

Vulvodynia

Pelvic Floor Biometric Changes Assessed by 4D Translabial Ultrasound in Women With Vulvodynia Submitted to Physical Therapy: A Pilot Study of a Randomized Controlled Trial

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Background: Vulvodynia is a disabling condition in which pelvic floor muscles' (PFM) hypertonicity plays an important role. **Aim:** To evaluate biometric changes in PFM in women with vulvodynia undergoing kinesiotherapy treatment protocol (KTP). **Methods:** A single-blinded randomized controlled trial of 57 women with vulvodynia randomly assigned to either KTP + amitriptyline or amitriptyline alone (controls) for treatment. Four-dimensional translabial ultrasound assessed PFM regarding symphysis-levator distance at rest, anorectal angle at rest, excursion of the levator plate angle, and levator hiatal narrowing. Volunteers underwent a vaginal examination for a cotton swab test (CST), fulfillment of Friedrich criteria score and PFM power of contraction, and completed a diary of sexual pain and frequency of vaginal intercourse. Outcomes were assessed at baseline and after 8 weeks of treatment. **Outcomes:** Primary outcomes were differences in biometric parameters assessed by four-dimensional translabial ultrasound after treatment, between groups. Secondary outcomes were changes in clinical variables (CST, Friedrich criteria, PFM power of contraction, frequency of intercourse, and intensity of sexual pain) between groups and correlation analysis between biometric parameters and clinical variables. **Results:** Only the KTP group had statistically significant changes in biometric parameters after treatment (symphysis-levator distance: 0.22 ± 0.2 , 95% CI = 0.1-0.4, $P = .008$; levator hiatal narrowing: -0.33 ± 0.2 , 95% CI = -1 to -0.2, $P = .04$). Comparisons between groups showed that symphysis-levator distance (0.3, 95% CI = 0.2-0.6, $P = .005$) and excursion of levator plate angle (4.9, 95% CI = -0.4 to 10.1, $P = .02$) improved significantly after KTP treatment. Clinical variables showed greater improvement in the group treated with KTP for CST (difference of -3.7, 95% CI = -7 to -0.4, $P = .01$), Friedrich criteria (difference of -1.9, 95% CI = -3.2 to -0.6, $P = .003$), PFM power of contraction (0.3, 95% CI = 0.1-0.6, $P = .05$) and intensity of sexual pain (reduction of 1.7, 95% CI = -3.1 to -0.2, $P = .01$). Some clinical and biometric variables correlated positively, for example, frequency of vaginal intercourse and anorectal angle ($P = .04$; $r = 0.25$), or inversely, for example, pain intensity at CST and anorectal angle ($P = .004$, $r = -0.31$). **Clinical implications:** This study provides evidence on efficiency of a physical therapy protocol for

improvement of symptoms of vulvodynia and hypertonicity changes. **Conclusion:** This pilot study suggests that KTP for women with vulvodynia promoted significant changes in PFM biometric measures, consistent with alterations in hypertonicity and clinical improvement. Bardin MG, Giraldo PC, Martinho N. Pelvic Floor Biometric Changes Assessed by 4D Translabial Ultrassound in Women With Vulvodynia Submitted to Physical Therapy: A Pilot Study of a Randomized Controlled Trial.

Double-blinding of an acupuncture randomized controlled trial optimized with clinical translational science award resources

Alana D Steffen, Larisa A Burke, Heather A Pauls, Marie L Suarez, Yingwei Yao, William H Kobak, Miho Takayama, Hiroyoshi Yajima, Ted J Kaptchuk, Nobuari Takakura, Diana J Wilkie, Judith M Schlaeger Clin Trials . 2020 Oct;17(5):545-551. doi: 10.1177/1740774520934910. Epub 2020 Jul 10.

<https://pubmed.ncbi.nlm.nih.gov/32650673/>

Background: Clinical trial articles often lack detailed descriptions of the methods used to randomize participants, conceal allocation, and blind subjects and investigators to group assignment. We describe our systematic approach to implement and measure blinding success in a double-blind phase 2 randomized controlled trial testing the efficacy of acupuncture for the treatment of vulvodynia.

Methods: Randomization stratified by vulvodynia subtype is managed by Research Electronic Data Capture software's randomization module adapted to achieve complete masking of group allocation. Subject and acupuncturist blinding assessments are conducted multiple times to identify possible correlates of unblinding. **Results:** At present, 48 subjects have been randomized and completed the protocol resulting in 87 subject and 206 acupuncturist blinding assessments. **Discussion:** Our approach to blinding and blinding assessment has the potential to improve our understanding of unblinding over time in the presence of possible clinical improvement.

Aetiology, diagnosis, and clinical management of vulvodynia

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Prz Menopauzalny . 2020 Mar;19(1):44-48. doi: 10.5114/pm.2020.95337. Epub 2020 Apr 27.

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Chronic vulvar pain or discomfort for which no obvious aetiology can be found, i.e. vulvodynia, can affect up to 16% of women, and it may be found in girls and women across all age groups and ethnicities. Most patients describe it as burning, stinging, irritation, or rawness. The symptoms may spread to the whole vulva (generalised vulvodynia) or only to part of it, such as the clitoris (clitorodinia) or the vestibule of the vagina (vestibulodynia). This condition is often underreported and underrecognised by health care providers. Vulvodynia is a significant burden to society, the health care system, the affected women, and their intimate partners. It has a negative impact on quality of life. Vulvodynia is a diagnosis of exclusion with unknown aetiology. The gynaecologist plays a key role in excluding other causes of vulvar pain, and collaborating with other health care providers to manage the patient's pain. Although many therapeutic options are available, such as vulvar care measures, psychological approaches, local treatment, oral medications, surgical procedures, electrical nerve stimulation, and laser therapy, there is no single treatment effective for all patients. That is why individualised management is needed. An individualised, holistic, and often multidisciplinary approach is needed to effectively manage the patient's pain and pain-related distress.

Vulvodynia

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Vulvodynia is a heterogeneous, chronic pain condition of unknown etiology that affects 7% to 15% of women. It affects sexual function and quality of life. Vulvodynia can be primary or secondary, localized or generalized, and spontaneous or provoked. Contributing factors for provoked vulvodynia might include vulvovaginal infections, low estrogen states, and underlying anxiety disorder. Generalized vulvodynia likely arises from underlying connective tissue or neurological dysfunction. Vulvodynia treatment must be individualized on the basis of the patient's presentation and physical examination findings. Surgical excision of the vulvar vestibule has high success rates but other modalities showing success include pelvic floor physical therapy and cognitive-behavioral therapy.

Vulvodynia

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The current International Society for the Study of Vulvovaginal Disease (ISSVD) definition of vulvodynia is a vulvar pain of at least three months' duration, without a clear, identifiable cause, which may have potential associated factors. It is a diagnosis of exclusion and is an idiopathic pain disorder.

Somatic Dysfunctions of Hip and Pelvis Overlooked in a Case of Vulvodynia

Athina Giovanis, Stephanie Zeszutek

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<https://pubmed.ncbi.nlm.nih.gov/33021627/>

Vulvodynia is chronic perineal pain in women. Repercussions of this disorder can have a negative effect on women's health and lifestyle. The origin is often multifactorial, including pelvic and lower extremity somatic dysfunctions. If left untreated, these somatic dysfunctions can directly alter ligamentous tension on the pelvic floor and surrounding regions, resulting in perineal pain. Management of vulvodynia must be individualized due to the multifactorial etiology and complicated structure and function of the pelvic floor muscles. The authors present a case of vulvodynia in which osteopathic manipulative treatment was an effective management technique.

Vulvodynia Viewed From a Disease Prevention Framework: Insights From Patient Perspectives

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Introduction: Persons with vulvodynia (a chronic vulvar pain condition) suffer many barriers to diagnosis and treatment, several of which may be exacerbated by the sociocultural and geographical context in which they live. **Aim:** We drew on the experiences of patients with vulvodynia who were living in small

urban and rural communities to learn what they perceived as the major barriers to diagnosis and treatment as well as to probe for possible solutions. **Methods:** For this qualitative case study, we conducted 3 focus groups with a total of 10 participants, drawn from patients seen at our academic tertiary referral center, with a goal of understanding their lived experience with vulvodynia.

Main outcome measures: The patient dialogue was coded into themes and temporally grouped to illustrate struggles and victories in diagnosis and treatment. **Results:** Participants confirmed that healthcare provider knowledge and attitudes as well as system challenges (specialist and allied healthcare provider availability) are major barriers to timely diagnosis. Of novel interest are other factors that exacerbate distress and delay diagnosis such as patients' inadequate knowledge of sexual functioning and sociocultural messages regarding "normal" sexual activity. Our work suggests that a disease prevention framework that includes comprehensive sexual education before or at the onset of sexual activity may be of benefit in reducing the burden of vulvodynia when added to strategies to increase healthcare provider knowledge and improve access to effective treatments. **Conclusion:** While healthcare provider knowledge and attitudes are often at the forefront of barriers to diagnosis, our study suggests that to minimize patient distress and expedite diagnosis, resources must also be directed to promoting comprehensive sexual health education. Webber V, Miller ME, Gustafson DL, et al. Vulvodynia Viewed From a Disease Prevention Framework: Insights From Patient Perspectives.

Psychosocial factors associated with pain and sexual function in women with Vulvodynia: A systematic review

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Background and objective: Vulvodynia is a prevalent chronic vulval pain condition affecting 10%-28% of women, and significantly impacting their health and quality of life. It is currently poorly understood and biomedical treatments achieve only modest benefits for pain and sexual functioning. A wider psychosocial conceptualization of this condition may improve outcomes. There is currently no coherent understanding of how psychosocial factors may contribute to outcomes in Vulvodynia. The aim of this review is to identify and systematically review psychosocial factors associated with pain and sexual outcomes and to inform a psychosocial model of Vulvodynia. **Databases and data treatment:** Observational/experimental studies reporting on the association between psychosocial factors and pain/sexual outcomes in adult women with Vulvodynia were eligible. Two reviewers independently conducted eligibility screening, data extraction and quality assessment. Twenty-one studies were included, all focused on women with Provoked Vestibulodynia (PVD). Most of the studies were low-to-medium quality. **Results/conclusion:** A range of general/pain-related distress and avoidance processes, and sex/intimacy avoidance or engagement processes were significantly associated with pain, sexual functioning or sexual distress and sexual satisfaction, supporting the role of a psychosocial approach to PVD. Depression, anxiety, catastrophizing, pain-anxiety, pain acceptance, body-exposure anxiety, attention to sexual cues, partner hostility and solicitousness, self-efficacy and penetration cognitions are highlighted as potentially important treatment targets in PVD. Due to the limited data available, developing a psychosocial model was not possible. Directions for future research include examining the replicability and generalizability of the factors identified, exploring differences/similarities across Vulvodynia subsets and testing tailored theoretically based treatments. **Significance:** The systematic review highlights the role of psychosocial factors associated with pain and sexual functioning in Vulvodynia. The review findings reveal that Vulvodynia presents both similar and unique cognitive, behavioural and interpersonal features compared to other chronic pain conditions. There may be

important roles for negative sexual cues, body image-related factors during intercourse, partner factors, self-efficacy beliefs and penetration cognitions, in relation to pain and sexual functioning.

Provoked Vestibulodynia

Botulinum Toxin A as a Treatment for Provoked Vestibulodynia: A Randomized Controlled Trial

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Objective: To evaluate pain reduction after two injections of 50 units botulinum toxin A compared with placebo for provoked vestibulodynia. **Methods:** We conducted a double-blinded, placebo-controlled randomized trial of 50 units botulinum toxin A or placebo injected in the bulbocavernosus muscles twice, 3 months apart, in women with provoked vestibulodynia. Primary outcome was self-reported dyspareunia or pain at tampon use on a visual analog scale (VAS, 0-100). Secondary outcomes were pain at weekly tampon insertion (VAS score), reduction of pelvic floor hypertonicity (measured with a vaginal manometer), adverse events, and sexual function and distress. A sample size of 38 participants for each group was calculated to achieve a statistical power of 80% based on an effect size of 20 VAS units (0-100) (mean score range 56-76±31 SD). **Results:** Between May 2016 and June 2018, 124 women with provoked vestibulodynia were assessed, and 88 were randomized to botulinum toxin A (BTA group, n=44) or placebo (placebo group, n=44). Primary outcome showed a lower but statistically nonsignificant pain rating by 7 VAS units (95% CI -15.0 to 0.4) in the BTA group compared with the placebo group. Secondary results showed a significant decrease in pain at weekly tampon insertion by 11 VAS units (95% CI -16.6 to 6.0) with botulinum toxin A injection. The vaginal manometer measured lower maximum contraction strength by 7 mm Hg (95% CI -12.7 to -2.4) and lower 10-second endurance strength by 4 mm Hg (95% CI -7.72 to -1.16) in the BTA group compared with the placebo group. No changes were observed for sexual function and distress, but there was a significant increase in women attempting vaginal intercourse in the BTA group (0.27, 95% CI 0.06-0.48). No severe adverse events were reported. **Conclusion:** Twice-repeated injections of 50 units of botulinum toxin A in women with provoked vestibulodynia did not reduce dyspareunia or pain at tampon use, but secondary outcomes suggested positive effects of the treatment.

Multimodal physical therapy versus topical lidocaine for provoked vestibulodynia: a prospective, multicenter, randomized trial

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Background: Provoked vestibulodynia is the most common subtype of chronic vulvar pain. This highly prevalent and debilitating condition is characterized by acute recurrent pain located at the entry of the vagina in response to pressure application or attempted vaginal penetration. Although physical therapy is advocated as a first-line treatment for provoked vestibulodynia, evidence supporting its efficacy is scarce. **Objective:** The purpose of this study was to establish the efficacy of multimodal physical therapy compared with topical lidocaine, a frequently used first-line treatment. **Study design:** We conducted a

prospective, multicenter, parallel-group, randomized clinical trial in women diagnosed as having provoked vestibulodynia recruited from the community and 4 Canadian university hospitals. Women were randomly assigned (1:1) to receive either weekly sessions of physical therapy or overnight topical lidocaine (5% ointment) for 10 weeks. Randomization was stratified by center using random permuted blocks from a computer-generated list managed by an independent individual. Physical therapy entailed education, pelvic floor muscle exercises with biofeedback, manual therapy, and dilation. Assessments were conducted at baseline, posttreatment, and 6-month follow-up. Outcome assessors, investigators, and data analysts were masked to allocation. The primary outcome was pain intensity during intercourse evaluated with the numeric rating scale (0-10). Secondary outcomes included pain quality (McGill-Melzack Pain Questionnaire), sexual function (Female Sexual Function Index), sexual distress (Female Sexual Distress Scale), satisfaction (numeric rating scale of 0-10), and participants' impression of change (Patient Global Impression of Change). Intention-to-treat analyses were conducted using piecewise linear-growth models. **Results:** Among 212 women who were recruited and randomized, 201 (95%) completed the posttreatment assessment and 195 (92%) completed the 6-month follow-up. Multimodal physical therapy was more effective than lidocaine for reducing pain intensity during intercourse (between-group pre-post slope difference, $P < .001$; mean group postdifference, 1.8; 95% confidence interval, 1.2-2.3), and results were maintained at 6-month follow-up (mean group difference, 1.8; 95% confidence interval, 1.2-2.5). The physical therapy group also performed better than the lidocaine group in all secondary outcomes (pain quality, sexual function, sexual distress, satisfaction, and participants' impression of change) at posttreatment and 6-month follow-up. Moreover, the changes observed after physical therapy were shown to be clinically meaningful. Regarding participants' impression of change, 79% of women in the physical therapy group reported being very much or much improved compared with 39% in the lidocaine group ($P < .001$). **Conclusion:** The findings provide strong evidence that physical therapy is effective for pain, sexual function, and sexual distress and support its recommendation as the first-line treatment of choice for provoked vestibulodynia.

The Vulvodynia Experience Questionnaire: Qualitative Development of a New Patient-Reported Outcome Measure for Vulvodynia

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Introduction: Vulvodynia is defined as vulvar pain of at least 3 months duration without a clear identifiable cause. There are currently no validated questionnaires that assess the experience of women with localized vulvodynia of the vestibule (vestibulodynia, previously known as vulvar vestibulitis) that meet the requirements of the Food and Drug Administration's Patient Reported Outcome (PRO) Guidance. **Aim:** To develop a new content-valid PRO assessment in accordance with the Food and Drug Administration's PRO guidance to assess the symptoms and impacts of localized vulvodynia. **Material and methods:** Participants were recruited for concept elicitation interviews (ie, interviews with open-ended questions with the goal of eliciting volunteered data about the symptoms and impacts of vulvodynia). Participants were identified as having localized vulvodynia by clinicians who were experts in treating vulvar disorders. Eligibility was confirmed by the recruiting clinician, and informed consent was obtained; participants were then scheduled for in-person interviews. 25 participants were interviewed from United States (US). After concept elicitation interviews, the draft Vulvodynia Experience Questionnaire (VEQ) was developed based on the results. Cognitive interviews were conducted with 20 participants from US sites to assess the content validity of the VEQ (eg, interpretation and clarity of the

items, relevance of concepts). The VEQ was further revised after cognitive interviews. All interviews were conducted face-to-face, audio-recorded, transcribed verbatim, anonymized, and analyzed using a qualitative data analysis software program. **Results:** 17 unique symptoms and 32 unique impacts were reported during concept elicitation interviews. Pain (n = 25, 100%) and burning (n = 24, 96%) were the most frequently reported symptoms of localized vulvodynia, and negative impact on emotional well-being (n = 25, 100%) was the most frequently reported impact. After analysis, item generation, and cognitive interviews, the resulting VEQ v2.0 contains 3 parts (part 1, pain; part 2, associated symptoms; part 3, impacts) with a total of 25 items that measure the most frequently reported symptoms and impacts of localized vulvodynia. **Strength and limitations:** The VEQ is a multidimensional assessment of the core symptoms and impacts of localized vulvodynia that, after additional psychometric testing including the ability to detect change, may be used in clinical trials to characterize the benefits of novel treatments. The VEQ requires additional testing to establish its cultural relevance and linguistic validity in other countries. **Conclusion:** The VEQ is a novel method of collecting information on localized vulvodynia symptoms and impacts that may be suitable for use in clinical trials after psychometric testing. Goldstein AT, Diez PMQ, Kapanadze S, et al. The Vulvodynia Experience Questionnaire: Qualitative Development of a New Patient-Reported Outcome Measure for Vulvodynia.

Primary Dysmenorrhea and Painful Sex: Canaries in the Coal Mine?

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Objective: Primary dysmenorrhea and provoked vestibulodynia (PVD) are common pain conditions in young women. The purpose of this study was to document the severity of dysmenorrhea in women with confirmed PVD to further clarify reports of comorbidity. Since central sensitisation (CS) of the nervous system is present in both conditions, diagnosis of either, but especially both conditions, may reflect past chronic stress. **Methods:** We investigated this comorbidity in a sample of 63 women who met diagnostic criteria for PVD, and a comparison group of 89 women with low sexual desire and arousal but no pain during sex. All women completed questionnaires about the history and severity of their dysmenorrhea. **Results:** Of the women with PVD, 28.6% recalled moderate and 34.9% severe dysmenorrhea. For women in the comparison group, these figures were 22.5% and 19.1%, respectively. Women with PVD reported that the periods they experienced as teenagers were more painful, longer, more debilitating, and persistently painful for more years than those recalled by women in the comparison group. **Conclusions:** Our findings suggest that the origins of the early-onset CS require serious investigation. Research into the potential to reduce future chronic pain conditions through early effective treatment of primary dysmenorrhea is also needed.

Vestibular Anatomic Localization of Pain Sensitivity in Women with Insertional Dyspareunia: A Different Approach to Address the Variability of Painful Intercourse

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The pathophysiology underlying painful intercourse is challenging due to variability in manifestations of vulvar pain hypersensitivity. This study aimed to address whether the anatomic location of vestibular-provoked pain is associated with specific, possible causes for insertional dyspareunia. Women (n = 113)

were assessed for "anterior" and "posterior" provoked vestibular pain based on vestibular tenderness location evoked by a Q-tip test. Pain evoked during vaginal intercourse, pain evoked by deep muscle palpation, and the severity of pelvic floor muscles hypertonicity were assessed. The role of potential confounders (vestibular atrophy, umbilical pain hypersensitivity, hyper-tonus of pelvic floor muscles and presence of a constricting hymenal-ring) was analyzed to define whether distinctive subgroups exist. Q-tip stimulation provoked posterior vestibular tenderness in all participants (6.20 ± 1.9). However, 41 patients also demonstrated anterior vestibular pain hypersensitivity (5.24 ± 1.5). This group (circumferential vestibular tenderness), presented with either vestibular atrophy associated with hormonal contraception use ($n = 21$), or augmented tactile umbilical-hypersensitivity ($n = 20$). The posterior-only vestibular tenderness group included either women with a constricting hymenal-ring ($n = 37$) or with pelvic floor hypertonicity ($n = 35$). Interestingly, pain evoked during intercourse did not differ between groups. Linear regression analyses revealed augmented coital pain experience, umbilical-hypersensitivity and vestibular atrophy predicted enhanced pain hypersensitivity evoked at the anterior, but not at the posterior vestibule ($R = 0.497, p < 0.001$). Distinguishing tactile hypersensitivity in anterior and posterior vestibule and recognition of additional nociceptive markers can lead to clinical subgrouping.

Moderators of Improvement From Mindfulness-Based vs Traditional Cognitive Behavioral Therapy for the Treatment of Provoked Vestibulodynia

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Background and aim: The goal was to evaluate the moderators of mindfulness-based cognitive therapy (MBCT) and cognitive behavioral therapy (CBT) to improve dyspareunia, reduce pain catastrophizing, and improve overall sexual function in women with provoked vestibulodynia (PVD). Both treatments effectively reduced self-reported pain, sexual dysfunction, and pain catastrophizing in women with PVD. **Methods:** A total of 130 women with PVD were assigned to CBT or MBCT. **Outcomes:** Potential moderators included (i) PVD subtype (primary or secondary), (ii) baseline pain intensity, (iii) trait mindfulness, (iv) treatment credibility, (v) relationship duration, and (vi) age. Outcomes were pain intensity, sexual function, and pain catastrophizing at 4 time points: before and after treatment and 6- and 12-month follow-up. Moderation was tested using multilevel models, nesting 4 time points within participants. The interaction of the moderator, time effect, and treatment group was evaluated for significance, and a simple slope analysis of significant interactions was performed. **Results:** Pain reduction across 4 time points was the greatest in women who were younger, in relationships of shorter duration, and with greater baseline pain. Treatment credibility moderated pain intensity outcomes ($B = 0.305, P < .01$) where those with higher treatment credibility ratings (for that particular treatment) improved more in MBCT than CBT. PVD subtype moderated pain catastrophizing ($B = 3.150, P < .05$). Those with primary PVD improved more in the CBT condition, whereas women with secondary PVD improved more in the MBCT condition. Relationship length moderated sexual function ($B = 0.195, P < .01$). Women in shorter relationships improved more with MBCT, whereas women in longer relationships improved more on sexual function with CBT. No other tested variables moderated outcomes differentially across both treatment conditions. **Clinical implications:** Women who present with high credibility about mindfulness, in shorter relationships, and with secondary PVD might respond better to MBCT whereas those with primary PVD and longer relationships might respond better to CBT. **Strengths & limitations:** Clinical sample. Half the women who were not sexually active were omitted from analyses of sexual function. **Conclusion:** Overall, treatment credibility, relationship length, and PVD

subtype were found to moderate improvements differently in MBCT and CBT. These findings may assist clinicians in individualizing psychological treatment for women with PVD. **Clinical trial registration:** This clinical trial was registered with clinicaltrials.gov, [NCT01704456](https://clinicaltrials.gov/ct2/show/study/NCT01704456). Brotto LA, Zdaniuk B, Rietchel L, et al. Moderators of Improvement From Mindfulness-Based vs Traditional Cognitive Behavioral Therapy for the Treatment of Provoked Vestibulodynia.

Co-morbid Disorders

Repeated dermal application of the common preservative methylisothiazolinone triggers local inflammation, T cell influx, and prolonged mast cell-dependent tactile sensitivity in mice

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Occupational exposure to toxic chemicals increases the risk of developing localized provoked vulvodynia—a prevalent, yet poorly understood, chronic condition characterized by sensitivity to touch and pressure, and accumulation of mast cells in painful tissues. Here, we topically sensitized female ND4 Swiss mice to the common household and industrial preservative methylisothiazolinone (MI) and subsequently challenged them daily with MI or acetone and olive oil vehicle on the labial skin. MI-challenged mice developed significant, persistent tactile sensitivity and long-lasting local accumulation of mast cells alongside early, transient increases in CD4+ and CD8+ T cells, eosinophils, neutrophils, and increases in pro-inflammatory cytokines. Therapeutic administration of imatinib, a c-Kit inhibitor known to inhibit mast cell survival, led to reduced mast cell accumulation and alleviated tactile genital pain. We provide the first pre-clinical evidence of dermal MI-induced mast-cell dependent pain and lay the groundwork for detailed understanding of these intersections between MI-driven immunomodulation and chronic pain.

Vulvar pain: The revealing scenario of leading comorbidities in 1183 cases

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<https://pubmed.ncbi.nlm.nih.gov/32563924/>

Objectives: This study set out to investigate the epidemiological characteristics and comorbidities of chronic vulvar pain. Secondary goals were to identify the preferred approaches for managing vulvodynia in Italy. **Study design:** A cross-sectional study (the VuNet -Vulvodynia Network project) was performed in consecutive female patients with chronic vulvar pain attending 21 Italian medical centers (public hospitals, university clinics and private outpatient services) in the period December 2016 to November 2018. Study data were entered by healthcare professionals in a special web-based medical record system (PRIDE- Progetto Rete Italiana Dolore vulvarE). These data covered epidemiological aspects, demographic characteristics, obstetric and gynecological history, presence and duration of current and/or past symptoms, associated disorders, details of physical examination and treatment approaches.

Results: A total of 1183 subjects with a diagnosis of chronic vulvar pain were included in the study. The main reason for consultation was superficial dyspareunia, present in 64.2 % of the women. 43.4 % of the sample reported comorbid sexual disorders (of desire in 22.1 % and arousal in 21.3 %). 48.3 % of the patients reported prolonged pain lasting between one and five years. Factors associated with vulvar pain included a relatively high family history of diabetes mellitus (father = 8.6 %; mother = 8.4 %), recurrent vulvovaginal candidiasis (32 %), and urinary tract infections (37.4 %: recurrent cystitis in 19.5 % and post-coital cystitis in 17.9 %). Irritable bowel syndrome (28 %), constipation (23.5 %), headache (25.7 %: migraine in 18.0 % and menstrual headache in 7.7 %), allergies (17.5 %: food allergies in 10.1 %, respiratory allergies in 7.4 %), anxiety (15.0 %), dyschezia (11.7 %), invalidating dysmenorrhea/endometriosis (11.1 %), and major depression (7.6 %) were also reported. Vestibulodynia was diagnosed in 837 of the 1183 patients (70.8 %) and generalized vulvodynia in 323 (27.3 %). Notably, 69.1 % of the patients stated that previous therapies had not changed their pain. **Conclusions:** The diagnoses of vestibulodynia and vulvodynia must be considered in patients with chronic vulvar pain. The VuNet study contributes to a more comprehensive reading of the predisposing, precipitating and maintaining factors that contribute to vulvar pain, and of the key comorbidities.

Botulinum toxin injection for chronic pelvic pain: A systematic review

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Introduction: Botulinum toxin has proven therapeutic effects in alleviating pain in several myofascial disorders, with an expanding potential in chronic pelvic pain. The objective of this systematic review is to evaluate the efficacy and safety of botulinum toxin injection as an off-label treatment for female chronic pelvic pain. **Material and methods:** Using PRISMA guidelines, MEDLINE, EBM Reviews, PubMed, CINAHL, TRIP Database, EMBASE, Web of Science and gray literature were searched. Studies assessing the efficacy of botulinum toxin for chronic pelvic pain in adult females, with 10 or more women, published in English up to 13 January 2020, were included. All eligible studies were reviewed and data were extracted by two independent reviewers using a standardized form. Quality of evidence was graded using the Cochrane Risk of Bias 2 tool for randomized controlled trials and the Ottawa-Newcastle scale for observational studies. **Results:** In all, 491 records were screened. Seventeen articles were included in the final review: 5 randomized controlled trials and 12 observational studies. The quality of evidence ranged from low to high. There was a large degree of heterogeneity in study designs, and thus a meta-analysis was not feasible. All observational studies concluded that botulinum toxin was an effective treatment for chronic pelvic pain, with the greatest change in visual analog scale from 8.69 at baseline to 3.07 at 24 months post-injection. However, only one of the five randomized controlled trials found statistical significant differences favoring botulinum toxin in the reporting of the EQ-5D (botulinum 0.78 [0.69-1.00], control 0.69 [0.25-0.81], $P = .03$) and frequency of intercourse (botulinum 1 [1-1.75], placebo 1 [0-1], $P = .025$). The most common adverse effect was transient localized pain at injection site (6%-88%). No serious adverse events were reported. **Conclusions:** Although observational studies were encouraging, there is insufficient high quality evidence to recommend botulinum toxin injection for chronic pelvic pain. However, it appears to be safe to use. Future studies of higher quality in its treatment efficacy are indicated.

Common Benign Chronic Vulvar Disorders

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Common benign chronic vulvar conditions include genitourinary syndrome of menopause (formerly called vulvovaginal atrophy), lichen sclerosus, lichen planus, lichen simplex chronicus, and vulvodynia. Genitourinary syndrome of menopause results from the hypoestrogenic state that leads to atrophy of normal vulvar and vaginal tissues. It is typically treated with lubricants, moisturizers, and intravaginal estrogen. Lichen sclerosus is an inflammatory condition characterized by intense vulvar itching. It is treated with topical steroids or, in some cases, topical calcineurin inhibitors. Patients with lichen sclerosus are at risk of vulvar squamous cell carcinoma and should be monitored closely for malignancy. Lichen planus is an inflammatory autoimmune disorder that can affect the vulva and vagina in addition to other skin and mucosal surfaces. The first-line treatment is topical steroids, and significant scarring can occur if left untreated. Lichen simplex chronicus manifests as persistent itching and scratching of the vulvar skin that leads to thickened epithelium. Breaking the itch-scratch cycle, often with topical steroids, is the key to treatment. Vulvodynia is a common vulvar pain disorder and is a diagnosis of exclusion. A multimodal treatment approach typically includes vulvar hygiene, physical therapy, psychosocial interventions, and antineuropathy medications.

Dyspareunia

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Painful sexual intercourse is a common female health problem. In medical terminology, it is called dyspareunia. It is a complex disorder that often goes neglected. The prevalence of dyspareunia varies from 3 to 18% worldwide, and it can affect 10 to 28% of the population in a lifetime. dyspareunia can be further categorized into superficial or deep, and primary or secondary. Superficial dyspareunia is limited to the vulva or vaginal entrance, while deep dyspareunia means the extension of pain into the deeper parts of the vagina or lower pelvis. Deep Dyspareunia is frequently associated with deep penetration. Primary dyspareunia pain initiates at the start of sexual intercourse, while in secondary dyspareunia, pain begins after some time of pain-free sexual activity. Dyspareunia is sometimes intermixed with vulvodynia, a genital pain that lasts more than three months with or without the association of sexual intercourse. Dyspareunia can also lead to sexual difficulties, such as lack of sexual desire and arousal, and can cause trouble in sexual relationships. It can have a significant impact on physical as well as mental health. It can lead to depression, anxiety, hypervigilance to pain, negative body image, and low self-esteem. So prompt management is crucial to address this disorder. In this review, we will focus on the etiology, epidemiology, evaluation, management, and prognosis of the dyspareunia.

Pudendal neurolysis by laparoscopy

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Objective: To show how pudendal neurolysis can be safely managed with a laparoscopic approach.

Design: Stepwise demonstration of the technique with narrated video footage **SETTING:** Pudendal nerve is formed from spinal roots at levels S2, S3 and S4. It passes through the pelvis parallel to the pudendal vein and artery. This nerve exits the pelvis between the sacrospinous and sacrotuberous ligaments, then through the Alcock's canal. It can be compressed and responsible for pain in the gluteal and perineal region. After confirmation of the diagnosis by positive analgesic block with CT infiltration of the pudendal nerve, surgical decompression may be considered. The usual access procedures are the transgluteal and the trans-ischiorectal ways. **Interventions:** This video shows a total laparoscopic approach for a right pudendal neurolysis. It is a step by step didactic video. This technique of decompression of the right pudendal nerve by laparoscopy via dissection of the ischiorectal fossa along the right internal obturator muscle, after visualization of the obturator vessels, and identification of the pudendal nerve, allows the section of the right sacrospinous ligament and complete removal with repositioning of the nerve in its path. The nerve is followed until it passes through the Alcock's canal where it passes freely. The procedure went well and without complications, with clinical improvement upon waking up. **Conclusion:** Pudendal nerve neurolysis by laparoscopic technique is a reproducible and safe method for treating pudendal neuralgia, allowing good visualization and dissection of the entire pelvis towards the ischiorectal fossa.

Pilot study: pudendal neuromodulation combined with pudendal nerve release in case of chronic perineal pain syndrome. The ENTRAMI technique: early results

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Introduction and hypothesis: Chronic perineal pain syndrome due to pudendal nerve impingement is difficult to diagnose and to treat. All the known treatment options leave room for improvement considering the outcome. Early neuromodulation of the pudendal nerve after its surgical release could improve outcomes. **Objectives:** The aim of the study was to evaluate the potential beneficial effect of pudendal neuromodulation combined with release surgery using the ENTRAMI technique (endoscopic transgluteal minimally invasive technique). **Study design:** This is a single-center prospective descriptive study. Between March 2019 and March 2020, 16 patients (2 males, 14 females) were included. Data were collected at baseline and 1 month after surgery. **Methods:** Patients eligible for inclusion had chronic perineal pain for at least 3 months in the area served by the pudendal nerve. We combined pudendal nerve release with neuromodulation. **Results:** At 1 month, the numeric pain rating scale (NPRS) dropped from 9.5 at baseline to 3.5 ($p = 0.003$). Seventy-six percent of patients showed a global impression of change (PGIC) of $> 50\%$ at 1 month, and optimal treatment response (PGIC $\geq 90\%$) was found in 41% of patients. **Limitations:** The drawback of our study was that it was not randomized or blinded. The peripheral nerve evaluation lead (PNE) used could only be implanted for 1 month because of infection risk and is also prone to dislocations and technical failures. **Conclusion:** Pudendal nerve

liberation by the ENTRAMI technique combined with short-term pudendal neuromodulation seems feasible and promising in treating patients with chronic perineal pain.

Laparoscopic transperitoneal pudendal nerve and artery release for pudendal entrapment syndrome

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Introduction: Pudendal nerve and artery entrapment is an underdiagnosed pathology responsible of several urinary, sexual and anorectal complaints. The aim of our study was to evaluate safety and feasibility of laparoscopic transperitoneal pudendal nerve and artery release in a large retrospective cohort of patients with pudendal nerve entrapment syndrome with both a short and long-term follow-up. Technical details and outcomes are also reported. **Methods:** A series of 235 patients with pudendal syndrome underwent laparoscopic transperitoneal pudendal canal release between June 2015 and February 2020. Operative data were recorded prospectively for all patients. A complete history, pain visual analog scale (VAS) for perineodynia, and three scores evaluating the main symptoms (USP, IIEF-5, PAC-SYM) were obtained before and at least 24 months after surgery for 32 patients only. Post-operative complications were also evaluated using Clavien-Dindo classification at regular interval. **Results:** The mean operating time per side was 33.9 ± 6.8 min and the average hospital stay was 1.9 ± 0.3 days. Blood loss was $20 \text{ cc} \pm 10 \text{ cc}$ with no patients needing transfusion. The only significant per-operative complication was hemorrhage (600 ml) in one patient induced by a pudendal artery laceration, successfully treated by laparoscopic suturing. Post-operative complications were noted in 18.7% of patients with no serious Clavien-Dindo complications. Perineodynia VAS dropped from 6.8 ± 0.9 to 2.2 ± 1.8 after surgery ($p < 0.001$). Mean IIEF-5 scores significantly improved one month after the surgery (15.2 vs 19.3 , $p = 0.036$). Mean USP scores significantly improved for the dysuria domain (4.2 vs 1.6 , $p = 0.021$) but not for stress urinary incontinence (3.9 vs 4.1 , $p = 0.082$) or overactive bladder symptoms (14.1 vs 13.8 , $p = 0.079$). Mean PAC-SYM scores significantly improved after the procedure (1.8 vs 1.1 , $p < 0.001$). **Conclusion:** A complete laparoscopic pudendal nerve and artery release, from the sciatic spine through the Alcock's canal, is a fast and safe surgery with promising functional results. A large prospective trial is needed to validate such an approach.

Peripheral Nerve Stimulation for Pudendal Neuralgia: A Technical Note

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Pain Med . 2020 Aug 1;21(Suppl 1):S51-S55. doi: 10.1093/pm/pnaa171.

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Background: Pudendal neuropathy is a chronic, disabling form of perineal pain that involves the pudendal nerve, a mixed somatic and autonomic nerve that originates from sacral nerve roots. Peripheral nerve stimulation of the pudendal nerve can be useful to decrease symptom burden in patients who have failed initial conservative treatment modalities. **Methods:** In this manuscript, we describe an approach to the placement of a peripheral nerve stimulator for the treatment of pudendal neuralgia. We present a case of complex pelvic neuropathy and review the factors that lead to successful placement. Technical aspects of stimulator placement and ultrasound landmarks are reviewed. **Results:** A lateral to medial approach with ultrasound guidance at the level of the ischial spine

is likely to facilitate proper lead placement along the course of the pudendal nerve. Aftercare and adherence to postimplant activity restrictions-particularly avoiding use of the extremes of hip flexion and extension for four weeks-lead to the absence of lead migration. **Conclusions:** Pudendal nerve stimulation is an emerging technique for neuromodulation of refractory pudendal neuralgia. Ultrasound-guided pudendal nerve stimulation is a viable technique for neuromodulation of pudendal neuralgia. Optimization of patient selection, ultrasound guidance, and proper adherence to postimplant activity restrictions may be helpful for long-term therapeutic success.

Pudendal Nerve Entrapment Syndrome

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Pudendal neuralgia caused by pudendal nerve entrapment (PNE) is a chronic and severely disabling neuropathic pain syndrome. It presents in the pudendal nerve region and affects both males and females. It is mostly underdiagnosed and inappropriately treated and causes significant impairment of quality of life. Anatomy of the Pudendal Nerve: The pudendal nerve emerges from the S2, S3, and S4 roots' ventral rami of the sacral plexus. It carries sensory, motor, and autonomic fibers; however, an injury to the pudendal nerve causes sensory deficits more than motor. It courses between two muscles, the piriformis and coccygeus muscles. It departs the pelvic cavity through the greater sciatic foramen ventral to the sacrotuberous ligament. It passes medial to and under the sacrospinous ligament at the ischial spine level to re-enter the pelvic cavity through a lesser sciatic foramen. The pudendal nerve then courses in the pudendal canal, which is also called the Alcock canal. The three last branches of the pudendal nerve terminate in the ischioanal fossa. These are the inferior rectal branch, perineal branch, and dorsal sensory nerve of the penis or clitoris. However, there are case reports which have shown variability in the anatomy of the pudendal nerve. Pudendal nerve compression based on anatomy: The pudendal nerve entrapment syndromes subdivide into four types based on the level of compression.

Pudendal Neuralgia

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2020 Sep 3.

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Pudendal neuralgia (PN) is the pain component of the pudendal syndrome that is caused by pudendal neuropathy. Pudendal neuropathy affects both genders and occurs in children due to congenital anomalies in the nerve pathway. It is commonly a bilateral process. Characteristic perineal pain that is aggravated by sitting is present in over 50% of patients. The pudendal nerve is a mixed nerve having sensory, motor, and autonomic functions. As a result, inflammation or injury to the nerve can also result in the bladder, bowel, sexual and autonomic dysfunctions. The pudendal nerve is generally composed of fibers from the nerve roots of S2, 3, and 4. The nerve travels anterior to the piriformis muscle then passes between the sacrotuberous and sacrospinous ligaments, which are analogous to a "clamp" or "lobster claw," "pinching" or impinging on the nerve. Upon leaving this site, the nerve travels through the pudendal canal (Alcock canal) and divides into the perineal nerve, the dorsal nerve of the penis or clitoris, and the inferior rectal nerve. Many variations in the nerve structure have been noted during

surgery or anatomical dissections. Bony remodeling in the pelvis occurs commonly and is related to repetitive use of pelvic floor muscles, which results in changes in the ischial spine and the inferior lateral angle of the sacrum. When untreated pudendal neuropathy progresses from minor symptoms, often beginning with bladder complaints, and progresses gradually as nerve damage continues. Severe pain may occur in many sites and may be confused with morphologic/organ disease. Symptoms are often treated by end-organ specialists, including gynecologists, colorectal surgeons, and urologists. The diagnosis is usually made after many years of symptoms, during which time the patients have undergone multiple evaluations, trials of medications, and surgeries. Tragically, this often leads to opioid addiction, and patient suicides have been confirmed. When treated, long term symptom control is possible and total relief of symptoms has been reported up to 20 years after treatments.

Treatment of radiation-induced vulvar pain via pudendal nerve block under fluoroscopic guidance

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Vulvar pain is a common complaint in women during reproductive and post-reproductive years. A 70-year-old woman experienced severe intractable vulvar pain after bladder cancer surgery and adjuvant radiation therapy. We performed five fluoroscopy-guided pudendal nerve blocks. Her numeric rating scale decreased from 10 to 3, and after 5 months, her pain was controlled only with oral medication. Pudendal nerve block might stop ongoing sensitization which lead acute nociceptive vulvar pain into chronic neuropathic vulvodynia by attenuating nociceptive stimulation and inflammation.

Dermatological Conditions

Clinical and Dermoscopic Assessment of Vulvar Lichen Sclerosus After 5-Aminolevulinic Acid Photodynamic Therapy : A Prospective Study

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Background: To date, there have been no satisfactory treatments to cure vulvar lichen sclerosus (LS). 5-Aminolevulinic acid photodynamic therapy (ALA-PDT) has been introduced in the treatment of vulvar lichen sclerosus (VLS), but no dermoscopic assessment has been conducted. **Methods:** The included patients received six ALA-PDT sessions at 2-week intervals. After the third and sixth treatment, all patients were evaluated for clinical and dermoscopic variables with numeric scores assigned to each parameter. **Results:** Twenty-four VLS patients were included in this study. Both primary objective signs (lesion size and depigmentation) and subjective symptoms (itching and burning pain) were improved remarkably after the third treatment, and further improvements were obtained after the sixth treatment. Among the dermoscopic variables, the early changes were the decreased score of bright white or white-yellowish structureless areas and the increased score of vessels, and further changes of these two dermoscopic features were observed after the sixth treatment. There were no changes in pink structureless areas, white shiny streaks, follicular plugs, brown structureless areas, purple dots, and erosions after the third treatment, but after the sixth treatment, the scores of these dermoscopic features decreased significantly except that the score of brown structureless areas increased

significantly. There was no change in the score of peppering blue-gray dots. Both pain and erosions during the treatment could be tolerated. **Conclusions:** ALA-PDT is effective for VLS. In addition, dermoscopic assessment may be more precise for indicating minute changes invisible to unaided eyes which are useful to monitor the response to treatments.

Sinecatechins ointment as a potential novel treatment for usual type vulval intraepithelial neoplasia: a single-centre double-blind randomised control study

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Objective: To compare the safety and efficacy of 10% sinecatechins (Veregen®) ointment against placebo in the treatment of usual type vulvar intraepithelial neoplasia (uVIN). **Design:** A Phase II double-blind randomised control trial. **Setting:** A tertiary gynaecological oncology referral centre. **Population:** All women diagnosed with primary and recurrent uVIN. **Methods:** Eligible patients were randomised 1:1 to receive either sinecatechins or placebo ointment (applied three times daily for 16 weeks) and were followed up at 2, 4, 8, 16, 32 and 52 weeks. **Main outcome measures:** The primary outcome measure, recorded at 16 and 32 weeks, was histological response (HR). Secondary outcome measures included clinical (CR) response, toxicity, quality of life and pain scores. **Results:** There was no observed difference in HR between the two arms. However, of the 26 patients who were randomised, all 13 patients who received sinecatechins showed either complete (n = 5) or partial (n = 8) CR, when best CR was evaluated. In placebo group, three patients had complete CR, two had partial CR, six had stable disease and two were lost to follow up. Patients in the sinecatechins group showed a statistically significant improvement in best observed CR as compared with the placebo group (P = 0.002). There was no difference in toxicity reported in either group. **Conclusion:** Although we did not observe a difference in HR between the two treatment arms, we found that 10% sinecatechins application is safe and shows promise in inducing clinical resolution of uVIN lesions and symptom improvement, thus warranting further investigation in a larger multicentre study.

Forming diagnostic criteria for vulvar lichen planus

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Background/objectives: Vulvar lichen planus is a debilitating skin condition usually complicated by delayed diagnosis due to its highly variable clinical appearance and inconsistent histopathological characteristics. This study aims to devise a clinical diagnostic tool for the disease and to correlate this with histopathology findings. **Methods:** The retrospective single-centre chart review was conducted for patients presenting between January 2010 and December 2019. Clinical features were compared between 243 women with clinically suspected vulvar lichen planus with available histopathology, 50 patients with biopsy-proven vulvar lichen sclerosus and 50 patients with culture-proven chronic vulvovaginal candidiasis. Features which significantly differentiated between conditions were further studied using multivariate nonlinear regression analyses to formulate a score-based diagnostic criteria. Criteria was then applied to the remaining patients with inconclusive biopsies (classified as 'normal', 'non-specific' or 'suggestive or lichenoid') to determine sensitivity and specificity. **Results:** The clinical features that significantly differentiated the conditions were the presence of erosions (P < 0.001), glazed

erythema ($P < 0.001$), oral involvement ($P < 0.001$), pain/burning sensation ($P < 0.001$) and hyperkeratotic border ($P < 0.001$). A score ≥ 2 correlated with a histopathological diagnosis of vulvar lichen planus with a sensitivity of 100%. The specificity was 92% and 88% when compared against vulvar lichen sclerosis and chronic vulvovaginal candidiasis, respectively. Sensitivity was 97%, 97% and 93% in suggestive, nonspecific and normal histopathological subgroups, respectively. **Conclusions and relevance:** The proposed criteria may aid clinicians in diagnosing patients if histopathology is inconclusive. Nonspecific and suggestive findings on biopsy for patients with ≥ 2 features on diagnostic criteria are comparable to a conclusive biopsy.