Acupuncture in Premenopausal Women With Hypoactive Sexual Desire Disorder: A Prospective Cohort Pilot Study



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ABSTRACT

Introduction: Female sexual dysfunction affects up to 43% of women in the United States and hypoactive sexual desire disorder (HSDD) is the most common type; however, we lack treatment options showing improvement for this condition.

Aims: To investigate whether acupuncture therapy could improve HSDD.

Methods: Premenopausal women with a primary diagnosis of HSDD were included in a single-arm prospective pilot study that was approved by the institutional review board. After providing informed consent, subjects completed validated questionnaires. Participants underwent 25-minute twice-weekly acupuncture sessions for 5 weeks with one certified acupuncturist. Questionnaires were completed again 6 weeks after onset of treatment.

Main Outcome Measures: Based on a statistically significant change in the desire domain of the Female Sexual Function Index from 2.0 (at baseline) to 2.4 (after intervention with a specialist) in our population of patients diagnosed with HSDD, a sample of 13 was determined, with 90% power and α 0.05.

Results: Fifteen women were enrolled and 13 completed the study. Mean age was 36.9 ± 11.4 years. Most were white (n = 9, 60%), heterosexual (n = 15, 100%), and non-smokers (n = 14, 93%). Most were sexually active more than four times per month (n = 8, 53%) and none had a history of sexual abuse (n = 15, 100%). Participants received a mean acupuncture needle application of 17 ± 2 at each session. Sexual function improved after intervention, particularly desire (2.1 \pm 0.6 to 3.3 \pm 1.2, P < .0001), arousal (P < .0001), lubrication (P = .005).

Conclusion: In this cohort of premenopausal women with HSDD, 5 weeks of acupuncture therapy was associated with significant improvements in sexual function, particularly desire. This supports a role for acupuncture as a therapeutic option for women with low desire.

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Key Words: Hypoactive Sexual Desire Disorder; Female Sexual Dysfunction; Acupuncture

INTRODUCTION

Female sexual dysfunction (FSD) affects up to 43% of women in the United States. 1,2 Hypoactive sexual desire disorder (HSDD) is the most common form of sexual dysfunction in

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women.³ Although several approaches for management of this medical condition have been suggested, standard options have not demonstrated symptomatic improvement, and traditional pharmacologic treatments have not been consistently helpful.⁴ Alternative therapies, such as acupuncture, are beneficial in treating a myriad of problems, such as urinary incontinence, chronic lower back pain, and migraines.^{5–10}

Acupuncture, as part of traditional Chinese medicine (TCM), has existed for many centuries and is considered a safe procedure when provided by a licensed practitioner. The skin is penetrated by sterile needles to stimulate specific points related to three principal concepts of TCM: harmony between yin and yang forces, qi (vital energy flowing through the body), and the five elements (fire, earth, wood, metal, and water). Although these concepts of TCM are not generally assessed in scientific

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²Acupuncture and Holistic Health, TriHealth, Cincinnati, OH, USA; This work was presented at the 41st Annual Scientific Meeting of the Society of Gynecologic Surgeons; Orlando, FL; March 2015.

studies, previous research evaluating the use of acupuncture for medical conditions, such as male sexual dysfunction, has shown good results. However, we are lacking similar evaluation of this treatment modality for female sexual disorders.

AIM

We hypothesized that low libido for premenopausal women with HSDD would improve with acupuncture therapy.

METHODS

This single-arm prospective cohort pilot study (institutional review board approval number 12053-12-071; National Clinical Trials registry identification number NCT02070029) included premenopausal women with a primary diagnosis of HSDD given by a gynecologist or urogynecologist. Women 18 to 55 years old were eligible if sexually active (defined as at least four sexual encounters in the month before enrollment), were in a monogamous relationship, and had a documented diagnosis of HSDD as the primary cause of FSD (defined as a non-adjusted score ≤ 6 in the desire domain [range = 0-10] of the Female Sexual Function Index [FSFI] questionnaire). 12 Exclusion criteria included postmenopausal women (defined as absence of menstruation in the prior 12 months), pelvic pain or dyspareunia as the primary cause of FSD (defined as a non-adjusted score ≤ 6 in the pain domain [range = 0-10] of the FSFI), prior hysterectomy and/or oophorectomy, history of chemotherapy and/or pelvic irradiation, use of hormonal contraception or hormone replacement therapy, active skin infection or disease preventing insertion of acupuncture needles, known allergy to acupuncture needles, or blood dyscrasia.

Potential participants were identified by recruitment posters in the local clinic and by referral from their primary gynecologist or after consultation with an urogynecologist. Subjects were screened for eligibility by the primary investigators and, after informed consent was obtained, baseline data were collected. Demographic data included age (years), body mass index (kilograms per meter squared), ethnicity, relationship status, sexual orientation (heterosexual, homosexual, bisexual), smoking status, medical comorbidities, surgical history, obstetric and gynecologic history, documentation of prior sexual trauma or abuse, and current medications. In addition, enrolled and consented subjects were interviewed by the certified acupuncturist (J.W.-L.) to determine at least one TCM diagnosis related to female abdominal and pelvic organs (kidney yang deficiency, liver qi stagnation, generalized blood deficiency, spleen yang deficiency, and/or heart fire), because these are not mutually exclusive. Symptoms, appearance of the tongue, palpation of peripheral pulses, and anatomic meridians factor into one's TCM diagnosis. Each diagnosis is associated with certain "external factors" and the pressure points indicated for TCM acupuncture are specific to each diagnosis to relieve symptoms and prevent "external factors" from continuing to influence the patient's symptoms. Yang deficiencies are associated with psychological stress and overwork. Qi stagnation is associated with

physical trauma and depression. Blood deficiency is associated with emotional strain. Heat or heart fire is associated with psychological strain. Therefore, patients can be diagnosed with more than one TCM pattern.

Functional Data

Five validated questionnaires were completed by all participants at enrollment and at 6 weeks after initiation of intervention. The FSFI^{13,14} is a 19-item questionnaire that can be administered in any age group and focuses on individual function by six domains: desire, arousal, lubrication, orgasm, satisfaction, and pain. Higher scores, with a possible maximum of 36, indicate better sexual function, with scores no higher than 26.5 indicating sexual dysfunction.¹⁵ The Female Sexual Distress Scale—Revised (FSDS-R)¹⁶ is a 13-item questionnaire based on a five-point Likert-type scale that provides a measurement of sexual distress. The revised version includes a question that asks women to rate distress related to HSDD. A score of at least 11 effectively discriminates women with FSD from women without FSD. The Short Form 12 (SF-12) is a 12-question validated survey about one's general health that assesses mental and physical composites. 17 Each domain is given a weighted score, ranging from 0 to 100, with 50 considered comparable to the mean health of the general U.S. population and 30 considered to be two SDs below the general population's health, indicating "below average" health status. The General Anxiety-Disorder-7 (GAD-7) and Prime Health Questionnaire-9 (PHQ-9)¹⁸ are a brief 16-item, Likert-type questionnaires assessing the frequency of anxiety and depression symptoms during the past 2 weeks. Each item is assigned a score from 0 (not at all) to 3 (nearly every day), with a score of 15 to 21 representing severe anxiety on the GAD-7 and a score of 16 to 20 representing severe depression on the PHQ-9. The World Health Organization Quality of Life BREF (WHOQOL BREF)¹⁹ is an instrument comprised of 26 items that measure the following four domains: physical health, psychological health, social relationships, and environment; it is a shorter version of the original instrument and is more convenient for use in large research studies or clinical trials. Domain scores denote subjects' perception of their quality of life within that domain and each is scaled positively, with higher scores representing higher quality of life. Mean item scores are added for a domain score and then multiplied by 4 to remain comparable to the 0 to 100 scoring on the WHOQOL-100 questionnaire. There is no predetermined cutoff value; however, scores higher than 50 indicate a better-perceived quality of life.

Intervention

All participants underwent 25-minute twice-weekly acupuncture sessions for 5 consecutive weeks (total = 10 sessions) with one certified acupuncturist. Patients gave consent after being informed of potential but rare risks of acupuncture, including, but not limited to, soreness, bleeding, bruising, or irritation at the needle site, infection, and internal organ damage from deeply placed needles. The initial session included a detailed patient history with

e178 Oakley et al

routine questions, in accord with the acupuncturist's practice, regarding dietary habits, level of diaphoresis, average water intake, digestive function, sleep habits, and overall mood. In addition, the acupuncturist inspected the patient's tongue and palpated central and peripheral pulses. These data were not recorded but rather used to formulate a TCM diagnosis, which was the single data point recorded. Subsequent sessions included only the acupuncture therapy without additional history or physical examination details being obtained. The intervention was administered in a sterile fashion using a predetermined range of needles (8-20) based on the acupuncturist's routine approach. Single-use MAC 30-gauge, 1- to 1.5-inch-long filiform needles were supplied by a single company (AA Wellness Supply LLC, New Hyde Park, NY, USA). The needles were placed along the scalp, nape of the neck, lower back, lower abdomen, elbows, and/or knees depending on the predetermined primary TCM diagnosis; however, participants could have more than one TCM diagnosis. Therefore, location of needle insertion was not part of the data collection process. While the needles were left in place for 25 minutes, the patient was given instructions to relax without moving and practice slow, deep breathing exercises inside a dimly lit examination room with quiet instrumental-based music playing in the background.

Sample Size Calculation

Based on a statistically significant change in the desire domain of the FSFI from 2.0 (at baseline) to 2.434 (after intervention with a specialist) in our population of patients diagnosed with HSDD, a sample of 13 was determined. This calculation (N=13) has 90% power to detect a difference in means of 0.434 assuming an SD of 0.434 using paired t-test with a 0.05 two-sided significance level. All calculations were performed using n-Query Advisor (Statistical Solutions Ltd, Los Angeles, CA, USA).

Statistical analysis was performed using IBM SPSS Statistics 19.0 for Windows (IBM Corp, Armonk, NY, USA). Descriptive statistics were calculated based on the general demographics of subjects involved in the study, including TCM diagnosis and number of acupuncture needles used. For functional (questionnaire) outcome data, ratings scales were treated as scale data and differences between groups were compared using the Student t-test for normally distributed data or the Wilcoxon signed rank test for non-parametric data. Enrolled and consented participants who completed the study received a \$25 stipend.

MAIN OUTCOME MEASURES

The primary outcome was determined by a change in the desire domain of the FSFI from baseline at enrollment to study completion at 6 weeks after initiation of intervention.

Secondary outcome measurements were determined by functional data points distributed at enrollment and 6 weeks: FSFI total and domain scores, FSDS-R total score, SF-12 mental and physical composite scores, GAD-7 and PHQ-9 total scores, and WHO-QOL-BREF domain scores.

RESULTS

Fifty women were screened for eligibility; 15 women were enrolled and 13 completed the study after 2 were lost to follow-up (mean age = 36.9 ± 11.4 years; mean body mass index = 30.6 ± 6.8 kg/m²). Most were white (n = 9, 60%), married (n = 9, 60%), heterosexual (n = 15, 100%), and non-smokers (n = 14, 93%; Table 1). No woman reported a history of polycystic ovarian syndrome or endometriosis. Two women reported pelvic organ prolapse (13%) and one woman had urinary incontinence (7%); however, no participant admitted to prior

Table 1. Demographics

Age (y), mean (SD)	36.87 (11.43)
BMI (kg/m²), mean (SD)	30.62 (6.83)
Gravida, mean (SD)	2.00 (1.78)
Vaginal births (n), mean (SD)	1.33 (1.45)
Cesarean births (n), mean (SD)	0.07 (0.26)
Acupuncture needles used per session (n), mean (SD)	16.93 (2.31)
Ethnicity, n (%)	
White	9 (60.0)
Black	5 (33.3)
Asian	0 (0.0)
Other	1 (6.7)
Relationship status, n (%)	
Married or involved	9 (60.0)
Single	5 (33.3)
Divorced	1 (6.7)
Widowed	0 (0.0)
Sexual orientation, n (%)	
Heterosexual	15 (100.0)
Smoking status	
Non-smoker	14 (93.3)
Smoker	1 (6.7)
Average sexual encounters (monthly), n (%)	
≥4	7 (46.7)
5-8	5 (33.3)
9-12	2 (13.3)
>12	1 (6.7)
History of sexual trauma or abuse, n (%)	
None	15 (100.0)
Medical conditions, n (%)	
Diabetes	1 (6.7)
Asthma	1 (6.7)
Prolapse	2 (13.3)
Urinary incontinence	1 (6.7)
Depression	3 (20.0)
Chinese diagnosis, n (%)	JE (100 C)
Kidney yang	15 (100.0)
Liver qi	11 (73.3)
Generalized blood	0 (0.0)
Spleen yang	13 (86.7)
Heart fire	1 (6.7)
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BMI = body mass index.

pelvic floor surgery. Most participants were sexually active at least four times per month (n = 7, 47%), five women reported five to eight encounters per month (33%), and three women were active at least nine times per month (20%). All participants denied a history of sexual trauma or abuse (Table 1).

At baseline, participants reported a low mean FSFI desire domain score (2.08 \pm 0.59) demonstrating HSDD for study inclusion. In addition, mean total FSFI score (19.43 \pm 5.96) was lower than 26.55 and mean total FSDS-R score (32.64 \pm 12.76) was higher than 11, indicating FSD. There were no other noteworthy baseline questionnaires scores (Table 2).

All subjects (N = 13, 100%) completed twice-weekly acupuncture sessions for 5 consecutive weeks for a total of 10 sessions. All subjects were diagnosed with kidney yang deficiency (n = 15, 100%) and most also received a diagnosis of spleen yang deficiency (n = 13, 87%) or liver qi stagnation (n = 11, 73%; Table 1). TCM diagnoses were not mutually exclusive. Participants received a mean acupuncture needle application of 16.9 ± 2.3 at each session. There were no adverse events or negative reactions to the acupuncture therapy.

At week 6, overall sexual function improved for the cohort (Table 2). FSFI mean total score increased from 19.43 ± 5.96 to

Table 2. Questionnaires

	Baseline	Week б	P value*
FSFI (n $=$ 15), mean (SI	0)		
Desire	2.08 (0.59)	3.28 (1.15)	<.0001
Arousal	2.44 (1.12)	3.90 (1.30)	<.0001
Lubrication	3.86 (1.80)	4.64 (1.39)	.024
Orgasm	2.74 (1.49)	3.77 (1.43)	.005
Satisfaction	3.23 (1.23)	4.06 (1.38)	.099
Total score	19.43 (5.96)	25.45 (5.59)	<.0001
FSDS-R ($n = 14$), mean (SD)	32.64 (12.76)	23.71 (14.06)	.031
SF-12 ($n = 14$), mean (S	SD)		
MCS	47.55 (8.89)	50.35 (7.45)	.152
PCS	54.72 (8.05)	54.81 (4.26)	.875
GAD-7 (n = 15), mean (SD)	8.00 (10.00)	2.00 (5.24)	.038
PHQ-9 (n = 15), median (IQR)	4.60 (3.89)	4.73 (4.93)	.896
WHOQOL-BREF ($n = 15$), median (IQR)			
Perception of QOL	4.00 (1.00)	4.00 (1.00)	_
Perception of health	4.00 (1.00)	4.00 (1.00)	_
Health	17.14 (1.67)	16.72 (1.79)	.174
Psychological	15.48 (2.31)	15.24 (1.97)	.595
Social relationships	13.33 (2.67)	13.33 (4.00)	.473
Environment	17.00 (1.50)	16.50 (2.00)	.470

FSDS-R = Female Sexual Distress Survey—Revised; FSFI = Female Sexual Function Index; GAD-7 = Generalized Anxiety Disorder 7; IQR = interquartile range; MCS = mental composite score; PCS = physical composite score; PHQ-9 = Prime Health Questionnaire 9; SF-I2 = Short Form 12; WHOQOL-BREF = World Health Organization Quality of Life, abbreviated version.

25.45 \pm 5.59 (P< .0001). Specifically, the FSFI desire domain increased from 2.08 \pm 0.59 to 3.28 \pm 1.15 (P< .0001). Arousal (P< .0001), lubrication (P= .03), and orgasm (P= .005) also improved. Participants' mean total FSDS-R score decreased from 32.64 \pm 12.76 to 23.71 \pm 14.06 (P= .03), indicating less distress related to their sexual symptoms. Regardless of this improvement, scores remained higher than 11, which demonstrated a continued sense of distress. Although GAD-7 scores at baseline were not consistent with severe anxiety, there was a significant improvement after the intervention, from 8.00 \pm 1.00 to 2.00 \pm 5.24 (P= .04). No other statistically significant relations were noted.

DISCUSSION

In this pilot study of a prospective cohort of premenopausal women with HSDD, 5 weeks of acupuncture therapy was associated with significant improvement in low desire. Furthermore, overall sexual function, distress due to symptoms, and general anxiety improved.

There are several proposed mechanisms of action for acupuncture. Older research reported a release of endorphins during therapy sessions, ^{21,22} whereas more recent literature has focused on the physiologic effects of these endorphins on the brain as seen at functional magnetic resonance imaging. ^{23–26} However, our study did not include laboratory data or brain imaging. Instead, we focused on symptomatic improvement. Acupuncture is widely used and has been studied as treatment for several chronic medical conditions, from migraines²⁷ and pelvic pain syndromes such as dysmenorrhea^{28,29} to urinary incontinence⁹ and fertility issues,³⁰ with improvement in patient symptoms. Similarly, we noted improvement in our subjects' symptoms, primarily that of low sexual desire. After intervention with acupuncture, we noted a much greater difference in our primary outcome measurement than was anticipated by our power analysis, which was based on intervention by specialist consultation alone. This could illustrate that acupuncture has a positive impact.

In general, most studies evaluating the efficacy of acupuncture assess patient symptomatology rather than hormone levels. Lammerink et al³¹ focused on the outcome measurements of selfreported hot flashes and impaired sexual functioning from breast cancer treatments after intervention with acupuncture. De Valois et al³² found improved vasomotor symptoms after acupuncture therapy. Our study focused on symptomatic improvement using validated questionnaires for a more robust assessment of change. Nonetheless, some rat model studies by Wang et al^{33,34} evaluated hypothalamic function after activation by acupuncture and showed increased electrical activity of excitatory neurons related to stimulation of sexual arousal. Although we did not use an animal model, our population included reproductive-age women similar to the research of Wang et al and our subjects reported increased sexual arousal. In addition, our study design focused on a single prospective cohort, similar to the research by De Valois et al, and included premenopausal women. However, the

^{*}P < .05 is considered significant.

e180 Oakley et al

participants in the study by De Valois et al were taking tamoxifen, which could have influenced hormonal status regardless of age, and our study design controlled for this.

Research is lacking regarding the use of acupuncture for FSD. A systematic review from 20118 confirmed that the evidence was insufficient for drawing any positive conclusions about the application of acupuncture to improve FSD. In addition, the review concluded there was a considerable risk of bias. In contrast, our study found positive improvements in FSD and our methodology included stringent exclusion criteria. More recent research by Khamba et al³⁵ in 2013 examined the benefit of acupuncture to manage sexual dysfunction secondary to antidepressant use. Although men and women of different ages were included, improvements were noted in libido and lubrication for the women. Interestingly, our study saw improvements in libido and lubrication with only 10 consecutive acupuncture sessions, whereas the protocol used by Khamba et al used 12. Furthermore, our study showed a modest decrease in symptom-related distress similar to the decrease of anxiety and depression in the subjects described by Khamba et al.

The strengths of this study are its prospective nature, use of validated questionnaires, and use of a single certified acupuncturist. To standardize our study population, perimenopausal and postmenopausal women, typically those most affected with HSDD, were excluded to decrease any influence of variable hormone levels on level of sexual desire. Nonetheless, there were limitations. The generalizability of our study is limited by our stringent exclusion criteria. Also, because it is difficult to doubly blind this type of study to the acupuncturist, we did not include a sham treatment group for comparison. In addition, acupuncture therapy is specific to the patient's symptoms, not to a "Western" medical condition. Therefore, although all participants had HSDD, there was some variation among needle combinations and application sites at each session, depending on the type of TCM diagnoses given. Studies of this nature also have inherent selection bias, and participants had to be willing to undergo several weeks of treatment, which complicated enrollment. Moreover, we did not control for dietary influence, level of daily exercise, use of antidepressants, or other alternative therapies such as pelvic floor physical therapy and massage.

In conclusion, there is a paucity of clinical evidence evaluating the use of acupuncture for FSD despite its application in other chronic health conditions. This preliminary study supports a role for acupuncture as a therapeutic option for women with sexual dysfunction, particularly low desire; however, further research including a sham treatment arm could be beneficial to determine the significance of our results.

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