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Provoked vestibulodynia: Psychological predictors of topical and cognitive-behavioral treatment outcome

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ABSTRACT

Psychological factors have been found to impact the pain experience and associated sexual impairment of women suffering from provoked vestibulodynia (PV). Despite a lack of randomized treatment outcome studies, particularly concerning psychological predictors of outcome, recent studies have shown that topical applications and cognitive-behavioral therapy (CBT) are among the most popular first-line interventions for PV. The present study aimed to determine the extent to which baseline fear-avoidance variables and pain self-efficacy were differentially associated with topical application and CBT outcomes at six-month follow-up. Data were obtained from 97 women who completed a randomized trial comparing these two treatments. Regression analyses revealed that for topical treatment, higher levels of baseline avoidance predicted worse pain and sexual functioning outcomes, whereas higher levels of pain self-efficacy predicted better outcomes. For CBT, higher levels of baseline fear of pain and catastrophizing contributed to higher pain intensity at follow-up, whereas higher levels of pain self-efficacy were associated with less pain. Psychological factors did not predict sexual functioning outcomes for CBT. Consistent with biopsychosocial models of pain and sexual dysfunction, results indicate that psychological factors contribute to pain and sexual impairment following treatment for PV. Specifically, findings suggest that fear-avoidance variables and pain self-efficacy are significant predictors of topical and CBT treatment outcomes in women with PV.

Introduction

Provoked vestibulodynia (formerly known as vulvar vestibulitis syndrome) represents the most common type of dyspareunia or recurrent pain during intercourse in women of reproductive age (Meana, Binik, Khalife, & Cohen, 1997). This condition is characterized by cutting and/or burning sensations, located at the entry of the vagina, and provoked by pressure applied to the vestibular area (Friedrich, 1987). The lifetime prevalence of provoked vestibulodynia (PV) is estimated to be up to 12% in the general population (Harlow & Stewart, 2003). However, there is an important gap in the literature concerning the diagnosis and classification of PV. This may be partly explained by the fact that vestibulodynia is still conceptualized in a dualistic fashion – either as a psychogenic sexual dysfunction or as a biomedical problem (Binik, 2005). This dichotomous view has hampered research efforts, which have focused either on unidimensional questions concerning pathophysiological mechanisms, or attempts to find a psychosexual origin to the pain – with little work aiming to identify maintaining and exacerbating factors. To date, biomedical findings suggest the presence of an inflammatory response of the vestibular tissue that would lead to nociceptor sensitization and the subsequent development of a chronic, recurrent pain (Foster, Sazenski, & Stodgell, 2004; Gerber, Bongiovanni, Ledger, & Witkin, 2003; Witkin, Gerber, & Ledger, 2002). Conversely, sexual abuse has been identified as a possible precursor of chronic vulvovaginal pain, including PV (Harlow & Stewart, 2005). The need to treat women afflicted with this distressing and quality-of-life impairing condition has lead to approaches being advanced without the benefit of empirical validation. Most notably, the lack of research examining predictors of outcome is striking.

Despite this diagnostic and etiologic confusion, there is little doubt that PV impacts negatively on the psychological, sexual and

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relationship adjustment of afflicted women (for a review see Desrochers, Bergeron, Landry, & Jodoin, 2008). In fact, several controlled studies have shown that women with PV consistently report suffering from sexual impairment including decrease in sexual arousal and desire, a lower frequency of intercourse, difficulty achieving orgasm, and a decrease in sexual satisfaction (Meana et al., 1997; Reed, Advincula, Fonde, Gorenflo, & Haefner, 2000; Reed, Haefner, & Cantor, 2003). In addition, studies have also demonstrated that women with PV report higher anxiety levels than controls (Meana et al., 1997; Payne, Binik, Amsel, & Khalife, 2005; Payne et al., 2007). Recently, studies have also revealed that women suffering from dyspareunia reported poorer dyadic adjustment (Meana et al., 1997; Reed et al., 2000). Moreover, a recent study has also shown that partner hostility and solicitousness are related to reports of a more intense pain in women with PV (Desrosiers et al., 2008).

Concurrently, an important literature regarding the role of psychological factors in the experience of chronic pain and associated disability has emerged (see Leeuw et al., 2007). Specifically, the Fear Avoidance Model (Norton & Asmundson, 2003; Vlaeyen & Linton, 2000) is the most validated theoretical framework to date and represents an attempt to explain the mechanisms by which acute pain problems become chronic, with a view to determining which factors are involved in the exacerbation and maintenance of pain and disability. This model postulates that several psychological variables such as pain-related fears, catastrophizing and hypervigilance are leading to two opposing behavioral responses to pain: confrontation or avoidance, which respectively predict recovery, or a downward spiral of increasing avoidance, disability and pain (for a review see, Vlaeyen & Linton, 2000). In addition, more recent studies have also demonstrated the importance of another psychological variable called pain self-efficacy. In fact, studies have shown that pain self-efficacy may be even more important than fear-avoidance when it comes to disability (Ayre & Tyson, 2001; Woby, Urmston, & Watson, 2007). In fact, it has been suggested that pain self-efficacy should be included in the fear-avoidance model (Woby et al., 2007). Based on this recent conceptual development, studies have begun to show that higher baseline levels of pain-related fears (tendency to fear pain), catastrophizing (tendency to display exaggerated negative thoughts and feelings about the meaning of pain), hypervigilance to pain (tendency to constantly scan the body for sensations of pain) and avoidance (tendency to avoid pain and related activities) are associated with reduced treatment efficacy irrespective of the type of treatment condition (pain management-relaxation and exercise or CBT) (see Leeuw et al., 2007). Moreover, several studies have also demonstrated that higher baseline levels of pain self-efficacy (beliefs regarding capacity to cope with pain and to control it) predict better treatment outcome as much for pain as for disability (Vlaeyen, de Jong, Geilen, Heuts, & van Breukelen, 2001; Vlaeyen, De Jong, Onghena, Kerckhoffs-Hanssen, & Kole-Snijders, 2002).

However, these variables have never been investigated in treatment studies for PV. Nevertheless, controlled studies have shown that women suffering from PV consistently report higher levels of fear of pain and catastrophizing than controls do for other types of pain (Meana et al., 1997; Payne et al., 2007; Pukall, Binik, Khalife, Amsel, & Abbott, 2002). In addition, a recent study has shown that specific cognitive and affective factors such as fear-avoidance variables (e.g., anxiety, catastrophizing, fear of pain and hypervigilance) and pain self-efficacy are significantly associated with pain and related sexual impairment in PV (Desrochers, Bergeron, Khalifé, Dupuis, & Jodoin, 2009). Indeed, results of this study show that the more women with PV report higher levels of fear of pain, hypervigilance and catastrophizing and lower levels of pain self-efficacy, the more they report intense pain. In addition, results indicate that when it comes to sexual functioning, higher levels of state anxiety and avoidance as well as lower levels of pain self-efficacy are associated with more sexual impairment in women with PV.

Although various therapeutic interventions have been proposed in the last two decades, namely systemic and topical medical treatments (e.g., anesthetic gels and creams, tricyclic antidepressants, etc.), vestibulectomy (i.e. localized surgery), physical therapy/biofeedback and cognitive-behavioral therapy (CBT) (Landry, Bergeron, Dupuis, & Desrochers, 2008), there is a dearth of randomized controlled studies investigating the efficacy of these interventions. In particular, attempts to identify predictors of treatment outcome have been few and far between (Bergeron, Khalifé, Glazer, & Binik, 2008). Specifically, a recent review has shown that because of the lack of sound outcome research, it remains difficult to draw conclusions concerning the choice of treatment for women with provoked vestibulodynia (Landry et al., 2008). In a context where multiple interventions are attempted on a trial and error basis – some of which may cause iatrogenic harm – this state of affairs is problematic (Bergeron et al., 2008).

Nonetheless, medical topical treatments are typically prescribed as the first-line intervention irrespective of the patient's clinical presentation (Haefner, 2000). Most of the topical treatments are based on the inflammatory hypothesis and aim to decrease or interrupt this process (Witkin et al., 2002). Only a handful of prospective studies have been conducted in this area, showing that daily applications of lidocaine gel and ketoconazole or cromolyn cream seem to reduce pain intensity for some women (Morrison et al., 1996; Murina, Radici, & Bianco, 2004; Nyirjesy et al., 2001; Zolnoun, Hartmann, & Steege, 2003). However, no published studies to date have focused on predictors of outcome for topical interventions. Thus, even if this treatment option is effective for some women, we do not know who these women are and what factors to consider as guidelines in the prescription of a topical treatment.

Cognitive-behavioral therapy is another non-invasive modality for which there is a lack of knowledge about predictors of outcome. To date, one prospective study has shown that CBT success rates are almost as good as those of other medical options reported in previous studies (e.g., vestibulectomy) (Ter Kuile & Weijenborg, 2006). Moreover, CBT has the advantage of targeting both the pain and its associated psychosexual impairment. However, to our knowledge, only one published study has examined who can benefit from CBT interventions (Bergeron et al., 2008). In this study, baseline levels of pain, psychological distress and presence of erotophobia were investigated as potential predictors of pain outcome. Findings show that baseline level of pain during the gynaecological examination was the only significant predictor of outcome at a 2.5 year follow-up. Results show that the more women with PV reported worse pain during the gynaecological examination before treatment, the less they benefited from therapy. No psychological predictors were identified, which may be partly explained by the small sample size and the broad band measures of psychological distress used in the study. There is thus a need to examine more specific cognitive and affective variables. In addition, even if sexual impairment is considered to be an important target of CBT treatment, predictors of sexual functioning outcomes have never been examined in vestibulodynia treatment studies.

In summary, medical topical treatments and CBT are both commonly recommended interventions that are effective for some women afflicted with PV, but knowledge concerning for whom these interventions work is almost non-existent. Moreover, even if recent studies have shown the importance of psychological factors in the clinical presentation and etiology of PV, these variables have been ignored so far in the few available treatment studies. Thus, based on the available studies on psychological variables involved in the aetiology of PV and on the fear-avoidance model proposed by the

chronic pain literature, the present research aimed to determine whether baseline levels of state-trait anxiety, fear of pain, catastrophizing, hypervigilance to pain, avoidance and pain self-efficacy may predict pain and sexual functioning outcomes for topical and CBT interventions at six-month follow-up. We hypothesized that higher anxiety, fear of pain, catastrophizing, hypervigilance to pain and avoidance, as well as lower levels of baseline pain self-efficacy, would be related to poorer pain and sexual functioning outcomes.

Method

Original study outline

The present study is a component of a randomized trial which compared two active treatments frequently offered to women with PV – a topical application of a corticosteroid analgesic cream (topical treatment) and a group cognitive-behavioral therapy. The study comprised three assessment times: baseline, post-treatment and six-month follow-up, with intent-to-treat evaluations of outcome. Based on the original RCT results (see RCT results), the six-month follow-up time was chosen as the endpoint for the analyses conducted in the present study.

Participants

Potential participants were recruited through local media announcements and gynaecologist referrals in a large metropolitan area (convenience sample). Participants were initially screened during a short preliminary telephone contact to determine their eligibility based on the study selection criteria. Inclusion criteria were the following: 1) pain during intercourse which is/was subjectively distressing and occurs/occurred on most (75%) intercourse attempts for at least 6 months; 2) pain limited to intercourse and other activities involving pressure to the vestibular area (e.g., tampon insertion); 3) moderate to severe pain at one or more locations of the vestibule during the cotton-swab test (see Assessment procedures), with a minimum mean of at least 4 on a Likert scale from 0 *no pain at all* to 10 *worst pain ever felt*; 4) age between 18 and 45. Exclusion criteria were: 1) pelvic or vaginal pain not related to intercourse or pressure to the vestibular area; 2) major medical or psychiatric illness (assessed via the Brief Symptom Inventory and structured interview in the original study); 3) presence of a) active infection, b) vaginismus, c) dermatological lesion, or d) deep dyspareunia; 4) co-occurring treatment for vestibulodynia; 5) pregnancy; 6) insufficient fluency in written English or French. Eligible women were invited to take part in a baseline assessment including a gynaecological examination, where the study procedures were first re-explained and informed consent was obtained. Participants were then randomized to one of the two treatment conditions (topical or CBT) and followed the treatment protocol for 13 weeks (for treatment description see Statistical analyses). After the treatment phase, participants were again invited to take part in two assessments; one just after the completion of the treatment, i.e. post-treatment, followed by a six-month follow-up assessment. Participants were reimbursed for their transportation costs for each assessment ($10). The study was approved by the participating hospitals' and universities' institutional review boards.

Assessment procedures

Structured interview

Sociodemographic information as well as relationship, gynaecological and vulvo-vaginal pain history were collected during a structured interview. A shorter version of this interview was used for post-treatment and six-month follow-up assessments.

Gynaecological examination

The baseline gynaecological examination was performed according to a standardized protocol and consisted of the following procedures: (1) vaginal cultures in order to evaluate the presence of infections (Candida, Gardnerella, and Trichomonas); (2) a short interview carried out by the gynaecologist concerning obstetric-gynaecological history, medication, and vulvo-vaginal pain; (3) palpation with a finger of the following areas: vagina, uterus, and ovaries; (4) a standard bi-manual palpation of the uterus and ovaries; (5) randomized cotton-swab test palpation of three vestibular sites. A modified version was performed for the two post-treatment assessments including a shorter interview focussing on the improvement of dyspareunia, the palpation exam and the cotton-swab test. The cotton-swab test consists of the palpation with a dry cotton-swab in a randomized fashion of three locations around the part of the vestibule surrounding the hymeneal ring (i.e. 3–6–9 o'clock). A research assistant recorded the pain ratings for each palpation site for diagnostic purposes. The diagnosis was also noted on a standardized form by the gynaecologist. In a previous study, vestibular participant pain ratings were found to correlate significantly between gynaecologists for each palpation site, with inter-rater agreement correlations of .61–.80, $p < .001$ and Kappa coefficients ranging from .42 to .64, $p < .001$ (Bergeron, Binik, Khalifé, Pagidas, & Glazer, 2001).

Outcome measures

Pain

The intercourse pain intensity outcome was assessed using two different measures: 1) the Pain Numeric Visual Analogue Scale (VAS) is a horizontal 10 cm line anchored with (0) *no pain* and (10) *worst pain*. Participants were invited to indicate verbally their level of pain during intercourse in the last month as part of the structured interview at baseline, post-treatment and at follow-up. The reliability and validity of the VAS as a measure of pain has been established in multiple and various acute pain, chronic pain and experimentally induced pain samples (internal consistency $> .85$) (Holdgate, Asha, Craig, & Thompson, 2003; Jensen & Karoly, 2001; Melzack & Katz, 2001; Tamika et al., 2002). This pain measure has also been found to be sensitive to treatment change (Scrimshaw & Maher, 2001). 2) Pain during intercourse was also measured at the three assessment times using the McGill-Melzack Pain Questionnaire (MPQ) – short form (Boureau, Luu, & Doubrère, 1992; Melzack, 1975), with reference to pain during intercourse in the last three months for baseline and one month for post-treatment and follow-up assessments. The MPQ – short form is probably the most widely used questionnaire for pain measurement and has demonstrated excellent psychometric properties across acute and chronic pain populations, with a good test–retest reliability (between .75 and .95) (Boureau et al., 1992; Melzack & Katz, 2001; Strand, Ljunggren, Bogen, Ask & Johnsen, in press). Studies have also demonstrated the good psychometric properties of this questionnaire to reflect changes due to treatment (Scrimshaw & Maher, 2001; Strand et al., in press). Moreover, this measure provides a more global and multidimensional evaluation of pain severity using 78 adjectives that describe the pain experience (Pain Rating Index-PRI). Finally, for both pain measures, we asked single participants to refer to other kind of penetrative activities, as we have done successfully in previous studies (Bergeron et al., 2001, 2008; Meana et al., 1997; Payne et al., 2007), such as finger insertion or use of vaginal dilatators (both of which were part of the CBT arm).

Sexual functioning

The Female Sexual Function Index (FSFI – Rosen et al., 2000) was used to assess global sexual functioning for each assessment time.

The FSFI is a 19-item brief self-report questionnaire composed of six subscales related to the six dimensions of female sexual function: desire, arousal, lubrication, orgasm, sexual satisfaction and pain. For the purpose of this study and in order to avoid a possible over-estimation bias, the pain subscale items were ignored in the total score. The FSFI has demonstrated good psychometric properties with sexually functional and dysfunctional samples and serves to differentiate clinical from non-clinical populations (Daker-White, 2002; Meston, 2003; Rosen et al., 2000). It has also demonstrated excellent internal consistency (Chronbach's alpha $>$ .89) and test–retest reliability with chronic pelvic pain populations (Verit & Verit, 2007). Moreover, a recent study has confirmed a stable factorial structure and has established a clinical cut-off point (below 26.55) (Wiegel, Meston, & Rosen, 2005). The French version of this questionnaire was previously used in a vestibulodynia study and analyses were conducted to confirm the comparability of the translated French version to the original English one. Results of this study have shown a good internal consistency (Cronbach's alpha .73) and a similar factorial structure (Desrochers et al., 2009).

Psychological predictors

While they were waiting to take part in the structured interview or the gynaecological examination, participants were asked to complete a battery of five self-report questionnaires. English and French versions of each questionnaire were available.

Anxiety

The Spielberger State-Trait Anxiety Inventory (STAI – Spielberger, Gorsuch, & Lushene, 1970; ASTA – Gauthier & Bouchard, 1993) is a 40-item, well-known and widely used measure of state and trait anxiety that has demonstrated very good psychometric properties (Chronbach's alpha State .93 Trait .97) in various clinical and non-clinical samples including pain populations (Gauthier & Bouchard, 1993; Greenberg & Burns, 2003; Rule & Traver, 1983; Tanaka-Masumi & Kameoka, 1986).

Fear of pain

The Pain Anxiety Symptoms Scale (PASS-20-McCracken & Dhingra, 2002) is a shorter version adapted from the original 40-item questionnaire (McCracken, Zayfert, & Gross, 1992). It is a self-report measure of fear of pain designed for individuals with chronic pain problems and has been adapted for use in a sexual context (i.e. the word *sexual* has been added before the word *activity* for several items). Items are measured on a 6-point Likert scale with the end points (0) *never* and (5) *always*. This questionnaire includes four subscales: Cognitive Anxiety, Escape/Avoidance, Fearful Appraisal and Physiological Anxiety. In this study, the score on the Escape/Avoidance subscale has been used as the Avoidance score in the analysis. The PASS-20 has demonstrated good internal consistency (Chronbach's alphas between .90 and .92), test–retest reliability and a stable factorial structure (Abrams, Carleton, & Asmundson, 2007; Coons, Hadjistavropoulos, & Asmundson, 2004; McCracken & Dhingra, 2002). The PASS-20 has also been found to be sensitive to change after therapy (Vowles & McCracken, 2008). In a previous study, the French version of the questionnaire demonstrated a good internal consistency (Chronbach's alpha total score .86 and Avoidance .70) and a stable factorial structure in a vestibulodynia sample (Desrochers et al., 2009).

Pain catastrophizing

The Pain Catastrophizing Scale (PCS-CF – French et al., 2005; PCS – Sullivan, Bishop, & Pivik, 1995) consists of 13 items measuring exaggerated negative thoughts and feelings about the meaning of pain (Sullivan et al., 1995). Items are scored on a 5-point scale with the end points (0) *not at all* and (4) *all the time*. The PCS is divided into three subscales to assess the different components of catastrophic thinking: rumination (e.g., "I keep thinking about how much it hurts"), magnification (e.g., "I wonder whether something serious may happen") and helplessness (e.g., "There is nothing I can do to reduce the intensity of the pain"). The PCS is a reliable and valid measure (Chronbach's alpha .92) (Roelofs, Peters, McCracken, & Vlaeyen, 2003) and has demonstrated a stable factorial structure across clinical and general populations (Chibnall & Tait, 2005; D'Eon, Harris, & Ellis, 2004; French et al., 2005; Osman et al., 2000; Sullivan et al., 1995; Van Damme, Crombez, Bijttebier, Goubert, & Van Houdenhove, 2002). This measure has also been shown to correlate with pain and disability measures in various chronic pain populations (D'Eon et al., 2004; Sullivan et al., 1995). Finally, the PCS has been found to be sensitive to therapeutic changes (Pikerman, Gironda, & Clark, 2006).

Hypervigilance to pain

Hypervigilance to pain during intercourse was assessed with the Pain and Vigilance Awareness Questionnaire (PVAQ – McCracken, 1997). This is a 16-item measure of attention to pain that has been used to evaluate awareness, consciousness and vigilance to pain in various clinical and non-clinical populations (McCracken, 1997; McWilliams & Asmundson, 2001; Roelofs et al., 2003; Roelofs, Peters, Muris, & Vlaeyen, 2002). It shows good test–retest reliability and internal consistency (Chronbach's alpha .87) (Roelofs et al., 2003). Several studies have also demonstrated good construct validity for chronic pain populations (McCracken, 1997; McWilliams & Asmundson, 2001; Roelofs et al., 2003; Roelofs et al., 2002) and a good capacity to reflect therapeutic changes (Moss-Morris, Humphrey, Johnson, & Petrie, 2007). In a previous study (Desrochers et al., 2009); the French version of the questionnaire demonstrated a good internal consistency (Chronbach's alpha .71).

Pain self-efficacy

The Painful Intercourse self-efficacy Scale is a 20-item questionnaire with subscales measuring the three dimensions of pain self-efficacy associated with pain during intercourse: 1) self-efficacy for sexual function, 2) self-efficacy for controlling other symptoms and 3) self-efficacy for controlling pain during intercourse. This questionnaire was adapted from the Arthritis self-efficacy Scale (Lorig, Chastain, Ung, Shoor, & Holman, 1989), developed to assess perceived pain self-efficacy in arthritis patients. Participants indicated their perceived ability to carry out sexual activity or to achieve specific outcomes in pain management. Responses were recorded on a 10-point scale ranging from (10) *very uncertain* to (100) *very certain*. Validity and reliability of the original version are supported in an arthritis sample with good internal consistency (Chronbach's alphas ranging from .76 to .89) and satisfactory test–retest reliability (Lorig et al., 1989). A short form of the original scale has also demonstrated a good capacity to be sensitive to therapeutic changes (Mueller, Hartmann, Mueller, & Eich, 2003). However, the adapted version has not been fully validated. In a previous study, the French version of the questionnaire demonstrated a good internal consistency for the total score (Chronbach's alpha = .89) and subscales (Chronbach's alphas ranging from .76 to .88). Factorial analyses also yielded a factorial structure identical to that of the original scale (Desrochers et al., 2009).

Treatment protocol

The treatment protocol consisted of one of the two aforementioned treatment conditions delivered over a 13-week period.

Topical treatment

Topical treatment consisted of three commonly recommended regimens: 1) localized application of a corticosteroid cream (1%) on the vestibule twice a day irrespective of the sexual activity frequency; 2) use of a water-based lubricant during intercourse or finger insertion, and 3) education concerning PV and its day to day management. However, the women were asked to stop using the cream after eight weeks if there was no improvement to prevent women to use a non-effective cream containing cortisone mostly because of the potential side effects. The protocol was delivered by one of the two gynaecologists involved in the study and comprised a first appointment with the physician for prescription of the corticosteroid cream and instructions for proper use, a telephone follow-up after one week and a follow-up appointment with a research assistant after four weeks to verify treatment adherence and to answer questions that the women may have related to the cream application or its effect.

Group cognitive-behavioral therapy (CBT)

The CBT treatment consisted of ten, 90-min group sessions with five to ten women per group and was provided by one of two Ph.D. level psychotherapists. The two therapists were trained and supervised in the use of a treatment manual developed for the purposes of delivering CBT group interventions to women with dyspareunia (Bergeron et al., 2001; Bergeron, Binik and Larouche, unpublished treatment manual). Sessions were videotaped and reviewed by two independent graduate students to ensure therapist adherence to the treatment manual. The group CBT treatment protocol included the following elements: education and information about dyspareunia, PV in particular, and how pain impacts on desire and arousal; education concerning a multifactorial view of pain; education about sexual anatomy; use of a pain diary; progressive muscle relaxation; abdominal breathing; Kegel exercises; vaginal dilatation; distraction techniques focussing on sexual imagery; rehearsal of coping self-statements; communication skills training, and cognitive restructuring. These strategies were used to reduce pain intensity, fear of pain during intercourse, catastrophic thinking and to improve global sexual functioning.

Statistical analyses

Treatment outcome: intention-to-treat analysis

The same intent-to-treat data analytic strategy employed in the original randomized clinical trial, including all participants that were originally enrolled in the study irrespective of their completing treatment or the entire assessment protocol, was used for all the analysis. This strategy is known to be more conservative than traditional analyses by including participants who may not have benefited from treatment. This procedure partially helps to resolve problems such as lack of power (sample size), inclusion of both compliant and less compliant participants, and maintains the comparability of groups allowed by randomization (Newell, 1992).

Data analysis

First, Pearson product moment correlations for continuous variables or Spearman correlations for non-continuous variables and descriptive statistics were computed and examined to confirm assumptions required for further analysis (normality, homoscedasticity, multicollinearity), as well as to identify potential covariates. To correct for multiple correlations, a $\rho < .01$ was used rather than $\rho < .05$ as the criteria for identifying potential psychological predictors to include in further analyses. The six-month follow-up was preferred to post-treatment scores as the endpoint because of the RCT results showing larger differences for both treatments at this assessment time in comparison to post-treatment. Then, multiple regression analyses using a Residual Gain Scores approach (Rachor & Cisez, 1996) were conducted to evaluate the relative contribution of baseline levels of state-trait anxiety, fear of pain, catastrophizing, hypervigilance, avoidance and pain self-efficacy to the prediction of six-month follow-up levels of reported pain during intercourse and global sexual functioning, using a $p \leq .05$ level of significance. First, residual scores for each outcome measure were computed and saved as new variables. These new residual score variables were then used as dependent variables in further analyses. Because of the exploratory purpose of this study, the choice of potential predictors to be included in the regression analyses was based on correlation results, so that significant correlates were all entered as a block in the regression.

Results

RCT results

Results of the original RCT showed that participants of both treatment groups reported significant pain reduction and improvement in their global sexual functioning at post-treatment and six-month follow-up. However, at follow-up, women in the CBT group reported significantly more improvements in pain and sexual functioning, in addition to significantly lower catastrophizing scores and higher treatment satisfaction, than participants in the topical treatment group (Bergeron, Khalifé, & Dupuis, 2008).

Final sample size and drop-out analysis

In total, 111 women were recruited throughout the entire study protocol. Fig. 1 shows the flow of participants at each stage of assessment. The final sample size included 97 women suffering from provoked vestibulodynia randomized to one of two treatment conditions using blocked randomization (Bland, 2000): 51 to the topical treatment and 46 to the group CBT condition. Comparison analyses (chi-square) and *t*-tests showed that women who completed the entire study protocol did not differ from non-completers on any baseline demographic or clinical variables or on any of the dependent measures except on baseline level of fear of pain (total score), which was found to be significantly higher for non-completers ($t(66) = -.237$ $p = .034$).

Baseline sample characteristics

Sociodemographic characteristics of the sample for the two treatment conditions (medical/CBT) are presented in Table 1. Globally, results show that participants were young, with a mean age of 27 (SD = 6.5/5.5) and well educated, with a mean of 16 years of education (SD = 2.0/1.2). The majority of participants were in a committed relationship (76%/70%). The mean relationship duration was 3.2/2.3 years (SD = 3.8/3.0). Participants also reported a mean pain duration of 6.5/4.6 years (SD = 5.2/4.2). These results are similar to those obtained in previous PV studies (Meana et al., 1997; Payne et al., 2005, 2007).

Chi-square and *t*-test analyses indicated that participants in the two treatment conditions (topical and CBT) did not significantly differ on baseline demographic or clinical variables or on any of the dependent measures except on pain duration that was found to be significantly longer for women assigned to the topical treatment condition ($t(93) = 1.957$ $p = .039$).

Correlations among variables

Results of the correlational analyses between the psychological baseline predictors, pain and sexual functioning outcome measures for the two treatments are presented below, by treatment condition.

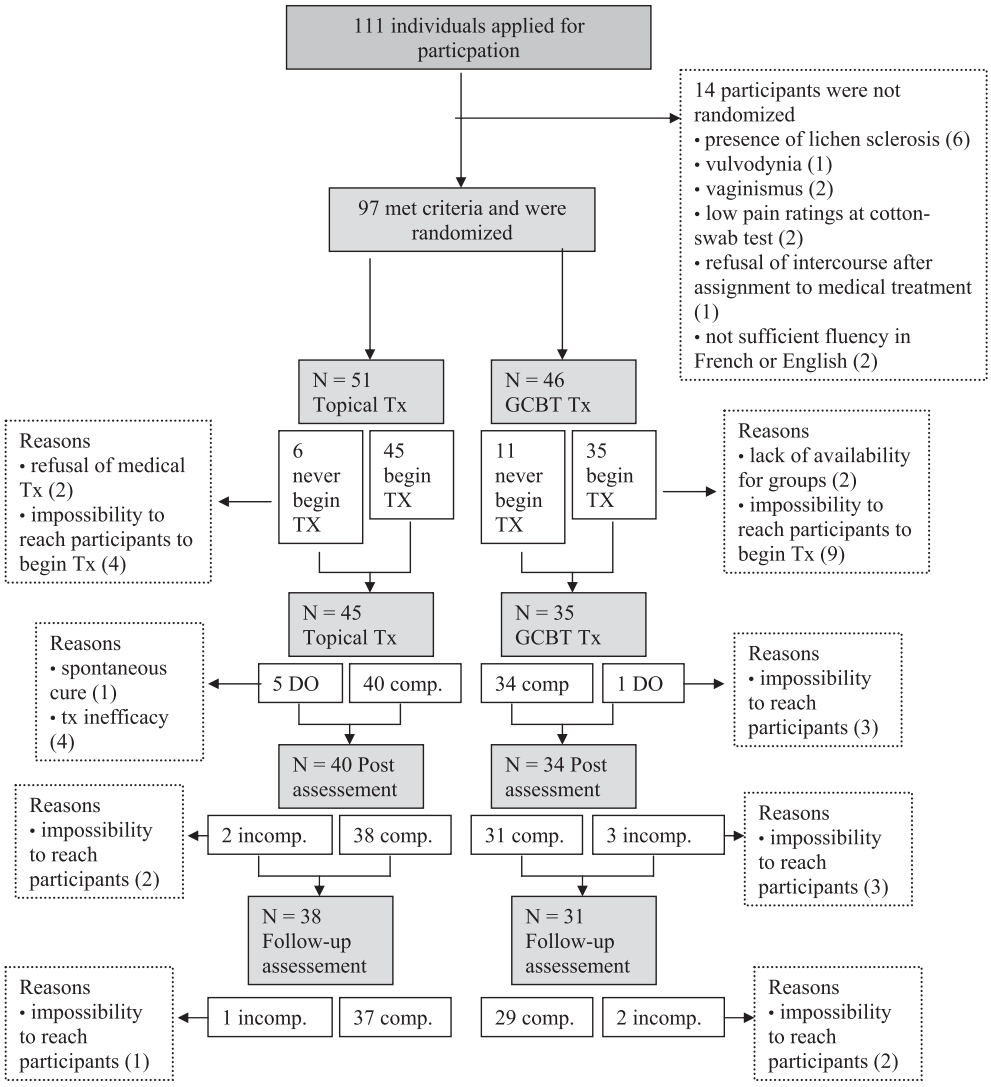

Fig. 1. Flow of participants.

Topical application results

First, none of the correlations between sociodemographic and outcomes measures reached significance for the topical application analysis. For pain intensity results (VAS), only correlations between baseline level of pain intensity and follow-up pain intensity reached significance whereas none of the psychological variables were correlated with the residual VAS score. For pain severity results (MPQ-PRI), baseline levels of catastrophizing-total score, catastrophizing-magnification and pain self-efficacy-functioning were related to residual six-month follow-up pain severity score. Moreover, baseline levels of fear of pain-total score, avoidance and pain self-efficacy-functioning were significantly associated with residual six-month follow-up sexual functioning score (Tables 2 and 3).

CBT results

Again, none of the correlations between sociodemographic and pain outcomes were found to be significant except for baseline age of first contraceptive use that was found to be significantly correlated with follow-up pain intensity residual score. Baseline levels of pain self-efficacy-pain were significantly related to residual six-month follow-up pain intensity score (VAS). Furthermore, baseline catastrophizing-total score was found to correlate with residual six-month follow-up pain severity score (MPQ-PRI). For the sexual functioning outcome, only baseline level of sexual functioning was found to be significantly associated with six-month follow-up sexual functioning whereas none of the psychological variables were found to be associated with residual six-month sexual functioning score.

Predictors of outcome for topical application treatment

In order to identify the relative contribution of the psychological predictors over and above the baseline levels of the outcomes measures (pain and sexual functioning), a series of multiple regression analyses via a Residual Gain Score approach using the SPSS Enter method were conducted. Psychological predictors significantly correlated ($\rho < .01$) with the outcome measure were entered as a block in the regression analysis.

Topical application regression analysis

For the pain intensity outcome, results showed that the regression including pain self-efficacy did not reach significance. However, for pain severity (MPQ-PRI) variations, baseline levels of catastrophizing-magnification, catastrophizing-total and pain self-efficacy-functioning were significantly associated with pain severity, so that the entire model accounted for 15% of the pain severity outcome ($F(3,47) = 2.83$ $p = .048$). Moreover, standardized

Table 1
Baseline sample characteristics.

Characteristics	Medical condition	GCBT condition
	N or *X* (SD or %)	*N* or *X* (SD or %)
Age (years)	27 (6.5)	26 (5.5)
Education (years)	16 (2.6)	16 (1.2)
Cultural affiliation		
French Canadian	42 (82%)	31 (68%)
English Canadian	2 (4%)	9 (20%)
European	5 (10%)	2 (4%)
Others	1 (2%)	3 (6%)
Two affiliation	1 (2%)	1 (2%)
Annual income ($Canadian)		
0–9999$	8 (15%)	10 (22%)
10,000–19,999$	8 (15%)	8 (17%)
20,000–29,999$	4 (8%)	5 (11%)
30,000–39,999$	7 (14%)	8 (17%)
40,000–49,999$	8 (15%)	3 (7%)
50,000–59,999$	7 (14%)	3 (7%)
60,000$ and more	9 (19%)	9 (19%)
Marital status		
Single	8 (16%)	8 (17%)
Dating	17 (33%)	15 (33%)
Cohabiting with partner	22 (43%)	17 (37%)
Married	4 (8%)	6 (13%)
Relationship duration (years)	3.2 (3.8)	2.3 (3.0)
Pain duration (years)	6.5 (5.2)	4.6 (4.2)

Note. Medical $N = 51$ GCBT $N = 46$.

beta coefficients indicated that only catastrophizing-magnification (8%) and pain self-efficacy-functioning (11%) significantly predicted unique variance for six-month follow-up pain severity outcome. As for the sexual functioning outcome, baseline levels of fear of pain-total score, avoidance and pain self-efficacy-functioning were significantly related to follow-up sexual functioning outcome. Together, these variables explained 29% of sexual outcome variations at six-month follow-up ($F(3,30) = 5.39$ $p = .004$). However, the beta weights analysis showed that only avoidance (17%) significantly accounted for unique variance in the six-month sexual functioning outcome.

Predictors of outcome for CBT treatment

The same protocol of analyses was followed in order to identify psychological predictors of CBT pain and sexual functioning outcomes.

CBT regression analysis

First, results showed that age of first contraceptive use contributed to 6% of the variance in follow-up pain intensity (VAS). For pain intensity, adding pain self-efficacy-pain contributed to another 9% of variance. The entire model for pain intensity significantly explained 13% of the variance ($F(1,43) = 4.67$ $p = .036$). Examination of the beta weights indicated that pain self-efficacy-pain contributed unique variance (10%) over and above age of contraceptive use. For pain severity, adding catastrophizing-total did not reach significance. Finally, none of the psychological predictors were correlated with the residual sexual functioning outcome.

Discussion

The role of specific cognitive and affective factors was examined in relation to the prediction of pain and sexual functioning outcomes of two frequently recommended treatments – topical corticosteroid and CBT – for women afflicted with provoked vestibulodynia, the most common subtype of dyspareunia in women of reproductive age (Harlow & Stewart, 2003). This study represents one of the first attempts to resolve the question of which treatment works best for whom in the field of women's sexual dysfunction.

Table 2
Summary of results of multiple hierarchical regression analysis for residual pain and sexual functioning as dependant variables for medical topical treatment condition.

Dependent variable	Stand. β	*Unique* R^2	*p*
Residual pain with VAS outcome			
Step 1			
$\Delta R^2 = .04$, $F = 3.04$, $p =$ ns			
Baseline PISES-functioning	−0.24	ns	ns
Residual pain with MPQ-PRI outcome			
Step 1			
$\Delta R^2 = .15$, $F = 2.83$, $p = .048$			
Baseline PCS-magnification	0.38	0,08	0.042
Baseline PCS-total	0.37	ns	ns
Baseline PISES-functioning	−0.34	0.11	0.019
Residual sexual functioning with FSFI outcome			
Step 1			
$\Delta R^2 = .29$, $F = 5.39$, $p = .004$			
Baseline PASS-total	−0.04	ns	ns
Baseline PASS-avoidance	−0.57	0.17	0.019
Baseline PISES-functioning	0.25	ns	ns

Note. VAS = visual analogue scale (pain intensity); MPQ-PRI = McGill Pain Questionnaire – Pain Rating Index (pain severity); FSFI = Female Sexual Function Index (sexual functioning); PASS = Pain Anxiety Symptom Scale (fear of pain); PISES = Painful Intercourse Self-Efficacy Scale (Self-efficacy); PCS = Pain Catastrophizing Scale (catastrophizing).

Topical treatment

The first aim of the present study was to investigate the potential maintaining effect of fear-avoidance factors and pain self-efficacy in topical treatment outcome. As expected, several psychological factors were found to be associated with topical treatment pain and sexual functioning outcomes over and above levels of potential covariates. Globally, results indicated that the more women with PV reported catastrophizing before treatment, the more they reported severe pain at six-month follow-up. Also, the more they reported high levels of pain self-efficacy-functioning prior to treatment, the less they reported severe and intense pain at follow-up. Moreover, both catastrophizing-magnification and pain self-efficacy-functioning made unique contributions to outcome. These results are in line with findings from the chronic pain literature whereby catastrophizing and pain self-efficacy are considered to be important psychological predictors of both pain and disability outcomes (Keefe et al., 1999; Vlaeyen et al., 2001; Vlaeyen et al., 2002). Catastrophizing being the

Table 3
Summary of results of multiple hierarchical regression analysis with residual pain intensity and sexual functioning as dependant variables for GCBT treatment condition.

Dependent variable	Stand. β	*Unique* R^2	*p*
Residual pain with VAS outcome			
Step 1			
$\Delta R^2 = .06$, $F = 3.59$, $p = .056$			
Baseline age of first contraceptive use	−0.27	0.07	0.056
Step 2			
$\Delta R^2 = .13$, $F = 4.67$, $p = .036$			
Baseline PISES-pain	−0.31	0.10	0.036
Residual pain with MPQ-PRI outcome			
Step 2			
$\Delta R^2 = .38$, $F = 13.15$, $p = .064$ trend			
Baseline PCS-total	0.26	ns	trend

Note. VAS = visual analogue scale (pain intensity); MPQ-PRI = McGill Pain Questionnaire – Pain Rating Index (pain severity); PISES = Painful Intercourse Self-Efficacy Scale (Self-efficacy); PCS = Pain Catastrophizing Scale (catastrophizing).

most robust psychological predictor of chronic musculoskeletal pain, the present finding suggest that it may also play a significant role in the treatment outcome of recurrent, provoked pain (Desrochers et al., 2009; Keefe, Rumble, Scipio, Giordano, & Perri, 2004).

As for sexual functioning, globally, results demonstrated that the more women with PV reported a strong sense of self-efficacy over their sexuality prior to treatment, the less they reported sexual impairment after treatment. However, results also showed that higher avoidance but also higher fear of pain were predictive of increased sexual impairment at six-month follow-up, with only avoidance contributing unique variance to outcome. These results are coherent with a recent study showing that pain self-efficacy is an important contributor to sexual impairment in dyspareunia resulting from PV (Desrochers et al., 2009) and with studies from the chronic pain field indicating that pain self-efficacy is the strongest psychological correlate of disability (Woby et al., 2007). Moreover, studies of individuals with chronic pain have demonstrated the important role of fear of pain in disability. Indeed, it is thought that fear of pain could elicit negative behavioral responses to pain such as avoidance. Further, low self-efficacy combined with fear of pain has been found to be related to the maintenance of disability for several pain populations (see Keefe et al., 2004; Leeuw et al., 2007).

In addition, comparison of fear of pain baseline levels between completers and non-completers showed a significant group difference, in that fear of pain was found to be higher in the non-completers group. This result raises questions concerning the role of fear of pain in treatment compliance and readiness to change, two variables considered to be inter-related (see Strong, Westbury, Smith, McKenzie, & Ryan, 2002). To date, studies on readiness to change and treatment compliance have focused more on the impact of self-efficacy (see below). However, because fear of pain leads to more escape/avoidance, it may interfere with treatment compliance by eliciting treatment avoidance or preventing the individual to move from a stage of preparation to one of action.

Of particular interest is the finding that catastrophizing, avoidance and pain self-efficacy seem to be the most important and robust predictors of outcomes for topical treatment – each predicting unique variance. These findings can be interpreted using the fear-avoidance pain model (Norton & Asmundson, 2003; Leeuw et al., 2007; Vlaeyen & Linton, 2000), which suggests that avoidance becomes a maintaining factor when escape/avoidance behaviors persist after the healing process (Asmundson, Norton, & Norton, 1999; Leeuw et al., 2007; Phillips, 1987). The model suggests that this phenomenon is related to the presence of pain-related fears such as catastrophizing. Thus, it is hypothesized that, even if the physical harm is relieved, pain-related fears, mostly catastrophizing thoughts, lead to automatic behavioral protection responses – avoidance. In addition, this model postulates a bi-directional relation between avoidance and pain self-efficacy, so that avoidance leads to decreased pain self-efficacy and more expectations that functional activities – in this case sexual activities – will increase pain which, in turn, leads to more avoidance (Asmundson et al., 1999; Leeuw et al., 2007; Phillips, 1987). In a therapeutic context, this model sheds light on how this negative vicious cycle between avoidance and pain self-efficacy could interfere with topical treatment by decreasing treatment adherence. If patients do not use the cream properly because they are avoiding pain and pain eliciting activities and because they do not believe that they are able to cope with their pain, this could impact negatively on treatment effectiveness.

Group cognitive-behavioral therapy (CBT)

The second aim of this study was to examine the same maintaining effect of fear-avoidance factors and pain self-efficacy in CBT treatment outcome. Similarly to results obtained for the topical treatment, the more women with PV reported higher levels of pain self-efficacy prior to treatment, the less they reported intense pain at six-month follow-up. It is not surprising to find that the beliefs of these women about their ability to cope with and to control their dyspareunia symptoms predict pain outcomes considering that negative pain self-efficacy can easily interfere with readiness to change, particularly in the case of CBT which involves a more active participation for treatment success (Strong et al., 2002). Combined with results concerning predictors of success for topical treatment, the present findings suggest that pain self-efficacy is the most consistent predictor of treatment outcome in women with PV, independent of type of treatment. Higher baseline pain self-efficacy thus appears to facilitate engagement in topical and psychological interventions and to predict successful outcomes.

Finally, contrary to our expectations, none of the psychological factors under study emerged as significant predictors of the sexual functioning outcome. This finding may indicate that patients benefited similarly from CBT in terms of their sexuality, which is one of the two main foci of this intervention, contrary to the topical treatment. Another potential explanation is that 1) improving self-efficacy with regards to sexuality and 2) confronting the fear and avoidance of sex, are two actively pursued goals of CBT. Hence whereas these variables may have an impact in the prediction of sexual functioning in the topical condition, which ignores sex altogether, their significance may be much less in a treatment condition that addresses these issues head on.

Study limitations

Despite a randomized, prospective design and rigorous selection criteria, the present study has some limitations. First, our sample consisted of patients with provoked vestibulodynia, so the extent to which our results can be generalized to other types of dyspareunia remains unclear. Moreover, a possible selection bias is to be considered since participants were enrolled for a treatment study that included a free treatment. Nonetheless, our study includes as many women from the general population as from clinical settings. Also, data were collected from self-report measures, with their inherent biases including social desirability, retrospective recall as well as shared method variance. However, this study aimed to explore constructs that are difficult to assess without self-reporting, in particular because of the nature of the condition – dyspareunia, and the main context in which it occurs – sexual activity. Further, even if the entire sample was of 97 women, the number of participants per treatment was somewhat small. This may have impacted on our capacity to detect some relations between predictors and outcomes by reducing our statistical power. Finally, notwithstanding our efforts to ensure comparability of the two treatment conditions, a difference was observed on the pain duration score. Moreover, we also observed a difference on the baseline fear of pain score between completers and non-completers. Consequently, these differences may have influenced our results and must be taken into account in their interpretation.

Study implications

Despite the above limitations, the results of this investigation have a number of significant implications. From a theoretical standpoint, results provide further support to the biopsychosocial conceptualization of dyspareunia showing that, even for a medical treatment, specific cognitive and affective factors have an impact on treatment outcome. They also provide additional support to the proposed conceptualisation of dyspareunia as a pain disorder rather than as a sexual dysfunction (Binik, 2005), by showing that

its treatment outcome is influenced by the same psychological factors that contribute to the outcome of chronic pain conditions (see Leeuw et al., 2007). Moreover, these results further validate the fear-avoidance model of chronic pain and its usefulness in explaining the maintenance of pain and associated disability following treatment. Specifically, findings of the present study suggest that this model may be applicable to non-musculoskeletal, provoked pain. Finally, our results highlight the need to study further the role of pain self-efficacy in treatment outcome of pain conditions and add further support to the idea that this variable should be included in the fear-avoidance model, as was recently recommended (see Woby et al., 2007).

From a clinical perspective, findings suggest that psychological factors may play a significant role in the outcome of topical and CBT treatments for PV. They highlight the importance of assessing psychological factors prior to the beginning of treatment in order to tailor interventions to patients' different clinical profiles. Choosing the most relevant treatment option based on specific patient characteristics using simple and timeless tools also promotes treatment efficacy and reduces cost. Our results also suggest that medical treatment outcomes could be improved by complementing these modalities with psychological interventions to help women with PV (dyspareunia) reduce their avoidance and regain a sense of efficacy over their pain and their sexuality. These implications should nonetheless be regarded with caution considering that this is the first study of its kind and that replications with larger samples are required in order to draw firmer conclusions.

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