A Prospective 2-Year Examination of Cognitive and Behavioral Correlates of Provoked Vestibulodynia Outcomes

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Background: Provoked vestibulodynia (PVD) is a common genital pain disorder in women that is associated with sexual dysfunction and lowered sexual satisfaction. A potentially applicable cognitive-behavioral model of chronic pain and disability is the fear-avoidance model (FAM) of pain. The FAM posits that cognitive variables, such as pain catastrophizing, fear, and anxiety lead to avoidance of pain-provoking behaviors (eg, intercourse), resulting in continued pain and disability. Although some of the FAM variables have been shown to be associated with PVD pain and sexuality outcomes, the model as a whole has never been tested in this population. An additional protective factor, pain self-efficacy (SE), is also associated with PVD, but has not been tested within the FAM model.

Aims: Using a 2-year longitudinal design, we examine (1) whether initial levels (T_1) of the independent FAM variables and pain SE were associated with changes in pain, sexual function, and sexual satisfaction over the 2-year time period; (2) the prospective contribution of changes in cognitive-affective (FAM) variables to changes in pain, and sexuality outcomes; and (3) whether these were mediated by behavioral change (avoidance of intercourse).

Methods: A sample of 222 women with PVD completed self-report measures of FAM variables, SE, pain, sexual function, and sexual satisfaction at time 1 and at a 2-year follow-up. Structural equation modeling with Latent Difference Scores was used to examine changes and to examine mediation between variables.

Main Outcomes: Questionnaires included the Pain Catastrophizing Scale, McGill Pain Questionnaire, Trait Anxiety Inventory, Pain Self-Efficacy Scale, and Global Measure of Sexual Satisfaction, Female Sexual Function Index.

Results: Participants who reported higher SE at T_1 reported greater declines in pain, greater increases in sexual satisfaction, and greater declines in sexual function over the 2 time points. The overall change model did not support the FAM using negative cognitive-affective variables. Only increases in pain SE were associated with reductions in pain intensity. The relationship between changes in SE and changes in pain was partially mediated through changes in avoidance (more intercourse attempts). The same pattern of results was found for changes in sexual satisfaction as the outcome, and a partial mediation effect was found. There were no significant predictors of changes in sexual function other than T_1 SE.

Discussion: Changes in both cognitive and behavioral variables were significantly associated with improved pain and sexual satisfaction outcomes. However, it was the positive changes in SE that better predicted changes in avoidance behavior, pain, and sexual satisfaction. Cognitive-behavior therapy is often focused on changing negative pain-related cognitions to reduce avoidance and pain, but the present results demonstrate the potential importance of bolstering positive self-beliefs as well. Indeed, before engaging in exposure therapies, SE beliefs should be assessed and potentially targeted to improve adherence to exposure strategies.

Provoked vestibulodynia (PVD) is one of the most common genital pain conditions in women, with prevalence rates estimated around 12%.[1] PVD is characterized by burning and cutting pain at the vulvar vestibule that is generally elicited by pressure or rubbing to the area. Not surprisingly, PVD is associated with significant sexual dysfunction and lowered sexual satisfaction.[2] Both biomedical and psychosocial factors have been hypothesized to be involved in the development and maintenance of PVD. Proposed biomedical pathways suggest that initial trauma to the genitalia may trigger inflammatory processes, pelvic floor muscle dysfunction, and other local changes, leading to increased pain sensitization and pain persistence.[3] Alternative psychosocial explanations for the development and maintenance of PVD include maladaptive pain-related cognitions and behaviors that exacerbate pain and contribute to pain-related disability and sexual dysfunction.[4] At present, no convincing evidence justifies 1 single biomedical or psychosocial explanation.

To add to the complexity of PVD, the triggers associated with the onset of the condition are often unclear and may be distinct from the factors that maintain and exacerbate it, and the predictors of pain outcomes can differ from those of sexuality outcomes, both of which are important to patient well-being. Unfortunately, much of the research to date has focused on trying to identify factors associated with the development of this prevalent condition, with little work examining variables that may modulate the pain experience and associated sexual difficulties. Furthermore, the few published studies tend to be cross-sectional and therefore only provide partial information.[2,5] The present 2-year prospective study examined how changes in pain-related cognitions and emotions predicted changes in pain and sexual outcomes in women with PVD, and whether these changes were mediated through behavioral avoidance.

One of the most influential cognitive-behavioral theories of chronic pain and pain-related disability is the fear-avoidance model (FAM).[6,7] Although the model is most often applied to musculoskeletal pain, it may also be

appropriate, in a modified form, to the prediction of PVD symptomatology. The FAM proposes a number of cognitive, affective, and behavioral steps that lead from pain to pain-related disability. Initially, individuals prone to pain catastrophizing tend to focus, ruminate, and magnify the pain they experience. Catastrophic thinking about pain leads to fear of pain or anxiety, and more specifically, the belief that movement and movement-related pain will lead to reinjury. The behavioral effect of fear of pain and movement is an avoidance of potentially pain-inducing activities. The results of avoiding pain-inducing stimuli are that these beliefs are not challenged, which perpetuates the cycle and leads to disuse, disability, and depression. The FAM can also be conceptualized as a cycle by which disuse, disability, and depression lead to further pain.

The FAM may be a useful model for explaining some of the cognitive-behavioral aspects of pain and disability in PVD. Indeed, higher levels of pain catastrophizing have been shown to be associated with increased PVD pain,[8] which is the first step of the FAM. Furthermore, higher pretreatment levels of catastrophizing have also been found to predict increased pain intensity after cognitive-behavior therapy (CBT).[9] Although fear of movement and behavioral avoidance of movement are not strictly applicable to PVD, avoidance of sexual intercourse is common in these women.[10] This has previously been proposed as the circle of fear, by which fear of pain leads to avoidance of penetration.[4] Avoidance may then lead to lowered sexual arousal, vaginal dryness, and pelvic floor tension, which in turn may result in greater pain during the sexual experience. Indeed, harm-avoidance has been shown to be elevated in women with vaginismus, another sexual pain disorder, as compared with controls, whereas women with dyspareunia had means that were intermediate between the 2.[11] Hence, it is reasonable to hypothesize that the FAM could apply to women with PVD as well. Fear of pain has been examined specifically in PVD, but was not found to be an independent predictor of pain or disability above and beyond catastrophizing, although this study did not take into account the sequential aspects of the FAM.[8] However, another study showed that pain-related fear reduced sexual arousal in women with PVD as well as pain-free controls.[12] Thus, the role of fear in PVD remains unclear to date.

In addition to FAM variables, self-efficacy (SE) has recently been shown to be an important predictor of pain and disability in individuals with chronic pain,[13] and sometimes a better predictor than FAM variables in low-back pain.[14] Pain SE is conceptualized as the degree to which someone feels they can cope with difficult situations, in this case, situation that may provoke vulvovaginal pain. Better SE would mean a greater sense of being able to cope with pain, and feelings of being able to engage in activities despite pain. SE has also been studied in women with PVD using cross-sectional designs[8] and as a predictor of treatment outcomes.[9] In this randomized trial comparing cognitive-behavior therapy and a topical medical treatment, higher pretreatment levels of SE were a significant predictor of better sexual function (disability) at 6-month follow-up, although not pain intensity. One possible explanation is that SE mediates the relationship between pain and disability by increasing patients' engagement in the pain-provoking behavior (sexual intercourse), thereby functioning to extinguish the association between pain and intercourse.

Both FAM variables and SE have important implications for the treatment of PVD. One increasingly common treatment option for PVD is CBT.[15] The FAM dovetails nicely with CBT as it points toward explicit negative cognitions to work on as well as behaviors to target by way of graduated exposure assignments. It also provides a temporal framework to work within, as the therapist must initially focus on challenging negative cognitions before explicitly addressing avoidance behaviors. A similar model has been used in the cognitive-behavioral treatment of vaginismus, with improvements using both group therapy and bibliotherapy.[16] In particular, the actual behavioral engagement in the fear-provoking stimuli (vaginal penetration) was shown to predict less fear of pain at later time points, and both fear of pain and penetration behaviors mediated outcomes.[17] Furthermore, speed in treatment responding was mediated by fear of pain, such that late responders had higher levels of fear of pain than early responders. These results, however, were for women with vaginismus, and may not apply to PVD. Nonetheless, in another CBT trial for women with PVD, higher perceived pain control was related to more improvement in pain outcomes, but only in women who reported an ability to engage in intercourse after the treatment.[15] This suggests that perceived control, which shares much conceptual overlap with SE, is related to behavior.

An examination of FAM cognitive-affective variables and SE is not novel in genital pain. Several studies have demonstrated that fear of pain, SE, and pain catastrophizing are all related to pain intensity and sexual function and satisfaction.[8,9,11,17] There are, however, a number of areas where this research can be expanded upon to refine cognitive-behavioral theoretical conceptualizations of PVD and to improve utility for clinical applications. One issue is the cross-sectional design of much of the previous research. Although cross-sectional data give important information about cognitive factors that are related to pain and sexual dysfunction, they do not allow us to determine whether changes in these cognitive variables are related to changes in outcomes. Second, these data assume a relationship between cognitive and behavioral variables, but within the PVD literature, these have not been tested in a sequential manner as proposed by the FAM. Doing so will allow this research to inform the development of targeted therapeutic interventions. Finally, to our knowledge, behavioral avoidance has never been measured in the context of the FAM as applied to PVD. Instead, previous studies on PVD assume that cognitions related to avoidance lead to actual behavioral avoidance, although this relationship has never been tested. The present study aimed to rectify this by measuring the number of attempts at intercourse as an indicator of avoidance and examining their association with pain-related cognitions and emotions.

The goals of the present 2-year prospective study were 3-fold. First, we aimed to examine whether initial levels of the independent FAM variables and pain SE predicted changes in pain and sexuality outcomes. Second, using change scores over 2 years, we aimed to examine whether changes in cognitive-affective variables would predict changes in pain and sexual outcomes over the same 2-year period. Third, we aimed to examine whether the relationship between changes in cognitive-affective variables and changes in pain and sexuality outcomes was mediated by changes in behavioral avoidance as proposed by the FAM.

It was hypothesized that higher initial (T_1) levels of catastrophizing, fear, and anxiety would be associated with less changes in pain, sexual function, and sexual satisfaction, whereas higher initial levels of SE would be

associated with more changes. It was further hypothesized that decreases in catastrophizing, fear, and anxiety, as well as increases in SE, would be associated with increases in sexual satisfaction, and decreases in pain and sexual dysfunction over the 2-year period, and that these changes would be accounted for by increases in number of attempts at sexual intercourse (ie, decreases in behavioral avoidance).

METHODS

Participants

Participants were recruited during clinic visits to either gynecologists or other health professionals, as a well as through newspaper in a large urban center and Web site advertisements. Because this was part of a larger study on couples, women were required to be in a relationship. If women indicated an interest in the study, they were screened either face-to-face or by telephone to determine eligibility. The specific inclusion criteria for women were: (1) pain during intercourse that was subjectively distressing, occurred on 80% of intercourse attempts, and lasted > 1 year; (2) pain limited to intercourse and other activities that caused pressure to be exerted on the vestibule; (3) if recruited through a gynecologist, severe pain in one or more vestibular locations during the cotton swab test; and (4) married or cohabiting with a partner for at least 6 months. The exclusion criteria were: (1) vulvar pain not clearly linked to intercourse or pressure to the vestibule; and (2) presence of major medical or psychiatric illness, active infection, deep dyspareunia, physician-diagnosed vaginismus, dermatologic lesion, pregnancy, age of less than 18 years.

Procedure

This study was approved by the Centre Hospitalier de l'Univeristé de Montréal Institutional Review Board. All participants gave written informed consent. If women were interested in participating, they were either given a questionnaire package in person at the gynecology clinic or, in the case where they were recruited via an advertisement, the package was sent to their home. They were asked to complete it on their own and without the help of their partner. Two years later, a research assistant contacted all participants who participated at time 1. If they agreed to participate in the time 2 data collection, they were sent 1 package each through regular mail and were asked to complete the measures as per the same initial instructions. If participants were now single or had a new partner, they were excluded from the present analysis, as behavioral measures of intercourse attempts required consistency of partners.

Measures

Dependent Variables

Pain intensity: Pain intensity was measured using a Visual Analogue Scale by asking participants to estimate their average vulvovaginal pain over the past month. Participants rated pain intensity on a scale from 0 to 10, with 0 representing no pain and 10 representing the worst pain ever. The VAS has good validity and reliability in measuring many different types of pain.[18] This method of pain measurement is sensitive to treatment effects in PVD,[19] and correlates well with other measures of pain[8] in PVD.

Sexual satisfaction: The Global Measure of Sexual Satisfaction (GMSEX)[20] was used to measure sexual satisfaction. The GMSEX is a 5-item measure that assesses satisfaction and affective descriptors regarding the sexual relationship with one's partner. Each item is rated on a 7-point Likert scale, with higher scores indicating greater satisfaction. The scale has good psychometric properties including good reliability and excellent validity.[21] The Cronbach α in the present sample was 0.90.

Sexual function: The Female Sexual Function Index (FSFI) is a well-validated measure of sexual function in women.[22] The scale is divided into 6 dimensions: desire, arousal, lubrication, orgasm, sexual satisfaction, and pain, with higher scores indicating better sexual function. The present study calculated a total FSFI score without the pain subscale, as the aim was to measure aspects of sexual function other than pain. Inclusion of the pain subscale would likely lead to inflated correlations with other measures of pain. The Cronbach α for the present sample was 0.80.

Independent Variables

Pain catastrophizing: The Pain Catastrophizing Scale[23] is a well-validated and widely used measure of pain catastrophizing from the chronic pain literature. In the present study, women were asked to fill out the Pain Catastrophizing Scale regarding the thoughts and feelings they had when experiencing pain during intercourse. Although there are subscales of rumination, magnification, and helplessness, the total score was used in the present study. Higher scores indicate more catastrophizing. Cronbach α in this sample was 0.87.

Pain self-efficacy: The Painful Intercourse Self-Efficacy Scale (PISES) is a scale adapted from the Arthritis Self-Efficacy Scale.[24] The original scale is widely used and cited in the general pain literature, and has been found to be reliable and valid in arthritis populations.[24] The adapted version has been used in previous research in women with PVD and was predictive of pain-related variables,[9] with higher scores indicating more SE. Previous studies using an adapted version of the scale have found a Cronbach α of 0.89, and the Cronbach α for the present study was 0.90.

Anxiety: The Spielberger State-Trait Anxiety Inventory (STAI)[25] was used to measure anxiety. This is a 40-item, well-known, and well-validated measure of anxiety with excellent psychometric properties. There are 2 subscales: State and Trait. Only the trait subscale was used in the present study, as the questionnaire was completed at home, hence state anxiety could not be accounted for. Higher scores indicate more anxiety. The Cronbach α for the trait scale in the present sample was 0.93.

Fear: Each participant filled out the McGill Pain Questionnaire (MPQ),[26] which is a widely used measure of affective, cognitive, and sensory descriptors of pain. Participants were asked to fill out the questionnaire specifically regarding their pain during intercourse. Participants are asked to choose pain-related adjectives from a list to describe their pain. There are 3 fear-related adjectives that may be chosen, and participants may choose between 0 and 3. The number of fear-related pain adjectives chosen was used as the fear score, and higher scores indicated more fear. The MPQ has been shown to be a reliable and valid measure of many types of pain.[18]

Behavioral avoidance: Participants were asked how many times in the past month they had attempted to have sexual intercourse with vaginal penetration. The actual number of attempts, successful or not, was taken as the behavioral measure of avoidance, with a lower number of attempts being indicative of more avoidance.

Analysis Strategy

To examine the influence of changes in cognitive, affective, and behavioral variables on the changes in pain, sexual satisfaction, and sexual function, a Latent Difference Score (LDS) approach was employed.[27,28] In contrast to observed difference score models, the LDS model accommodates the estimation of a reliable index of change by modeling change in perfectly reliable scores in time-ordered data.[29] LDS modeling permits the examination of within-person change and individual differences in this within-person change.[30] Specifically, within-person change is represented by a latent construct (ie, LDS) indexing the difference between adjacent scores in time-ordered data. Individual differences in this within-person change are modeled as a function of the individual differences in the level of the (1) same variable at the prior measurement occasion (ie, autoregressive lagged effect); and (2) other time-varying (eg, sexual satisfaction) and time-invariant covariates (eg, sex). Furthermore, this within-person change between 2 adjacent measurement occasions can be used as predictor of other time-varying variables thereby permitting an examination of the effect of the dynamic change in one process on other parallel change processes.

First, for each of the variables, we constructed autoregressive lagged paths from the same variable at T_1 on the LDS, depicting change in that variable between the 2 occasions. Next, the LDSs in pain, sexual satisfaction, and sexual dysfunction were examined in relation to (1) cognitive, affective, and behavioral variables at T_1; and (2) by the LDSs occurring between the 2 occasions in each cognitive, affective, and behavioral variable. Thus, these cross-variable lagged effects represent the influences of the cognitive-affective and behavioral variables' (1) T_1; and (2) LDSs on the dependent variables (ie, LDSs in pain, sexual satisfaction, and sexual function), controlling for the autoregressive lagged effects T_1 on the dependent variables. Finally, we reestimated the model by covarying out the influence of pain duration on LDSs in each of the dependent and independent variables. We examined mediation in the model by constructing indirect effects of the difference scores in cognitive-affective variables on difference scores in pain, sexual satisfaction, and sexual function through the LDS in the behavioral avoidance variable (number of attempts).

Analyses were conducted using the Mplus software package (Version 7; Muthen & Muthen, 1998 to 2012) and the maximum likelihood estimator with standard errors that are robust to non-normality of observations and to missing data. Fit of the model was examined using the root mean square error of approximation (RMSEA), standardized root mean square residual (SRMR), and comparative fit index (CFI). RMSEA and SRMR values of ≤ 0.08[31] and CFI values > 0.90[32] indicate good model fit.

RESULTS

Sample Characteristics

A total of 317 participants completed the questionnaires at time 1 (T_1), and 222 at time 2 (T_2), for a retention rate of 70.1%. Therefore, the final data analyzed included 222 women. There were no significant differences between T_1 variables between women who completed and women who did not complete T_2. Of these 222 women, 104 had been diagnosed with PVD by their gynecologist, and the remainder (118) met criteria for PVD based on the telephone screening. There were no differences in any of the T_1 variables based on the source of recruitment (gynecologist or other). The mean age of the sample at T_1 was 31.0 years (range, 18 to 68 y, SD = 10.9). The mean pain duration at T_1 was 5.6 years (range, 0.5 to 43.8 y, SD = 6.2), and the mean pain intensity at T_1 was 7.1/10 (range, 1 to 10, SD = 1.7). Seven participants left the T_1 pain intensity blank and were coded as missing data for further analyses. All women were in a relationship at T_1 and the mean relationship duration was 6.8 years (range, 0.5 to 38.4 y, SD = 7.4). The majority (97.3%) identified culturally as Québécois or Canadian, and had at least completed high school (88.9%). All women who did not engage in intercourse were asked the reason for not engaging in intercourse, and all indicated that pain or fear of pain were at least one of the potential reasons.

The means and SDs for each dependent and independent variable are provided in Table 1. The observed means for pain, catastrophizing, fear, and anxiety decreased over the 2-year period. The means for SE, sexual satisfaction, number of attempts, and sexual function increased. As expected, there were positive correlations (at the same time point) between the FAM cognitive-affective variables with the exception of anxiety and fear at T_1. The FAM variables were all negatively correlated with self-efficacy. These cognitive-affective variables were also correlated in the expected direction with the number of attempts in the last month, with the exception of fear at T_1 and T_2 and anxiety at T_1. Finally, FAM cognitive-affective variables (catastrophizing, fear, and anxiety) were generally positively correlated with pain and negatively correlated with sexual satisfaction, whereas SE and number of attempts were generally negatively correlated with pain, and positively correlated with sexual satisfaction. Sexual function was inconsistently correlated with cognitive, affective, and behavioral variables. All bivariate correlations are available in Table 1. In addition, the sociodemographic variables of age, pain duration, relationship duration, age of first pain, and years of education were correlated with the independent and dependent variables. None were correlated above 0.30, so it was decided not to covary them out of further analyses.

Main Effects Model

Goodness-of-fit indices for the model indicated good fit (RMSEA = 0.06, SRMR = 0.03, CFI = 0.99). We first examined the autoregressive, lagged effects of each variable at T_1 on the LDS for that variable. All the effects were significant and with a negative coefficient, indicating that, compared with participants with lower scores, those who scored higher on the initial status (ie, T_1) in each of the independent (catastrophizing, fear, anxiety, SE, and avoidance) and dependent (pain, sexual satisfaction, and sexual function) variables are expected to report lower scores at the subsequent time point (ie, T_2).

The first part of the model that was examined was the degree to which initial level (T_1) of the independent variables were associated with the degree to which the dependent variables changed (LDS). To do so, cross-variable lagged effects of the independent variables at the initial status (T_1) on the 3 dependent variables (LDS in pain, sexual satisfaction, and sexual function) were examined (Table 2). Findings indicate that participants who reported higher SE at T_1 reported greater declines in pain, greater increases in sexual satisfaction, and greater declines in sexual

TABLE 1. Correlations Between Cognitive-Affective, Behavioral, and Dependent Variables

	Anx T_1	Anx T_2	Pain T_1	Pain T_2	FSFI T_1	FSFI T_2	Eff T_1	Eff T_2	PCS T_1	PCS T_2	Att T_1	Att T_2	Fear T_1	Fear T_2	SexSat T_1	SexSat T_2
Anx T_1	—															
Anx T_2	0.67**	—														
Pain T_1	0.10	0.03	—													
Pain T_2	0.17*	0.29**	0.17*	—												
FSFI T_1	0.11	0.19**	−0.05*	0.07	—											
FSFI T_2	1.7*	0.24**	0.01	0.20**	0.09	—										
Eff T_1	−0.35**	−0.21**	−0.41**	−0.21**	0.16*	0.15*	—									
Eff T_2	−0.29**	−0.42**	−0.19**	−0.65**	−0.03	0.30**	0.37**	—								
PCS T_1	0.34**	0.24**	0.39**	0.18**	−0.03	0.05	−0.46**	−0.28**	—							
PCS T_2	0.27**	0.40**	0.22**	0.51**	−0.11	0.21**	−0.35**	−0.70**	0.46**	—						
Att T_1	−0.05	−0.02	−0.26**	−0.14*	0.18*	−0.01	0.28**	0.18*	−0.14*	−0.12	—					
Att T_2	−0.17*	−0.19**	−0.07	−0.30**	0.10	−0.13	0.07	0.33**	−0.16*	−0.21**	0.22**	—				
Fear T_1	0.09	0.07	0.11	0.09	−0.00	0.05	−0.15*	−0.16*	0.22**	0.14*	−0.07	−0.01	—			
Fear T_2	0.09	0.17*	0.12	0.20**	−0.01	0.01	−0.12	−0.27**	0.22**	0.28**	−0.11	−0.09	0.20**	—		
SexSat T_1	−0.34**	−0.20**	−0.15*	−0.10	0.16*	−0.13	0.32**	0.17*	−0.24**	−0.24**	0.20**	0.06	−0.15*	−0.10	—	
SexSat T_2	−0.24**	−0.32**	−0.05	−0.48**	0.17*	−0.29**	0.23**	0.60**	−0.20**	−0.51**	0.10	0.38**	−0.09	−0.16*	0.35**	—
Mean	43.31	40.26	7.09	4.19	15.04	19.36	59.65	71.14	28.18	20.03	3.64	4.44	0.56	0.32	23.74	25.53
SD	11.23	11.31	1.73	2.58	4.01	4.01	15.38	18.79	10.08	11.78	4.59	4.42	0.85	0.66	6.27	6.26

Anx indicates anxiety; Att, attempts; FSFI, Female Sexual Function Index; PCS, Pain Catastrophizing Scale; SexSat, sexual satisfaction.
*$P \geq 0.05$.
**$P \geq 0.01$.

dysfunction over the 2 time points. None of the T_1 values for any of the FAM variables (catastrophizing, fear, and anxiety) were significantly associated with LDS in pain, satisfaction, sexual function, or number of attempts.

The second part of the model that was examined was the degree to which changes (LDS) in the independent variables were associated with changes (LDS) in the dependent variables. To do so, cross-variable lagged effects of the LDS in independent variables (SE, catastrophizing, fear, and anxiety) on the 3 dependent variables (LDS in pain, sexual satisfaction, and sexual function) were examined (Table 3). Controlling for other effects in the model, LDS in SE and number of attempts was associated with LDS in pain such that participants who reported increases in SE and number of attempts (ie, a positive change score) between the 2 measurement occasions experienced greater declines in pain between T_1 and T_2: PISES: $B = -0.52$, $P < 0.001$; and number of attempts: $B = -0.12$, $P < 0.05$. Controlling for other sources of influence in the model, LDS in SE and LDS in number of attempts was also associated with LDS in sexual satisfaction. Participants who reported increases in SE and number of attempts from T_1 to T_2 experienced increases in sexual satisfaction between T_1 and T_2 (PISES: $B = 0.45$, $P < 0.001$; number of attempts: $B = 0.20$, $P < 0.001$). Finally, none of the LDSs for the independent variables (catastrophizing, fear, anxiety, and SE) or behavioral avoidance (number of attempts) predictors was significantly related to changes in sexual function (Table 3).

Mediational Analysis

The final portion of the model tested the degree to which the association between pain, sexual satisfaction, and sexual function by FAM cognitive-affective variables (fear, catastrophizing, anxiety, and SE) was accounted for by behavioral avoidance (number of attempts). The examination of the indirect effects indicated that LDS in number of attempts (estimated indirect effect = 0.03, $P < 0.05$) (Fig. 1) accounted for the relation between LDS in self-efficacy and LDS in sexual satisfaction. More specifically, participants who reported greater LDS in SE, experienced an increased number of attempts which, in turn, was associated with these participants' increases in sexual satisfaction between the 2 occasions.

DISCUSSION

Findings from the present 2-year prospective study show that only higher initial levels of SE were significantly associated with improved outcomes for pain and sexual satisfaction, and contrary to our hypothesis, of a worse outcome for sexual function. In addition, contrary to our hypothesis, changes in the FAM cognitive-affective variables were generally not associated with outcomes, whereas increases in pain SE were significantly associated with both decreases in pain and increases in sexual satisfaction. These findings are partially consistent with current cognitive-behavioral theories of chronic pain, as well as with results from studies examining the influence of cognitive-behavioral variables on pain and sexuality endpoints in women with PVD,[8,9] whereby only some of the expected predictors were significant. The mediation hypothesis that cognitive-affective variables and SE were associated with pain and sexual outcomes through changes in behavioral avoidance was only supported for SE.

TABLE 2. Influence of T_1 Cognitive-Affective Variables on Change Scores

Variables	Pain (LDS)		Sexual Satisfaction (LDS)		Sexual Dysfunction (LDS)		Attempts (LDS)	
	β	*P*	β	*P*	β	*P*	β	*P*
Attempts T_1	−0.119	0.06	0.106	0.08	−0.016	0.78	NA	
Self-efficacy T_1	−0.382	< 0.001	0.286	< 0.001	−0.197	< 0.05	0.047	0.61
Fear T_1	0.021	0.817	0.033	0.62	−0.048	0.57	0.047	0.43
Anxiety T_1	−0.027	0.63	−0.051	0.30	0.092	0.16	−0.128	0.13
Catastropizing T_1	0.076	0.31	−0.071	0.32	−0.027	0.74	−0.043	0.51

The bold values provided beside β.
LDS indicates Latent Difference Score.

There are a number of implications of these findings for the applicability of the FAM model to women with PVD. Despite the widespread use of the FAM in explaining pain-related disability in chronic pain, FAM cognitive-affective variables (catastrophizing, fear, and anxiety) were not the most important factors associated with outcomes, including pain, in the present study. Specifically, both initial levels and changes in FAM cognitive-affective variables were not associated with changes in pain, sexual satisfaction, or sexual function. Furthermore, the FAM is proposed as a sequential model, by which FAM cognitions and emotions influence outcomes through behavioral avoidance of pain-inducing stimuli. Therefore, it is important to test not only whether FAM cognitions are associated with final outcomes, but also whether they are associated with behaviors, and whether these behaviors, in turn, account for changes in outcomes. The behavior-mediated model using FAM variables was not supported, as none of the mediation models of FAM variables predicting pain and sexual outcomes through changes in number of attempts at intercourse were significant. In addition, none of the FAM cognitive-affective variables were associated with behavioral avoidance (number of attempts). In contrast to the FAM variables, SE was significantly associated with behavioral avoidance. Changes in SE from T_1 to T_2 were associated with changes in number of attempts in a positive direction. Furthermore, increase in number of attempts was significantly associated with both decreases in pain and increases in sexual satisfaction. Tests of indirect effects found that they partially accounted for sexual satisfaction. This indicates that the association between changes in sexual satisfaction and SE may be partially accounted for by changes in number of attempts at intercourse. This is directly in line with the sequential portion of the FAM, except that instead of negative cognitions and emotions (catastrophizing, fear, and anxiety) leading to increased avoidance, the positive cognition of SE

was associated with decreased avoidance, which in turn was associated with better sexual satisfaction.

SE was associated with behavior and outcomes throughout the model. Increases in SE were associated with both decreases in pain and increases in sexual satisfaction. Furthermore, SE at T_1 was associated with changes in all outcome variables (pain, sexual satisfaction, and sexual function), although in the opposite direction that was expected for sexual function. Finding SE to be more highly associated with outcomes than FAM cognitions and emotions is not entirely surprising. Recent studies in chronic pain have demonstrated that SE is a powerful predictor of pain and pain-related disability.[13,33] Furthermore, in women with PVD, using cross-sectional designs, SE has been found to be the only significant predictor of sexual function, although catastrophizing was a better predictor of pain.[8] In a CBT treatment trial, both initial levels of SE as well as initial levels of FAM variables predicted changes in outcomes.[9] Both the present study and these previous studies find SE to be important; however, the present study failed to find the same support for FAM cognitions and emotions. There are a number of reasons this may have occurred. In particular, our question of interest was how changes in independent variables predicted changes in dependent variables, as opposed to initial levels of the T_1 independent variables predicting T_2 endpoints. Although these are similar concepts, they are theoretically different models, as the former is dynamic, whereas the latter is static. Just because initial levels are high does not mean they will necessarily change over time and subsequently be associated with changes in the outcome. Indeed, using initial levels to predict outcomes at T_2 may only identify those participants who do not change over time. For example, high catastrophizers may remain high catastrophizers, and have little decrease in pain because of it. It may be that FAM cognitions are less amenable to change than SE without specific treatment. Therefore, one would not expect to see changes in FAM cognitions to be significantly

TABLE 3. Influence of Changes in Cognitive-Affective Variables on Changes in Behavior and Dependent Variables

Variables (LDS)	Pain		Sexual Satisfaction		Sexual Dysfunction		Attempts	
	β	*P*	β	*P*	β	*P*	β	*P*
Attempts	−0.120	< 0.05	0.203	< 0.001	−0.047	0.41	NA	
Self-efficacy	−0.516	< 0.001	0.448	< 0.001	−0.134	0.12	0.344	< 0.001
Fear	0.036	0.71	0.040	0.55	−0.074	0.36	0.030	0.57
Anxiety	−0.002	0.96	−0.054	0.34	0.084	0.20	−0.035	0.51
Catastrophizing	0.144	0.07	−0.088	0.18	0.052	0.48	0.065	0.41

The bold values provided beside β.
LDS indicates Latent Difference Score.
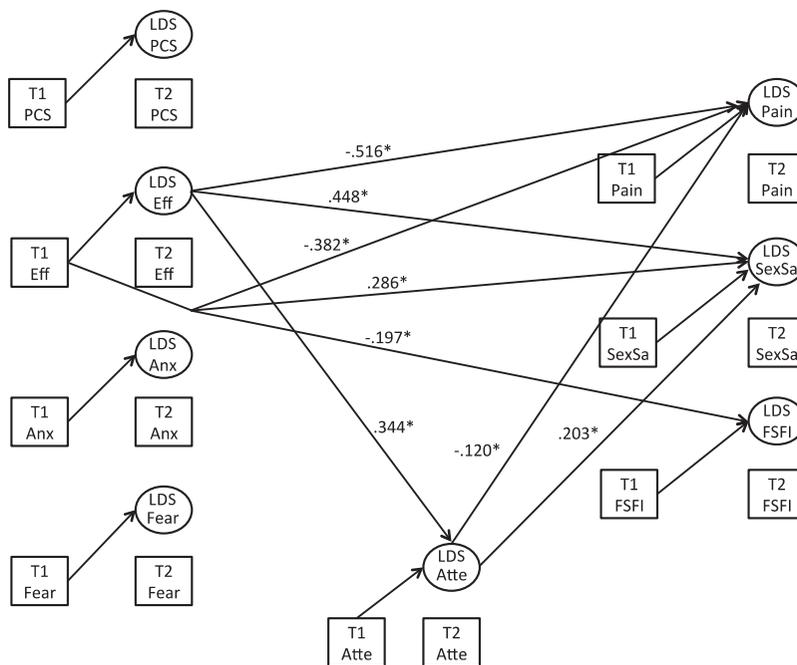
*All solid lines indicate significant prediction

FIGURE 1. The prediction of pain/sexual outcomes by cognitive-affective variables, mediated by behavior. FSFI indicates Female Sexual Function Index; LDS, latent difference scores; PCS, Pain Catastrophizing Scale.

associated with changes in outcome variables if these variables remain static over time. In contrast, analyzing change scores allows an examination of what changes are associated with improvements (LDS) in outcomes; in the present study, this was SE.

In the present sample, almost none of the cognitive, affective, or behavioral variables were associated with sexual function. The only exception was initial levels of SE, which surprisingly was associated with changes in sexual function in the opposite direction than was expected. This is in contrast with previous research which has found that sexual functioning is positively related to SE in women with PVD.[8,9] This difference could be explained by previous research's use of the full FSFI scale score, which includes a subscale for pain. Therefore, it is likely that if pain decreased, so would sexual dysfunction, as measured by the FSFI, and the 2 scales would be correlated. In our sample, the pain subscale of the FSFI was omitted to obtain a measure of sexual function that was not obscured by pain levels. Another potential problem is the scoring of the FSFI. Previous criticisms of the FSFI are that women who are not engaging in sexual activity are forced to score zero on many items.[34] This may be a problem in PVD research considering that avoidance of sexual activity is an important aspect of PVD. In the present sample, mean FSFI scores at both the time points were below a clinical cutoff (21)[35] for sexual dysfunction, which may suggest a potentially exaggerated lowering of scores due to avoidance. Prior recommendations have been made to only include women engaging in sexual activity on the FSFI,[34] but this would likely remove a large, clinically significant, and nonrandom portion of our sample.

Another explanation is simply that changes in sexual function were not influenced by the predictor variables of interest. The FAM cognitive-affective variables and SE are measured in relation to pain, and may not have had an effect on other aspects of sexual function (desire, arousal, and lubrication). Furthermore, resolution of pain does not necessarily mean that one will automatically have more desire for their partner, or become lubricated more easily. In fact, pain and sexuality outcomes are not always correlated among one another.[5,36] Despite this possibility, sexual satisfaction outcomes did improve when measured using the GMSEX, which does not have the same scoring issues as the FSFI for women with PVD. It is apparent that teasing apart the relationship between genital pain and sexual dysfunction in women with PVD will remain a needed focus of future research and the FSFI may not be the best scale with which to do this. There is certainly debate as to whether genital pain should be classified as a sexual dysfunction or a pain disorder,[37] although it will remain a sexual dysfunction in the diagnostic and statistics manual-5.[38,39]

Treatment Implications

These findings are clinically relevant for cognitive-behavioral of women with PVD. At present, CBT for women with PVD is often focused on challenging maladaptive cognitions regarding pain, such as catastrophizing, fear, and anxiety. Cognitive work is generally combined with assigning exercises of graduated vaginal penetration exposure (touch, fingers, and graduated dilator sets), with the ultimate goal of achieving penetrative sexual intercourse. The significant finding that behavior mediated the impact of SE on pain and sexual satisfaction supports the importance of engaging in exposure exercises. The present findings, however, highlight the need for improving patients' SE as a first step in reducing pain and increasing

sexual satisfaction. Because exposure exercises are often aversive to patients, these findings demonstrate the importance of bolstering SE before behavioral assignments are given to improve adherence to the homework. It is also worth noting that SE is a positive cognition that clinicians can aim to improve, rather than a maladaptive cognition that clinicians aim to extinguish. This may provide a unique positive psychology alternative that nicely complements the present treatments focused on the FAM.

Strengths

Although this is not the first study to examine cognitive, affective, and behavioral variables in PVD,[8,9,12,15] it does extend these findings in several important ways. The first is by exploring a meditational analysis of how cognitive, affective, and behavioral variables relate to one another, as well as to outcomes. This study also improves upon previous studies by using actual attempts at engagement in sexual intercourse as the measure of avoidance. Many previous studies of PVD assume that fear and avoidance cognitions are related to actual behavioral avoidance. By measuring reported engagement in sexual intercourse, we were able to demonstrate the meditational aspects of behavior in our model. Finally, the present study measured how changes in predictor variables predicted changes in outcomes, as opposed to using single time point measurements. In terms of creating effective cognitive-behavioral treatments, it is important to know that changing maladaptive cognitions and behaviors leads to changes in outcomes. By measuring change scores (LDS), the present study was able to do so.

Study Limitations

In addition to the strengths of the present study, there are a number of ways that it could be improved. A mediation analysis using 2 time points does not allow causal or truly mediation conclusions to be made from the data. By adding a third (or more) time point(s) to the study, it would have been possible to test whether early changes in cognitions led to later changes in behaviors, followed by changes in outcomes, in a sequential manner. Using only 2 time points, it is possible that changes in pain led to reductions in avoidance behaviors and changes in cognitions, instead of vice versa. Indeed, other studies in chronic pain have found that the FAM does not always hold up in a sequential analysis.[40] The potential applicability of the study could also be stronger if it were part of a CBT trial. It is possible that changes in FAM variables are actually more important than changes in SE, but are less likely to change without therapy. Perhaps targeting these variables specifically in therapy would have led to them being significantly associated with outcomes. Another limitation was that our measure of anxiety was a general measure, and our measure of fear was based on affective descriptions of pain. Specifically, the use of the fear adjectives of the MPQ has not been previously validated as a measure of fear. Although the measure of anxiety and fear correlated as expected with other FAM cognitions in the expected directions, they could have been improved by measuring the actual emotions of fear and anxiety as related to pain due to intercourse. For example, in musculoskeletal pain, the Tampa Scale of Kinesiophobia is often used to measure fear of movement and the pain and injury it is believed to cause.[41] To our knowledge, this scale does not exist for PVD. Nonetheless, these results may not be as directly applicable

to other examinations of the FAM model because of the difference in outcome measures used. In addition, the behavioral measure of sexual attempts relies on recall, which may be biased. Finally, the present study was only conducted in women who were in long-term romantic relationships and hence may not necessarily apply to those who are single.

CONCLUSIONS

In conclusion, cognitive, affective, and behavioral factors do play a role in the experience of pain and sexual health of women with PVD. Specifically, changes in SE appear to be the best predictor of changes in pain and sexual satisfaction over a 2-year time period. Furthermore, these changes are mediated by changes in avoidance behavior. These findings demonstrate the importance of targeting SE early in treatment to improve outcomes and to help reduce avoidance of potentially pain-provoking behaviors.

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