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Recommendations for the Study of Vulvar Pain in Women, Part 1: Review of Assessment Tools

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ABSTRACT

Introduction: The etiology and consequences of chronic vulvar pain are multidimensional, resulting in highly variable clinical presentations and no established treatment algorithm. Inconsistent use of measurement tools across studies is a significant barrier to drawing conclusions regarding etiology and treatment. In a companion paper, we review additional methodological challenges to the study of chronic vulvar pain and potential solutions.

Aim: To review and recommend assessment and measurement tools for vulvar pain and associated key outcomes.

Methods: The authors reviewed the scientific evidence related to measurement of vulvar pain and made decisions regarding recommendations via discussion and consensus.

Main Outcome Measure: We assessed measurement tools for vulvar pain and related outcomes and considered advantages and disadvantages of their use.

Results: Empirically validated measurement tools are available and should be used uniformly across studies to support comparisons and pooling of results. There is, at times, a trade-off between advantages and disadvantages when selecting a particular tool, and researchers should be guided by their specific research aims, feasibility, and potential to gain further knowledge in the field. Researchers should incorporate a biopsychosocial assessment of vulvar pain and its consequences.

Clinical Implications: This review provides a comprehensive list of measurement tool recommendations for use in clinical research, and in some cases, clinical practice.

Strengths & Limitations: This expert review can guide study design and decision-making for those researching vulvar pain and its consequences. The review content and recommendations are based on expert knowledge of the literature rather than a formal systematic review.

Conclusion: A thorough consideration of vulvar pain assessment tools is essential for continued progress toward identifying factors involved in the development and maintenance of vulvar pain and developing empirically supported treatments. **Rosen NO, Bergeron S, Pukall CF. Recommendations for the Study of Vulvar Pain in Women, Part 1: Review of Assessment Tools. J Sex Med 2020; 17:180−194.**

Key Words: Vulvar Pain; Vulvodynia; Genito-Pelvic Pain; Measurement

INTRODUCTION

Chronic vulvar pain severely disrupts the sexual function and sexual satisfaction of affected women and their romantic partners, and they also experience adverse impacts to their psychological and relationship health and well-being.[1] Although different nomenclatures related to vulvar pain have been put forth by a variety of organizations (eg, the ICD-11 published by the World Health Organization[2] and the DSM-5 published by the American Psychiatric Association[3]), the most comprehensive terminology (the *2015 Consensus Terminology and Classification of Persistent Vulvar Pain and Vulvodynia*) was published by a collaboration among the International Society for the Study of Vulvovaginal Disease, the International Society for the Study of Women's Sexual Health, and the International Pelvic Pain Society. The aim of the consensus terminology was to improve the diagnosis and description of vulvar pain.[4] They introduced terminology that differentiated between 2 broad categories: (i) vulvar pain caused by a specific disorder including infectious,

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inflammatory, neoplastic, neurologic, trauma, or iatrogenic disorder or hormonal deficiencies, and (ii) vulvodynia, defined as "vulvar pain of at least 3-month duration, without a clear identifiable cause, which may have potential associated factors." The potential associated factors—comorbidities and other pain syndromes, genetics, hormonal factors, inflammation, musculoskeletal, neurologic mechanisms, structural defects, and psychosocial factors—reflect factors that are known to contribute to the development and/or maintenance of vulvodynia. 4 categories of descriptors for vulvodynia were also included: pain location (localized, generalized, or mixed), provocation (provoked by physical contact, spontaneous/no contact, or mixed), onset (for provoked type only; primary or secondary), and temporal pattern (persistent, constant, intermittent, immediate, or delayed).[5] Provoked vestibulodynia (PVD)—an acute recurrent pain localized within the vulvar vestibule and experienced primarily during vaginal penetration—is the most frequent subtype of vulvodynia in premenopausal women.[6] Most women with vulvar pain are distressed by the condition and the resultant consequences to their lives; they typically also meet the criteria for genito-pelvic pain/penetration disorder in accordance with the 5th edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5).[3]

Population-based studies estimate the prevalence of vulvodynia to be 8%.[7] New onset of vulvodynia occurs in approximately 4.3 cases per 100 women over a year.[8] Women with vulvodynia frequently experience comorbid chronic pain conditions (eg, fibromyalgia, irritable bowel syndrome, migraines), and the prevalence of these comorbidities increases with the severity of vulvar pain symptoms.[9,10] The etiology of vulvodynia and its associated impairments are multifactorial and include biological, psychological, and interpersonal factors affecting the development and maintenance of this condition, resulting in highly varied clinical presentations and no widely accepted treatment algorithm.[11–13]

Although progress has been made over the last 2 decades to enhance understanding of vulvodynia and develop novel, effective treatments,[1,12,14–18] there remain significant gaps in knowledge further hindered by methodological challenges to conducting research with this population.[19] Our aim was to review the scientific literature related to the measurement of vulvar pain. This narrative review included an assessment of the advantages and disadvantages of various measurement tools, as well as identification of key methodological challenges to conducting research in this area and potential solutions for moving the field forward. As experts in the field, we made decisions regarding recommendations via discussion and consensus. Our review resulted in 2 companion articles entitled "Recommendations for the Study of Vulvar Pain in women." The present study represents Part 1, in which we review assessment and measurement tools for vulvar pain and associated key outcomes and discuss advantages and potential barriers to use of these tools in research studies. A second study, Part 2, reports on methodological challenges to conducting research in this area and proposes some potential solutions and directions for moving forward.[20] A thorough consideration of vulvar pain assessment tools and methodological challenges is essential for continued progress toward identifying factors involved in the development and maintenance of vulvar pain and developing empirically supported treatments.

Assessment of Vulvar Pain and Other Key Outcomes

For some studies, the diagnosis or symptom description might be sufficient for describing the sample. However, most vulvar pain studies offer a more in-depth characterization of the pain to, for example, understand potential etiology/pain type (eg, neuropathic vs nociceptive),[21,22] to aid in diagnosis,[5,23] to track treatment outcome,[24,25] and to descriptively compare vulvar pain with other forms of genito-pelvic pain.[26–28] Depending on the goals of the study, different questions and tools may be needed.

The question of how to measure vulvar pain in research studies is of utmost importance to enable comparisons and pooling of data across studies, reduce instances of conflicting results, and improve measurement in future studies (for a discussion of methodological challenges associated with how to establish diagnoses for vulvar pain conditions in research studies, see our Part 2 companion study).[20] Without established guidelines, researchers will continue to use different scales—ranging from single items to nonvalidated to validated measures—hindering the conclusions that can be drawn from these studies. In line with the Initiative on Methods, Measurement, and Pain Assessment in Clinical trials (IMMPACT),[29] the multidimensional aspects of vulvar pain should be assessed, including multiple measures of the pain itself as well as important associated impairments.[30] Pukall et al[30] adapted the IMMPACT recommendations to vulvodynia. The measures reported in the following sections are all in line with the general IMMPACT and vulvodynia-specific guidelines and recommendations, and we outline advantages and disadvantages of the measurement tools to guide researchers' decision-making. Our recommendations for specific measures take into account their psychometric properties, practical issues for particular studies (eg, need for brevity, availability in a given language), and prior use for contrasting results with similar studies.

VULVAR PAIN ASSESSMENT

Pain History

A detailed history of the pain is important for descriptive purposes and can be procured via an investigator-derived self-report questionnaire or structured interview. It should include questions about (i) pain characteristics including age and context of pain onset (primary vs secondary), temporal pattern (ie, of the pain over time), pain duration, and location; (ii) factors that ameliorate or exacerbate the pain; (iii) when the pain occurs

(provoked vs unprovoked or both); (iv) interference of the pain (ie, specific sexual activities, nonsexual activities such as tampon use, urination, tight clothing, etc.) coupled with a pain intensity rating for each activity (see section on pain intensity measures); and (v) previous treatment attempts and outcomes. There are no standardized measures for collecting the aforementioned comprehensive information about pain history. The Vulvar Pain Assessment Questionnaire (VPAQ) includes 1 question about when the pain occurs and 1 question on the temporal pattern of provoked pain specifically.[31]

A pain history is essential for accurately characterizing a sample and allowing for comparison across studies and for collecting information on potential covariates for relevant research questions. Some experts have suggested that pain descriptors may be useful for developing treatment algorithms based on subgroups (eg, provoked vs unprovoked pain), more so than those based on hypothesized etiology.[4,13] Indeed, the experiences of women with vulvar pain can differ by age of onset, location and quality of the pain, and presence of comorbidities.[8,32,33] Similarly, there is some evidence that those with primary PVD (ie, the pain has always been present) benefit less from treatment relative to those with secondary PVD (ie, pain that developed after a period that was pain free).[34] Evidence of empirically derived subgroups remains sparse.

A self-report instrument for collecting pain history is more practical when recruiting large and geographically diverse samples (eg, via online surveys). It can also be translated into multiple languages. A structured interview allows the researcher to clarify both the questions and participant responses to enhance accuracy, but there may be issues of social desirability and discomfort with disclosure. Nevertheless, structured interviews may facilitate the establishment of rapport with study participants and by doing so, enhance adherence to the study protocol.

Pain Outcome Measures

Pain outcome measures include standardized self-reports, measurements of pain in "real time" (cotton swab test, vulvalgesiometer, tampon test), and assessment of pelvic floor musculature (EMG, dynamometer, 4D ultrasound). IMMPACT guidelines recommend using 2 or more different measures of pain in outcome trials.[29] 2 studies of women with PVD have documented small to large positive correlations between self-reported pain during vaginal penetration and objective measures of vulvar pain including the cotton swab test, vestibular friction with a cotton swab, and the vulvalgesiometer.[35,36] In one of these studies, the authors found that 1 self-reported measure of pain during penetration (of 2) was associated with negative pain-related cognitions and affect, whereas pain scores from the vulvalgesiometer were not linked to these outcomes.[35] Thus, different pain measures appear to tap into both similar dimensions of vulvar pain, as well as distinct aspects.

Standardized Self-Reports

Standardized self-report measures are the "gold standard" for assessing pain, given the inherently subjective nature of pain.[29] A multidimensional assessment of pain includes pain intensity, pain quality and affect, and pain-related emotions and cognitions. In recognition of the interpersonal context in which the vulvar pain is typically experienced (ie, during sexual activity), its consequences on romantic relationships, and widespread acceptance of the social influences on pain,[1,37] self-report measures of partner responses to the pain should also be included when appropriate and feasible. A summary of the recommended self-report measures of pain and their key uses and advantages can be found in Table 1.

Pain Intensity

Pain intensity refers to the sensory experience of pain or how strong the person feels the pain to be. The most commonly used vulvar pain intensity rating scale—also recommended by IMMPACT—is an 11-point numerical rating scale (NRS) with anchors of 0 (no pain at all) to 10 (worst pain imaginable).[30] The instructions can vary depending on study goals and study design. Participants are asked to rate their pain by selecting the appropriate number on the scale, in reference to a particular time frame or pain experience such as "on average, in the last 6 months," "at its worst, in the last 6 months," "in the last week," "the last time you attempted vaginal penetration," etc. NRSs can also be used in gynecological examinations, such as during the cotton swab test, which is a key component of PVD diagnosis.[23,38] NRSs have well-established reliability and validity across many chronic pain populations,[39] positively correlate with other measures of vulvar pain intensity,[36] and detect significant treatment effects in women with PVD.[17,25,40]

With the advent of more data collection occurring online and the sophistication of online survey software, the visual analog scale (VAS) has become more feasible than when it was used in paper-and-pencil questionnaires. In a VAS, participants indicate—using their computer mouse/trackpad or finger—their pain intensity on a continuous line using the same 2 end points as in the NRS, and this more nuanced point on the line is automatically recorded by the software (in contrast to early days when researchers had to use a physical ruler). A verbal rating scale (VRS) for pain offers descriptive response options for pain intensity such as none, mild, moderate, and severe. The NRS, VAS, and VRS are equally reliable and valid and show similar responsiveness to treatment outcomes in general pain studies.[29] However, the NRS is most commonly used in vulvar pain studies and therefore has the advantage of ready comparisons to prior studies.

Specific to vulvar pain, the VPAQ includes 2 pain intensity VRSs—1 for average and 1 for worst pain intensity—and an 11-point NRS of pain intensity.[31] By assessing pain intensity with various scales and levels (eg, average or worst), reliability of the resulting data may be improved. This recent measure has demonstrated strong psychometric properties.[41]

Table 1. Recommended standardized self-report measures of pain

Pain	Measure	Uses/advantages
Pain intensity	Numerical rating scale (NRS)[30]	Most commonly used pain intensity measure in vulvar pain studies, ease of comparison with prior studies
		Can be used during gynecological examinations, aiding diagnosis
		Detects treatment effects in women with vulvar pain
		Can be used to assess partner's perception of the woman's pain intensity
		Can vary time frame or context to suit research goals
	Visual analog scale (VAS)	Allows for more nuance and specificity than the NRS
		Easy to integrate using online survey software
	Verbal rating scale (VRS)	More qualitative/descriptive pain ratings
		Includes 2 pain intensity VRSs: 1 for average pain intensity and 1 for worst pain intensity
	Vulvar Pain Assessment Questionnaire (VPAQ) pain intensity items[41]	Use of a variety of scales may result in more reliable data
Pain quality and affect	Short-Form McGill Pain Questionnaire (SF-MPQ)[45]	Brief and user-friendly
		Detects treatment effects in women with vulvar pain
	Vulvar Pain Assessment Questionnaire (VPAQ) pain descriptor subscale[41]	Allows for descriptive data in 3 different pain categories (burning, incisive pain, and sensitivity)
Pain-related emotions and cognitions		
Pain-related catastrophizing	Pain Catastrophizing Scale (PCS)[47]	Has been adapted for vulvar pain or pain during intercourse.
		Contains 3 subscales for tendency to ruminate, magnify, and feel helpless in relation to the pain
		Validated partner version
		Detects treatment-related changes in vulvar pain
Pain-related anxiety	Pain Anxiety Symptoms Scale (PASS-20)[54]	Separate subscales for fear of pain, cognitive and physiological anxiety, and avoidance
		Has been adapted for vulvar pain
		Detects treatment-related change in vulvar pain
Self-efficacy related to painful sex	Painful Intercourse Self-Efficacy Scale (PISES)[57]	Assesses 3 dimensions of self-efficacy: pain during intercourse, sexual function, and other symptoms.
		Adapted partner version available
Emotional and cognitive responses to pain	Vulvar Pain Assessment Questionnaire (VPAQ) Emotional Response and Cognitive Response subscales[41]	Emotional response subscale assesses feelings in relation to vulvar pain
		Cognitive response subscale assesses thoughts in relation to vulvar pain
Partner measures of pain		
Partner responses to painful intercourse	Significant Other Response subscale of the West Haven-Yale Multidimensional Pain Inventory (solicitous and negative subscales)[61]	Assesses perceptions of a partner's response to pain during intercourse
		Includes 2 subscales: solicitous (eg, sympathy) and negative (eg, frustration) responses
		Adapted partner version available to assess partner perceptions of own responses
	Facilitative subscale of the Spouse Response Inventory[62]	Assesses facilitative responses (eg, affection)
		Adapted partner version available

(continued)

Table 1. Continued

Pain	Measure	Uses/advantages
Partner responses, various	Vulvar Pain Assessment Questionnaire (VPAQ) Partner Factor subscale[41]	4 subscales: negative partner responses, supportive responses, relationship impact, and sexual communication comfort
		Assesses a greater range of partner variables beyond pain-related interactions and may provide a more global picture of relational dynamics

Measures of pain intensity tend to be brief and easily administered, making them highly useful clinically. However, researchers have traditionally used these measures for assessing pain during vaginal intercourse, neglecting other contexts in which the pain is elicited and marginalizing those for whom intercourse is not a regular or preferred sexual activity. Researchers should therefore endeavor to include at least 1 measure of pain intensity that is not specific to sexual intercourse.

Pain Quality and Affect

Pain quality refers to the sensory experience of the pain (eg, burning, cutting), whereas pain affect refers to the emotional response to the pain. The NRS, VRS, and VAS can each be used to assess pain affect, typically in the form of "pain unpleasantness" by changing the anchors from 0 (not unpleasant) to 10 (most unpleasant imaginable).[42] The Short-Form McGill Pain Questionnaire (SF-MPQ) is a reliable and well-validated measure that captures both the sensory and affective qualities of pain. It includes 15 sensory (eg, burning, tender) and affective (eg, fearful, tiring-exhausting) descriptors of the pain to which people respond on a scale of 0 (none), 1 (mild), 2 (moderate), and 3 (severe). Total or subscale scores can be calculated; subscales have demonstrated treatment responsiveness in vulvodynia studies.[43,44] Although the original 78-item version of the MPQ[45] has also been used effectively in vulvodynia studies,[25,40] the SF-MPQ is briefer, more user friendly, and more specific to pain quality and affect.[30] The VPAQ includes a Pain Descriptors subscale in its supplemental domains that queries how the vulvar pain feels.[31] It comprises 10 adjectives that are further divided into different pain categories (burning, incisive pain, and sensitivity) rated on a 5-point Likert scale (not at all, a little, somewhat, a lot, very much).

Pain-related Emotions and Cognitions

Pain-related emotional responses and cognitions—including pain catastrophizing, pain self-efficacy, and pain anxiety—are robust predictors of vulvar pain.[46] The well-validated Pain Catastrophizing Scale (PCS), with adapted instructions to refer specifically to vulvar pain or pain during intercourse, consists of 13 items that assess the tendency to ruminate, magnify, and feel helpless in relation to the pain.[47] Respondents indicate how frequently they experience these thoughts and feelings on a scale of 0 (not at all) to 4 (all the time). Greater catastrophizing predicts more pain and impairments[48–51] and poorer treatment outcome,[52] and it is sensitive to treatment-related change.[17,53]

The Pain Anxiety Symptoms Scale assesses participant fear of pain, cognitive and physiological anxiety, and avoidance on a scale of 0 (never) to 5 (always).[54] It is a well-validated measure that has been adapted for use in a vulvar pain context.[55,56] Greater pain-related anxiety contributes to the experience of vulvar pain and sexual impairment[51,55] and is sensitive to change post-treatment in PVD.[52]

The Painful Intercourse Self-Efficacy Scale (PISES)[55] was adapted from the Arthritis Self-Efficacy Scale.[57] It measures 3 dimensions of self-efficacy (ie, confidence in one's ability to cope): (i) pain during intercourse, (ii) sexual function, and (iii) other symptoms. Participants indicate their perceived ability to carry out sexual activities or to achieve symptom or pain management on a 10-point scale ranging from 10 (very uncertain) to 100 (very certain). The adapted version has good internal consistency and retains the 3-factor structure of the original measure.[55] Improvements in pain self-efficacy over time predict reduced pain intensity and increased sexual satisfaction in women with PVD, and lower initial levels of pain self-efficacy predict poorer treatment outcome.[52,58]

The VPAQ includes an Emotional Response subscale that consists of 15 statements related to feelings that respondents may have in relation to their vulvar pain (eg, sad, like my body has let me down) that are rated on a 5-point Likert scale (not at all, a little, somewhat, a lot, very much).[31] The Cognitive Response subscale consists of 8 statements rated on the same Likert scale to the question "In the past 6 months, how much do you experience thinking/worrying about the following related to your vulvar pain?" Example items on this subscale are "That I am a bad sexual partner" and "That my partner(s) will leave me." Selecting a measure(s) for pain-related emotions and thoughts should be guided by theory and a specific hypothesis. For example, the PCS, Pain Anxiety Symptoms Scale, and PISES assess particular psychological constructs, whereas the VPAQ captures more general, emotional, and cognitive responses to the experience of vulvar pain.

Partner Measures of Pain

The partners of women with vulvodynia are both a witness to the pain during sexual activity and also experience its sexual and relationship consequences.[1] Male partners tend to underestimate women's pain during intercourse,[59] which may have implications

for their emotional and behavioral responses to women's pain. Partners' greater pain catastrophizing and lower perceptions of women's pain self-efficacy are also associated with women's greater pain intensity during intercourse.[58,60] These studies used partner versions of an NRS for pain intensity, the PCS and the PISES, whereby the instructions were adapted to ask them to reflect on the woman's pain experience (for the NRS and PISES) or their own thoughts and feelings in relation to the woman's pain (for the PCS). The reliability of the original measures was retained.

Partner responses specific to painful intercourse are a robust predictor of women's pain and couples' psychosocial adjustment.[1] Partner responses have been assessed using individual and partner versions of the Significant Other Response subscale of the West Haven-Yale Multidimensional Pain Inventory (solicitous and negative subscales)[61] and the facilitative subscale of the Spouse Response Inventory.[62] Solicitous responses involve expressions of sympathy and promote avoidance of the pain, negative responses indicate frustration and hostility, while facilitative responses express affection and encourage adaptive coping with the pain. These measures have been adapted for the context of painful intercourse, and the factor structure of the original measures were retained.[63] Respondents indicate the frequency of perceived partner or one's own responses on a scale of 1 (never) to 6 (very frequently).

The Partner Factors subscale of the VPAQ consists of 24 items divided into 4 sections.[31] The first 2 sections are rated on a 5-point Likert scale (never, rarely, sometimes, often, always), with the first section querying partner responses to the vulvar pain (eg, wants to talk about it, blames me; 8 items) and the second asking about pain-related interactions (eg, seek emotional support, problem solve; 4 items). The third section is rated on a 5-point Likert scale ranging from much worse to much better, on which respondents answer questions about the impact of the vulvar pain on their romantic relationship (eg, physical intimacy, general communication). The last section focuses on comfort with communication about difference aspects of sexuality when in pain. Responses are recorded on a 5-point Likert scale (from largely uncomfortable to largely comfortable), and examples of items are sexual desire and frequency of sexual activity. Taking the mean of certain items will result in scores on the following subscales: negative partner responses, supportive responses, relationship impact, and sexual communication comfort.

Partner responses to painful intercourse measures have been primarily used in the context of daily diary studies,[63] that is, they assess partner responses in the immediate circumstances surrounding the painful interaction. Researchers might select these measures when examining questions that relate to changes within person or over time. The VPAQ partner factors subscale assesses a greater range of partner variables beyond pain-related interactions and may provide a more global picture of relational dynamics. Because it is a new measure, there are fewer published studies for making comparisons.

An important strength of including partner measures in research is that it integrates the social context in which the pain is experienced.[64,65] However, typically dyadic studies are limited to those in committed relationships, thereby excluding more casual sexual encounters where patterns of partner responses might be different.

"Real-time" Pain Measures

To capture pain ratings in real time, some studies have measured various aspects of pain during the application of painful stimuli to the vulvar area. The main advantage of these measures is that the pain is being measured in the present time as opposed to retrospectively; however, the devices used and the context in which they are used do not parallel the real-life experience of the affected women's main complaint—that of pain during sexual activities involving penetration. Choosing the best method of measuring various aspects of the vestibular pain index (VPI) can depend on the goals of the study and the available resources (eg, trained staff, equipment).

Cotton Swab Test

The cotton swab test is the standard diagnostic test for PVD.[66] During this test, the vulvar vestibule is palpated with a cotton-tipped applicator to determine the precise location and extent of the pain. Different health-care providers perform this test in different ways (eg, using a moistened vs dry cotton swab, testing various locations) and record the presence/extent of the pain using different methods (eg, present/absent, NRS).[67] However, it is not a standardized method of assessment; its precision depends on the type, extent, and manner of pressure exerted by the person performing the test, which can influence the resulting pain intensity ratings,[67] if recorded. When the study protocol involves the randomization of cotton swab test locations[67] and the same tester, reporting method, and cotton swab properties (eg, always using moistened tips with the same lubricant), then the cotton swab test—in conjunction with other measures of vestibular pain—can be useful for measuring pain intensity in research and treatment outcome studies.

Indeed, most studies in the area of PVD include cotton-swab pain intensity ratings as one of their core measures[68,69]; typically, the individual pain ratings (usually measured on an NRS) are averaged over the vestibular sites to yield a VPI as formalized by Bergeron et al.[23] Some studies include a certain VPI score as part of their eligibility criteria (eg, scoring a minimum of 3 on 10),[70] most studies include the VPI as part of the "participant characteristics" information,[71] and treatment studies typically include the VPI as one of several outcome measures.[25] Part of its wide use is due to its ease of administration and the face validity of the resulting scores; however, there is no way to completely control the amount of pressure applied to the vestibule because it is completely user-dependent.

Vulvalgesiometer

The vulvalgesiometer was developed as a "standardized" cotton swab test by attaching a cotton swab to a spring-based device that,

at certain markings on a syringe housing, delivers set pressure amounts.[67] Pukall et al[72] examined the pressure at which pain was first reported (at the posterior portion of the vestibule) and found that women with PVD reported pain at, on average, 16.4 grams, as compared with 285.7 grams in the control group. (Ratings of pain intensity and unpleasantness were also recorded but are not reported here.) Pukall et al[72] then simplified the design of the vulvalgesiometer and conducted 2 validation studies. The first demonstrated that women with PVD reported the first sensation of pain at lower pressure levels than control women (165.3 g vs 820 g) and that the pressure levels were significantly correlated with the VPI (obtained during the cotton swab test) and with intercourse pain intensity ratings (using an NRS). The second study demonstrated high inter-rater reliability between 2 testers. There are many strengths of the vulvalgesiometer; however, its use requires equipment that is not readily available and testing takes more time than with the cotton swab test; in addition, associating pain ratings with certain pressure levels may not be considered useful for certain studies, depending on their goals (eg, if they are focusing outcome measures on intercourse-related pain). However, the vulvalgesiometer has been used in a variety of studies examining pain processes in women with PVD, as well as in several treatment outcome studies.[73]

The Tampon Test

For some studies, assessing intercourse pain intensity is the "gold standard" as a main outcome measure. Certainly, numerous studies use NRSs to assess intercourse pain intensity during recent sexual activity involving (attempted) penetration; however, many women with vulvar pain may choose to not engage in sexual activities involving vaginal penetration because of the pain. The tampon test was developed as an alternative measure of penetration pain intensity.[74] It involves the insertion and immediate removal of a nonlubricated regular-sized Tampax tampon (cardboard applicator) and rating the pain intensity on an NRS. The authors report that the tampon test is an accurate, easily accessible, and cost-effective primary outcome measure because of its limited participant burden and strong methodological properties. The tampon test has excellent construct validity; the ratings from the tampon test correlate with intercourse pain intensity, VPI, daily pain, and a validated self-report measure of pain. In addition, it has demonstrated discriminant validity and test-retest reliability. It has been used primarily in outcome studies.[75,76] Disadvantages of the tampon test include that some women may not be comfortable with, or use, internally inserted menstrual products; the experience of inserting a tampon and immediately removing it does not approximate the sexual context in which women with vulvar pain typically experience their pain; and the lack of sexual arousal and lubrication during insertion may lead to feelings of mild irritation.

Real-time pain measures should be considered for inclusion in research studies of women with vulvar pain, depending on the study goals, and they should be used in conjunction with self-report measures of pain. The cotton swab test can be useful in many domains, specifically for eligibility purposes, describing participant characteristics, and as one of many measures examining pain intensity. Its sole use as a real-time pain measure is not recommended given that the pressure applied and the methods used (eg, moistened or dry cotton swab tip) are not standardized. Use of the vulvalgesiometer is recommended when the goals of the study include the real-time measurement of more than just the presence of pain or pain intensity; it should be used when self-reported real-time pain and a more objective "threshold" (eg, pressure level that is needed to elicit pain) is important for the study aims. The tampon test should be used when at-home recordings of real-time pain are preferred, or if the more dynamic nature of the painful intercourse experience needs to be captured. It may facilitate data collection from all study participants, independent of whether they engage in vaginal intercourse or not.

Pelvic Floor Musculature

Pelvic floor muscles (PFMs) play an important role in the pathophysiology of vulvodynia.[38] However, their involvement remains misunderstood as the assessment of muscle tone is complex. Muscle tone (also referred to as general PFM tone) is defined as the resistance provided by an innervated muscle when stretching is applied. Muscle tone comprised an active (electrogenic) and a passive (viscoelastic) component.[77] Controversy in determining the specific contribution of the PFM may stem in part from methodological limitations related to its assessment, namely, the pain elicited by the measurement itself, which may trigger a PFM reaction and introduce a bias. Several studies to date have used digital palpation measure, a general but subjective approximation of muscle tone that can be biased by patient fear or pain reactions, which could influence the evaluator toward scoring tone level as higher.[78,79] The present section will focus on objective measures—electromyographic (EMG) amplitude, dynamometer, and 4D ultrasound—in the measurement of the PFM in women with vulvar pain.

EMG Amplitude

EMG amplitude is used in the clinic to assess pelvic floor muscle activity, specifically, the muscle's ability to relax, by measuring contraction, relaxation, and bulge.[80] It is an index of the active component (electrogenic) of muscle tone and can detect muscle overactivity. However, despite its widespread clinical use, this measure has several limitations when used for inter-subject comparison, that is, for research purposes.[81] Because confounding factors such as vaginal lubrication, position of the electrodes in relation to the muscle fibers, thickness of the vaginal tissue and contact between the electrodes and the mucosa can all influence EMG amplitude and compromise comparison between participants, it is recommended to use ratio/normalized EMG values or muscle activation in musculoskeletal research.[82–84] Another confound has to do with the different types of EMG recording equipment and electrodes (eg, needle

vs surface EMG, different intravaginal probes, etc.). Specifically, the intravaginal approach can be a key problem as the pain instigated by the assessment itself might trigger a PFM contraction and an increase in tone.[16] For all these reasons, EMG is not considered a gold standard measurement for research purposes.

Dynamometer

To circumvent some of the problems associated with digital palpation and EMG, Morin et al[85–87] developed a methodology combining EMG and an intravaginal dynamometric speculum, initially devised to investigate general PFM tone as well as the relative contribution of both active and passive PFM components in women with stress urinary incontinence. This novel tool also holds the advantage of capturing alterations in PFM contractility such as strength, speed of contraction, coordination and endurance—rarely studied in women with vulvar pain.[88–92] The assessment of PFM tone during static and repeated cyclic stretching using this dynamometer in other populations showed strong reliability and validity.[85,86] To allow the assessment of women with vulvar pain, the speculum's upper and lower branches were reduced to the size of a pediatric speculum. A linear position transducer (Honeywell MLT-38000-101) enables real-time monitoring of the vaginal antero-posterior aperture. EMG recordings can also be used to monitor muscle activity (active component) during PFM tone measurements. In 1 study, 4 pairs of disposable electrodes were stuck on the lower branch with a 4-mm distance between each pair and covered the entire length of the lower branch inserted in the vaginal cavity.[87] The combined assessment of the PFM using dynamometry and EMG holds the additional advantage of excluding electrogenic sources in the measurement of the resistance/force exerted by the PFMs.[79] Nevertheless, the dynamometer can only be administered by an experienced physical therapist and as such is better reserved for studies focusing exclusively on the role of PFM in vulvar pain or treatment studies evaluating the efficacy of physical therapy.

4 Dimensional Ultrasound

4 dimensional (4D) transperineal ultrasound, which consists of a probe applied on the surface of the perineum without any vaginal insertion and is mostly used in women with pelvic organ prolapse,[93,94] can overcome many of the limitations of traditional assessment methods such as digital palpation because it is a pain-free procedure in which a convex probe is gently applied on the perineum without vaginal insertion. Women can be evaluated in a supine position at rest and during PFM maximal contraction, and different parameters can be measured in sagittal and axial planes: anorectal angle, levator plate angle, displacement of the bladder neck, and levator hiatus area. To avoid bias, the investigator analyzing the raw ultrasound data has to be blind to the clinical characteristics of participants. The parameters measured to date in studies of women with vulvar pain have demonstrated good test-retest and inter-rater reliability.[94–101] Moreover, supporting the validity of this method, transperineal ultrasound parameters have shown to be associated with findings from different pelvic floor assessment techniques and diagnostic tools.[100–102] Unfortunately, this measure has a steep learning curve, even for physical therapists and gynecologists, and requires sophisticated and costly equipment. Still, it has the advantage of not involving any insertion, and hence can be used with women who do not tolerate, or are fearful of, vaginal penetration. It has been used in a recent randomized clinical trial assessing the efficacy of multimodal physical therapy for provoked vestibulodynia.[24]

Other Key Outcomes

There are many aspects of women's (and their partners') lives that are adversely impacted by vulvar pain. Affected women report disruptions to their sexual well-being (reduced sexual function in areas other than pain, lower sexual satisfaction, higher sexual distress), more psychological distress (anxiety and depressive symptoms), a negative toll to their romantic relationships, and overall poorer quality of life.[46,103] However, these impairments do not necessarily correlate with women's vulvar pain. Aerts et al[36] found that in women with PVD, both subjective and objective ratings of pain were not significantly associated with women's sexual function and satisfaction. Such findings are in line with IMMPACT guidelines that encourage researchers to approach chronic pain from a multidimensional perspective and to assess key outcomes beyond pain. Importantly, although the IMMPACT guidelines applied to vulvodynia primarily focused on women's outcomes,[30] because partners of women with vulvar pain also report negative consequences[104–106] and influence women's pain experience and impairments,[1] researchers should consider administering measures to partners as well, where appropriate, for instance in treatment studies.[18] A summary of recommended self-reported measures for assessing key outcomes other than pain can be found in Table 2.

Medical History, Physical Function, and Comorbid Conditions

As with any comprehensive assessment, medical history (including comorbid conditions) and physical functioning should be assessed in addition to pain-related information. This information is typically captured via a researcher-derived self-report survey or interview. A general medical history includes the following domains: previously diagnosed medical and mental health conditions; surgical history; musculoskeletal history; pregnancy and birth history; past and current medication and supplement use as well as recreational drug and alcohol use; and current health concerns. Given the high frequency of comorbid conditions with PVD,[32] specific questions for the following conditions should be asked: bowel and bladder conditions (eg, irritable bowel syndrome, interstitial cystitis/painful bladder syndromes); other pain conditions/concerns (eg, fibromyalgia,

Table 2. Other key outcomes

Variable	Measure
Sexual function	Female Sexual Function Index[116]
	NATSAL sexual function scale[113]
	PROMIS sexual function scale[114]
Interference with sexual function	Sexual Function Interference subscale of the VPAQ[41]
Solitary sexual activity	Self-stimulation/Penetration subscale of the VPAQ[41]
Sexual satisfaction	Global Measure of Sexual Satisfaction[115]
Sexual distress	Female Sexual Distress Scale[111]
Mood and anxiety	Beck Depression Inventory[120]
	State subscale of the State-Trait Anxiety Inventory[121]
Relationship satisfaction	Couple Satisfaction Index[125]
	Revised-Dyadic Adjustment Scale[127]
Quality of life	SF-36 Health Survey[129]
	SF-12 Health Survey[130]
Childhood trauma	Childhood Trauma Questionnaire[133]
Treatment satisfaction/ degree of improvement	Patient Global Impression Change Scale[17]

NATSAL = National Survey of Sexual Attitudes and Lifestyles; PROMIS = Patient-Reported Outcomes Measurement Information System; VPAQ = Vulvar Pain Assessment Questionnaire.

headaches); other genital discomfort concerns (eg, persistent genital arousal)[107]; and mood- and trauma-related diagnoses (eg, depression, post-traumatic stress syndrome). In addition, overall physical function should be assessed when possible by asking questions about general health and activity levels.

Sexuality

Numerous controlled studies have demonstrated that women with vulvar pain report significantly lower levels of sexual desire, sexual arousal, orgasm frequency, intercourse frequency, and sexual satisfaction; studies have also shown that affected women have more negative sexual attitudes and more sexual distress than control women.[108] Despite these significant sexual issues, more than 80% of women with vulvar pain continue to engage in penetration-related sexual activities for many reasons, including to feel closer to their partner, to avoid losing their partner, and to fulfill their duties as a sexual partner.[42,109,110] Given the significant interference of vulvar pain with sexual activity, questions related to all aspects of sexuality (eg, desire, fear of pain, partner factors, interference with solitary, and partnered activities) should be asked.

Sexual function in women with vulvar pain is most commonly assessed via the Female Sexual Function Index (FSFI).[111] The FSFI consists of 19 items and 6 subscales (ie, desire, arousal, lubrication, orgasm, satisfaction, and pain), and it yields a total score and scores for each subscale. Its use is most appropriate for those who have been sexually active in the preceding 4 weeks. A clinical cutoff score has been established for potential sexual dysfunction (<26.5),[112] and the FSFI has been demonstrated to have strong psychometric properties.[111] For women who have not been sexually active in the preceding 4 weeks, researchers should consider using the desire subscale of the FSFI, as well as measures of sexual function interference, sexual satisfaction, and sexual distress (see below), which can also be used with sexually active populations. In addition, researchers can use the 17-item National Survey of Sexual Attitudes and Lifestyles sexual function scale, which provides an estimate of the level of sexual function in the previous year[113] or the Patient-Reported Outcomes Measurement Information System sexual function scale.[114]

Interference with sexual function can be measured with the Sexual Function Interference subscale of the VPAQ, which contains 10 questions, whereas solitary sexual activity can be assessed with the Self-stimulation/Penetration subscale of the VPAQ, which consists of 5 items.[31] Sexual satisfaction should be measured with the 5-item Global Measure of Sexual Satisfaction,[115] and sexual distress should be assessed with the 12-item Female Sexual Distress Scale.[116] These measures are well validated and have been recommended for vulvodynia-focused treatment outcome studies.[30]

Mood

Although several studies have indicated that women with vulvar pain have increased levels of depressive symptoms as compared with control women, these results have not been consistently replicated.[108] However, 1 trend that seems to be consistently reported is that the levels of depressive symptoms in women with vulvar pain are rare in the clinical range. Rates of anxiety symptoms[117] and post-traumatic stress disorder[118] are also higher in women with vs without vulvar pain. With respect to depression and anxiety, which are frequently comorbid, an epidemiological study found that the odds of chronic vulvar pain were 4 times more likely among women with a history of depression or anxiety as compared with control women.[119] This study also found that chronic vulvar pain was associated with a new or recurrent onset of depressive or anxiety disorder, suggesting a complex interrelationship between mood disorders and chronic vulvar pain development. Recommendations based on IMMPACT guidelines applied to vulvodynia supported the administration of the Beck Depression Inventory[120] and the State subscale of the State-Trait Anxiety Inventory,[121] for assessing depression and anxiety, respectively.[30] Within a clinical interview, questions about previous mood disorder diagnoses and current symptoms, in addition to onset, interference, and coping should be asked.

Relationship Satisfaction

Broadly speaking, women affected by vulvar pain report similar levels of general relationship satisfaction as unaffected women.[122] Still, couples coping with vulvar pain experience

lower feelings of intimacy, difficulty expressing affection, communication challenges, and they report that the pain has had a negative impact on their relationship.[103,104,123,124] The Couple Satisfaction Index is a 32-item empirically derived measure of relationship satisfaction that can be administered to any couple in a committed relationship.[125] Participants respond to Likert-type scales to rate the quality of their relationship across several factors (eg, happiness, frequency of disagreements). There are also validated 16- and 4-item versions of this measure; the 4-item version may be especially useful when brevity is important such as in clinical trials and daily diary studies. The Dyadic Adjustment Scale (DAS, 32 items)[126] and the Revised Dyadic Adjustment Scale (RDAS; 14 items)[127] are validated only for couples who are married or cohabitating. They assess dyadic adjustment in relation to 3 subscales: consensus, satisfaction, and cohesion. Participants indicate their responses on a scale ranging from 0 (always disagree/all of the time) to 5 (always agree/never). There is also a 4-item version, which assesses couple satisfaction only.[128] The Couple Satisfaction Index, Dyadic Adjustment Scale, and Revised Dyadic Adjustment Scale have all been used in many prior studies of vulvar pain.

Quality of Life

Quality of life is closely tied to one's overall health and physical function. Given that vulvar pain likely entails comorbid health conditions, some of them pain-related and some of them related to mental health, querying those with vulvar pain on their quality of life is important. Asking questions about the direct and indirect impact of their vulvar pain on activities of daily living, especially for those who have constant or almost constant pain, is key to understanding the broader effects of the pain.[30] It is important to keep in mind that, when interviewing women with provoked vulvar pain, as in the case of PVD, overall quality of life may not be as significantly impacted as in those with constant pain. Rather, there will likely be a more specific activity that is significantly impacted (eg, sexual activities involving vaginal penetration). 1 well-validated measure that is commonly used in the health and pain literatures is the SF-36 Health Survey,[129] which consists of 36 items divided into 8 subscales; however, a more brief measure is the SF-12 (containing 12 items divided into physical and mental health subscales).[130]

Childhood Trauma

Women with vulvodynia report more childhood trauma than control women.[131,132] Trauma can be assessed using the Childhood Trauma Questionnaire, a 28-item self-report measure focusing on childhood maltreatment.[133] The Childhood Trauma Questionnaire is the only self-report measure of childhood victimization with demonstrated criterion validity to detect actual abuse and neglect histories. Items are rated on a 5-point Likert scale from 1 (never true) to 5 (very often true). The questionnaire includes 5 subscales: emotional abuse, physical abuse, sexual abuse, emotional neglect, and physical neglect, in addition to a subscale assessing minimization/denial. Total scores range from 25 to 125, with higher scores indicating a greater likelihood of having experienced childhood trauma.

Treatment Satisfaction/Degree of Improvement

Subjective assessments of participants' impression of post-treatment improvement are required in pain clinical trials, including vulvar pain.[117] These measures were introduced in response to critiques concerning the extent to which statistically significant results reported in clinical trials were clinically relevant and meaningful in the lives of the patients.[29] The Patient Global Impression Change Scale is a 7-point rating scale with scores ranging from very much improved (score of 1) to very much worse (7). Widely used in chronic pain clinical trials, this scale was adapted to women with vulvar pain to assess subjective improvements in both the pain and sexuality domains and is sensitive to treatment changes.[17] As an important indicator of the clinical significance of findings reported in clinical trials, it is recommended as a core end point for vulvar pain clinical trials. Treatment satisfaction is also important to assess, for example, using an 11-point NRS (0 = completely dissatisfied to 10 = completely satisfied).[17]

Other Measures Relevant to Specific Research Questions

Based on the Interpersonal Emotion Regulation Model of Women's Sexual Dysfunction[1] and on studies in the field of vulvar pain, other measures of interest may include, but are not limited to, distal factors such as women and partners' intimacy—disclosure and empathic response—both from observational and self-report perspectives but referring to a discussion task that just took place rather than a retrospective self-report,[134] romantic attachment, that is, secure and insecure (anxious and avoidant) attachment,[135] pain attributions,[136] emotion regulation,[137] sexual communication,[138] and proximal factors such as sexual motivation,[139,140] self-compassion,[141] pain acceptance,[142] and mindfulness[143] — the latter 3 being anchored in more contemporary, third generation cognitive-behavioral models.

CONCLUSIONS

The last 2 decades have seen much progress in understanding biopsychosocial factors involved in the etiology and maintenance of vulvar pain and associated consequences.[1,12,14–18] Yet the heterogeneity of measurement tools used has made comparisons and pooling of results across studies difficult, hindering firm conclusions. The present study sought to evaluate and recommend measurement tools—both subjective self-report and real-time measures including those that assess the PFM—that will improve standardization across studies. It should be noted that the review content and recommendations are based on expert knowledge; we did not conduct a formal systematic review of the literature. It is therefore possible that other useful vulvar

pain measures exist that we are not aware of. In conclusion, we recommend that researchers bear in mind their specific study aims and constraints (eg, participant burden, feasibility) when selecting appropriate tools, but at the same time, we encourage broadening of scope beyond pain as a primary outcome, given the interference to other aspects of the affected couples' lives.

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