

The ACTIV Study: Acupuncture Treatment in Provoked Vestibulodynia

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ABSTRACT

Introduction. Provoked vestibulodynia (PVD) is a distressing genital pain condition affecting 12% of women. Treatment modalities vary and although vestibulectomy has the highest efficacy rates, it is usually not a first-line option. Acupuncture has a long history in the traditional Chinese medicine (TCM) system and operates on the premise that pain results from the blockage or imbalance of important channels. The main principle of treatment is to move Qi and blood to cease genital pain.

Aim. To explore effect sizes and feasibility in a pilot study of acupuncture for women with PVD.

Methods. Eight women with PVD (mean age 30 years) underwent 10 1-hour acupuncture sessions. Specific placement of the needles depended on the woman's individual TCM diagnosis. TCM practitioners made qualitative notes on participants' feedback after each session.

Main Outcome Measures. Self-reported pain (investigator-developed), pain-associated cognitions (Pain Catastrophizing Scale [PCS], Pain Vigilance and Awareness Questionnaire), and sexual response (Female Sexual Function Index) were measured before and after treatment sessions 5 and 10. Qualitative analyses of TCM practitioner notes were performed along with one in-depth case report on the experience of a participant.

Results. A repeated measures analysis of variance revealed significant decreases in pain with manual genital stimulation and helplessness on the PCS. An examination of effect sizes also revealed strong (though nonsignificant) effects for improved ability to have intercourse and sexual desire. Qualitative analyses were overall more positive and revealed an improvement in perceived sexual health, reduced pain, and improved mental well-being in the majority of participants.

Conclusions. Effect sizes and qualitative analyses of practitioner-initiated interviews showed overall positive effects of acupuncture, but there were statistically significant improvements only in pain with manual genital stimulation and helplessness. These findings require replication in a larger, controlled trial before any definitive conclusions on the efficacy of acupuncture for PVD can be made. **Curran S, Brotto LA, Fisher H, Knudson G, and Cohen T. The ACTIV study: Acupuncture treatment in provoked vestibulodynia. J Sex Med **,**:**-**.**

Key Words. Provoked Vestibulodynia; Vulvodynia; Vulvar Pain; Genital Pain; Acupuncture; Traditional Chinese Medicine; Eastern Approaches

Introduction

Provoked vestibulodynia (PVD) is a chronic, persistent clinical syndrome characterized by severe pain upon touch of the vulvar vestibule and/or attempted vaginal entry [1]. It is generally diagnosed through the use of a standard gynecological

cotton swab test, where a cotton swab is applied along Hart's line and around the vestibule in a clock-like fashion. The qualities of pain reported when the vestibule is palpated include: tearing, cutting, burning, and stabbing. PVD has a high prevalence, with reported rates of 12% in the general population [2] and approximately 15% in

general gynecological practice [3]. A large study in adolescent women (aged 12–19 years) found that among young women with genital pain complaints lasting 6 months or more, the prevalence of dyspareunia was 20% [4]. Because PVD appears most prevalent in young women, it can have lasting effects on sexual identity and possibly on sexual self-confidence. It is also significantly associated with somatic health including urinary tract infections (odds ratio [OR] = 6.15), yeast infections (OR = 4.24), chronic fatigue syndrome (OR = 2.78), fibromyalgia (OR = 2.15), depression (OR = 2.99), and irritable bowel syndrome (OR = 1.86) [5]. In addition, the generalized pain of PVD affects daily living and has a severe negative impact on sexual functioning [6–9].

Current standards of care for PVD include the use of oral and/or topical medications, pelvic floor physiotherapy with biofeedback, psychological treatment, and surgery. Among these, prospective nonrandomized trials of vestibulectomy have shown the highest rates of improvement ranging from 61% to 83% [10–13] and a randomized controlled trial showing near complete or complete pain improvement in 68% [14]; however, vestibulectomy is typically reserved as a last-resort treatment option for very carefully selected patients [15]. As reviewed by Landry and colleagues, topical formulations have shown less impressive improvements compared with surgery [16]. For example, approximately 57% of women reported a moderate improvement with topical lidocaine, 44% had complete improvement with topical ketoconazole, and 54% showed a positive response to topical cromolyn. However, given the large placebo response [17], randomized trials in this area are sorely needed. Oral medications have shown similar efficacy rates to the oral preparations ranging from no response to a 60% response with amitriptyline (as reviewed by Landry et al [16]). Because of the known hypertonicity of the pelvic floor in women with PVD [18], physiotherapy (with biofeedback) is a frequent adjunct of treatment and has shown efficacy rates ranging from 52% for physiotherapy [19] to 83% for biofeedback alone [20], with improved outcomes not only on pain but also on sexual response [21]. A psychological intervention focusing on cognitive-behavioral skills has shown improvements in 21–28% of patients [14] with no deterioration of improvement in sexual function and continued improvement in genital pain when assessed 2.5 years later [22]. Overall, research on new, effective methods of pain and distress reduction for women

with PVD is sorely needed given the negative side effects of oral medications [23] and the fact that surgery is typically a last-resort option [15,16].

Acupuncture is one of the treatment modalities within the medical system of traditional Chinese medicine (TCM). It has been practiced for thousands of years in China and other Asian countries, and is gaining acceptance within the Western medical community. According to the TCM theory, there are more than 2,000 acupuncture points on the human body connecting 12 main and eight secondary “meridians” or channels. Pain and disease are the result of these channels becoming blocked and/or imbalanced. To restore healthy energy and balance, thin, sterile needles are inserted into specific points along these meridians. Each acupoint is then activated by applying very small rotations and thrusting movements of the needle to elicit “de chi”—a sensation of numbness and fullness in the area. Because the liver, kidney, and spleen channels pass through the genital region [24], TCM theory presumes that any combination of these channels are affected in women with PVD. The main principle of treatment is to move Qi and blood to stop pain and to unblock meridians. Table 1 lists the specific areas of imbalance presumed to play a role in contributing to the pain of PVD [24] and the associated acupuncture principles of treatment. In China, acupuncture is typically administered daily, though in North America, it is more customary to have one to two sessions per week.

Western medicine’s view is that the placement of acupuncture needles at specific pain points releases endorphins and opioids, the body’s natural painkillers. Acupuncture is also purported to improve immune and central nervous system function. According to the National Institutes of Health’s National Center for Complementary and Alternative Medicine [25,26], there is also evidence that stimulating acupuncture points enables electromagnetic signals from the brain to be relayed at a greater rate than under normal conditions. This may increase the flow of healing or pain-killing natural chemicals to injured areas.

Reviews of acupuncture treatment studies (in patients with chemotherapy-induced nausea and vomiting, postoperative dental pain, addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, duodenal ulcers, and asthma, for example) conclude that there is strong evidence to support that acupuncture provides pain relief, often where

Table 1 Common traditional Chinese medicine (TCM) diagnosis themes and principles of acupuncture treatment for women with provoked vestibulodynia (PVD)

Diagnosis	Acupuncture principle of treatment
Spleen deficiency: when the spleen is not functioning optimally (due to dietary irregularity, over consumption of cold damp foods or sweats, or restriction from another organ system), dampness forms and then accumulates. The accumulation of dampness can then flow down to the genital region and stagnate the local flow of energy and blood, causing heat and/or blood stasis. When there is heat present, itchiness and red color change are present. Stagnation causes the pain associated with PVD. Dampness is associated with discharge and the chronic nature of this disorder. The spleen organ system is the primary organ involved in digestion, therefore it is not surprising to see that many of the patients of this pilot study also had digestive complaints.	Nourish spleen to transform dampness
Blood stasis component: can be caused by dampness, as outlined above, or can develop from prolonged stagnation of Liver Qi or trauma to the local area. Blood stasis increases the intensity of pain and contributes to itching being worse at night.	Move blood to stop pain
Liver Qi stagnation: among the patients treated for PVD, the two common causes of Liver Qi stagnation were from dampness accumulation and emotional disturbance. Chinese medicine theory states that the liver is the first organ to feel emotions. When emotions are excessive or a patient becomes depressed, the free flow of Qi in the meridians is affected. In the case of depression, the Qi becomes stagnant. When stagnation builds up, heat is often created. Heat then intensifies the pain and itchiness. Liver Qi stagnation is associated with symptoms of cramping, irritability or emotional sensitivity, digestive changes, tender breasts, bloating and headaches during the premenstrual period.	Move qi to stop pain, relieve heat if present
Heart Blood deficiency: the emotion anxiety is said to consume Qi and blood due to excessive use of the mind. The meridians become depleted causing a restricted flow of Qi and blood. This then also leads to stagnation and eventually pain. Stagnation also inhibits the circulation of Qi and blood to nourish tissues thereby giving rise to dryness and irritation. Heart blood deficiency is associated with insomnia, poor sleep, and poor memory.	Nourish Heart blood, calm mind, regulate sleep
Phlegm damp accumulation: when dampness stagnation persists, the dampness further congeals giving rise to phlegm. The nature of a phlegm disorder when compared with dampness alone is that the condition tends to be more long standing, less responsive to treatment, and may exhibit uncharacteristic symptoms (i.e., allergic type reactions, indescribable sensations, or numbness).	Transform phlegm damp
Liver–spleen disharmony: in an ideal working relationship of the organ systems the Liver is responsible for the smooth flow of Qi and blood throughout the body. When out of balance, the Qi and blood are able to stagnate and the role of digestion is compromised. The Spleen is said to loose its role in separating the usable nutrients and energy from our food and instead allowing food to clump in the digestive tract leading to the formation of dampness (mucous or undigestible food waste). We then see a combined pattern of Liver Qi stagnation with the Spleen system becoming relatively deficient and unable to process food effectively. Stagnation and dampness are the result. The combined symptoms of this disharmony will be most evident during stressful times, the premenstrual period, and with a lack of exercise.	Harmonize Liver and Spleen, move Qi, resolve dampness

Reference: Deadman and Al-Khafaji [22].

traditional methods have failed [27–30]. Acupuncture's beneficial effects may have a delayed onset and occur gradually but continue well after the needles have been removed. Murray [30] found that acupuncture is considered safe, relatively free of side effects, does not disturb internal physiology, and is considerably less expensive for patients than more traditionally Western approaches, such as pharmacotherapy.

Despite the demonstrated efficacy of acupuncture for other pain syndromes, only two studies have examined acupuncture in women with PVD. Powell and Wojnarowska studied 12 women with chronic PVD and used an unspecified “general inquiry,” a visual analogue pain scale, and a quality of life questionnaire (unspecified) following five, once-weekly acupuncture sessions. Although acupuncture was helpful for five patients, the authors provided an overall tempered conclusion because of the lack of a control group [31].

Danielsson, Sjöberg, and Östman used acupuncture to treat 14 women with PVD once or twice a week for a total of 10 sessions. Treatment effects were measured in terms of a quality of life visual analogue scale and pain to self-provoked vestibular stimulation. Of the 13 participants who completed treatment, 11 rated their pain as being less pronounced following treatment, with 10 reporting that they continued to perceive an improvement 3 months following treatment. Twelve reported a reduction in negative quality of life and nine reported an improvement in positive quality of life [32]. In both studies [31,32], acupuncture was well tolerated and perceived by the participants and the authors to be of overall benefit.

The objective of this pilot study was to explore the effectiveness of acupuncture for PVD from a perspective beyond the limited endpoints examined in earlier studies and to recognize that the

benefits of acupuncture may extend beyond improvements in intercourse pain [32]. We administered self-report measures of: (i) sexual response (desire, arousal, orgasm, pain, satisfaction); (ii) pain with sexual activity; (iii) pain catastrophizing; (iv) pain hypervigilance; and (v) general well-being (fatigue, sleep quality, confidence). To complement these quantitative findings, we also explored the qualitative observations of two acupuncture therapists and the feedback they received from patients. Finally, we report more in-depth on the experiences of one participant who noted quite marked improvements in sexual response.

Method

Participants

Participants in this study were Caucasian women diagnosed with PVD by a physician with expertise in the diagnosis and management of genital pain syndromes. Inclusion criteria included: being older than 19; diagnosis of PVD; premenopausal; and agreement to maintain constant any concomitant treatment of PVD (i.e., medications) for the duration of this study. During the genital examination by the physician, all participants had some degree of pelvic floor hypertonicity. Among the eight consecutive women informed about the study, all contacted the acupuncture clinic and participated. The average age was 30 (SD 10.6, range 21 to 49). Six of the eight women were university educated.

Procedure

Following a genital examination and cotton swab test by the physician to confirm the diagnosis of PVD, those women who met entry criteria were given an information brochure outlining the study and contact details for further information and scheduling. Interested women contacted a receptionist at the acupuncture clinic where the treatment sessions took place. Women took part in an initial TCM assessment performed by one of the two TCM practitioner coauthors, which consisted of a full history and details of the woman's main presenting symptom/complaint obtained via interview. Detailed questions about all aspects of the body systems (such as sleep, headaches, menses, digestion, urination, and emotions) were asked. Other relevant factors, such as the woman's complexion, body type, nails, skin, and any other visual information, were also considered. A TCM diag-

nosis included an evaluation of the tongue by visual inspection and pulse. The resulting TCM diagnosis was then used to individualize the acupuncture points.

At the end of this 1-hour assessment, women received further information about acupuncture, and were permitted to join the study at least 24 hours later. The 10 acupuncture sessions were scheduled directly with the treatment clinic and took place over 5 weeks (one to two sessions/week). Women completed a questionnaire package immediately prior to beginning acupuncture and immediately following the fifth and final (10th) acupuncture sessions. Upon completion of the acupuncture, women were directed back to their referring physician for further management of their PVD if necessary. Participants were also given the option of continuing acupuncture treatment on a fee-for-service basis.

Measures

The questionnaire package contained demographic questions as well as measures of sexual response, pain with sexual activity, pain catastrophizing, pain hypervigilance, and general well-being. The Female Sexual Function Index (FSFI) [33] was used to capture sexual desire, arousal, lubrication, orgasm, pain with intercourse, and sexual satisfaction. Higher scores on FSFI subscales indicate better levels of sexual functioning. Test-retest reliability for the FSFI is high (ranging from $r = 0.79$ to 0.86 for the different domains) and internal consistency is high (Cronbach's alpha values were 0.82 and higher). The FSFI has also been shown to significantly differentiate women with and without PVD [34]. Because we were also interested in self-reported pain with other sexual activities, we developed questions to assess these domains which were rated on a 10-point Likert scale (see Appendix).

Pain catastrophizing is fearing the worst when anticipating pain, and has been found to be significantly associated with PVD [35,36]. This was measured with the Pain Catastrophizing Scale (PCS) [37], a 13-item scale meant to identify individuals who are more likely to experience elevated distress responses to pain. Subscales examined included the rumination, magnification, and helplessness subscales; coefficient alphas were 0.87 , 0.60 , and 0.79 for the subscales, respectively. Test-retest correlations were high over a 6-week period, $r = 0.75$, $P < 0.001$ ($N = 40$). Hypervigilance to pain is focusing on and being sensitive to any

symptoms of pain and was assessed by the Pain and Vigilance Awareness Questionnaire [38]. 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 nonclinical populations [39–41]. It has shown good test–retest reliability and internal consistency; several studies have also demonstrated good construct validity for chronic pain populations [39–41].

Investigator-derived items were based on questions practitioners commonly ask in the acupuncture setting. These items included well-being, self-confidence, energy, and sleep, and were assessed on a Likert scale (see Appendix). Finally, we asked one question about the anticipated benefit with acupuncture.

Description of Acupuncture

Acupuncture treatment appointments were approximately 1 hour in length and consisted of 20–25 minutes of needle placement on both the front and back sides of the body. Participants were appropriately draped and placed in both the prone and supine positions. The practitioners utilized single-use sterile Seirin needles (ETD Inc. Canada), which were made specifically for use in acupuncture. The diameter for these needles was 0.16 mm, and the lengths were 15 mm (SJ1615), 30 mm (SJ1630), or 40 mm (SJ1640) depending on the placement points and their surface anatomy. Seirin needles are extremely flexible needles that deliver less pain and irritation to the patient and contain much lower nickel content than other brands of needles; therefore they are less likely to cause local skin irritation at the site of insertion. The needles were made of medical grade JIS-G 4308 stainless steel. The tips were mirror finished and coated with medical grade silicon oil as lubricant for near painless insertion. All needles were sterilized with an electrolytical bath to remove impurities and then treated with ethylene oxide gas as well as a high pressure boiler for more than 24 hours by the manufacturer.

TCM practitioners proceeded with treatment according to the TCM diagnosis established during the assessment session. As each participant had different symptoms and medical histories, the exact points of needle placement varied (Table 2). Approximately 10 to 20 needles were inserted at each session, depending on the individual TCM diagnosis. Needle placement sites included the forehead and scalp, the inside of the knees and elbows, the upper middle region of the abdomen

above the pubic bone, and the back above the tailbone. No needles were placed in the genitals.

At the end of each session, needles were removed and pressure was applied with a cotton ball to any areas that had minor bleeding. Participants were alerted to the possibility of experiencing slight dizziness when they got up from the table, and were told to sit up slowly and only stand when they felt ready to do so safely. It is very common for an individual to report that they feel quite relaxed after their treatment so participants were advised to plan post-treatment activities accordingly.

TCM practitioners recorded any adverse effects or events and how they were managed. Women were encouraged to rest and limit their activity level immediately following treatment. All procedures were approved by the University of British Columbia's research ethics board.

Statistical Analyses

A repeated measures multivariate analysis of variance (MANOVA) was used to measure the effect of acupuncture across three time points (baseline, mid-treatment, and post-treatment) for pain catastrophizing (PCS) only given that these scores were significantly correlated at baseline. For statistical analysis of all other endpoints, a univariate repeated measures ANOVA was used. Given the small sample size and the aim of this study in generating effect sizes for future study development, we were more interested in the effect size and therefore focused on partial η^2 as the primary statistical parameter of interest. Values greater than 0.06 have been accepted as indicating moderate effects and greater than 0.14 as indicating strong effects [42,43]. We therefore focused our discussion on any analysis of partial η^2 greater than 0.14.

In addition to presentation of the quantitative endpoints, acupuncture practitioners collected qualitative information from each participant at the end of each visit in the form of a semistructured interview and documented perceived areas of improvement, no change, or deterioration. Questions were asked about: whether and what type of sexual activity had taken place since the last acupuncture session, level of pain during and after sexual activity, perceptions of sexual arousal or orgasm, pain during nonsexual daily activities, menstrual pain, and questions about the other systems identified as being problematic during the initial TCM assessment (e.g., sleep, digestion,

Table 2 Acupuncture points that were needed for at least half of the ACTIV participants

Acupoint name	# Patients needed	Selection rationale	Location
BL 32	8	Location: second sacral foramen corresponds to the pudendal nerve <i>*electrostimulation was applied each session to BL32 & BL33</i>	Second posterior sacral foramen
BL 33	8	Location: Third sacral foramen corresponds to the pudendal nerve	Third posterior sacral foramen
BL 40	5	Type of point: Xi-cleft point (indicated in the treatment of acute and painful conditions)	Midpoint of popliteal fossa
CV 3	4	Location: very close relationship with uterus and to entire reproductive system including internal and external genitalia Type of point: meeting point of conception vessel with Spleen, liver, and kidney meridians	Approx 1 in. above midpoint of pubic symphysis
LU 7	4	Type of point: confluent point of conception vessel	Proximal to the styloid process of the radius, approx 1.5 in. from the wrist
KI 6	4	Type of point: confluent point of Yin Heel Vessel	Inferior to medial malleolous
PC 6	6	Type of point: confluent point of Yin Linking Vessel, Luo connecting point of Pericardium meridian Pathway: connects with Liver meridian and therefore has effect on soothing/moving stagnant Liver Qi	Approx 2 in. proximal to midpoint of medial/flexor aspect of the wrist
SP 4	5	Type of point: confluent point of Penetrating Vessel	Medial foot, distal and inferior to base of 1st metatarsal bone
SP 6	7	Type of point: Crossing point of spleen, liver and kidney channels	One handbreadth superior to medial malleolous, posterior to crest of tibia
SP 8	4	Type of point: Xi-cleft point of Spleen channel (indicated in the treatment of acute and painful conditions)	Handbreadth below the medial condyle of the tibia, posterior to the crest of the tibia
SP 10	5	Action: (i) invigorates blood and dispels stasis; and (ii) cools blood	Approx 2 in. proximal to superior medial border of patella
ST 30	4	Type of point: Meeting point of Stomach channel with the Penetrating Vessel (point where Penetrating vessels emerges on the abdomen after surfacing at the perineum)	Approx 2 in. lateral to midline, level with the superior border of pubic symphysis
ST 36	4	Type of point: He-Sea and Earth point of Stomach channel, command point of abdomen	Handbreadth below the patella, lateral to the anterior crest of tibia
LR 2	5	Type of point: Ying-spring and Fire point of Liver channel	In webbing between 1st and 2nd toes
LR 3	5	Type of point: Shu-stream, Yuan Source, and Earth point of Liver channel	Depression distal to junction of the 1st & 2nd metatarsal bones
LR 5	4	Type of point: Luo-Connecting point of Liver Channel (ascends to genitals)	Approx 5 in. above the medial malleolous, posterior to crest of tibia
GB 34	5	Type of point: He-Sea and Earth point of Gallbladder channel, meeting point of Sinews	Depression approx 1 in. anterior and inferior to head of fibula
GB 41	4	Type of point: Shu-stream and Wood point of Gallbladder channel, confluent point of Girdling Vessel	Depression distal to junction of 4th and 5th metatarsal bones (lateral to tendon)

Reference: Deadman and Al-Khafaji [22].

mood). At the conclusion of the study, each of the two TCM practitioners independently read every file carefully for notable themes, looking particularly at areas of improvement common to the majority of participants. Independent notes were kept that formed the early draft of a code book for further qualitative analysis. Following a second independent reading of the participant files, the initial themes were refined and/or deleted and corresponding changes to the emerging code book were made. On the third pass through the participant files, the TCM practitioners were joined by one of the other investigators who was not directly involved in the acupuncture treatment and had no direct contact with participants. They then discussed the emerging list of themes, reached consensus on any important themes that were identified by only one practitioner, and established

a finalized code book which the two TCM practitioners then used to independently code themes from (each practitioner evaluated half the files). It is important to note that qualitative analyses were carried out prior to the analyses of any quantitative data so as not to bias the assessment of themes.

Because one of the participants reported a dramatic improvement in her sexual responding and reduction in her pain in an unsolicited manner, she was further interviewed in depth by the second author. Her case is presented.

Results: Part I Quantitative Findings

Sexual Health Demographics

Seven of the eight women were currently in relationships averaging 7.7 years (range 0–29 years) with the longest term relationship being 7.9 years

Table 3 Demographic, gynecologic, sexual behavior, and PVD symptom information for participants (N = 8)

Marital status	
Single	1 (12.5%)
Unmarried, in relationship	4 (50%)
Common law	1 (12.5%)
Married	2 (25%)
Oral contraceptive use (N)	
Ever taken birth control pills	8
Currently taking birth control pills	2
Sexual behavior and health	
Age of sexual debut	18 years (range 15–21)
Ever received treatment for sexual difficulty	6
History of sexual abuse	3
Intercourse orgasmic consistency	6.21 (out of 10 intercourse)
Gynecologic health	
Age of menarche	12.94 years (range 12–16)
Ever experienced a vaginal yeast infection	7
Frequency of yeast infections	
Rarely	2 (25%)
Occasionally	4 (50%)
Frequently	1 (12.5%)
Ever used over the counter yeast medication (N)	8
PVD symptom information	
Duration of PVD symptoms	2.63 years (range 0.5–6)
Pain varies with menstrual cycle	5
Ever been able to use tampons	7
Currently able to use tampons	3

(range 0.58–29 years). Six women reported being satisfied with the level of closeness in their relationship. Six women had previously sought treatment for a sexual difficulty. The average age of first intercourse was 18 years and the average number of pregnancies was 0.625 (range 0 to 2). Three of the women answered yes to the question asking about any history of coerced or forced sexual activity. Demographic information related to relationship factors, gynecologic history, sexual behavior, and PVD duration is shown in Table 3.

Baseline subscale scores for each domain on the FSFI were then calculated. The mean desire score was 2.85 (range 1.2–4.2), which is slightly lower than desire scores among the validation group of

women with dyspareunia on whom normative data were obtained [44]. The mean arousal score was 3.49 (range 1.2–6) and was comparable with arousal scores found in the validation group of women with pain. Lubrication scores were 4.16 (range 1.5–6) and mean orgasm scores were 3.75 (range 1.2–6) and both were higher than those found in the validation group. The mean satisfaction score was 3.5 (range 1.2–5.2) and was comparable with those in the validation group. The pain subscale mean was 1.85 (range 0–4.8) and was the same as those in the validation group. The overall mean FSFI total score was 19.5 (range 8.2–28.7) which was identical to scores in the validation group and also is below the clinical cutoff of 26.55 [44] indicating that this indeed was a clinical sample of women.

Effects of Acupuncture on Pain-Related Measures

In response to the pain-related questions developed for this study, there was a significant improvement in pain with manual genital stimulation, $F(2,14) = 3.508$, $P = 0.05$ with a strong effect size. There was no significant decrease in the intensity of pain in general in the last week, $F(2,14) = 0.357$, $P > 0.05$. The ability to have intercourse improved nonsignificantly, $F(2,12) = 0.844$, $P > 0.05$, and there was a moderate effect size (Table 4). There was no significant improvement in pain with oral sex, $F(2,12) = 0.150$, $P > 0.05$, intensity of pain with intercourse, $F(2,12) = 0.322$, $P > 0.05$, or pain with other nonsexual activities $F(2,14) = 0.094$, $P > 0.05$. All effect sizes are presented in Table 4.

Effects of Acupuncture on Sexual Response

A repeated measures ANOVA failed to show significance for the improved FSFI desire scores, $F(2,14) = 1.793$, $P > 0.05$; however, the partial η^2 measure of effect size was strong (0.204; Table 5). All other FSFI subscale scores did not reach statistical significance, and effect sizes were small to

Table 4 Effects of acupuncture on pain

Measure	Pretreatment		Mid treatment		Post-treatment		Effect size Partial η^2
	Mean	SD	Mean	SD	Mean	SD	
Intensity of pain in last week*	5.00	3.02	4.63	1.92	4.38	2.33	0.048
Able to have intercourse†	4.43	3.69	4.14	4.14	4.86	4.41	0.123
Manual stimulation painful‡	5.13	3.37	3.38	2.72	3.25	2.12	0.334
Oral stimulation painful‡	2.28	1.98	2.43	1.72	2.0	1.9	0.024
Intensity of pain in intercourse‡	7.00	3.37	7.71	2.14	6.86	3.44	0.051
Pain with other activities†	4.25	3.58	4.50	3.30	4.75	1.83	0.013

*Items measured on a 0 (absent) to 10 (severe) Likert scale.

†Items measured on a 0 (not at all) to 10 (completely) Likert scale.

‡Items measured on a 0 (no pain) to 10 (unbearable) Likert scale.

Table 5 Effects of acupuncture on sexual response (Female Sexual Function Index [FSFI])

Measure	Pretreatment		Mid-treatment		Post-treatment		Effect size
	Mean	SD	Mean	SD	Mean	SD	Partial η^2
Desire	2.85	1.15	2.93	1.13	3.30	1.20	0.204
Arousal	3.49	1.78	3.19	1.45	3.60	1.55	0.133
Lubrication	4.16	1.67	4.37	1.86	4.16	1.74	0.078
Orgasm	3.75	2.12	3.75	1.75	4.15	1.67	0.136
Satisfaction	3.43	1.65	3.60	1.71	3.71	1.68	0.048
Pain	1.71	1.65	1.83	1.60	1.89	1.75	0.006
Total score	19.46	8.17	19.71	7.81	20.63	7.69	0.052

Scale range: FSFI Arousal, Lubrication, Orgasm, Satisfaction, and Pain scores range from 0 to 5 with higher scores denoting better sexual function. FSFI Desire scale ranges from 1 to 5 with higher scores denoting more desire. FSFI Total Score scale ranges from 2 to 36 with higher scores denoting better overall sexual function.

moderate: arousal scores, $F(2,14) = 1.076$; orgasm scores, $F(2,14) = 1.098$; sexual satisfaction scores, $F(2,12) = 0.306$; lubrication scores, $F(2,12) = 0.505$; and pain scores, $F(2,12) = 0.033$, all $P > 0.05$. Also, the overall FSFI Total score was not significant, $F(2,12) = 0.332$, $P > 0.05$, and the effect size was small (Table 5).

Effects of Acupuncture on Pain-Associated Cognitions

A repeated measures MANOVA was used to analyze PCS scores given that these were significantly correlated at baseline. The overall effect was not significant, $F(2,6) = 1.46$, $P > 0.05$. However, an examination of effect sizes revealed a very strong effect for PCS helplessness (partial $\eta^2 = 0.454$; Table 6). Effect sizes for rumination and magnification were small to moderate only. Overall pain hypervigilance decreased by 5 units, though this was not statistically significant, $F(2,14) = 0.466$, $P > 0.05$, and the effect size was small (Table 6).

Effects of Acupuncture on Emotional Well-Being Measures

There was no significant change in emotional well-being, $F(2,14) = 0.467$; self-confidence, $F(2,14) = 0.372$; restful sleep, $F(2,12) = 0.209$; or energy $F(2,14) = 6.254$, from the start to end of treatment, all $P > 0.05$.

At baseline, women had a moderate degree of belief in whether they thought acupuncture would

help their pain (mean = 6.25 on a scale from 1 to 10), and there was no effect of acupuncture treatment on this belief, $F(2,14) = 0.208$, $P > 0.05$.

The only side effects experienced and noted during treatment were the occasional small bruise and a feeling of fatigue. Bruising was treated by applying appropriate pressure after withdrawing the needles; following this, no further complications were reported. Fatigue following treatment was experienced in some of the participants but was limited to the first few visits.

Part II Qualitative Findings

Theme 1: Improvement in Pain with Sexual Activity

Seven of the eight women reported decreased pain with intercourse. Overall sexual frequency also increased for the majority of women. A related theme was that for some women, the pain all but disappeared and was replaced with a mild but non distressing vulvar itching that did not interfere with sexual activity. Notably, the one participant who did not experience any reduction in pain was a 49-year-old, surgically menopausal woman who had undergone a hysterectomy at age 40. She had a 6-month duration of intense PVD symptoms, with a longer history of more mild symptoms, and had experienced no pain relief with her use of centrally acting pain medications prescribed for her chronic low back pain.

Table 6 Effects of acupuncture on pain catastrophizing (PCS) and pain hypervigilance (PVAQ)

Measure	Pretreatment		Mid-treatment		Post-treatment		Effect size
	Mean	SD	Mean	SD	Mean	SD	Partial η^2
Rumination	8.38	4.34	7.38	5.15	6.75	4.65	0.113
Magnification	3.75	2.82	3.50	2.78	3.38	2.39	0.020
Helplessness	12.63	6.00	10.00	6.87	8.13	5.19	0.454
PVAQ	47.25	12.13	48.38	11.51	42.38	20.21	0.062

Higher scores on the PCS indicate more pain catastrophizing. Higher scores on the PVAQ indicate more pain hypervigilance.

Theme 2: Improvement in Desire/Arousal

Four of the participants spontaneously described a welcomed increase in sexual desire and arousal with acupuncture that coincided, in some cases, with increased orgasmic ability. One woman described waking in the middle of the night feeling sexually aroused for the first time in 2 years. She and her partner proceeded on to nonpenetrative sexual activity, leading to orgasm. None of these women felt that the increase in desire/arousal was a direct result of a reduction in vestibular pain; however, for these same women, there was a parallel improvement in this measure as well.

Theme 3: Improvement in Non-Sexual Somatic Symptoms

Six of the eight women reported notable improvements in non-PVD related symptoms. For example, one participant with psoriasis noted a reduction in her inflammatory symptoms during the treatment period. She noted a concurrent reduction in subjective feelings of stress and improved ability to “unwind.” Another woman with a long history of eczema and seasonal allergies as well as bowel symptoms of alternating diarrhea and constipation reported a marked improvement in all these domains. A similar reduction in irritable bowel syndrome symptoms was reported by two other participants. Another woman with frequent and problematic night sweats reported a reduction in these symptoms during the acupuncture period.

Theme 4: Improvement in Symptoms of Well-Being

Seven of the eight women reported a significant increase in their sense of mindfulness and calmness during the treatment period. There were notable improvements in the ability to calm oneself in the face of a stressor, an enhanced ability to remain in the present moment during the day, and an overall improved sense of well-being. Among most women, these improvements were also associated with a significant improvement in sleep quality. The one participant who did not report an improvement in subjective well-being was the same woman who reported no improvements in pain or any other nonsexual symptoms.

Part III Case Report

Jennie is a 23-year-old, nulliparous university student in a 2.5-year long relationship. She had been diagnosed with PVD 2 years earlier after a

significant period of pain-free sexual activity, including intercourse, and a high level of sexual enjoyment. She linked the onset of PVD to side effects from the use of oral contraceptives, which led her to switch to a copper intrauterine device (IUD). Following complications and the removal of the IUD, she developed a uterine infection, which was followed by dysmenorrhea, and the onset of pain with sexual contact. Although she continued to engage in sexual intercourse, she reported several days of pain afterwards.

When she enrolled in the acupuncture study, her sexual frequency had been reduced to once every 10 days, and she was quite skeptical about any improvement. However, after her seventh of 10 sessions, she began to have a reduction in the duration of pain following intercourse. The initial post-intercourse pain of 3 days steadily decreased in increments of a day until, 1 month following her last acupuncture session, she did not experience any pain following intercourse. Her overall sexual frequency had also increased to twice per week. She had been orgasmic prior to the onset of her PVD, but was completely anorgasmic since her pain began. She reported resuming her orgasmic ability with intercourse following her acupuncture treatment. Although there was not a significant increase in her sexual desire, she was more motivated to engage in sexual activity. She reported that she was more relaxed and that the level of pain during sexual activity had reduced by 50%. When the results from her questionnaires were examined, she did report at baseline that overall pain levels were an 8/10 and upon completion of acupuncture they reduced to 3/10.

Jennie remained convinced that acupuncture was responsible for her improvement in symptoms given that there were no other interventions or behavioral changes made during the time when she noticed an improvement. In fact, Jennie added that her participation in the acupuncture sessions took place during a particularly stressful period of her life, so she was doubtful that it would have been helpful at all.

Discussion

Acupuncture is a complex system of healing that, in most instances, is based on a nonbiomedical conception of the body [45]. Acupuncture originated in countries with different conceptions of health and wellness where there are unique views on how diseases are conceived (e.g., patterns of disharmony, that do not usually correspond with

Western diseases, are implicated). Acupuncture developed thousands of years before the era of evidence-based medicine, though increasingly researchers have sought to understand the biomedical mechanisms underlying acupuncture's effects [26]. The process of diagnosis is complex and there are many therapeutic strategies to address a single condition [46].

A strength of this study is the combination of quantitative and qualitative methods. In sexuality research, it has been argued and demonstrated that such a mixed-methods approach may afford greater depth of analysis than either modality alone [47–49]. In the case of the mixed-methods approach adopted in this study, overall, we found modest improvements with acupuncture when adopting a quantitative analytic approach and a more impressive outcome with acupuncture when a qualitative analysis was undertaken. There were strong effect sizes for reduced pain with manual genital stimulation, sexual desire, and helplessness on the Pain Catastrophizing Scale. All other endpoints showed small (to moderate) effect sizes only. The lack of statistical significance in tests of repeated measures ANOVAS was not unexpected given the small sample size, and this is why we made the a priori decision to focus our results on measures of effect size.

The qualitative observations, on the other hand, suggested a more positive effect, and there were notable improvements after acupuncture on a number of different domains. Seven of the eight women told the TCM practitioner of a perceived improvement in pain with intercourse following their treatment. Overall sexual frequency increased and half the women experienced a simultaneous increase in other aspects of the sexual response—desire, arousal, and orgasmic ease. Others have found a positive impact of acupuncture treatment on sexual desire [50]. Sexual desire and libido are typically considered functions related to the Minister fire and Kidney system in TCM. This is something that typically declines with age [51]. However, six of the eight women in our study were in their 20's and did not present with Kidney deficiency symptoms. Instead, we observed the presence of Liver imbalance and stagnation in most of the women, presenting as difficulty with depression and frustration. In TCM, the Liver channel encircles the genitals. Arousal and orgasmic ability require the free flow of Qi, therefore stimulating the flow of energy and blood through the Liver meridian could have a positive effect on sexual response and desire [51].

The case report further detailed the significant improvements in sexual health and pain in one particular woman as a result of acupuncture. What is notable from her case history is the postcoital pain, which had been speculated to involve such factors as a vascular component (i.e., congestion or lack of drainage from the “aroused” pelvis) or hyper-irritability of pelvic muscles. From a Chinese medicine perspective this would be diagnosed as a stagnation of both Qi and blood. It follows, therefore, that acupuncture would directly target this stagnation and lead to an improvement in symptoms.

Another aspect to women's sexual desire is the connection of the Heart with Uterus (which includes the entire reproductive system and genitals) via the Uterus vessel. In TCM, the Heart is closely related and affected by the mind and emotions. In our study, all of the women reported experiencing some form of emotional disturbance, anxiety or stress as a result of their PVD symptoms. Sexual desire is intimately connected to the mind and therefore nourishing the Heart and “calming the spirit” also could have played a role in the positive influence that was observed in sexual response [51].

In addition to these improvements in dyspareunia and sexual response in the case study, the qualitative findings pointed to an improvement in other symptoms such as psoriasis, IBS and eczema which is consistent with prior research showing the benefits of acupuncture [52]. As validated measures of these endpoints were not administered, the extent to which these positive outcomes were due to a wish to please the practitioner is unknown. As TCM is holistic in its philosophy and treatment approach, it is not surprising to see other systemic symptoms improve along with the chief complaint. The observed patterns (see Table 1) and principles of treatment that were employed would have influenced the concurrent conditions as well.

Seven of the eight women described marked improvements in aspects of mental health and general well-being including: sleep, confidence, and ability to calm oneself in the face of a stressor though these were not measured with validated questionnaires. When the Liver system is balanced, it functions to control the smooth and free flow of Qi throughout the body. In TCM, constraint and stagnation in the Liver can cause difficulty in managing stress and a feeling of being easily overwhelmed. The treatment principle for relieving stress and promoting relaxation is to move Liver Qi, which was one of the common

themes observed in our analysis of this study (see Table 1). The connection of the Heart and Mind as described above would have contributed to an overall improvement in the participant's sense of well-being as well. Chang et al. also observed that acupuncture plays a significant role in stress and relaxation [53].

Selecting an acupoint prescription can be among the most challenging parts of the treatment protocol. As there is rarely a one-to-one correspondence between the TCM diagnosis and the Western diagnosis [46,54], patients may have multiple TCM diagnoses [55–57], and each sub-group or syndrome requires a slightly different combination of acupuncture points. Although a single prescription for one biomedical condition is sometimes possible (e.g., one or two points are usually used to treat post-operative nausea and vomiting for everyone [58,59]), the foundation and strength of TCM lies in its individualized treatment approach.

Although clinical trial designs cannot easily accommodate individualized treatments, requiring all patients to be treated with the same set of acupuncture points may seriously under-evaluate the efficacy of the treatment being assessed [60,61]. Consequently, we wanted to avoid using a rigid recipe of points for treating PVD in this study and chose to diagnose and treat each patient according to their TCM pattern.

We believe that the initial results of this study provide a foundation for further controlled investigations in which individualized acupuncture is compared against a sham control group. Our findings suggest that there are significant improvements on pain (manual genital stimulation), sexual response (desire) and pain-associated cognitions (helplessness) but a much more optimistic set of improvements are detected when qualitative analyses of participant feedback is analyzed. Overall, acupuncture is generally considered to be safe and free from side-effects [30]. However, the improper delivery of treatment or inadequate sterilization of needles could occasionally result in adverse side effects such as infections or punctured organs [62]. A cumulative review conducted of 12 prospective studies which surveyed more than a million treatments, showed that the risk of a serious adverse event with acupuncture is estimated to be 0.05 per 10,000 treatments, and 0.55 per 10,000 individual patients [63]. The authors concluded that the risk of serious events occurring in association with acupuncture is very low—below that of many common medical treatments.

The range of adverse events reported is wide and some events, specifically trauma and some episodes of infection, are likely to be avoidable. A 2005 review of 9408 acupuncture patients showed that 29.7% of patients experienced side effects that could be defined as negative. The majority of these symptoms were relatively minor and were predominantly pain or bruising at the site of needle placement. Only 1.8% of patients reported that their symptoms worsened and only 0.0013% stated that their side effects were cause for them to discontinue acupuncture treatment [64]. The TCM practitioners involved in this pilot study similarly noted few and minor adverse effects. In all cases, the adverse effects were considered minor and did not serve as a deterrent to treatment for any of the participants.

There are limitations of this study that must be considered. First, the sample size was very small and statistical analyses of repeated measures ANOVAS were nonsignificant for all but two study endpoints. However, we made an a priori decision to focus on effect sizes given that this was a pilot study. On the other hand, the qualitative findings and in-depth case study suggested that acupuncture had positive effects on pain, sexual response, somatic symptoms, and quality of life related variables. The discrepancy in these findings deserves comment. It is possible that the self-report questionnaires were limited in their assessment of these domains and that when face-to-face, women were able to articulate their noted changes in more depth. It must also be recognized that feedback on acupuncture effects, which were analyzed qualitatively, were obtained from the acupuncture therapists themselves during semi-structured interviews following each session. The expectancy bias involved may have led some women to present a more positive picture than they did when completing anonymous self-report questionnaires. Another limitation is the fact that there was no sham-acupuncture control group. In the treatment of chronic low back pain, both an acupuncture as well as a sham acupuncture group showed significantly greater benefits than a “treatment as usual group” [65]. Because the placebo response is robust in studies of women with sexual dysfunction [66], and in particular among women with PVD [67], and because the placebo response in studies of acupuncture has been demonstrated [68], the possibility of a placebo response accounting for some of the benefits must be considered.

Overall, these data suggest that acupuncture may be an alternative treatment for women with

PVD, however, further study in a larger sample of women, along with a sham control group, is needed. Because of acupuncture's purported mechanisms of effect, we believed that adopting a purely quantitative method of analysis would not shed light on the full range of outcomes experienced. This was particularly evident in the case report where one group participant experienced a rather pronounced benefit on several aspects of her sexual response. This clearly deserves further study. Notably, the beneficial effects extended beyond pain into sexual response functioning and also affected cognitions associated with pain. Given the TCM philosophy on which acupuncture theory is based, it is not surprising that this ancient Eastern practice would have such varied benefits. Future research should aim to study acupuncture for PVD in larger, more methodologically rigorous trials in order to definitively conclude whether or not acupuncture is effective for PVD.

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Appendix

- How would you rate the intensity of your pain over the past week?

Absent	moderate	severe
0 1 2 3 4 5 6 7 8 9 10		
- Do you think acupuncture treatment will improve your pain?

Not at all	moderately	completely
0 1 2 3 4 5 6 7 8 9 10		
- How would you rate your sense of wellbeing?

Absent	moderate	excellent
0 1 2 3 4 5 6 7 8 9 10		
- How would you rate your self confidence?

Absent	moderate	excellent
0 1 2 3 4 5 6 7 8 9 10		

5. How would you rate your energy?
Absent moderate excellent
0 1 2 3 4 5 6 7 8 9 10

6. Are you having restful sleep?
Not at all moderately completely
0 1 2 3 4 5 6 7 8 9 10

7. Is it painful for you/your partner to perform manual stimulation of your genitals?
No pain moderate unbearable
0 1 2 3 4 5 6 7 8 9 10

8. Is it painful for your partner to perform oral stimulation of your genitals?
No pain moderate unbearable
0 1 2 3 4 5 6 7 8 9 10

9. Are you able to have intercourse?
Not at all partially completely
0 1 2 3 4 5 6 7 8 9 10

10. If intercourse is painful, please rate the intensity of the pain?
No pain moderate unbearable
0 1 2 3 4 5 6 7 8 9 10

11. Do you experience pain with any other activities or bodily functions
Not at all moderately completely
0 1 2 3 4 5 6 7 8 9 10