

## PAIN

# Patterns in Vulvodynia Treatments and 6-Month Outcomes for Women Enrolled in the National Vulvodynia Registry—An Exploratory Prospective Study

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## ABSTRACT

**Background:** Vulvodynia is a poorly characterized condition with multiple treatment options that have been described as largely ineffective in research settings.

**Aim:** To describe treatment patterns in women enrolled in the National Vulvodynia Registry and determine if there is an association between selected treatments and patient-reported outcomes such as pain, sexual function, and psychological distress after 6 months of treatment.

**Methods:** Participants completed questionnaires on general medical history and patient-reported outcomes using the short-form McGill Pain Questionnaire, the Female Sexual Function Index, the Short Form-12 quality-of-life questionnaire, the Coping Strategies Questionnaire, and the State-Trait Anxiety Inventory. The evaluation also included pain sensitivity assessment of the vaginal mucosa using a cotton-tipped applicator and the vaginal muscles using a single-digit. In this prospective cohort study, all measurements were collected at baseline and again at 6 months after treatment.

**Outcomes:** Type of treatment, number of treatments, self-reported pain intensity, dyspareunia, and pain-related psychological distress measures are reported at baseline and 6 months.

**Results:** Of 344 women enrolled, 282 received treatment; 78 different treatments were identified and categorized by type (eg, topical, oral, physical therapy) and number. The most commonly used treatments were topical (85%,  $n = 241$ ), physical therapy (52%,  $n = 147$ ), and oral medications (45%,  $n = 128$ ). Notably, 73% of participants received  $\geq 2$  treatments. There was no association between type or number of treatments and patient characteristics. At 6 months, women reported improvements in general pain ( $P = .001$ ), pain during intercourse ( $P = .001$ ), catastrophizing ( $P = .000$ ), and anxiety ( $P = .000$ ). The Short Form-12 quality-of-life questionnaire showed improvements in physical limitations ( $P = .024$ ), emotional limitations ( $P = .003$ ), well-being ( $P = .025$ ), and social function ( $P = .010$ ). However, all domains of the Female Sexual Function Index indicated worsening in sexual function ( $P = .000$ ) except for pain.

**Clinical Translation:** Multi-modal treatments were most commonly used in clinical practice and improvements in patient-reported outcomes such as quality of life, distress, and pain were noted; however, participants who returned at 6 months continued to report poor sexual function.

**Conclusions:** Strengths include a prospective and long-term study design that evaluated women in clinical settings. Limitations include a high rate of loss to follow-up for certain measures and inability to evaluate efficacy of individual treatments. In a setting where women were receiving highly specialized care, we found wide variation in the type and number of treatments used to treat vulvodynia. Despite this heterogeneity in treatment selection, women reported significant improvements in all study measures except sexual function.

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**Key Words:** Vulvodynia; Painful Intercourse; Dyspareunia; National Vulvodynia Registry; Treatment; Outcomes

## INTRODUCTION

Vulvodynia is a chronic pain disorder that affects nearly 14 million women in the United States.<sup>1</sup> Approximately 18% of women have had pain consistent with vulvodynia at some point in their lives.<sup>1–3</sup> Vulvodynia is defined as vulvar pain of unknown etiology lasting longer than 3 months.<sup>4</sup> According to the International Society for the Study of Vulvovaginal Diseases (ISSVD) vulvodynia can be additionally described by location (generalized or localized to vaginal entrance or clitoris), whether the pain is provoked by contact or unprovoked, onset (primary from first genital contact or secondary if it occurred after a period of pain-free intercourse), and whether the pain is intermittent or persistent.<sup>4,5</sup> Research shows that vulvodynia is consistently associated with poor quality of life, poor sexual function, and impaired physical function.<sup>2,6,7</sup> In spite of this burden and the negative impact on women's lives, less than 6% of women with vulvodynia receive an initial appropriate diagnosis and experience pain for many years.<sup>3</sup>

Research suggests that vulvodynia is a heterogeneous disorder and current diagnostic criteria may not adequately describe the full spectrum of disease.<sup>8</sup> In 2003, vulvodynia was categorized by the ISSVD using diagnostic criteria based solely on location, timing, and onset of pain.<sup>9</sup> More recent studies indicate that vulvodynia may co-exist with other disorders and should also be characterized based on associated pelvic floor muscle dysfunction, co-morbid pain disorders, and emotional distress.<sup>4,10–13</sup> In the 2015 ISSVD criteria, the definition of vulvar pain was updated to include vaginal infections, neoplasms, or neurologic disorders; when pain with this type is identified it is defined as “vulvar pain caused by a specific disorder.”<sup>13</sup> On the other hand, vulvodynia is defined as “vulvar pain of at least 3 months” duration, without clear identifiable cause, which may have potential associated factors, and thus “women may have both a specific disorder (eg, lichen sclerosus) and vulvodynia.”<sup>13</sup> The challenge of defining vulvodynia and differentiating it from conditions that cause vulvar pain is further complicated by the fact that some inflammatory and neuropathic conditions associated with pain are not easily identified.<sup>5</sup> Therefore, variation in disease presentation and the potential for multiple co-existing conditions make vulvodynia difficult to diagnose, and consequently difficult to treat.<sup>14,15</sup>

A wide range of vulvodynia treatments are available including topical anesthetics (lidocaine), anti-convulsants, tricyclic anti-depressants, surgical removal of the painful tissue

with vestibulectomy, physical therapy, and cognitive behavioral therapy.<sup>5,16</sup> In a 2005 systematic review of outcomes, most vulvodynia treatments were described as having insufficient evidence of efficacy.<sup>17</sup> Yet, although not reported in the literature, we suspect that patients and providers often combine and improvise treatments, most with unknown efficacy and safety data.<sup>18</sup> In 2016, Goldstein and colleagues<sup>16</sup> concluded that there is still insufficient evidence to support the use of topical lidocaine, corticosteroids, or capsaicin for the treatment of localized vestibular pain. Additionally, they reported that the evidence does not support the use of botulinum toxin A, interferon, hormonal treatments, anti-depressants, or anti-convulsants. Stronger evidence was available for psychological interventions, pelvic floor physical therapy, and vestibulectomy (for localized vestibular pain).<sup>16</sup> Interdisciplinary treatment was considered useful in the management of vulvodynia, although there was little evidence to support this approach.<sup>16</sup> In spite of these recent recommendations, we suspect that the heterogeneity of this disease leads to significant variation in treatment selection. However, after an extensive PubMed search, using combinations of the MeSH terms “vulvodynia treatments” and “treatment patterns AND vulvodynia,” we were not able to identify any prospective studies that empirically describe treatments prescribed for vulvodynia by providers in the United States outside of a 2008 survey of members of the ISSVD.<sup>17</sup> This survey showed that over 80% of respondents reported beliefs that anti-depressants, physical therapy, and psychological counseling were effective treatments for vulvodynia; however, the survey did not investigate actual treatments selected in clinical settings.<sup>19</sup>

Understanding how clinicians manage vulvodynia in tertiary settings will help determine: (1) the types of treatments prescribed; (2) the patient characteristics that guide physicians in selecting therapy; and (3) whether clinician practices are aligned with treatment recommendations.<sup>15,16</sup> Although there is little published on these 3 factors, we speculate that they are important to study because they may contribute significantly to treatment outcomes. Therefore, our primary research goal was to perform an exploratory analysis of patients enrolled in the National Vulvodynia Registry (NVR) to better understand treatment patterns and factors that guide treatment selection. Our secondary goal was to determine if there was any association between selected treatments and patient-reported outcomes such as pain, sexual function, and psychological distress after 6 months of treatment.

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