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Does Degree of Vulvar Sensitivity Predict Vulvodynia Characteristics and Prognosis?

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Abstract: Although women with vulvodynia typically have increased vulvar sensitivity, data on characteristics associated with the degree of vulvar sensitivity are lacking. We measured vulvar sensitivity using cotton swab test and vulvodolorimeter among a subset of 335 women, aged younger than 70 years, in the longitudinal Woman to Woman Health Study. Comparing the vulvodynia screening results from their online/paper survey to that at the time of the examination, 42 women had ongoing vulvodynia, 66 had a recent remission, 22 control participants had a recent onset of vulvodynia, and 205 control participants remained asymptomatic. Vulvar sensitivity was greater in each vulvodynia group compared with the control group ($P < .001$), and was associated with younger age at first onset of pain ($P = .025$), pain after intercourse ($P = .008$), describing the pain as a "pressure," "burning," or "irritating" ($P = .015$, $P = .005$, and $P = .006$, respectively), with increased severity of pain ever ($P = .012$), and with subsequent persistent or relapsing vulvodynia ($P < .001$ for each). A score of >1 for the cotton swab summary score best differentiated case from control participants (sensitivity 71.9%; specificity 72.0%). Although 13.8% of women with vulvodynia had no increased sensitivity on cotton swab testing, they did not differ in most clinical characteristics or clinical course from those with increased vulvar sensitivity.

***Perspective:** This study showed that women with vulvodynia have more vulvar sensitivity than control women, but the spectrum of sensitivity is broad. Furthermore, those with and without vulvar sensitivity did not differ in most vulvar pain characteristics or in prognosis, suggesting a positive swab test is not required to substantiate the diagnosis.*

***Key words:** Vulvodynia, vulvar sensitivity, vulvodolorimeter, cotton-swab test, diagnosis.*

Vulvodynia is a relatively common chronic pain disorder that is frequently misdiagnosed.[20,34] Vulvar hypersensitivity, measured by exerting pressure with a cotton swab or quantitative vulvodolorimeter, has been documented to be increased among groups of women with vulvodynia, compared with those without.[6,19] However, the current consensus statement on vulvodynia describes vulvodynia (as opposed to vulvar pain caused by a specific disorder) as "vulvar pain of at least 3 months duration, without clear identifiable cause, which may have potential associated factors."[8] Yet, it remains unclear whether all women with symptoms of vulvodynia have vulvar sensitivity to pressure. Because most studies on vulvar sensitivity have been conducted at one point in time, it is unknown whether the presence or magnitude of the vulvar sensitivity predicts clinical course or other outcomes (treatment response, natural history, etc). In addition, the relative benefits of using the cotton swab test versus a more quantitative vulvar pressure device are unclear.[1]

Risk characteristics for vulvar sensitivity were assessed in this study, with attention to characteristics associated with vulvar sensitivity in general and those associated with characteristics of pain with vulvodynia. In addition, we evaluated the relationship between results of cotton swab testing and the vulvodolorimeter to determine

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whether the clinically expedient, but less quantitative, cotton swab test is a reasonable tool for use in the office and in research. Last, we assessed whether the presence of vulvar sensitivity predicted the clinical course of vulvar symptoms, and whether the lack of enhanced vulvar sensitivity negates the vulvodynia diagnosis.

Methods

Study Design

This study was approved by the University of Michigan Medical institutional review board (HUM17098), and informed consent was obtained. In 2008, 2,542 women aged 18 and older, living in a 4-county area in southeast Michigan, were enrolled via random-digit dialing for the Woman to Woman Health Study (also known as the Longitudinal Population-Based Study of Vulvodynia). Of those enrolled, 2,269 completed the initial 26-page survey, which inquired about demographic characteristics, health status, and detailed information about past and present vulvar symptoms. It also included validated screening instruments for vulvodynia,[32] for several comorbid pain conditions (fibromyalgia,[9,39] interstitial cystitis,[4] and irritable bowel syndrome[12,37]), and for depression and post-traumatic stress disorder (PTSD).[24,28] Follow-up surveys were sent every 6 months for 3 years to assess changes in symptoms and in risk factors.

Women who screened positive for vulvodynia and a random sample of those who screened negative were contacted via telephone and invited to have a clinical examination. Five attempts were made to reach each selected woman. Office visits were offered on weekdays and Saturday mornings and a payment of $40 to offset time and travel was provided.

Two research assistants conducted all of the in-office examinations. At the beginning of the study, they worked together to assure they conducted the interviews and examinations in a consistent manner. At the visit, an in-office computer-assisted interview was conducted by 1 of 2 research assistants, asking about current symptoms, and rescreening with the previously verified vulvodynia criteria (pain at the opening to the vagina [introitus] for 3 or more months, that has not resolved), to document changes in screening outcome since the previous survey.[32,33] A standardized gynecologic examination was conducted that concentrated on the external genitalia, the vulvar region, and the vagina, including presence of erythema, swelling, discharge, and other dermatologic changes. Discharge from the lateral walls of the vagina was obtained and assessed for pH, amine odor on application of KOH (whiff test), microscopic examination findings, and *Candida* culture. Any woman with a visible vulvar dermatosis or symptoms in the presence of vaginal *Candida* was excluded.

Two methods were used to assess vulvar sensitivity, including the semiquantitative cotton swab test, and the vulvodolorimeter quantitative assessment. The cotton swab test consisted of exerting mild pressure (indentation of the skin/membrane gently to one-third centimeter depth) perpendicular to the tissue at 7 sites—left and right posterior interlabial sulci; 5, 6, and 7 o'clock positions of the introitus; and 8 and 4 o'clock positions of the hymen. Participants rated each pressure as 0 (no discomfort), 1 (mild discomfort), 2 (moderate discomfort), or 3 (severe discomfort). If discomfort was present, the participant was asked to describe the discomfort (ie, burning, sharp, prickly, pressure, irritation, itch, etc).

The vulvodolorimeter consisted of a calibrated handheld pressure-based device used in our previous research,[19] that consisted of 2 low-resistance 6-cc syringes, a 3-way stopcock, and a disposable 3-inch Dacron swab (Fig 1). A small hole had been drilled in the plunger of the syringe to allow the swab to be inserted. Pressure applied to the swab would allow the plunger to compress the air in the syringe (set at the beginning of each test to the maximum cubic centimeters of the syringe), and the level of the plunger when the participant first felt discomfort, and the level at which the discomfort was moderately severe, were determined and recorded. The vulvodolorimeter was calibrated using a desktop scale to determine the grams of pressure exerted at each half cubic centimeter of excursion of the plunger. The greatest pressure measurable with the vulvodolorimeter was 1,500 g, and hence the data were right-censored at this level. Vulvar sensitivity (minimal and maximal) measured using the vulvodolorimeter was determined at 17 sites—2 at the upper leg (right and left), 4 at the labia majora (right and left anterior and posterior), 4 at the interlabial sulci (right and left anterior and posterior), 5 at the introitus (10, 2, 5, 7, and 6 o'clock), and 2 at the hymen (5 and 7 o'clock), with scoring at each site varying from 31 g (least pressure measurable) to 1,500 g (maximal pressure measurable).

Statistical Analysis

Data entry from the surveys was performed by professional data entry organizations, and examination data were entered by the department data manager using double data entry verification.

Patient characteristics at the time of in-office examination and clinical case status were compared using analysis of variance (ANOVA) and χ^2 tests. The relationship

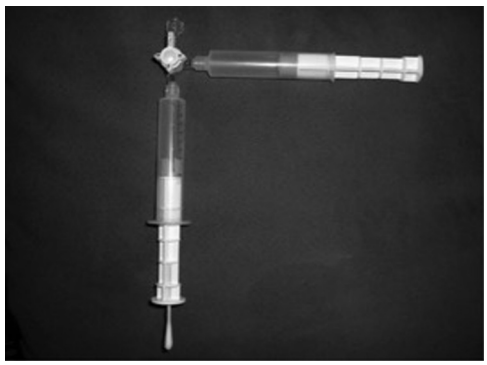

Figure 1. Vulvodolorimeter, consisting of 2 low-resistance 6-cc syringes, connected by a 3-way stopcock. One syringe had a small hole bored in the piston for insertion of a 3-inch cotton swab for use in applying pressure (designed by R. Gracely, PhD).