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A Feasibility Study on Treatment of Uterine Fibroids with Tung's Acupuncture

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ABSTRACT

Objective: This study seeks to evaluate the feasibility to conduct clinical studies on the treatment of uterine fibroids (UFs) and related symptoms with a 7-point Tung's acupuncture protocol.
Methods: Nine participants who met the study criteria were recruited into 2 treatment groups, a 6-week and a 12-week group, with 5 and 4 participants, respectively, in each group. Acupuncture was given twice a week. Ultrasound examination was performed before and after the program to evaluate uterine size, number of fibroids, and volume. Symptom Survey Questionnaire (SSQ) for 14 symptoms was given to the participants every time receiving acupuncture.
Results: All 9 participants completed the program. No adverse response nor concerns or complaints to the program was reported. The result from 1 subject was excluded from the study due to age limit. All 8 subjects reported improvement in SSQ after the 6-week acupuncture treatment. The reduction of the scores for 10 of the 14 surveyed symptoms was statistically significant. The average score showed reduction for both the 6- and 12-week groups, whereas the 12-week group appeared to have higher percentage reduction than the 6-week group. After 12 weeks of treatment, 9 of the 14 surveyed symptoms were completely eliminated. Ultrasound result for uterine size, number of fibroids, and volume was discussed. Subject recruitment, referrals, long-term follow-up, and challenges in the study were also addressed.
Conclusion: It is possible to conduct clinical trial with larger sample size for the treatment of UFs with acupuncture. The study also suggests that acupuncture might reduce symptoms related to UFs. Larger trials with negative control groups and long-term follow-up may help to confirm the result. The changes in uterine size and UF volume cannot be adequately determined due to technical issues for ultrasound examination in the study.

Keywords: acupuncture, Tung's acupuncture, Chinese Medicine, uterine fibroids, uterine leiomyomas

INTRODUCTION

Uterine fibroids (UFs), or uterine leiomyomas, are monoclonal tumors in the myometrium compartment of the uterus with extensive extracellular matrix containing collagen, fibronectin, and proteoglycan.[1] UFs are a common condition that affects women in their reproductive and postreproductive years with an estimated lifetime incidence of up to 77% of all women, including 50% in Caucasian women and 80% in women of African descent.[2–5] Development of UFs is still unknown. But genetic mutations and environmental factors such as obesity have been implicated in the development of UFs.[6]

The growth of UFs is regulated by complex feedback loops between sex steroid hormones and growth factors. UFs may also be estrogen and progesterone dependent, resulting in more fibroid prevalence in women who suffer from elevated levels of these hormones.[7,8] Although many UF patients are asymptomatic, some others do have various symptoms including emotional imbalance, painful menses,

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heavy menses, spotting between menses, abdominal pain, pelvic pain, low-back pain, pain with intercourse, bloating, nausea, frequent urination, urine leakage, bowel difficulty, bowel pain, pregnancy complications, and prolonged bleeding leading to anemia, among many other symptoms.[3,5,9]

Common treatments available to women suffering from UFs, ranging from the most conservative to the most invasive approaches, are symptomatic treatment with oral contraceptive pills, levonorgestrel-releasing intrauterine devices, ulipristal acetate treatment, high-intensity focused ultrasound treatment, myoma embolization, surgical myomectomy, and hysterectomy. Depending upon tumor size, surgical removal is still the primary approach used to treat UFs.[3,8] It is estimated that almost half of the 600,000 hysterectomies performed in the United States each year are performed to treat symptomatic UFs.[8,10]

A variety of factors affect the patients' choice of treatment protocol, including, but not limited to, personal preference, age, desire to bear children, future fertility, individual symptoms, and the patients' access to alternative protocols. Although there are considerable management options varying in methodology, patients are often disconcerted with the ramifications and side-effects of available contemporary treatments for UFs. Thus, safer and effective alternatives are needed for the management of UFs.

In China, acupuncture is a common treatment for UFs. Chinese Medicine categorizes UFs as Zhen Jia, defined as masses in the uterus with a feeling of pain, swelling, or fullness, and with bleeding in severe cases. The etiology of this condition is related to Qi deficiency and disharmony between Qi and Blood, and in most cases, agglomeration occurs due to Qi stagnation and Blood Stasis with Dampness and Phlegm accumulation in the Interior.[11] According to Chinese Medicine, acupuncture can stimulate Qi of the meridians and activate the body's regulating functions to restore the disharmony of the organs and systems. But the exact benefit of acupuncture remains unknown.[5]

Acupuncture may deliver a mechanical signal to the body through breaking the skin and connective tissue.[12] It is also been suggested that acupuncture results in the release of neurochemicals such as β endorphins or serotonin and has regulative effect on the endocrine and central nervous system.[13,14] As we know that the growth of UFs is regulated by the feedback loop between sex steroid hormones and growth factors, it may be legitimate to consider acupuncture as a potential therapy for UFs.

Various schools of acupuncture have been used to treat UFs worldwide. Tung's acupuncture, once a closely guarded oral family tradition, is a complete system that includes its own channels, points, and needling techniques.[15] According to Wei Chieh Young, this system predates the classical 14-channel system and is based on a unique Five-Element and Zang-Fu theory to treat disease. There are 740 Tung's acupuncture points, numbered by location in 10 segments of the body, including hand, arm, foot, leg, ear, and head. Although some Tung's points overlap with the points on the 14-channel system, their indications and curative effects are different.[16] Tung's acupuncture has also been researched for the treatment of female diseases such as polycystic ovary syndrome[17] and irregular menstruation.[18] However, the effectiveness of acupuncture for the management of UFs remains uncertain.[5]

For the purpose of this study, the authors designed a 7-point Tung's acupuncture protocol based on their specific functions to treat UFs and related symptoms. Zheng Hui (1010.01) was used for its strong sedative function and its role as meeting point of the Du, Liver, and Tai Yang channels.[19] Du channel warms the body and calms the mind. Both the Liver and Du channel pass directly through the uterus. Zhen Jing (1010.08), used to activate the peripheral nervous system, has a very strong sedative effect.[19] According to holographic acupuncture theory, this point corresponds to the heart, which dominates the mind and is, therefore, indicated in fullness in the chest with mental restlessness and startled sleep.[16] Qian Hui (1010.05) was used as neurasthenia point, as it connects to both Zhen Jing (1010.08) and Zheng Hui (1010.01), to calm both the peripheral and central nervous systems. These 3 points constitute a Tung's Dao Ma (synergetic point combination).[16]

Fu Ke (11.24), an empirical female gynecology point, is specifically indicated for the uterus, uterine pain, hysteromyoma and distention of the lower abdomen, female sterility, irregular menses, dysmenorrhea, menorrhea, and scanty menstruation. From the viewpoint of Traditional Chinese Medicine, the Lung and Urinary Bladder channels have extraordinary connections to the uterus, Tai Yin and Tai Yang, respectively, thereby explaining the application of Fu Ke (11.24) in female diseases.[16]

According to Carson, both Da Bai (22.04) and Ling Gu (22.05) treat irregular menstruation, amenorrhea, difficult labor, back pain, migraine, dysmenorrhea, intestinal pain, dizziness, and distended feeling of the head.[19] As a Dao Ma set along with Fu Ke (11.24), the lower Jiao and hypofunction of the Lung are also addressed. According to holographic acupuncture theory, Da Bai (22.04) dominates the lower Jiao and Ling Gu (22.05) corresponds to the upper Jiao. Thus, these 2 points affect the whole San Jiao to impart positive therapeutic effects.[16]

Shui Jing (66.13), translated as water crystal, is referring to the uterus and located on the Kidney channel, good for treating uterine diseases. This point is also known for treating metritis, distended feeling of the uterus, uterine tumors, and distended feeling and stuffiness of the abdomen.[19]

The objective of this study is to evaluate the feasibility to conduct clinical studies on the treatment of UFs with the 7-point Tung's acupuncture protocol and to determine the therapeutic effect of the protocol in treating UFs and related symptoms.

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MATERIALS AND METHODS

The study design and treatment protocol were reviewed and approved by the Atlantic Institute of Oriental Medicine Institutional Review Board. The study was conducted by a licensed acupuncturist in a private acupuncture clinic. Participants with ages of 18 to 45 years were recruited through advertisements and referral from licensed gynecologists. Nine participants were enrolled in the study using the diagnostic criteria given in Table 1. The participants were divided into 2 groups, with the first 5 in the 12-week group and the latter 4 in the 6-week group. All participants were provided with written informed consent before the study.

The primary outcome measurements of this study, uterine size, number of UFs and volume, were assessed by ultrasound examination. All subjects were screened at baseline. For those who had recent pelvic ultrasound examination before the study, radiology records from that examination were used to assess UF baseline status. The remaining subjects were asked to have a pelvic ultrasound examination at their referring gynecologist's office. Both transabdominal and transvaginal ultrasound examinations were performed at either POM Imaging, Plantation Gynecological Associates in Plantation, Florida, or DPI Imaging in Pembroke Pines, Florida. The transabdominal ultrasound evaluated UF status in the upper uterus that may have been obscured with a transvaginal approach alone. UFs were evaluated by size, quantity, and location.

Table 1. Diagnostic Inclusion, Exclusion, and Dropout Criteria

Diagnostic criteria	1. Diagnosis of UFs with both physical examination by physician and transvaginal and transabdominal ultrasound. 2. Primary complaint of 1 or more of the following: a. Emotional imbalance b. Painful menses c. Heavy menses d. Spotting e. Abdomen pain f. Pelvic pain g. Low-back pain h. Pain with intercourse i. Bloating j. Nausea k. Frequent urination l. Leakage of urine m. Difficulty with bowel movement n. Pain with bowel movement
Inclusion criteria	1. Age (between 18 and 45 years) 2. Prior diagnosis of UFs by ultrasound examination (transvaginal and transabdominal) by a qualified physician. 3. Availability twice a week for 6 or 12 weeks for acupuncture treatment. 4. Existence of current ultrasound imaging (within the prior 3 months), and if not, willingness to acquire a baseline ultrasound.
Exclusion criteria	1. Pregnancy during trial. 2. Hormone replacement or medication affecting hormone status.
Dropout criteria	Missing >1 consecutive treatment.

UF, uterine fibroid.

The secondary outcome measurement of this study, the Symptom Survey Questionnaire (SSQ), was developed to record each subject's individual sensory experience. The symptoms were measured on a standard numerical rating scale, with 0 equaling no symptoms and 10 worst symptom ever (0 = no symptom; 10 = worst symptom ever). Survey symptoms include emotional imbalance, painful menses, heavy menses, spotting, abdominal pain, pelvic pain, low-back pain, pain with intercourse, bloating, nausea, frequent urination, pelvic pain, difficulty with bowel, and pain with bowel. Mean scores were calculated for analysis. Each subject was asked to fill out the SSQ every time before receiving acupuncture treatment.

Tung's acupuncture points, their corresponding classical acupuncture points, point location, and depth and angle of needle insertion are listed in Table 2 and illustrated in Figure 1. During acupuncture session, subjects were instructed to lay face up on a massage table in a private room with calming music, dim lighting, and lavender aromatherapy. Sterile disposable acupuncture needles with gauge 30, 0.5, and 1 cun were manufactured by DBC™. Needles were inserted in the order that points appear on Table 2, starting at the head and proceeding down the subject's body moving from the right hand to the left hand, then to the right ankle and ending with the left ankle. This order was consistent throughout the trial with all subjects. The needles were applied with perpendicular insertion to the depth of each point given in Table 2, then stimulation by twisting the needle left and right was added for $\sim$10–15 seconds. The subjects were left in a darkened room with needles for 45 minutes.

The acupuncture protocol was consistent throughout the study. Acupuncture treatment was given twice a week. The time lapse between treatments may vary depending on the scheduling and subjects' availability. After the 6- and 12-week treatments were completed, each subject was asked to return to the refereeing doctor or the imaging center for a post-treatment ultrasound examination for assessment and analysis.

This study did not give any nutritional and lifestyle recommendations and ensured that the participants continued whatever they had already been doing in terms of diet and lifestyle.

Table 2. Acupuncture Point, Location, Insertion Angle, and Depth

Tung's points	*Corresponding classical points*	*Location*	*Depth (cun)*	*Angle*
Zheng Hui (1010.01)	DU 20 (Bai Hui)	At the crown of the head at the midpoint between the tip of the nose and the nape of the neck, level with the ear apex	0.1–0.3	Perpendicular insertion
Qian Hui (1010.05)	DU 21 (Qian Ding)	Between 1010.01 and 1010.08, where the hairline begins	0.1–0.3	Perpendicular insertion
Zhen Jing (1010.08)	0.3 cun above Yin Tang	Longitudinally above the midpoint between the 2 eyebrows	0.1–0.3	Perpendicular insertion
Fu Ke (11.24)	Not available	Two-point unit located on the ulnar aspect of the proximal segment on the dorsal side of the thumb, both one-third from the crease	0.2–0.3	Perpendicular insertion
Da Bai (22.04)	LI 4 (He Gu) area	Close to the bone in the junction between the first and second metacarpals	0.5–1.0	Perpendicular insertion
Ling Gu (22.05)	LI 4 (He Gu) area	Just proximal to Da Bai (22.04)	0.5–1.0	Perpendicular insertion
Shui Jing (66.13)	KI 6 (Zhao Hai)	Inferior to the apex of the medial malleolus	0.5–1.0	Perpendicular insertion

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RESULT

Baseline Demographic

All 9 participants completed the program. But 1 subject (242686) reached the age of 46 years before the end of the trial. Her data were not included in the analysis. Four subjects from the 6-week group (294702, 299646, 299775, and 302953) and 4 from the 12-week group (242672, 242818, 259843, and 275292) were recorded in the study. The 8 participants ranged in age from 30 to 44 years and were all African American. Baseline demographic and clinical characteristics are given in Table 3.

Symptom Survey Questionnaire

All 8 subjects reported improvement in SSQ scores after the 6-week acupuncture treatment. The scores before and after the 6-week treatment for all 8 subjects ($N=8$) are compared in Table 4. The reduction of the scores for 10 of the 14 surveyed symptoms, including emotional imbalance, painful menses, heavy menses, abdominal pain, low-back pain, bloating, nausea, frequent urination, leakage of urine, and pelvic pain, was statistically significant. Reduction of the scores for spotting, pain with intercourse, difficulty with bowel, and pain with bowel was also observed. But the reduction was not statistically significant probably due to the small sample size.

The average SSQ scores before and after treatment for the 6- and 12-week groups are shown in Figures 2 and 3, respectively. Percentage decrease in SSQ scores for the 6- and 12-week groups is compared in Figure 4. Both groups showed reduction in SSQ scores, whereas the 12-week group appeared to have higher percentage reduction in the symptoms of emotional imbalance, spotting, abdominal pain, pelvic pain, low-back pain, nausea, frequent urination, and difficulty with bowels. After 12 weeks of treatment, 9 of the 14 surveyed symptoms, heavy menses, spotting, abdominal pain, low-back

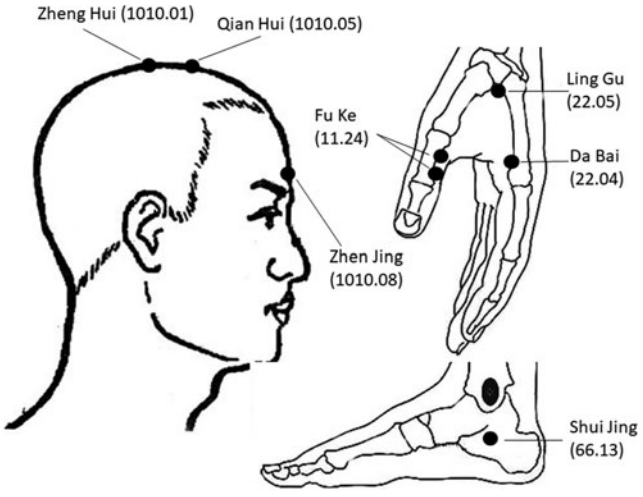

FIG. 1. Illustration of 7-Point Tung's Acupuncture Formula for uterine fibroid. The locations of the 7 acupuncture points are illustrated. The name and number of the points are labeled.

Table 3. Demographic and Clinical Characteristics

Subject ID	*Body weight (lb)*	*Height (feet)*	*BMI (kg/m^2)*	*Age (years)*	*Race*
294702	147.6	5′10	21.18	38	African American
299646	197.0	5′2	31.79	42	African American
299775	122.6	5′11	17.10	30	African American
302953	196.8	5′2	35.99	35	African American
242672	178.0	5′6	28.73	33	African American
242818	178.6	5′3	31.63	44	African American
259843	252.0	5′6	40.67	32	African American
275292	162.4	5′1	30.68	34	African American
242686	158.6	5′5	26.39	46	African American

BMI, body mass index.

Table 4. Symptom Survey Questionnaire Scores Before and After 6-Week Treatment for All 8 Subjects

Symptoms	*Before (mean ± SD)*	*After (mean ± SD)*	P
Emotional imbalance	4.88 ± 2.26	1.25 ± 1.39	0.003560478[a]
Painful menses	4.38 ± 4.18	0.00 ± 0.00	0.027764832[a]
Heavy menses	3.88 ± 3.22	0.00 ± 0.00	0.015376268[a]
Spotting	2.13 ± 2.32	0.25 ± 0.66	0.073313469
Abdomen pain	4.88 ± 3.69	1.00 ± 1.50	0.029970196[a]
Low-back pain	4.00 ± 2.92	1.50 ± 1.87	0.048145701[a]
Pain with intercourse	2.25 ± 2.73	0.00 ± 0.00	0.065367938
Bloating	6.50 ± 3.71	1.25 ± 1.64	0.006481573[a]
Nausea	6.25 ± 3.27	0.00 ± 0.00	0.003595106[a]
Frequent urination	7.75 ± 2.33	0.75 ± 1.09	2.94215E-05[a]
Leakage of urine	3.75 ± 3.27	0.63 ± 0.99	0.041845228[a]
Pelvic pain	4.50 ± 3.94	0.50 ± 1.00	0.031355752[a]
Difficulty with bowel	4.00 ± 3.87	1.38 ± 2.50	0.157636096
Pain with bowel	2.50 ± 3.61	0.00 ± 0.00	0.109222619

[a]Significantly lower post-treatment Symptom Survey Score as compared with before treatment.

SD, standard deviation.

pain, painful intercourse, nausea, leakage of urination, difficulty with bowels, and pain with bowels, were completely eliminated.

Ultrasound Examination for Uterine Size and UF Volume

We were not able to determine changes in uterine size or fibroids due to technical issues in the ultrasound examination, which is discussed later in the article.

Side-Effect and Safety Issue

There was neither adverse response reported after acupuncture treatment nor any complaints to the study procedure. All subjects completed the program without any safety concerns.

DISCUSSION

Technical Issues of Ultrasound Examination

Ultrasound examinations of this study were performed by 2 different imaging centers with different ultrasound technicians. Results from 1 center lacked digital imaging and radiology report. The ultrasound technician manually generated images of the UFs representing their size, location, and quantity. The inconsistency of the 2 imaging centers in their techniques in measuring, recording, and reporting UF information permitted an uncomfortable level of human error. Utilizing a standardized technique of ultrasound in measuring, recording, and reporting UF information is highly recommended in future studies.

Feasibility of Conducting Future Clinical Trials

The major patient source of this study was from referrals by licensed gynecologists. It looks that recruitment of large number of subjects for future studies may not be a difficult task. The acupuncture procedure is also easily acceptable by the patients. There was no adverse response reported from this study. Assessment with SSQ and ultrasound examination was performed according to the plan, although the

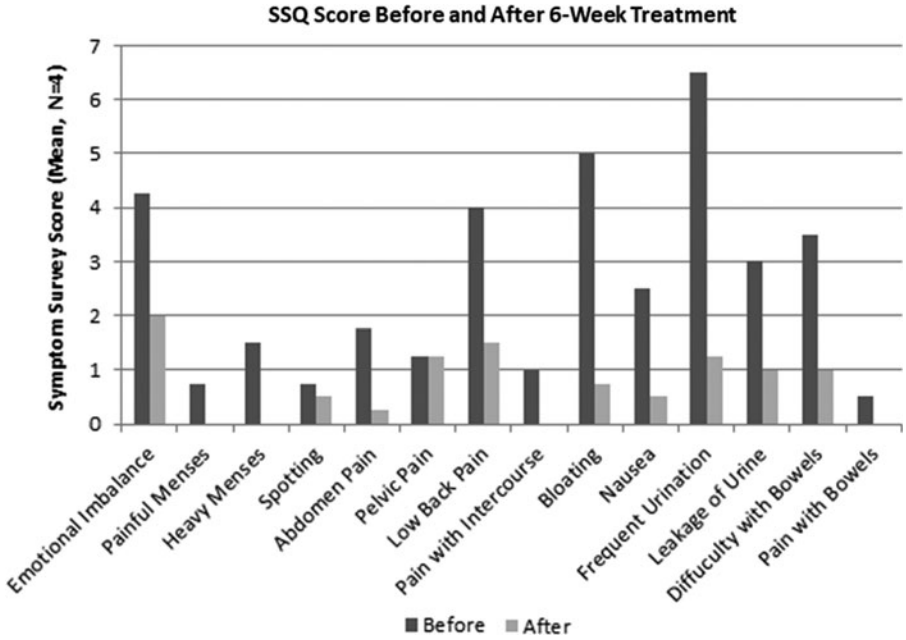

FIG. 2. SSQ score before and after 6-week treatment. The SSQ scores of the 6-week group before and after treatment were compared. The mean scores ($N=4$) are plotted in a bar graph. SSQ, symptom survey questionnaire.

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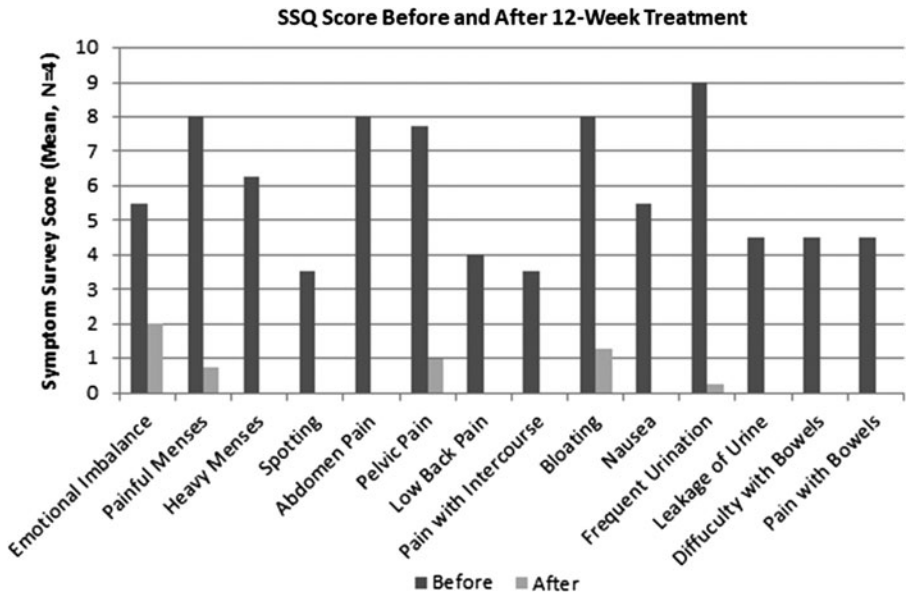

FIG. 3. SSQ score before and after 12-week treatment. The SSQ scores of the 12-week group before and after treatment were compared. The mean scores ($N=4$) are plotted in a bar graph.

scheduling of ultrasound before day 10 of the subjects' menstruation cycle needs to be reinforced and the ultrasound technique needs to be standardized in the future. Finally, there was no dropout from the study due to any reasons. Subject retention of the study was 100%. Thus, it is reasonable to conclude that it is feasible to conduct larger clinical trials for the treatment of UFs with acupuncture.

This feasibility study was conducted without a negative control group. Future clinical trials may include self-control group, or ''waiting-list control'' group, to introduce negative control into the study. A 6-week follow-up after the treatment is also needed to evaluate long-term effect of acupuncture. Another feasibility study of treating UFs with Chinese herbs has also been conducted previously and reported promising result.[20] Multiarm design with acupuncture, Chinese herbs, and a combination of Chinese herbs with acupuncture may be used in future studies. Introducing negative control, randomization, and more treatment control groups will greatly improve the design of future studies.

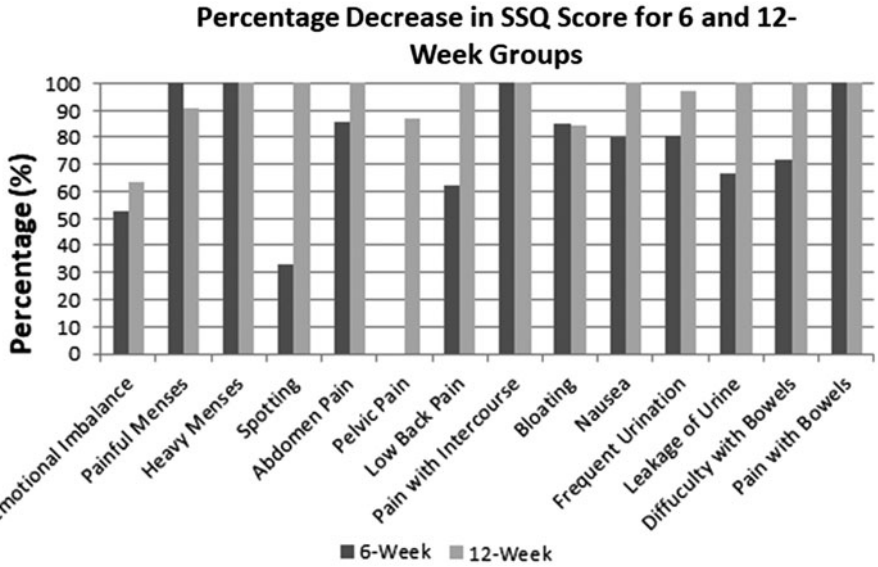

FIG. 4. Percentage decrease in SSQ score for 6- and 12-week groups. The percentage decrease in SSQ scores after acupuncture treatment was calculated for the 6- and 12-week groups. The results are plotted and compared in a bar graph.

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Change of SSQ Score

The study produced clear evidence that acupuncture significantly reduced the scores for majority of the symptoms surveyed in SSQ even only after 6 weeks of treatment. After longer treatment until the end of the 12-week period, 9 of the 14 surveyed symptoms, heavy menses, spotting, abdominal pain, low-back pain, painful intercourse, nausea, leakage of urination, difficulty with bowels, and pain with bowels, were completely eliminated. Other surveyed symptoms were also markedly improved. However, this study was conducted without a negative control group. Acupuncture was performed with the subjects laying face up on a massage table in a private room with calming music, dim lighting, and lavender aromatherapy for 45 minutes, a common practice for clinical acupuncture. This relaxation technique may promote parasympathetic function and help acupuncture regulate neuroendocrine controls and achieve homeostasis of the body. To distinguish the effect of the mentioned relaxation technique from acupuncture needling effect, a control group duplicating acupuncture treatment but without acupuncture needling is needed. Sham acupuncture control is an option. Our result suggests that acupuncture with the mentioned relaxation technique might be effective toward reducing UF-related symptoms. Clinical trials with larger sample size and negative control are warranted. A 6-week follow-up is also needed to determine long-term effect of acupuncture treatment toward UF-related symptoms.

Change of Uterine Size, Number of UFs, and Volume

Owing to the technical issues of ultrasound examination in the study, we conclude that the changes in uterine size and UF volume cannot be adequately determined. Future studies with larger sample size and standardized ultrasound procedure are needed.

Acupuncture Mechanism of Action

Many studies with functional magnetic resonance imaging have shown that acupuncture stimulates the central nervous system including major integration centers in the brain.[21–23] Our results support that acupuncture has a central effect on UFs and related symptoms because none of the acupuncture points used in the study are local points. Acupuncture signals central nervous system with the participation of autonomic afferents to regulate female hormones through neuroendocrine controlling pathways.

CONCLUSION

This feasibility study concludes that it is possible to conduct clinical trial with larger sample size for the treatment of UFs with Tung's acupuncture. The study also suggests that acupuncture might reduce symptoms related to UFs. Larger trials with negative control groups and long-term follow-up may help to confirm the result. The changes in uterine size and UF volume cannot be adequately determined due to technical issues for ultrasound examination. To further study the effect of Tung's acupuncture on UFs, larger clinical trials with randomized negative controls are warranted.

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AUTHOR DISCLOSURE STATEMENT

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