

Title:

Women with provoked vestibulodynia experience clinically significant reductions in pain regardless of treatment: Results from a 2-year follow up study.

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Abstract

Introduction:

Provoked vestibulodynia (PVD) is a prevalent genital pain syndrome that has been assumed to be chronic, with little spontaneous remission. Despite this assumption, there is a dearth of empirical evidence regarding the progression of PVD in a natural setting. Although many treatments are available, there is no single treatment that has demonstrated efficacy above others.

Aims:

The aims of this secondary analysis of a prospective study were to (1) assess changes over a two-year period in pain, depressive symptoms and sexual outcomes in women with PVD and (2) examine changes based on treatment(s) type.

Main Outcome Measures:

Visual Analogue Scale of genital pain, Global Measure of Sexual Satisfaction, Female Sexual Function Index, Beck Depression Inventory, Dyadic Adjustment Scale, sexual intercourse attempts over the past month.

Results:

239 women with PVD completed both time one and two questionnaires. For the sample as a whole, there was significant improvement over two years on pain ratings, sexual satisfaction, sexual function, and depressive symptoms. The most commonly received treatments were physical therapy, sex/psychotherapy, and medical treatment, although 41.0% did not undergo any treatment. Women receiving no treatment also improved significantly on pain ratings. No single treatment type predicted better outcome for any variable except depressive symptoms, in which women who underwent surgery were more likely to improve.

Discussion:

These results suggest that PVD may significantly reduce in severity over time. Participants demonstrated clinically significant pain improvement, even when they did not receive treatment. Furthermore, the only single treatment type predicting better outcomes was surgery, and only for depressive symptoms, accounting for only 2.3% of the variance. This data does not demonstrate the superiority of any one treatment and underscores the need to have control groups in PVD treatment trials, otherwise improvements may simply be the result of natural progression.

Introduction

Provoked vestibulodynia (PVD) is a genital pain disorder in women characterized by burning and cutting pain at the vulvar vestibule. The prevalence rate among women in the general population is estimated to be 12%¹. Physiological and psychosocial mechanisms such as inflammation, pelvic floor muscle dysfunction, pain sensitization², and maladaptive pain cognitions³ have been suggested to explain etiology, however there is no systematic evidence supporting any single pathway. While pain is the primary symptom, PVD is also associated with sexual dysfunction and sexual dissatisfaction⁴. Unfortunately, little is known about how PVD progresses over time. The present prospective study, carried out over a two-year period, aimed to describe pain, psychosocial, and sexual changes in women with PVD.

Perhaps because there are a number of diverse etiological hypotheses, there are also a wide variety of potential treatments for PVD. Common modalities include topical lidocaine, tricyclic antidepressants, botox injections, cognitive-behavioral (CBT) sex therapy and pain management, pelvic floor physical therapy, vestibulectomy and alternative therapies such as acupuncture⁵⁻⁷. Despite many promising preliminary treatment studies, many of these studies lack a control or placebo condition⁸⁻¹⁰ and post-treatment follow-ups are generally short. Furthermore, with a few exceptions, treatments are rarely compared with one another^{11,12} and patients typically receive more than one treatment¹³. The best outcome efficacy evidence supports vestibulectomy^{5,6}, although large scale RCTs are lacking. These limitations are problematic, as without a control group, outcomes cannot be specifically attributed to the treatment being investigated. The present study aimed to examine 2-year outcomes by treatment type, as well as for women who did not undergo any treatment.

Although PVD is generally conceptualized as a chronic condition, there may be significant variation in symptoms over time. The few prospective follow-up studies of women with PVD have tended to examine only changes in prevalence and incidence over time^{14,15}, rather than change in pain and sexuality outcomes. Reed et al.¹⁴ have demonstrated a significant change in diagnostic group (PVD to non-PVD or vice versa) at two-year follow-up, with 22.2% of those initially classified as PVD going into remission. In a second follow-up study with 2 and 4-year follow-ups, it was found that only 44% of the women with PVD at year 2 were still classified as PVD cases at year 4¹⁶. One limitation of this study was that diagnosis was made using an online survey. In separate 1-year follow-up study of 72 women with PVD at time 1, only 35 reconfirmed (48%) PVD at time 2¹⁵. However, among those who no longer had PVD symptoms, 36 claimed to have never had such symptoms, which makes these findings difficult to interpret. Despite their limitations, these studies are important in demonstrating a wide variation in long-term outcomes for women with PVD. Unfortunately, none of these longitudinal studies assessed whether or not participants received treatment in the interim. Furthermore, women were simply classified based on a dichotomous variable; hence little is known about the variation in pain symptomatology for women that stay within a diagnosis, nor is anything known about changes in psychosocial or sexual variables.

In order to further document treatment outcomes, better longitudinal data are needed on the natural progression of women treated for PVD. Randomized trials have the advantage of providing a controlled

environment within which to assess treatment efficacy, however, they are limited by their strict selection criteria, which may result in a more homogeneous and potentially unrepresentative sample. Finally, when assessing long-term outcomes in women with PVD, treatment type needs to be taken into account to create a more complete picture of long-term changes.

Aims

The overarching aim of this secondary analysis of a prospective, non-treatment study was to assess, over a two-year period, changes in pain, psychosocial and sexual outcomes in women with PVD. Based on prior empirical evidence, we hypothesized that there would be significant decreases in pain between time 1 and time 2 assessments. We also hypothesized that women receiving vestibulectomy would report significantly greater pain reductions than women undergoing other treatments or no treatment. It was also hypothesized that women receiving multiple treatments would have the best outcomes on pain, psychosocial, and sexual variables.

Methods

Participants

Participants were recruited through gynecologists or other health professionals, as well as through newspaper and website advertisements. Because these data were drawn from a larger study on women with PVD and their partners, all women were required to be in a relationship at time 1. If women indicated an interest in the study, they were screened in person or by telephone to determine eligibility. The specific inclusion criteria for women with PVD were: a) pain during intercourse that was subjectively distressing, occurred on at least 80% of intercourse attempts, and had lasted > 1 year; b) pain limited to intercourse and other activities that caused pressure to be exerted on the vulvar vestibule; c) if recruited through a gynecologist, severe pain in one or more vestibular locations during the cotton swab test; d) married or cohabiting with a partner for at least 6 months. The exclusion criteria were: a) vulvar pain not clearly linked to intercourse or pressure to the vestibule; b) presence of major medical or psychiatric illness, active infection, deep dyspareunia, vaginismus, dermatologic lesion, pregnancy, age < 18 years old or > 45 years old.

Main outcome measures

Pain intensity

Pain intensity was measured using a Visual Analog Scale (VAS) by asking participants to estimate (0-10) their average provoked vulvo-vaginal pain over the past month. This measure has good validity and reliability in assessing different types of pain¹⁷. It has been shown to be sensitive to PVD treatment effects¹⁸, and correlates well with other measures of pain¹⁹.

Sexual Satisfaction

The Global Measure of Sexual Satisfaction (GMSEX)²⁰ was used to measure sexual satisfaction. The GMSEX is a five-item measure that assesses satisfaction using a 7-point Likert scale. The scale has good reliability and excellent validity²¹. The Cronbach alpha in the present sample was 0.90.

Sexual Function

The Female Sexual Function Index (FSFI) is a well-validated measure of sexual function in women²². The FSFI is divided into 6 dimensions: desire, arousal, lubrication, orgasm, sexual satisfaction, and pain. In the present study the total score was calculated omitting the pain subscale, in order to separate sexual dysfunction from pain. Higher scores indicate better sexual function, and the proposed cutoff for sexual dysfunction is 26, but because we did not include the pain subscale, the cutoff for the present sample would be 20. The Cronbach alpha for the present sample was 0.78.

Beck Depression Inventory

The Beck Depression Inventory (BDI) is a widely used, sensitive, and validated measure of depressive symptoms in adults²³. Greater scores indicate greater depressive symptoms, with scores from 0-9 indicating minimal symptoms, 10-18 indicating mild to moderate, and 19 and over indicating moderate to severe. The Cronbach alpha in the present study was 0.89.

Dyadic Adjustment Scale

The revised Dyadic Adjustment Scale (DAS)²⁴ measures relationship satisfaction, with higher scores indicating better satisfaction, and scores under 50 indicating potential distress. The original dyadic adjustment scale shows good psychometric properties, and the revised scale is a shorter version that shows high correlation with the original²⁴. The Cronbach alpha in the present study was 0.83.

Sexual behavior

Participants were asked how many times they had attempted to have sexual intercourse with vaginal penetration over the past month. The actual number of attempts, successful or not, was taken as the measure of intercourse attempts.

Procedure

This study was approved by the _____ Institutional Review Board, and all participants gave written informed consent. A research assistant was present at weekly vulvo-vaginal pain clinics. The gynecologists told eligible participants about the study, and if they were interested were instructed to meet with the research assistant. Women were either given a questionnaire package in person at a gynecology clinic or, if recruited via advertisement, the package was sent to their home. Two years later, a research assistant contacted each woman who participated at Time 1. If they agreed to participate for the follow-up they were sent a package via regular mail and were asked to complete the measures using the same instructions as at Time 1. As compensation for their time, women who completed all questionnaires at Time 1 were offered a 30-minute telephone consultation with a clinical sexologist, focusing on education about vulvo-vaginal pain and its treatment. They were also given information about health professionals (physical therapists, gynecologists, and psychologists) working in their area. The compensation at Time 2 was 25\$ per member of the couple.

Statistical analyses

All data was analyzed using SPSS version 20 (IBM corporation, USA). At the second time point, each participant was asked whether they had engaged in any type of treatment over the past 24 months. If

they reported yes, they were given a checklist with the following options: physical therapy, sex therapy/psychotherapy, medical management, surgery, acupuncture, or other. Pearson's r was used to examine correlations between demographics and variables of interest. Paired samples t -tests were used to examine the changes between T1 and T2 for the entire sample. Following this, the entire sample was split by treatment type, and paired samples t -tests were used to compare outcome variables within these groups. Finally, six multiple regression analyses were conducted using change in pain, sexual function, sexual satisfaction, dyadic adjustment, attempts at intercourse, and depressive symptoms as the outcome variables. A change score was calculated for each outcome by subtracting T1 scores from T2 scores. A separate multiple regression analysis was conducted for each outcome variable. To control for T1 variables, T1 pain was entered in the first block, followed by all other T1 variables in the second block, and treatment type entered into the third block.

Results

Sample characteristics

A total of 354 participants completed the questionnaires at Time 1 (T1), and 239 at Time 2 (T2), for a retention rate of 67.5%. Reasons for not completing T2 included not being able to re-contact or lack of interest in participating. Therefore, the final data analyzed included 239 women. Using independent samples t -tests, there were no significant differences ($p > 0.05$) on T1 variables, age or pain duration between women who completed and women who did not complete T2. Pain VAS scores at T1 in the present sample were similar to previous studies of women with PVD, which range from 6.9-7.5/10^{12,19,25}. Of these 239 women, 117 had been diagnosed with PVD by their gynecologist, and the remainder (122) met criteria for PVD-like symptoms based on the telephone screening. Other than age, there were no significant differences on any demographic, T1, or change variables between women who had been diagnosed by a gynecologist, and those that had not. Women who had been diagnosed by a gynecologist were significantly younger (28.7 vs. 33.1, $t = 3.11$, $p < 0.01$). The mean age of the sample at T1 was 30.9 years (range = 18-68, SD = 10.9). The mean pain duration at T1 was 5.5 years (range = 0.5 – 43.8, SD = 6.0), and the mean pain intensity was 6.9/10 (range = 1-10, SD = 1.9). There were no significant differences in pain duration between treatment types, although women who underwent surgery had significantly higher pain intensity at T1 compared to all other groups combined ($t = 1.92$, $p < 0.05$), and those who reported taking part in "other" treatment(s) had significantly lower pain intensity at T1 compared to all other groups combined ($t = 1.14$, $p < 0.05$) (see table 2 for means). All women were in a relationship at T1 and the mean relationship duration was 6.9 years (range = 0.5-38.4, SD = 7.6). At T2, 188 (80%) remained in the same relationship, 26 (11.1%) were with a new partner, and 21 (8.9%) were now single. Using one-way ANOVA with tukey's HSD, the only difference on any T1 variable was for T1 DAS, in which women who had a new partner at T2, had significantly lower relationship satisfaction at T1 ($F = 3.15$, $p < 0.05$). The majority (94.1%) identified culturally as XXXXX or XXXX (**blinded for review**), and had at least completed high school (95.3%). The number of women who had engaged in the different treatment types is included in Table 1, with physical therapy being the most common treatment.

Group changes

There were no significant associations between demographic variables or pain duration with change variables. On the whole, using paired samples t -tests, there were general improvements on four out of six outcome variables between T1 and T2 (see Table 2). Pain (Δ -2.8) and depressive symptoms (Δ -2.4)

were significantly lower, while sexual function ($\Delta+1.4$) and sexual satisfaction ($\Delta+1.8$) significantly increased. The only variables that did not significantly change were number of attempts at intercourse over the past month and dyadic adjustment, although the scores for the dyadic adjustment scale were within the non-distressed norms at both time points²⁴.

Changes based on treatment type

Differences between T1 and T2 variables were also examined within each treatment type (Table 2) using a significance level of $p < 0.01$ to control for multiple comparisons. For all treatments except acupuncture, there was a significant reduction in pain. There was also a significant reduction in pain for those receiving no treatment. None of the treatment groups showed significant changes in number of attempts at intercourse or relationship satisfaction. Changes in sexual function, depressive symptoms, and sexual satisfaction varied with treatment type (see Table 2), although tended to generally improve. Using norm-based scores, for DAS, all groups were in the healthy range at T1 and T2. For FSFI, all groups were in dysfunctional range at T1 and only the other-treatment group was in the functional range at T2. For BDI, all groups were in the mild group at T1, and all groups were in the minimal range at T2 except for the no-treatment group, which remained in the mild range.

Treatment comparison

Six hierarchical regression models were tested, one for each of the outcome variables. After controlling for T1 variables, no treatment type was a significant predictor of any outcome except depressive symptoms. In the model predicting change in depressive symptoms, the first step (T1 pain) was not significant ($F = 0.08, p = 0.773$) and explained 0.5% of the variance. The second step, adding T1 variables, provided a significant F-change ($F = 12.68, p < 0.001$) and explained an additional 27.5% of the variance. The significant predictors of change in depressive symptoms were T1 FSFI, T1 DAS, and T1 depressive symptoms. The third step, adding treatment types, provided a significant F-change ($F = 6.61, p < 0.01$), and explained an additional 2.3% of the variance. The only significant predictor of change in depressive symptoms at this last step was surgery ($\beta = -0.169, p < 0.05$).

Discussion

The most remarkable finding of the present study is that women with PVD generally improved over two years on pain, psychosocial, and sexuality outcomes. On the other hand, no significant changes were found for any group on dyadic adjustment or number of attempts at intercourse, despite improvements in pain. When examining outcomes based on treatment type, results showed that all treatments except acupuncture were associated with significantly lower pain levels at T2, including the 'no treatment' group. Equally striking is the fact that 41% of study participants did not receive any treatment over the two-year period despite being motivated enough to take part in research.

An examination of the entire sample indicated that there was a statistically significant change on all outcome variables with the exception of dyadic adjustment and number of attempts at intercourse. Although statistical change is important, it does not necessarily imply clinical relevance. The IMMPACT recommendations for clinical trials in chronic pain state that changes in perceived pain intensity from

baseline of 10-20% or 1/10 reflect minimal change, while changes >30% or 2/10 represent at least moderately important clinical differences²⁶. Based on these recommendations, the changes in the present sample do reflect a clinically significant change. IMMPACT recommendations are also made for depressive symptoms (BDI scores), indicating that scores that begin over 10 and are reduced to <10 at follow-up are clinically significant²⁶. Again, the present data indicate that these criteria are met for all groups except the no treatment group, leading us to conclude that women with PVD as a whole showed clinically significant changes in pain over a two-year period, even if they did not undergo treatment, while all groups except the no treatment group had clinically significant reductions in depressive symptoms. The IMMPACT guidelines do not make recommendations regarding sexual function, but despite improvements on the FSFI, scores were still in the dysfunctional range at T2.

It was also remarkable that women who did not take part in any treatment over the two-year period reported statistically significant reductions in pain that would be considered clinically significant based on IMMPACT guidelines. This is important information for treatment trials, as the majority of trials in PVD do not have a control group⁵. Considering that there appears to be a significant improvement in pain over time without treatment, it is imperative that randomized trials yield an improvement above and beyond what appears to be the natural progression of PVD. Indeed, in the present sample, when treatment type was used to predict change in outcome variables, after controlling for pre-treatment levels of all outcomes, only surgery predicted any outcome, which was depressive symptoms, and all treatment types only accounted for 2.3% of the variance. It is also important to note that, other than for two women, all women undergoing surgery had also had other treatment, hence one cannot necessarily attribute these changes to surgery alone. On the other hand, these also likely represent women for whom other conservative treatments have not worked, and thus may represent a group of particularly difficult PVD. Furthermore, this was not a randomized trial, hence women underwent treatments based on their own volition and may have been influenced by their status at Time 1. Indeed, women who underwent surgery had the greatest reductions in pain, but also had higher levels of pain initially, and this change was not significant after controlling for T1 variable. This may indicate a source of selection bias in non-randomized treatment trials. Overall, type of treatment accounted for very little variance in the models of change (<5%), suggesting that no single modality appears superior to any other. Finally, T1 variables accounted for much more of the variance than treatment type. This may indicate a wide variation initial variable levels that should be taken into account when assessing treatments, both in a clinical and research setting.

There were also certain psychosexual outcomes that did not improve, despite pain improvement. This is particularly the case for the no treatment group, which did not have any significant improvement on any variables except pain. For all groups, number of attempts at intercourse did not change significantly, despite improvements in pain and other psychosocial variables. In addition, although there was a significant improvement in sexual function, average scores were still below the recommended cut-off on the FSFI for sexual dysfunction²². Despite low sexual function, dyadic adjustment did not change, but was within healthy norms at both time points. It is tempting to assume that when the pain is reduced, there will be a commensurate improvement in psychosexual variables, but this was often not the case. While pain reduction is an important goal in treatment of PVD, once the pain is reduced, further

treatment tailored to the individual or couple may be needed to improve other aspects of quality of life. This may be a way in which some of the treatments outperform the no treatment group, as the no treatment group did not improve significantly on any psychosexual measures, while other treatment groups did. This suggests that better targeted interventions may need to be developed. Finally, this highlights the need to assess more than pain in PVD treatment trials, as other important variables may not improve, even when pain does.

The present study provides interesting data on treatment preferences, although women may have been biased because they were provided with information about treatment options. In general, women who were referred by gynecologists were more likely to engage in treatments of all type except acupuncture (table 1). This may reflect both an interest in treatment, as they were already being followed as well more options provided by their health care provider. The most common treatment by far was PT (41.0%), followed by sex therapy/psychotherapy (19.2%) and medical management (18.8%). These are likely perceived as low risk treatments, hence are more popular. Surgery was not common, and in all cases except two, was combined with some other type of treatment. This may reflect the choice of surgery as a last resort. Of particular interest is the number of women who did not undergo treatment (41%), which is consistent with previous studies¹. This high number is in spite of being given a list of treatment providers in the area, and many having been referred to the study by a gynecologist. In addition, it is not clear whether this represents the treatment preferences of the patient, or the provider.

These results make it difficult to draw clear conclusions about the natural progression of PVD. On the positive side, PVD pain appears to lessen in severity over time. On the negative side, it is not clear what the best treatment options are. Without randomization of treatments and careful controls, it is impossible to make clear conclusions about treatment effectiveness. Considering the potential for adverse outcomes, it remains important to continue to search for lower impact treatments. Empirical validation of the efficacy of each treatment type will need to be provided in the form of randomized, placebo-controlled trials before a gold-standard treatment strategy can be developed.

There are a number of limitations to the present study. First, due to this sample being part of a larger study, all women were in a heterosexual relationship. It is not known whether the present results would generalize to a sample of non-partnered or non-heterosexual women. Indeed, being in a stable and supportive relationship may have an impact on PVD over time²⁷. Nonetheless, women in this group did appear to be within the pain range of other studies on this population. Second, this study was not designed as a treatment trial, hence there is likely a treatment selection bias. Furthermore, treatments were divided into simple categories and the specific details of the treatments are not known, nor are the lengths of treatments. Therefore, there could be significant differences between the treatments received by two people in the same category, whether in duration or in the type of modalities used. In addition, treatments that women received that were not for PVD, but may have had a secondary effect on PVD were not assessed. Another limitation is that this sample was comprised of a majority of participants who sought out and took part in some form of treatment. However, considering that only 60% of women in the general vulvodynia population are thought to actually receive treatment¹, our sample, of which 59% sought treatment, appears to be representative in terms of treatment-seeking

patterns. Another bias may stem from the simple fact of taking part in a study and receiving attention from a skilled health professional in the form of an educational telephone consultation. This may have also influenced the treatments that women chose. In addition, not all women were diagnosed with PVD by a physician, but instead met criteria over a telephone screening form, hence could only be said to have “PVD-like symptoms.” It would have improved the study to have women assessed at Times 1 and 2 by a physician.

Conclusion

The course of PVD appears to reduce in severity over time. As a whole, women with PVD tend to improve on pain, whether they receive treatment or not, however some treatment appear to confer better outcomes on psychosexual variables. The present findings did not provide clear evidence in support of the superiority of any one treatment, and highlight the need for randomized, placebo-controlled trials that compare treatments in the future.

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