

ARTICLE



Exclusive manual perineal rehabilitation with lidocaine 2% gel in the treatment of provoked vestibulodynia: results from a single-arm interventional study

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As of now, there is no adequate therapeutic strategy for provoked vestibulodynia (PVD). Pelvic Floor Muscle Therapy (PFMT) is a widely used technique in general pelvic floor rehabilitation. The objective of this study is to examine the effects of exclusive manual perineal rehabilitation with lidocaine 2% gel on PVD. During the first session, recruited patients ($n = 68$; mean age 31 ± 8.6 ; range: 18–52) received a questionnaire (Q1) on general well-being and health, pain of the genital area, sexual function, and symptoms during vaginal penetration. This questionnaire was based on a generalised questionnaire on the quality of life, the Medical Outcomes Study 36-item (SF-36), the Female Sexual Function Index (FSFI), and the Visual Analogue Scale (VAS). A second identical questionnaire with an additional set of open-ended questions concerning the assessment of the treatment was collected after treatment (Q2). A total of 45 questionnaires were completed. Statistical results showed a significant improvement of all items before and after treatment ($p < 0.001$): perceived general well-being and health, perceived vulvar pain, perceived sexual function, and perceived vaginal penetration. In conclusion, exclusive manual perineal rehabilitation using lidocaine 2% gel seems to be a safe and effective treatment option for vulvodynia in women.

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INTRODUCTION

Vulvodynia is defined by the International Society for the Study of Vulvovaginal Disease as chronic pain or discomfort in the area of the vulva for more than three months, with no identifiable aetiological cause [1]. Despite its prevalence, it is poorly known among healthcare professionals and is currently underdiagnosed and under-treated [2–5]. Lifetime prevalence is estimated at 3–14% in women of all ethnicities, with a mean age of onset of 30 [3–6].

Generalised vulvodynia concerns the whole vulva, but pain may be localised specifically on the clitoris (clitorodynia) or the vestibule of the vagina (vestibulodynia) [1]. Provoked vestibulodynia (PVD) may be induced by contact (cotton-swab, tampon, penetration), while unprovoked vulvodynia is characterised by pain without any trigger. Women can present with mixed vulvodynia [1]. Likewise, primary vulvodynia, where pain is reported since the first attempt of tampon insertion or sexual penetration, can be distinguished from secondary vulvodynia, which arises after a period of more than 3 months of pain-free intercourse [1, 7]. Temporal patterns (intermittent, persistent, constant, immediate, or delayed) are described [1, 8].

The impact of PVD is significant, causing dyspareunia and avoidance of sexual activities, which can seriously affect relationships and quality of life as well as lead to other psychological alterations such as anxiety and depression [9–12].

In the literature, information about idiopathic vulvodynia therapy is limited, and no consensus has been reached [13]. De Andres et al. stated that the optimal therapy for vulvar pain syndrome remains elusive, with low percentages of therapeutic success, especially using local or systemic pharmacological approaches [14]. Morin et al. concluded in their systematic review that physical therapy techniques such as biofeedback, dilators, education, electrical stimulation, multimodal physical therapy, and multidisciplinary approaches were effective in decreasing pain during intercourse and improving sexual function [15].

The aetiology of PVD is hypothesised to be multifactorial with an interdependency on biopsychosocial factors [16–19]. The involvement of the pelvic floor muscles (PFMs) is well known and has been demonstrated in several controlled studies [20–24]. Women with PVD show raised resting PFM tone, reduced coordination, strength and flexibility, impaired voluntary relaxation, and decreased endurance [21, 23, 24]. Several clinical guidelines have defined PFMT as a first-line treatment of PVD [2, 19, 25].

However, Morin et al. [15] concluded in their systematic review that there were no studies evaluating manual therapy as an isolated modality in the selected population. Given the lack of a precise and detailed physiotherapeutic treatment protocol for PVD, this study aims to investigate the effects of exclusive manual perineal rehabilitation with lidocaine 2% gel on PVD. Additionally,

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the study aimed to evaluate the sexual function and pain perception of the patients, the degree of pain before, during and after vaginal penetration, and the type of pain.

POPULATION AND METHOD

The present cohort study is an interventional multicentric study conducted between March 2019 and December 2020. Protocol of the study was approved by the Ethical Committee of Erasme-Université Libre de Bruxelles (Belgium; B07601939478). Informed consent of all patients was obtained. The patients were recruited in the pelvic floor departments of the Clinique Saint Jean and the Medicis Medical Center, Brussels.

Women presenting with symptoms of vulvar pain at the outpatient clinic and subsequently diagnosed with PVD ($n = 68$) received a questionnaire at the first session of physiotherapy (Q1) from the physiotherapist experimenter. Patients underwent perineal rehabilitation at least once a week. The same questionnaire was presented at the end of the treatment with open-ended questions about perceived improvement as a result of the treatment (Q2).

Sample and recruitment

Patients had to meet the following inclusion criteria to be eligible to participate in this study: a positive cotton-swab result (which is the standard gynaecological method for diagnosing PVD) [2, 19], vulvodynia persisting for >3 months, defined as experiencing pain on a daily basis, 18–65 years of age, and signed consent form. The exclusion criteria could be defined according to the recommendations of the guidelines concerning the treatment of vulvodynia [19, 25]: other ongoing therapeutic treatment (pain medication, anti-inflammatory drugs, antidepressants, anticonvulsants, topical vulvovaginal cream, oestrogen cream, injection of dermocorticoids, lidocaine or botulinum toxin), clinically significant dermatological disease such as eczema, lichen sclerosus and planus, psoriasis and clinically significant neurological disease such as pudendal neuralgia.

Based on the data in the study of Glazer et al. [24], it was decided to include at least 42 patients in the study, with a power of 80% and a margin of error of 5%.

Population

A questionnaire and a protocol of treatment were established for this study in French, Dutch, and English. The questionnaire was based on validated questionnaires, the SF-36 and the FSFI, and on the VAS. The SF-36 relates to perceived general health and is recommended as a self-report outcome measure in vulvodynia clinical trials [26]. The FSFI is the most commonly used index for assessing sexual function in women with vulvar pain [27, 28]. The VAS has well-established reliability and validity across general pain populations [28]. Vulvar pain was quantified using a 10 cm linear VAS (with 0 = no pain and 10 = maximum pain).

The questions were subdivided into four different items: general well-being and health, pain of the genital area, sexual function, and vaginal penetration. Some open-ended questions relating to the perceived improvement as a result of physiotherapy treatment were added in the Q2. Multiple-choice closed questions are scored from 0 to 4 points, while closed dichotomous questions are scored from 0 or 1 point. Each item represents one score: (i) score on 17 points for the general well-being and health item; (ii) 25 points for the pain of genital area item; (iii) 40 points for the sexual function item; and (iv) 71 points for the vaginal intercourse item. The final score is the sum of the scores of all the items. The maximum score that can be achieved is 153 (153 = negative global feeling; 0 = positive global feeling). Open-ended questions did not require a score since they reported each participant's personal opinion of the treatment.

A description of the pelvic floor's anatomy and physiopathology was given by the caregiver. It is essential to begin treatment with an explanation of the disease and determine realistic treatment goals [19, 25].

According to Bergeron et al. [29], physical therapy interventions aim at rehabilitating the PFMs by (i) increasing PFMs awareness and proprioception; (ii) improving PFMs dissociation and relaxation; (iii) normalising PFMs tone; (iv) increasing elasticity of the muscle and vaginal tissues; and (v) reducing fear of vaginal penetration [15, 29]. The authors of the present study added some specifications to their protocol: (vi) desensitising the painful area with lidocaine 2% gel; (vii) teaching the practice of self-massage at home; (viii) decreasing apprehension of vaginal penetration by using vaginal dilators of increased diameters with breathing techniques; (ix) counselling about lifestyle and personal hygiene, and (x) coaching about sexuality. The same therapist carried out all sessions lasting 30 min at two different centres. Due to the variability of progress, an individual treatment was preferred.

The vulvar pain is often localised between 4 and 8 o'clock on the introitus, just exterior to the hymenal ring [30]. Technique was achieved through half a phalanx of a single finger insertion to the painful spot with lidocaine 2% gel. Depending of the peak points within pain-related regions, delicate pressure-massage was carried out at the 5, 6 and 7 o'clock positions of the vestibule, the entire vestibule, and/or on the clitoris. Patients were advised to perform the same massage at home twice a day. Some preceding findings exhibited a significantly lower pressure-pain threshold in women with PVD than control women [31, 32]. Others provide further evidence of allodynia in women with PVD, finding that control women perceived a touch sensation at levels of pressure that were already painful for women with PVD [32].

Delicate genital hygiene is recommended such as use of clean water (no vulvar irritating agents), cotton underwear, cotton sanitary pads, and a good lubricant for sexual intercourse [2, 25, 33].

Statistical analysis

The data collected with the questionnaires were analysed using JASP system (version 0.13.0.0). To begin with, the normality of the variables was evaluated by Shapiro-Wilk's test statistics. Because the p -value was above 0.05, the variable was considered normal. Next, two different statistical tests were used to compare the data before and after treatment: (i) the parametric test of t -Student to analyse the data of the general, well-being and health, painful, and sexual function items; (ii) the nonparametric Wilcoxon signed-ranks test for paired sample to assess the VAS before, during and after vaginal intercourse. For all analyses, a p value of less than 0.05 was set as statistically significant.

RESULTS

Overall, 68 women, aged 18–65 years, diagnosed with objective vulvodynia, defined as vulvar pain for at least 3 months in the past 6 months, engaged in the study. On this panel, 45 women (66%) filled out both the questionnaires, and 23 (34%) were excluded due to exclusion criteria, lack of compliance of therapy, and failure to follow up due to the COVID-19 pandemic. Among the patients, 40% ($n = 18$) were diagnosed by a gynaecologist, 58% ($n = 26$) by the experimenter and researcher (AC), and only one by a dermatologist (2%). In all, 58% ($n = 26$) of the study sample suffered from primary vulvodynia and 42% ($n = 19$) experienced secondary vulvodynia. Primary vaginismus was found in 22% of the patients ($n = 10$), localised PVD in 91% ($n = 41$), and generalised PVD in the rest of the sample ($n = 4$) (Table 1). Relating to psychological comorbidities, the most widespread complaint was anxiety with 62% before treatment ($n = 28$) and 40% after ($n = 18$). Thirteen women (29%) presented no psychological affections

before treatment compared to 23 after treatment (51%) (Table 2). The average number of physiotherapy sessions was 9.67 (SD \pm 3.88; range 4–20) for a duration of 30 min and a period of treatment of 2.78 months (SD \pm 2.5; range 1–6) (Table 1).

Table 1. General data.

| | Mean | s.d. | Range |
|-------------------------------|----------|------|-------|
| Age | 31 | 8.6 | 18–52 |
| | <i>N</i> | % | |
| Primary PVD | 26 | 58 | |
| Secondary PVD | 19 | 42 | |
| Localised PVD | 42 | 93 | |
| Generalised PVD | 3 | 7 | |
| Primary vaginismus | 10 | 22 | |
| Diagnosed by the experimenter | 26 | 58 | |
| Diagnosed by a gynaecologist | 18 | 40 | |
| Diagnosed by a dermatologist | 1 | 2 | |
| Number of sessions | 9.67 | 3.88 | 4–20 |
| Period of treatment (months) | 2.78 | 2.5 | 1–6 |

Perceived global score per item

A significant difference in the perceived global score at the start of treatment compared to the end of treatment was demonstrated ($p < 0.001$). The scores of all items before and after treatment were significantly improved ($p < 0.001$): perceived general well-being and health, perceived vulvar pain, perceived sexual function and perceived vaginal penetration (Table 2; Fig. 1).

Pain evaluation and characteristics

A statistically significant positive evolution is shown for perceived genital pain before, during, and after intercourse through the VAS score (mean 3.11–1.21; 7.70–4.67; 5.78–2.52, respectively; $p < 0.001$) (Table 2). Burning, stinging, irritation, stabbing, and rawness are the symptoms described in the literature [1, 19, 33]. In this study, the most pronounced pain characteristics at the beginning of treatment were burning ($n = 35$; 78%) and then stabbing ($n = 24$; 53%). At the end of treatment, 67% of the sample presented burning ($n = 30$) and 40% experienced tugging ($n = 18$) (Table 2).

Self-massage score

Self-massage of the painful area using lidocaine 2% gel was reported by 38 women (84%), out of which 26 individuals applied it every day (58%). Frequency varied from once a week (4%) to

Table 2. Comparisons of patients between pre and posttreatment.

| | Before treatment | | After treatment | | <i>p</i> -value | Difference before/after |
|------------------------------------|------------------|-------------|-----------------|-------------|-----------------|-------------------------|
| | <i>N</i> | % | <i>N</i> | % | | |
| <i>Psychological comorbidities</i> | | | | | | |
| Anxiety | 28 | 62 | 18 | 40 | | |
| Depressed | 6 | 13 | 2 | 4 | | |
| Sad | 8 | 18 | 2 | 4 | | |
| None | 13 | 29 | 23 | 51 | | |
| | <i>Mean</i> | <i>s.d.</i> | <i>Mean</i> | <i>s.d.</i> | | |
| <i>Score per items</i> | | | | | | |
| Perceived well-being and health | 6.22 | 2.86 | 4.64 | 2.26 | <0.001 | –25% |
| Perceived vulvar pain | 8.91 | 3.32 | 5.71 | 3.36 | <0.001 | –36% |
| Perceived sexual function | 21.60 | 6.76 | 17.78 | 7.10 | <0.001 | –18% |
| Perceived vaginal penetration | 40.05 | 12.40 | 29.17 | 12.99 | <0.001 | –27% |
| Perceived global score | 70.76 | 22.77 | 53.61 | 22.52 | <0.001 | –24% |
| <i>VAS Visual Analogue Scale</i> | | | | | | |
| Before vaginal penetration | 3.11 | 3.47 | 1.21 | 2.34 | <0.001 | –61% |
| During vaginal penetration | 7.70 | 2.01 | 4.67 | 2.88 | <0.001 | –39% |
| After vaginal penetration | 5.78 | 2.75 | 2.52 | 2.41 | <0.001 | –56% |
| | <i>N</i> | % | <i>N</i> | % | | |
| <i>Characteristics of pain</i> | | | | | | |
| Burning | 35 | 78 | 30 | 67 | | |
| Stabbing | 24 | 53 | 14 | 31 | | |
| Tugging | 22 | 49 | 18 | 40 | | |
| Tingling | 20 | 44 | 14 | 31 | | |
| Pinch | 19 | 42 | 15 | 33 | | |
| Rawness | 19 | 42 | 14 | 31 | | |
| Irritation | 17 | 38 | 14 | 31 | | |
| Stinging | 13 | 29 | 11 | 24 | | |
| Electric shock | 5 | 11 | 4 | 9 | | |
| Swarming | 4 | 9 | 3 | 7 | | |
| Numbness | 4 | 9 | 2 | 4 | | |

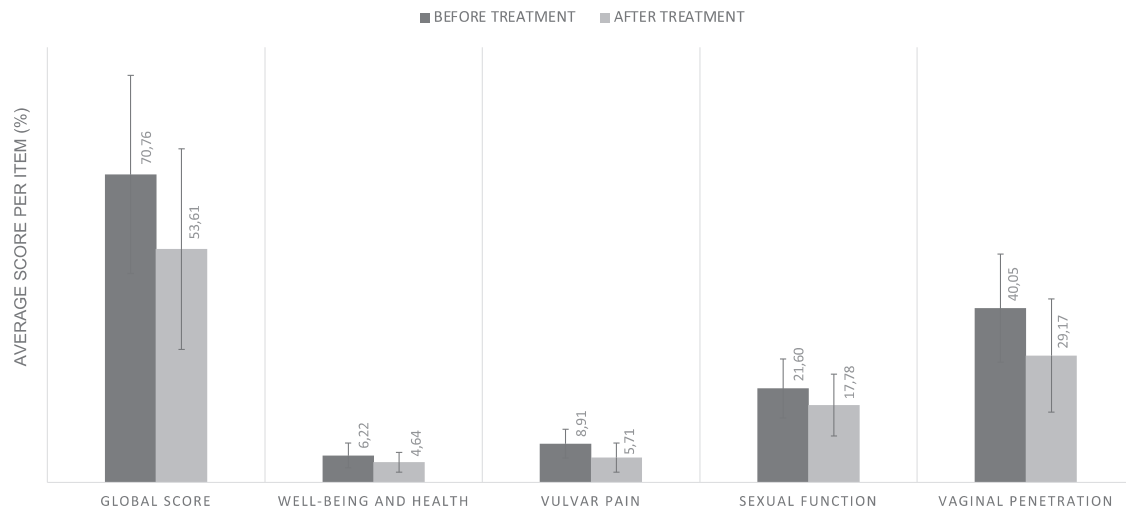


Fig. 1 Perceived global score per item before and after treatment. The scores of perceived general well-being and health, perceived vulvar pain, perceived sexual function and perceived vaginal penetration were significantly improved after treatment. The means of each item are indicated for pre and posttreatment.

three times a day (2%), with the majority massaging the area once a day (38%) (Fig. 2).

Opinions and feelings about the treatment

The question “*What do you think about treatment?*” was included in Q2. To this, 24% of the sample answered that physical treatment was extremely helpful ($n = 11$), 49% ($n = 22$) stated that it helped very much, and 22% ($n = 10$) felt it was moderately helpful. None of them stated that the treatment did not help them at all (Fig. 3).

DISCUSSION

To our knowledge, this is the first study to suggest the exclusive use of manual perineal rehabilitation with lidocaine 2% gel for the treatment of vulvodynia in women. Many studies have evaluated the effect of physiotherapy on vulvodynia using biofeedback, electrostimulation and/or PFMT [15], transcutaneous electrical nerve stimulation [34], and recently extracorporeal shock wave therapy [13]. Other studies concern medical treatment, psychological treatment or vestibulectomy [15].

Recovering the functionality of the pelvic floor, in term of awareness, contraction, relaxation, and normal tone, is one of the most important points of physical treatment. According to other studies [35, 36], the present one used both active PFMs contraction and active PFMs relaxation to achieve a reduction in tone and an improvement of the awareness of the pelvic floor [35–37]. Likewise, some authors added the simultaneous intervention of global muscle relaxation and breathing techniques to their studies [38, 39].

Women with PVD show a lower score of perception of general health compared to controls [37]. Based on the SF-36 results, Naess et al. indicated the perceived impact of PVD on these women’s lives in their study [37]. They highlighted the need to learn techniques to control the fear of pain, decrease the apprehension of a future attempt of vaginal penetration, and manage the pain-coping strategies [37, 40], which is a reason for including global relaxation and breathing techniques in the protocol of treatment. And because higher rates of sexual dysfunctions have been reported among women with PVD [17], psychoeducation on sexuality was delivered by the physiotherapist during the sessions. Vaginal dilators were not used to dilate the vagina but to regain self-confidence for the resumption of possible sexual intercourse. Patients were suggested to avoid

vaginal penetration before this step of the treatment. Talking about foreplay and sexual positions and advising patients to apply lidocaine 2% gel before intercourse were a crucial part of the treatment [2, 25].

Given that sensitisation of the peripheral vestibular nerves has been suggested as a possible mechanism of the pain in PVD [30], local anaesthetics could induce desensitisation of the vestibular area. Lidocaine ointment 5% is the most commonly recommended local medication [2, 19, 41]. In this study, lidocaine 2% gel was preferred due to previous reports of patients experiencing severe sensation of vulvar burning after the application of the lidocaine ointment 5%. Statistically, the manual perineal rehabilitation using lidocaine 2% gel had a positive impact on all the items. Regular sessions and frequent self-massage using lidocaine 2% gel reinforced the effectiveness of the treatment. It was observed that patients who continued massaging during the first COVID-19 lockdown had better results than those who gave up.

Pukall et al. reported in their review that at that time of publication, no single validated questionnaire existed that covered all the recommended domains for PVD clinical trials [26]. But Dargie et al. developed a multidimensional assessment questionnaire in their research—the Vulvar Pain Assessment Questionnaire (VPAQ), which concerns pain characteristics, emotional/cognitive functioning, physical functioning, coping skills, and partner factors [42]. A limitation of this study is that more appropriate scales and questionnaires could have been used; for example, the VPAQ, the Goetsch scale to assess subjective pain by the cotton-swab test, or the Female Sexual Distress Scale to evaluate sexually related personal distress in women [26, 43].

In the present study, a single physiotherapist carried out the treatments. This may lead to bias by installing trust and sympathy towards the experimenter and thus distorting the study results. This was reported in the responses to the open-ended questions in Q2 about perceived improvement as a result of the treatment. Some patients specified that treatment helped a lot at the beginning but stagnated after a few sessions, that it was emotionally difficult and not pleasant. Nevertheless, others stated that treatment was very beneficial and pain during intercourse was greatly reduced or even disappeared. Also, various patients added that they felt their discomfort was understood and felt less alone in their suffering.

Alternatively, since the reproducibility of the experienced therapeutic gesture is applicable, it could be a proof of the robustness of the study. Another strength of the study is that the

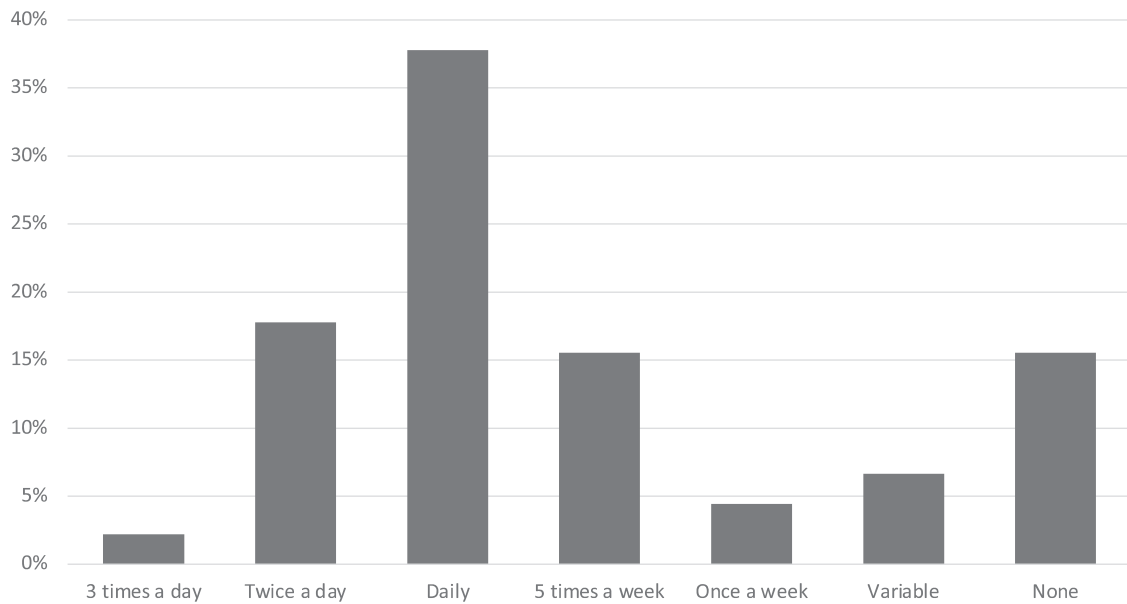


Fig. 2 Representation of the practice and frequency of self-massage with lidocaine 2% gel. 84% of the sample practiced self-massage, out of which 38% applied it once a day.

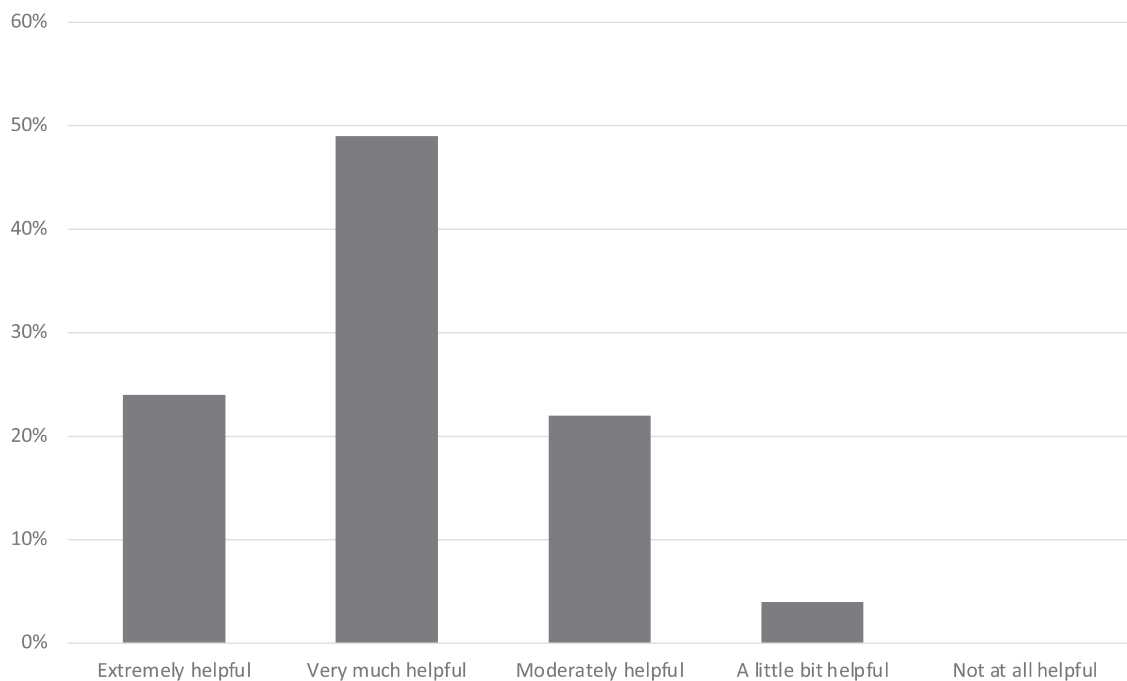


Fig. 3 Distribution of subjects' responses on treatment effectiveness. Physical therapy with lidocaine 2% gel improved 95% of the sample (24% extremely; 49% very much; 22% moderately). 5% felt it was a little bit helpful, and none of them stated that it did not help them at all.

treatment was patient-dependent according to the individual case and not the personal preference of a health care provider.

Not being able to identify a reason of their vulvar pain, women with PVD are often very affected [33]. Based on the open-ended questions of Q2, it appears that naming this pain allowed the patients to make progress in resolving this condition.

Women presenting with vulvodynia often experience medical nomadism before receiving the diagnosis [3, 4, 6, 44, 45]. American researchers showed that 60% of women with PVD consulted three or more specialists without reaching a diagnosis [2]. This confirms the results as more than half of the patients were

diagnosed by the experimenter himself. And almost all others received the diagnosis by the same gynaecologist specialised in vulvar pain, which is not representative of healthcare providers. In addition, by analysing the medical prescriptions of the sample included in this study, we found that the diagnosis of PVD is often confused with that of vaginismus. And, depending on the time taken to get the diagnosis, the duration of genital pain lasted from a few months to 21 years, and the number of specialists seen ranged from 1 to 9.

The women included in the sample who reported pain before sex might have confused it with the apprehension of pain [40].

This can probably be explained by negative emotional feelings about sexual activity despite high satisfaction in the relationship. In this study, partners are often very understanding, caring, and patient. Thus, it would be interesting to study the impact of the partner on the efficacy of the treatment.

Finally, our present study was not a randomised controlled trial (RCT), and there is a need for robust and well-designed RCTs to establish the effect of an unindividualised physiotherapy treatment in women with PVD. With this in mind, future work could include a placebo or comparison group in studies on this subject of treatment of vulvodynia. However, given the lack of RCTs, it remains inconclusive whether multimodal approaches are more effective than single treatments [46]. Furthermore, it could be interesting to evaluate the effects of the said treatment at 6 months or 1 year post-treatment.

CONCLUSION

Exclusive manual perineal rehabilitation using lidocaine 2% gel seems to be a safe and effective treatment option for provoked vestibulodynia in women in addition to self-massages, significantly improving vulvar pain, sexual function and quality of life of women with PVD.

Vulvodynia puts a significant onus on affected women, their intimate partners, and the healthcare system [33]. To date, there is no standardised, effective, and isolated physiotherapy treatment protocol in connection with PVD [33]. Therefore, the aim of this study was to present a protocol of physical treatment for women suffering from vulvodynia.

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AC: investigator, experimenter and principal author. MC: methodology of the paper and reviewer. VA: methodology of the study, principal prescriber of the sample and reviewer specialised in the subject. GV: methodology of the study and reviewer specialised in the subject.

COMPETING INTERESTS

The authors declare no conflict of interest.

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