occult carcinoma on final pathology was 17.2%; these rates were similar among the surgeon types. Determining the extent and severity of premalignant vulvar lesions is difficult even for experienced gynecologic surgeons.

### Results in the context of what is known

The existing literature on vulvar surgery outcomes has centered on vulvar cancer and the complications following radical surgeries. The complication rates following these procedures are variable, with the estimates of wound breakdown or separation ranging from 17% to 47%<sup>14–18</sup> and those of infection ranging from 6% to 47%.<sup>14,17,18</sup> Little is known about WLE/SPV outcomes, yet more patients undergo these surgeries. The

TABLE 3

**Univariate and multivariate linear regression model of risk factors for postoperative wound complication**

Variable	Univariate uOR (95% CI)	Multivariate aOR (95% CI)
Obesity (BMI >30 kg/m <sup>2</sup> )	1.57 (1.02–2.44)	1.48 (0.90–2.42)
Smoking status		
Current	1.57 (1.00–2.45)	1.45 (0.83–2.56)
Former	1.16 (0.70–1.92)	1.18 (0.64–2.18)
Diabetes	1.51 (0.85–2.70)	1.27 (0.67–2.42)
≥2 specimens	1.50 (0.93–2.42)	1.34 (0.79–2.26)
Specimen length	1.02 (1.01–1.03)	1.03 (1.01–1.05)
Surface area excised	1.00 (0.99–1.01)	1.00 (0.99–1.01)
HSIL (VIN 2-3) or dVIN	2.22 (1.37–3.60)	1.83 (1.06–3.15)
Lesion location(s)		
Periclitoral	0.83 (0.45–1.52)	0.65 (0.32–1.31)
Periurethral	0.33 (0.07–1.59)	0.26 (0.03–2.35)
Perineum	2.78 (1.77–4.37)	2.25 (1.38–3.66)

aOR, adjusted odds ratio; BMI, body mass index; CI, confidence interval; dVIN, differentiated vulvar intraepithelial neoplasia; HSIL, high-grade squamous intraepithelial lesions; uOR, unadjusted odds ratio; VIN, vulvar intraepithelial neoplasia.

Boyles. Vulvar excision for nonmalignant lesions. *Am J Obstet Gynecol Glob Rep* 2021.

rates of wound complication in this cohort are similar to those reported for radical vulvar procedures, though we speculate that the severity and impediment to wound healing are likely to a lesser degree.

Our data complement the work by Mullen et al who report the only other study strictly related to simple vulvectomy and cite a 29% incidence of composite wound complication.<sup>12</sup> Both studies were conducted at large, Midwest academic medical centers, and the populations were similar with respect to age (51.2 vs 52 years), race (87.3% vs 83.1% White), ever-smoking status (62.7% vs 65.2%), and the presence of diabetes (16.3% vs 16.2%) and cardiovascular disease (48.5% vs 43.8%), whereas our patients had a higher rate of obesity (53.0% vs 38.4%). The proportions of vulvar dysplasia were also similar among the studies (70.0% vs 67.2%).<sup>12</sup> Our higher rate of wound complication may in part be related to the greater prevalence of obesity, which was associated with a nonstatistically significant trend toward complication. It is also possible that the physical

distribution of lesions within the vulva, particularly on the perineum, predisposed our cohort to poor wound outcomes. Overall, the rates of wound complication were comparable for two moderately large-sized retrospective studies, and the differences may owe to subjectivity in diagnosing and reporting the outcomes.

With respect to the risk factors for complication, our study evaluates several variables that are novel in the literature. Foremost, the lesion location on the perineum was the strongest predictor of wound complication, and it persisted on multivariate analysis. To the best of our knowledge, no other studies have evaluated the relationship between specific locations within the vulva and the complication rates. Surgeon training (GO vs GYN) has also not been previously evaluated. However, it was not associated with differential rates of complication. The technical procedures and the extent of vulvar excisions were comparable between these two groups as evidenced in the operative notes and the pathology specimen reports. High-grade vulvar dysplasia was an important

predictor of wound complication, agreeing in part with previous work, whereas VIN 3 was indeed more common among those with complications in the Mullen et al cohort (74.7% vs 63.5%); this variable was not included in their final multivariate logistic regression model.<sup>12</sup> The latter study also identifies smoking as a strong predictor of wound complication. Interestingly, smoking status was associated with complications only on our univariate analysis and not when controlling for the presence of vulvar dysplasia.

A positive margin status has been the sole factor consistently associated with high-grade VIN recurrence,<sup>9,19</sup> carrying an estimated risk of 31.5% to 46%.<sup>10,19</sup> Up to 50% of those with positive margins will require additional treatment within the next 5 years.<sup>20</sup> The rate of positive margins in our study (50.2%) was congruent with previous estimates (49%–66%).<sup>9–11</sup> This rate should be interpreted in the setting of a large academic center in which the lesions themselves and/or the patients' surgical complexities may be advanced. Our results agree with the assertion by Modest et al<sup>10</sup> that microscopic disease clearly extends beyond the acetowhite changes in the vulva and underscores the difficulty in visually identifying both the severity and the physical extent of the lesions. We were also interested in the rates of occult vulvar carcinoma, as the presence of invasive disease may warrant more extensive additional surgery. Our observed rate of 17.7% was also congruent with previous studies, ranging from 16% to 23%.<sup>10,21,22</sup> It is to be noted that ours may be considered as a robust estimate, as the former studies were substantially smaller (n=26–73 patients).

### Clinical and research implications

Our findings have immediate use for counseling patients on postoperative expectations and appropriate follow-up and for providing insight into those patients who are at the highest risk for wound complications.

As previously mentioned, the risk factors for complications that remained significant on our multivariate model

were the presence of vulvar dysplasia, location on the perineum, and incision length. It follows that aberrant, dysplastic cells may have a poorer healing ability than those in healthy tissue. This combined with the fact that the microscopic areas of dysplasia are left on the vulva following approximately half of WLE/SPVs is a plausible explanation for the high occurrence of wound complication in this group. We hypothesize that the increased frequency of complications with perineal excisions may be related to the degree of tension and friction placed on this area with normal activity (eg, walking, sitting), the close proximity to the anus, vascular supply to this relatively fibrous tissue compared with more muscular or fatty areas of the vulva, or a combination of these factors. The risk of wound complications involving the perineum did not seem to be heightened by prior vaginal birth. The association between the incision length and wound complications is also intuitive; clinically, the risk of disrupting more tissue should be balanced with that of incompletely excising a lesion. Smoking has been associated with wound breakdown in the vulva<sup>7,12</sup> and is an established risk factor for poor surgical wound healing.<sup>23</sup> Given that smoking was associated with wound complication on univariate analysis and that the trend toward wound complication on multivariate analysis was stronger—albeit not statistically significant—among current smokers compared with former smokers, we predict that our multivariate model was underpowered to recognize the impact of active smoking on wound complication, rather than this factor being immaterial. Larger studies or prospective trials could help clarify this important relationship. Finally, our study could not evaluate the impact of specific wound care measures as these were not regularly documented during the postoperative visit. It is common to recommend frequent sitz baths or loose-fitting underwear following vulvectomy, though this is not necessarily evidence-based. We identified only one randomized controlled trial in the gynecology literature evaluating sitz baths following episiotomy, which

showed a nonsignificant trend toward less wound breakdown.<sup>24</sup>

Our data highlight the importance of efforts to prevent complications and improve postoperative wound care in inherently high-risk groups. Prospective data with interventions such as smoking cessation or vulvar hygiene and wound care regimens are in severe need. Applying interventions for wound complication in the presence of select risk factors may be a useful approach. Another direction for future research is investigating the factors influencing referral to a GO for nonmalignant lesions. Our data suggest that the GO and GYN surgeons are equally suitable to offer these procedures, which could influence referral practice and invite opportunities for healthcare cost savings. Although the rates of complications and positive margins seem similar, further research is warranted as these populations may have unrecognized differences that this study was not designed to investigate.

### Strengths and limitations

We consider our study to have several strengths. First, given the paucity of literature on simple vulvar excision and its associated complications, it fills an unmet need in clinical and research settings. This information is timely, given the renewed interest in vulvar disease with the recent publication of the Enhanced Recovery after Surgery Society guidelines for vulvar and vaginal surgery.<sup>25</sup> This study evaluates several variables of clinical significance, and it identifies lesion location within the vulva as an important prognostic consideration. Our multivariate analysis of the risk factors further strengthens our results by limiting the effects of confounding. Finally, our study involved a moderately large sample size sufficiently powered to draw meaningful conclusions.

A potential weakness of our study is its retrospective nature, which is associated with biases such as confounding and outcome misclassification. We cannot exclude the possibility that a subset of our population was preferentially less likely to present with complications

after the initial postoperative visit. In addition, our study did not necessarily evaluate the clinical significance of wound complications. Although, the overall rate of wound complication was high, its impact on the patients' quality of life was largely unmeasured. For instance, few patients required intravenous antibiotics (0.6%), reoperation (0.3%) or hospital readmission (0.9%). Finally, our single-department, academic, tertiary care setting and our predominantly White, non-Hispanic study population may present limitations to the generalizability of our results, particularly with respect to community-based practice and more diverse populations.

### Conclusions

The previous literature on vulvar surgery is focused on radical vulvectomy in patients with cancer, though more women undergo WLE/SPV for nonmalignant lesions, which are done by both general gynecologists and gynecologic oncologists. Wound complications following WLE/SPV are common; the knowledge of specific risk factors should inform patient counseling and should guide research efforts aimed to mitigate adverse wound outcomes. In those with vulvar dysplasia, the incidence of positive surgical margins and of occult minimally invasive carcinoma is also high, reflecting the challenging nature of diagnosing and treating vulvar disease. ■

### REFERENCES

1. Judson PL, Habermann EB, Baxter NN, Durham SB, Virnig BA. Trends in the incidence of invasive and in situ vulvar carcinoma. *Obstet Gynecol* 2006;107:1018–22.
2. Hildesheim A, Han CL, Brinton LA, Kurman RJ, Schiller JT. Human papillomavirus type 16 and risk of preinvasive and invasive vulvar cancer: results from a seroepidemiological case-control study. *Obstet Gynecol* 1997;90:748–54.
3. Iwasawa A, Nieminen P, Lehtinen M, Paavonen J. Human papillomavirus in squamous cell carcinoma of the vulva by polymerase chain reaction. *Obstet Gynecol* 1997;89:81–4.
4. Bleeker MC, Visser PJ, Overbeek LI, van Beurden M, Berkhof J. Lichen sclerosus: incidence and risk of vulvar squamous cell

carcinoma. *Cancer Epidemiol Biomarkers Prev* 2016;25:1224–30.

**5.** National comprehensive cancer networks. Vulvar Cancer (Squamous Cell Carcinoma). 2021. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/vulvar\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/vulvar_blocks.pdf). Accessed April 3, 2021.

**6.** Management of vulvar intraepithelial neoplasia. ACOG Committee Opinion No. 675. *Obstet Gynecol* 2016;128:e178–82.

**7.** Wills A, Obermair A. A review of complications associated with the surgical treatment of vulvar cancer. *Gynecol Oncol* 2013;131:467–79.

**8.** Green MS, Naumann RW, Elliot M, Hall JB, Higgins RV, Grigsby JH. Sexual dysfunction following vulvectomy. *Gynecol Oncol* 2000;77:73–7.

**9.** Satmary W, Holschneider CH, Brunette LL, Natarajan S. Vulvar intraepithelial neoplasia: risk factors for recurrence. *Gynecol Oncol* 2018;148:126–31.

**10.** Modesitt SC, Waters AB, Walton L, Fowler Jr WC, Van Le L. Vulvar intraepithelial neoplasia III: occult cancer and the impact of margin status on recurrence. *Obstet Gynecol* 1998;92:962–6.

**11.** Heaps JM, Fu YS, Montz FJ, Hacker NF, Berek JS. Surgical-pathologic variables predictive of local recurrence in squamous cell carcinoma of the vulva. *Gynecol Oncol* 1990;38:309–14.

**12.** Mullen MM, Merfeld EC, Palisoul ML, et al. Wound complication rates after vulvar excisions for premalignant lesions. *Obstet Gynecol* 2019;133:658–65.

**13.** Sideri M, Jones RW, Wilkinson EJ, et al. Squamous vulvar intraepithelial neoplasia: 2004 modified terminology, ISSVD Vulvar Oncology Subcommittee. *J Reprod Med* 2005;50:807–10.

**14.** Gaarenstroom KN, Kenter GG, Trimbos JB, et al. Postoperative complications after vulvectomy and inguinofemoral lymphadenectomy using separate groin incisions. *Int J Gynecol Cancer* 2003;13:522–7.

**15.** Rouzier R, Haddad B, Dubernard G, Dubois P, Paniel BJ. Inguinofemoral dissection for carcinoma of the vulva: effect of modifications of extent and technique on morbidity and survival. *J Am Coll Surg* 2003;196:442–50.

**16.** Lin JY, DuBeshter B, Angel C, Dvoretzky PM. Morbidity and recurrence with modifications of radical vulvectomy and groin dissection. *Gynecol Oncol* 1992;47:80–6.

**17.** Senn B, Mueller MD, Cignacco EL, Eicher M. Period prevalence and risk factors for postoperative short-term wound complications in vulvar cancer: a cross-sectional study. *Int J Gynecol Cancer* 2010;20:646–54.

**18.** Leminen A, Forss M, Paavonen J. Wound complications in patients with carcinoma of the vulva. Comparison between radical and modified vulvectomies. *Eur J Obstet Gynecol Reprod Biol* 2000;93:193–7.

**19.** Wallbillich JJ, Rhodes HE, Milbourne AM, et al. Vulvar intraepithelial neoplasia (VIN 2/3): comparing clinical outcomes and evaluating risk factors for recurrence. *Gynecol Oncol* 2012;127:312–5.

**20.** Jones RW, Rowan DM, Stewart AW. Vulvar intraepithelial neoplasia: aspects of the natural history and outcome in 405 women. *Obstet Gynecol* 2005;106:1319–26.

**21.** Herod JJO, Shafi MI, Rollason TP, Jordan JA, Luesley DM. Vulvar intraepithelial neoplasia with superficially invasive carcinoma of the vulva. *Br J Obstet Gynaecol* 1996;103:453–6.

**22.** Chafe W, Richards A, Morgan L, Wilkinson E. Unrecognized invasive carcinoma in vulvar intraepithelial neoplasia (VIN). *Gynecol Oncol* 1988;31:154–65.

**23.** Sorensen LT. Wound healing and infection in surgery. The clinical impact of smoking and smoking cessation: a systematic review and meta-analysis. *Arch Surg* 2012;147:373–83.

**24.** Oladokun A, Babarinsa IA, Adewole IF, Omigbodun AO, Ojengbede OA. A sitz bath does not improve wound healing after elective episiotomy. *J Obstet Gynaecol* 2000;20:277–9.

**25.** Altman AD, Robert M, Armbrust R, et al. Guidelines for vulvar and vaginal surgery: Enhanced Recovery after Surgery Society recommendations. *Am J Obstet Gynecol* 2020;223:475–85.