REVIEW

Physical Modalities for the Treatment of Localized Provoked Vulvodynia: A Scoping Review of the Literature from 2010 to 2023

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Introduction: Localized provoked vulvodynia (LPV) is a prevalent sexual health condition with significant negative impacts on quality of life. There is a lack of consensus regarding effective management.

Methods: We used Arksey and O'Malley's five-step method to identify, collate, and evaluate literature published between 2010 and 2023. The scoping review investigated the efficacy or effectiveness of interventions in the management of LPV. The aim of this paper is to map the literature on the efficacy or effectiveness of physical interventions.

Results: The review produced 19 primary studies of physical interventions for LPV. These include acupuncture, laser therapy, physiotherapy, transcutaneous electrical nerve stimulation, low-intensity shockwave therapy, transcranial direct current stimulation, and vestibulectomy.

Conclusion: Published studies that investigated a range of physical treatments for LPV showed some positive effects, except for transcranial direct-current stimulation. The remaining modalities demonstrated improved sexual pain and treatment satisfaction, when measured. Findings were mixed for non-sexual pain. There was insufficient evidence to draw conclusions regarding other outcomes. Researchers are encouraged to conduct larger, high-quality studies that sample more diverse patient populations and use patientoriented outcomes to assess effectiveness of physical modalities.

Keywords: chronic vulvar pain, vestibulodynia, dyspareunia, laser therapy, physiotherapy, physical therapy, acupuncture, vestibulectomy, low-intensity shockwave therapy, transcranial direct-current stimulation, tDCS, transcutaneous electrical nerve stimulation, TENS

Introduction

Vulvodynia is a complex chronic vulvar pain condition of at least three months duration without an identifiable cause.¹ The estimated point prevalence is 8% with a reported lifetime prevalence of 10–28%.² Prevalence may be underestimated as individuals with vulvodynia often do not seek treatment for their pain.³

Localized provoked vulvodynia (LPV) is the most common type of vulvodynia.^{4,5} LPV is vestibular pain provoked by superficial contact or vaginal penetration such as during tampon use, intercourse, and pelvic examination. It is often described as a stabbing or burning sensation which may be mild to severe.⁶

Three articles published prior to 2010^{7-9} and two reviews published since $2010^{10,11}$ summarized the treatment of vulvodynia across all intervention categories. Since the publication of Andrews' review,¹⁰ no studies have specifically evaluated treatments for LPV with the exception of our review of pharmacological management of LPV.¹² This reveals limited dedicated attention to physical interventions for managing LPV.

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The purpose of our scoping review was to describe studies published between 2010 and 2023 that examined the efficacy or effectiveness of treatments for LPV. Due to the large number of studies and to allow for a thorough discussion of the range of interventions, we divided our findings into four categories to be published separately.^{12,13} This paper focuses solely on studies of physical interventions. We highlight interventions that show beneficial effects, discuss gaps in the LPV treatment literature, and provide recommendations for future research.

Methods

Arksey and O'Malley's¹⁴ five-stage method was used to identify, collate, and evaluate literature that addressed the question: What is the current evidence regarding the efficacy or effectiveness of interventions in the management of LPV? We chose a scoping review to address this question because it is a helpful tool for mapping research activity in a particular field, distilling key research findings and identifying gaps in the existing literature.¹⁵

A health sciences information scientist (MS) in collaboration with subject experts (KB and MEM) on the team developed the inclusion and exclusion criteria (<u>Appendix 1</u>) and the search strategy (<u>Appendix 2</u>). An initial PubMed search included controlled vocabulary and keyword terms relating to vulvodynia. The search was then translated into other subject-specific databases. The first search collected data from January 2010 to June 2021 with an updated search from June 2021 to March 2023. Both searches followed the same screening process.

All studies were uploaded to Covidence. After duplicates were removed, all study titles and abstracts were screened for relevance as the initial step. Articles not in English or French were excluded. Those that did not address LPV or therapies and those that focused primarily on diagnostic or epidemiologic issues were excluded. Systematic reviews, meta-analyses, editorials, and commentaries were excluded. The remaining eligible articles underwent full text review. The reference lists of eligible articles were hand-searched for additional citations that fit the inclusion criteria. No new citations were produced. Details that addressed the research question were extracted by one reviewer, verified by a second reviewer, and records were exported to Excel. At each stage, two team members independently reviewed documents with conflicts resolved by content experts (KB or MEM). Treatment modalities were categorized as physical, psychological, pharmacological, or multidisciplinary/multimodal. Narrative details of each study of physical modalities are charted in (Supplementary Table 1).

Results

This scoping review identified 19 primary studies of physical interventions for LPV published between 2010 and 2023 (Figure 1). These included acupuncture, laser therapy, pelvic floor physiotherapy/physical therapy (including transcutaneous electrical nerve stimulation [TENS]), low-intensity shockwave therapy, transcranial direct current stimulation (tDCS), and vestibulectomy. Research findings on physical interventions for LPV were reported in 22 publications. Studies were conducted in Canada (n = 4), Israel (n = 4), USA (n = 4), USA & Italy (n = 2), Finland (n = 1), Netherlands (n = 1), Australia (n = 1), Japan (n = 1), or were unspecified (n = 1). Studies that compared physical interventions with pharmacological or psychological interventions were categorized as multidisciplinary/multimodal and are reported elsewhere.^{12,13}

Acupuncture

One case series evaluated LPV symptoms among eight participants who underwent ten, one-hour acupuncture sessions over five weeks.¹⁷ Sessions involved needle placement for 20–25 minutes on each of the anterior and posterior aspects of the body. Outcomes were assessed before and after treatment sessions five and ten. Analyses showed statistically significant reduction in pain with manual genital stimulation, and on the helplessness subscale of the Pain Catastrophizing Scale. The overall effect on measures of emotional well-being, other pain outcomes, and sexual response as measured by Female Sexual Function Index (FSFI) was not statistically significant. There were minimal side effects. The results of the qualitative analysis were more promising, with decreased dyspareunia, increased desire and sexual frequency and improvements in mindfulness, calmness, and other medical conditions. Authors recommended larger controlled trials before the efficacy of acupuncture can be determined.

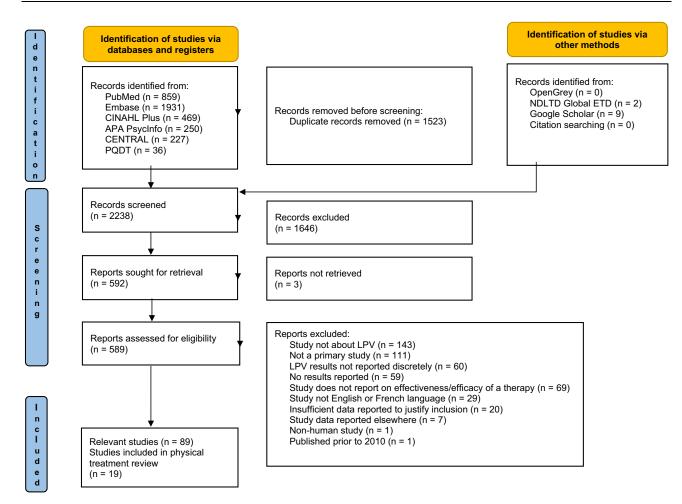


Figure I PRISMA 2020 Flow Diagram.

Note: Adapted from Page M J et al (2021). The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ, 372 n71 10.1136/bmj.n71.¹⁶ Abbreviations: PRISMA, preferred reporting items for systematic reviews and meta-analyses; LPV, localized provoked vulvodynia.

Laser Therapy

Five studies with six publications reported outcomes of laser therapy for management of LPV. Studies reported mixed results with some improvement in subjective measures. Authors reported no or minimal adverse effects.

CO2 Fractional Laser Therapy

One randomized controlled trial $(RCT)^{20,21}$ and two case series^{18,19} of patients undergoing fractional CO2 laser therapy for LPV reported positive outcomes.

Both case series investigated the effectiveness of CO2 fractional laser therapy using the same device. Murina et al¹⁸ administered treatments over 3 sessions using irradiation output settings of 30W power over a 30-day period. There were 37 participants diagnosed with LPV and 33 diagnosed with genitourinary syndrome of menopause. Ninomiya and Sekiguchi¹⁹ administered three treatments at one-month intervals to twenty premenopausal participants using fractional CO2 laser at "basic settings" that could be adjusted at the physician's discretion. The randomized trials reported by Goldstein et al^{20,21} examined the effectiveness of CO2 fractional laser therapy (30W) among 70 LPV participants, followed by an open-label treatment of those in the control group. Participants were randomized 2:1 for active treatment and sham, respectively. Placebo and treatment arms each consisted of three treatment sessions at four-week intervals.

The RCT and both case series consistently demonstrated success in alleviating dyspareunia. Goldstein et al^{20,21} reported improvements in subjective pain measures, FSFI pain scores, and O'Leary/Sant scores. Similarly, Murina et al¹⁸ documented statistically significant improvements in dyspareunia and NRS vulvar pain scores, which decreased from 8.5

prior to treatment to 5.1 at an unspecified post-treatment time. These positive effects persisted for at least four months. Additionally, 67.6% of LPV participants reported substantial improvements following the laser procedure.

Reported side effects across CO2 fractional laser studies were minimal and transient. Goldstein et al^{20,21} reported that adverse events included burning, itching, and pain after treatment with none deemed serious adverse events. Murina et al¹⁸ reported that 1 patient in the LPV group experienced transient burning after treatment which resolved in 5–6 days, while Ninomiya and Sekiguchi¹⁹ reported no "obvious" side effects.

Authors concluded that placebo-controlled studies with longer follow-up are needed to further support the efficacy of CO2 fractional laser therapy.

Other Laser Therapy

Two RCTs evaluated other laser therapies: low-level laser²² and High-Intensity Laser Therapy (HILT).³⁸

A small double-blinded RCT examined the effectiveness of CO2 low-level laser therapy among 34 participants with LPV.²² Eighteen participants received laser therapy and sixteen received sham. Patients in the placebo group were offered treatment after study completion. There were no significant differences in study groups at baseline. The primary outcome measure was dyspareunia VAS, but this score was converted to one of three categories; VAS improvement of <30% was classified as "no improvement", VAS improvement of 30-70% was classified as "moderate improvement", and greater than 70% VAS improvement was classified as "great improvement." Seventy-eight percent of the treatment group reported dyspareunia improvement to 44% of the placebo group (p = 0.42). Neither group reported significant improvement in LPV interference with social activities, frequency of sexual encounters, desire, lubrication, and sexual satisfaction. Those with improvement were followed for 1 year, of which 57% (8/14) had sustained improvement.

A conference abstract describing a randomized, triple-blind sham-controlled, pilot study assessed the effects of HILT on 40 LPV participants aged 18–45 years with 20 assigned to each group.³⁸ Other demographic characteristics were not provided, and HILT parameters were not described. The treatment group received bi-weekly HILT sessions for six weeks, while the sham group underwent bi-weekly sessions for the same duration. Both the treatment and sham groups demonstrated a significant reduction in dyspareunia, with the treatment group showing a decrease from baseline 7.3 to 4.1 (p < 0.001) and the sham group decreasing from baseline 7.4 to 5.4 (p = 0.002). The results indicated that 79% of participants in the active HILT group reported significant improvement in the Patient Global Impression of Change (PGIC) score, compared with 47% in the sham group (no p-value stated). Ten percent of the sham group reported a worsening of their condition. Treatment group participants exhibited statistically higher satisfaction, with a mean of 6.6/10, compared to 4.6/10 in the sham group. The study suggests that bi-weekly HILT may offer significant improvements in treatment satisfaction. The authors concluded that it would be feasible to conduct a larger RCT of HILT to confirm efficacy.

The authors described both laser therapy studies as pilots and recommended RCTs with larger populations to further assess efficacy. Lev-Sagie, Kopitman, and Brzezinski²² also stipulated flexible treatment protocols, with the goal of evaluating different LPV phenotypes.

Physiotherapy/Physical Therapy/Pelvic Rehabilitation (PT)

Researchers used different terminologies for therapies to restore the health and function of the pelvic musculature: physiotherapy, physical therapy, and pelvic muscle rehabilitation. While there may be minor conceptual and regional differences in the use of these terms, we refer to all these therapies as PT. Four studies reported the outcomes of PT for the management of LPV.^{23–26} Outcomes were generally positive. Side effects were not consistently reported.

Two studies evaluated the impact of pelvic floor PT programs. One study compared pelvic floor muscle tone and function, as measured by surface electromyography and digital intravaginal assessment, between 11 participants with LPV prior to PT and 11 control participants.²³ Pelvic floor muscles were reassessed in participants with LPV after eight physiotherapy sessions, within four weeks of completing treatments. The other, a case series, asked 24 patients with LPV to report on their pain, functioning and treatment satisfaction via a questionnaire 10 years after a series of PT sessions.²⁴ In both studies, outcomes were positive.

Gentilcore-Saulnier et al²³ reported that several measures of pelvic floor muscle function were compromised among LPV participants as compared with control participants at baseline. Following eight PT sessions, several of these

parameters normalized to control participants' baseline measures. However, the amount of pressure applied to the vestibule to produce pain did not normalize. Most of these outcomes were not patient-oriented and subjective measures were not blinded. Jahshan-Doukhy and Bornstein²⁴ reported that the majority (83%) of participants experienced a significant reduction in patient-oriented pain outcomes after treatment. Limitations to interpretation included the absence of a control group of participants with LPV not undergoing treatment²³ and possible recall bias.²⁴

Hartmann²⁵ surveyed 218 women's health physical therapists from 12 countries, who treated patients with LPV. Of those, 100 reported that more than 80% of LPV patients were discharged with symptoms "well controlled and/or managed." More than 70% of therapists agreed on 16 treatment options; however, specific treatment allocation and outcomes were not reported. Therapists reported seeing patients with LPV for 7–15 weekly, hour-long sessions. Hartmann reported that only 3% of therapists used the FSFI. Since the abstract lacked more detailed information, further analysis and interpretation of the study's findings was not possible.

Another case series evaluated the efficacy of TENS on alleviating LPV symptoms among 39 participants who had already undergone multimodal management.²⁶ A physiotherapist administered the first TENS treatment and instructed participants to self-administer the treatment at home, 2–3 times a day for a total of 90 minutes per day, until they achieved satisfactory results or up to 16 weeks. Vulvar pain, pain perception, and sexual functioning significantly improved from baseline and continued at follow-up (mean duration of 10.1 months). Sexual distress was also significantly lower after TENS, but this was not maintained at follow-up. In this study group, only one participant (4%) had a vestibulectomy at follow-up. The authors compared their study's 4% vestibulectomy rate with a historical control group drawn from one of the author's prior publications which showed a 23% vestibulectomy rate in participants treated with multimodal management without TENS. No quantitative data were presented on treatment compliance. The authors concluded that self-administered TENS before resorting to vestibulectomy. Authors recommended randomized studies that account for attention from a provider and varying compliance with treatment.

Transcranial Direct-Current Stimulation (tDCS)

A triple-blinded RCT investigated the efficacy of tDCS, which involves placing electrodes on the scalp and delivering a constant, low-level direct current.²⁷ Participants (n = 40) underwent a series of ten 20-minute sessions over 14 days with either active (2 mA) stimulation or placebo stimulation. Baseline and follow-up assessments with the McGill Pain Questionnaire (MPQ), FSFI, and FSDS revealed a significant reduction in dyspareunia, sexual distress, catastrophizing, pain anxiety, and an improvement in sexual function in both treatment arms. There were no significant differences in pain or sexual function between the treatment and the placebo group. The authors described commonly reported side effects associated with the treatment, including tingling (more common in the sham group), burning (more common in the treatment group), and headache, fatigue, and dizziness (no difference between groups). No participants withdrew from the study due to these effects.

Authors concluded the use of tDCS treatment for LPV was not supported by their findings.

Low-Intensity Shockwave Therapy

Two studies evaluated the efficacy of low-intensity shockwave therapy at specified dosages.^{28,29} The first was a case series of 14 patients that examined the efficacy of 6 treatment sessions of low-intensity shockwave therapy.²⁸ Each session involved 3000 shocks to the vestibule with energy determined by patient tolerance. PGIC, CST, and vulvar/ vestibular appearance showed improvement with treatment, although the length of follow-up was not specified, and p-values were not provided.

The second study was a double-blinded RCT which evaluated low-intensity shockwave compared to sham treatments. These were applied to the introitus among 34 participants.²⁹ The treatment group (n = 24) received 500 pulses of low-intensity shockwaves (0.09 mJmm²) twice weekly for 6 weeks, while the sham group (n = 10) received the same protocol without shockwave generator activation. Participants were evaluated before the first treatment, and at one and three months after the final treatment. Those in the treatment group reported a significant reduction in dyspareunia, increased pain threshold and tolerance, and increased sexual function. The placebo group did not show any changes in

measurements. A moderate correlation between reduced dyspareunia and improved sexual function was found. One participant reported self-limited abdominal pain.

Authors of both papers concluded that low-intensity shockwave therapy was a feasible treatment for LPV and called for larger randomized studies to further evaluate efficacy.

Vestibulectomy

Six studies reported in eight publications discussed outcomes of vestibulectomy. Four studies reported outcomes of some version of posterior vestibulectomy,^{30–33,37} with two studies reporting on total vestibulectomy in three publications.^{34–36} For both types of vestibulectomy, success rates were high. Dyspareunia success rates were 70–95% for posterior vestibulectomy, 88% for complete vestibulectomy³⁴ and for a small number of those having repeat vestibulectomy, dyspareunia success was 70–80%.^{31,35,36} In five publications, when participants reported improvements in TT or CST score, they also had improvements in dyspareunia. Authors across these studies consistently report safe, successful long-term outcomes with high levels of patient satisfaction.

Vestibulectomy After Failed Multimodal/Interdisciplinary Management

There were five publications from four case series of patients choosing vestibulectomy after failure of multimodal/ interdisciplinary management.^{30–33,37} All of these described some version of a posterior vestibulectomy.

Ingram³¹ reported results of 190 individuals, with LPV undergoing vestibulectomy/modified vestibulectomy between 1976 and 2011 with three-year follow-up. Initially, excision was localized to the tender and erythematous areas, but in 1980, they transitioned to U-shaped incision due to treatment failures. Tommola, Unkila-Kallio and Paavonen³³ performed posterior vestibulectomy on 57 participants, with in-person short- and long-term follow-up at 1 and 36 months. The abstract by Paavonen, Päivi, and Unkila-Kallio³² describes the same cohort. One hundred and fifteen patients returned a questionnaire a median of six years after "modified" vestibulectomy (U-shaped incision) by Swanson et al.³⁷ Brokenshire, Pagano and Scurry³⁰ performed posterior vestibulectomy with additional, separate excision of periurethral glands if tender, on 30 participants with follow-up at 6 weeks, 3 months and 3 years.

Generally, scant demographic characteristics were reported. Three studies^{30–33} included patients in their 50s, which represents a wider age range than in other studies of vestibulectomy. Data on ethnicity were presented in two studies,^{31,37} with the vast majority of patients identifying as white or "Caucasian".

All case series reported very high success rates for dyspareunia.^{30,31,33,37} One case series reported CST NRS³³ and another vestibular pain via questionnaire.³⁷ Posterior vestibular CST pain and vestibular pain were substantially improved. Despite periurethral gland excision in cases of tenderness, improvements in anterior CST pain were not as robust. CST pain and dyspareunia were highly correlated in the case series by Tommola, Unkila-Kallio and Paavonen.³³ At three-year follow-up, Ingram³¹ described 95% as "pain-free", without further details.

With respect to complications, Tommola, Unkila-Kallio and Paavonen³³ reported short-term complications most reliably, in addition to patient-oriented descriptors of duration of postoperative recovery. The overall rate of any adverse event was 21.4%. Hematoma occurred in 6 (8.6%) with 4 requiring surgical management. Wound pain or infection requiring clinic visit occurred in 11 (15.7%). Bartholin's cyst formation was 5.7% at 24-month follow-up. Fifty-seven presented for 36-month follow-up where no scarring was noted on exam. Four patients had "fissures", but these were already present at baseline in three. Median time to full recovery was 5 weeks but ranged from 1 to 25 weeks. Ingram³¹ also described 5 patients who had postoperative bleeding requiring "re-suturing" within 1–48 hours. He also described a Bartholin's cyst rate of 5%, with 8 of those having surgical management.

Although all the case series demonstrated improvements to dyspareunia and vestibular pain with substantial long-term follow-up, the lack of comparator group and use of survey for outcome assessment³⁷ may have influenced results.

Vestibulectomy Without Description of Prior Management

David and Bornstein³⁴ described a case series of 32 participants with a mean follow-up of 19 years after total vestibulectomy performed between 1991 and 2003. There was no information about participants' use of prior

pharmacological, physical, or psychological interventions. Participants were offered vestibulectomy for "significant" dyspareunia and positive CST.

Thirty (94%) of participants reported that no subsequent treatments beyond vestibulectomy were required. Of the two remaining participants, one had intramuscular interferon and one, an unspecified topical cream. Dyspareunia was dramatically reduced, with a mean of 4 months to pain-free intercourse. Recovery from vestibulectomy was two months. Most other patient-oriented outcomes were also significantly improved. The most painful activity was intercourse. Preand postoperative pain scores were retrospectively estimated at long-term follow-up, allowing for recall bias. Ninetyseven percent would undergo the procedure again, and 100% would recommend it to a friend. Of these, 84% would do so "wholeheartedly" and 16% would do so "hesitantly." Five participants (16%) stated they would have preferred to exhaust conservative management before resorting to vestibulectomy. In contrast, one participant felt that they wasted time on non-invasive treatments and would have preferred surgical management as an initial treatment option. There were no differences in outcomes between the nine participants with primary LPV and the fifteen with secondary LPV. The authors reported "no complications were recorded during or after surgery."

The authors felt surgery should not be withheld as an initial treatment option. They also recommended that different types of vestibulectomy should be studied in randomized trials.

Repeat Vestibulectomy

Three publications reported on two small case series suggesting an overall failure rate of 20–30% for repeat vestibulectomy.^{31,35,36}

In 2015, Ingram³¹ performed repeated posterior vestibulectomies on 25 of 190 (13%) participants. Twenty participants had two vestibulectomies, and five had three. There were five "failures" among those with repeat procedures (20%). Two conference abstracts reported a retrospective case series of 14 participants having total vestibulectomy for persistent entry dyspareunia after prior posterior vestibulectomy.^{35,36} Patients were offered complete vestibulectomy if provoked anterior vestibular pain with CST was demonstrated. Two participants had two prior posterior vestibulectomies, and one participant had three. Success, defined as pain-free penetration, was 71%. There was an additional 50mL blood loss in those with a prior vestibulectomy, and posterior fibrosis was noted to result in more challenging dissection than in those without prior surgery.

Authors concluded that restricting vestibulectomy to the posterior vestibule was insufficient for neuroproliferative LPV.

Discussion

What is the Landscape of Physical Management?

Nineteen primary studies evaluated the effectiveness of physical modalities in people with LPV, that is, acupuncture, laser therapy, PT (including TENS), low-intensity shockwave therapy, tDCS, and vestibulectomy. Of these, 5 were RCTs, 1 quasi-experimental study, 1 survey, and 13 case series. The vast majority of participants were satisfied with their treatments when asked. The most commonly reported participant demographic characteristics were age (n = 18), relationship status (n = 6), duration of LPV symptoms (n = 6), OCP use (n = 5), race (n = 4), education (n = 3), type of LPV (n = 3), and parity (n = 2). Age range across studies was 17 to 74, which was a broader age range than in our companion manuscripts.¹² The majority of participants were partnered when asked, and most participants were "Caucasian" or white. Single studies also showed that the most commonly used outcome measures were scales of dyspareunia (NRS, VAS, and Marinoff Turner scoring) (n = 9), vulvar pain NRS or VAS (n = 5), CST (n = 5), FSFI (n = 5), FSDS (n = 4), PGIC (n = 4), and the MPQ (n = 4). Various other measures of pain (eg, investigator-developed metrics, brief pain inventory, dichotomous pain questions, pain with algometer use, "sexual problem" indices) were employed by investigators. Other outcome measures included vulvoscopic assessment, qualitative reviews of practitioner notes, quality of life questionnaires, and survey tools.

All studies of physical modalities except for tDCS reported some positive effects. The remaining modalities demonstrated improved sexual pain when measured. Findings were mixed for non-sexual pain. Sexual functioning was not measured in many studies, and where measured, results were mixed. Mood and quality of life were not assessed in enough studies to conclude treatment impact on these domains. Satisfaction with treatment was not consistently reported

but was rated as high in the studies that did report on this measure. Most papers did not report on treatment compliance; among those who did, compliance was high.^{19,22,38}

Laser therapy and low-intensity shockwave therapy demonstrated improvement in LPV symptoms compared to sham. The TENS study used a historical control group as a comparator, which may limit the ability to draw reliable conclusions. While PT and vestibulectomy did demonstrate efficacy in various domains, these were investigated without the presence of comparator groups. This finding warrants increased investigation through head-to-head trials with other treatments, as construction of appropriate sham groups is less feasible in these instances.

A small case series of acupuncture for LPV had mixed results. Quantitative measures showed improvement in pain with manual genital stimulation and reduction in participant-perceived helplessness subscale of the Pain Catastrophizing Scale¹⁷ with no improvements in other measures of sexual health or emotional well-being. These findings are in keeping with Davis et al,³⁹ where acupuncture was the only LPV treatment that did not result in pain improvement and Hullender Rubin et al⁴⁰ where acupuncture targeting three "core points" for genital pain was inferior to the control procedure of four needles targeted on "non-specific points." The qualitative findings of Curran et al¹⁷ were more promising, with participants describing decreased dyspareunia, increased desire and sexual frequency and improvements in general well-being. The lack of convincing quantitative evidence for acupuncture is consistent with previous reviews and the Vulvodynia Guidelines.^{8,10,13,41}

Study results of laser therapies were encouraging, though there were some methodological limitations. The fractional CO2 laser RCT²¹ found favourable results for pain and sexual function measures. While the RCT supported the improvements in pain reported in the two case series,^{18,19} there was no sample size calculation for the study, and the follow-up period was relatively short, at 16 weeks. Adverse events were not consistently evaluated across all studies although, if reported, were described as "transient" and "mild to moderate in severity".²¹ Moreover, this RCT was not powered to assess complications. Additionally, the primary outcome of the RCT, change in vestibular appearance, may not be as important as a patient-oriented outcome. Studies of low-level laser therapy²² and HILT³⁸ were small pilot trials concluding that larger RCTs are needed to further assess efficacy/effectiveness. While the three of the five laser therapy studies used a sham group for comparison, none established effective blinding. Additionally, the exact laser settings were not consistently described such that the treatments could be replicated. The overall impression is that more research is needed to establish efficacy/effectiveness.

There was limited evidence to support the efficacy/effectiveness of PT interventions. Study designs were limited to a case series, a small quasi-experimental study, and a cross-sectional survey. While no RCT of PT compared to other physical interventions was identified, our companion publication¹³ explores treatment versus treatment trials of PT relative to other treatment categories (eg, psychologic, pharmacologic). PT often combines various interventions for pelvic floor muscle dysfunction, including pelvic floor muscle assessment, manual therapy, biofeedback, vaginal dilators, and TENS. Hartmann's²⁵ survey of women's health physiotherapists described agreement amongst >70% of respondents on 16 treatment options. Contrary to other studies, participants described in one publication³³ showed similar voluntary muscle relaxation across response groups, with authors calling into question the role of pelvic muscle dysfunction in dyspareunia. These different treatments under the umbrella of "PT" and disagreement on the role of muscle dysfunction make it difficult to isolate the effects of the individual components of treatment. Additionally, practitioners individualize therapy to the patient and varied practice patterns limit the generalizability of results. Finally, these studies did not control for the attention and empathetic care by the physical therapist. These factors contribute to the difficulty in researching the efficacy of PT interventions.

There were several physical modalities that had limited evidence for efficacy/effectiveness. Evidence for the beneficial effects of TENS was limited to a single study.²⁶ The Gruenwald et al.²⁹ RCT of low-intensity shockwave therapy was small in scale but included a sample size calculation, although the study had a relatively short follow-up period. Yih,²⁸ a case series of low-intensity shockwave therapy, was also small in scale. Both these studies reported benefits with minimal reported side effects, without evidence that side effects were systematically evaluated. Despite these methodological limitations, the potential benefits of low-intensity shockwave therapy warrant further investigation. tDCS was the only physical modality that did not show beneficial effects.²⁷ While the tDCS study noted a sample size calculation, the editorial commentary appended to the article highlighted concerns that concluding this modality is ineffective based on a single small study, where negative results may be due to random error, was premature. Given the limited number of studies available for these

interventions, caution should be exercised when drawing conclusions about their efficacy or effectiveness, and further investigation is warranted to establish their clinical utility and safety.

Publications included in this study support vestibulectomy as an effective treatment for LPV pain. Most vestibulectomy studies did not specify details of preceding treatments. While the case series discussed in this paper had globally positive results for dyspareunia, studies comparing vestibulectomy with conservative management, discussed in our companion paper,¹³ generally reported that dyspareunia outcomes were comparable to multimodal/interdisciplinary therapies, underscoring the importance of comparator groups for this intervention. Lack of comparator groups may have inflated treatment response due to possible spontaneous improvements over time. Those studies measuring treatment effects via survey were subject to selection bias, response bias, and, particularly given the relatively long follow-up intervals, recall bias. Among the present studies, dyspareunia improvement was congruent with TT and CST score improvement. However, we found that dyspareunia was not correlated with CST and TT scores in our previous reviews.^{12,13} Two small case series suggested an overall failure rate of 20–30% for repeat vestibulectomy. Generally speaking, authors considered vestibulectomy safe with minimal side effects. However, Ingram³¹ reported a 3% "re-suturing" rate in the early postoperative period. Tommola, Unkila-Kallio, and Paavonen,³³ who appeared to most rigorously evaluate complications among the studies of vestibulectomy, also reported an overnight admission rate of 20%, a 5.7% rate of reoperation to control bleeding, and 15.7% of participants who required early follow-up for pain and wound complications.

What are the Gaps in Our Knowledge?

While all reviewed studies provide evidence for physical LPV treatments, there are many gaps in the current knowledge that make it difficult to conclude superiority of one intervention over others. In general, quantitative studies require more rigorous research methods that control for various bias domains, such as comparing active treatments with one another, sham, and no-treatment groups, consistent blinding and randomization, and adequate statistical power. Some of the studies included in this review were qualitative and pilot studies. They have the potential to identify patient-oriented outcomes and lay the groundwork for methodologically sound quantitative assessment of treatment efficacy/effective-ness. Triangulating qualitative studies with quantitative data would also increase rigour and validity.

Generally, there was a lack of consistency in reporting demographic characteristics, leaving gaps in our knowledge about the effectiveness of physical treatments across the full range of those living with LPV. When reported, study participants were predominantly white, highly educated, and partnered cisgender women. There was a notable absence of participants across the gender spectrum (ie, non-binary, trans, two-spirit). Additionally, sexual expression/sexual orientation was not routinely reported, with one exception where all but one of 34 study participants reported being heterosexual.²² One optimistic note was the broader age ranges of study participants^{30–33} than those reported in our previous reviews of pharmacologic¹² and multimodal/interdisciplinary¹³ interventions for LPV. Given that LPV can affect individuals across a range of demographic categories, the lack of diversity in study participants limits the external validity of the results and generalizability of findings.

There are two issues relating to outcome measures. The first is the lack of consistency in outcome measures, making it difficult to compare efficacy across studies. Dyspareunia was the most common outcome assessed using VAS, NRS, and Marinoff-Turner scales. As in our companion papers,^{12,13} the NRS in some studies was incorrectly referred to as the VAS. The NRS and VAS are not interchangeable. VAS, a multidimensional measure, is more reflective of the overall pain experience, including the character, intensity, and emotional valent of pain.⁴²

The second issue relates to assessing the breadth of patient-oriented outcomes and functional goals. Improvements in dyspareunia do not necessarily equate to improved sexual function. Several studies did assess sexual function using validated measures such as the FSFI and FSDS. The outcome used to measure insertional pain is often dyspareunia, however dyspareunia is only one functional goal. Having a speculum exam is necessary for disease prevention and is a more universal outcome of interest. Insertional pain may also compromise patients' ability to use tampons or menstrual cups and affect psychosocial functioning by limiting access to desirable activities like swimming, social events, and certain jobs. Distinct from insertional pain, pain at the vestibule provoked with touch negatively affects non-penetrative sexual intimacy, and the use of menstrual pads, wearing tight clothing, sitting, and bike-riding. Limited research explores participants' ability to tolerate these activities and procedures. Failure to investigate these parameters limits what we know about how LPV affects quality of life, activities of daily living, and other patient goals.

Additionally, "conservative" treatments may involve extensive time, commitment, effort, or cost, leading to decreased adherence or infeasibility. Only three studies^{20,21,38} (excluding vestibulectomy) reported adherence rates on treatments or treatment protocols.

How Might Future Research Be Guided by This Scoping Review?

Demographics and Participant Recruitment

Researchers are encouraged to recruit participants from across the spectrum of gender, sexuality, race, ethnicity, age, and educational identities. This will address the limited evidence that exists for physical treatment modalities among people with LPV of diverse demographic characteristics. Participants from various races, ethnicities, ages, sexual orientations, and gender identities should be recruited to improve generalizability of findings. While there may be challenges in engaging diverse populations, the first step is to ask participants about these characteristics and report them.

When relationship data was collected, the majority of participants reported having a partner. Given the use of sexual pain and functioning as outcome measures and the evidence that facultative partner interactions may facilitate improvements to these measures,⁴³ we recommend increased collection of partner data. Given the potential diversity of sexual and romantic partnership, researchers should consider collecting more comprehensive information. By doing so, researchers may be able to both improve generalizability of findings and identify LPV interventions which most appropriately improve patient outcomes in particular relationship contexts.

Treatment Parameters

Researchers are encouraged to collect and report detailed data on all treatment parameters such that the procedure could be replicated. For example, a detailed description of device settings and treatment protocol is recommended in studies of laser and low-intensity shockwave therapy. In pragmatic studies where treatment protocols are adjusted based on patient characteristics and treatment tolerability, the sample should be of adequate size to allow for dilution of treatment effect.

Outcome Measures

There was significant heterogeneity and inaccuracy in outcome measures among the studies evaluated in this scoping review. Some authors reported "VAS" when they appeared to use NRS, which has not received the same validation as the VAS.⁴³ Other outcome measures varied from study to study, making comparison of interventions difficult. Researchers are encouraged to incorporate validated outcome measures such as the VAS and tools such as the Vulvovaginal Symptoms Questionnaire to measure psychosocial impacts of treatment.⁴⁴

Researchers are encouraged to expand their choice of outcome measures for the efficacy/effectiveness of physical interventions. Pain with penetrative sex and changes in vestibular appearance, for example, may be less important to some patients living with LPV than other patient-oriented outcomes such as the ability to wear certain clothes, use menstrual products, or engage in activities such as cycling. In particular, upholding penetrative sex as the gold standard may undermine the role of other sexual activities and promote phallocentricity in LPV research.^{45–47}

Governing bodies such as the ISSVD, ISSWSH and IPPS are in a position to provide consensus recommendations on appropriate outcome measures and adverse event/complication reporting. In addition, these and other discipline-specific societies are in a better position to guide the study of PT programs, which is made challenging by, for instance, varied practice patterns, individualized treatment protocols, and the numerous modalities which fall under this umbrella.

Comparator Groups

Researchers are encouraged to incorporate appropriate comparator groups, especially in those modalities which have only been evaluated in case series. Where sham procedures are used, such as in trials of laser therapy or tDCS, we recommend assessing the effectiveness of the blinding techniques by asking participants to guess their group assignment and reporting these results. For those treatments which are not compatible with a sham control (eg, acupuncture, PT), efficacy/effectiveness may be better assessed in head-to-head trials compared with other treatments. In order to assess whether improvement in symptoms is an effect of the treatment or of the natural time course of LPV, a no-treatment arm is encouraged.

Other Methodological Considerations

Further studies of physical modalities should incorporate and report sample size calculations. Where the goal is to establish safety, trials must be adequately powered to assess this. Otherwise, conclusions about safety should not be made. Longer follow-up periods are recommended to establish the duration of treatment effect.

Vestibulectomy has traditionally been reserved as a last-line treatment, however, the evidence for this warrants further investigation. In one study, a mere 16% of participants stated they would have preferred to exhaust conservative management before vestibulectomy.³⁴ Head-to-head trials comparing vestibulectomy with other interventions may clarify the role of vestibulectomy in the treatment paradigm for LPV management. Our companion paper on multimodal/ interdisciplinary modalities supports this recommendation.¹³

Adverse Events and Adherence

Researchers are encouraged to systematically evaluate and report side effects of physical interventions. In the case of the case of vestibulectomy studies, researchers are encouraged to consistently report adverse events including assessment of immediate postoperative pain, hospital admission rate, reasons for readmission, re-operation rates, wound complication rates, and, where applicable, assess for congruence between surrogate measures such as TT/CST and dyspareunia or other patient-oriented outcomes.

The constraints of "conservative" treatment warrant further study. Researchers are encouraged to report adherence to treatments which require multiple, intensive, or painful sessions or protracted treatments. This may more accurately reflect intervention accessibility and help to establish potential effectiveness.

Strengths and Limitations

This article represents one component of a large scoping review of LPV treatments across intervention categories. While this publication solely addresses physical interventions, the division of our scoping review into multiple components allowed for detailed critical analysis of each category of intervention (ie, pharmacologic, psychological, multidisciplin-ary/multimodal).

The aim of a scoping review was to map the landscape of literature, synthesize research findings, and highlight knowledge gaps, in this case, physical management of LPV. We adhered to an accepted methodology that invited quality checks at several junctions, and which can be reproduced in future studies. Unlike a systematic review or meta-analysis, its aim was not to guide clinical practice or policy on the management of LPV. Non-English and non-French language studies were excluded, and we did not consider other types of vulvodynia. This review was limited to research published since 2010 that reflects the current landscape of LPV research.

Conclusions

This scoping review is a thorough description of the breadth of current research on physical interventions for LPV management and reveals that we lack sufficient evidence supporting any single physical treatment modality. Shortcomings in existing literature were identified and highlight the need for rigorous methodological designs with appropriate control groups and GRADE-structured consensus guidelines. Specific recommendations relate to reporting demographic characteristics, recruiting more diverse participants, describing treatment parameters to allow for replication, collecting and reporting of validated and patient-oriented outcomes, using appropriate comparator groups, and reporting adherence. We call upon governing organizations to provide researchers, with specific recommendations regarding outcome measures and adverse event reporting. Given the complexity of studying PT interventions, we also call upon PT and LPV societies to make recommendations to guide research design that promotes the rigorous study of physical modalities for LPV treatment.

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Disclosure

Dr Krisztina Bajzak reports being the Co-Chair of the International Liaison Committee of the International Pelvic Pain Society. The authors report no other conflicts of interest in this work.

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