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Factors Associated With Vulvodynia Incidence

Barbara D. Reed, MD, MSPH¹, Laurie J. Legocki, PhD¹, Melissa A. Plegue, MA², Ananda Sen, PhD^{1,3}, Hope K. Haefner, MD⁴, and Sioban D. Harlow, PhD⁵

¹Department of Family Medicine All at the University of Michigan, Ann Arbor, MI

²Center for Statistical Consultation and Research All at the University of Michigan, Ann Arbor, MI

³Department of Biostatistics, School of Public Health All at the University of Michigan, Ann Arbor, MI

⁴Department of Obstetrics and Gynecology All at the University of Michigan, Ann Arbor, MI

⁵Department of Epidemiology, School of Public Health All at the University of Michigan, Ann Arbor, MI

Abstract

Objective—To assess incidence rates of and risk factors for vulvodynia.

Methods—We conducted a longitudinal population-based study of women in southeast Michigan (Woman to Woman Health Study) using a validated survey-based screening test for vulvodynia that was repeated at 6-month intervals over 30 months. Unadjusted incidence rates were determined using Poisson models. Demographic and symptom-related risk factors for incidence were assessed using discrete time survival analysis.

Results—Women who screened negative for vulvodynia at baseline and were followed through at least one additional survey (n=1786), were assessed for onset of vulvodynia. The incidence rate was 4.2 cases per 100 person-years, and rates per 100 person-years were greater in women who were younger (7.6 cases per 100 person-years at age 20, compared with 3.3 cases per 100 person-years at age 60), Hispanic (9.5), married or living as married (4.9); had reported symptoms of vulvar pain but did not meet vulvodynia criteria on the initial survey (11.5); or had reported past symptoms suggesting a history of vulvodynia (7.5). Increased risk of new onset vulvodynia also included baseline sleep disturbance, chronic pain in general, specific comorbid pain disorders, and specific comorbid psychological disorders.

Conclusions—The incidence rates of vulvodynia differ by age, ethnicity and marital status. Onset is more likely among women with previous symptoms of vulvodynia or those with intermediate symptoms not meeting criteria for vulvodynia, and among those with preexisting sleep, psychological, and comorbid pain disorders. This suggests vulvodynia is an episodic condition with a potentially identifiable prodromal phase.

Vulvodynia is a vulvar pain disorder that is typically chronic, and occurs in women of all ages and ethnic groups. The pain varies from mild to excruciating, and may be provokable or spontaneous or both. Vulvodynia is known to be present in over 8% of women, and to affect women across the lifespan and across ethnic and socioeconomic groups. However, information on the onset (incidence) of vulvodynia is limited, and factors associated with this onset are not well understood. Women with vulvar pain are infrequently evaluated by

Corresponding Author and Reprints: Barbara D. Reed, MD, MSPH University of Michigan, Department of Family Medicine 1018 Fuller Street, Ann Arbor, MI 48104-1213 Phone: 734-998-7120; Fax: 734-998-7335; barbr@umich.edu.

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medical providers, and most affected women remain undiagnosed and untreated. The availability of survey-based screening tests for vulvodynia (1, 2) has allowed longitudinal epidemiological assessment of women in the community. The objective of this study was to determine the incidence of vulvodynia in the population-based sample of women in the Woman-to-Woman Health Study, and to assess risk factors that may predict this new onset.

METHODS

This study was approved by the University of Michigan Medical Institutional Review Board on January 17, 2008 (HUM00017098). The methods for population-based recruitment of 2,542 women, ages 18 and over, living in one of four counties in southeastern Michigan have been previously described (3). In short, women were recruited using random digit dialing, followed by a brief telephone interview, and subsequent completion of an online or written 24-page survey assessing demographic characteristics, health status, current and past symptoms, medications, and symptoms associated with intercourse and with vulvar pain. Consent was implied by survey completion after reading the cover letter detailing human subjects issues. Follow-up surveys were sent with a small stipend (\$5 to \$25 per survey) every 6 months, with follow-up emails or letters, and telephone calls to encourage completion as needed. Each survey included a validated screening test for vulvodynia, (2) which was used to determine the case status at that time (vulvodynia case, past case, intermediate symptoms not meeting criteria for vulvodynia, controls having intercourse, or controls denying intercourse). To be eligible for this analysis women had to have screened negative for vulvodynia at the initial survey, and participated in a minimum of one additional follow-up survey that included complete information needed to evaluate vulvodynia status.

The vulvodynia case definition consisted of those women reporting vulvar pain (at the opening to the vagina) that had been present for at least 3 months and had not resolved. No exclusions were made for vulvodynia that was primary versus secondary, generalized versus localized, or provoked versus non-provoked.

Past vulvodynia cases were those who reported symptoms that met the criteria for vulvodynia that had occurred in the past, but had resolved. Those with intermediate symptoms were women reporting recent pain with intercourse, or vulvar pain that wasn't at the opening to the vagina or hadn't lasted 3 months. Controls were those denying pain with intercourse and had no history of vulvar pain. They were divided into two groups: those who had participated in intercourse in the past 6 months, and those who had not (since they may have vulvar sensitivity of which they are unaware).

Demographic characteristics were determined based on self-reported information from the initial questionnaire. Further validated screening tests were used to assess Post Traumatic Stress Disorder (PTSD) (using the 4-item primary care PTSD screen), (4) and depression (using the eight-item Patient Health Questionnaire depression scale), (5) and (beginning at the 6-month survey) current fibromyalgia (using the Fibromyalgia Impact Questionnaire), (6) interstitial cystitis (using the Rice High Specificity definition), (7) and irritable bowel disorder (using the Rome II criteria) (8).

Incidence rates were evaluated using a Poisson model with a log link, with the logarithm of the length of follow up time used as an offset. Incidence rates were calculated for the population overall, and separately for subgroups based on age categories, ethnicity, and presence of comorbidities, and symptom severity status.

Risk factors identified before becoming an incident case were assessed individually and in a multivariable model using discrete time survival analysis. Since the underlying time scale is

continuous despite the discrete nature of data collection, the discrete time analysis is carried out using a binomial regression model with a complimentary log-log link function. The exponentiated regression coefficients obtained from this model are interpreted analogously to hazard ratios. Potential risk factors included age, ethnicity, sleep and pain self-assessments, screening test outcomes for comorbid pain conditions (fibromyalgia, interstitial cystitis, and irritable bowel syndrome) and for psychological comorbidities (PTSD or depression), and vulvodynia characteristics (severity, impact on intercourse, provokable-only versus spontaneous pain). The unequal inter-survey interval length was adjusted by including length of interval as a covariate in the model. As comorbid conditions were first assessed at 6 months, models including these variables included only those women who screened negative at the baseline and 6-month surveys, assessing incidence after the 6-month survey.

RESULTS

Figure 1 demonstrates the numbers of women enrolled and reasons participants were excluded from the analysis. Of the 2,542 women originally enrolled in the Woman-to-Woman Health Study, 2,277 (89.6%) completed the initial survey, with 1940, 1890, 1848, 1833, and 1760 completing the 6-, 12-, 18-, 24-, and 30-month surveys, respectively. Of those completing the initial survey, 2,193 (96.3%) completed the questions needed for the vulvodynia screen and, of these, 2,013 completed at least one additional follow-up survey, with 83.3% of these completing five or more surveys. Of the 2013 who completed at least one additional survey, 75.4% were White, 17.4% Black, 2.4% Hispanic, and 4.8% other ethnicity. The average age was 50.0 ± 16.3 years, with 11.4% age 18-29, 16.0% age 30-39, 20.2% age 40-49, 22% age 50-59, 17.1% age 60-69, and 9.0% age 70-79, and 4.4% 80 years and over. The majority (65.5%) were married or living as married, 40.6% indicated it was hard or very hard to pay for basics, 96.6% had graduated from high school and 48.9% had graduated from college. Those completing at least one additional survey did not differ from those completing only the first survey in age ($p=0.22$) or by vulvodynia case status at the initial survey ($p=0.16$), but were more likely to be White (75.4% versus 62.2%, $p=0.001$), and to be married or living as married (65.5% vs. 53.7%, $p=0.002$).

The case screening for vulvodynia of this cohort at the initial survey identified 1,786 women (88.7%) who did not screen positive for vulvodynia, who were therefore eligible for this analysis. Of these, 19.5% ($N=393$), had a history consistent with past vulvodynia that had resolved, 30.2% ($N=607$) had no symptoms of vulvodynia currently or in the past and were having intercourse, 27.8% (558) had no symptoms of vulvodynia but did not report current intercourse activity, and 11.3% (228) had had vulvar pain or dyspareunia at some point that did not meet criteria for vulvodynia (intermediate phenotype).

Incidence of vulvodynia

New onset of vulvodynia among those who were not a current case at the time of the initial survey occurred in 203 women (11.3%) over the three years of follow-up (mean time to new onset 1.34 ± 0.82 years). The number of new cases decreased over time, as expected in a fixed cohort. Hence, 74, 45, 35, 29, and 20 of the incident cases were detected at the 6-, 12-, 18-, 24-, and 30-month surveys, respectively.

The average age at study entry among those becoming incident cases was 45.6 ± 14.4 years compared to 51.0 ± 16.7 years among those who did not become an incident case during follow-up ($p<0.001$). Of the incident cases, 36.9% ($N=75$) had described past pain consistent with vulvodynia at the initial visit, but had indicated it had resolved, 15.8% ($N=32$) had been a control without dyspareunia or a history of vulvar pain and were having intercourse, 15.3% ($N=31$) had been a control but were not having intercourse, and 32.0% ($N=64$) had

intermediate symptoms initially, including either dyspareunia or a history of vulvar pain, but had not met criteria for vulvodynia ($p<0.001$).

The incidence rate was 4.2 new cases per 100 person-years (95% CI 3.7, 4.9) and differed by ethnic group, age, marital status, and screening diagnosis at the initial survey (Table 1). The incidence rate among black women was approximately half that of white women (Hazard Ratio (HR)=0.48, 95% Confidence Interval (CI) =0.30, 0.77)), but increased incidence rates were noted in Hispanic women (HR= 2.04, 95% CI=1.04, 3.99) and among women who were younger (HR=0.98 per year of age, 95% CI=0.97, 0.99, or approximately 0.90 per 5 years of age difference), or were married or living as married (HR=1.60, 95%CI=1.17, 2.18). Markedly increased rates were noted in those who had reported past symptoms consistent with vulvodynia (HR=4.00, 95%CI=2.64, 6.05) or had had intermediate symptoms of dyspareunia or vulvar pain not meeting criteria for vulvodynia (HR=6.16, 95%CI=4.03, 9.41) at the initial visit. The incidence rate similarly increased markedly if a woman had reported pain during (HR=4.37, 96% CI=3.30, 5.79) or after intercourse (HR=3.20 95% CI=2.38, 4.29) in the 6 months prior to the initial survey. Similar results were found when controlled for age, ethnicity, and marital status (data not shown). Estimates of incidence rates at increasing ages of 20, 40, and 60 in Figure 2 illustrate the similarity of the age effect within each ethnic group.

Table 2 presents the unadjusted incident rates and age-adjusted hazard ratios for vulvodynia that were associated with various potential risk factors. All analyses were based on incidence following a negative initial survey, other than the comorbid pain disorders, which were based on incidence following the 6-month survey at which time these screening tests were first administered. Incidence was higher among women with poor sleep quality, with reported chronic pain or who screened positive for PTSD or depression or other chronic pain comorbidities.

Sleep disturbances, reported pain, and psychological disorders were statistically associated with each other at baseline (all pairwise comparisons associated at $p<0.001$ using chi-square test). In order to assess their independent relationships with the incidence of vulvodynia, we created dichotomous variables for PTSD, depression, having restless or very restless sleep versus average or better sleep, and reporting any pain compared with no pain initially. Interaction terms for each variable pair were not significant. The final multivariable model is provided in Table 3. In this model self-reported sleep dysfunction, reported pain, and PTSD, but not depression, remained significantly associated with new onset vulvodynia.

DISCUSSION

Assessing the incidence of vulvodynia in a population-based sample of women is critical if we are to determine factors associated with risk, which may in turn suggest pathophysiologic mechanisms as well as preventive measures. In this study of women in southeast Michigan who were followed prospectively over time, symptoms consistent with vulvodynia in those who had previously screened negative for this disorder occurred in 4.2 women per 100 person-years, and varied based on age, ethnicity, and marital status. Women with other urogenital symptoms, a history consistent with past vulvodynia, other comorbid pain conditions, PTSD, and sleep disturbances were also found to be at increased risk, and parallel disparities previously identified in studies of prevalence (3, 9). These results suggest vulvodynia is an episodic condition with a potentially identifiable prodromal phase.

The incidence rate of 4.2 cases per 100 person-years is consistent with two other published studies evaluating incidence. Our previous evaluation of women members of a Women's Health Registry, using the same validated survey,(2) estimated an incidence rate of 3.1% per

year over four years of follow-up (10). Sutton et al. performed a one-year follow-up telephone survey of a national sample of women with and without vulvodynia, and found 4.6% reported vulvodynia symptoms that had started in the previous year (11). Although both studies assessed women in the community, neither was comprised of a population-based sample of women. The incidence rates across the current study and these previous studies are nonetheless consistent, with the current study providing important evidence of incidence rates in a randomly selected well-characterized population-based sample. We also confirmed our previous findings suggesting increased risk of vulvodynia onset among those with pain after intercourse, those with an intermediate phenotype (current pain with intercourse or history of vulvar pain, but not meeting criteria for vulvodynia), and those reporting urinary burning (10, 12).

We included in this analysis the subgroup of women who by history met screening criteria for vulvodynia at some point in the past, but who indicated the symptoms had resolved, because the history of vulvar pain may suffer from under- and over-reporting, as evidenced by others (11). It is therefore possible that a subset of our incident cases may be relapsing rather than new onset. If these women with a history consistent with past vulvodynia are excluded from the calculation of incident cases, the adjusted incidence rate becomes 3.4 cases per 100 person-years (95% CI 2.8, 4.0) – a number only marginally less than that found with this group included. The subgroup we identified with the highest risk of new onset vulvodynia were those who reported intermediate symptoms at the initial survey, but who did not meet criteria for vulvodynia currently or previously. Clinically, these data suggest that screening for symptoms may help identify women at risk of vulvodynia, possibly providing the opportunity for early identification and treatment.

An increased risk of vulvodynia was also associated independently with sleep disturbances, chronic pain in general, the presence of other comorbid pain conditions, and of psychological disorders such as PTSD, each of which is associated with neuropathic-type pain disorders, such as vulvodynia, (13-17) fibromyalgia, (18, 19) temporomandibular syndrome, (19) low back pain, (20) interstitial cystitis, (21-23) endometriosis, (24) and irritable bowel disorder. (23) However, little evidence of the temporal relationship of these dysfunctions and vulvodynia onset has been available (25). In addition, the risk of any of these conditions may be further exacerbated by the presence of the other conditions (26). This study suggests these conditions may be premorbid identifiers of vulvodynia risk, the recognition of which may help identify pathophysiologically similar phenotypic subgroups that may help advance understanding of etiologic and therapeutic mechanisms that will benefit this population (15, 27-30).

Consistent with studies of prevalent vulvodynia, we identified important differences in vulvodynia incidence across ethnic or racial subgroups. The higher rates of vulvodynia among Hispanic women and lower rates among Black women compared to White women has been previously reported in prevalence studies (3, 9). Our results suggest that these ethnic groups differ not only in the likelihood of having vulvodynia but also in the likelihood of experiencing new onset. This finding contrasts with that reported by Sutton et al, who did not find a significantly different incidence by racial categories, however, the number of non-White women in their study was small, limiting the power of that study to detect such differences. Further research is needed to understand these ethnic differences.

Limitations to this study exist. It is unclear whether answering similar questions about urogenital symptoms repeatedly over time might result in bias, either by increasing the numbers of cases due to increased awareness of symptoms addressed by the questions, or by decreasing the numbers of cases due to a change in the interpretation of the questions. Also, the screening criteria used for the diagnoses of vulvodynia, the other comorbid pain

conditions, and the psychological diagnoses for PTSD and depression have all been validated previously. However, the use of these may result in findings that differ somewhat from those determined using a face-to-face interview and physical examination. Furthermore, although follow-up over the course of the study was good (over 88% completed at least one additional survey), those lost to follow-up may have differed in risk for incident vulvodynia.

In summary, the incidence rate for new onset vulvodynia after a negative screen in a population-based cohort of women was 4.2 cases per 100 person-years, and varied by age, ethnicity, marital status, as well as by other pain, sleep, and psychological characteristics. Further longitudinal study of the episodic clinical course of vulvodynia, and of factors associated with remission and relapse following the onset of vulvodynia are needed as is research into the possibility of a prodromal syndrome that may place women at high risk of developing this disorder.

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Précis

Vulvodynia incidence occurs in 4.2 women per 100 person-years at risk, and differs among those with differing demographic and premorbid symptom profiles.

Figure 1.
Enrollment and exclusion flowchart.

Figure 2.
Vulvodynia cases per 100 person-years stratified by age and ethnicity.

Table 1

Relationship of Incidence Rates to Demographic Characteristics and Prior Symptom History

	n	Unadjusted Incidence (Cases per 100 Person-Years [95% CI]) [*]
Overall incidence rate	1786	4.2 (3.7, 4.9)
Ethnicity		
White	1334	4.6 (4.0, 5.4)
Black	329	2.2 (1.4, 3.4)
Hispanic	40	9.5 (4.9, 18.3)
Other	83	3.5 (1.8, 7.1)
Age (continuous variable)	1786	
At age 20	--	7.6 (5.8, 9.8)
At age 40	--	5.0 (4.3, 5.8)
At age 60	--	3.3 (2.8, 4.0)
Age categorical		
< 50 years of age	849	5.3 (4.4, 6.3)
50 years	937	3.3 (2.7, 4.1)
Married or living as married		
No	646	3.1 (2.4, 4.0)
Yes	1128	4.9 (4.2, 5.7)
Screening diagnosis at initial survey	1786	
Control (having intercourse)	607	1.9 (1.3, 2.7)
Control (denied recent intercourse)	558	2.1 (1.4, 3.1)
Vulvodynia symptoms in past	393	7.5 (6.0, 9.4)
Intermediate vulvar symptoms [†]	228	11.5 (9.0, 14.7)
Pain with intercourse past 6 months		
No	1560	2.8 (2.4, 3.4)
Yes	453	12.5 (10.1, 15.4)
Pain after intercourse in past 6 months		
No	1655	3.2 (2.7, 3.8)
Yes	358	10.6 (8.4, 13.5)

CI, confidence interval.

^{*} Incident rate derived from an unadjusted Poisson model with log of observation length used as offset.[†] Intermediate symptoms included pain with intercourse without vulvar pain, or vulvar pain not lasting more than 3 months.

Table 2

Risk Factors for New Onset of Symptoms Consistent With Vulvodynia Among Those Who Did Not Have Current Vulvodynia at Study Onset (n=1786)

Factors at Enrollment (Prior to Screening Positive for Vulvodynia)	Sample distribution n (%)	Incidence* (Cases per 100 Person-Years) (95% CI)	Hazard Ratio (95% CI) [†]
Sleep function			
Very sound	106 (6.0)	2.6 (1.3, 5.3)	Referent
Restful	340 (19.1)	3.0 (2.1, 4.4)	1.16 (0.53, 2.56)
Average	741 (41.7)	4.2 (3.4, 5.2)	1.75 (0.84, 3.62)
Restless	472 (26.6)	5.1 (4.0, 6.5)	2.22 (1.06, 4.63)
Very restless	117 (6.6)	6.9 (4.5, 10.7)	2.84 (1.25, 6.47)
Chronic pain (general)			
No pain	337 (19.0)	2.8 (1.9, 4.1)	Referent
A little pain	825 (46.4)	4.7 (3.9, 5.7)	1.86 (1.21, 2.86)
Moderate amounts of pain	478 (26.9)	4.6 (3.5, 5.9)	1.93 (1.21, 3.08)
A lot of pain	138 (7.8)	4.1 (2.5, 6.8)	1.88 (0.99, 3.57)
Psychological distress [‡]			
Depression	199 (11.2)	6.7 (4.8, 9.4)	1.76 (1.26, 2.47)
PTSD	178 (10.0)	5.6 (3.8, 8.4)	1.72 (1.18, 2.49)
Other chronic comorbid pain conditions ^{‡§}			
Fibromyalgia	182 (11.2)	3.8 (2.3, 6.0)	1.58 (1.07, 2.33)
Interstitial cystitis	104 (6.3)	6.2 (3.8, 10.2)	2.65 (1.72, 4.08)
Irritable bowel disorder	156 (9.5)	5.1 (3.3, 8.0)	2.50 (1.71, 3.66)

CI, confidence interval; PTSD, posttraumatic stress disorder.

* Incident rate derived from an unadjusted Poisson model with log of observation length used as offset.

[†] Hazard ratios derived from a discrete time survival model using binomial regression with a complementary log-log link, and controlled for age (similar results were found when controlled for age, ethnicity, and marital status - data not shown).

[‡] Identified by validated screening tests.

[§] These comorbid pain conditions were first assessed at the 6-month survey, and hence were evaluated on those becoming an incident case after that time. The overall incidence rate after screening negative at 6-months was 2.7 (2.3, 3.3) cases per 100 person-years overall.

Table 3Multivariable Model of Factors Associated With Vulvodynia Incidence^{*}

Factor (Covariate)	<i>P</i>	Hazard Ratio	95% CI
Age	<0.001	0.98	0.97, 0.99
Ethnicity	0.002		
Caucasian		Reference	
Black	0.003	0.47	0.29, 0.78
Hispanic	0.067	1.88	0.96, 3.68
Other	0.199	0.63	0.31, 1.28
Married or living as married	0.005	1.59	1.15, 2.21
Any current pain	0.026	1.61	1.06, 2.46
Sleep dysfunction	0.039	1.37	1.02, 1.85
PTSD	0.019	1.61	1.08, 2.40
Depression	0.087	1.39	0.95, 2.03

CI, confidence interval; PTSD, posttraumatic stress disorder.

^{*} Hazard ratios derived from a discrete time survival model using binomial regression with a complementary log-log link.