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Predictors and Moderators of Provoked Vestibulodynia Treatment Outcome Following a Randomized Trial Comparing Cognitive-Behavioral Couple Therapy to Overnight Lidocaine

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Provoked vestibulodynia is a vulvar pain condition causing sexual dysfunction, affecting 8% to 10% of women. Our recently published randomized clinical trial ($N = 108$ couples) found that cognitive behavioral couple therapy (CBCT) and topical lidocaine reduced women's pain and associated sexual symptoms, with CBCT showing more benefits. Little is known about pretreatment predictors of treatment outcomes in couples sex therapy. In the current study, we examined women and their partners' pretreatment demographic (age, relationship length), clinical (pain duration, anxiety) and interpersonal (partner responses to pain, sexual goals) predictors/moderators of women's pain intensity, pain unpleasantness, and sexual function at posttreatment and 6-month follow-up. Longer relationship duration, lower anxiety in women, partner higher solicitousness and partner higher approach sexual goals predicted better pain outcomes for women with PVD irrespective of treatment condition. CBCT was more effective than lidocaine for improving women's sexual function at posttreatment when, at pretreatment, women had partners with higher anxiety and women reported lower approach sexual goals, whereas lidocaine was more effective for improving women's sexual function at follow-up when partners had higher approach sexual goals. Findings can assist clinicians in determining what treatment will be most beneficial for whom.

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Provoked vestibulodynia (PVD) is the most common cause of the sexual dysfunction known as Genito-Pelvic Pain/Penetration Disorder in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5; American Psychiatric Association, 2013). PVD is an acute recurrent vulvar pain specific to the vulvar vestibule (i.e., the entrance to the vagina), elicited via pressure, and for which there is no identifiable cause (Goldstein et al., 2016). PVD has a population prevalence of 8% to 10% in women of all ages and a multifactorial etiology that includes peripheral and central pain mechanisms, pelvic floor muscle and autonomic dysfunction, as well as cognitive–affective, behavioral, and interpersonal dimensions (Bergeron et al., 2020). This debilitating pain condition adversely impacts the relationship, mental health (e.g., heightened anxiety), and especially the overall sexual function (i.e., sexual desire, arousal, orgasm, and satisfaction) of affected women and their partners, relative to unaffected couples (Rosen & Bergeron, 2019, for review). In response to growing evidence that both partners are impacted by and impact the woman's pain and the couple's adjustment, as well as guidelines recommending cognitive-behavioral therapy as a first-line treatment (Goldstein et al., 2016), we developed and tested a novel cognitive-behavioral couple therapy (CBCT; Bergeron et al., 2021).

The results of this parallel randomized clinical trial (RCT) comparing a 12-week manualized CBCT to nightly application of topical lidocaine—recommended as an effective first-line medical treatment for PVD in published treatment algorithms (Mandal et al., 2010)—have previously been published. A full description of the study can be found in Bergeron et al. (2021). In summary, both treatments resulted in similar significant improvements in pain intensity during intercourse (i.e., the magnitude of the pain experienced), and in sexual function, at posttreatment and 6-month follow-up. Moreover, CBCT yielded greater reductions in pain unpleasantness—the affective aspect of pain—at 6-month follow-up relative to lidocaine. Women in CBCT also reported higher treatment satisfaction and global sexuality improvements at both time-points compared to lidocaine, reflecting the clinical significance of these changes.

Beyond overall efficacy, an important question is whether all women benefited uniformly from the two treatments. The current study examined pretreatment demographic, clinical, and interpersonal predictors and moderators of women's treatment outcome—pain and sexual function—to CBCT and lidocaine. Pain intensity, pain unpleasantness, and sexual function reflect the core symptoms of PVD (i.e., pain and disability). Predictors are pretreatment characteristics of women or their partners that are related to women's outcomes in a consistent way regardless of which treatment the couples received. Moderators are the same pretreatment characteristics that are associated with women's outcomes differently depending on the treatment they received, thus specifying for whom which treatment is most likely to be more effective. Understanding predictors and moderators of treatment outcome will direct couples to the most appropriate intervention based on their initial clinical presentation.

PREDICTORS AND MODERATORS OF TREATMENT OUTCOME

Although they are widely used clinically, to our knowledge there are no studies examining predictors or moderators of treatment outcome of couple therapy for sexual dysfunction. Similarly, there are no studies predicting lidocaine outcomes despite being among the most commonly prescribed medical treatments for PVD (Bergeron et al., 2020). Researchers in the fields of both pain and couple therapy recommend a theoretically driven approach to selecting predictors given inconsistent findings in past studies (Baucom et al., 2011; Gilpin et al., 2017). Indeed, in the two prior RCTs that compared predictors of treatment outcomes in PVD for group CBT relative to medical treatments theoretically relevant pretreatment psychological variables predicted pain and sexual function outcomes at posttreatment and 6-month follow-up (Bergeron et al., 2008; Desrochers et al., 2010).

In the current study, selection of our predictors and our hypotheses were therefore informed by theory, clinical relevance, and prior studies examining (a) predictors of psychological treatment outcome in PVD and (b) predictors of women's pain and sexual function in PVD (nontreatment studies). In line with prior studies examining pretreatment predictors of couple therapy outcomes (Atkins et al., 2005; Doss et al., 2012; Williamson et al., 2015), we selected predictors/moderators that included demographics (age, relationship duration), clinical (anxiety, pain duration i.e., number of years with PVD pain), and interpersonal (partner responses to pain, sexual goals; i.e., motives for engaging in sexual activity) variables.

Demographic variables are clinically useful as predictors of treatment outcome because they can be easily assessed in the clinic without the need for validated measures. We selected age because in a longitudinal study of women with PVD, those

who were older were more likely to have persistent pain 7 years later (Pâquet et al., 2019). Similarly, in a recent RCT comparing two group-based psychological treatments for women with PVD—mindfulness-based cognitive therapy (MBCT) to CBT—older women experienced less pain reduction posttreatment regardless of the treatment group (i.e., no moderation by treatment; Brotto et al., 2020). We also selected relationship duration given that couples who are married longer consistently show stronger treatment gains following couple behavioral therapy for relationship distress (Baucom et al., 2015). In the aforementioned RCT by Brotto et al. (2020), women with PVD in longer relationships improved more in their sexual function with CBT relative to MBCT.

Regarding clinical variables, we selected pretreatment levels of women and their partners' global anxiety given its strong clinical and theoretical relevance to PVD. Anxiety disorders are an established antecedent and consequence of PVD (Khandker et al., 2011). Although controlled studies do not generally show higher anxiety in partners of women with PVD, partners report a significant emotional toll of PVD in their lives (Rosen & Bergeron, 2019). Moreover, higher anxiety—both the women's own and their partner's—is associated with greater pain during intercourse and poorer sexual function in women with PVD (Pâquet et al., 2018). Pain duration is another clinical characteristic that predicts treatment outcomes following CBT in other pain populations (Gilpin et al., 2017). Consistent with the fear-avoidance model (Desrochers et al., 2010), the psychological sequelae of the pain (e.g., catastrophizing) may be more entrenched in those with a longer history of pain, making them more resistant to treatment.

Interpersonal variables are the most consistent predictors of treatment outcome in the broader couple therapy literature (Atkins et al., 2005; Baucom et al., 2009; Doss et al., 2012; Williamson et al., 2015). We selected two sets of empirically supported interpersonal predictors that were explicitly targeted in CBCT: partner responses to pain (as perceived by the woman or reported by the partner), and women and their partners' sexual goals. According to the Interpersonal Emotion Regulation Model of women's genito-pelvic pain, interpersonal factors affect couples' emotion regulation concerning the pain and sexual difficulties and, in turn, women's pain and couples' sexual function (Rosen & Bergeron, 2019). Across several studies, greater facilitative partner responses (e.g., demonstrations of affection and support for adaptive coping) were associated with women's lower intercourse pain and better sexual functioning, whereas greater negative (e.g., expressions of hostility or frustration) and solicitous (e.g., expressions of attention and sympathy) partner responses were associated with poorer outcomes (Rosen et al., 2015, 2013). With regard to sexual goals, on days when women with PVD reported engaging in sexual activity in order to pursue positive relationship outcomes such as intimacy (i.e., approach goals), they reported less pain and greater sexual function (Rosen et al., 2018). In contrast, on days when women reported having sex to avoid negative relationship outcomes, such as partner disappointment or conflict (i.e., avoidance goals), they reported greater pain and poorer sexual function. In sum, prior research and theory has established partner responses and sexual goals as critical to symptom maintenance in PVD; they may therefore be especially relevant to predicting treatment outcome for a couples-based treatment relative to a medical treatment.

THE CURRENT STUDY

The objective of this study was to examine pretreatment predictors or moderators of women's pain intensity during intercourse, pain unpleasantness during intercourse, and sexual function, following treatment in a RCT comparing CBCT to lidocaine. We examined predictors/moderators of outcomes at posttreatment and 6-month follow-up as there might be differences in short- and long-term treatment outcomes (Baucom et al., 2015). Consistent with prior studies, we grouped predictors into three categories: demographics (age, relationship length), clinical (anxiety, pain duration), and interpersonal (partner responses to pain, sexual goals) variables. Anxiety and the interpersonal predictors were assessed from both the women's and partners' perspectives, accounting for their interdependence and allowing us to examine their unique contributions. This study is mainly exploratory given the limited evidence regarding pretreatment predictors of PVD treatment outcomes. Conceptually, on the one hand, it is possible that those entering treatment with lower anxiety, who have been coping with PVD for a shorter period, and who have more adaptive relationship interactions surrounding the PVD might benefit more from treatment as they could be better equipped and motivated to engage in therapeutic processes. On the other hand, couples who are struggling more relationally in coping with PVD (and for longer periods of time) when they enter treatment might show greater improvements as they have more room to benefit. We did, however, expect that anxiety and the

interpersonal predictors would moderate treatment outcomes such that these predictors would be more relevant to the CBCT condition where they are directly targeted, relative to the lidocaine condition.

Method

PARTICIPANTS

Participants were 108 women diagnosed with PVD and their partners (3 women, 105 men). As reported in Bergeron et al. (2021), an a priori power analysis suggested we would need 124 couples to detect small effects (i.e., d = 0.32, f = 0.16) based on our pilot study (Corsini-Munt et al., 2014) and previous clinical trials (Bergeron et al., 2016), with 2 treatment conditions, 3 measurement time-points, and a moderate correlation between repeated measures. As recruitment was slower than expected and resources were limited, we ended recruitment at 108 couples. A Monte Carlo simulation indicated that with 108 couples and 303 observations, we had 80% power to detect small effects of r = .25. We recruited 47 couples from Halifax and 61 couples from Montréal, between May 2014 and March 2018. Two research sites increased the pace of recruitment and diversity of our sample. At both sites, couples were recruited through newspaper advertisements, websites, universities, hospitals and medical clinics (42%), participation in prior studies by the authors (34%), referrals by a physician (23%), and referral by a friend (1%). The inclusion criteria were: (1) at least 18 years of age; (2) women experiencing pain on at least 80% of vaginal penetration attempts in the last 6 months; (3) women's pain limited to vaginal intercourse or other activities involving pressure to the vulvar vestibule (e.g., tampon insertion); (4) women having a confirmed diagnosis of PVD; (5) penetration or attempted penetration at least once a month during the last three months (main RCT outcome was pain during intercourse); (6) being in a couple relationship for at least six months, and (7) cohabiting and/or having at least four in-person contacts per week with partner in the last six months. The exclusion criteria were: (1) women with pain being over 45 years of age and/or having started menopause because of the genital changes associated with perimenopause and menopause; (2) actively receiving treatment for PVD; (3) women with pain having an active infection (e.g., candida) or dermatological condition (e.g., lichen sclerosis, lichen planus); (4) severe untreated self-reported medical or psychiatric condition (e.g., depression) in either partner that would interfere with their ability to participate and benefit from treatment; (5) being pregnant or planning a pregnancy during the duration of the clinical trial; (6) currently being in couple therapy; (7) clinical levels of relationship distress, based on the cut-off score of the Couple Satisfaction Index (Funk & Rogge, 2007); and (8) self-reported intimate partner violence. From an ethical and clinical standpoint, relationship distress and/or violence have to be addressed before starting targeted sex therapy, especially in the context of a manualized treatment focusing on genito-pelvic pain (Cobia et al., 2008). See supplemental Figure 1 for participant flow.

PROCEDURE

A research assistant conducted a brief telephone screening with the woman experiencing pain. Potentially eligible couples were then invited to a laboratory-based session with a research assistant. First, informed consent was obtained, followed by a structured interview with both partners (together), and finally individuals completed online self-report questionnaires independently via Qualtrics. The research team determined couple eligibility by reviewing their interview and questionnaire responses. All women eligible after the pretreatment evaluation attended a gynecological examination to confirm their PVD diagnosis. This examination included a standardized cotton swab test whereby a swab was used to palpate the 3-, 6-, and 9-o'clock positions of the vulvar vestibule, while the woman rated her pain intensity.

Eligible couples were randomized to either CBCT or lidocaine, according to the independent stratified randomization method provided by Dacima Software (Dacima Software Team, 2014). In each stratum, allocation was computer-generated randomly by blocks varying from 4 to 6 in order to maintain equilibrium between the two study arms. All research personnel and investigators were blind to treatment condition for the duration of the study, with the exception of each site's research coordinator, the research assistant dedicated to the lidocaine condition, and the CBCT therapists. Immediately following the 12 weeks of treatment and again at 6-months follow-up, couples completed an assessment that included the same structured interview and self-report questionnaires as at pretreatment. Treatment was considered complete if the couple did not withdraw or drop out prior to the 12 weeks. Couples were compensated $30 per assessment. The study was approved by the Research Ethics Boards at our institutions.

CBCT

CBCT consisted of 12 weekly, 75-minute face-to-face sessions. Therapists followed a detailed treatment manual, which can be obtained by contacting the first or last author. A treatment outline can also be found on the Open Science Framework: https://osf.io/u72rd/?view_only=4908e258287846d1a29e6b949845a924. The CBCT was adapted from an empirically supported group CBT treatment for PVD (Bergeron et al., 2016), and revised to incorporate research on interpersonal factors relevant to PVD as well as tenets of couple therapy (Rosen & Bergeron, 2019). The goals of the CBCT were to help couples (1) reconceptualize PVD as a multidimensional pain problem influenced by thoughts, emotions, behaviors, and couple interactions whereby both partners affect and are affected by the pain; (2) modify factors associated with pain during intercourse by increasing adaptive coping and decreasing pain intensity; (3) improve sexual function, satisfaction and distress; and (4) consolidate skills. Interventions included information about CBCT, education about PVD (impacts to sexuality and a multifactorial view of pain), breathing techniques, vaginal dilation exercises; cognitive defusion (learning to separate or detach from unhelpful thoughts about pain/sexuality so they have less hold over the self), distraction with sexual imagery, expansion of sexual repertoire, and exercises to improve pain and sexuality-related couple interactions (e.g., communication).

Therapists were advanced clinical psychology Ph.D. students (n = 10) or junior clinicians (Psy. D. or Ph.D., n = 2; M.A. in clinical sexology, n = 1) who received training in psychotherapy as part of their program, training in sex and couple therapy, and approximately 6 hours of specific training in delivering the CBCT manual interventions. All therapists attended discussion-based weekly supervision with a registered clinical psychologist (n = 1 in Halifax, n = 2 in Montréal). One of the supervisors from each site was the therapist for the pilot study of the CBCT (Corsini-Munt et al., 2014) and they had 15 (Halifax) and 5 (Montréal) years of experience delivering cognitive-behavioral sex and couple therapy. The third supervisor (Montréal) had 5 years of experience delivering cognitive-behavioral sex and couple therapy, including working with women with PVD. Two independent clinical associates viewed and coded a random sample of 25% of all therapy sessions in their entirety to assess adherence to the treatment manual. They obtained an inter-rater reliability of .70 (mean weighted kappa), indicating substantial agreement, and found that therapists adhered to the treatment manual 93.8% of the time. Both members of the couple were required to attend the CBCT; couples in CBCT attended 10.6 out of 12 (SD = 3.53; 88.7%) sessions, inclusive of those who did and did not complete treatment. We assessed participant treatment adherence via frequency ratings of weekly home practice of exercises during the week it was assigned; women completed 67.7% of homework exercises, whereas partners completed 58.6% of homework exercises.

Topical Lidocaine

For 12 weeks, participants randomized to this condition followed a standardized protocol (Zolnoun et al., 2003). They applied a 5% lidocaine ointment on the vulvar vestibule nightly (50mg/g, Xylocaïne®, AstraZeneca, tube of 35g). A marble-sized amount of the ointment was applied to a cotton ball positioned at the entry of the vagina, secured via the participant's underwear overnight to ensure continuous contact for 7 to 8 hours. Participants were told to remove the ointment before having intercourse or for the male partner to wear a condom. After being trained by one of the Co-I physicians, a research assistant explained the protocol to participants in a standardized manner and provided them with a pamphlet detailing how to apply the ointment. A research assistant performed standardized weekly phone calls to monitor for adverse events. Participants tracked their own adherence in a booklet, with women reporting that they applied the lidocaine 79.4% of the nights during the treatment period.

MEASURES

Women's Pain Intensity and Unpleasantness

As recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT; Dworkin et al., 2005), and adapted for vulvodynia by Pukall et al. (2017), pain treatment outcome measures included a numerical rating scale (NRS) for pain intensity during intercourse and an NRS for pain unpleasantness during intercourse. Women with PVD provided ratings on a scale from 0 = *no pain/not unpleasant* to 10 = *worst pain ever/most unpleasant ever* in reference to their pain during intercourse in the last 3 to 6 months depending on the assessment point. These measures are positively correlated with other validated self-report pain measures (e.g., r = .33–.38 with McGill Pain Inventory; Aerts et al., 2016) and show good sensitivity to detecting significant treatment effects, including in women with PVD (Bergeron et al., 2016).

Women's Sexual Function

Women's global sexual function in the previous 4 weeks was measured with the 19-item Female Sexual Function Index (FSFI; Rosen et al., 2000), which assesses sexual desire, arousal, lubrication, orgasm, satisfaction, and pain. As is common in studies of PVD (e.g., Bergeron et al., 2016), the three pain items were removed from the total score to avoid overlap with pain outcomes. Scores in each domain were summed and multiplied by a respective factor that homogenizes the influence of each dimension, resulting in a total score ranging from 2 to 30, with higher scores reflecting better sexual function. Women who reported no sexual activity in the last 4 weeks (i.e., $n = 4$ at pretreatment, $n = 3$ at posttreatment, and $n = 8$ at follow-up) were coded as missing to avoid biasing the score towards dysfunction (Meyer-Bahlburg & Dolezal, 2007). The FSFI has strong discriminant validity as demonstrated by significant mean difference scores between women with sexual dysfunction and control groups ($p < .001$; Rosen et al., 2000), and convergent validity with other sexuality measures in PVD samples (e.g., $r = .54$ with sexual satisfaction; Aerts et al., 2016).

Demographics

Women with PVD and their partners reported their age and women with PVD reported their relationship duration in years. Additional sociodemographic information was self-reported by women with PVD (primary or secondary pain, household income, relationship status) and by both partners (education, cultural background).

Trait Anxiety

The trait subscale of the well-validated State-Trait Anxiety Inventory is a 20-item measure assessing the predisposition to react with anxiety in stressful situations (Speilberger, 1983). Participants indicated their responses on a Likert scale ranging from 1 = *almost never* to 4 = *almost always*. Total scores range from 20 to 80 and higher scores indicate higher anxiety.

Pain Duration

Women with PVD reported the duration of their PVD pain in years.

Partner Responses to Pain

Women completed a measure of their perceptions of their partners' responses to their PVD pain and partners completed a measure of their own responses on a scale ranging from 1 = *never* to 6 = *very frequently*. Solicitous (4 items; e.g., *comforts me*) and negative (4 items; e.g., *expresses frustration at me*) responses were measured with the significant other response subscale of the West Haven-Yale Multidimensional Pain Inventory (WHYMPI; Kerns et al., 1985), and facilitative (6 items; e.g., *tells me that they love me*) responses were measured with the facilitative subscale of the Spouse Response Inventory (SRI; Schwartz et al., 2005). The solicitous and negative subscales positively correlated with the factor of the WHYMPI representing support from significant others ($rs = .79$ and $-.58$, respectively; Kerns et al., 1985), and the facilitative subscale of the SRI also correlates positively with a measure of relationship satisfaction ($r = .65$; Raichle et al., 2011), demonstrating convergent validity. These measures have previously been adapted and validated in a PVD population including acceptable reliability coefficients ($r = .73–.85$, $.72–.85$, and $.86–.91$ for solicitous, negative, and facilitative responses, respectively), showing a three-factor structure in a confirmatory factor analysis, and significant associations with women's pain intensity and sexual function (Rosen et al., 2015, 2013). Higher scores indicate a greater frequency of this partner response and are represented as mean scores.

Sexual Goals

Participants rated the importance of eight approach (e.g., "to promote intimacy in my relationship") and five avoidance (e.g., "to prevent my partner from becoming upset") goals for engaging in sexual activity with a partner on a scale ranging from 1 = *not at all important* to 7 = *extremely important* (Rosen et al., 2018). A principal components factor analysis has yielded a two-factor solution, and approach goals were associated with positive (but not negative) affect and avoidance goals with negative (but not positive) affect, providing support for convergent and discriminant validity (Impett et al., 2005). In prior PVD samples, reliability coefficients were acceptable for both approach ($r = .78–.87$) and avoidance ($r = .86–.89$) goals (Rosen et al., 2018). Higher scores indicate higher goals and are represented as means.

DATA ANALYSES

Descriptive statistics and bivariate correlations were first examined using SPSS 26.0. To examine the associations between pretreatment predictors/moderators and outcome measures, data were analyzed using multilevel models (hierarchical linear modeling) with maximum-likelihood (ML) estimation of parameters in M*plus* 8.2 (Muthén & Muthén, 1998–2017). Three models were estimated—one per outcome—in which we examined the main effect of time (simultaneously estimated separate linear slopes of change from pre- to posttreatment and from pretreatment to follow-up)

with pretreatment as the reference (within-subjects variable), the main effect of all predictors (between-subjects variables), the main effect of treatment condition and treatment site (between-subjects variables), and the interaction of the within- and between-subjects factors (i.e., time*predictor) as cross-level interactions. We included random effects on the intercepts and time slopes. A significant cross-level interaction indicated that the response to treatment varied at different levels of the predictor.

We also examined if the predictors significantly moderated the effect of treatment condition on the outcomes by adding separately all cross-level interactions between time, the predictor, and the treatment condition (predictor*time*treatment). A significant three-way cross-level interaction indicated that the effect of the treatment condition on the response to treatment varied at different levels of the predictor (Kraemer et al., 2002). Only significant three-way cross-level interactions were kept in final models. To interpret significant three-way interactions, simple slopes tests were estimated for one standard deviation (SD) above and below the mean on the moderator. All predictors/moderators were centered prior to analysis and calculation of interactions. Treatment condition and site were effect coded with lidocaine = -0.5 and CBCT = 0.5 for treatment condition and Montréal = -0.5 and Halifax = 0.5 for treatment site. Data from participants who dropped-out of the study and score-level missing data were handled using Full Information Maximum Likelihood (FIML; Muthén & Muthén, 1998–2017); all randomized participants are included in the analyses based on the intention-to-treat principle. The coefficients reported are unstandardized betas (b). At Level-1, the intercept represents the outcome variable at pretreatment, and the T1-T2 and the T1-T3 coefficients represent the pre- to posttreatment (T1-T2 slope) or the pre- to follow-up (T1-T3 slope) treatment response on this outcome. At Level-2, the coefficients represent the change in the pre- to posttreatment (T1-T2 slope) or the pre- to follow-up (T1-T3 slope) treatment response (i.e., the value reported at Level-1) for every one-unit increase in the predictor. Explained variance (approximate R^2) was calculated using the Level 2 residual variance difference divided by the Level 2 variance of the null model which included only time as a within-subjects factor.

Results

DESCRIPTIVE AND PRELIMINARY ANALYSES

All de-identified data and syntax for the analyses can be found on the Open Science Framework: https://osf.io/u72rd/?view_only=4908e258287846d1a29e6b949845a924. Couples (N = 108) were randomized: 53 to CBCT and 55 to topical lidocaine. Overall, 88.0% (n = 95) of couples completed treatment with no significant differences by treatment condition. Couples who did not complete treatment were still invited to take part in the posttreatment and follow-up assessments and, similarly, couples who did not complete the posttreatment were invited to complete the follow-up assessment. Posttreatment and follow-up completion rates were 90.7% (n = 98), with no differences by treatment condition. Sociodemographic characteristics are presented in Table 1 and did not differ between treatment conditions.

Means and standard deviations for pretreatment predictors and outcome measures at each timepoint are in Table 2. No measures differed significantly by treatment condition. Pretreatment pain unpleasantness, sexual function, and predictors were not significantly different by treatment site. Pain intensity at pretreatment was significantly higher in Montréal (M = 7.13, SD = 1.47) vs Halifax (M = 6.04, SD = 2.00), $t(106)$ = 3.14, p = .002. Treatment site was included as a covariate in all analyses. Correlations between all study variables are in supplemental Table S1.

PREDICTORS AND MODERATORS OF TREATMENT PAIN OUTCOMES

Pain Intensity

Results of the multilevel model for pain intensity are presented in Table 3. Pain intensity was at an average level of 6.56/10 and decreased significantly between pre- and posttreatment as well as between pretreatment and 6-month follow-up. Longer relationship duration predicted a steeper decrease in pain intensity at posttreatment and 6-month follow-up. Higher pretreatment anxiety in women with PVD predicted a weaker decrease in pain intensity at posttreatment. Higher pretreatment partner-reported solicitous responses predicted a steeper decrease in pain intensity at posttreatment, and higher pretreatment partner approach sexual goals predicted a steeper decrease in pain intensity at posttreatment and 6-month

Table 1
Sociodemographic and Clinical Characteristics (N = 108)

	Women with PVD *M*(*SD*) or %(*n*)	Partner *M*(*SD*) or %(*n*)
Sex: Women/Men	100% (108) / 0% (0)	2.8% (3) / 97.2% (105)
Age (years)	27.06 (6.26)	29.04 (7.76)
Education	17.06 (2.29)	16.14 (2.56)
Primary pain/Secondary pain[a]	32.4% (32) / 67.6% (73)	
Cultural background		
French Canadian	39.8% (43)	31.5% (34)
English Canadian	36.1% (39)	42.6% (46)
European	7.4% (8)	12.0% (13)
Other[b]	15.7% (17)	13.9% (15)
Relationship status		
Not living together	20.4% (22)	
Cohabiting	51.9% (56)	
Married	27.8% (30)	
Couple's annual income		
$0-$19,999	18.5% (20)	
$20,000-$39,999	20.4% (22)	
$40,000-$59,999	13.9% (15)	
$60,000-$79,999	14.8% (16)	
$80,000 and over	31.5% (34)	
Halifax	43.5% (47)	

Note. [a] Primary vs. secondary pain was determined by asking women whether they had pain during their first sexual intercourse and whether that pain was the same as the pain they experience now.
[b] Other included: American, African, Asian, Middle Eastern, Latin/South American, Caribbean, New Zealand, French Acadian, and mixed cultural identities.

Table 2
Means, Standard Deviations, and Cronbach's α for Pain Measures, Sexual Function, and Pretreatment Predictors

	Women with PVD				Partners			
	n	α	*M*	SD	*n*	α	*M*	SD
Pain intensity Pretreatment	108		6.66	1.80				
Pain intensity Posttreatment	96		4.69	2.24				
Pain intensity Follow-up	96		4.58	2.54				
Pain unpleasantness Pretreatment	107		7.20	2.52				
Pain unpleasantness Posttreatment	96		4.64	2.73				
Pain unpleasantness Follow-up	93		4.82	3.01				
Sexual function Pretreatment	104	.92	17.12	4.75				
Sexual function Posttreatment	94	.94	19.09	5.35				
Sexual function Follow-up	88	.93	19.37	5.28				
Women age	108		27.06	6.26				
Relationship duration	108		65.21	49.67				
Pain duration	108		78.22	62.44				
Anxiety	108	.89	42.94	9.31	108	.92	35.62	9.78
Approach sexual goals	108	.86	5.36	1.18	108	.88	5.48	1.17
Avoidance sexual goals	108	.90	3.85	1.84	108	.89	3.19	1.70
Solicitous responses	108	.79	4.32	1.28	108	.62	4.65	0.96
Facilitative responses	108	.82	4.89	1.14	108	.78	4.95	1.02
Negative responses	108	.88	1.59	0.84	108	.87	1.50	0.69

follow-up. The effects of treatment condition on pain intensity were not significantly moderated by any of these predictors. The model explained 49.7% of the variance in pain intensity at post-treatment and 7.2% of the variance at 6-month follow-up.

Table 3
Multilevel Model for the Associations Between Pretreatment Predictors and Pain Intensity

Level-1	b (SE)	*t*	*p*	b (SE)	*t*	*p*
Intercept	6.56 (0.16)	41.77	.000			
Time (T1-T2)	-1.96 (0.19)	-10.56	.000			
Time (T1-T3)	-2.02 (0.21)	-9.72	.000			
Level-2	**Effect on time T1-T2 slope**			**Effect on time T1-T3 slope**		
Treatment condition	-0.64 (0.41)	-1.58	.113	-0.86 (0.46)	-1.85	.064
Women age	-0.01 (0.05)	-0.25	.801	0.01 (0.06)	0.22	.827
Relationship duration	**-0.01 (0.01)**	**-2.23**	**.026**	**-0.01 (0.01)**	**-2.12**	**.034**
Pain duration	-0.003 (0.004)	-0.76	.450	0.003 (0.01)	0.70	.486
Women anxiety	**0.05 (0.02)**	**2.13**	**.034**	0.02 (0.02)	0.63	.526
Partner anxiety	-0.02 (0.02)	-0.85	.396	0.04 (0.02)	1.53	.127
Women approach sexual goals	0.04 (0.25)	0.16	.877	0.02 (0.28)	0.05	.957
Partner approach sexual goals	**-0.54 (0.21)**	**-2.51**	**.012**	**-0.50 (0.24)**	**-2.10**	**.036**
Women avoidance sexual goals	0.09 (0.16)	0.59	.557	0.10 (0.18)	0.56	.579
Partner avoidance sexual goals	0.05 (0.15)	0.36	.719	0.16 (0.17)	0.93	.354
Women solicitous responses	-0.14 (0.17)	-0.82	.414	-0.24 (0.20)	-1.22	.221
Partner solicitous responses	**-0.70 (0.22)**	**-3.19**	**.001**	-0.10 (0.24)	-0.39	.695
Women facilitative responses	0.08 (0.19)	0.44	.661	0.04 (0.21)	0.18	.860
Partner facilitative responses	0.25 (0.20)	1.24	.216	-0.17 (0.22)	-0.77	.445
Women negative responses	-0.32 (0.29)	-1.11	.267	0.12 (0.32)	0.37	.710
Partner negative responses	0.35 (0.35)	1.01	.314	-0.54 (0.38)	-1.39	.163

Note. Recruitment site was included as a covariate; Treatment: -0.5 = lidocaine, 0.5 = CBCT.

Pain Unpleasantness

Results of the multilevel model for pain unpleasantness are presented in Table 4. At pretreatment, pain unpleasantness averaged 7.15/10 and it decreased significantly between pre- and posttreatment as well as between pretreatment and 6-month follow-up. Longer relationship duration predicted a steeper decrease in pain unpleasantness at posttreatment and follow-up. Higher partner-reported solicitous responses at pretreatment predicted a steeper decrease in pain unpleasantness at posttreatment. Higher pretreatment partner

Table 4
Multilevel Model for Associations Between Pretreatment Predictors and Pain Unpleasantness

Level-1	b (SE)	*t*	*p*	b (SE)	*t*	*p*
Intercept	7.15 (0.22)	31.85	.000			
Time (T1-T2)	-2.61 (0.27)	-9.65	.000			
Time (T1-T3)	-2.33 (0.30)	-7.76	.000			
Level-2	**Effect on time T1-T2 slope**			**Effect on time T1-T3 slope**		
Treatment condition	-0.93 (0.59)	-1.56	.118	-1.30 (0.66)	-1.97	.049
Women age	0.04 (0.07)	0.53	.597	0.10 (0.08)	1.21	.225
Relationship duration	**-0.02 (0.01)**	**-2.36**	**.018**	**-0.02 (0.01)**	**-2.37**	**.018**
Pain duration	-0.01 (0.01)	-0.80	.426	0.00 (0.01)	0.004	.996
Women anxiety	0.04 (0.03)	1.24	.217	-0.02 (0.04)	-0.46	.644
Partner anxiety	-0.04 (0.03)	-1.37	.170	0.001 (0.04)	0.03	.977
Women approach sexual goals	0.26 (0.36)	0.72	.474	-0.01 (0.40)	-0.01	.990
Partner approach sexual goals	**-0.77 (0.31)**	**-2.47**	**.013**	**-0.82 (0.34)**	**-2.39**	**.017**
Women avoidance sexual goals	-0.05 (0.23)	-0.21	.837	-0.05 (0.26)	-0.20	.846
Partner avoidance sexual goals	0.07 (0.22)	0.33	.739	0.36 (0.24)	1.49	.137
Women solicitous responses	0.04 (0.25)	0.15	.880	-0.06 (0.28)	-0.21	.835
Partner solicitous responses	**-0.67 (0.32)**	**-2.07**	**.039**	-0.15 (0.35)	-0.43	.669
Women facilitative responses	0.15 (0.27)	0.53	.596	0.22 (0.30)	0.72	.474
Partner facilitative responses	-0.13 (0.29)	-0.44	.663	-0.20 (0.32)	-0.64	.523
Women negative responses	-0.35 (0.42)	-0.83	.405	0.35 (0.46)	0.75	.456
Partner negative responses	-0.12 (0.51)	-0.23	.819	-0.70 (0.56)	-1.23	.218

Note. Recruitment site was included as a covariate. Treatment: -0.5 = lidocaine, 0.5 = CBCT.

approach sexual goals predicted a steeper decrease in pain unpleasantness at posttreatment and follow-up. The effects of treatment condition on pain unpleasantness were not significantly moderated by any of these predictors. The model explained 48.3% of the variance in pain unpleasantness at posttreatment and 7.4% of the variance at 6-month follow-up.

Sexual Function

Results of the multilevel model for sexual function (without the items on pain) are presented in Table 5. Women's sexual function was at an average level of 16.91 and it increased significantly between pre- and posttreatment as well as between pretreatment and 6-month follow-up. None of the pretreatment variables significantly predicted women's change in sexual function from pretreatment to posttreatment or follow-up. However, three predictors significantly moderated the effects of treatment condition on sexual function: partners' pretreatment anxiety, women's pretreatment approach sexual goals, and partners' pretreatment approach sexual goals. First, women in the CBCT condition whose partners had higher levels of anxiety pretreatment reported a steeper increase in their sexual function from pre- to posttreatment (b = 3.59, SE = 0.91, $p < .001$) compared to women in the lidocaine condition with partners with higher levels of anxiety (b = 0.86, SE = 0.83, $p = .302$), effect of treatment condition: b = 2.73, SE = 1.21, $p = .024$. For women with partners with lower levels of pretreatment anxiety, there was no significant difference between treatment conditions, effect of treatment condition: b = -1.72, SE = 1.28, $p = .178$.

Second, women with PVD who reported lower approach sexual goals (-1 SD) at pretreatment in the CBCT condition reported a steeper increase in their sexual function from pre- to posttreatment (b = 3.96, SE = 1.18, $p = .001$) compared to women with lower approach sexual goals in the lidocaine condition (b = 1.19, SE = 0.85, $p = .162$), effect of treatment condition: b = 2.77, SE = 1.32, $p = .035$. For women with higher levels of approach sexual goals (+1 SD), there was no significant difference between treatment conditions, effect of treatment condition: b = -1.76, SE = 1.29, $p = .173$.

Finally, pretreatment partners' approach sexual goals significantly moderated the effect of treatment condition on women's sexual function at

Table 5
Multilevel Model for the Associations Between Pretreatment Predictors and Sexual Function

Level-1	b (SE)	*t*	*p*	b (SE)	*t*	*p*
Intercept	16.91 (0.41)	41.03	.000			
Time (T1-T2)	2.43 (0.43)	5.67	.000			
Time (T1-T3)	2.40 (0.44)	5.42	.000			
Level-2	**Effect on time T1-T2 slope**			**Effect on time T1-T3 slope**		
Treatment condition	0.51 (0.93)	0.54	.589	-1.36 (0.98)	-1.38	.167
Women age	0.03 (0.11)	0.23	.817	-0.13 (0.12)	-1.16	.248
Relationship duration	0.02 (0.01)	1.90	.057	0.01 (0.01)	0.93	.355
Pain duration	-0.01 (0.01)	-0.48	.629	0.004 (0.01)	0.39	.696
Women anxiety	0.01 (0.05)	0.24	.813	0.01 (0.05)	0.20	.845
Partner anxiety	-0.02 (0.05)	-0.42	.675	-0.07 (0.05)	-1.27	.203
Women approach sexual goals	-0.13 (0.57)	-0.23	.821	0.12 (0.59)	0.21	.836
Partner approach sexual goals	-0.03 (0.50)	-0.06	.949	-0.58 (0.50)	-1.15	.251
Women avoidance sexual goals	0.49 (0.36)	1.35	.177	0.23 (0.37)	0.62	.535
Partner avoidance sexual goals	0.16 (0.34)	0.48	.631	0.50 (0.36)	1.41	.159
Women solicitous responses	0.14 (0.40)	0.36	.720	-0.03 (0.42)	-0.06	.949
Partner solicitous responses	0.28 (0.51)	0.55	.581	0.64 (0.52)	1.23	.217
Women facilitative responses	-0.61 (0.43)	-1.42	.155	-0.52 (0.44)	-1.18	.238
Partner facilitative responses	0.26 (0.45)	0.59	.554	0.48 (0.47)	1.02	.308
Women negative responses	0.87 (0.65)	1.34	.180	0.88 (0.70)	1.26	.208
Partner negative responses	-0.54 (0.77)	-0.69	.488	0.69 (0.82)	0.85	.397
Treatment condition × Women approach sexual goals[a]	**-1.96 (0.79)**	**-2.49**	**.013**			
Treatment condition × Partner anxiety[a]	**0.23 (0.09)**	**2.71**	**.007**			
Treatment condition × Partner approach sexual goals[a]				**-1.98 (0.72)**	**-2.77**	**.006**

Note. Recruitment site was included as a covariate. Treatment: -0.5 = lidocaine, 0.5 = CBCT.
[a] See text for results of tests of simple effect.

follow-up. Women in the lidocaine condition whose partners had higher levels of approach sexual goals at pretreatment reported a steeper increase in their sexual function from pretreatment to follow-up (b = 3.57, SE = 0.87, $p < .001$) compared to women in the CBCT condition with partners with higher levels of approach sexual goals (b = -0.15, SE = 1.09, $p = .894$), effect of treatment condition: b = -3.72, SE = 1.30, $p = .004$. For women with partners with lower levels of approach sexual goals, there was no significant difference between treatment conditions, effect of treatment condition: b = 1.01, SE = 1.30, $p = .439$. The model explained 19.3% of the variance in sexual function at posttreatment and 9.9% of the variance at 6-month follow-up.

Discussion

We examined pretreatment predictors and moderators of women's pain intensity and unpleasantness during intercourse, and sexual function, following treatment of PVD in a RCT comparing CBCT to lidocaine. For both treatment conditions, longer relationship duration, women's lower pretreatment anxiety, and partners' higher pretreatment solicitous responses and approach sexual goals predicted steeper decreases in women's pain intensity and unpleasantness at posttreatment and 6-month follow-up. Moreover, CBCT was more effective than lidocaine for improving women's sexual function at posttreatment when their partners had higher pretreatment anxiety and when women reported lower pretreatment approach sexual goals, whereas lidocaine was more effective than CBCT for improving women's sexual function at follow-up when partners had higher pretreatment approach goals. Findings are consistent with theory and prior studies that support the involvement of psychological and interpersonal factors in treatment outcomes for women with PVD (Brotto et al., 2020; Desrochers et al., 2010; Rosen & Bergeron, 2019). This is the first study to our knowledge to identify predictors and moderators of a sex and couple therapy for sexual dysfunction, and for PVD specifically, as well as for the oft-recommended lidocaine treatment for PVD.

Predictors of Change in Women's Pain Intensity and Unpleasantness

We selected specific demographic, clinical, and interpersonal predictors based on theory and empirical evidence from the PVD literature. Women's age, duration of women's PVD pain, facilitative and negative partner responses, and avoidance sexual goals did not predict or moderate treatment outcome. These nonsignificant findings, coupled with the efficacy of both CBCT and lidocaine in the RCT, indicate that clinicians can recommend either treatment as first-line intervention for PVD regardless of these baseline characteristics.

We found four significant predictors of pain outcomes, which did not differ by treatment condition. Thus, these predictors identified who is more likely to benefit from treatment, whether psychological or medical in nature. First, a longer relationship duration predicted a steeper decrease in pain intensity and pain unpleasantness at posttreatment and 6-month follow-up. Consistent with other studies of couple therapies (e.g., Baucom et al., 2015), being in a longer relationship reflects a greater commitment to the union and may translate into heightened motivation to engage in treatment. Second, higher pretreatment anxiety in women with PVD predicted a weaker decrease in pain intensity at posttreatment, suggesting that women who enter treatment with greater anxiety benefited less at the end of treatment. This finding is consistent with a prior RCT, which found that higher pretreatment pain catastrophizing predicted more severe pain at 6-month follow-up among women with PVD who received a topical treatment (Desrochers et al., 2010). Anxiety interferes with sexual arousal and enhances pelvic floor muscle dysfunction, which increases pain during intercourse (Benoît-Piau et al., 2018). Although PVD-related anxiety is directly targeted in CBCT to reduce this interference, women who enter treatment with higher anxiety are likely to be more avoidant of interventions, and similarly those in the lidocaine condition may be less compliant with the treatment. Indeed, anxiety and avoidance of pain exhibit strong positive correlations in PVD (Desrochers et al., 2010).

Finally, two significant interpersonal predictors emerged. These predictors were reported by women's partners rather than by the women with PVD themselves, which underscores the importance of the dyadic context of PVD and its treatment. Higher pretreatment partner-reported solicitous responses predicted a steeper decrease in pain intensity and unpleasantness at posttreatment, and higher pretreatment approach sexual goals reported by partners predicted a steeper decrease at posttreatment and 6-month follow-up. Thus, when partners reported greater solicitousness and higher approach goals at pretreatment, women benefited more in terms of their pain. It is likely that these predictors are tapping into partners who are more empathic, value intimacy, and who are consequently more personally

engaged with the treatment. The solicitous finding might at first seem counterintuitive given that prior studies have linked higher solicitousness with women's greater pain during intercourse (Rosen et al., 2015). But in the context of treatment, a partner who is overly concerned about the woman and her pain might be more treatment compliant (e.g., reminding the woman to apply lidocaine, participating actively in therapy), which could account for its positive benefits posttreatment and longer term.

MODERATORS OF CHANGE IN WOMEN'S SEXUAL FUNCTION BY TREATMENT CONDITION

CBCT was more effective than lidocaine for improving women's sexual function at posttreatment when women had partners with higher pretreatment anxiety and when women reported lower pretreatment approach sexual goals. Thus, those who had pretreatment deficits in areas targeted directly by CBCT benefited more in their sexual function from this treatment relative to lidocaine. In CBCT, partners learned tools for coping with their anxiety, which may have created more space for them to be responsive to women's sexual needs, resulting in women's greater sexual function (Muise et al., 2017). The CBCT also directly helps women to focus on reasons for having sex that are beneficial for their relationship (i.e., approach sexual goals); prior studies have shown that these goals are difficult to maintain for women with PVD despite being linked to enhanced sexual function (Rosen et al., 2018). In contrast, lidocaine was more effective than CBCT for improving women's sexual function at follow-up when partners had higher pretreatment approach sexual goals, whereas for women with partners lower in approach goals, both treatments were equally effective. When partners are already motivated to have sex to promote positive relationship outcomes, women may be more receptive and responsive to their partners (e.g., initiation of sexual activity) as their pain is reduced via the lidocaine, resulting in a steeper increase in their own sexual function over time.

THEORETICAL AND CLINICAL IMPLICATIONS

Our findings support theoretical predictors and moderators of treatment outcome for key symptoms experienced by women with PVD. With the exception of anxiety, the significant predictors and moderators of women's outcomes were interpersonal variables, emphasizing a dyadic approach to conceptualization and treatment of PVD (Rosen & Bergeron, 2019). When recommending CBCT or lidocaine, clinicians should note that women benefited more in terms of their pain when they were in a longer relationship, had partners who scored higher in solicitousness and approach sexual goals, and when women were less anxious pretreatment. Given that these predictors did not differ by treatment, it might be useful to complement medical treatments such as lidocaine with psychological interventions to promote partner empathy and engagement. Women with high pretreatment anxiety might benefit from a stronger and earlier focus on anxiety reduction to improve the efficacy of their treatment. Our findings indicate that women will improve more in their sexual function when areas of deficit are directly addressed via CBCT (relative to lidocaine), such as partner anxiety and women's approach goals for sex.

STRENGTHS AND LIMITATIONS

This study was the first to our knowledge to examine theoretical predictors and moderators of a sex and couple therapy for sexual dysfunction, and PVD in particular. The RCT was methodologically rigorous with a strong sample size and high retention rates. However, two of our study criteria limit the generalizability of our findings. First, our sample was restricted to women with PVD to increase internal validity and the findings may not generalize to other types of genito-pelvic pain. Second, couples who were highly relationally distressed or who reported intimate partner violence were excluded from participating due to ethical reasons and the nature of the intervention, and a history of sexual trauma was not assessed. These exclusions limited the range of relationship dynamics as predictors/ moderators. In addition, our sample was predominantly White and heterosexual, limiting generalizability to more diverse populations. The pain items were removed from the FSFI, resulting in unclear validity for this measure. As the variances in the observed slopes in our data were small and the effect sizes of moderation analyses are often smaller than .25 as it is an interaction between two effects, the present study may have been underpowered to detect some associations. We did not ask participants about psychotropic medication use, which may be a relevant covariate. We compared CBCT to a medical treatment, lidocaine, but a treatment approach that combines CBCT and lidocaine may be even more beneficial as it would target multiple dimensions of PVD simultaneously. The lack of RCTs that include a multimodal option makes it unclear whether it is superior to single treatments or how it would

compare to an approach that attempts to match couples to treatment (Bergeron et al., 2020). Finally, we focused on predicting treatment outcome for two core symptoms of PVD (pain and sexual dysfunction) and examining other outcomes such as sexual and psychological distress is likely to reveal additional information about treatment efficacy.

CONCLUSIONS

In conclusion, we identified novel predictors and moderators across demographics, clinical, and interpersonal factors, suggesting that there are a range of pretreatment variables that are important to assess to maximize treatment efficacy. Lower pretreatment anxiety in women as well as a longer relationship duration, partner higher solicitousness and partner higher approach sexual goals predicted better pain outcomes for women with PVD irrespective of treatment condition. In addition, CBCT was more effective than lidocaine for improving women's sexual function at posttreatment when women had partners with higher anxiety and when women reported lower approach sexual goals at pretreatment, whereas lidocaine was more effective than CBCT for improving women's sexual function at follow-up when partners had higher approach sexual goals pretreatment. Results contribute to a small but growing literature aimed at determining what treatment for sexual dysfunction will be most beneficial and for whom.

Conflict of Interest Statement

The authors declare that there are no conflicts of interest.

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