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The Journal of Acupuncture and Oriental Medicine

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Effect of Chinese Herbal Formula, Soothe & Shrink, on Uterine Fibroids:
an Eight-Case Clinical Study

Making the Case for Workers' Compensation: Acupuncture for Low Back Pain

Systematic Review of Acupuncture for Low Back Pain: Efficacy and
Clinically-Meaningful Change

Case Report: Vertigo Treated with Acupuncture and Dietary Changes

Report from the 2018 International Congress on Integrative Medicine and Health

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The NCCAOM also celebrates another achievement this year! The 2018 Standard Occupational Classification Manual published by the Office of Management and Budget now features “Acupuncturists” with its own classification as a federally-recognized labor category. The new designation is the result of a decade-long initiative spearheaded by NCCAOM in conjunction with other leading acupuncture professional organizations.

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Cover: Golden Rod herbs in summer sun. Photo © Grigoriy Pil



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MERIDIANS

The Journal of
Acupuncture and
Oriental Medicine

Letter from Editor in Chief Jennifer A. M. Stone, LAc



Welcome to the summer 2018 issue of *Meridians: The Journal of Acupuncture and Oriental Medicine*!

The spring 2018 issue was Lynn Eder's last issue as managing editor of the journal. Lynn has provided invaluable support to our profession for many years, helping to build a solid foundation for the work of Executive Director Rebekah Christiansen, Denise Graham, and years of AAAOM boards. Prior to her work with *Meridians*, she was the managing editor of *The American Acupuncturist* for four years, supporting editors Bill Reddy, Adam Burke, Lixing Lao, and myself.

Lynn's dedication to managing operations expertly and perfectly made it possible for myself and other leaders in our profession to strategize for the future, secure in the knowledge that Lynn would keep day-to-day operations running. But Lynn's work with *Meridians* was so much more than managing operations. She personally mentored multiple first-time authors and DAOM students, working closely with them to convert their manuscripts into solid, scientific publications worthy of indexing on MEDLINE. Lynn is the very best at what she does and I'm so grateful to have had the opportunity to work with her for 8 years. She will be missed.

Moving forward, I would like to introduce you to *Meridians'* new support staff, Kyra Triebold and Rachel Kindler.

Kyra will be serving as Production and Editorial Coordinator. Kyra graduated from Indiana University this May with a double major in English (with honors) and Near Eastern Languages and Cultures (Arabic) and a minor in Latin. She will begin her Masters of Library Science this fall. This semester, Kyra completed an internship at Indiana University Press in electronic publishing, generating DOIs (necessary for impact factor), and using open source software that collects data for metadata harvesting (necessary for inclusion in MEDLINE).

Rachel will be serving as Marketing and Advertising Coordinator. Rachel graduated from Indiana University with degrees in History and Political Science. She has since worked with the Indiana University Press in production, marketing, and open-access publishing.

Kyra and Rachel have the skills needed to help *Meridians* obtain and improve our impact factor and have a fighting chance as we prepare to apply for inclusion in MEDLINE.

In this summer issue we're pleased to present two original research pieces. The first is a systematic review of the literature on acupuncture for low back pain. A team of researchers prepared this research to satisfy a request by the Washington State Bureau of Labor and Industries, who required evidence to support the inclusion of acupuncture in the state workman's compensation program. Please read both the review and the introduction to see how this research informed policy makers in Washington state and opened access to acupuncture services for workers there.

The second original research piece is a clinical study on the impact of a Chinese herbal formula on uterine fibroids. A research team at the Atlantic Institute of Oriental Medicine examined the impact of the herbal formula "Sooth and Shrink" and evaluated changes using transvaginal ultrasound.

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welcomes letters to the
editor from our readership.
Please send them to
info@meridiansjaom.com
and be sure to include your
full name and any licenses
and/or titles, your phone
number, and email address.

Continuing our commitment to providing resources for practitioners in the clinic, we also present to you a case study on the successful use of acupuncture and dietary changes on a case of benign paroxysmal positional vertigo.

Be sure not to miss our Clinical Pearls in this issue and see how the experts treat multiple sclerosis in their clinics. Additionally, this issue includes a letter to the editors of *JAMA* by Lee Hullender Rubin and Carmelo Sgarlata. The letter concerns the use of sham acupuncture as a control in a study the journal published on the effect of acupuncture on live births among women undergoing in vitro fertilization.

Finally, this May ASA representatives David Miller, Eric Buckley, and Jennifer Stone attended the International Congress on Integrative Medicine and Health, hosted by the Academic Consortium for Integrative Medicine and Health and the International Society for Complementary Medicine and Research in Baltimore, MD. The theme of this year's congress was *Collaboration in Action: Advancing Integrative Health through Research, Education, Clinical Practice and Policy*. Included in this issue is a summary of the plenary speakers' presentations, along with an overview of the various panels, sessions, and posters presented at the conference.

As always, we invite your questions, feedback, submissions and letters to the editor: meridiansjaom@gmail.com.

Respectfully,

Jen

Editor in Chief, *Meridians: JAOM*



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Effect of Chinese Herbal Formula, Soothe & Shrink, on Uterine Fibroids: an Eight-Case Clinical Study

By Serene Feng and Harry Hong*

Please see bios at end of the article.

Abstract

Objective: This study seeks to observe the effect of the Chinese herbal formula, Soothe & Shrink, on treatment of uterine fibroids.

Methods: A total of 10 participants who met the study criteria were recruited into two treatment groups, a 6-week treatment group and a 12-week treatment group, with 5 participants in each group. Soothe & Shrink herbal formula in granule form (10.8 g) was given to participants, taken orally twice a day. A trans-vaginal ultrasound was performed on all participants before and after treatment to evaluate uterine size and fibroid volume. Symptom severity and quality of life were also evaluated using the Uterine Fibroid Symptom and Health-Related Quality of Life Questionnaire.

Results: Two of the 6-week-group participants dropped out due to personal reasons. A total of 8 participants completed the program. In 6 out of the 8 participants, 4 from the 12-week group and 2 from the 6-week group, a reduction in uterine size was found. A higher percentage of participants in the 12-week group (4 out of 5, 80%) showed a reduction of uterine size than in the 6-week group (2 out of 3, 66.7%). In 4 out of the 8 participants, 3 from the 12-week group and 1 from the 6-week group, a reduction in UF volume was found. A higher percentage of participants in the 12-week group (3 out of 5 and 60%) showed a reduction in UF volume than in the 6-week group (1 out of 3 and 33.3%). The scores for Uterine Fibroid Symptom and Health-Related Quality of Life Questionnaire showed substantial improvement in both groups. Symptom-severity subscale scores were found decreased for all participants except one. A significantly higher rate of reduction was observed for the 12-week group than the 6-week group ($p < 0.01$). The quality of life subscale scores showed marked improvement for all participants except one. The increase in general quality-of-life score after treatment for the 8 participants was statistically significant ($p < 0.05$). The increase of the score for the 12-week group was significantly higher than that for the 6-week group ($p < 0.01$).

Conclusions: The Chinese herbal formula, Soothe & Shrink, may reduce uterine size and fibroid volume as well as improve the clinical symptoms and quality of life of UF patients. A minimal treatment duration of 12 weeks may have better results than shorter treatment duration. Further clinical studies with negative controls, blinding, longer treatment duration, and larger sample size are recommended.



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Keywords: uterine fibroids, Uterine Fibroid Symptom and Quality of Life Questionnaire, Chinese herbal medicine, Soothe & Shrink formula

Introduction

Uterine fibroids (UFs) are benign tumors of the smooth muscle cells of the uterus.¹ UFs are among the most common diseases in women, occurring in about 25% of all women of reproductive age and up to 30–40% of women over 40 years old.² It is estimated that in up to 50% of the cases, UFs can cause symptoms such as excessive abdominal bleeding, abdominal pain, irregular menstruation, and infertility.³ If left untreated, the symptoms can persist until menopause, severely impacting a woman's quality of life. UFs affect approximately 25 million women in the United States annually, with approximately six million women seeking medical treatment for severe symptoms each year.¹

The cause of UFs remains unknown. Estrogen and progesterone receptors have been identified in fibroid tissue at levels greater than surrounding myometrial cells. It has also been recognized that fibroid growth and maintenance are stimulated and affected by hormonal cyclic changes.^{1,4}

Contemporary management of fibroids includes pharmaceutical options for the symptoms of UFs and surgical options such as hysterectomy, myomectomy, and uterine artery embolization (UAE). Pharmaceutical treatments use medications such as gonadotropin-releasing hormone (GnRH) agonists, progesterone antagonists, and female hormone replacement to relieve symptoms and decrease the growth of fibroids. The main effects of GnRH agonists, which suppress pituitary ovarian function, are the temporary control of bleeding and a reduction in fibroid and uterine size. Progesterone antagonists block progesterone signals to fibroid tissue and reduce the growth. Surgical approaches, such as hysterectomy, remain a mainstay of fibroid treatment. It is estimated that almost half of the 600,000 hysterectomies performed in the United States each year are performed to treat symptomatic UFs.^{2,4}

Current medical protocols for UFs have their limits. The side effects of GnRH agonists include menopausal symptoms and bone loss with long-term use. After therapy is stopped, there is regrowth of both the fibroids and the uterus almost to their pretreatment size and a recurrence of symptoms in most patients.² Progesterone antagonists and other hormonal therapies that alter estrogen and progesterone production or function may lead to further hormonal imbalance. The surgical approach is associated with operative mortality and morbidity. These medical and hormonal therapies also have critical shortcomings such as causing meno-

pausal syndrome and infertilities.^{2,5,6} Thus, safer therapies are needed for clinical management of UFs.

In China, traditional Chinese medicine (TCM) is a common treatment for UFs. TCM categorizes UFs as *zhen jia*, "the agglomeration/lumps in lower abdomen, accompanied with pain, distending or bloating sensation, and even bleeding."⁷ 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.⁷

Gui Zhi Fu Ling Wan (Cinnamon and Poria Pill) is one such common herbal formula for this condition.⁸ First described in *Jin Gui Yao Lue* (Essential Prescriptions from the Golden Cabinet) by famous TCM doctor Zhang Zhong Jing of the Han Dynasty (third century A.D.), the formula consists of five herbs: *gui zhi* (Ramulus Cinnamomi), *fu ling* (Poria), *tao ren* (Semen Persicae), *chi shao* (Radix Paeoniae rubra) or *bai shao* (Radix Paeoniae alba), and *dan pi* (Cortex Moutan). The functions of this formula include invigorating Blood, dissolving stasis, and resolving masses.⁹ Studies found that *Gui Zhi Fu Ling Wan* may help the shrinkage of UFs and could be an alternative to drug therapies and surgery.⁵ However, the effectiveness of the formula is still controversial due to an insufficient number of studies utilizing large sample sizes and commonly accepted standards in research methodology.¹⁰

Gui Zhi Fu Ling Wan has been researched on therapeutic mechanisms for various conditions. It has been reported that the formula helped hot flashes through modulating peripheral blood circulation. Studies found that blood flow in the face and upper body decreased significantly with both estrogen and *Gui Zhi Fu Ling Wan* treatment. But the herbal formula significantly increased the blood flow in the lower extremities, whereas estrogen decreased the blood flow.¹¹ *Gui Zhi Fu Ling Wan* has also been reported to induce apoptosis of endometriotic cells and inhibit cell proliferation and metastasis through the mitochondrial apoptotic pathway.¹² In addition, both in vitro and in vivo studies found that *Gui Zhi Fu Ling Wan* had anti-tumor function with inhibition of growth and angiogenesis of human cervical cancer cells.¹³ Thus, it is reasonable to believe that *Gui Zhi Fu Ling Wan* reduces UF through similar pathways. However, detailed therapeutic mechanisms remain unclear.

In addition to the symptoms directly associated with UFs such as irregular menstruation, menorrhagia, pelvic pain and discomfort, many other symptoms have also been observed among UF patients. These include anxiousness, fatigue, mood change, worry, and low sex drive.¹⁴ Considering that nowadays working women must cope with high stress in balancing their careers and families, the above symptoms further reduce their quality of life.

Many Chinese herbs have been studied and found beneficial in treating the above symptoms. *Chai hu* (Radix Bupleuri), *bai shao* (Radix Paeoniae alba), and *dang gui* (Radix Angelicae sinensis)—major ingredients of the classical formula *Xiao Yao Wan* (Free and Easy Wanderer)—have been found to reduce psychological stress, as well as the negative emotions of depression and/or anxiety. It is suggested that *Xiao Yao Wan* regulates nervous and endocrine systems through enhancing levels of plasma β -endorphins and decreasing epinephrine and dopamine release.¹⁵ Furthermore, *dang gui* (Radix Angelicae sinensis) has been found to have estrogen receptor binding activity and to promote progesterone receptor gene expression in vitro.¹⁶ Clinical studies have also reported that *dang gui* can ameliorate the symptoms of menopausal syndrome and helps related physical and psychological symptoms.¹⁷ Study suggests that *dang gui* may modulate estrogen receptor function through activation of estrogen receptor signaling pathways.¹⁶ Thus, it is reasonable to believe that this herb may also help decrease the growth of UFs.

San qi (Panax notoginseng) is another widely used Chinese herb that has wide-ranging pharmacological effects and can be used to treat cardiovascular diseases, pain, inflammation, and internal and external bleeding. Study suggests that the herb helps to stop bleeding and speed up wound healing through enhancing platelet aggregation via activating signaling pathways.¹⁸ Although *San qi* (Panax notoginseng) is often used to stop bleeding caused by trauma, according to TCM theory, its dual-functions, stopping bleeding and moving stasis, suggest that this herb could also be a good choice to treat UFs and related symptoms.

For the purpose of this study, the authors designed an herbal formula to treat UFs, Soothe & Shrink (S&S) formula, based on modern research and traditional formulation strategy. This formula uses a combination of *Gui Zhi Fu Ling Wan*, *Xiao Yao Wan*, and other Chinese herbs, including *fa ban xia* (Processed Rhizoma Pinelliae Ternatae), *shan zha* (Crataegi Fructus), *xiang fu* (Cyperus Rhizome), *yi mu cao* (Herba Leonuri), *ju he* (Semen Citri reticulatae), *san qi* (Radix Notoginseng), and *jiu chao da huang* (Wine Processed Radix et Rhizoma rhei). The objective of the study is to determine the therapeutic effect of the S&S formula in reducing uterine size and UF volume as well as controlling related clinical symptoms.

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 were recruited through digital and print advertisements. Ten participants were enrolled in the study using the diagnostic criteria shown in Table 1. The participants were divided into two

groups, with the first 5 in the 12-week group and the latter 5 in the 6-week group. All participants were provided with written informed consent before the study and a list of board-certified physicians in the event that they experienced psychologically, emotionally, or physically adverse effects during the study.

Table 1. Diagnostic, Inclusion, Exclusion and Dropout Criteria

Diagnostic Criteria	<ol style="list-style-type: none"> Primary complaint includes one or more of the followings: <ul style="list-style-type: none"> Heavy or prolonged menstrual periods Abnormal bleeding between menstrual periods Pelvic pain (caused as the tumor presses on pelvic organs) Frequent urination Low back pain Pain during intercourse A firm mass, often located near the middle of the pelvis, can be felt by a physician In addition to 1 above, diagnosis of UF must be confirmed with physical examination by a physician and with transvaginal ultrasound (also known as ultrasonography).
Inclusion Criteria	<ol style="list-style-type: none"> Met the diagnostic criteria described above for UF Were between 25 and 51 years old Were at pre-menopause stage Had fewer than 4 missed periods within the past year Signed Informed Consent and Release of Liability Forms Were reported to have one or more of the fibroids equal or smaller than 1.97 x 1.97 x 1.97 cubic inches or 5 x 5 x 5 cubic centimeters. Received a minimum of junior high school education Read the provided list of the formula's ingredients to ensure no known allergies
Exclusion Criteria	<ol style="list-style-type: none"> Used one or more of the UF interventions including Gonadotropin-releasing hormone agonists (GnRH agonists), anti-hormonal agents, and anti-progestin one month before the study Had myomectomy and/or uterine artery embolization done within 6 months Experienced excessive uterine bleeding with one or more of the following symptoms: <ol style="list-style-type: none"> A need to use double the amount of feminine hygiene products typically used and having to change them during the night, or use protective barriers on the bed Menstrual bleeding extended to more than 10 days 3 months prior to the study Anemia or signs of abnormal functions of liver and kidney using complete blood count (CBC) and comprehensive metabolic panel (CMP)
Dropout Criteria	Missed more than 3 consecutive days of taking herbal formula

The ingredients of the S&S formula and daily dosage are shown in Table 2. Herbal extracts were manufactured by Beijing Kang Ren Tang Pharmaceutical Co. and sponsored by Acupuncture Corporation of America, New York. Participants were instructed to take one dose of herbal extract (10.8 g) twice a day, half an hour after breakfast and half an hour after dinner. The extract was dissolved in hot water of 88-100 C by stirring and cooled down for about 2 minutes before taking. Stevia extract (1 g) and lemon juice powder (5 g) were available upon request for patients who experienced difficulties in drinking the decoction. Herbs were skipped during menstruation. Weekly interviews were scheduled with the participants. During the interview, 1) the implement of the study procedure was monitored; 2) general health conditions of participants were assessed with a pulse and tongue read; 3) questions and concerns from the participants were discussed; and 4) one week of herbs were given to the participants. No nutritional or lifestyle changes were recommended and no additional modalities of treatment were used.

Table 2. Ingredients of S&S Formula and Daily Dosage

Name of Herbs	Ratio (Extract vs Raw Herb)	Raw Herb Dosage (g)	Exact Dosage (g)
<i>gui zhi</i> (Ramulus Cinnamomi cassiae)	1:20	10	0.5
<i>fu ling</i> (Sclerotium Poriae cocos.)	1:5	10	2
<i>bei chai hu</i> (Radix Bupleuri)	1:10	10	1
<i>huang qin</i> (Radix Scutellariae baicalensis)	1:10	7	0.7
<i>dan pi</i> (Cortex Moutan Radicis)	1:10	10	1
<i>chi shao</i> (Radix Paeoniae Lactiflorae)	1:10	10	1
<i>tao ren</i> (Semen Persicae)	1:20	10	0.5
<i>fa ban xia</i> (Processed Rhizoma Pinelliae Ternatae)	1:10	8	0.8
<i>shan zha</i> (Crataegi Fructus)	1:5	10	2
<i>xiang fu</i> (Cyperus Rhizome)	1:20	7	0.35
<i>yi mu cao</i> (Herba leonuri)	1:10	7	0.7
<i>ju he</i> (Semen Citri reticulatae)	1:20	5	0.25
<i>san qi</i> (Radix Notoginseng)	1:1	8	8
<i>jiu chao da huang</i> (Wine Processed Radix et Rhizoma rhei)	1:20	8	0.4
<i>dang gui</i> (Radix Angelicae sinensis)	1:5	7	1.4
<i>gan cao</i> (Radix Glycyrrhizae uralensis)	1:5	5	1
Total		132	21.6

The primary outcome measurements of this study, uterine size, UF volume, and number of UFs, were evaluated with transvaginal ultrasounds performed by the Flushing Imaging Center, New York. Both the volume of the UFs and/or the volume of uterine were calculated by the Prolate Ellipsoid Method, via the formula: $0.52 \times \text{length} \times \text{width} \times \text{height}$.² All participants received a transvaginal ultrasound before and after the treatment at around 10 days after the first day of the participants' menstrual period.

The secondary outcome measurement of this study, i.e., the symptoms and quality of life, were evaluated using a modified version of the "Uterine Fibroid Symptom and Quality of Life Questionnaire (UFS-QOL)."^{14,19} The UFS-QOL is a UF-specific questionnaire that assesses symptom severity and the quality of life in patients with uterine fibroids. It consists of an 8-point Symptom Severity scale questionnaire and 29 Quality of Life questions comprising 6 areas: concern (about unpredictability of the menstruation and embarrassment caused by heavy bleeding), activities (daily physical activities and exercise), energy/mood (energy level and mood change), control (feelings of lost control of own life, health, and mood), self-consciousness (about appearance, weight, and size of cloth), and sexual function (sexual desire and relations). All questions are scored on a 5-point Likert scale, ranging from "not at all" to "a very great deal" for symptom severity questions and "none of the time" to "all of the time" for the quality-of-life questions. Symptom Severity and Quality-of-Life subscale scores are summed into a 0–100 point scale. The Symptom Severity scale and Quality-of-Life subscale scores are inversely related with higher Symptom Severity scores, indicating greater symptoms, while higher Quality-of-Life subscale scores indicate better quality of life.¹⁹

The UFS-QOL has been used in a number of studies assessing a variety of UF therapies²⁰⁻²², and has been found to be a useful outcome measurement for UF treatment.¹⁹ The original UFS-QOL questionnaire consisted of 37 questions. Three additional questions were added to the end of the questionnaire to further evaluate the severity of the irregular menstruation, abdominal pain, and trouble sleeping. The questions added are: "(38) Fluctuation in your irregular menstrual cycle"; "(39) Abdominal pain of your periods"; and "(40) Interfered with your sleeping." The UFS-QOL was given to each participant before treatment to establish a baseline, and then administered at the end of the study. The scores collected were entered into a Microsoft Excel spreadsheet for comparison and statistical analysis.

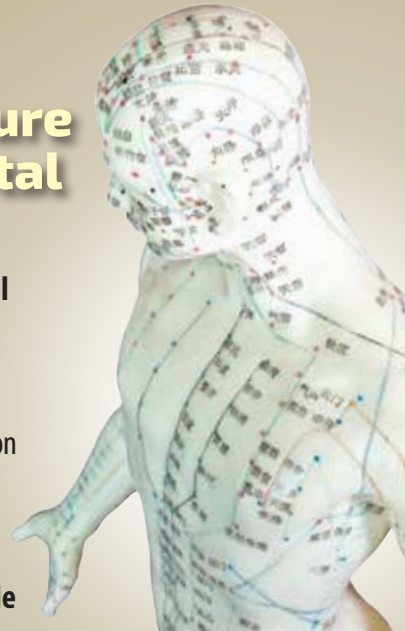
The Complete Blood Count (CBC) and Complete Metabolic Panel (CMP) were conducted before and after the study to check for anemia and liver and kidney function and to ensure that the participants would not be adversely affected during the course of the study.

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Results

1. Baseline Demographics

Among the 10 participants who completed the baseline UFS-QOL and received initial UF treatment, 5 of the 5 participants in the 12-week group completed the treatment and 3 of the 5 participants in the 6-week group finished the treatment. Two participants of the 6-week group did not finish the treatment due to personal reasons, resulting in a total sample size of 8 participants. Among the 8 participants, ages ranged from 35 to 51, with a mean age of 45 years old. 7 participants were Asian and 1 was Caucasian, with a mean body mass index (BMI) of 23.3 (Table 3). Each participant received a patient code based on the number of weeks they participated (e.g. those in the 12-week group have number "12" in their codes, while those in the 6-week group have a number "6" in their codes) and their name initials.

Table 3: Baseline Demographic and Clinical Characteristics

Patient Code	Body Weight (lb)	Height	BMI*	Age	Race
PT12ACN	120	5'3"	21.3	49	Asian
PT12BWX	115	5'1"	21.7	46	Asian
PT12CXJ	120	5'5"	20.0	48	Asian
PT12DWL	140	5'1"	26.5	35	Asian
PT12ECD	153	5'3"	27.1	44	Asian
PT06AWM	170	5'10"	24.4	47	Asian
PT06BDX	130	5'2"	23.8	37	Asian
PT06CAT	115	5'1"	21.7	51	Caucasian
Mean	132.9	5'3"	23.3	44.6	Asian=7; Caucasian=1

*BMI-body mass index

2. Change of Uterine Size

Among the 8 participants who finished the program, 6 showed a reduction in uterine size, while 1 participant (PT06BDX) in the 6-week group showed an increase and 1 (PT12DWL) in the 12-week group showed no change. A higher percentage of participants in the 12-week group (4 out of 5, 80%) showed a reduction of uterine size than in the 6-week group (2 out of 3, 66.7%) (Table 4). No statistically significant change in uterine size was observed before and after treatment among the 8 participants.

3. Volume of UFs

Four out of 8 participants showed a reduction in UF volume. In the 12-week group, 3 out of the 5 participants showed a reduction, while 1 participant (PT12BWX) showed an increase and the other (PT12ACN) showed no change. In the 6-week group, 1 out of 3 participants showed a reduction in UF volume, while the other 2 participants (PT12BWX and PT06CAT) showed an increase (Table 4). A higher percentage of participants in the 12-week group (3 out of 5 and 60%) showed a reduction in UF volume than in the 6-week group (1 out of 3 and 33.3%). No statistically significant change in UF volume was observed before and after treatment among the 8 participants.

4. Number of UFs

A decrease in number of fibroids was observed in 2 participants (PT12CXJ and PT12DWL) in the 12-week group and 1 (PT06BDX) in the 6-week group. Two participants (PT12ACN and PT12BWX) in the 12-week group and 1 (PT06AWM) in the 6-week group showed no change in number of fibroids, while 2 participants (PT12ECD and PT06CAT), 1 in each group, showed an increase in number of fibroids (Table 4). There was no statistically significant change in number of fibroids before and after treatment among the 8 participants, nor were there between the two groups.

Table 4. Change in Uterus Size, Fibroid Volume, and Number of Fibroids

Patient Code	Uterus Size			Fibroid Volume			Number of Fibroids		
	Before (cm ³)	After (cm ³)	Change (%)	Before (cm ³)	After (cm ³)	Change (%)	Before	After	Change
PT12ACN	102.1	44.2	-56.71	520.0	520.0	0	1	1	0
PT12BWX	212.4	128.8	-39.36	49.7	62.3	+25.35	2	2	0
PT12CXJ	1630.6	735.9	-54.87	1270.7	924.0	-27.28	10	7	-3
PT12DWL	73.6	74.1	+0.68	26.3	13.0	-50.57	3	2	-1
PT12ECD	500.8	186.1	-62.84	231.4	119.5	-48.36	1	3	+2
PT06AWM	295.7	116.8	-60.50	289.0	355.3	+22.94	3	3	0
PT06BDX	500.4	687.1	+37.31	319.9	233.0	-27.16	2	1	-1
PT06CAT	118.2	89.2	-24.53	1.1	18.5	+1581.82	1	3	+2

"Results suggest that S&S formula is an effective treatment for UFs through reducing uterine size and UF volume and through improving symptoms and quality of life for UF patients."

5. UFS-QOL Symptom Severity

UFS-QOL Symptom Severity scores and the three additional scores for irregular menstruation, abdominal pain, and sleeping disturbance were reduced for all participants except for one, PT06AWM, who showed an increase in all scores but one, a mild reduction (33.3%) in trouble sleeping. The average scores before and after treatment are shown in Table 5 and Figure 1 and further compared between the 12-week and the 6-week groups in Figure 2. A statistically significant higher rate of symptom reduction, $t(6)=4.33$, $p<0.01$, was observed for the 12-week than the 6-week group.

continued on page 13

Table 5. UFS-QOL Subscale Scores of Symptom Severity

UFS-QOL Subscales	6-Week Group (N=3)			12-Week Group (n=5)			Both Groups (N=8)		
	Before Mean (SD)	After Mean (SD)	Decrease (%)	Before Mean (SD)	After Mean (SD)	Decrease (%)	Before Mean (SD)	After Mean (SD)	Decrease (%)
Symptom Severity	40.6 (6.8)	37.5 (15.5)	7.6	44.4 (27.9)	19.4 (10.3)	56.3	43.0 (22.5)	26.2 (15.3)	39.0
Irregular menstrual Cycle	58.3 (23.6)	50.0 (35.4)	14.2	45.0 (29.2)	10.0 (12.2)	77.8	50.0 (28.0)	25.0 (30.6)	50.0
Abdominal pain	33.3 (11.8)	33.3 (47.1)	0.0	45.0 (40)	0.0 (0)	100.0	40.6 (32.9)	12.5 (33.1)	69.2
Trouble Sleeping	50.0 (20.4)	25.0 (20.4)	50.0	40.0 (40.6)	5.0 (10)	87.5	43.8 (34.8)	12.5 (17.7)	71.5

Abbreviations: SD-standard deviation; UFS-QOL-Uterine Fibroid Symptom and Quality of Life Questionnaire

Figure 1. Changes in Symptom Severity Scores before and after Treatment

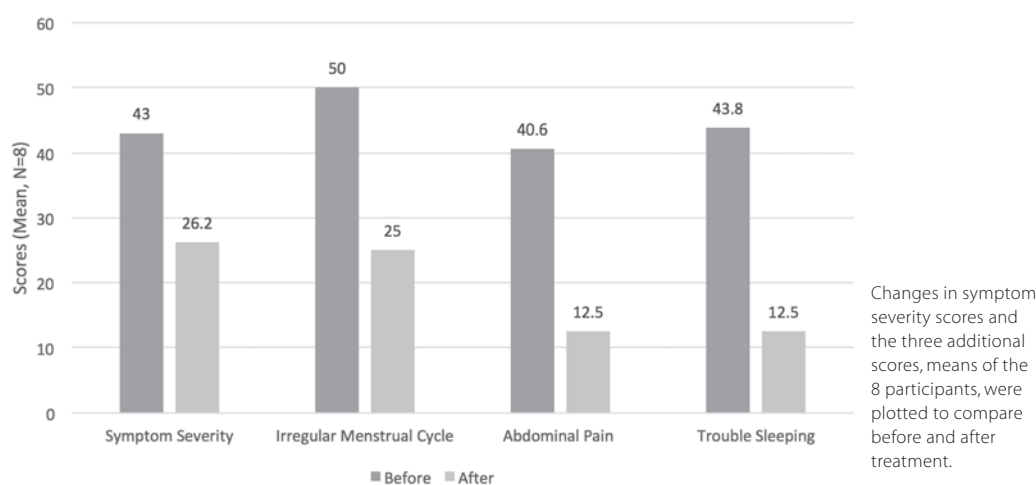
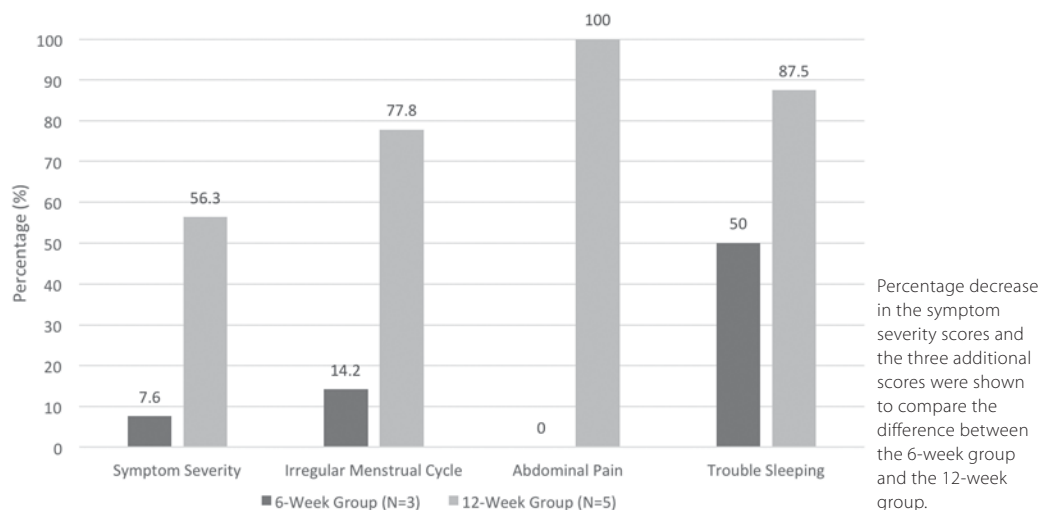


Figure 2. Decrease in Symptom Severity Scores between Two Groups





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6. UFS-QOL Quality of Life

UFS-QOL Quality of Life scores for all subscales including concern, activities, energy/mood, control, self-consciousness, and sexual function increased for all participants with one exception, PT06AWM, who showed a slight decrease in all categories. The average scores before and after treatment are shown in Table 6 and Figure 3 and further compared between the 6-week and 12-week groups in Figure 4. There is significant change for the UFS-QOL General score, $t(9) = -2.29, p < 0.05$, with the patients reporting higher scores after treatment than before treatment. This indicates that the increase of overall UFS-QOL score is statistically significant. There were also significant effects for the subscale scores of energy/mood and self-consciousness, $t(9) = -2.59, p < 0.05$ and $t(9) = -3.70, p < 0.01$, respectively, with higher scores after treatment than before treatment. This indicates that the increase in these scores after treatment is statistically significant. A statistically significant higher rate of increase in the scores for the 12-week group than the 6-week group was also observed, $t(5) = 5.94, p < 0.01$.

Figure 3. Changes in Quality of Life Score before and after Treatment

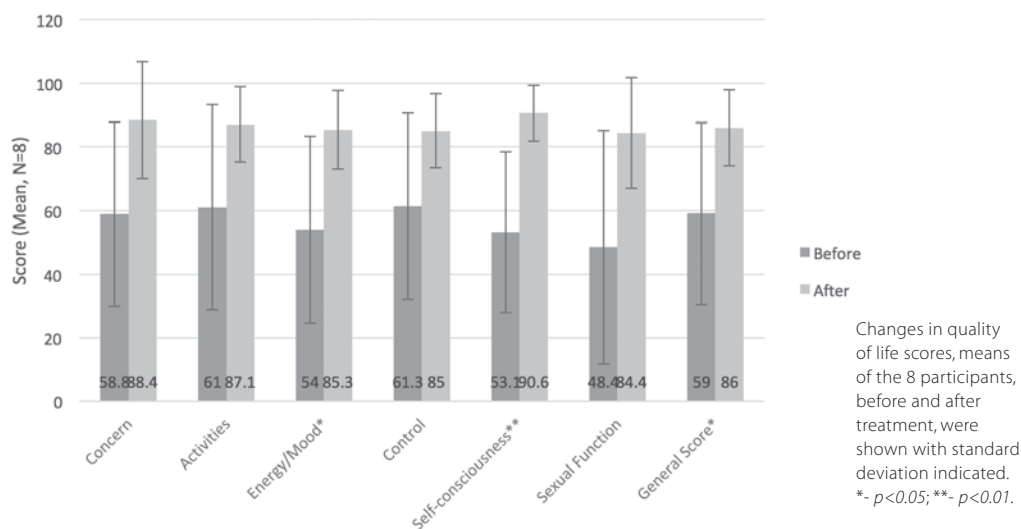


Figure 4. Increase in Quality of Life Scores between Two Groups

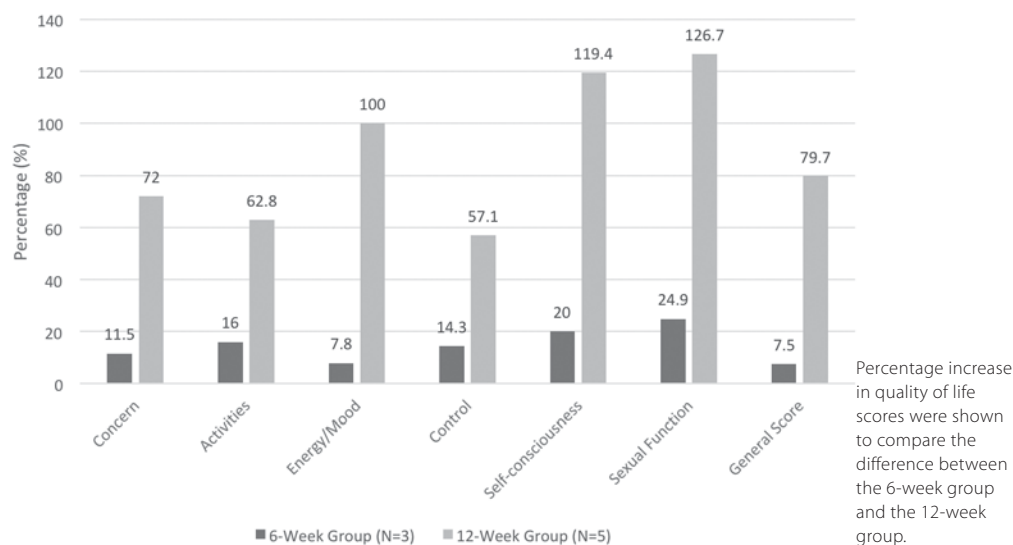


Table 6. UFS-QOL Subscale Scores of Quality of Life

UFS-QOL Subscales	6-Week Group (N=3)			12-Week Group (n=5)			Both Groups (N=8)		
	Before Mean (SD)	After Mean (SD)	Decrease (%)	Before Mean (SD)	After Mean (SD)	Decrease (%)	Before Mean (SD)	After Mean (SD)	Decrease (%)
Concern	73.3(16.5)	81.7(19.3)	11.5	50.0(31.3)	86.0(17.4)	72.0	58.8(29.0)	84.4(18.3)	43.5
Activities	69.8(21.2)	81.0(12.1)	16.0	55.7(36.5)	90.7(10.3)	62.8	61.0(32.3)	87.1(12.0)	42.8
Energy/Mood	69.0(6.7)	77.4(12.1)	7.8	45.0(33.7)	90.0(9.9)1	100.0	54.0(29.4)	85.3(12.4)1	58.0
Control	70.0(12.2)	80.0(10.8)	14.3	56.0(35.0)	88.0(11.2)	57.1	61.3(29.4)	85.0(11.7)	38.7
Self-consciousness	69.4(19.6)	83.3(6.8)	20.0	43.3(23.2)	95.0(6.7)2	119.4	53.1(25.3)	90.6(8.8)2	70.6
Sexual Function	66.7(31.2)	83.3(11.8)	24.9	37.5(35.4)	85.0(20)1	126.7	48.4(36.7)	84.4(17.4)	74.4
General Score	74.6(9.9)	80.5(11.4)	7.5	49.7(32.1)	89.3(11.2)1	79.7	59.0(28.7)	86.0(12.1)1	45.8

1-P≤0.05; 2-P≤0.01 Abbreviations: SD-standard deviation; UFS-QOL-Uterine Fibroid Symptom and Quality of Life Questionnaire.

7. Side Effect and Safety Assessment

There were no reports on any side effect of the S&S formula based on clinical observation. Pre- and post-treatment blood work, including CBC and CMP, were conducted to check for anemia and liver and kidney functions. No participants were adversely affected during the course of the study.

Discussion

Primary outcome measurement of the study shows a reduction of uterine size in 6 out of 8 participants and a reduction of UF volume in 4 out of 8 participants. The reduction is not statistically significant, probably due to the small sample size of the study. Secondary outcome measurement with the questionnaires also indicates that all but 1 participant improved on the UF Symptom Severity and Quality of Life scales. The improvement for General Quality of Life score and subscale scores of Energy/Mood and Self-Consciousness is statistically significant. No obvious side effects were observed after 12 weeks of treatment. Results suggest that S&S formula is an effective treatment for UFs through reducing uterine size and UF volume and through improving symptoms and quality of life for UF patients. It also indicates that the S&S

“One of the difficulties in conducting clinical studies with Chinese herbs is finding ways to help participants overcome the taste of the herbs. Taste was one of the reasons cited by the 2 participants for the decision to discontinue participation in the study.”

formula may be a safe and promising alternative to hormonal therapy and surgery to UF patients.

The results also indicate that the 12-week protocol works better than the 6-week one in terms of reduction of uterine size and UF volume, as well as symptom management. Uterine size generally reduced within 6 weeks, but UF volume didn't, which suggests that different mechanisms may be involved in reduction of uterine size and UF volume. Nevertheless, increase in treatment time very likely helps in the reduction of uterine size and UF volume and the management of clinical symptoms.

The limitations of this pilot study include its small sample size and the lack of negative controls. Future studies with standard design are needed to verify the result. Treatment longer than 12 weeks, e.g. 4-6 months, should be considered in the future studies. A 3-month follow-up after treatment is also needed to evaluate long-term effect of the formula.

The S&S formula used in the study is designed based on TCM patterns of *qi* stagnation and Blood stasis with Dampness and Phlegm. In the study, no further pattern differentiation was conducted for each patient. Improvement has been found for most of the patients, suggesting that the formula works for majority of the UF patients. However, detailed pattern differentiation for each patient and individualized modification to the S&S formula may still help to improve efficacy of this formula in everyday clinical practice.

This study didn't give any nutritional and lifestyle recommendations and ensured that the participants continued whatever they had already been doing in terms of diet and lifestyle. However, dietary and lifestyle change is very important in TCM therapies. For the condition of UFs, *qi* stagnation and Blood stasis with Dampness and Phlegm accumulation, it is recommended that patients avoid consuming crab, shrimp, sea cucumbers, royal jelly, and *e jiao* (Colla Corii Asini, Donkey-Hide Gelatin) in their diet. These foods and supplements may promote Dampness and Phlegm and worsen *qi* stagnation and Blood stasis. In fact, some the participants in this study did consume these regularly, which likely interfered with the treatment of the S&S formula. To achieve the best clinical outcomes, dietary recommendation is a must in clinical practice.

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One of the difficulties in conducting clinical studies with Chinese herbs is finding ways to help participants overcome the taste of the herbs. Taste was one of the reasons cited by the 2 participants for the decision to discontinue participation in the study. In fact, drinking herbal decoctions for more than 1 month has always been an issue for patients in daily clinical practice. By adding lemon juice powder and stevia leaf powder to the herbal granule decoction, 7 out of 8 participants reported that the taste of the decoction improved significantly and became more tolerable. Thus, lemon juice and stevia extract may be helpful in clinical practice as well as clinical studies involving Chinese herbal decoction.

Conclusion

Although conducted with a small sample size and lack of negative controls, this pilot study found that S&S formula was an effective treatment and safe alternative to drugs and surgery for UF patients. The formula helps UF patients by reducing uterine size and UF volume and by improving symptom severity and quality of life with a minimum of 12 weeks of continuous treatment. Further clinical studies with longer treatment durations, larger sample size, and randomized controls are warranted.

Acknowledgements

We thank Ya Li Zhu for her encouragement and participation in the study. Also thank Dai Yi Tang, Di Fu, Allyson Wilson, Sloane Vesbinski, and Johanna Yen for their support and advice.

Conflict of Interests

We don't have any conflict of interests in this study.

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Making the Case for Workers' Compensation: Acupuncture for Low Back Pain

By Lisa Taylor-Swanson,
PhD, MAcOM, EAMP and
Megan K. Gale,
EAMP, MSAOM, EAMP/LA

Why are systematic reviews important?

Systematic reviews represent the type and quality of research that is used to change or enact policy, especially at the state and national level. Quality systematic literature reviews in our field of work can be used to change or create policy to include acupuncture treatments as covered services and acupuncturists as covered providers.

"Like it or lump it, [research] is the language of modern science. And if we cannot speak that language, we are mute." –Lisa Taylor-Swanson, PhD, MAcOM, EAMP

Background

The workers' compensation program administered by the Washington State Department of Labor and Industries (L&I) currently prohibits licensed acupuncturists (now with the state title of East Asian Medicine Practitioners, EAMPs) from treating injured workers or billing for treatment of injured workers under administrative rules WAC 296-20-03002 and WAC 296-20-01505.

The Washington East Asian Medicine Association (WEAMA) has worked for over thirty years to establish acupuncture as an authorized treatment for injured workers under RCW 51.04.030. A new rule will classify EAMPs as ancillary providers under the Washington state's workers' compensation program at Labor and Industries (L&I). In addition, the existing rule prohibiting acupuncturists under L&I Administrative Code (WAC) will be removed. Acupuncture will be allowed, similar to chiropractic, physical, and massage therapy, under their statutes.

WEAMA's most recent concerted effort to educate L&I about the safety and efficacy of acupuncture began in 2015 when WEAMA agreed to conduct a systematic review (SR) of the literature. The goal of the SR was to demonstrate that there is sufficient evidence that acupuncture is a safe, effective, and cost-effective treatment for low back pain, with the eventual goal of informing and changing policy on this issue. The Office of the Medical

“The goal of the SR was to demonstrate that there is sufficient evidence that acupuncture is a safe, effective, and cost-effective treatment for low back pain, with the eventual goal of informing and changing policy on this issue.”

Director of L&I committed to technical assistance and to review the report, policy analysis, and a decision. The SR volunteer team was initially led by Mercy Yule, EAMP, and was subsequently led by Lisa Taylor-Swanson, PhD, MACOM, EAMP.

The L&I medical committee approved, reviewed again, and then presented the systematic review to the Washington state Industrial Insurance Medical Advisory Committee (IIMAC) in January 2017. IIMAC approved the review. With that approval, the process for the rule change could begin.

Since this is the first time in over ten years that an entire profession will be added to the Washington L&I system, L&I is conducting internal research for how to proceed. The Washington L&I medical committee decided to run an Acupuncture Pilot Program concurrently with rule-making. L&I's goal for the Acupuncture Pilot Program is to learn how to align acupuncture coverage to quality purchasing strategy.

The pilot program allows L&I to: (1) waive existing rules and gather information to help L&I determine how best to implement and cover acupuncture treatment; and (2) determine future coverage and payment methodology for acupuncture given pilot results and experiences. The pilot began in October 2017 and will run for at most two years; however, the pilot will stop sooner if the State Pilot Program lead team receives enough data from the provider paperwork to make decisions on the details of the final L&I rule.

For now, the pilot program will continue to observe how well the enrolled EAMPs can follow L&I's established rules and documentation standards. The quality of the provider participation in their pilot program will dictate the final ruling from L&I on the details of EAMP participation as L&I providers beyond the pilot.

To help maintain the program's momentum, Megan Gale, EAMP, created a documentation toolkit¹ to help pilot providers be successful participants by measuring functional change from their patient care paradigm, using validated assessment tools,

and turning in paperwork to the correct location. The toolkit introduces practitioners to using the return-to-work clinic model and to documenting functional change using validated tools. Demonstrating, with documented metrics, patients' improved function, sleep quality, decreased or eliminated need for pain medications, and ability to self-manage pain conditions all leads to decreased disability risk factors, which supports L&I's Healthy Worker 2020 Strategic Plan.

It is our hope that the pilot data will again demonstrate the safety and effectiveness of acupuncture to treat low back pain experienced by injured workers. Additionally, we hope and anticipate that L&I will elect to expand acupuncture coverage to other conditions in addition to low back pain for injured workers. If so, the SR will have achieved its intended long-term goal of informing and changing policy in Washington state.

1. Location of toolkit: <https://hospital-practice-basics.teachable.com/p/ini-acupuncture-pilot-project-wa-state-documentation-training>

WEAMA has sponsored free access to the "Workers' Comp Documentation Toolkit", an online course bundle, for providers throughout the Pilot Program. Contact info@weama.info for a coupon code.

Please see the following page for the Systematic Review of Acupuncture for Low Back Pain: Efficacy and Clinically-Meaningful Change



Systematic Review of Acupuncture for Low Back Pain: Efficacy and Clinically-Meaningful Change

Abstract

Low back pain has a substantial effect on the quality of life for those affected and places a significant economic burden on healthcare systems. The purpose of this study is to identify, document, and appraise reports of randomized controlled trials on the treatment of low back pain with acupuncture. Relevant studies were identified through systematic searches in scientific databases. Eighteen of 948 papers retrieved met all inclusion criteria and were reviewed. Acupuncture significantly outperformed usual care in 10 of 11 trials. Sham acupuncture outperformed waitlist in 1 trial and conventional care in 2 trials. Needleless placebo acupuncture outperformed conventional care in 1 of 3 trials reviewed. No moderate or severe adverse events related to the intervention were reported. Concerns of cost and missed work were studied in some trials. Acupuncture was associated with fewer days absent from work in 1 reviewed trial. The identified evidence suggests that 1) acupuncture is a safe, effective, and possibly cost-effective treatment for low back pain; and 2) sham and needleless placebo acupuncture do not appear to be inert. Further trials investigating the cost and potential cost-saving strategies of acupuncture are merited.

Perspective

This article presents a systematic review of trials of acupuncture in the treatment of low back pain. The evidence suggests that acupuncture is a safe, effective, and possibly cost-effective treatment for low back pain and that sham and needleless placebo acupuncture do not appear to be inert.

Keywords: acupuncture, low back pain, efficacy, clinically meaningful change

Introduction

Low back pain (LBP) has a substantial effect on the quality of life of those affected by it. As well as a major health problem for these individuals, LBP also places a significant economic burden on healthcare systems. Approximately 1 in 4 people affected by LBP seek medical attention within a 6-month period.¹ Workers with acute lumbar sprain account for 42% of all occupational injuries (www.bls.gov/iif).

Authors: All authors are listed and all have contributed substantially to the manuscript. There are no other manuscripts in publication or in submission from this project.

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The magnitude of the burden from low back pain has increased in recent years. In 1990, a study ranking the most burdensome conditions in the U.S. in terms of mortality or poor health as a result of disease ranked low back pain in sixth place; in 2010, low back pain jumped to third place, with only ischemic heart disease and chronic obstructive pulmonary disease ranking higher. (http://www.ninds.nih.gov/disorders/backpain/detail_backpain.htm)

Significance

Even though low back pain has such an important impact on general health, this condition is often treated insufficiently. Poor efficiency in treatment has led to the necessary creation of guidelines that address evidence-based strategies for treatment of LBP.² The effectiveness of acupuncture for the management of LBP has been reviewed systematically in 1999,³ in 2005,⁴ in 2008,⁵ in 2012,⁶ and again in 2013.^{7,8}

The largest study previously reviewed was the highly publicized German acupuncture trial including 1,162 patients from 340 practices. The results of the study revealed that the effectiveness of acupuncture, either verum or sham, was almost twice that of conventional therapy.⁹ However, many of the trials reviewed in the systematic reviews, particularly by van Tulder and Furlan, were conducted 10-30 years ago and were of poor methodologic quality. Several of the systematic reviews³ and meta-analyses¹⁰ had inconclusive results. The present study was undertaken to summarize more recent trials of acupuncture for LBP and to analyze the findings in light of recent evidence indicating that sham acupuncture is not an inert control.

The aim of the present study is to identify and summarize findings from relevant recent trials of acupuncture for the treatment of low back pain. The identified trials were reviewed and findings were summarized regarding statistical significance, clinical relevance, as well as quality, as many older trials have been deemed to be of poor methodologic quality. Lastly, findings were analyzed with respect to type of sham comparison employed.

Methods

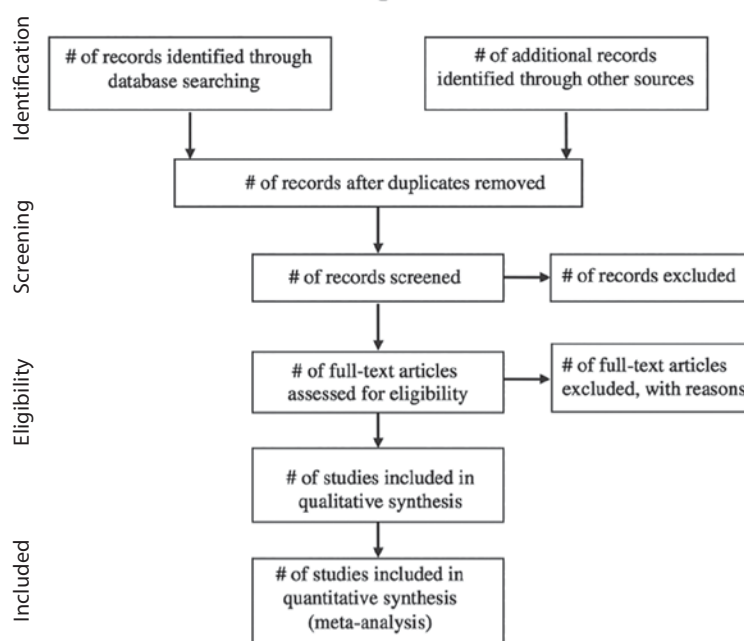
Relevant studies were identified through systematic searches in scientific databases (MEDLINE, Cochrane Library, CINAHL), "similar article" searches, and reference list scanning. Inclusion criteria were randomized controlled trial (RCT), acupuncture, electro-acupuncture, dry needling, low back pain (LBP), ages 18-65, published 2004-2014, and full text available in English. Exclusion criteria included pregnancy, pediatric, not acupuncture, not randomized controlled trial, animal studies, systematic analyses, meta-analyses, and feasibility studies. The date range of 2004-2014 was selected to capture the most recent literature because many older trials have been deemed to be of poor methodologic quality.⁴ The age

range of 18-65 was used to capture studies with adult working-age individuals as relevant to Labor and Industries. PRISMA guidelines were followed to design and execute the study.¹¹

Search terms of "low back pain" or "lower back pain" and "acupuncture," "acupuncture therapy," "electro-acupuncture," "electro-acupuncture therapy," "electro-acupuncture" or "electro-acupuncture therapy," in [ti] title or [majr] major topic of an article and English in [language] resulted in a retrieval of 948 articles dated 2004-2014. All abstracts were independently reviewed by two assessors, and 18 papers met all inclusion criteria and none of the exclusion criteria.

Study quality was assessed using the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) Criteria checklist. STRICTA was developed with the Consolidated Standards of Reporting Trials (CONSORT) Group and is an official extension of the CONSORT statement. The CONSORT guideline is the most well-known reporting guideline and has been listed among the top health research milestones of the twentieth century, according to the Patient-Centered Outcomes Research Institute (PCORI) (Gabriel & Normand, 2012). There are six key acupuncture-related items highlighted to ensure clear and transparent reporting of trials: 1) acupuncture rationale, 2) details of needling, 3) treatment regimen, 4) other components of treatment, 5) practitioner background, and 6) control or comparator interventions (MacPherson, et al., 2010). This project gathered data on all 25 CONSORT items and all 6 acupuncture-related items. Reviews were independently carried out by six reviewers, and data were input into customized extraction forms. Data were compiled and summarized by the two Primary Investigators (LJTS & JAS).

Fig. 1. Flow of information through the different phases of systematic review



“The CONSORT guideline is the most well-known reporting guideline and has been listed among the top health research milestones of the twentieth century...”

Results

Database searches identified 986 papers, and an additional 12 papers were identified through reviewing references. After duplicates were identified and 286 records were removed, the remaining 712 records were screened. Records were excluded if they were not published in English, not relevant to the project, or if the full text was unavailable; in all, 694 records were assessed for eligibility and were excluded as they did not meet eligibility criteria. Eighteen (18) papers were identified as eligible and subsequently reviewed using the criteria set forth in the CONSORT and STRICTA checklists. A total of 7,161 subjects were randomized in the studies analyzed for this review. Studies randomized a range of 26-3,093 subjects.

Study interventions included:

- (1) traditional acupuncture according to traditional Chinese medicine (TCM) differential diagnosis, Korean acupuncture, medical acupuncture;

- (2) acupuncture with electric stimulation—electrical stimulation leads connected to acupuncture needles after insertion and the unit turned on to the level of patient comfort;
- (3) modified acupuncture—superficial sparrow pecking method, single insertion at most tender point.

Control or comparators included:

- (1) usual care consisting of physiotherapy, manipulation, and/or medication,
- (2) sham needling, e.g., sham superficial needling, not in the area of the lower back,¹²
- (3) needleless placebo, e.g., contact was made with the skin by touching with a toothpick.¹³

Interventions assessed within each category varied in terms of their components and delivery. (See Table 1)

Table 1. Study Characteristics

Year	First Author	Acupuncture Intervention	Control / Comparison	# Subjects Randomized
2014	Bahrami-Taghanaki	TCM	Chrono-acupuncture	60
2006	Brinkhaus	Medical Acupuncture	Sham: superficial needling not in the lower back	301
2009	Cherkin	TCM	Simulated acupuncture: toothpick + guide tube Usual care	641
2013	Cho	Korean	Non-penetrating sham needles	130
2007	Haake	TCM	Sham acupuncture, usual care	1,162
2006	Inoue	Acupuncture sparrow pecking method	Injection of 5 mg of dibucaine hydrochloride /5 ml	31
2009	Inoue	Single insertion at most tender point	Needleless placebo using guidetube	26
2010	Miao	TCM	Electro-Acupuncture	80
2013	Pach	TCM	Standardized vs. individualized treatment	150
2006	Thomas	TCM	Usual care	241
2004	Tsui	TCM	Acupuncture + electrical heat; control group	42
2012	Vas	TCM	Sham acupuncture using non-specific acu-points	275
2013	Weiss	TCM	Usual care	160
2006	Witt	NR	Waitlist 3 mos.	3,093
2011	Yeh	EA	Sham, usual care	90
2013	Yuan	TCM	Usual care	408
2012	Zaringhalam	TCM	Usual care: massage, PT, and medication	187
			Total randomized: 7,161	

Acupuncture vs. Usual Care

Of the 18 trials reviewed, 11 trials compared acupuncture to usual or conventional care; acupuncture outperformed usual care in all 11 reports (statistically significant in 10 trials). Acupuncture was compared to other types of acupuncture (sham acupuncture, placebo acupuncture, acupuncture with heat) or to other types of control groups in 15 of 19 papers; acupuncture outperformed the comparator in 10 of those 15 reports. For example, Cherkin et al.¹³ found that individualized, standardized, and simulated (toothpick contact) acupuncture all outperformed usual care (all three groups $p < .001$). Three studies reported findings of both verum and sham acupuncture outperforming usual care.^{9,13,14} Six studies found that acupuncture outperformed usual care without sham arms⁵⁻²⁰ and with sham arms.²¹

Clinically Meaningful Change

Clinically meaningful change is defined here as change of 30% or more in reported scale scores after study intervention.²² Refer to these findings in Table 2. Of the 18 papers reviewed, 13 studies reported acupuncture (including true/verum, sham, and/or placebo) resulting in clinically meaningful change in scale scores.

Looking specifically at scales: a clinically meaningful change was reported in Visual Analogue Scale scores (7 studies), Short Form-36 scores (1 paper), and Numeric Pain Rating Scale (NPRS) (1 paper). Disability was reported with the Rowland Morris Disability Questionnaire (5 studies), the Oswestry Disability Index (2 studies), and the Hanover Functional Ability Questionnaire (2 studies). One study reported that acupuncture did not result in a clinically meaningful change in scale scores. In 4 of 18 papers, clinically meaningful change could not be determined from the data provided in the published paper.

Acupuncture vs. Sham

Four of the studies reviewed used sham needling as a comparator.^{9,12,14,21} Of those, 2 had an additional usual care arm.^{9,21} Acupuncture outperformed usual care ($p < .001$) but there were no significant differences between acupuncture and sham except in the study by Yeh et al.,²¹ which found that sham and verum acupuncture were both associated with decreased VAS-reported pain scores as reported.

Table 2. Results

Year	First Author	Did Acupuncture Outperform Usual Care?	Did It Reach Statistical Significance?	Did Acupuncture Out-Perform Comparator?	Did It Reach Statistical Significance?	Did acu group(s) meet 30% change criteria? Y/N?
2014	Bahrami-Taghanaki	NA	NA	Yes	Yes	Yes: both acu+ time points and acu
2006	Brinkhaus	NA	NA	Yes	Yes	?*
2009	Cherkin	Yes	Yes	No	No	Yes: all 3 acu groups
2013	Cho	NA	NA	Yes	Yes	Yes: real and sham acu
2007	Haake	Yes	Yes	No	No	Yes: verum acu and sham acu
2006	Inoue	NA	NA	Yes	Yes	No
2009	Inoue	NA	NA	Yes	Yes	Yes
2010	Miao	NA	NA	Yes	Yes	?*
2013	Pach	NA	NA	No	No	Yes*: both acu groups
2006	Thomas	Yes	Yes	NA	NA	Yes
2004	Tsui	Yes	Yes	Yes	Yes	Yes**: electro acu & electro heat acu
2012	Vas	Yes	Yes	No	No	Yes: true acu, sham acu, placebo acu
2013	Weiss	Yes	Yes	NA	NA	?
2006	Witt	Yes	Yes	NA	NA	Yes
2011	Yeh	Yes	Yes	Yes	Yes	?*
2013	Yuan	Yes	Yes	NA	NA	Yes
2012	Yun	Yes	Yes	Yes	Yes	Yes: Both Hegu acu & standard acu
2010	Zaringhalam	Yes	NR	Yes	Yes	Yes: acu, acu + Baclofen

NOTES:

NA Not applicable

NR Not reported

?* Insufficient data reported to determine clinically significant change

SCALES:

HVAC Hannover Functional Ability Questionnaire

ODQ Oswestry Low Back Pain Disability Questionnaire

SF-36 Short Form 36

SF - MPQ McGill Pain Questionnaire Short Form

VAS Visual Analogue Scale

VRS Verbal Rating Scale

Acupuncture vs. Needleless Placebo

Three of the studies reviewed used a needleless placebo as a comparator.^{13,23-25} Cherkin et al.¹³ found that individualized, standardized, and simulated (with toothpicks) acupuncture all performed better than usual care ($p < .001$). However, individualized and standardized acupuncture did not perform better than simulated (toothpick) sham acupuncture. This is possibly due to minimal tissue damage initiating a local inflammatory response like true acupuncture.²⁶ Cho et al.²⁴ and Inoue et al.²⁵ found that real acupuncture outperformed needleless placebo acupuncture.

Acupuncture vs. Modified Acupuncture Only (No Usual Care Arm)

Three trials reviewed in this study examined two different forms of acupuncture. Bahrami-Taghanaki et al.²⁷ found that chrono-acupuncture (standardized acupuncture plus acupoints added that relate to time of day) outperformed acupuncture. Neither group was compared to usual care. Miao²⁸ found that electro-acupuncture outperformed classical acupuncture and Pach et al.²⁹ found that both individualized and standardized acupuncture showed clinically meaningful pain reduction after eight weeks; however, statistical significance was not demonstrated.

Acupuncture vs. Medication

Two trials investigated acupuncture compared to the medications Hydrochloride injection²³ and Baclofen.³⁰ Acupuncture outperformed local anesthetic injection²³ and outperformed Baclofen at the end of study and at a 10-week follow-up.³⁰

Methodologic Quality of Trials

Overall, the 18 trials reviewed met many of the CONSORT methodologic quality standards listed in Table 3, with a few exceptions as noted. These instances of missing data are indicated as "NR," not reported. All 18 papers were indeed randomized controlled trials (RCTs), as indicated in the title (#1a); eligibility was specified in all 18 papers (#4a); all papers indicated primary and secondary outcomes (#6a); the rationale for the type of comparator was discussed in 16 of 18 papers (#6b); randomization method was described in 16 of 18 papers (#8a); statistical methods were discussed in all papers (#12a); baseline demographics were provided in all but one paper (#15); adverse events were reported in 11 of 18 papers (#19); and the study findings were interpreted in a way that was consistent in all papers (#22).

Table 3. Methodologic Quality

Year	First Author	RCT	Eligibility	Outcomes Defined; Primary Outcome	Randomization Method	Baseline Demographics	Adverse Events
2014	Bahrami- Taghanaki	Yes	Yes	Yes; VAS	Yes	Yes	NR
2006	Brinkhaus	Yes	Yes	Yes; VAS	Yes	Yes	Yes; mild: bleeding, hematoma
2009	Cherkin	Yes	Yes	Yes; RMDQ & sx bothersomeness	Yes	Yes	Yes. Mild: dizziness, back spasms, short-term pain, pain lasting 1 month
2013	Cho	Yes	Yes	Yes; VAS	Yes	Yes	Yes; mild: increased pain, bruising
2007	Haake	Yes	Yes	Yes; Von Korff Chronic Pain Grade Scale & HFAQ	Yes	Yes	Yes; no AEs
2006	Inoue	Yes	Yes	Yes; VAS	Yes	Yes	NR
2009	Inoue	Yes	Yes	Yes; VAS & Schober test	Yes	Yes	NR
2010	Miao	Yes	Yes	Yes; pressure point pain intensity test	Yes	No; Only age	NR
2013	Pach	Yes	Yes	Yes; VAS	Yes	Yes	Yes; no AEs
2006	Thomas	Yes	Yes	Yes; SF-36 bodily pain subscale	Yes	Yes	Yes; mild transient pain at the site of needling, temporary worsening of back pain
2004	Tsui	Yes	Yes	Yes; NPRS, SLR, RMDQ	NR	Yes	NR
2012	Vas	Yes	Yes	Yes; RMDQ	Yes	Yes	Yes; mild epigastritis, nausea, increased pain after the treatment session
2013	Weiss	Yes	Yes	Yes; all items on the SF-36	NR	Yes	Yes; mild nausea, dizziness, urgency, pain at puncture site
2006	Witt	Yes	Yes	Yes; HFAQ & Back Function Loss	Yes	Yes	Yes; mild bleeding, bruising, needle pain
2011	Yeh	Yes	Yes	Yes; BPI pain intensity subscale	Yes	Yes	Yes; mild fainting, increased pain
2013	Yuan	Yes	Yes	Yes; VAS & C-SFODI	Yes	Yes	Yes; mild worsening pain
2012	Yun	Yes	Yes	Yes; RMQ & VAS	Yes	Yes	NR
2010	Zaringhalam	Yes	Yes	Yes; VAS & RMQ	Yes	Yes	NR

Risk of Bias

Details regarding risk of bias are reported in Table 4. All but two papers provided details regarding randomization. All but two papers provided treatment allocation concealment detail, such as discussion of who generated the allocation sequence, who enrolled participants, and/or who assigned participants to interventions. Fourteen papers reported on blinding after assignment, 11 of which blinded or masked participants. Trial limitations were discussed in 15 papers and generalizability was discussed in 16 of 18 papers.

“Many studies of acupuncture conducted in 1980s-2000 were of low methodologic quality, and the field has worked to improve study quality. For this reason, the current study only reviewed trials published in 2004-2014.”

Table 4. Risk of Bias

Year	Author	Randomization Method Discussed?	Treatment Allocation Concealed: Discussion of who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions	Blinding After Assignment: Participants, healthcare providers, data collectors, and outcome adjudicators	Trial Limitations Discussed?	Generalizability/ Applicability Discussed?
2014	Bahrami-Taghanaki	Yes	Yes	Yes; participants, statistician	Yes	NR
2006	Brinkhaus	Yes	Yes	Yes; participants~	Yes	Yes
2009	Cherkin	Yes	Yes	Yes; outcome assessors, diagnostic acupuncturists~	Yes	Yes
2013	Cho	Yes	Yes	Yes; participants~	Yes	Yes
2007	Haake	Yes	Yes~	Yes; participants~	Yes	Yes
2006	Inoue	Yes	Yes	Yes; evaluation acupuncturists, participants	Yes	Yes
2009	Inoue	Yes	Yes	NR	Yes	Yes
2010	Miao	Yes	Yes	Yes; participants	Yes	NR
2013	Pach	Yes	Yes	Yes; participants	Yes	Yes
2006	Thomas	Yes	Yes	Yes; second statistician	Yes	Yes
2004	Tsui	NR	NR	Yes; evaluation acupuncturists, participants	NR	Yes
2012	Vas	Yes	Yes	Yes; participants	NR	Yes
2013	Weiss	NR	Yes	NR	Yes	Yes
2006	Witt	Yes	Yes	NR	Yes	Yes
2011	Yeh	Yes	Yes	Yes; participants, medical staff	Yes	Yes
2013	Yuan	Yes	Yes	NR	Yes	Yes
2012	Yun	Yes	NR	Yes; participants, outcome assessor, statistician	Yes	Yes
2010	Zaringhalam	Yes	Yes	Yes; outcome assessor	NR	Yes

KEY:

~ Details of trial published elsewhere

NR Not reported

Adverse Events

Adverse events were reported in 11 of 18 papers (see Table 3). No moderate or severe adverse events related to the intervention were reported in the papers reviewed. Minimal adverse events included minor bleeding, bruising, nausea, and temporary worsening of symptoms.

Discussion

The trials of acupuncture for LBP reviewed here indicate acupuncture is likely a safe modality of care because no severe or adverse events were reported in any of the papers reporting adverse events (11 of 18 papers). Acupuncture also appears to be an effective intervention: acupuncture significantly outperformed standard or conventional care in 10 of 11 studies and demonstrated clinically significant change in scale scores of 13 of 18 studies reported here.

This finding is in line with the American College of Physicians & Pain Society,³¹ the American Family Physician,³² and the NIH positions that all now recommend acupuncture for low back pain (https://nccih.nih.gov/news/press/pain_review). Furthermore, The Joint Commission clarified in January 2015 that acupuncture therapy is one evidence-informed, non-pharmacologic option that should be included in pain management strategies (www.jointcommission.org).

Results in Context of Current Literature

Although all 18 studies meet the methodological criteria for RCTs, many studies lack adequate blinding of subjects, study personnel, and outcome assessors. Some studies also lack adequate concealment of treatment allocation to various study staff. These are important safeguards necessary to reduce bias. Many studies of acupuncture conducted in 1980s-2000 were of low methodologic quality, and the field has worked to improve study quality. For this reason, the current study only reviewed trials published in 2004-2014.

Some prior systematic reviews of acupuncture for LBP have reached different conclusions than the present review; this is for several reasons. First, two trials reviewed much older evidence, none of which met the present study inclusion criteria. They also concluded, based only on statistical significance, that acupuncture is not effective in the management of pain³ and not effective in the management of acute low back pain but may be effective for chronic low back pain.⁴ More recent trials have reached similar conclusions, including Yuan et al.,³³ which found “there is moderate evidence that acupuncture is more effective than no treatment, and strong evidence of no significant difference between acupuncture and sham acupuncture, for short-term pain

relief. There is strong evidence that acupuncture can be a useful supplement to other forms of conventional therapy for nonspecific LBP...” (p.E887). Lam, Galvin & Curry⁷ state that “acupuncture had a clinically meaningful reduction in levels of self-reported pain...when compared with sham, and improved function...when compared with no treatment immediately post intervention. Levels of function also clinically improved when acupuncture in addition to usual care, or electro-acupuncture was compared with usual care alone.” (p. 2124).

A second reason for differing conclusions concerns the topic of sham acupuncture. Prior trials interpreted findings of verum acupuncture not outperforming sham acupuncture as indicative of: 1) non-significance of between-group findings, and 2) that acupuncture is not an effective intervention. However, these trials are in effect comparing a full dose (complete treatment) of acupuncture (verum) to a diluted or decreased dose of acupuncture (sham). There are long-standing traditions of providing acupuncture on non-acupoints thought to be active in an individual patient—this is what has been used in clinical trials as one type of sham acupuncture. There is also a longstanding tradition of using contact needling in Japanese meridian therapy—this is used as needleless placebo acupuncture in three trials reviewed here. Both sham and needleless placebo acupuncture are therefore, in fact, types of acupuncture. It is not appropriate to compare sham and verum acupuncture and conclude that acupuncture is no better than “sham” when these trials are actually comparing various types of physiologically active and historically utilized types of acupuncture.

Sham as a Comparator

The fact that sham acupuncture is not inert must be taken into account when interpreting findings of studies comparing verum to sham acupuncture. Sham acupuncture might be thought of as a diluted or decreased dose of acupuncture, but this “diluted or decreased dose” of acupuncture is still physiologically active. Four of the studies examined used sham needling as a comparator revealed that sham acupuncture produced analgesic effects similar to verum.

Though imaging studies reveal that true acupuncture points modulate central processing mechanisms where other points do not,^{34,35} the impact of needling so-called sham points stimulate additional peripheral mechanisms such as adenosine,³⁶ opioid peptides,³⁷ fibroblast cells,³⁸ and cytokines³⁹ regardless of the point location. It is for this reason that sham acupuncture does not make a worthy comparator. Given these findings, NIH's division for Integrative Health, the NCCIH, specifically states that sham-controlled studies are a low programmatic funding priority (<https://nccih.nih.gov/grants/acupuncture/priorities>).

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Case Report

Vertigo Treated with Acupuncture and Dietary Changes

By Jenn Hudson, LAc, MAcOM

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Vertigo is the number one symptom of vestibular disease. "The vestibular system has a 'behind the scenes' role of maintaining spatial orientation and driving reflexes that stabilize and balance. To do this, it transforms forces associated with head acceleration and gravity into biological signals that travel directly to motor centers for postural and ocular stability and to the cortex to aid in orientation. When the system functions normally, you have no awareness of these ongoing activities."¹

"Vertigo-dizziness presentations accounted for 2.5% (95% confidence interval [CI] = 2.4% to 2.6%) of all ED presentations during this 10-year period. From 1995 to 2004, the rate of visits for vertigo-dizziness increased by 37% and demonstrated a significant linear trend ($p < 0.001$). Even after adjusting for age (and other covariates), every increase in year was associated with increased odds of a vertigo-dizziness visit."⁷

While the terms "dizziness" and "vertigo" are often used interchangeably by patients, they refer to different sensations. Dizziness is "a general, non-specific term to indicate a sense of disorientation."⁴ Vertigo, on the other hand, "is a subtype of dizziness and refers to an erroneous perception of self- or object-motion or an unpleasant distortion of static gravitational orientation that is a result of a mismatch between vestibular, visual, and somatosensory systems."⁴ According to Dr. Alan Berger, "Dizziness is a sensation of lightheadedness, faintness, or unsteadiness, [while] vertigo has a rotational, spinning component, and is the perception of movement of the self or surrounding objects."¹⁸ Basically, vertigo is generally a severe sensation that involves a feeling of movement, either of the self or the world around you; dizziness tends to be a more mild sensation of unsteadiness, but not movement. Vertigo can be debilitating for patients, especially when the sensations of movement are accompanied by nausea and vomiting. At its worst, vertigo can incapacitate patients for days, or longer, at a time.

There are two main causes of vertigo, central and peripheral. Central type vertigo is most often caused by hemorrhagic or ischemic insults to the brain and brain stem. Central type vertigo tends to develop gradually and then becomes more severe over time. Peripheral causes of vertigo stem from Cranial Nerve VIII and distal structures. Peripheral vestibular issues often improve or worsen based on which direction a person is looking.²

Patients with peripheral vestibular disease “report a variety of symptoms, including vertigo, lightheadedness, unsteadiness, nausea, visual disturbance and pressure in the ear. These symptoms may result in both physical, social and emotional dysfunction—e.g., the inability to perform daily activities and general emotional distress.”³ These symptoms also tend to appear very suddenly, in contrast to the slow onset of central vertigo.

There are at least eight different types of vertigo syndromes that are due to peripheral vestibular disease: Benign Paroxysmal Positional Vertigo, Endolymphatic Hydrops (also known as Meniere Syndrome), Labyrinthitis, Vestibular Neuronitis, Traumatic Vertigo, Perilymphatic Fistula, Cervical Vertigo, Migrainous Vertigo, and Superior Semicircular Canal Dehiscence.

“Benign Paroxysmal Positional Vertigo (BPPV) is the most common cause of dizziness in the general population with a lifetime prevalence of about 10%.⁶ BPPV is the most common vestibular issue to be treated in emergency rooms and outpatient clinics that focus on neurology. It appears to affect women slightly more than men, but studies show that the difference is not statistically significant.⁶ BPPV often has spontaneous remission but has a recurrence rate of approximately 50% within five years.⁸

Treatment of Benign Paroxysmal Positional Vertigo ranges from “watchful waiting” to surgery. The most common treatment for BPPV is the Epley Maneuver, which “uses a series of head movements” to move canaliths (small crystals in the ear) which have moved out of the ear canal back into place.⁹ In a retrospective chart review done on 107 patients with BPPV, the Epley Maneuver was done an average of 1.23 times per patient, with a success rate of 93.4%.¹⁰ In patients for whom the Epley Maneuver does not eliminate their vertigo and who have severe symptoms that interfere with their daily lives, one option is surgery. Posterior Semicircular Canal Occlusion is a procedure performed through an incision behind the external ear. A mastoidectomy is then performed and is required to remove the bone between the scalp and the inner ear. Common side effects of this procedure are short-term hearing loss and short-term tinnitus, most cases of which clear up by six months post-surgery.¹¹ There are no pharmaceutical treatments currently recommended for BPPV.¹²

Acupuncture and Oriental Medicine Perspective

In Chinese Medicine, dizziness and vertigo are called *Xuan Yun*. *Xuan* means blurred vision and *Yun* means dizziness.¹³ According to traditional theory there are three main etiologies for *Xuan Yun* in Chinese Medicine: emotional strain, overwork or excessive sexual activity, and irregular diet. These various etiologies lead to different pathologies. The most common TCM patterns causing

“Benign Paroxysmal Positional Vertigo (BPPV) is the most common cause of dizziness in the general population with a lifetime prevalence of about 10%... There are no pharmaceutical treatments currently recommended for BPPV.”

dizziness are Liver *Yang* Rising, Liver Fire, Liver Wind, and Phlegm. One deficiency which can lead to dizziness is Kidney deficiency.

Overwork and/or excessive sexual activity affects the Kidney. When the Kidney is deficient, this can lead to a type of dizziness which is slight and often presents with blurred vision. Dizziness caused by pathogenic factors is usually more severe. When Phlegm is the cause of dizziness, it is often associated with blurry vision, heaviness of the head, and difficulty concentrating.¹¹ Turbid Phlegm in the head and Phlegm Damp in the Middle *Jiao* can both lead to dizziness.

Acupuncture and herbs are the main modalities used to treat *Xuan Yun*. However, points and formulas vary dramatically based on the TCM pattern diagnosis. Depending on the pattern diagnosis for a patient, the approach will be different in treating this disorder, from dietary recommendations to herbs to acupuncture points used. In diagnosing a disorder like vertigo, it is helpful to have a differential diagnosis chart to help determine patterns. The most common symptoms and acupuncture points used to treat the different patterns are:

- **Liver *Yang* Rising:** Pounding or distending headache, worse with stress/anger, irritability, tinnitus, blurred vision, dream-disturbed sleep, insomnia, flushed face, red eyes, and a bitter taste in the mouth. Some acupuncture points for this diagnosis are *Yongquan* Kid-1, *Touwei* ST-8, and *Ganshu* BL-18.
- **Phlegm/Damp in the Middle *Jiao*:** Heaviness in the head, cloudy thinking, poor concentration, nausea, poor appetite, sleepiness, heavy feeling in chest, and obesity. See treatment used for acupuncture points.
- **Phlegm Fire in the Middle *Jiao*:** Heaviness in the head, nausea, headache, irritability, red eyes, bitter taste in mouth, thirst without desire to drink, and a heavy feeling in the chest. Some acupuncture points for this diagnosis are *Xingjian* Liv-2, *Quchi* LI-11, and *Fenglong* ST-40.
- **Qi and Blood Deficiency:** Positional dizziness and vertigo, fainting (in severe cases), pale face, nails, lips, shortness of breath, disinclination to speak, palpitations, poor memory, insomnia, and low appetite. Some acupuncture points for this diagnosis are *Zusanli* ST-36, *Sanyinjiao* SP-6, and *Taixi* Kid-3.

- **Kidney Essence and Yin deficiency:** Constant dizziness and vertigo, listlessness, insomnia and/or dream disturbed sleep, poor memory, weak and sore low back and knees, seminal emission, tinnitus, five palm heat, and night sweats. Some acupuncture points for this diagnosis are *Taixi* Kid-3, *Zhaohai* Kid-6, and *Sanyinjiao* SP-6.
- **Kidney Essence and Yang deficiency:** Constant dizziness and vertigo, cold body and extremities, listlessness, poor memory, weak and sore low back and knees, impotence, tinnitus, and insomnia. Some acupuncture points for this diagnosis are *Taixi* Kid-3, *FuLiu* Kid-7, and *Sanyinjiao* SP-6.

There have not been any large-scale studies to determine the efficacy of Chinese Medicine for dizziness and vertigo. This author was unable to find any studies that used acupuncture to treat Benign Paroxysmal Positional Vertigo. However, a systematic review was done using acupuncture to treat Cervical Vertigo. That systematic review determined that, “acupuncture may be more effective than conventional medicine therapy (CMT) in effectiveness and improvement of clinical symptom and average blood flow velocity of vertebral-basilar artery compared with conventional medicine therapy for CV.”¹⁴ Another systematic review was done to determine if acupuncture was a beneficial treatment for Meniere’s disease. That systematic review determined that “the overall conclusion is of the potential benefit of acupuncture for persons with Ménière’s disease, including those in an acute phase.”¹⁵

Case History

Description

The patient was a 33-year-old female who was otherwise in very good health. However, when she presented for her first appointment she had been dealing with an acute attack of vertigo for over a month. This primarily manifested as dizziness and a feeling of spinning, often with severe nausea and occasionally with some vomiting. During the attacks she also had sensitivity to light and sound. All of these symptoms would come on with even slight head movements. She had been taught the Epley Maneuver and another maneuver called the “Half Summersault,” which would help temporarily, but the feelings would come back quickly. She had been dealing with attacks of vertigo for a year, which could last for several days at a time and leave her feeling incapacitated for an additional one to two days even after the worst symptoms had passed. Between acute attacks she would often have feelings she described as “floaty” and unsteady. She was not aware of anything that made the symptoms better or worse; they would just come on. When she first came for treatment she had had five very severe episodes in the past year and several other mild occurrences of vertigo. These symptoms were dramatically affecting her life. She was a mother of two young biological children and was in the process of adopting a third child from China.

She had seen her primary care doctor, who had ordered an MRI. The MRI came back normal. She had also gotten care from a chiropractor, who taught her the Epley Maneuver and the Half Summersault Maneuver. These helped some, but the vertigo was dramatically affecting her life.

The patient was in good health overall. She was physically active, working out four to five days a week. Her weight was in the normal range. In terms of temperature, she stated that she ran cold, especially her feet. She reported nothing unusual about her eyes, ears, nose, and throat. She had no palpitations or unexplained shortness of breath. Digestion was an issue for her. She often got bloated after eating and experienced gas. Her bowel movements were loose and sometimes sticky. Menses were regular cycles of 28 days. Bleeding lasted for five days with red blood. There were moderately painful cramps on the first and second days, along with some irritability and sensitivity on those days. She did not have any bleeding between cycles or any other discharge that she noticed. In addition to the dizziness and nausea/vomiting, during the attacks she would also experience heaviness in her head, cloudy thinking, poor concentration, neck pain and stiffness, and sleepiness.

Her tongue, on her first visit, was dusky red, puffy with scallops and a thin white coat. Her pulses were deep, slippery and soft on the right side, and soft on the left side with some tightness in the *guan*.

On palpation, this patient had tenderness along the Spleen channel. She had some swelling in her lower legs as indicated by indentations from her socks and pant legs.

Even though she was in some pain and in the middle of an acute attack of dizziness, her *shen* was good, her eyes were bright, and she was engaging.

Diagnostic Assessment

This patient was diagnosed with *Xuan Yan* due to Phlegm Damp in the Middle *Jiao*. In addition to the severe episodes of dizziness, she also experienced heaviness in her head, cloudy thinking, poor concentration, nausea, vomiting, a poor appetite, sleepiness, and a heavy feeling in the head and chest. An irregular diet (greasy foods, a lot of dairy, and irregular meal times) led to the weakening of the Spleen. This led to the formation of dampness and phlegm, which kept the *Qi* from rising to the head, causing dizziness.

Treatment

The patient came in for weekly acupuncture treatments. Treatments were very similar over time. Regular points were used, and their functions are listed in the chart on the following page.¹⁶

Table 1.

Points:	Functions:
Ren-12 (<i>Zhong Wan</i>)	Strengthens and harmonizes the Spleen and Stomach, resolves Dampness.
Sp-6 (<i>San Yin Jiao</i>)	Strengthens the Spleen and Stomach, resolves Dampness.
SP-9 (<i>Yin Ling Quan</i>)	Resolves Dampness (especially of the Lower <i>Jiao</i>), regulates the Spleen.
ST-36 (<i>Zu San Li</i>)	Tonifies <i>Qi</i> and Blood, Harmonizes and Strengthens SP and ST.
ST-40 (<i>Feng Long</i>)	Resolves Phlegm throughout the whole body
LI-4 (<i>He Gu</i>)	Good for any condition related to the face and head.
Liv-3 (<i>Tai Chong</i>)	Used with LI-4 to move <i>Qi</i> and Blood throughout the body.
Liv-8 (<i>Qu Quan</i>)	Moves Blood, resolves damp-heat in the Lower <i>Jiao</i> .
ST-8 (<i>Tou Wei</i>)	Treats dizziness

Balance brand needles with a pipe handle, usually 25-30 sized, were used in treatments. Retention time was 30 minutes. Generally needles were placed, but no tonifying or reducing techniques were used. No herbs were given, but changes to her diet were strongly recommended. The patient was encouraged to cut out dairy, sugar, and gluten from her diet.¹⁷ She was willing to make this large change to her diet, and followed through with the recommendations.

Results

This patient was treated weekly for eight weeks, and then placed on a maintenance schedule of every two to three weeks after that. The change in this patient has been remarkable. Since beginning treatment she has only had two episodes of dizziness. Instead of lasting days, these episodes are only 1-2 minutes in duration. She was able to participate on a family trip to Disneyland and rode all the rides with no dizziness or “floaty” feelings. She has also tolerated air travel and has flown without flare-ups.

For the first several months of treatment she was nervous much of the time about an acute onset occurring. As the period of time between episodes has lengthened and the intensity has decreased, she has gained an improved quality of life. She is more able to relax and enjoy her life without fear of an attack of vertigo. Prognosis for this patient is good. As she has continued to follow a Paleo-type diet (no grains, sugar, or dairy) and has received regular acupuncture treatment, her digestive complaints have improved as well. Other areas of improvement are reduced symptoms of heaviness in her head, tenderness on the Spleen channel, and lower leg swelling.

“As the period of time between episodes has lengthened and the intensity has decreased, [the patient] has gained an improved quality of life. She is more able to relax and enjoy her life without fear of an attack of vertigo.”

Discussion

In this single case, a 33-year-old female found significant relief from vertigo using a combination of acupuncture and dietary changes. After experiencing five severe episodes and several minor episodes in the previous year, she has had no severe episodes and only two very minor episodes since beginning treatment 18 months ago. Her case was very clearly due to phlegm and dampness, and her treatments have focused almost exclusively on transforming phlegm and draining dampness. The dietary changes she was willing to make have also helped in reducing dampness and strengthening the Spleen and Stomach. It would be worth further study utilizing acupuncture and dietary changes for cases of vertigo with phlegm and dampness as the predominant Chinese Medicine pattern.

Conclusion

Treatment using a combination of acupuncture and dietary changes can be an effective treatment for Benign Paroxysmal Positional Vertigo. Further research is needed to determine the efficacy of these treatments. This case study shows the positive and relatively quick results that one patient found in using this combination of treatments. The results for this patient were dramatic and contributed to an enhanced quality of life. Acupuncture and dietary changes may hold a key to treating patients with BPPV.

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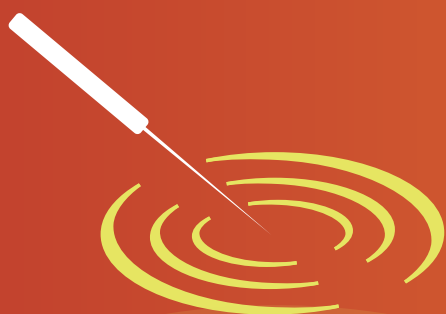


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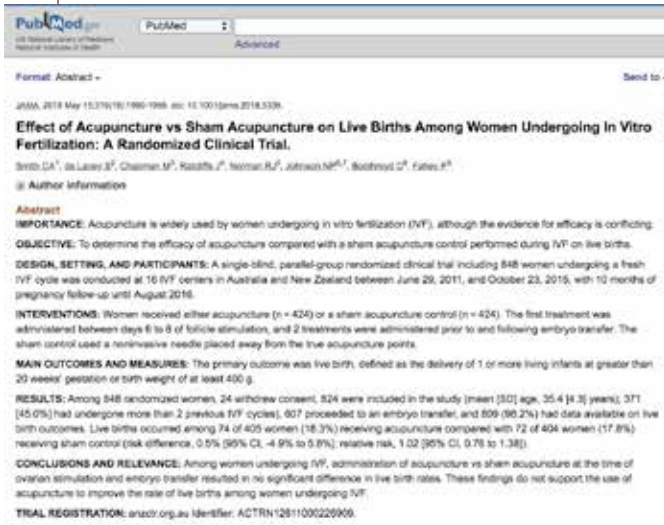
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A Comment on

“Effect of Acupuncture vs. Sham Acupuncture on Live Births Among Women Undergoing In Vitro Fertilization: A Randomized Clinical Trial”

By Lee E. Hullender Rubin, DAOM and Carmelo S. Sgarlata, MD



The May 15, 2018 issue of *JAMA: The Journal of the American Medical Association* included a piece by Caroline Smith et al., entitled “Effect of Acupuncture vs Sham Acupuncture on Live Births Among Women Undergoing In Vitro Fertilization: A Randomized Clinical Trial.”¹

In the largest trial to date looking at acupuncture’s effect on in vitro fertilization (IVF) outcomes, Dr. Smith and colleagues compared verum acupuncture with “sham” non-penetrating needle control on the primary outcome of live birth. They conclude that their “findings do not support the use of acupuncture to improve live births among women undergoing IVF.” We see two important limitations to their conclusion.

The treatment protocol in this study has a small dose of acupuncture: up to three acupuncture sessions. Just as the dose of a medication is vital to its effectiveness, so may be the dose of acupuncture. Hullender Rubin et al. found 15 sessions were associated with significant increase in live births [OR=1.62, 95% Confidence Interval (CI) 1.04 – 2.52] and fewer

biochemical pregnancies [OR=0.25, 95% CI 0.07 – 0.82] compared with two sessions of acupuncture.² Magarelli et al.³ reported eleven sessions of acupuncture were associated with more live births compared with no acupuncture ($p < 0.05$). In that study, they provided nine sessions prior to embryo transfer and two sessions around the day of embryo transfer. A more accurate conclusion is that Smith et al.’s¹ findings do not support the use of *three* sessions of adjuvant acupuncture during IVF to improve live births.

Second, the use of a non-penetrating needle control confounds the outcomes. The authors suggest the control arm methods had weak physiological effects. However, the use of both penetrating and non-penetrating needle controls remain controversial⁴ and may not be the inert control needed for unbiased investigations of acupuncture.⁵

The rejection of acupuncture as an adjuvant to IVF is premature, as the optimal dose of acupuncture to improve IVF outcomes remains unknown. Moreover, the ideal inert comparator has yet to be discovered and validated.

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Report from the 2018 International Congress on Integrative Medicine and Health

By Jennifer A.M. Stone, LAc
and Bill Reddy, LAc

This May, David Miller, Eric Buckley, and Jennifer Stone attended the International Congress on Integrative Medicine and Health (ICIMH) as ASA representatives. This year's congress, held from May 8-11 in Baltimore, MD, focused on the theme of *Collaboration in Action: Advancing Integrative Health through Research, Education, Clinical Practice, and Policy*. Attendees included academic leaders, faculty, students, clinicians, and policy makers.

The ICIMH is hosted by the Academic Consortium for Integrative Medicine & Health and the International Society for Complementary Medicine and Research. Members of the Academic Consortium include over 70 academic medical centers, healthcare systems, and research institutions that contain integrative medicine (IM) clinics, conduct IM research, or include IM training in their curricula. Members include Stanford, Harvard, Johns Hopkins, Memorial Sloan Kettering, Cleveland Clinic, and many more. The organization's high standing and

"Members of the Consortium study integrative medicine's approach to physician burnout, veteran health, and the opioid crisis, as well as the training and development of current and future integrative medicine practitioners in medicine and research."

importance in the field is evident by its impressive membership¹ and by the pronounced attendance, involvement, and support of the NIH/NCCIH (formerly NCAAM) at each meeting.

Members of the Consortium study integrative medicine's approach to physician burnout, veteran health, and the opioid crisis, as well as the training and development of current and future integrative medicine practitioners in medicine and research.

The conference opened with a motivating keynote speech by Senator Barbara Mikulski, the longest-serving woman in the US Congress and a strong proponent of Integrative Medicine. Her speech focused on self-care for activists. She exhorted Integrative Medicine proponents and providers to forge a new path together, with MDs, LAcS, PhDs, RNs, LMTs, and NDs uniting to disseminate scientific research, share educational curricula, and inform health care policy together.



“One of the most interesting and well attended of the concurrent sessions was the panel on the use of ketamine, MDMA, and psychedelics in psychiatry. Results are promising in the use of these psychedelics in a controlled setting for the treatment of severe depressive disorders; in some cases, benefits last up to a year following a single dose.”

Below (Clockwise from left to right): Senator Barbara Mikulski, the longest-serving woman in the US Congress and a strong proponent of Integrative Medicine, delivers the keynote address

Peter Wayne during his talk on gait and aging at the Friday plenary session

An audience member asks Helen Langevin a question after she presents her research on the effects of stretching on tumor size in rodents

David Miller, ASA Chair, at the Wednesday poster reception



Plenary speakers included Peter Wayne, Tracy W. Guadet, Helene M. Langevin, Fabrizio Benedetti, Steven Woolf, and Alessio Fasano. The first plenary address was delivered by Tracy Gaudet, MD, Executive Director of the Veterans Health Administration's National Office of Patient Centered Care and Cultural Transformation. Dr. Gaudet discussed the problems inherent in a healthcare system that focuses on the disease rather than on the patient, and proposed new rules for radically redesigning health care to place greater emphasis on the patient. She advocates for working together with patients, families, and communities; customizing healthcare to the individual rather than to the disease; promoting the understanding that health and happiness may not require healthcare; and creating joy in the healthcare workforce.

Helen Langevin, MD, who serves as director at Harvard's Osher Center for Integrative Medicine, presented her latest research assessing the effects of stretching on tumor size in rodents. She found that stretching, such as that practiced in yoga, decreased tumor size in mice. Dr. Langevin theorizes that stretching releases and activates resolvants of the inflammatory response. Therefore, stretching increases the cytotoxic activity of T-cells and cleans up the inflammatory mess.

Another dynamic plenary speaker was Steven Woolf, MD, MPH, Professor of Family Medicine and Population Health and Director of the Center of Society and Health at the Virginia Commonwealth University Center. Dr. Woolf presented multiple scenarios that might explain why the life expectancy of Americans has decreased when in most other countries it is on the rise. Fabrizio Benedetti, MD, Professor at the University of Turin Medical School in Italy, discussed common mechanisms in the brain that explain the effectiveness of pharmaceutical drugs, spoken words, and placebo.

Peter Wayne, PhD, Director of Research at Harvard's Osher Center for Integrative Medicine, gave a fantastic presentation on qualitative assessments of aging. In opposition to heart rate variability, greater variability in gait points towards poorer general health and wellbeing and a greater risk of falls. Using an electronic mat and specialized video equipment to measure gait, Dr. Wayne demonstrated how patients' gait improved between going into and out of a chiropractor and acupuncturist's office. He also demonstrated gait improvement from the practice of tai chi.

“Dr. Woolf presented multiple scenarios that might explain why the life expectancy of Americans has decreased when in most other countries it is on the rise.”

Representatives from the National Center for Complementary and Integrative Health (NCCIH), an office in the National Institutes of Health (NIH), gave sessions on past and future NCCIH funding strategies; research on spinal manipulation for back and neck pain; and current research in creative therapies, including music, dance, and visual arts.

Concurrent sessions—including workshops, panels, and oral research presentations—covered topics as varied as yoga, mindfulness, Ayurveda, acupuncture, herbs, Tai Chi, massage, microbiome, nutrition, public health, the opioid crisis, and health policy change. Sessions focused on patients of all ages, including pediatric patients, young adults, seniors, and veterans.

A dynamic panel worth mentioning was presented by a group from Maryland University of Integrative Health (MUIH) on different traditional medicine perspectives in the treatment of pain. Tyme Gigliotti, LAc, Marlysa Sullivan PT, Emily Telfair, ND, and Betsy Miller, MS were delightful to watch as they bounced ideas off one another in a roundtable setting, discussing different perspectives on the treatment of a complicated chronic pain patient.

One of the most interesting and well attended of the concurrent sessions was the panel on the use of ketamine, MDMA, and psychedelics (psilocybin, peyote, and ayahuasca) in psychiatry. Results are promising in the use of these psychedelics in a controlled setting for the treatment of severe depressive disorders; in some cases, benefits last up to a year following a single dose. Researchers theorize that the drugs cause a disassociated state where the brain has an opportunity to stop unwanted synaptic patterns and reconstruct new ways of thinking. Researchers at Johns Hopkins have been studying the effect of psilocybin (“magic mushrooms”) for many years.²

In addition, there were 470 posters presented on a variety of integrative medicine topics during three poster receptions. Multiple posters on Chinese and East Asian medicine were presented by students visiting from China, Korea, and Japan, as well as students from medical schools in the US. Topics included Chinese herbs, Kampo, acupuncture, *Tui Na*, and *Qi Gong*, in both animal models and human subjects in all clinical settings.

The next ICIMH conference to be held in the US is scheduled for April 28-May 1, 2019, in Cleveland, Ohio.³ AOM schools should consider sending a representative if they have an interest in advancing research, accessing federal and private funding, and collaborating in research with western medical schools and research institutions.

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The topic selected for this issue is:

How do You Treat Multiple Sclerosis in Your Clinic?

“More than 2.1 million people are affected by the disease worldwide, although that number is thought to be even greater.”

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Multiple sclerosis (MS) is a potentially disabling disease of the brain and spinal cord. In MS, the immune system attacks the protective myelin sheath that covers nerve fibers, which causes communication problems between the brain and the rest of the body. Eventually, the disease can cause the nerves themselves to deteriorate or become permanently damaged.

Physical symptoms and severity range from person to person, depending on the amount of nerve damage and which nerves are affected. Tingling and numbness in the joints, chronic pain, spasms, fatigue, and weakness are not just indicators of chronic tiredness but can often be the early symptoms of MS. More than 2.1 million people are affected by the disease worldwide, although that number is thought to be even greater. The most common form of MS seen in the initial diagnosis of patients is relapsing-remitting MS, in which the patient experiences relapses or episodes of deteriorating neurological function interspersed with periods of remission.

Some people with severe MS may lose the ability to walk independently or at all, while others may experience long periods of remission without any new symptoms. According to a paper published by the Multiple Sclerosis International Federation, “this variability has led some to conclude that MS might be a syndrome or spectrum of different disorders rather than a single disease” (MSIF, 2009). A successful treatment for MS must be highly individualized, with a focus on relief from symptoms and preventing progression of the disease. Unfortunately, biomedical treatments for MS can come with significant side effects, and may not always be effective.

The cause of MS is not known. Scientists believe MS is triggered by a combination of factors. To identify the cause, research is ongoing in areas of immunology, epidemiology, and genetics. Some hypothesize that genes may not be functioning correctly in people who develop MS. Scientists are also studying infectious agents that may play a role.

In Traditional Chinese Medicine (TCM), MS is associated with a *wei* or flaccidity syndrome, which results in muscular weakness. This is an association, not a classification, however—*wei* syndromes generally do not result in pain, and some symptoms of MS may be painful. Aspects of MS are associated with *bi* or blockage syndrome as well.

Like *wei* syndrome, TCM theorizes the origin of MS to be an invasion of external pathogenic factors such as Dampness (which affects the Spleen and muscles) in patients with a weak Spleen *zang*, or a deficiency in the Liver and Kidney *zang* (which affects the tendons and bones). Both are thought to play a role in the function of the nervous

system. Hence, the etiology of MS may be varied and include factors such as early exposure to Damp environments (and pathogens that enter the body via this climate), improper diet, excessive sexual activity, shock, and a predisposition towards Liver and Kidney *zang* deficiency. The initial stages of MS usually result from Dampness invading the muscles. As the disease progresses, symptoms of Liver and Kidney organ deficiency frequently begin to develop and may progress from symptoms of Liver *Yang* rising, such as dizziness or stiffness, to Liver Wind, resulting in tremors and paralysis.

While Traditional Chinese Medicine cannot cure MS, it provides an important complementary treatment approach. Each of the modalities is important, and currently acupuncture and moxibustion are likely considered the most immediately effective approach (due to nerve issues, muscle spasms, and sometimes pain involvement), with *qi gong* (breath/movement/mindfulness) playing a supportive role as a lifestyle strategy. It should be mentioned that while anecdotal evidence of the effectiveness of acupuncture for MS exists, favorable evidence-based research is scarce. This is often considered more an issue of research methods than actual effectiveness of treatment.

Nutrition is considered highly important due to the role that Dampness may play. Terry Wahls, a medical researcher whose MS is currently reversed, has famously attributed her turnaround to her version of the paleo diet (daily: 3 cups of leafy greens, 3 cups of sulfur rich vegetables, 3 cups colorful fruits and veggies, animal based omega 3 fatty-acids, grass fed meat and organ meat, seaweed). Wahls' concern is that processed foods are leading to a major decline in the American population's health. Environmental toxicity is another area of concern and can be considered part of TCM's interest in environmental pathogenic factors disturbing the organs and channels.

More recently, practitioners who have studied with master herbalists in China claim to have seen more dramatic results in some treatments of MS from classical herbal medicine styles. These types of herbal medical systems are based on lineages that pre-date the People's Republic of China's organization of the *zang fu* system, and are not widely known by Western practitioners or verified in the US for specific outcomes. Regardless, patients who take herbal medicine from classical or *zang fu* approaches may have reduced intensity in their symptoms, experience an improved quality of life, and tolerate the negative side effects of medications (like fatigue and headache) more easily.

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How do You Treat Multiple Sclerosis in Your Clinic?

By Korina St John Rongitsch, DACM, Diplom (NCCAOM), LAc

In every population of 100,000, ninety people are diagnosed with Multiple Sclerosis (MS) in the United States.¹ There is no identified cause nor cure for MS, but East Asian Medicine (EAM) offers effective symptom relief and lasting clinical results.

Determine Disease Progression

First establish if the patient is in an early or later stage progression of MS. Histological evidence reveals that inflammation in the central nervous system (CNS) damages the myelin sheath and axons in the earlier course of the disease.² During this stage, patients commonly experience numbness/tingling, muscle spasms, heavy sensation in muscles, aversion to wind, damp or cold, edema, skin disorders, allergies, anxiety, palpitations, poor vision, or dizziness.

There is significantly less active inflammation found in later stages of MS, and symptoms are found to derive more from degenerative changes.¹ Chronic deficiency weakens the interior, causing fatigue, depression, poor digestion, diarrhea, constipation, urinary incontinence, and poor memory.

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CLINICAL PEARLS

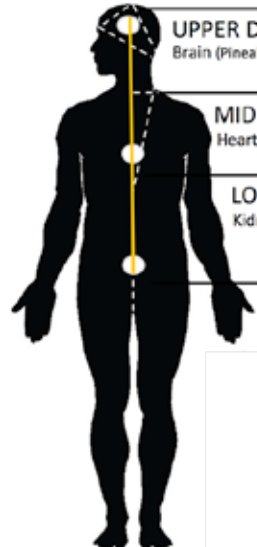
Identify Symptom Location

The *Zhong Mai* (central channel) follows the same anatomical pathway as the central nervous system, and both function to accumulate and emit metabolic energy (true *qi*).³ The location of MS lesions on the brain or spine correlates directly with symptomology. For best clinical results, determine where symptoms are occurring and treat all affected levels of the upper, middle, and lower *dantians* using points on the *du* and *ren* channels.

TREATMENT RECOMMENDATIONS

Determine a diagnosis and guiding treatment principle based on disease etiology, location, and disease. Biweekly treatments are recommended until symptoms resolve, then provide monthly preventative care. Offer hope and support throughout the therapeutic process to reduce stress, speed healing, and enhance overall wellbeing.

Table 1. Treatment Strategies



LOCATION	SYMPTOMS	MOXA/POINTS
UPPER DANTIAN Brain (Pineal gland, Hypothalamus)	INSOMNIA, HEADACHE, POOR CONCENTRATION, DEPRESSION, POOR VISION	GV 20, GV 16 YIN TANG, CV 22 SCALP ACUPUNCTURE
MIDDLE DANTIAN Heart, Lungs	CHEST PAIN, SHORTNESS OF BREATH, COUGH, WEAK UPPER EXTREMITIES	GV 9, GV 11 CV 12, CV 17 SCALP ACUPUNCTURE
LOWER DANTIAN Kidney, Intestines	FATIGUE, POOR GAIT, IMBALANCE, INVOLUNTARY TWITCHING/SPASM, DIARRHEA, CONSTIPATION	GV 4, BL 23, BL 25 CV 4, CV 6 SCALP ACUPUNCTURE

Early Stage MS: Promote sweat, clear heat, harmonize or warm the center. In cases of stagnation, move *qi* then tonify.

Later Stage MS: Warm the center, strengthen the SP/ST and KD, or clear internal heat. In cases of severe deficiency, begin with moxa, nutritional and herbal therapy, limiting acupuncture until energy improves. Moxa to improve the nerve-endocrine-immune network and circulatory system.⁴

PATIENT RECOMMENDATIONS

Medical Qi Gong Breathwork

- 15 minutes of daily practice to strengthen and support CNS function
- Inhale, hold for five seconds to tonify, exhale; encourage the breath at the affected dantian level(s); practice daily and during treatments

Exercise

- 30-60 minutes daily
- Cross body and proprioception exercises

Nutritional Therapy

- Recommend appropriate medicinal foods based on diagnosis
- Encourage warm, cooked food and drinks; strongly discourage the consumption of sugar, alcohol, and processed foods to avoid inflammation and symptom relapse
- 1-2 tablespoons of coconut oil daily and foods rich in omega-3 fatty acids

Restorative Sleep

- Encourage at least 6-8 hours of sleep to improve therapeutic outcome

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How do You Treat Multiple Sclerosis in Your Clinic?

By Tracy Soltesz, DAC, Dipl Ac (NCCAOM), LAc

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Five Element tradition treats multiple sclerosis by recognizing the effect of pre-heavenly disharmony on the patient's Constitutional Factor (CF), or primary element, and the dynamic relationship between affected elements. By treating this dynamic interchange, the patient experiences relief from acute symptoms and slows the degeneration associated with this progressive disease.

Multiple sclerosis occurs in any element, and therefore is not diagnostic of a CF. The disease is caused by a fault in the development of Kidney Essence during the embryonic phase, which then presents as post-heavenly deficiency in the *Jing* energy, manifesting as a malfunctioning of the "nervous system." This malfunction will present for multiple sclerosis patients as significant fatigue, inability to think clearly due to mental fog, inability to perform simple physical tasks, and compromised coordination.

Acute symptoms flare with high stress. Which situations the patient identifies as "stressful" is diagnostic because each of the five CF types perceive "stress" according to their elemental lens.

In addition to strengthening the Kidneys, the Triple Heater is also treated. The Triple Heater is a Fire Official, and represents the "Water within Fire." It is the "water way" which transports Fire energy throughout the body. Triple Heater is the actuary that distributes Kidney *Yang* throughout the body. During the embryonic phase, the Triple Heater distributes *yuan qi* from the Kidneys to the source point of each Official.¹ When this process fails, the Official does not receive an adequate infusion of *yuan qi*, and the patient experiences a lifetime of symptoms manifesting in that Official's associated element.

Strengthen the Kidneys, regardless of the patient's CF, and tonify the source points on the CF in order to infuse the constitutional element with the source *qi* not received during development. The functioning of the Triple Heater is improved by tonifying the Fire points on the CF in order to strengthen the continued transporting of *qi* along the "water way" to the CF. This transportation of *qi* between the elements can also be achieved by tonifying the corresponding element point on the Triple Heater. This treatment scenario can be successfully employed with any of the elements and is dependent on correct diagnosis of the CF.

For example, the Wood CF did not receive adequate *yuan qi* infusion of the Liver during embryonic development and therefore complains of existential anxiety surrounding decision making, a primary function of the Liver. Decisions are viewed as two extremes with no flexibility to perceive additional options between these poles. The stress of committing to a decision triggers acute symptoms. Liver 2 "Walk Between," the Fire point on the Wood channel, brings Fire's compassion to Wood, allowing the patient to let go of the "right or wrong" worldview and gracefully walk the middle path with ease of being.

Similarly, Triple Heater 3 "Middle Islet," the Wood point on the Fire channel, creates vision towards the horizon, stimulating the patient's mental functioning.² In addition to supporting the ability to step forward and commit to a decision, this point improves balance and coordination by clearing the "mental fog" associated with multiple sclerosis. The treatment is completed by tonifying the source points on Liver and Kidney to further strengthen these elements that suffered the original developmental deficiency.

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Cost-Effectiveness

In addition to effectiveness and safety, concerns regarding cost and missed work were studied in some of the reviewed trials. Several studies reported on costs associated with acupuncture care. Acupuncture was found to be cost-effective at 24-months follow-up in a large study conducted in the UK, compared to usual care.⁴⁰ Another large trial conducted in Germany found acupuncture to be cost-effective.¹⁸ Furthermore, a systematic review of various non-pharmacological interventions reported that acupuncture is likely to be a cost-effective option for LBP.⁴¹ Acupuncture was associated with fewer days absent from work in one reviewed trial.²⁷

Limitations

Due to the heterogeneity of the studies, a systematic review of the best evidence available was undertaken. Areas of heterogeneity included studies of various types of low back pain and various types of measures used. Interventions included different styles of acupuncture (both standardized treatments and individualized point combinations tailored for each subject). Many different comparators were used, and usual care differed in the different countries where the trials were conducted. All these levels of heterogeneity must be taken into account when interpreting findings in the present study.

Furthermore, 7 of the studies included fewer than 100 participants. Trials included 2 to 4 arms or groups and as few as 20 people per arm. Trials having such small sample sizes call to question the validity of extending generalizability beyond the trial sample.

Although all 18 studies met the methodological criteria for RCTs under Cochrane collaboration group recommendations, some studies lacked adequate blinding of subjects, study personnel, and outcome assessors, which weakens the interpretations of the findings (Table 4). The subjective nature of reporting outcomes is especially problematic in LBP studies, as many variables can influence subjective perception of pain, anxiety, depression, and fear of returning to work. Future studies including objective measures such as quantitative sensory testing are needed to confirm these results.

Suggestions for future work are: 1) that trials of acupuncture be conducted specifically for injured workers with acute LBP; and 2) ideally, a Patient Centered Outcomes Research Institute (PCORI)-funded trial allowing the collection of data relevant to how acupuncture delivered by licensed East Asian medicine practitioners performs for the treatment of injured workers. This would provide specific and relevant evidence to inform policy and coverage of care for injured workers in the USA.

“Several studies reported on costs associated with acupuncture care. Acupuncture was found to be cost-effective at 24-months follow-up in a large study conducted in the UK, compared to usual care.”

Conclusion

The evidence analyzed by previous investigators who have systematically reviewed acupuncture for low back pain, as well as the current evidence collected in the 18 studies analyzed for this review, supports the use of acupuncture as a safe and potentially effective option in the treatment of low back pain. Additional studies are needed to further validate these findings and to examine the mechanisms behind the positive effects of acupuncture for low back pain.

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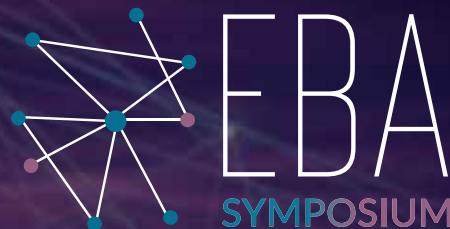
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