Multidisciplinary Treatment for Provoked Vestibulodynia

Treatment Trajectories, Predictors, and Moderators of Sexual Distress and Pain

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Objectives: Multidisciplinary treatment programs for provoked vestibulodynia (PVD) are recommended, yet few have been evaluated. This study examined women's symptom trajectories over time, as well as baseline demographic, psychosocial and pain characteristics as predictors/ moderators of sexual pain and distress following treatment at a clinic using multidisciplinary concurrent methods. We also examined the impact of baseline variables on the probability of having low sexual distress scores following treatment.

Materials and Methods: Women attending a multidisciplinary treatment program for PVD were invited to complete questionnaires before, following, and at 6 and 18 months after program completion. Questionnaires included the Female Sexual Function Index (FSFI), Female Sexual Distress Scale (FSDS), State-Trait Anxiety Inventory (STAI), Pain Catastrophizing Scale (PCS), Painful Intercourse Self-Efficacy Scale (PISES), and Pain Vigilance and Awareness Questionnaire (PVAQ). Linear mixed-effects models evaluated the FSDS and FSFI pain subscale as criterion variables, and the other baseline variables as predictors and moderators.

Results: Significant improvements in sexual distress and pain were observed over time. No significant moderators were identified, but higher baseline levels of FSFI desire and arousal predicted greater improvements in sexual distress. Similarly, higher baseline levels of desire predicted greater improvements in pain. Among women distressed at baseline and with 6 month FSDS scores, 25% (n = 35) were no longer sexually distressed at 6 months; higher baseline levels of desire were associated with greater probability of having low sexual distress at 6 months.

Discussion: Although global improvements were observed, women with poorer baseline sexual functioning were less likely to improve after multidisciplinary treatment.

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Vulvodynia is defined as vulvar pain without clear identifiable cause that lasts at least 3 months and may have associated factors (eg, psychosocial, genetic).[1] Provoked vestibulodynia (PVD) is the most common subtype, and is pain at the vaginal entrance in response to contact or penetration. Population-based studies find that ~8% of women have PVD.[2,3] Women with PVD may experience difficulties in several areas of their lives, including sexual, relationship, psychological difficulties,[4,5] and high levels of associated distress.[4,6]

PVD etiology is multifactorial[7] and multidisciplinary treatment combining medical, psychological, and physical therapy care is recommended.[8–11] A few studies suggest improvements in pain and sexual functioning following multidisciplinary treatment for PVD[12–14]; for example, our team reported improvement in all domains of women's sexual functioning and sex-related distress after multidisciplinary treatment, with gains maintained at 2 to 3 months.[14] However, literature documenting the evidence for multidisciplinary treatment for PVD is scarce[15] and a recent systematic review[16] noted that only 1 small randomized trial has examined multidisciplinary/multimodal treatment for women with PVD; the randomized trial compared behavioral therapy that was preceded by vulvar surgery and included education, pelvic floor exercises, and sexual/relational therapy (if appropriate) to behavioral therapy only, and did not include a no treatment control group.[17] The individual treatments that comprise a multidisciplinary approach for vulvodynia have varying levels of evidence to support their use (see Goldstein et al[10] for a review)—for example, randomized (noncontrolled) trials indicate that cognitive-behavioral therapy reduces pain with intercourse in women with PVD[18–20] as well as pain during physical examination,[21] whereas mixed evidence exists for various nonsurgical medical therapies. It has been noted in the literature though that the multifactorial nature of the pain suggests that combining individual therapies may provide increased benefit for affected women.[16]

More research is needed to evaluate multidisciplinary treatment for PVD as well as to examine predictors of women's outcomes following such treatment. Such information could help direct patients to optimal treatments and improve treatment practices. It has been recommended, for example, that self-efficacy be targeted early in PVD treatment, given that self-efficacy was the best cognitive/behavioral predictor of pain reduction and increased sexual satisfaction at 2 years.[22] Demographics such as age[23] and pretreatment sexual functioning[14]

have also predicted outcomes in women who received multimodal treatment for PVD, and patient expectations regarding chronic pain treatment can predict outcomes in a multidisciplinary treatment setting.[24] Overall, however, little research has examined predictors of women's outcomes following multidisciplinary treatment for PVD and it is thus not known which women may benefit most from combined treatment.

The goals of this study were to (1) assess the trajectory of women's sexual pain and distress over time, and (2) examine demographic, treatment confidence, psychosocial, and baseline pain characteristics as predictors and moderators of sexual pain and distress following participation in multidisciplinary treatment for PVD. The specific demographic, pain, and psychosocial variables that were considered as predictors/moderators in this study were: age, relationship status, PVD type (lifelong or acquired), length of PVD symptoms, anxiety, pain catastrophizing, pain self-efficacy, pain vigilance, sexual function, confidence in psychological therapy, and confidence in physiotherapy. Finally, in order to inform precision medicine approaches aimed at tailoring treatments to patients' characteristics, another aim was to examine the baseline characteristics of women who reported having low levels of posttreatment sexual distress.

MATERIALS AND METHODS

Participants

Women with PVD were referred by their physician and invited to take part in the Multidisciplinary Vulvodynia Program (MVP), as described below. Inclusion criteria were being over the age of 18 and premenopausal, having geographical access to the MVP, experiencing provoked vulvar pain for 6 months or more, and a diagnosis of PVD by a program gynecologist using a cotton swab test. Exclusion criteria for the MVP were: vulvar pain not due to PVD (eg, vulvar Crohn's disease) and having recently given birth without regular resumption of menses. Furthermore, women who reported largely unprovoked vulvar pain were not eligible to participate since the focus of the MVP to date has been provoked vulvar pain (ie, PVD). However, those women with unprovoked vulvar pain were eligible for the MVP if they also had provoked vestibular pain. Potential participants were not excluded based on any other medical or psychological factors unless such factors (eg, severe anxiety or phobia of vaginal penetration) would have interfered with program participation.

In total there were 316 women with baseline data entered: 311 with FSDS data at baseline, and 167 with baseline FSFI pain data.

Procedures

This study was approved by the clinical research ethics board at the University of British Columbia and Vancouver Coastal Health Research Institute. Participants were not compensated for their participation, and written informed consent was obtained.

Participants referred to the MVP were assessed by a program gynecologist through a comprehensive biopsychosocial interview and pelvic examination to determine whether a diagnosis of PVD would be appropriate. Program gynecologists had extensive training in vulvo-vaginal disease and sexual medicine. The pelvic examination included a visual inspection of the external genitals; speculum and bimanual examination (if tolerated); and palpation of several areas of the vulva/vestibule, such as the Skene's and minor vestibular glands (eg, 5 and 7 o'clock), with a cotton-swab. The assessment appointment also typically included recommendations about general skin care and medical therapy (eg, use of topical estradiol; lidocaine). We did not systematically collect information from physicians regarding medications that women may have been prescribed, changed, or discontinued during the course of the program. In addition, while a woman's general ability to participate in the MVP was typically assessed upon referral to and assessment for the program, we did not systematically collect information from participants regarding adherence to the various treatment components or extent of program completion.

Those women who were eligible to participate in the MVP were asked to complete a battery of questionnaires, including questions regarding demographic information, confidence in treatment, general mental health, pain-related cognitions, and sexual functioning. The timing of questionnaire administration was changed a few years after inception of the MVP, in which women were asked to fill out questionnaires for this study 6 and 18 months following program completion in addition to the baseline and discharge questionnaires; we refer to this group of women below as MVP2.

After the initial assessment, participants were grouped into cohorts of ~10 to 14 participants who advanced through the program together. The program lasted 10 to 12 weeks, and included group and individual sessions with various providers (eg, gynecologist, psychologist, physiotherapist) in the MVP. The content of the MVP has been described elsewhere.[14] In brief, participants took part in educational seminars led by a gynecologist and/or psychologist, individual pelvic floor physiotherapy sessions, group psychological skills training sessions, a group education seminar for partners, and an individual discharge appointment with a gynecologist. The purpose of this discharge appointment was to summarize progress made through the MVP and plan for continued progress, including connecting participants to additional community resources where appropriate. Referring physicians were also sent a comprehensive letter that included a treatment summary and further recommendations.

Measures

Predictor/Moderator Variables

In addition to administering the validated measures listed below, several investigator-derived questions were administered and additional information was obtained from a chart review. Information captured included participant age, relationship status, how long the participant had experienced PVD symptoms, and whether the PVD pain was primary (ie, present since first penetration attempt) or secondary (ie, developed after a period of pain-free penetration). A subset of participants was also asked about their confidence in psychological skills training and physiotherapy, rated on a scale from 0 (*not confident*) to 10 (*completely confident*). All of the validated measures indicated below have been used in the vulvodynia research literature, and almost all are among the most common tools used in the assessment of women with vulvodynia.[10]

State-Trait Anxiety Inventory (STAI). The 20-item state anxiety subscale of the STAI was utilized in the current study.[25] Participants indicated how they currently felt using a 4-point scale from 1 (not at all) to 4 (very much so), with higher scores indicating higher levels of anxiety. Possible scores on this scale range from 20 to 80. The state subscale of the STAI has high internal consistency.[25]

Pain Catastrophizing Scale (PCS). The PCS captures the degree to which participants experience certain thoughts

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or feelings when experiencing pain.[26] For the purposes of this study, we asked participants to think specifically of their vulvar pain when completing the PCS. Although subscales can be calculated from the 13 items administered (ie, rumination, magnification, and helplessness), the PCS total score was utilized for the current study. Items are rated on a scale from 0 (not at all) to 4 (all the time), with higher scores indicating greater levels of catastrophizing. Possible total scores on the PCS range from 0 to 52. Past research has demonstrated high internal consistency and validity among outpatient and community samples.[27]

Painful Intercourse Self-Efficacy Scale (PISES). The PISES assesses women's perceived ability to participate in sexual and penetrative activity and to reach certain pain management goals. Twenty items were administered to assess 3 dimensions of self-efficacy associated with pain during intercourse, as adapted from the Arthritis Self-Efficacy Scale.[28–30] Specifically, items assessed self-efficacy for: (1) reducing such pain and its sexual/relational impact; (2) performing certain sexual activities and other activities involving penetration; and (3) controlling other symptoms associated with intercourse pain (eg, frustration). Items were rated on a 10 to 100 point scale ranging from 10 (very uncertain), 50 (moderately uncertain) to 100 (very certain), and the total score of the PISES, calculated by taking the mean of the 3 subscale scores, was used for analyses. Higher scores on this measure indicate higher levels of self-efficacy and scores can range from 10 to 100.

Pain Vigilance and Awareness Questionnaire (PVAQ). The PVAQ is a 16-item measure that captures pain awareness, consciousness, vigilance, and observation.[31] Participants were asked to consider any pain experiences over the past 2 weeks, and indicate how frequently each item described their pain response. Items were rated on a scale from 0 (never) to 5 (always), with higher scores indicating greater attention to pain and a possible score range of 0 to 80. Previous research has demonstrated evidence of validity and internal consistency.[31]

Female Sexual Function Index (FSFI)—desire and arousal. This questionnaire measures female sexual function over the past 4 weeks.[32] It consists of 19 items which are scored on various subscales. The desire and arousal subscales were utilized as predictors for the current study, with higher scores indicating greater sexual functioning/levels of desire and arousal. Item scores on the individual FSFI subscales are added and the resulting sum is multiplied by a domain factor; the desire subscale score can range from 1.2 to 6 and the arousal subscale score can range from 0 to 6. For this study, modified scoring criteria were used, where only the data from sexually active participants were included in the calculation of the arousal score.[33] Sexually inactive participants were excluded because scores on the FSFI are negatively biased if a respondent reports no sexual activity in the previous 4 weeks (ie, a person might appear to experience sexual dysfunction when they really were just sexually inactive). The FSFI has been demonstrated to have good internal consistency for scale scores, with $\alpha = 0.89$,[32] and research suggests that the FSFI is reliable and valid for use with women with vulvodynia.[34]

Outcome Variables

Two outcome measures were selected.

FSFI—pain. The first outcome was the FSFI pain subscale. Similar to the arousal subscale, modified scoring criteria were used in scoring the FSFI pain subscale, whereby only those participants who reported being sexually active and attempting intercourse/penetration in the past 4 weeks were included.[33] Higher scores on this subscale indicate less frequent and/or lower levels of pain associated with vaginal penetration, and scores can range from 0 to 6.

Female Sexual Distress Scale (FSDS). The FSDS consists of 12-items designed to capture sexual distress, rated on a scale from 0 (never) to 4 (always).[35] Higher scores reflect greater levels of sexually-related distress, scores can range from 0 to 48, and a score of ≥ 15 has been recommended to identify women with clinically significant distress. Previous research has demonstrated evidence of high internal consistency, moderate test-retest reliability, and discriminant validity.[35]

Data Analyses

All data analyses were performed using R.[36]

Characterizing Missing Data

For the validated measures used in this study, means replacement was used if participants were missing 20% or less of items on a particular questionnaire/subscale. In addition, to determine whether those participants who provided data at each time point differed from those who did not provide such data, 2 techniques were utilized. In general, baseline data presented in Tables 1 and 3 were compared between the 2 groups (those with complete and incomplete data). Similarly, we compared the baseline variables for those participants who were sexually active at baseline versus those who were not sexually active. If the variable in question was categorical, Fisher's exact test was used. If the variable was continuous, the Wilcoxon-rank sum test was utilized.

Measuring Treatment Outcome

To assess the trajectory of the outcome variables over time, linear mixed-effects models were utilized with intercept modeled as a random effect and independent variance/covariance structure of the residuals. There were insufficient data for each individual to model time as a random effect. Thus, time was entered as a fixed effect, and was split into 2 epochs. The first (Time 1) describes the difference between baseline to discharge, and the second (Time 2) describes the slopes from discharge to 18 months postdischarge. This allowed for modelling of attenuation effects where the largest differences are likely to be seen immediately post-treatment, and any subsequent changes are likely to level off or change more slowly in the postdischarge time period, an approach used by others in treatment research.[37] Finally, mixed-effects models allow for the use of all available data for any given participant. This means that women did not have to have complete outcome data at all times to be included in the model for making point estimates; however, the interaction terms were estimated using only complete data. Estimates for baseline and discharge values were calculated with more data than the later time points, which would appear as wider confidence intervals for later times.

Identifying Predictors and Moderators

To model the impact of baseline variables on the change or magnitude of values of FSDS or FSFI pain scores posttreatment, we used linear mixed-effects models with baseline FSDS or FSFI pain scores as a covariate, time since discharge as a main effect (0, 6, and 18 mo), intercept modeled as a random effect, and independent variance/

TABLE 1. Baseline Demographic and Clinical Variables and Baseline Validated Questionnaire Scores for those with FSDS at Baseline (n = 311)

	Total No. 311 (n [%] Unless Otherwise Indicated)
Age (y)	
Mean (SD)	28.8 (± 6.6)
Missing	1 (0.3)
Marital status	
Partnered	150 (48)
Not partnered	159 (51)
Missing	2 (1)
Sexual orientation	
Heterosexual	291 (94)
Other	12 (4)
Missing	8 (3)
Relationship length (mo)	
Median (IQR)	48.0 (25.0-84.0)
Missing	50 (16.1)
Education	
High school or less	19 (6)
Some college	59 (19)
2 y college	41 (13)
4 y college	103 (33)
Postgraduate degree	87 (28)
Missing	2 (1)
Annual income	
< $20,000	51 (16)
$20,000-$39,999	47 (15)
$40,000-$59,999	53 (17)
$60,000-$79,999	42 (14)
$80,000-$99,999	29 (9)
$100,000 or more	53 (17)
Missing	36 (12)
Current pain with penetration*	
No	3 (1)
Yes	285 (92)
Missing	23 (7)
Average pain intensity during penetration in the last 4 wk	
Mean (SD)	6.4 (± 2.4)
Missing	76 (24)
Attempted penetration in the last 4 wk	
Attempted vaginal penetration	235 (76)
Did not attempt vaginal penetration	56 (18)
Missing	20 (6)
Length of symptoms (mo)	
Median (IQR)	52.0 (24.0-108.0)
Missing	12 (4)
PVD type	
Acquired	174 (56)
Life long	114 (37)
Missing	23 (7)
FSFI desire (possible range of scores = 1.2-6)	
Mean (SD)	2.7 (± 1.2)
Missing	6 (2)
FSFI arousal (possible range of scores = 0-6)†	
Mean (SD)	3.5 (± 1.4)
Missing	56 (18)
STAI state subscale (possible range of scores = 20-80)	
Mean (SD)	41.8 (± 11.2)
Missing	9 (3)
PCS (possible range of scores = 0-52)	
Mean (SD)	25.9 (± 12.2)
PISES (possible range of scores = 10-100)	
Mean (SD)	54.3 (± 17.2)
Missing	18 (6)
PVAQ (possible range of scores = 0-80)	
Mean (SD)	40.5 (± 12.4)
Missing	10 (3)
FSFI pain (possible range of scores = 0-6)‡	
Mean (SD)	2.1 (± 0.9)
Missing	145 (47)
FSDS (possible range of scores = 0-48)	
Mean (SD)	31.5 (± 10.2)
Confidence in psychological treatment (possible range of scores = 0-10)§	
Mean (SD)	4.7 (± 2.6)
Missing	130 (42)
Confidence in physiotherapy treatment (possible range of scores = 0-10)§	
Mean (SD)	6.9 (± 2.2)
Missing	128 (41)

Percentages may not add up to 100% due to rounding.

*In order to participate in the Multidisciplinary Vulvodynia Program (MVP), participants needed to have a diagnosis of PVD. This variable refers to current pain with penetration; it is possible that participants who answered "no" may have responded as such given that they were likely not experiencing provoked pain at the actual time of questionnaire completion.

†Arousal was measured only among women who were sexually active over the previous 4 weeks. Among the 56 missing, 32 indicated that they were not sexually active, and 9 did not indicate whether they were sexually active or not. The remaining 15 indicated that they were sexually active, but did not provide responses to the arousal questions.

‡Pain was measured only among women who were sexually active and attempted penetration over the previous 4 weeks.

§These variables were only available for women in the MVP2 group as these questions were not asked for earlier cohorts.

FSDS indicates Female Sexual Distress Scale; FSFI, Female Sexual Function Index; PCS, Pain Catastrophizing Scale; PISES, Painful Intercourse Self-Efficacy Scale; PVAQ, Pain Vigilance and Awareness Questionnaire; PVD, provoked vestibulodynia; STAI, State-Trait Anxiety Inventory.

covariance structure of the residuals. Variables measured at baseline were added and their interaction with time was measured to assess if they moderated change in outcomes. Significant interaction terms would indicate that the rate of change posttreatment was different among levels of the variable measured at baseline (ie, a moderator). If the interaction was not significant, it was removed and tested for the main effects of the variable in predicting the magnitude of the outcomes posttreatment (ie, a predictor). Similarly, if time was not significant, it was removed from the model and the main effect of the predictor was assessed across all time points collapsed.

Baseline variables considered as predictors/moderators were age, relationship status, PVD type (lifelong or acquired), length of

TABLE 2. Estimated Means and 95% CI for FSDS and FSFI Pain Scores at Each Time Point From the Mixed-Effects Regressions

	n	FSDS Total Score (95% CI)	n	FSFI Pain Subscale (95% CI)
Baseline	311	31.54 (30.31-32.78)	167	2.12 (1.94-2.30)
Discharge	251	24.43 (23.17-25.69)	92	3.13 (2.95-3.31)
6 mo	145	22.38 (21.20-23.57)	62	3.24 (3.09-3.40)
18 mo	76	18.29 (16.25-20.32)	28	3.47 (3.17-3.76)

CI indicates confidence interval; FSDS, Female Sexual Distress Scale; FSFI, Female Sexual Function Index.

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PVD symptoms (months), anxiety (STAI), pain catastrophizing (PCS total score), painful intercourse self-efficacy (PISES total score), PVAQ, and desire (FSFI) and arousal (FSFI). These variables were selected given that they have all been examined as predictors in previous PVD or chronic pain research.[14,22,28,38,39] Additional baseline variables that were also considered as predictors/moderators were confidence in psychological treatment (0 to 10) and confidence in physiotherapy (0 to 10) given research indicating relationships between expectations and outcomes among patients receiving multidisciplinary treatment for chronic pain.[24]

Identifying Predictors of FSDS <15 at 6 Months

We defined women as treatment responders if their FSDS scores at 6 months were below the cut-off of 15, but their baseline scores were above 15. We excluded 5 women who had baseline scores <15 as well as 6 month scores <15 (ie, they were neither responders or nonresponders) in order to focus our analyses on women who were distressed before the treatment program but no longer distressed postprogram. We used logistic regressions to model the impact of baseline variables on the probability of being a responder.

RESULTS

Internal Consistency of Measures

Cronbach's α is a measure of internal consistency of a scale. All of the baseline questionnaires utilized in this study had high Cronbach's α scores,[40] with the exception of the FSFI pain subscale: STAI (0.94), PCS (0.93), PISES (0.91), PVAQ (0.87), FSFI desire (0.94), FSFI arousal (0.91), and FSDS (0.93). For the FSFI pain subscale, Cronbach's α was 0.61 at the pretreatment assessment; this lower α may be due to the fact that participants could have experienced infrequent pain but the pain was severe upon occurrence. It may also be due to the small number of items in the FSFI pain scale.

Baseline Characteristics of Overall Sample

A total of 316 women had baseline data entered for at least 1 of the outcome measures (FSDS; FSFI pain). The age of these participants ranged from 18 to 59 years. On average, participants were in their late 20s ($M = 28.8 \pm 6.6$ y). Approximately half (48%) were in a romantic relationship at baseline, and the majority (94%) identified as heterosexual. Length of relationship varied greatly (0 to 480 mo), with a median length of 48.0 months (4 y). Just over half (61%) held 4-year college or postgraduate degrees and 40% of participants reported an annual income > $60,000 (Canadian dollars).

In addition, approximately half of participants (55%) reported that their pain was acquired, and the majority (91%) indicated that they were experiencing current pain with penetration when they began services with the MVP. When rating their average pain intensity on a scale from 0 to 10, participants reported experiencing moderate to severe pain over the past 4 weeks ($M = 6.4 \pm 2.4$), though only 3 quarters of participants attempted vaginal penetration during that time. The length of time having experienced vulvar pain varied greatly (range = 5 to 492 mo), though the median length was 53.5 months (~4.5 y).

Sexually Active Versus Not Active Participants

We compared the baseline variables for women who were sexually active at baseline versus those women who were not sexually active. Women who reported no sexual activity at baseline (n = 34) were significantly different from those who were sexually active at baseline (n = 282) for several characteristics. For those women who were not sexually active, relationship length was significantly longer ($M = 77.8 \pm 55.3$ vs. 61.2 ± 56.2 mo, $P = 0.04$), they had significantly lower FSFI desire scores ($M = 2.1 \pm 1.1$ vs. 2.8 ± 1.2, $P = 0.0006$), higher STAI scores ($M = 47.9 \pm 13.7$ vs. 41.0 ± 10.6, $P = 0.007$), and lower PISES scores ($M = 42.2 \pm 17.0$ vs. 55.6 ± 16.7, $P < 0.0001$).

Sexual Distress: Missing Data

A total of 311 participants had FSDS recorded at baseline, 251 had FSDS recorded at discharge, 145 had FSDS recorded at 6 months postdischarge, and 76 had FSDS recorded at 18 months postdischarge. Six and 18 months follow-up was only included for the 184 MVP2 women who had FSDS at baseline. For the 311 women with baseline FSDS data, a summary of their baseline demographic and clinical variables, as well as their baseline scores for the validated questionnaires utilized in this study, is shown in Table 1.

Participants missing FSDS at discharge (n = 60) did not differ significantly from those not missing FSDS discharge data (n = 251) for any of the baseline variables in Table 1.

A similar pattern was observed for participants missing 6 months follow-up data (n = 39), with no significant differences in baseline variables.

Finally, none of the variables listed in Table 1 were significantly different between those participants missing 18 months of follow-up data (n = 108) versus those not missing (n = 76).

Sexual Distress Over Time

There was a significant relationship between time in both time chunks and FSDS at the 3 follow-up times (Time 1 $P < 0.0001$, Time 2 $P < 0.0001$). This suggests that FSDS changed from baseline to discharge, and also in the postdischarge phase out to 18 months. The estimated means and 95% confidence intervals (CIs) are reported in Table 2 while Figure 1 provides a graphical representation. Both show that the mean FSDS score dropped substantially at discharge from baseline, and that it continued to decline at 6 and 18 months follow-up, albeit at a slower rate. The mean FSDS score at each time point, however, still remained above the clinical cut-off score of ≥ 15.

Sexual Pain: Missing Data

A total of 167 women had FSFI pain recorded at baseline, 92 had FSFI pain recorded at discharge, 62 had FSFI pain recorded at 6 months postdischarge, and 28 had FSFI pain recorded at 18 months postdischarge. Six and 18 months follow-up was only included for the 100 MVP2 women who had FSFI pain data at baseline. A summary of baseline demographic, clinical, and questionnaire scores information is presented in Table 3 for the 167 women with baseline FSFI pain data. Participants missing FSFI pain scores at baseline (n = 149) did not differ significantly from those not missing (n = 167) except that they were less likely to be partnered (42% vs. 54%, $P = 0.04$) and had lower PISES scores (46.8 ± 16.4 vs. 60.6 ± 15.2, $P < 0.0001$).

Participants missing FSFI pain scores at discharge (n = 75) did not differ significantly from those not missing for any of the baseline variables (n = 92) in Table 3. Of the 75 missing scores at discharge, 9 women indicated that they were not sexually active, 37 were missing sexual activity information, and 29 indicated that they were sexually active but were missing the pain subscale.

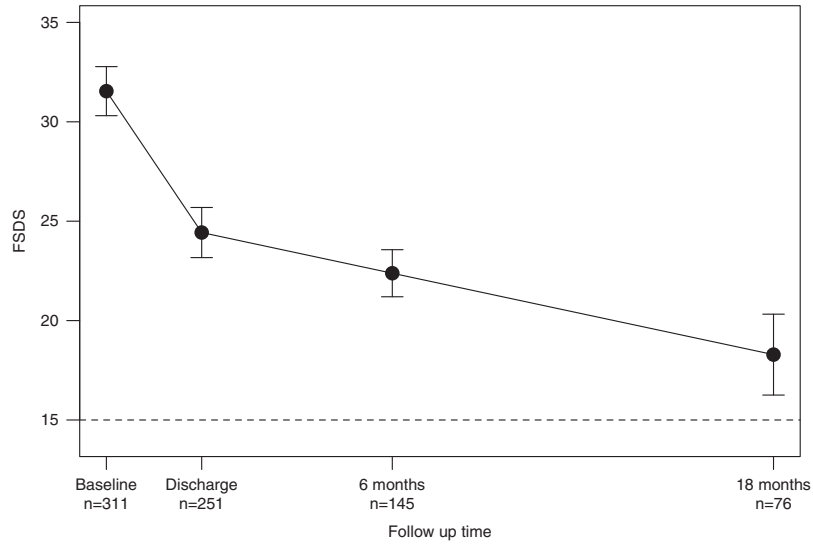

FIGURE 1. Mean Female Sexual Distress Scale (FSDS) at each time point, with bars representing 95% confidence intervals. The dotted line represents the recommended cut-off (≥15) to identify women with clinically significant levels of distress. Follow-up times at 6 and 18 months include only Multidisciplinary Vulvodynia Program (MVP) 2 participants. Higher scores indicate higher levels of sexual distress.

Finally, none of the variables listed in Table 3 were significantly different between those participants missing 6 months of follow-up data (n = 38) versus not missing (n = 62), or at 18 months of follow-up data (n = 72) versus those not missing (n = 28) (*P*'s > 0.05). Of the 38 missing pain scores at 6 months, 7 participants indicated that they were not sexually active, 22 were missing sexual activity information, and 9 indicated that they were sexually active but were missing the pain subscale. Finally, of the 72 missing pain scores at 18 months, one participant indicated that she was not sexually active, 56 were missing data about sexual activity, and 15 indicated that they were sexually active, but were missing the pain subscale.

Sexual Pain Over Time

There was a significant relationship between time in both time periods and FSFI pain scores at the 3 follow-up times (Time 1 $P < 0.0001$, Time 2 $P = 0.05$), although the slope is much weaker postdischarge. These results suggest that there was an increase in FSFI pain scores (ie, corresponding with a reduction in pain and/or corresponding with a reduced frequency of pain) at discharge compared with baseline, and that the FSFI pain scores continued to increase very slightly out to 18 months postdischarge. The estimated means and 95% CIs are reported in Table 2 and represented graphically in Figure 2.

Moderators and Predictors of Sexual Distress and Pain

Sexual Distress

No significant moderators were identified, and most variables were not significant as predictors (*P*s > 0.05, Table 4). However, FSFI desire and FSFI arousal were significantly associated with FSDS posttreatment.

FSFI desire subscale scores at baseline were significantly associated with FSDS scores posttreatment ($b = -1.98$, 95% CI = −3.00 to −0.95, $P = 0.0002$) after baseline FSDS scores were accounted for. The model coefficient suggests that for every increase in 1 unit of the FSFI desire subscale, the FSDS score posttreatment was ~2 points lower for any given time point (SE = 0.52, $t = -3.78$). This suggests that those women with higher levels of desire at baseline saw larger improvements in sexual distress at posttreatment than those with lower baseline desire scores.

FSFI arousal subscale scores at baseline were significantly associated with FSDS scores posttreatment ($b = -1.39$, 95% CI = −2.36 to −0.41, $P = 0.01$) after baseline FSDS scores were accounted for. The model coefficient suggests that for every increase in 1 unit of the FSFI arousal subscale, the FSDS score posttreatment was 1.4 points lower for any given time point (SE = 0.50, $t = -2.79$). This suggests that those women with higher levels of arousal at baseline saw larger improvements in FSDS posttreatment scores than those with lower scores.

Sexual Pain

No significant moderators were identified, and most variables were not significant as predictors (*P*s > 0.05; Table 4). However, FSFI desire at baseline was significantly associated with FSFI pain scores posttreatment ($b = 0.19$, 95% CI = 0.01-0.36, $P = 0.04$) after baseline FSFI pain scores were accounted for. The model coefficient suggests that for every increase in 1 unit of the FSFI desire subscale, the FSFI pain score posttreatment was 0.19 points higher (indicating less frequent/lower levels of pain) for all time points collapsed (SE = 0.09, $t = 2.04$). This suggests that those women with higher levels of desire at baseline saw larger improvements in FSFI pain scores than those with lower baseline desire scores. All results for FSFI pain relate only to women who reported being sexually active and attempting penetration/intercourse (see the Materials and Methods section).

Predictors of FSDS Scores <15 at 6 Months

FSDS scores were only available at 6 months for women in the MVP2 group. At 6 months, there were 148 women with FSDS scores, 40 (22%) of whom had FSDS scores <15. At baseline, 7 (5%) of these 148 women had FSDS scores <15. Of those 7, 5 remained below 15 at 6 months, while 2 were above 15 at 6 months. Of the 141 women that were ≥15 at baseline, 35 (25%) changed from ≥15 to <15 by 6 months. This is a significant increase in the

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TABLE 3. Baseline Demographic and Clinical Variables and Baseline Validated Questionnaire Scores for those with FSFI Pain* Data at Baseline (n = 167)

	Total No. 167 (n [%] Unless Otherwise Indicated)
Age (y)	
Mean (SD)	28.2 (± 6.3)
Marital status	
Partnered	90 (54)
Not partnered	76 (46)
Missing	1 (1)
Sexual orientation	
Heterosexual	156 (93)
Other	7 (4)
Missing	4 (2)
Relationship length (mo)	
Median (IQR)	48.0 (26.5-83.0)
Missing	20 (12.0)
Education	
High school or less	9 (5)
Some college	37 (22)
2 y college	26 (16)
4 y college	56 (34)
Post-graduate degree	39 (23)
Annual income (Canadian dollars)	
< $20,000	33 (20)
$20,000-$39,999	24 (14)
$40,000-$59,999	27 (16)
$60,000-$79,999	25 (15)
$80,000-$99,999	13 (8)
$100,000 or more	25 (15)
Missing	20 (12)
Current pain with penetration†	
No	2 (1)
Yes	163 (98)
Missing	2 (1)
Average pain intensity during penetration in the last 4 wk	
Mean (SD)	6.4 (± 2.2)
Missing	7 (4)
Attempted penetration in the last 4 wk	
Attempted vaginal penetration	160 (96)
Did not attempt vaginal penetration	1 (1)
Missing	6 (4)
Length of symptoms (mo)	
Median (IQR)	50.0 (24.0-84.0)
Missing	6 (4)
PVD type	
Acquired	94 (57)
Life long	60 (36)
Missing	13 (8)
FSFI desire (possible range of scores = 1.2-6)	
Mean (SD)	2.8 (± 1.2)
Missing	2 (1)
FSFI arousal (possible range of scores = 0-6)‡	
Mean (SD)	3.4 (± 1.3)
Missing	3 (2)
STAI state subscale (possible range of scores = 20-80)	
Mean (SD)	40.9 (± 10.2)
Missing	2 (1)
PCS (possible range of scores = 0-52)	
Mean (SD)	25.2 (± 12.2)
Missing	1 (1)
PISES (possible range of scores = 10-100)	
Mean (SD)	60.6 (± 15.2)
Missing	8 (5)
PVAQ (possible range of scores = 0-80)	
Mean (SD)	40.6 (± 12.3)
Missing	4 (2)
FSFI pain (possible range of scores = 0-6)	
Mean (SD)	2.1 (± 0.9)
FSDS (possible range of scores = 0-48)	
Mean (SD)	31.1 (± 10.3)
Missing	1 (1)
Confidence in psychological treatment (possible range of scores = 0-10)§	
Mean (SD)	4.8 (± 2.5)
Missing	69 (41)
Confidence in physiotherapy treatment (possible range of scores = 0-10)§	
Mean (SD)	7.0 (± 2.1)
Missing	68 (41)

Percentages may not add up to 100% due to rounding.

*Pain was measured only among women who were sexually active and attempted penetration over the previous 4 weeks.

†In order to participate in the MVP, participants needed to have a diagnosis of PVD. This variable refers to current pain with penetration; it is possible that participants who answered "no" may have responded as such given that they were likely not experiencing provoked pain at the actual time of questionnaire completion.

‡Arousal was measured only among women who were sexually active over the previous 4 weeks. Among the 3 missing, all 3 indicated that they were sexually active, but did not fill in the arousal questions.

§These variables were only available for women in MVP2 as these questions were not asked for earlier participants.

FSDS indicates Female Sexual Distress Scale; FSFI, Female Sexual Function Index; PCS, Pain Catastrophizing Scale; PISES, Painful Intercourse Self-Efficacy Scale; PVAQ, Pain Vigilance and Awareness Questionnaire; STAI, State-Trait Anxiety Inventory.

proportion of women with scores below the cut-off from baseline to 6 months (McNemar test $P < 0.0001$).

Logistic regressions revealed associations between the odds of having FSDS <15 at 6 months if FSDS was >15 at baseline and the FSFI desire subscale (odds ratio = 1.76, 95% CI = 1.25-2.53, $P = 0.001$) at baseline. The model suggests that increasing levels of FSFI desire at baseline were associated with a greater probability of being a responder for FSDS at 6 months (ie, having a FSDS score <15).

DISCUSSION

The results of this study demonstrated self-reported improvement in sexual pain and distress upon taking part in a multidisciplinary treatment program for PVD. This study is the first to predict women's treatment trajectories following multidisciplinary treatment for PVD, and the findings contribute to the currently small body of literature supporting a multidisciplinary approach to managing this pain.[14] It has been theorized that multidisciplinary approaches to the treatment of PVD have been successful due to addressing the biopsychosocial needs of patients, along with the strength of a team approach, the way that the therapies complement each other, and patients' feelings of safety at being cared for by an interdisciplinary team.[13,41] While the current study did not address the reasons for this success, the results presented here support further use and study of such programs.

The results of the current study suggest that baseline desire and arousal are associated with posttreatment sexual

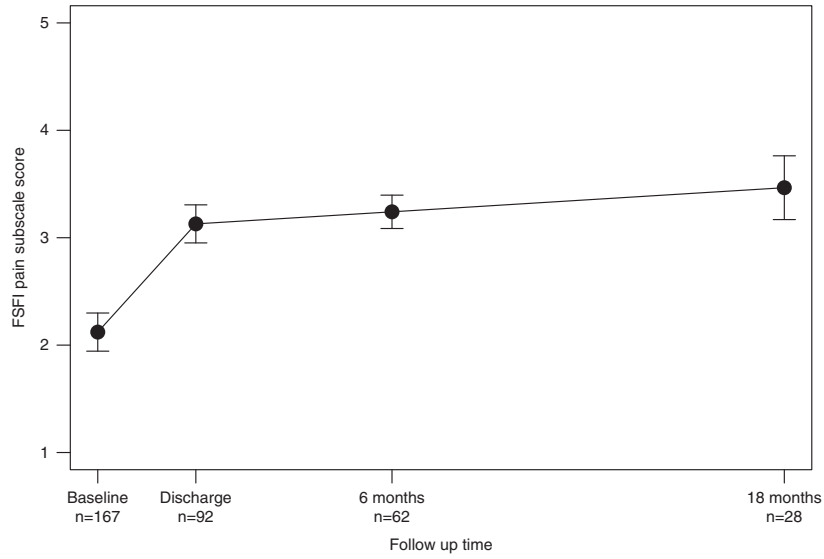

FIGURE 2. Estimated Female Sexual Function Index (FSFI) pain at each follow-up time, with bars representing 95% confidence intervals. Follow up times at 6 and 18 months include only Multidisciplinary Vulvodynia Program (MVP) 2 participants. Higher scores indicate less frequent/lower levels of pain associated with vaginal penetration.

distress. On average, sexual distress was lower for those with higher baseline desire and arousal. Similarly, baseline desire was a statistical predictor of pain posttreatment. On average, posttreatment pain scores were better for those women with higher levels of baseline desire. These results highlight the importance of sexual functioning in predicting treatment trajectory. In order to gain further insight into whom may benefit most from multidisciplinary treatment for PVD, we also examined the proportion of women who went from sexually distressed before the program to nondistressed at 6-month follow-up (ie, below the cut-off score on the FSDS). Twenty-five percent of women in our sample reported sexual distress at baseline but were not distressed 6 months following the treatment program. These "treatment responders" were more likely to have higher levels of sexual desire before receiving the multidisciplinary treatment program. Future research is needed to test whether women with poorer reported sexual functioning may require additional support and/or alternative programming (eg, increased number of psychological and/or physiotherapy sessions),

TABLE 4. Regression Coefficients From Mixed-effects Models Investigating Predictors/Moderators of Change Up to 18 Months Posttreatment for FSFI Pain and FSDS, and Up to 6 Months Posttreatment for FSDS Responders

	Outcome Variables								
	FSFI Pain*			FSDS*			FSDS Responders at 6 mo		
Variables	**N**	**Coefficent**	**95% CI**	**N**	**Coefficent**	**95% CI**	**N**	**OR**	**95% CI**
Age (y)†	167	0.03	−0.001 to 0.06	310	−0.06	−0.25 to 0.12	142	0.99	0.93-1.05
Marital status: partnered	166	Reference		309	Reference		142	Reference	
Marital status: not partnered		0.29	−0.11 to 0.69		−0.71	−3.03 to 1.62		1.18	0.42-3.01
Symptom length (mo)	161	0.001	−0.001 to 0.004	299	0.004	−0.01 to 0.02	142	1.00	0.99-1.002
PVD type: acquired	154	Reference		288	Reference		131	Reference	
PVD type: lifelong		0.03	−0.38 to 0.45		0.43	−1.95 to 2.81		0.89	0.39-2.00
STAI state subscale	165	−0.005	−0.02 to 0.02	302	0.06	−0.05 to 0.17	141	1.00	0.96-1.03
PCS	166	−0.01	−0.03 to 0.004	311	0.02	−0.09 to 0.14	142	0.99	0.96-1.03
PISES	159	0.01	−0.002 to 0.03	293	−0.07	−0.14 to 0.01	126	1.02	1.00-1.05
PVAQ	163	−0.01	−0.03 to 0.006	301	−0.02	−0.12 to 0.08	137	0.99	0.96-1.02
FSFI desire	165	**0.19**	**0.01-0.36**	305	**−1.98**	**−3.00 to −0.95**	140	**1.76**	**1.25-2.53**
FSFI arousal	164	0.15	−0.01 to 0.32	255	**−1.39**	**−2.36 to −0.41**	113	1.25	0.93-1.71
Confidence in psychological treatment	98	0.03	−0.06 to 0.13	181	−0.44	−1.07 to 0.18	142	0.95	0.82-1.11
Confidence in physiotherapy	99	−0.02	−0.13 to 0.08	183	−0.47	−1.21 to 0.28	142	1.10	0.90-1.35

FSFI pain and FSDS were analyzed using linear models, while FSDS responders were analyzed using logistic regressions. Shown are the linear regression coefficients and 95% CI, and the OR and 95% CIs for the logistic regressions.

*These models include the main effect of time and are adjusted for baseline values of the outcome variable.

†Age was centered and scaled.

CI indicates confidence intervals; FSDS, Female Sexual Distress Scale; FSFI, Female Sexual Function Index; OR odds ratio, PCS, Pain Catastrophizing Scale; PISES, Painful Intercourse Self-Efficacy Scale; PVAQ, Pain Vigilance and Awareness Questionnaire; STAI, State-Trait Anxiety Inventory.

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particularly given that individualized, multidisciplinary treatment has been recommended in the PVD literature.[8,42] The majority of women in the current study reported elevated FSDS scores across the program and follow-up time periods, suggesting that other variables and/or treatment regimens may be important for addressing women's sexual distress in the context of PVD.

Despite our significant findings, several variables were not significant in predicting or moderating outcomes. For example, pain catastrophizing was not a significant predictor of either sexual pain or distress, despite being related to outcomes in previous PVD research[28] as well as temporomandibular disorder.[39] Self-efficacy was also not significantly associated with sexual pain or distress in the current study even though previous research has indicated that it is likely an important variable in PVD treatment and symptom trajectory. For example, Davis et al[22] reported that pain self-efficacy in women with PVD (who were not in a treatment study) was a significant predictor of women's improvement in sexual function, pain intensity, and sexual satisfaction 2 years later, and that increases in self-efficacy were associated with greater numbers of penetration attempts. Furthermore, age did not emerge as a significant predictor in the current study, in contrast with past vulvodynia research,[23,43] and a similar nonsignificant pattern was observed regarding patient expectations/confidence, relationship status, and pain characteristics (eg, symptom length). Perhaps these predictor variables would be related to outcome measures that were not included in the current study or, alternatively, these variables may predict outcomes for other treatment modalities. Differences between our sample and that of previous studies may also account for the lack of consistency in results (eg, our sample was comprised of treatment-seeking women who were not randomized). Further study is required to determine a more nuanced understanding of the findings to date.

Nevertheless, the current study provides insight into factors that can predict treatment outcomes, and represents an important step towards investigating the critical question of which women may benefit most from treatment for PVD. Future research should examine similar predictor variables across a range of treatment options for PVD to determine whether these predictors are universal or particular to this type of multidisciplinary treatment; doing so may help develop guidelines for triaging patients and reduce time spent on the "trial-and-error" approach that often characterizes the treatment experiences of women with PVD. Similarly, certain patient characteristics may respond better to certain types of treatment; the current study was not designed to examine what specific treatment components work best for whom, but this question requires future research to help optimize treatment selection and clinical care decisions. Furthermore, determining what "active ingredients" are most important to treatment success would be helpful in optimizing treatment effectiveness for PVD. Previous literature has noted that validation, normalization, education, and change in sexual beliefs could be key ingredients,[9,14] and the current study suggests that desire and arousal are worth further investigation. Given the discrepancy between the current findings and that of previous PVD research regarding self-efficacy,[22,30] more research is needed to further investigate this variable as well; the use of self–efficacy-enhancing strategies to optimize treatment outcomes in women with PVD also warrants future research attention. Other factors to consider may include the presence of multiple pain sites, other non-specific physical problems, and symptoms of depression.[39] In the absence of a core outcome set specific to vulvar pain, the current study captured experience of pain during sexual activity as well as perceived sexual distress. Adding outcome variables such as pain intensity or interference with sexual activity, however, would enhance our understanding of these processes.

The strengths of this study include the use of validated measurement tools, prospective data collection, and use of longer term follow-up periods. However, there are also a number of limitations. This study was not part of a randomized control trial, so there are no comparisons with other treatments or a wait-list control group. Moreover, women's improvements following the program may be due to factors other than the treatment program itself, including remission or pursuit of other treatments following the MVP. Although women with provoked vulvar pain have been found to be less likely to have symptom remittance, previous research has suggested a high rate of remission associated with vulvodynia.[44] We also do not have systematic information regarding women's attendance or adherence to the MVP treatment recommendations. Thus, firm conclusions cannot be drawn about the efficacy of the treatment program itself nor do we know how women's level of adherence to treatment may or may not have impacted the study results.

Furthermore, because these data were collected in a clinical setting over several years and multiple cohorts, complete data were not available for all measures included in these analyses and only a portion of the women were invited to complete questionnaires at the longer-term follow-up periods. It is possible that women who did not complete data at follow-up differ from participants who did provide follow-up data; for example, women without follow-up data may have experienced the treatment program differently by having had a more (or less) beneficial outcome. Similarly, FSFI scores were only available for those women who had been sexually active 4 weeks before completing the questionnaire, contributing to further missing data and limiting statistical power. Some differences were found between women with FSFI pain data at baseline versus women without such data in that women missing baseline FSFI pain data were less likely to be partnered and reported lower self-efficacy scores.

A number of differences were also found between women who were sexually active at baseline versus not; specifically, women who were not sexually active at baseline reported longer relationship duration, lower levels of desire, higher levels of anxiety, and lower levels of self-efficacy. Our results as they pertain to sexual pain cannot be generalized to nonsexually active women with PVD and more research is needed to understand the treatment needs and experiences of such women. Finally, medical care is an important component of the MVP but we did not systematically collect information from our physicians regarding medications (eg, estradiol; lidocaine) women may have started during the course of the program.

In conclusion, although there are many questions still to be explored, the current study indicates that sexual pain and distress decreased throughout a multidisciplinary treatment program for PVD, a pattern that continued following treatment completion. Furthermore, the predictors identified indicate that pretreatment sexual functioning may be important for recognizing those women who might benefit the most from such treatment programs. These variables should be taken into account to aid clinical decision-making and when discussing treatment options with women with PVD.

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