Volume 7, No. 4 · Fall 2020

Chrysanthemum morifolium (Ju hua)

The Journal of the American Society of Acupuncturists

INSIDE

JASA
The Journal of the American Society of Acupuncturists

JASA
357 S. Landmark Ave. Bloomington, IN 47403

www.meridiansjaom.com

meridiansjaom@gmail.com
https://www.facebook.com/MeridiansJournal

ISSN 2377-3723 (print)
ISSN 2377-3731 (online)

CONTENTS

Volume 7, No. 4 · Fall 2020

ORIGINAL RESEARCH

CASE REPORTS

PERSPECTIVES

BOOK REVIEW

Cover: Chrysanthemum morifolium (Ju hua)
Photo by David Russell, LAc

JASA
The Journal of the American Society of Acupuncturists

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

Dear JASA readers,

This fall issue of the *Journal of the American Society of Acupuncturists* was published at the end of a year that has been full of unexpected surprises, both positive and negative.

In the acupuncture and Chinese medicine industry, 2020 began with the Centers for Medicare and Medicaid Services announcement that Medicare will now cover acupuncture for chronic low back pain. This was somewhat unexpected by all, including those most closely involved, and it rocked our foundation a bit. Questions about implementation needed answers and answers were unavailable.

Soon after this good news, the world turned inside out when, starting in March, COVID-19 changed everything. So much illness, death, sadness, hunger still persists despite the promise of vaccine protection.

We all have had to adapt to the restrictions that COVID-19 required. Most of the profession's clinicians had to close down during the quarantine. Many acupuncturists who work for hospitals or in healthcare systems were furloughed. But we are a resilient group and we know how to adapt and survive. We know how to find resources.

Data from the NCCAOM/ASA COVID-19 workforce survey showed that the majority of the profession applied for economic assistance and unemployment, and most of us who did apply have received assistance. As I see it, the majority of acupuncturists are now back to work with new COVID screening protocols using PPE and practicing under the most up to date state and federal guidelines.

Update on U.S. Acupuncture Profession Planning Project:

Funded by the David and Lura Lovell foundation, the ASA board and council, representing 36 state associations along with representatives from ACAOM and CCAOM, have participated in two of four strategic planning meetings focused on refining mission and vision of the ASA to collaboratively better serve all stakeholders. Additionally, representatives from NCCAOM and other stakeholder organizations have been interviewed by our consulting firm to collect qualitative anonymous feedback on the state of the profession from leaders of partnering organizations.

A large market workforce analysis survey study was conducted to collect data on satisfaction with career choice, income, practice setting, state and national society/association involvement, preferences in society benefits, sources of continuing education and scholarly content. The data from the market workforce analysis survey has been analyzed and a workforce analysis/white paper is being developed to report the findings of the survey as well as the interviews.

The resulting data will serve as benchmark data to measure the success of future initiatives. The white paper will be widely distributed and published in a high-profile peer reviewed

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

Chrysanthemum moritolium
(Ju hua)

journal for ease in referencing. The data suggests that although acupuncturists are not super satisfied with their incomes, they are very satisfied with their quality of life. The data can be used to help attract more providers into this field that's rapidly expanding into the mainstream medical systems in the U.S.

There has been significant progress made on establishing a solid foundation and governance structure for the journal business as we move forward with requesting proposals and enter into negotiations with potential publishers for JASA. In the process, we have secured the commitment of the European Traditional Chinese Medicine Association (ETCMA) that has indicated interest in collaborating with the ASA to form a joint affiliation with JASA. We are hoping this collaboration will lead to future collaborations with the European organization.

We thank our readers, authors, reviewers and advertisers and welcome your questions, feedback, letters to the editor and submissions: jasasubmissions@gmail.com

Respectfully,

Jennifer A. M. Stone, MSOM, LAc
Editor in Chief, JASA

JASA Editorial Board

Our Extensive Chinese Herbal Formula Line Includes:

Kan Herbals
Kan Traditionals
Kan Essentials
Chinese Modular Solutions
Gentle Warriors
Sage Solutions
Jade Woman/Jade Man Herbals
MycoHerb
Alembic Herbals
Kan Singles

Kan Herb COMPANY

CHINESE HERBAL PRODUCTS YOU CAN TRUST

380 Encinal Street, Suite 100 • Santa Cruz, CA 95060
800.543.5233 • customer@kanherb.com • www.kanherb.com

Scientifically Assured Quality, Consistency, Potency and Purity.

All formulas are manufactured and tested exclusively in the USA from imported Chinese herbs.

Only the freshest and highest quality herbs are procured, many of them organic when possible.

Identity testing is performed to ensure that the right herb is being used every time.

Quality control tests and examinations are performed on all incoming ingredients.

Quality control tests and examinations are performed at every stage of production.

Because we manufacture our products from beginning to end at our state of the art facility in California, we ensure that the quality of our products is guaranteed every time.

Effectiveness of Acupuncture in Treating Four Autoimmune Diseases: A Literature Review

By Kyoung H. Seo, PT, DAOM, LAc

Kyoung Seo, PT, DAOM, LAc graduated from Tri-State College of Acupuncture in 2007 and completed the DAOM program at Virginia University of Integrative Medicine (VUIM) in 2019. She has extensive clinical experience in diverse clinical settings, including acute care hospitals and outpatient rehabilitation facilities. Kyoung served as the director of clinical education at VUIM in 2018 and currently practices physical therapy and acupuncture in her clinic in Bethesda, Maryland. Email: kseo@vuim.edu

Abstract

The incidence of autoimmune disease in the United States has been significantly increasing for the past 20 years. In 1996, it was estimated that more than 8.5 million people were diagnosed with at least one of the 24 most common autoimmune diseases. The National Institutes of Health reported in 2005 that U.S. prevalence for all autoimmune diseases was between 14.7 million and 23.5 million. This trend has serious implications, including the future physical, psychosocial, and financial toll of these illnesses. In recent years, acupuncture has been more widely utilized in the U.S. as a complementary medicine, especially for treating painful conditions. However, there is a lack of available quality studies showing the efficacy of acupuncture in treating autoimmune disease.

This paper is a review of the current research on the effectiveness of acupuncture in treatment of four autoimmune diseases: Rheumatoid Arthritis, Multiple Sclerosis, Systemic Lupus Erythematosus, and Inflammatory Bowel Disease. A total of 15 research articles published in the last 20 years were reviewed. The results show some evidence of the effectiveness and clinical implications of acupuncture for treating these four autoimmune diseases. However, this review also suggests that further research is warranted concerning higher quality clinical trials that apply a standardized reporting system, specific outcome measurements, and treatment protocols based on the patient population, including females with autoimmune diseases, and different disease characteristics.

Keywords: Acupuncture, rheumatoid arthritis, multiple sclerosis, systemic lupus erythematosus, inflammatory bowel disease, systematic review

Introduction

Autoimmune disease (AD) is a chronic disabling disorder involving dysregulated immune responses against self-antigen that cause organ and tissue damage in the body.[1] The incidence of autoimmune disease in the United States has been significantly increasing for the past 20 years.[2]

Researchers have identified more than 80 different ADs.[3,5] In 1996, it was estimated that more than 8.5 million people were diagnosed with one of the 24 most common ADs.[4] In 2005, National Institutes of Health (NIH) reported that U.S. prevalence for all AD was between 14.7 million and 23.5 million.[3]

AD is the third most common category of disease in the U.S. after cancer and cardiovascular diseases and affects approximately 5-8% of the population.[6] Conservative estimates indicate that about 78% of the people affected with ADs are women.[6,7]

In addition, AD has been cited in the top ten leading causes of all deaths, representing the fourth-largest cause of disability among women in the U.S.[4] However, despite these statistics, AD is rarely discussed as a women's health issue. The chronic and debilitating nature of these diseases, which can lead to high medical costs and reduced quality of life, is a burden on patients, their families, and their communities.[8,9]

Despite the fact that many ADs require a lifetime of treatment, reliable clinical treatment strategies and their cures remain elusive.[10] Treatment of AD requires a comprehensive and multidisciplinary approach to the patients' individual needs as well as the diverse clinical manifestations of AD.[11]

Since acupuncture is one of the most common forms of complementary and alternative medicine (CAM) in the United States (Barnes, 2008, Zhang, 2012),[12,13] it is critical that good quality clinical studies be conducted that can then be integrated into the current medical trend of evidence-based medicine and practice. Evidence that acupuncture is effective in treating chronic pain has been suggested in a meta-analysis (Vickers et al., 2012),[14] and there are multiple in vitro studies and clinical trials showing a potential role of acupuncture in the anti-inflammatory and immune regulatory function.[14-19]

This paper reviews current research on the effectiveness of acupuncture in treating four autoimmune diseases: Rheumatoid Arthritis, Multiple Sclerosis, Systemic Lupus Erythematosus, and Inflammatory Bowel Disease. This review hypothesizes that acupuncture can be effective in treating pain, swelling and inflammation, which are symptoms of these four autoimmune diseases.[7]

Methods

A comprehensive electronic literature search was undertaken. The database used for the MeSH term search was Pubmed.gov (U.S. National Library of Medicine National Institute of Health). PubMed is one of the most widely used in biomedical literature search tools in the U.S. As of 2010, more than 20 million citations have been indexed through PubMed.[20] The key words used for the four separate searches were: Acupuncture and Rheumatoid Arthritis (RA); Acupuncture and Multiple Sclerosis (MS); Acupuncture and Systemic Lupus Erythematosus (SLE); and Acupuncture and Inflammatory Bowel Disease (IBD).

"AD is the third most common category of disease in the U.S. after cancer and cardiovascular diseases and affects approximately 5-8% of the population.[6] Conservative estimates indicate that about 78% of the people affected with ADs are women.[6,7]"

Inclusion criteria consisted of articles with both key words, acupuncture and each disease's name in the title, articles published within the last 20 years (September 1998 to September 2018), and articles involving human clinical trials, clinical observation, or systematic reviews (SR). Studies involving electroacupuncture, auricular acupuncture and acupuncture combined with moxibustion were also included. Exclusion criteria were articles published in a language other than English, articles involving in-vitro or animal clinical studies, prospective studies, articles included in all SRs, and articles where the focus of study was not one of the four ADs or treatment modalities other than acupuncture.

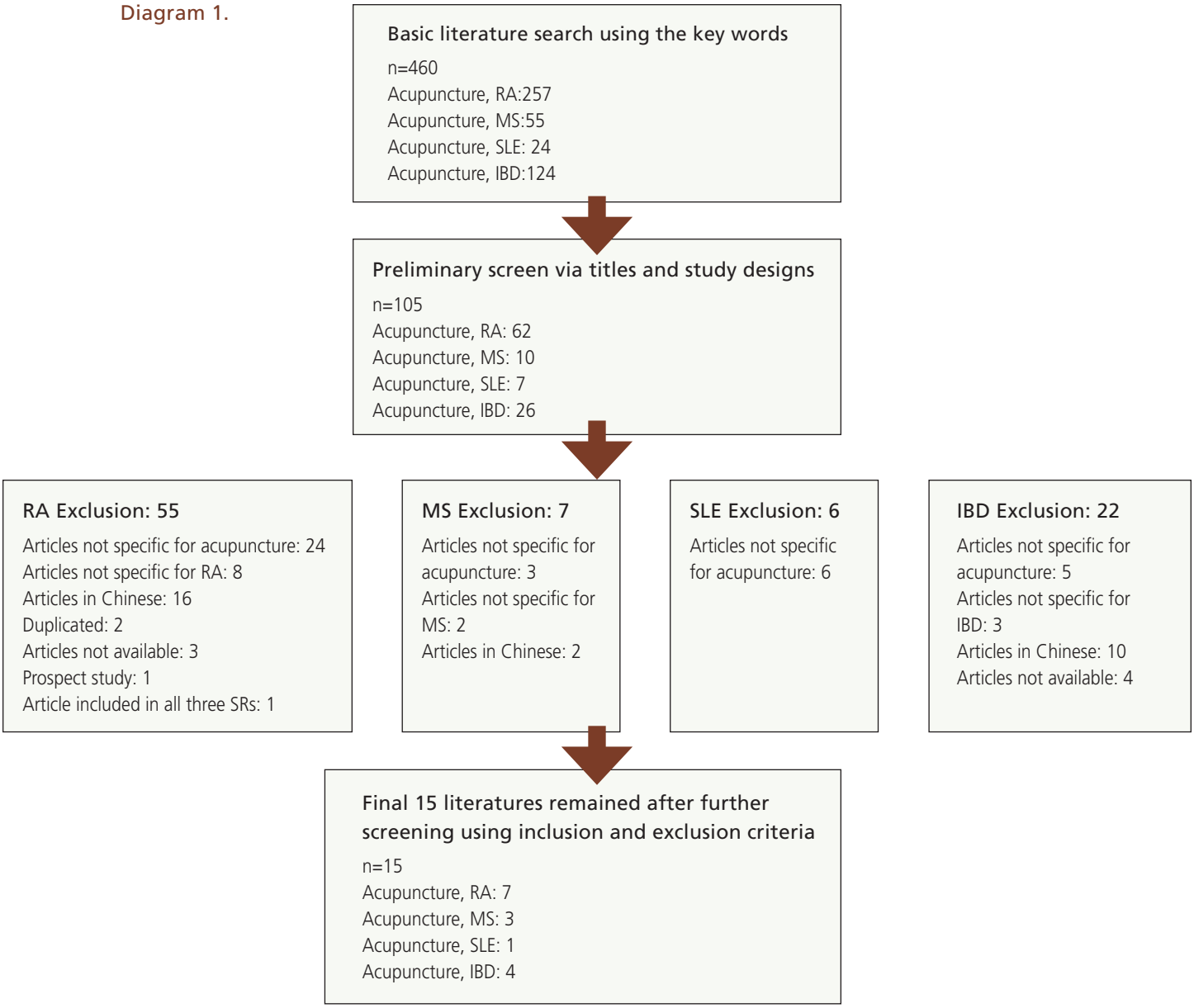
Outcome Measurement

The selected articles were analyzed based on the type of study design, the quality of study using Jadad score, the type of intervention, outcome assessments and the respective effectiveness of acupuncture and the combined modalities. Jadad score, also known as Oxford Quality Scoring System, is a five-point system based on the five items to assess the quality of clinical trials. A score greater than 3/5 is considered as high quality.[21]

Results

A total of 460 articles were collected from the initial search using the paired key words. Of 460 articles, 257 articles were related to RA, 55 to MS, 24 to SLE and 124 to IBD. All articles were thoroughly screened using the inclusion and exclusion criteria. Of these, a total of 15 articles—seven articles for RA (three randomized controlled trials (RCTs), one clinical observation, three SRs), three RCTs for MS, one RCT for SLE and four RCTs for IBD—were selected for this review. One RCT for RA (Tam et al., 2007) was included in the two SRs (Wang et al., 2009 and Lee et al., 2008).

Diagram 1.



3-1. Rheumatoid Arthritis

An RCT (Tam et al., 2007) showed that both TJC (Tender Joint Count) and physician's global score were significantly improved in the EA group while the traditional acupuncture (TA) group and the sham acupuncture (SA) group demonstrated a statistically significant improvement in patient's global scale.[22]

The American College of Rheumatology Criteria (ACR) responses in 23 RA patients were assessed in a pilot study that involved 14 sessions of Sa-am acupuncture throughout six weeks. In this study, 83% of patients achieved improved responses in ACR post treatment (Lee et al., 2008).[23] In another RCT of 44 patients (Bernateck et al., 2008), there was a significant reduction in the VAS in the Auricular Electroacupuncture group (AE) compared to Autogenic Training group (AT).[24]

In addition, these two studies indicate a role of acupuncture in modifying inflammation. Lee's study (2008) showed significantly reduced ESR and Swollen Joint Count (SJC) (p=0.024, p=< 0.001respectively) after six weeks of intervention. In Bernateck's study, the AE group also showed significant changes in ESR (p=0.010 and TNF-α, p=0.020) after six weeks of treatment.[23,24]

The role of different therapeutic courses was assessed in a clinical observation of 47 patients (Ruihui et al., 2007).[25] The outcome showed 8.2% pain reduction and 80.9% stiffness reduction after the sixth course of treatment. The study also showed that the number of acupuncture courses was closely related to the outcomes—both symptoms and inflammatory markers (ESR 53.8+19.1 vs. 28.2+18.5, CRP 23.7+12.6 vs. 15.4+9.8) showed more significant improvement at the end of the sixth course.[25]

In Wang's review (2008) of eight RCTs, seven studies demonstrated a statistically significant reduction in Tender Joint Count and five showed statistically significant pain reduction compared to control groups.[26] In another SR of eight RCTs, only two studies showed a significant pain reduction (Lee et al., 2008).[27] Although both reviews include six of the same studies, Wang's review was overall more favorable to acupuncture than Lee's (Table 1-2).

Casimiro et al. (2002) reviewed two studies involving 84 RA patients (Townsend et al., 1999, Man et al., 1974).[28] While Man's study showed a significant reduction of knee pain in the treatment group, no significant intergroup difference of the outcome measures was reported in Townsend's study. Casimiro precludes a recommendation for clinical use of acupuncture stating that Man's study showed only the temporary pain reduction and had a poor quality (Jadad score 2/5) with a small sample size of 20.

Despite some favorable outcomes, all three reviewers conclude there is no clear evidence of acupuncture being effective in treating RA compared to control groups.[26-28] This finding is not surprising considering that six of the same studies were included in the three reviews. Also, all three reviewers critique the lack of standardized study protocol, poor quality of the trials, and small sample sizes.

Table 1-1. Rheumatoid Arthritis

Article	Study Design and Quality Score	Type of Acupuncture and Intervention	Main Outcome Assessment	Acupuncture Shown Effectiveness	Acupuncture Shown No Effectiveness or Inconclusive
1. Acupuncture for Pain Relief in Patients with RA: Systematic Review, Chenchen Wang et al., 2008[26]	Systematic Review: Eight RCTs with a total of 536 patients:160 from four placebo controlled, 407 from 4 active controlled. Jadad Score: Three trials: 5/5, Three trials:3/5, Two trials:2/5	TA vs. EA vs. Sham: one trial EA vs. Sham: one trial TA vs. active drug controlled: Four trials	TJC	Thee out of four placebo-controlled trials showed a reduction in TJC: EA: p=0.03, p=<0.05 TA: p=0.01, p=0.145, p=0.6 Four out of four active-drug controlled trials showed a significant reduction in TJC: Two trials p <0.05 Two trials p <0.01	One out of four placebo-controlled trials did not show a significant improvement in TJC p=0.6
2. Acupuncture for Rheumatoid Arthritis: A Systematic Review, MS Lee et al., 2008[27]	Systematic Review: Out of eight RCTs reviewed, six were included in the Chenchen's systemic review[29] Jadad Score: Three trials: 5/5, Two trials: 2/5, Three trials: 1/5	TA vs. Sham: Two trials TA vs. EA vs. Sham: one trial EA vs. Sham: one trial TA vs. active drug control: four trials	Pain reduction	Two out of eight trials demonstrated positive analgesic effects of acupuncture: one trial (Man): p <0.01 one trial (Xiang): p <0.05	Six out of eight trials demonstrated no significant analgesic effects of acupuncture compared to penetrating, non-penetrating sham acupuncture or with conventional drug therapy. No improvement in CRP, ESR showed
3. Acupuncture and Electroacupuncture for the Treatment of RA (Review), Casimiro et al., 2002[28]	Review: Two clinical trials, which were included in SR of Chenchen et al.[29] and Lee et al.[30] Jadad Score: Townsend et al. 1999: 4/5, Man et al.1974: 2/5	The Townsend: TA in bilateral LI3 point only The Man: EA in GB34, SP9 and ST43	VAS SJC TJC Pain reduction scale	The Townsend: Outcomes after 5 weekly sessions: No significant difference found between the acupuncture group and the sham group. The Man: Outcomes after 24 hrs of treatment showed a significant pain reduction in the acupuncture group.	No significant improvement in SJC and TJC
4. Acupuncture in the Treatment of Rheumatoid Arthritis, Lai-Shan Tam et al., 2007[22]	RCT of 36 patients with RA. A double -blind controlled pilot study Jadad Score: 5/5	20 sessions of EA vs. TA vs. Sham acupuncture over a period of 10 weeks	Pain score ACR score DAS28 score at week 10	EA group showed a significant reduction in physician's global score p=0.04 and TJC p=0.03 TA group showed a significant reduction in patient's global score and TJC p=0.01 Sham group showed an improved patient's global score p=0.03	No significant differences in the pain score among three groups. No significant difference of DAS 28 score in all three groups. No improvement in ESR and CRP values in all three groups
5. The Role of Different Therapeutic Courses in Treating 47 Cases of Rheumatoid Arthritis with Acupuncture, Wang Ruihui et al., 2007[25]	Clinical Observation of 47 RA patients. Jadad Score: N/A	TA with moxibustion at ST36 and other adjunct points for 6 courses of 10 consecutive treatments No medications for RA given during the study.	Pain Morning stiffness & swelling RF, ESR, CRF values at third course and sixth course	Outcomes after sixth course: Pain reduction: 87.2% Stiffness reduction: 80.9% Swelling reduction: 64.3% RF: positive in 12/47 Reduced ESR: 53.8+19.1 vs. 28.2+18.5 Reduced CRP: 23.7+12.6 vs. 15.4+9.8	No statistical difference in ESR and CRP after the third course treatment and before the treatment. Both symptoms and laboratory markers showed more significant improvements at the end of sixth course than third course.

Table 1-1. Rheumatoid Arthritis *(continued)*

Article	Study Design and Quality Score	Type of Acupuncture and Intervention	Main Outcome Assessment	Acupuncture Shown Effectiveness	Acupuncture Shown No Effectiveness or Inconclusive
6. Acupuncture for Symptom Management of Rheumatoid Arthritis: A Pilot Study, Hyangsook Lee et al., 2008[23]	A pilot study of 23 RA patients Jadad Score: N/A	14 sessions of Sham acupuncture (KD10, HT8, SP3, ST36) for 6 weeks 12 patients were on RA medication, 11 patients were on no medication	ACR DAS ESR PI SJC TJC	At 6 weeks: ACR 20 responses 48%, ACR 50 responses 22%, ACR 70 responses 13% DAS score: 4.1+1.0 vs. 3.1+1.1, $p<0.001$ PI: 53.9+20.5 vs. 38.8+27.7, $p=0.004$ SJC: 5.2+3.5 vs. 1.4+1.9, $p=0.001$ ESR:18.3+14.4 vs. 13.3+14.7, $p=0.024$	No significant changes in TJC: 5.9+4.2 vs. 4.2+4.0, $p=0.099$
7. Adjuvant Auricular Electroacupuncture and Autogenic Training in Rheumatoid Arthritis: A Randomized Controlled Trial, Bernateck et al., 2008[24]	RCT of 44 patients Jadad Score: 1/5	6 weekly AE (Auricular Electroacupuncture) vs. AT (Autogenic training)	PI PDI DAS CGI ESR TNF-α Cytokine	Both the AE group and the AT group showed a statistically meaningful pain reduction after six treatments and at the three months follow up. AE: $p=0.009$, AT: $p=0.045$ A significant group differences in favor of AE were found in pain intensity after the fourth treatment week. Morning: $p=0.040$, Evening: $p=0.037$ A significant reduction in ESR AE: $p=0.010$ AT: NS An increase in TNF-α serum level AEA: $p=0.020$ AT: NS	No significant difference in cytokine level between the groups

*TA: Traditional Acupuncture, *EA: Electro Acupuncture, *TJC: Tender Joint Count, *PI: pain Intensity, * SJC: Swollen Joint Count, *QS: Quality Score, *ACR: The American College of Rheumatology Criteria, https://eprovide.mapi-trust.org/instruments/american-college-of-rheumatology-20-50-70-criteria *DA: Disease Activity Score, https://www.niehs.nih.gov/research/resources/assets/docs/disease_activity_score_instructions_508.pdf *ESR: Erythrocyte Sedimentation Rate, *CRP: C-Reactive Protein, *VAS: The Visual Analogue Scale, *PDI: The Pain Disability Index, https://pubmed.ncbi.nlm.nih.gov/3606368/ *CGI: the Clinical Global Impression, https://eprovide.mapi-trust.org/instruments/clinical-global-impressions-scale-improvement-severity-change-and-efficacy DAS28 score: Disease Activity Score using the 28 joint counts, https://www.nras.org.uk/the-das28-score * JADAD Score: Oxford Quality Scoring System, http://www.pmidcalc.org/?sid=8721797&newtest=Y

Table 1-2. Quality Score and Effectiveness of Acupuncture in 3 Systematic Reviews

RCTs \ SR	Wang et al., 2008[29]	Lee et al., 2008[30]	Casimiro et al., 2002[31]
David J. Townsend et al., 1999 Five weekly sessions	Jadad Score: 5/5 Reduction in TJC: NS	Jadad Score: 5/5 Reduction in pain: NS	Jadad Score: 4/5 Reduction in pain or TJC: NS
Man et al., 1974 One session	Jadad Score: 3/5 (+) Reduction in Pain: $p<0.05$	Jadad Score: 2/5 (+) Reduction in Pain: $p<0.01$	Jadad Score: 2/5 (+) Short term pain reduction
Zanette et al., 2008 10 sessions, 2 x week for five weeks	Jadad Score: 5/5 (+) Reduction in TJC: $p=0.145$ (+) Reduction in ESR and CRP	Jadad Score: 5/5 Reduction in pain: NS	N/A
Tam et al., 2007 20 sessions, 2 x week for 10 weeks	Jadad Score: 5/5 (+) Reduction in TJC: EA group: $p=0.03$ TA group: $p=0.01$ (+) Reduction in ESR	Jadad Score: 5/5 Reduction in pain: NS	N/A
Zhou et al., 2000 15 sessions, 2 x weeks for four weeks	Jadad Score: 2/5 (+) Reduction in TJC: $p<0.01$ (+) Reduction in ESR and CRP	Jadad Score: 1/5 Reduction in pain: NS	N/A
Liu et al., 2003 180 sessions, 2 x day for 12 weeks	Jadad Score: 2/5 (+) Reduction in TJC: p<0.05 (+) Reduction in ESR	Jadad Score: 1/5 (+) Reduction in SJC: $p<0.05$	N/A
Jiang et al., 2003 15 sessions, 2 x week for four weeks	Jadad Score: 3/5 (+) Reduction in TJC: $p<0.05$ (+) Reduction in ESR and CRP	N/A	N/A
Cui et al., 2001 90 sessions, 1 x day for 12 weeks	Jadad Score: 2/5 (+) Reduction in TJC: $p<0.01$	N/A	N/A
Wang et al., 2002 14 sessions, 2 x day for seven days	N/A	Jadad Score: 1/5 Total effective rate: $p<0.01$	N/A
Xiang et al., 2005 45 sessions, three courses of daily Tx for 15 days with one - two-day rest between the course of treatment	N/A	Jadad Score: 1/5 (+) Reduction in Pain: $p<0.05$	N/A
Mean Jadad score and Effectiveness	**Mean Jadad score:** 3.5/5.5 **Effectiveness:** Inconclusive	**Mean Jadad score:** 2.75/5 **Effectiveness:** Not favorable	**Mean Jadad score:** 3.5 **Effectiveness:** Inconclusive

"Despite some favorable outcomes, all three reviewers conclude there is no clear evidence of acupuncture being effective in treating RA compared to control groups.[26-28]"

3-2. Multiple Sclerosis

The impact of electroacupuncture (EA) on Quality of Life (QOL) for 31 patients showed favorable outcomes in the treatment group (Cabanillas et al., 2012).[29] The true electroacupuncture (TEA) group reported significantly reduced pain levels compared to the sham electroacupuncture (SEA) group after three months ($p=0.014$) and six months ($p=0.0001$). The TEA group also reached a statistically significant intergroup difference ($p=0.0026$, $p=0.0001$) in the total Functional Assessment of Multiple Sclerosis Score (FAMS score).

A favorable result was shown in the true acupuncture group that assessed the gait of 20 patients using The 25-Foot Walk test (T25FW) (Criado et al., 2017).[30] As the result of the intervention, only the true acupuncture group showed a statistically significant improvement with T25FW test, $p=0.000$.

An individually-tailored Chinese medical acupuncture strategy was compared to minimal acupuncture (MN) in assessing Quality of Life (QOL) in 14 MS patients (Donnellan et al., 2008).[31] On intention to treat analysis, the MN group demonstrated a significantly greater improvement in the Multiple Sclerosis Impact Scale 29 (MSIS-29) psychological score compared with the Chinese medical acupuncture group, $p=0.04$.

Table 2. Multiple Sclerosis

Articles Reviewed	Study Design and Quality Score	Type of Acupuncture and Intervention	Main Outcome Assessment	Acupuncture Shown Effectiveness	Acupuncture Shown No Effectiveness or Inconclusive
1. Impact of Electroacupuncture on Quality of Life for Patients with Relapsing-Remitting Multiple Sclerosis Under Treatment with Immunomodulators: A Randomized Study, Juan G Quispe-Cabanillas et al., 2012[29]	RCT of 31 patients with a confirmed diagnosis of RRMS **Jadad Score:** 2/5	True Electroacupuncture (TEA) vs. Sham Electroacupuncture (SEA) A weekly 30-minute treatment for 6 consecutive months	Pain using VAS EDSS FAMS FAMS Mobility Subscale FAMS QOL subscale	**VAS:** the TEA group reported better pain reduction then the SEA group; after 3 months: TEA: p=0.014 SEA: p =0.028 after 6 months: TEA: p=0.0001 SEA: p=0.1 **Total FAMS:** TEA vs. SEA after 3 months: p=0.0026 after 6 months: p=0.0001	No significant improvement in EDSS score: TEA vs. SEA: p=0.055 after 6 months
2. Effects of Acupuncture on Gait of Patients with Multiple Sclerosis, Maria Begona Criado et al., 2017[30]	Randomized Single blinded Clinical Trial of 20 patients with RRMS **Jadad Score:** 2/5	True Acupuncture (TA) group vs. Sham Acupuncture (SA) group TA group and SA group were switched after one month	Gait Assessment using the 25-Foot Walk test immediately after TA or SA	**T25FW:** TA group improved in T25FW score by 13.9%, p=0.000 SA group showed no positive improvement, p=0.370	N/A
3. Comparison of the Effect of Two Types of Acupuncture on Quality of Life in Secondary Progressive Multiple Sclerosis, Clare P Donnellan et al., 2008[31]	A Preliminary Single Blind RCT of 14 patients with SPMS **Jadad Score:** 2/5	Individualized Chinese Medical Acupuncture group vs. Minimal Acupuncture group 10 Bi-weekly treatment for 5 consecutive weeks.	MSIS -29 FSS GHQ-12	The minimal acupuncture group demonstrated statistically significant improvement in MSIS-29 psychological score compared to Chinese Medical Acupuncture group. p=0.04	

*RRMS: Relapsing-Remitting Multiple Sclerosis, *VAS: The Visual Analogue Scale, *EDSS: The Expended Disability Status Scale, https://www.va.gov/MS/Professionals/Diagnosis/Kurtzke_Expanded_Disability_Status_Scale.asp *FAMS: The Functional Assessment of Multiple Sclerosis, https://pubmed.ncbi.nlm.nih.gov/8710066/ * QOL: Quality of Life, *TCM: Traditional Chinese Medicine * JADAD Score: Oxford Quality Scoring System, http://www.pmidcalc.org/?sid=8721797&newtest=Y * SPMS: Secondary Progressive Multiple Sclerosis * MSIS -29 score: Multiple Sclerosis Impact Scale 29, https://pubmed.ncbi.nlm.nih.gov/8710066/ *FSS: Fatigue Severity Score. https://best.ugent.be/BEST3_FR/download/moeheid_schalen/FSSschaal_ENG.pdf * GHQ-12: General Health Questionnaire 12, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC280704/

3-3. Systemic Lupus Erythematosus

A pilot study (Greco et al., 2008) assessed the feasibility and safety of using acupuncture in treating SLE.[32] In this study, 24 patients were assigned randomly to the acupuncture (AC) group, the MN group or the usual medical care (UC) group. Approximately 40% of both AC and MN participants showed improvement on the Arthritis Impact Measurement Scale version 2 pain scale (AIMS2 pain scale) or the Short Form-36 Health Survey bodily pain scale (SF-36 bodily pain scale). However, the MN group demonstrated better outcomes on the Short Form-36 vitality scale (SF-36 vitality scale), AC 13% vs. MN 25% improvement, and cytokine values (post-pre-mean changes: -0.38 vs. -0.03) compared to the AC group. The study showed no major benefit of AC over MN.

Table 3. Systemic Lupus Erythematosus

Articles Reviewed	Study Design and Quality Score	Type of Acupuncture and Intervention	Main Outcome Assessment	Acupuncture Shown Effectiveness	Acupuncture Shown No Effectiveness or Inconclusive
Acupuncture for Systemic Lupus Erythematosus: A Pilot RCT Feasibility and Safety Study, CM Greco et al., 2008[32]	A Pilot RCT of 24 patients with SLE **Jadad Score:** 5/5	AC vs. MN vs. UC 10 treatments throughout 5 weeks. AC included electrical stimulation to paraspinal points	Pain Scales: AIMS2 pain MPI-Interference, MPI-severity SF-36 bodily pain FSS SF-36 vitality SLEDAI SLAM-R Cytokines	AC and MN both groups showed clinical improvement in pain and fatigue scales MN and UC groups showed better improvement in SLEDAI score MN showed better improvement in IL-6 value	Acupuncture did not show significant improvement in SLAM-R score and Cytokines

* JADAD Score: Oxford Quality Scoring System, http://www.pmidcalc.org/?sid=8721797&newtest=Y * *SLE: Systemic Lupus Erythematosus *AC: Acupuncture protocol with usual care *MN Minimal Needling protocol with usual care *UC: Usual Care protocol only * AIMS2 pain: Arthritis Impact Measurement Scales version 2 pain scale, https://onlinelibrary.wiley.com/doi/pdf/10.1002/art.11414 * MPI-Interference: Brief version of Multidimensional Pain Inventory-Interference scale, https://www.va.gov/PAINMANAGEMENT/docs/WHYMPI_Full-text.pdf# MPI-severity: Brief version of Multidimensional Pain Inventory-Pain severity scale, file:///C:/Users/isiac/Downloads/west_haven_yale_multidimensional_pain_inventory.pdf * SF-36 bodily pain: SF-36 Health Survey version 2 Bodily Pain scale, https://www.rand.org/health-care/surveys_tools/mos/36-item-short-form/survey-instrument.html *FSS: Fatigue Severity Score, https://best.ugent.be/BEST3_FR/download/moeheid_schalen/FSSschaal_ENG.pdf * SF-36 vitality: SF-36 Health Survey version 2 vitality scale * SLEDAI: the SLE Disease Activity Index, https://www.thecalculator.co/health/SLE-Disease-Activity-Index-(SLEDAI)-Calculator-1119.html * SLAM-R: Systemic Lupus Activity Measure-Revised, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3812450/

3-4. Inflammatory Bowel Disease

A clinical trial (Shang et al., 2015) assessed the effect of moxibustion combined with acupuncture in Tight Junction (TJ) protein expression in 60 patients with Crohn's disease (CD).[33] Based on post intervention histopathological exams, the study concludes that herb-partitioned moxibustion combined with acupuncture (HMA) induces mucosa inflammation remission similar to mesalazine in repairing the TJ barrier structure in intestinal epithelial mucosa.

An RCT of moxibustion and acupuncture for the treatment of 92 active CD patients showed favorable results for the treatment group (Bao et al., 2014).[34] The study compared HMA to wheat bran-partitioned moxibustion combined with superficial acupuncture (WMSA). The outcome showed a significant decrease in CD Activity Index (CDAI) score in the HMA group for both post-treatment and follow up assessment, p=0.000. In addition, the HMA group showed a significantly increased HGB (p=0.029) and decreased CRP (p=0.008) from the baseline. During the follow up of 12 to 24 weeks, the CDAI score in the HMA group was significantly lower compared to the baseline score, p=0.000, which implies a long-term effect of HMA.

Recent research indicates a close connection between the brain and the dysfunction of the digestive system. Bao et al. (2016) investigated changes in resting state brain activity in remissive CD patients.[35] In this study, 52 CD patients and 36 healthy participants were recruited. In the EA group, the decrease in CDAI score was positively correlated with the decrease in the regional homogeneity (ReHo) value in the anterior cingulate cortex (ACC), the dorsolateral prefrontal cortex (DLPFC) and the temporal pole. Both EA and moxa treatments were effective in normalizing the decreased cortical-subcortical coupling of the brain; however, the improvement in CDAI and Inflammatory Bowel Disease Questionnaire (IBDQ) scores did not reach a statistical significance.

An RCT of 51 patients with active CD received either traditional Chinese medical acupuncture (TCMA) or minimal acupuncture (MN) (Joos et al., 2004).[36] The TCMA group showed decreased CDAI score from the baseline in PP analysis, p=0.003. However, both groups demonstrated decreases in CDAI and IBDQ scores, and there was no significant intergroup difference, p=0.059.

Table 4. Inflammatory Bowel Disease

Articles Reviewed	Study Design and Quality Score	Type of Acupuncture and Intervention	Main Outcome Assessment	Acupuncture Shown Effectiveness	Acupuncture Shown No Effectiveness or Inconclusive
1. Moxibustion Combined with Acupuncture Increases Tight Junction Protein Expression in CD Patients, Hai-Xia Shang et al., 2015[33]	A controlled clinical trial with 2 parallel treatment groups of 60 patients. **Jadad Score:** N/A	Herb-Partitioned Moxibustion combined with acupuncture (HMA) 6/week for 12 consecutive weeks vs. Mesalazine (MESA) treatment per protocol.	Histopathological exams: Morphological and Ultrastructural observation Expression of TJ proteins; Occludin, Claudin-1, ZO-1 Expression of TJ protein mRNAs	**Histopathological exams:** More regularly arranged intestinal glands, mild and localized inflammatory cellular infiltration and tight intercellular connections observed in HMA group. **Expression of TJ proteins:** HMA group showed a significant increase in ZO-1expression; 2333.34+ 352.51 vs. 2160.38 +307.08, *p*=0.047 **ZO-1 mRNA expression:** 2378.17+308.77 vs. 2200.56+281.88, *p*=0.023	N/A
2. Randomized Controlled Trial: Moxibustion and Acupuncture for Treatment of CD, Chunhui Bao et al., 2014[34]	RCT of 92 patients **Jadad Score:** 5/5	HMA vs. WMSA 3/week for 12 weeks	CDAI score IBDQ Laboratory indicators: HGB, CRP, ESR,	**CDAI score** in PP analysis: The HMA group showed a significantly larger decrease in CDAI score post treatment: -115.35+55.05 vs. -35.68+46.91, *p*=0.000 **IBDQ:** The HMA group showed a larger increase in the score: 24.56+34.15 vs. 9.93+19.13, p=0.017 **CRP (mg/L):** Reduced from the baseline in the HMA group; -8.67+20.04, *p*=0.008 **ESR (mm/h):** Decreased from the baseline in the HMA group; -3.77+13.00, *p*=0.163	
3. Different Brain Responses to Electro-Acupuncture and Moxibustion Treatment in Patients with CD, Chunhui Bao et al., 2016[35]	RCT of 52 patients with CD in remission (CDAI<150) and 36 healthy subjects **Jadad Score:** 5	EA treatment vs. Moxibustion (MO) treatment on the same acupuncture points 3/week for 12 weeks	CDAI IBDQ Resting-state fMRI scan; ReHo	**CDAI:** Both EA (16) and Moxa (18) groups showed decreased scores from the baseline; -28.11+29.81 vs. -31.22+26.14, *p*=0.74 **IBDQ:** Both EA and Moxa groups showed increased scores from the baseline; 17.28+19.50 vs. 16.00+18.13, *p*=0.84 **ReHo:** Abnormal ReHo levels in multiple brain regions were corrected in both groups, *p*=0.05	N/A
4. Acupuncture and Moxibustion in the Treatment of Active CD, Stefanie Joos et al., 2004[36]	Randomized controlled single -blinded clinical trial of 51 patients with mild to moderately active CD **Jadad Score:** 4/5	TCM acupuncture vs. Minimal Sham acupuncture 10 sessions over 4 weeks with the 12 weeks follow-up	CDAI Remission rate of CD after the 4 weeks of treatment; CDAI lower than150-160 IBDQ	**CDAI:** In PP analysis, TCM group showed a significantly decreased CDAI score compared to the baseline; -87+43 vs. -39+46, *p*=0.003	Remission rates were not significantly different between the TCM group and the SA group; 41% vs. 33% in ITT analysis. IBDQ: the score improved from the baseline in both groups but there was no significant difference between the groups.

* JADAD Score: Oxford Quality Scoring System, http://www.pmidcalc.org/?sid=8721797&newtest=Y *HMA: Herb partitioned moxibustion combined with acupuncture * MESA: Mesalazine *TJ proteins: Tight junction proteins * WMSA: Wheat brain -partitioned Moxibustion with Superficial Acupuncture *CDAI: CD Activity Index, https://globalrph.com/medcalcs/crohns-disease-activity-index-cdai/ *CRP: C-reactive protein * ESR: Erythrocyte Sedimentation Rate * PP analysis: Per Protocol analysis * ITT analysis: Intention To Treat Analysis * IBDQ: The Inflammatory Bowel Disease Questionnaire, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7197888/ * EA: Electro Acupuncture *ReHo: Regional Homogeneity * TCM acupuncture: Traditional Chinese Medicine Acupuncture

Discussion

4-1. Rheumatoid Arthritis

The 2007 study by Ruihui et al. presents two important clinical implications.[25] The first is that a cumulative treatment effect from a longer period of intervention may result in better clinical outcomes. Both symptoms and inflammatory biomarkers showed more significant improvement at the end of the sixth course than the third course. The participants received six courses of acupuncture and moxibustion treatment throughout 11 weeks. Each course consisted of 10 treatments with an interval of three days between adjacent courses. The second implication is that systemic anti-inflammatory effects of acupuncture may be better produced by higher number of treatments over longer periods with resting intervals. Two additional studies that showed a significant reduction in inflammatory markers were done throughout six weeks.[23,24] The studies with no significant improvement in inflammatory biomarkers showed that the number and duration of treatment varied from one treatment for one day to 180 treatments throughout 12 weeks.

Based on the varying degrees of evidence shown in this review, inflammation modifying function of acupuncture may be

affected by certain factors such as the dosage of treatment, point selection and the length of study. However, the correlation between the study design, including the intensity of needle stimulation, point selection, the frequency of treatment and the duration of study, and the changes in post-intervention inflammatory markers needs to be investigated further.

Wang's review (2009) focuses on TJC outcomes, whereas Lee's review (2008) on pain reduction. Also, Lee applied more strict measures for quality score, resulting in the three out of the six studies scoring lower in Jadad scale compared to Wang's (Table 1-2). Regarding inflammatory biomarkers, Wang finds that five out of six studies showed a reduction in ESR or CRP levels. Although four of the same studies were also included in Lee's review, Lee concludes that acupuncture does not affect the inflammatory biomarkers. This discrepancy is due to a methodological difference between the two reviews. Wang compares the pre- and post-intervention biomarkers, whereas Lee's review is based on intergroup differences post-intervention.

None of the three SRs firmly concludes that acupuncture is effective in treating patients with RA. Despite six of the same studies being included in those SRs, grading of the quality score and analyzing the outcome measurements differ depending on the reviewer. Also, the RCTs with underutilized standardized reporting system such as the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) undermine reproducibility and clinical application.

All three reviewers point out that lack of quality clinical trials and treatment protocols may contribute to insufficient evidence about acupuncture's efficacy.[26-28] This critique seems to be validated by the fact that all RA clinical trials have Jadad scores ranging from 1 to 5, varying study protocols and different outcome measure tools applied.

A good example of a study with an inadequate treatment protocol is included in all three SRs (Townsend et al., 1999). In this study, only one acupuncture point (LI-3 sanjian, bilaterally) was needled for four minutes once a week for five weeks. At the conclusion of the study, Townsend refutes acupuncture as an effective adjunct in the treatment of RA. However, both the enrollment of patients with advanced RA and the suboptimal treatment protocol can be questioned.[28]

Based on TCM theory, which is the predominantly practiced style of acupuncture in the United States, multiple point combinations are commonly used to address root causes and symptomatic presentations. While this study meets the criteria for a good quality clinical trial (Jadad score: 5), the intervention applied seems to be insufficient to produce any measurable clinical improvements, especially when treating a complicated and systemic condition such as RA.

4-2. Multiple Sclerosis

All three RCTs included in this review scored poorly, with a mean Jadad score 2. Also, the power of the studies is undermined due to small sample sizes averaging only 21. The improvement in post intervention pain scale (VAS) was significantly greater in the TEA group after six months (p=0.0001) than after three months (p=0.014) in Cabanillas' study (2012).[29] This finding concurs with Ruihui's (2007) conclusion, which suggest cumulative effects of acupuncture.[25]

In addition, the self-reported mobility subscale of the FAMS in TEA group reached a statistically significant intergroup difference (p=0.005). Despite the small sample size, this result implies that the FAMS can be potentially utilized as an outcome assessment tool and used to advocate the efficacy of acupuncture in treating multiple sclerosis (MS) patients.[37]

Criado's study (2017) assessed only one objective physical performance using T25FW test.[30] Despite the favorable outcome, a small sample size and lack of internal validity undermine the credibility of the outcome. Both true and sham acupuncture were performed by one practitioner, which may have compromised the unbiased intervention. Also, Criado fails to report some critical details of the study such as use of assistive devices and antispasmodic regimen during the study.

Donnellan's study (2008) is unique in that Chinese medical pattern differentiation was made for the TCMA group based on a general health questionnaire, with questions relating to the Chinese medical patterns commonly seen in multiple sclerosis.[31] *De qi* was elicited in all points for the TCMA group whereas no stimulation was applied to the MN group. While there was no significant intergroup difference, the MN group showed a greater improvement on the MSIS 29 psychological subscale. This finding raises an important question about whether eliciting typical *de qi* sensations warrants better clinical outcomes as generally accepted in the field of TCMA.

Other forms of acupuncture, such as traditional Japanese acupuncture and wrist-ankle acupuncture, avoid inducing strong needle sensations in patients.[38] *De qi* involves a multitude of neural fiber types, ranging from the fast-conducting myelinated AB fibers, which have higher thresholds to the slow conducting unmyelinated C fibers with lower thresholds.[39] Since MS is a neurological condition involving the damaged myelin sheath, causing abnormal conduction of electrical impulses of neurons, a strong stimulation may result in adversarial reactions or nocebo effect.

"The tolerance and receptiveness to needle stimulation can differ depending on disease characteristics, individual make ups and cultural backgrounds. People from certain cultures are more familiar with acupuncture.[47] Therefore, those populations might be less averse to stronger needle stimulation."

4-3. Systemic Lupus Erythematosus

Only one systemic lupus erythematosus (SLE) clinical trial met the inclusion criteria for this paper's review, signifying a need for future research on the role of acupuncture in treating patients with SLE. Greco et al. (2008) supports that acupuncture is a safe adjunctive therapy option for patients with SLE.[32] However, the study's findings show no major benefit of AC over MN. Rather, the MN group showed better outcomes on a pain scale, a fatigue scale, and the cytokine level. Greco explains this result as a placebo effect and non-specific analgesic effects of needle insertion. However, that does not truly explain the superior outcomes of MN.

Providing that placebo and non-specific analgesic effects of needle insertion equally affected the outcomes of AC and MN, the outcome difference should have been insignificant between the two groups at the least. In essence, the MN treatment protocol entailed much less stimulation compared to the AC treatment protocol. Therefore, this result brings a similar question as in Donnellan's study (2008) that acupuncture can be overly stimulating to AD patients with hypersensitive and hypervigilant immune systems.[40,41]

4-4. Inflammatory Bowel Disease

Despite Shang's study (2015) showing a significant histological improvement, no clinical outcome was assessed. Clinical applications of acupuncture therefore cannot be inferred from this study. Bao's RCT (2014) also suggests the favorable long-term cumulative effects of acupuncture as shown in the studies by Cabanillas (2012) and Wang (2007). In Bao's study (2014), CDAI score of the treatment group was significantly lower after 12 weeks of treatments and during the follow-up of 24 weeks (p=0.000). Also, the treatment group showed better outcomes in total treatment efficacy (83.72% vs. 40.48%) and laboratory markers. However, it is unclear the extent of the role played by both the true and sham moxibustions in those study outcomes since moxibustions were combined with acupuncture.

Both EA and moxibustion appear to be similarly effective in decreasing CDAI, increasing IBDQ and the regulation of the homeostatic afferent processing network (Bao et al., 2016). This implies that there may be a potential role of acupuncture in modulating the immune system via the hypothalamus-pituitary-adrenal axis.[42-44] However, clinical implications of this study may be limited due to the low baseline mean CDAI score (71.22+42.03) indicating a state of remission.

In contrast to Bao's study (2016), Joos et al. (2004) recruited 54 patients with active CD and CDAI scores ranging from 150 to 350.[36] Out of the four studies of CD, this study was designed the best concerning current clinical acupuncture practice. The TCMA group was diagnosed based on TCM theories, then treatment was individually tailored in each session. The TCMA group showed significantly decreased CDAI scores compared to the MN group (p=<0.003) post-treatment. It should be noted that Seirin needles (size 0.30 x 30 mm) were used for both groups. Seirin needles are known for more soft and gentle penetration compared to other brand name needles.[45,46]

Even though *de qi* was elicited for the TCMA group, it might have been a milder stimulation compared to using other types of needles and electro stimulation. The tolerance and receptiveness to needle stimulation can differ depending on disease characteristics, individual make ups and cultural backgrounds. People from certain cultures are more familiar with acupuncture.[47] Therefore, those populations might be less averse to stronger needle stimulation. This may be one of the reasons that the RCTs from China in this review resulted in more favorable outcomes.[26,27,34,36] One should consider the varying levels of needle sensitivity, individual cultural backgrounds and disease characteristics for future clinical practice models and study protocols.

The data search was done only through PubMed and a significant number of studies in Chinese were excluded. More than 28 million medicine and healthcare-related research articles are currently available in PubMed. However, excluding other databases such as Excerpta Medica Database and The Cochrane Library might have reduced the number of qualified articles for the review. In addition, the exclusion of the studies published in Chinese could have limited the outcomes of the review.

The review for SLE was limited due to lack of available RCTs. Also, some of the RCTs reviewed had poor quality scores, with small sample sizes weakening the studies' power.

Comparing different studies was challenging due to lack of standardization in reporting and the treatment and study protocols. Overall, acupuncture showed some favorable outcomes in the most studies. Pain reduction and decreased TJC were notable for RA. The self-reported QOL score and gait quality showed improvement for MS. For SLE, pain reduction was significant though, the intergroup differences were not significant. Lastly, CDAI score improved in all three RCTs for CD.

Conclusion

This review included 15 clinical studies that explore the effectiveness of acupuncture in treating the four ADs.

Based on the above findings, it can be concluded that acupuncture may be beneficial in treating some symptoms of the four ADs and may have potential value as an adjunctive therapy. One of the important findings is that eliciting typical *de qi* sensations or applying strong stimulation may not only overstimulate but also undermine treatment outcomes of patients with AD. This is supported by three RCTs that showed MN producing either compatible or better clinical outcomes compared to TCMA.[22,31,32]

These findings warrant future clinical studies that explore the correlation between the intensity of needle stimulation and the effectiveness of acupuncture. Also, a review on the effect of TCMA and MN treating non-systematic conditions, such as musculoskeletal pain, would be valuable in understanding the correlation between the treatment protocol and the outcomes for different disease characteristics.

Since no sham acupuncture is inert, this author suggests that future acupuncture research should move away from trying to prove benefits of acupuncture against sham acupuncture, which is not a true placebo. Rather, acupuncture research should focus on conducting clinical trials that compare different styles or protocols of acupuncture when treating these diverse conditions.

Higher quality clinical trials are also needed that apply standardized reporting system (STRICTA), specific outcome measurements, and treatment protocols based on patient populations and diseases characteristics. Lastly, future acupuncture studies on the female patients with AD are warranted based on the disproportionate disease prevalence and the theory of immune regulation via HPA axis.[42-44]

References

1. Dharmananda S. ADs and the Potential Role of Chinese Herbal Medicine. Sept 2006, Retrieved from www.itmonline.org/arts/autoimmune.html.
2. "Autoimmune Diseases." Womenshealth.gov, 1 Apr. 2019, www.womenshealth.gov/a-z-topics/autoimmune-diseases.
3. "Autoimmune Disease." Autoimmune Registry, Autoimmune Registry.org, 17 Dec. 2017, www.autoimmuneregistry.org/autoimmune-statistics.
4. Jacobson DL, Gange SJ, Rose NR, Graham NM. Epidemiology and estimated population burden of selected autoimmune diseases in the United States. *Clinical Immunology and Immunopathology.* 1997;84:223-43. doi:10.1006/clin.1997.4412.
5. AD Knowledge base. (2017, April 29). Retrieved from https://www.aarda.org/knowledge-base/many-americans-autoimmune-disease
6. Fairweather D and Rose NR. Women and autoimmune diseases. *Emerging Infectious Diseases.* 2004;10(11), 2005-2011. https://dx.doi.org/10.3201/eid1011.040367.
7. Fairweather D, Frisancho-Kiss S, Rose NR. Sex differences in autoimmune disease from a pathological perspective. *Am J Pathol.* 2008;173(3):600–609. doi:10.2353/ajpath.2008.071008
8. Desai MK, Brinton RD. Autoimmune Disease in Women: Endocrine Transition and Risk Across the Lifespan. *Frontiers in Endocrinology.* 2019;10:265. doi: 10.3389/fendo.2019.00265.
9. National Institute of Allergy and Infectious Diseases (Internet). Bethesda; Women's Health 2016 (Cited 2020 October 18). Sex and Gender-Specific Health Challenges Facing Women; (About one screen). Available from: https://www.niaid.nih.gov/research/sex-specific-womens-health-challenges
10. Lerner A et al. The world incidence and prevalence of AD is increasing. *International Celiac Disease.* 2015;3(4):151-155. doi: 10.12691/ijcd-3-4-8.
11. Haija AJ, Schulz SW. The role and effect of complementary and alternative medicine in systemic lupus erythematosus. *Rheum Dis N Am.* 2011;37:47-62. doi: 10.1016/j.rdc.2010.11.005
12. Barnes PM. Complementary and alternative medicine use among adults and children: United States, 2007. *National Health Statistics Reports.* 2008;10(12):1-23.
13. Zhang Y, Lao L, Chen H, Ceballos R. Acupuncture use among American adults: What acupuncture practitioners can learn from National Health Interview Survey 2007? *Evid Based Complement Alternat Med.* 2012:710750. doi: 10.1155/2012/710750. Epub 2012 Feb 22. PMID: 22474517; PMCID: PMC3296189.
14. Vickers AJ et al. Acupuncture for chronic pain: Individual patient data meta-analysis. *Arch Intern Med.* 2012;172(19):1444-53.
15. Kavoussi B, Ross BE. The neuroimmune basis of anti-inflammatory acupuncture. *Integr Cancer Ther.* 2007 Sep;6(3):251-7. doi: 10.1177/1534735407305892. PMID: 17761638.
16. Qi YC et al. Effect of acupuncture on inflammatory cytokines expression of spastic cerebral palsy rats. *Asian Pac J Trop Med.* 2014;7(6):492-5. doi: 10.1016/S1995-7645(14)60081-X.
17. We Y et al. Acupuncture Attenuated Inflammation and Inhibited Th17 and Treg Activity in experimental asthma. *Evidence-Based Complementary and Alternative Medicine: eCAM,* 2015; 340126. doi:10.1155/2015/340126
18. Hsiao LS et al. TCM approach to scleroderma: A review. *The American Acupuncturist.* 2009;50:14-17.
19. Zhou W, Benharash P. Significance of "deqi" response in acupuncture treatment: Myth or reality. *Journal of Acupuncture and Meridian Studies.* 2014;7(4):86-189.
20. Lu Z. PubMed and beyond: A survey of web tools for searching biomedical literature. Database (Oxford). 2011 Jan 18;2011:baq036. doi:10.1093/database/baq036. PMID: 21245076; PMCID: PMC3025693.
21. Berger VW, Alperson SY. A general framework for the evaluation of clinical trial quality. *Rev Recent Clin Trials.* 2009 May;4(2):79-88. doi: 10.2174/157488709788186021. PMID: 19463104; PMCID: PMC2694951.
22. Tam LS et al. Acupuncture in the treatment of rheumatoid arthritis: A double-blind controlled pilot study. *BMC Complementary and Alternative Medicine.* 2007;7:35. doi:10.1186/1472-6882-7-35
23. Lee H et al. Acupuncture for symptom management of rheumatoid arthritis: A pilot study. *Clinical Rheumatology.* 2008;27:641-645. doi 10.1007/s10067-007-0819-3
24. Bernateck M et al. Adjuvant auricular electroacupuncture and autogenic training in rheumatoid arthritis: A randomized controlled trial. *Forsch Komplementmed.* 2008;15:187-193. doi:10.1159/000141929
25. Wang R et al. The role of different therapeutic courses in treating 47 case of rheumatoid arthritis with acupuncture. *Journal of Traditional Chinese Medicine.* 2007;27(2):103-105.

continued on page 45

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

By Serene Feng, DAOM, LAc and Harry Hong, PhD, LAc

Reprinted from *Meridians: The Journal of Acupuncture and Oriental Medicine, V5.3* with corrected Table 6.

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 five 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 eight participants completed the program. In six out of the eight participants, four from the 12-week group and two from the 6-week group, a reduction in uterine size was found. A higher percentage of participants in the 12-week group (four out of five, 80%) showed a reduction of uterine size than in the 6-week group (two out of three, 66.7%). In four out of the eight participants, three from the 12-week group and one from the 6-week group, a reduction in UF volume was found. A higher percentage of participants in the 12-week group (three out of five and 60%) showed a reduction in UF volume than in the 6-week group (one out of three 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 eight 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.

Keywords: Uterine fibroids, uterine fibroid symptoms 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 pre-treatment 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 menopausal 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 angiopoiesis 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 five in the 12-week group and the latter five 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	1. Primary complaint includes one or more of the followings: • 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 2. 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	1. Met the diagnostic criteria described above for UF 2. Were between 25 and 51 years old 3. Were at pre-menopause stage 4. Had fewer than 4 missed periods within the past year 5. Signed Informed Consent and Release of Liability Forms 6. 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 7. Received a minimum of junior high school education 8. Read the provided list of the formula's ingredients to ensure no known allergies
Exclusion Criteria	1. 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 2. Had myomectomy and/or uterine artery embolization done within 6 months 3. Experienced excessive uterine bleeding with one or more of the following symptoms: a. 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 b. Menstrual bleeding extended to more than 10 days 3 months prior to the study 4. 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 two 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)
gui zhi (Ramulus Cinnamomi cassiae)	1:20	10	0.5
fu ling (Sclerotium Poriae cocos.)	1:5	10	2
bei chai hu (Radix Bupleuri)	1:10	10	1
huang qin (Radix Scutellariae baicalensis)	1:10	7	0.7
dan pi (Cortex Moutan Radicis)	1:10	10	1
chi shao (Radix Paeoniae Lactiflorae)	1:10	10	1
tao ren (Semen Persicae)	1:20	10	0.5
fa ban xia (Processed Rhizoma Pinelliae Ternatae)	1:10	8	0.8
shan zha (Crataegi Fructus)	1:5	10	2
xiang fu (Cyperus Rhizome)	1:20	7	0.35
yi mu cao (Herba leonuri)	1:10	7	0.7
ju he (Semen Citri reticulatae)	1:20	5	0.25
san qi (Radix Notoginseng)	1:1	8	8
jiu chao da huang (Wine Processed Radix et Rhizoma rhei)	1:20	8	0.4
dang gui (Radix Angelicae sinensis)	1:5	7	1.4
gan cao (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 six 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 therapies,[20-22] 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.

Results

1. Baseline Demographics

Among the 10 participants who completed the baseline UFS-QOL and received initial UF treatment, five of the five participants in the 12-week group completed the treatment and three of the five 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 eight participants. Among the eight participants, ages ranged from 35 to 51, with a mean age of 45 years old. Seven participants were Asian and one 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 eight participants who finished the program, six showed a reduction in uterine size, while one participant (PT06BDX) in the 6-week group showed an increase and one (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 eight participants.

3. Volume of UFs

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

4. Number of UFs

A decrease in number of fibroids was observed in two participants (PT12CXJ and PT12DWL) in the 12-week group and one (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), one 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 eight 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

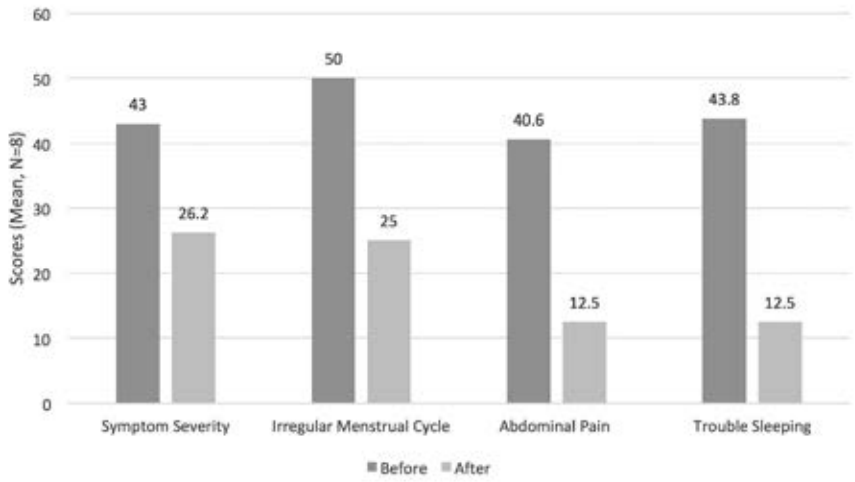
UFS-QOL Symptom Severity scores and the three additional scores for irregular menstruation, abdominal pain, and sleeping disturbance were reduced for all participants except for one, PT06AWM, who showed an increase in all scores but one, a mild reduction (33.3%) in trouble sleeping. The average scores 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.

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

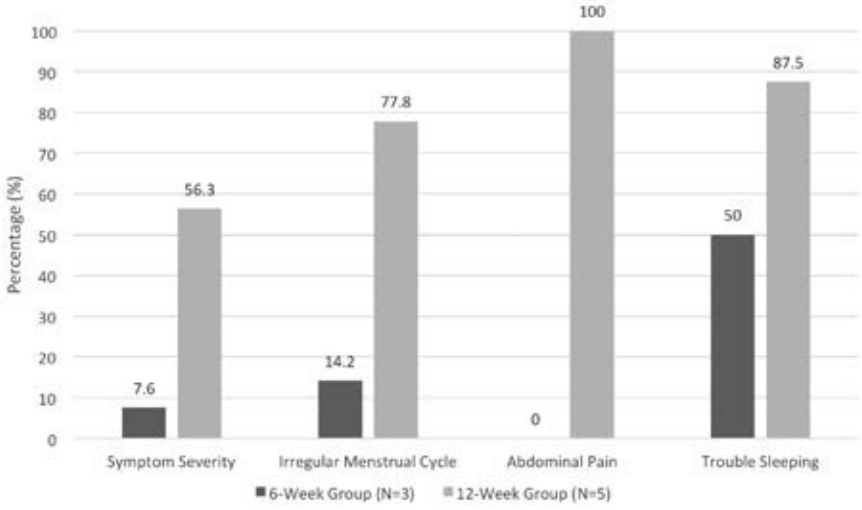
Abbreviations: SD-standard deviation; UFS-QOL-Uterine Fibroid Symptom and Quality of Life Questionnaire

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



Changes in symptom severity scores and the three additional scores, means of the 8 participants, were plotted to compare before and after treatment.

Figure 2. Decrease in Symptom Severity Scores between Two Groups

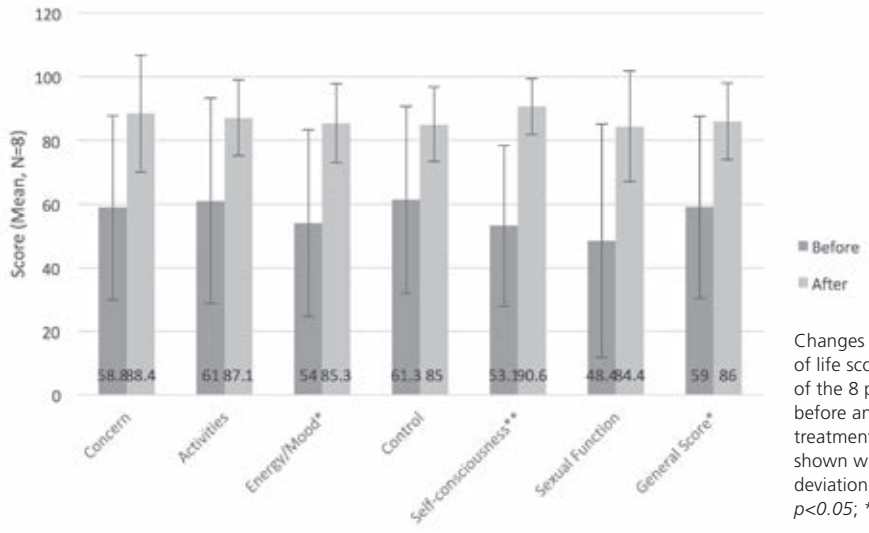


Percentage decrease in the symptom severity scores and the three additional scores were shown to compare the difference between the 6-week group and the 12-week group.

6. UFS-QOL Quality of Life

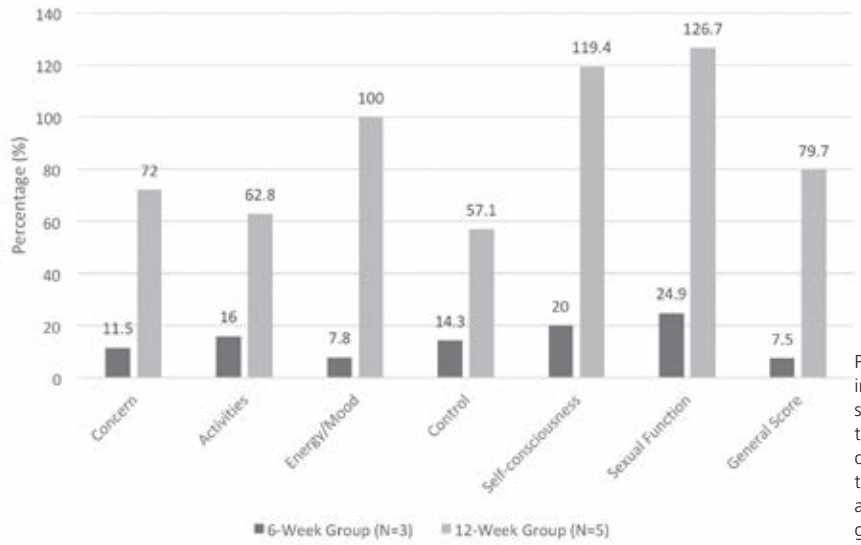
UFS-QOL Quality of Life scores for all subscales including concern, activities, energy/mood, control, self-consciousness, and sexual function increased for all participants with one exception, PT06AWM, who showed a slight decrease in all categories. The average scores before and after treatment are shown 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



Changes in quality of life scores, means of the 8 participants, before and after treatment, were shown with standard deviation indicated. *- $p<0.05$; **- $p<0.01$.

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



Percentage increase in quality of life scores were shown to compare the difference between the 6-week group and the 12-week group.

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)	Increase (%)	Before Mean (SD)	After Mean (SD)	Increase (%)	Before Mean (SD)	After Mean (SD)	Increase (%)
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 six out of eight participants and a reduction of UF volume in four out of eight 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 one 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 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 six 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.

"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 two participants for the decision to discontinue participation in the study."

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.

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 two participants for the decision to discontinue participation in the study. In fact, drinking herbal decoctions for more than one 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, seven out of eight 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

There are no conflicts of interest in this study.

References

1. Doherty L, Mutlu L, Sinclair D, Taylor H. Uterine fibroids: clinical manifestations and contemporary management. *Reprod Sci.* Sep 2014;21(9):1067-1092.
2. Lethaby A, Vollenhoven B, Sowter M. Efficacy of pre-operative gonadotrophin hormone releasing analogues for women with uterine fibroids undergoing hysterectomy or myomectomy: a systematic review. *BJOG.* Oct 2002;109(10):1097-1108.
3. Istre O. Management of symptomatic fibroids: conservative surgical treatment modalities other than abdominal or laparoscopic myomectomy. *Best Pract Res Clin Obstet Gynaecol.* Aug 2008;22(4):735-747.
4. Sankaran S, Manyonda IT. Medical management of fibroids. *Best Pract Res Clin Obstet Gynaecol.* Aug 2008;22(4):655-676.
5. Chen NN, Han M, Yang H, et al. Chinese herbal medicine Guizhi Fuling Formula for treatment of uterine fibroids: a systematic review of randomised clinical trials. *BMC Complement Altern Med.* Jan 2 2014;14:2.
6. Walker CL, Stewart EA. Uterine fibroids: the elephant in the room. *Science.* Jun 10 2005;308(5728):1589-1592.
7. Luo YKZ, J. G. *Gynecology of Chinese Medicine.* Shanghai, China: Shanghai Science and Technology; 1998.
8. Yen HR, Chen YY, Huang TP, et al. Prescription patterns of Chinese herbal products for patients with uterine fibroid in Taiwan: A nationwide population-based study. *J Ethnopharmacol.* Aug 2 2015;171:223-230.
9. Qiu PRO, Y. Y. *Ancient Chinese Medicine Classics Series.* Hainan, China: Hainan International Press and Publication Center; 1996.
10. Liu JP, Yang H, Xia Y, Cardini F. Herbal preparations for uterine fibroids. *Cochrane Database Syst Rev.* Apr 30 2013(4):CD005292.
11. Ushiroyama T, Ikeda A, Sakuma K, Ueki M. Comparing the effects of estrogen and an herbal medicine on peripheral blood flow in post-menopausal women with hot flashes: hormone replacement therapy and gui-zhi-fu-ling-wan, a Kampo medicine. *Am J Chin Med.* 2005;33(2):259-267.
12. Hu C, Wang Z, Pang Z, et al. Guizhi fuling capsule, an ancient Chinese formula, attenuates endometriosis in rats via induction of apoptosis. *Climacteric.* Aug 2014;17(4):410-416.
13. Yao Z, Shulan Z. Inhibition effect of Guizhi-Fuling-decoction on the invasion of human cervical cancer. *J Ethnopharmacol.* Oct 30 2008;120(1):25-35.
14. Spies JB, Coyne K, Guaou Guaou N, Boyle D, Skyrnarz-Murphy K, Gonzalves SM. The UFS-QOL, a new disease-specific symptom and health-related quality of life questionnaire for leiomyomata. *Obstet Gynecol.* Feb 2002;99(2):290-300.
15. Chen JX, Ji B, Lu ZL, Hu LS. Effects of chai hu (radix burpleuri) containing formulation on plasma beta-endorphin, epinephrine and dopamine on patients. *Am J Chin Med.* 2005;33(5):737-745.
16. Liu J, Burdette JE, Xu H, et al. Evaluation of estrogenic activity of plant extracts for the potential treatment of menopausal symptoms. *J Agric Food Chem.* May 2001;49(5):2472-2479.
17. Wang CC, Cheng KF, Lo WM, et al. A randomized, double-blind, multiple-dose escalation study of a Chinese herbal medicine preparation (Dang Gui Buxue Tang) for moderate to severe menopausal symptoms and quality of life in postmenopausal women. *Menopause.* Feb 2013;20(2):223-231.
18. Wang T, Guo R, Zhou G, et al. Traditional uses, botany, phytochemistry, pharmacology and toxicology of Panax notoginseng (Burk.) F.H. Chen: A review. *J Ethnopharmacol.* Jul 21 2016;188:234-258.
19. Harding G, Coyne KS, Thompson CL, Spies JB. The responsiveness of the uterine fibroid symptom and health-related quality of life questionnaire (UFS-QOL). *Health Qual Life Outcomes.* Nov 12 2008;6:99.

20. Stewart EA, Rabinovici J, Tempany CM, et al. Clinical outcomes of focused ultrasound surgery for the treatment of uterine fibroids. *Fertil Steril.* Jan 2006;85(1):22-29.
21. Ghezzi F, Cromi A, Bergamini V, Scarperi S, Bolis P, Franchi M. Midterm outcome of radiofrequency thermal ablation for symptomatic uterine myomas. *Surg Endosc.* Nov 2007;21(11):2081-2085.
22. Scheurig C, Gauruder-Burmester A, Kluner C, et al. Uterine artery embolization for symptomatic fibroids: short-term versus mid-term changes in disease-specific symptoms, quality of life and magnetic resonance imaging results. *Hum Reprod.* Dec 2006;21(12):3270-3277.

Serene Feng, DAOM, LAc has been working as a licensed acupuncturist and certified herbalist in Australia and the U.S. for nearly 20 years. She obtained her DAOM from the Atlantic Institute of Oriental Medicine in 2017. She is licensed to practice acupuncture in both New York and New Jersey, specializing in women's health, anxiety and pain management. Serene also worked as an herbal specialist and chef tea master in a NY teahouse for over 10 years.

Harry Hong, PhD, LAc received his medical degree from Beijing University of Chinese Medicine in China. He received his MS in Biology from the University of Idaho and his Ph.D. in biochemistry from the Medical College of Ohio. He did postdoctoral research at the National Institute of Health and the University of Illinois at Chicago. Harry has been practicing Chinese medicine in the U.S. since 1998. He is currently a professor in the DAOM program at the Atlantic Institute of Oriental Medicine.

Case Report

Acupuncture to Increase Range of Motion and Decrease Pain in a Post-Mastectomy Patient

By Dorene Bowe-Shulman, DAc, MAc, MMHS, Lic Ac

Dorene Bowe-Shulman, DAc, MAc, MMHS, Lic Ac is a faculty member at the New England School of Acupuncture at Massachusetts College of Pharmacy and Health Sciences (MCPHS) University. She received her doctoral degree from the Pacific College of Health and Science (formerly PCOM). Dorene maintains a private clinic in Acton, MA, and also practices at The Healing Garden Cancer Support Center in Harvard, MA. Dorene has post-graduate training in oncology acupuncture from Memorial Sloan Kettering Cancer Center in New York and holds professional certification from the National Association of Hospice and Palliative Care Acupuncturists (NAHPCA).
Email: CenterPointAcupuncture@gmail.com

Abstract

The American Cancer Society estimates that in 2020 there will be 276,480 new diagnoses of invasive breast cancer in the United States. Breast cancer treatment often involves mastectomy. Side effects of the surgery can result in pain in the surgical area and reduced range of motion in the adjacent arm and shoulder.

A 42-year-old woman was diagnosed in April 2015 with invasive ductal carcinoma in the right breast and ductal carcinoma in situ (DCIS) in the left breast. In May 2015 she underwent a bilateral mastectomy with removal of 15 lymph nodes near the right breast. In July 2015 she began chemotherapy every two weeks for four months with Adriamycin, Cytoxan, and Taxol. A 25-treatment course of radiation five times per week began at the end of November 2015 and concluded in early January 2016. From July-September 2015, the patient received four acupuncture treatments in this clinic for nausea, hot flashes and fatigue specifically related to the side effects of the chemotherapy.

Beginning in early October 2017, the patient had eight weekly physical therapy treatments to address the pain and decreased range of motion in her right shoulder, all of which had minimal effect. The patient next returned to this acupuncture clinic at the end of November 2017 with additional complaints of pain and decreased ROM of her right shoulder that she had been experiencing since the mastectomy.

A style of acupuncture referred to as the Image and Mirror approach combined with Balanced Channel Theory was used to treat her pain and decreased ROM. During the first treatment she experienced 100% improvement of pain as indicated by a VAS pain scale and a 25% improvement in range of motion. After three additional sessions, her pain resolved and her range of motion was fully restored.

The Image and Mirror approach combined with Balanced Channel Therapy may be an effective, safe, and relatively quick treatment approach to resolve pain and restore motion following a mastectomy. This technique should be further evaluated using larger sample sizes.

Key words: Acupuncture, mastectomy, pain, range of motion

"Acupuncture is routinely used as an effective treatment to address pain and ROM for orthopedic issues."

Introduction

The American Cancer Society estimates that in 2020 there will be 276,480 new diagnoses of invasive breast cancer in the United States.[1] Many of these patients' treatments will include bilateral or unilateral types of mastectomy. It is estimated that more than 100,000 mastectomies are performed each year typically to treat breast cancer or to prevent it.[2]

Common side effects of this surgery are pain and decreased range of motion (ROM) of the shoulder on the side of the mastectomy. Specific range of motion deficits are individually dependent on the location of the tumor and how the surgery was performed. Typical ROM deficits are to shoulder flexion and abduction. For some post-mastectomy patients, complications can result in pain and/or tingling in the chest wall, arm, and/or armpit.

When this type of post-surgical pain lasts longer than three months, it is defined as post-mastectomy pain syndrome (PMPS). In a 2016 study by Beyaz et al., it was determined that 20-68% of patients experienced pain for more than three months post-mastectomy. And for some, decreased ROM may accompany the pain and remain for months, even years, post-mastectomy.[3] It's also important to note that despite widespread recognition of PMPS, data suggest it often goes untreated or undertreated.[4]

Standard treatment for post-mastectomy pain (PMP) consists of stretching, exercises, myofascial techniques, and medications that include antiepileptics (gabapentin, pregabalin), tricyclic antidepressants (amitriptyline, imipramine, nortriptyline), serotonin-norepinephrine reuptake inhibitors (duloxetine, venlafaxine) and topical compounds (lidocaine, capsaicin).[5] However, despite widespread recognition of PMPS, data suggest it often goes untreated or undertreated. One reason for inadequate management of PMPS may be the lack of quality information about optimal treatment.[5]

Acupuncture is routinely used as an effective treatment to address pain and ROM for orthopedic issues. Although there are no clinical trials to date using acupuncture for PMP or PMPS, a case study from 2013 cited excellent results using acupuncture for a 47-year-old woman with PMPS after numerous other therapies failed. She was 27 months post-mastectomy.

Needles were superficially inserted around the incision area at SP-17 shidou, SP-21 dabao, ST-18 rugen, LU-1 zhongfu, REN-17 shanzhong. Other points used were DU-20 baihui and LI-4 hegu, SP-6 sanyinjiao and BL-60 kunlun bilaterally, with needle manipulation until *de qi* sensation was achieved.[6] However, for people who have had a recent mastectomy or breast surgery, needling locally near the incision is not typically recommended in the early stages of healing.

In addition, people who have had mastectomies often run the risk of lymphedema (swelling in the extremities) that is most typically caused by the removal of or damage to lymph nodes. Lymphedema is a condition that doesn't resolve and can be easily exacerbated by local irritation. Although acupuncture that included needling of the affected limb was recently shown to be beneficial for lymphedema in a 2013 study by Cassileth et al., the study cautioned that due to the risk of infection, this needling needs to be done by trained practitioners in a sterile environment.[7]

To treat the large numbers of people who experience PMPS, it's important to find safer and less risky treatments. When acupuncture is part of the treatment regimen, it is important that these approaches avoid treating recent, still-healing surgical sites and limbs affected by lymphedema.

Use of distal points is a common approach to treat pain and other musculoskeletal issues. There are many individual, extra, and empirical points that address remote or opposite areas of the body. Channel Theory is an approach that has a long history of treating pain and other issues distally. Channel Theory starts with the basic tenet of acupuncture: that *qi*, Blood, *ying* (energy that nourishes the internal body) and *wei* (protective energy) travel along the channels, making a continuous flow throughout the body. Needles are used to correct the flow of *qi*.[8] A healthy flow of these nutrients is deemed critical to a healthy body.

According to Schroeder et al., adding "balance" to Channel Theory may improve outcome. The concept of a balanced treatment has long been a part of traditional Chinese medicine as noted in the historical writings beginning with the *Ling Shu* (Ch. 2, vol. 1). While balancing *yin* and *yang* is one basic principle of Chinese medicine, balancing methods for combinations of meridians and acupoints have been described throughout the history of Chinese medicine.[9] The use of a balanced approach with Channel Theory will be referred herein as Balanced Channel Theory.

In *Chasing the Dragon's Tail*, Manaka et al. take this balance approach one step further and in doing so, propose a new system they call the "X-signal system." This system combines Channel Theory with a three-dimensional, symmetrical view of the body known as the "octahedral model."[8] The octahedral model consists of eight different quadrants that are formed by dividing the body into left/right, top/bottom and front/back sections. Their supposition is that early, more simplistic organisms from which humans evolved used less complex information systems than what currently exists. Communication transversed through these organisms in these eight different quadrants.

Manaka et al. propose that this rudimentary system of communication, retained during evolution, still resides in humans, with more complex systems overlaying it. They posit that the reason some of the more subtle techniques employed in acupuncture can be so remarkably effective is because the X-signal system is accessed in some fashion.[8]

Schroeder et al. refers to the use of this octahedral model as the "Image and Mirror Concept."[9] In this context, Image means you can project a part of the body (e.g., the arm) on another part of the body (e.g., the leg) to identify a connection. In this context, Mirror means that you also can project an upside-down picture of one body part to another body part to find connections. The Mirror approach is commonly used with auricular acupuncture: the body is reflected upside-down in the ear, with the head represented at the ear lobe and the feet at the apex of the ear.

Finding the right balancing meridians is even more useful if this is combined with the Image and Mirror Concept for finding the best points and the correct area on the chosen meridian. In combination, these two methods are extremely useful in the treatment of localized pain and can often produce immediate effects.[9]

It should be noted that these approaches are similar to the Balance Method created by the late master Dr. Richard Tan. Using Dr. Tan's method, the channel(s) with the imbalance are identified first, followed by the point(s) on these channels.[10] The channel selection starts with consideration of the variety of relationships between the channels. There are channel relationships with channels on upper and lower extremities that have the same Chinese-names, channels that are *yin/yang* pairs, and channel relationships based on the Chinese clock, to name a few.

The key is to select the best relationships between the channels for the presenting imbalance. To determine this, palpation is done along a variety of channels that have a relationship to the affected channel. Treatment is performed on the most painful balancing channel(s) in the most painful corresponding area(s) of that channel. These areas are called *ah shi* and can be areas or specific points. They are determined by a combination of the patient's sensitivity and the practitioner's determination of tightness, accumulation or denseness under the skin.

Treatment is done on this *ah shi* area with insertion of a needle into the most painful *ah shi* point. Additional needles can be applied in acupuncture or *ah shi* points; usually there are 1-2 proximal to the first needle and 1-2 distal to the first point on the acupuncture meridian. The number of needles depends on the size of the painful area on the affected meridian.[9]

According to Dr. Tan, in most cases, the frequency of treatment should be two to three times per week. As symptoms diminish, it is possible to decrease the frequency. It is to be expected that a degree of the symptom will reassert itself in the interval between the treatments. The time between treatments themselves should not be so great such that the symptoms revert to pre-treatment level.[11]

Case Description

In November 2017, a 42-year-old female Caucasian nurse practitioner of average height and slim build with a history of invasive ductal carcinoma of the right breast and DCIS of the left breast presented to the clinic to address side effects of the breast cancer treatment. The patient self-described as a happily married mother of two elementary school-aged boys. At the time of her cancer diagnosis and treatment, she regularly ran 2-5 miles each day.

In early May 2015 she had a bilateral mastectomy. That was followed by eight rounds of chemotherapy July through November 2015. From July-September 2015, the patient received acupuncture at this clinic to manage the nausea, hot flashes and fatigue resulting from the chemotherapy treatments. Although there were no signs of lymphedema, her medical team recommended she use caution with her right arm. Since 15 lymph nodes were removed from that side, no needles were inserted into it. She then received five weeks of radiation November 2015 through January 2016.

After a two year break from acupuncture, the patient returned to the clinic in November 2017 to seek relief from hot flashes and fatigue caused by monthly Lupron injections, since acupuncture had helped with these symptoms during her chemotherapy. These injections began in June 2017 to reduce risk of recurrence of the breast cancer. She also complained that the mastectomy caused restricted ROM and soreness in her right shoulder and was starting to interfere with her quality of life.

"Finding the right balancing meridians is even more useful if this is combined with the Image and Mirror Concept for finding the best points and the correct area on the chosen meridian."

No ROM issues or discomfort were present on the left shoulder. The mastectomy scar crossed the Stomach and Pericardium channels in the area of the right pectoralis. There was no diagnosis of PMPS, but even so, PMPS is highly untreated or under treated.[5] She noted that the massage, physical therapy, and chiropractic care she had received during the prior two years provided very minor, short-term relief.

The hot flashes occurred randomly and repeatedly throughout the day and also disrupted her sleep. Sweat was minimal. She felt anxiety at the surge of the hot flash. Energy averaged 4-5/10. Prior to breast cancer she experienced 8-9/10 daily on an energy scale. In addition, she experienced no libido and had vaginal dryness.

While lying supine on the table, her right shoulder flexion was 100 degrees (normal is 180 degrees) and abduction was 75 degrees (normal is 150 degrees). Her level of soreness at these positions was a 1-2/10 on a visual analog scale (VAS) pain scale. She stated it was the tightness more than the discomfort that restricted her movement.

She denied any digestive, bowel, urinary, respiratory, cardiac, head, ear, eye, nose, throat, or gynecological issues. Overall her pulses were of average strength with the Liver and Kidney pulses slightly weak. Width, depth, speed were all average. Her tongue was slightly red with red sides. The coat was slightly thinner than average.

During her initial November 2017 acupuncture treatment, the patient was diagnosed through a traditional Chinese medicine approach. It was determined that she had Kidney *yin* deficiency and Blood and *qi* stagnation as well as deficiency in the Stomach and Pericardium channels of the right upper quadrant and shoulder. Treatment that focused on the hot flashes and Kidney *yin* deficiency included bilateral needling with 30 mm x 0.18 gauge needles (Seirin-America Inc., Weymouth, Massachusetts, USA) at ST- 36 zusanli, SP- 6 sanyinjiao, KD-6 zhaohai; left HT-7 shenmen; and CV-6 qihai and yintang. Needling manipulation was done until *de qi* sensation was achieved.

Points specific for the right shoulder included eight *ah shi* points on the left Spleen and Liver channels of the lower calf, all within two inches distal and proximal to SP-6 sanyinjiao. All points were needled until a *de qi* sensation was felt. Bilateral auricular Endocrine and Kidney were both needled with a 15 mm x 0.16 gauge Seirin needle. Needles were retained for 30 minutes during each treatment. The patient was not given any lifestyle advice. During and immediately after treatment, the ROM of the right arm increased: flexion to 135 degrees and abduction to 100 degrees. Soreness had resolved.

The 2nd treatment was three weeks later in December 2017. She reported having 2-3 days with no hot flashes, and the intensity, frequency, and duration were all decreased. Her energy was up to 6-7/10 regularly. For the first two weeks after treatment she felt no soreness in her right shoulder. At the start of the 2nd treatment, the ROM of her right shoulder remained improved, although it was slightly diminished from results noted after her first treatment: flexion at 120 degrees, abduction at 90 degrees. Soreness returned to 1-2/10, the initial level of discomfort.

There were no other health history changes since the November 2017 visit. Her pulses remained very similar to that visit, with her overall pulses at average strength, although the Liver and Kidney pulses were slightly weak. Width, depth, and speed were all average. Her tongue was slightly red. The coat was slightly thinner than average. Diagnosis and treatment given was the same as the November 2017 visit. During and immediately after treatment, the ROM of the right arm increased: flexion to 150 degrees and abduction to 135 degrees. Soreness had resolved.

The 3rd treatment took place in February 2018. Approximately one week after her November 2017 treatment, her hot flashes had decreased to zero and remained minimal through January. At this appointment, however, she said hot flashes were once again disrupting sleep. The right shoulder flexion had decreased slightly again to 135 degrees and the abduction decreased slightly to 120 degrees. The soreness decreased to 0-1/10. Her energy was low for her at 5/10. Pulses were slightly weak with Liver and Kidney as the weakest. Tongue was slightly red and swollen with a thinner than average coat.

The diagnosis remained the same as the first two visits. The treatment used for the right shoulder pain, ROM deficits, and hot flashes was the same as before. The one exception was that left HT-6 yinxi was used instead of HT-7 shenmen to better treat the hot flashes caused by the Kidney yin deficiency. Presstacks (Pyonex, Seirin, 0.6 mm) were applied at KD-6 zhao-hai. Gold-plated stainless steel pressballs were used at bilateral auricular Endocrine and Kidney. The patient was instructed to leave them in for 3-5 days unless they caused discomfort at which time they should be removed. At the end of the 3rd treatment, right shoulder ROM had increased: flexion to 150 degrees, abduction to 135 degrees. Soreness had resolved.

At the 4th acupuncture treatment in April 2018, the patient reported that the results for hot flashes were similar to the 3rd treatment results. The right shoulder ROM and tightness held constant from the 3rd treatment. At the start of the treatment flexion was 150 degrees, abduction 135 degrees. Soreness was 0-1/10. The diagnosis remained the same as the first three treatments and the point prescription was the same as the 3rd treatment with the addition of left LU7. At the end of the 4th treatment, right shoulder ROM had increased: flexion to 180 degrees, abduction to 135 degrees. Soreness had resolved.

At the patient's 5th visit in June 2018 she reported normal ROM of her right shoulder (flexion 180 degrees, abduction 150 degrees) and no soreness in the Stomach and Pericardium channels of her right upper quadrant since the previous treatment. At this time, her acupuncture focused solely on her main complaint of hot flashes which presented as a diagnosis of Kidney *yin* deficiency. The points used were the same as in the 3rd and 4th treatments without the use of *ah shi* points. As of July 2020, the ROM has remained at the normal levels, the soreness has remained completely resolved and acupuncture has been used to keep her hot flashes manageable while she continues with monthly Lupron injections.

Ideally this patient would have received treatments weekly, but this was not possible due to her schedule. The treatment plan for her can be deemed successful, though, because between each treatment she never reverted back to the pre-treatment levels and ultimately her symptoms resolved.

Range of Motion, Soreness by Visit

Visit	Flexion (degrees)	Abduction (degrees)	Soreness (VAS Scale)
1st-initial	100	75	1-2/10
1st-end	135	100	0
2nd-initial	120	90	1-2/10
2nd-end	150	120	0
3rd-initial	135	120	1-1/10
3rd-end	150	135	0
4th-initial	150	135	1-1/10
4th-end	180	135	0
5th	180	150	0

Discussion

PMPS is highly untreated or undertreated. One reason for inadequate management of PMPS may be the lack of quality information about optimal treatment.[5] This case demonstrates successful acupuncture treatment of PMPS using a combination of the Image and Mirror approach and Balanced Channel Theory.

By using a combination of the Image and Mirror approach and Balanced Channel Theory, the area of the surgery did not need to be disturbed, which kept treatment in accordance with the patient's doctor who cautioned to avoid needling anywhere near potential lymphedema sites. In addition to the affected area remaining needle-free, the patient was able to test her ROM such that her feedback could determine the best points for the treatment. Also noted was the additional benefit of reduction in the patient's hot flashes and an increase in energy.

To use the Image and Mirror approach along with Balanced Channel Therapy it is important to first assess the channels that pair with the channel needing treatment. For this patient with limited right shoulder flexion and abduction and post-mastectomy scarring of the upper quadrant of the torso, the Stomach and Pericardium channels were the most affected channels.

A combination of the approaches of Channel Theory, Balance Method, and Image and Mirroring were used for this patient. With the soreness and ROM restrictions located along the Stomach and Pericardium channels of the right arm and breast area, a variety of channels that have relationships with these channels were palpated for patient sensitivity.

With each treatment, the left Spleen channel (the *yin yang* pair to the Stomach channel) and the left Liver channel (the *jue yin* pair to the Pericardium channel) were determined to be the best channels to treat with the greatest sensitivity just distal and proximal to SP-6 sanyinjiao. Eight *ah shi* points were found and needled in this area to where *de qi* was achieved. Once the points were all needled the patient flexed and abducted her right arm. After each time this needling was done, the ROM was significantly improved from baseline.

Conclusion

Breast cancer and its treatment are difficult especially when surgery is involved. Post-mastectomy pain and discomfort may affect a person's quality of life. Current treatments that include physical therapy, massage, and medication do not always resolve the problem. As discussed in this case, by using a combination of the Image and Mirror approach along with

continued on page 48

Case Report

Acupuncture and Medical *Qigong* to Treat Irritant-Induced Chronic Obstructive Pulmonary Disease

By Elizabeth Maximin, DAOM, LAc, Dipl OM (NCCAOM)

Elizabeth Maximin, LAc, DAOM, Dipl OM (NCCAOM) maintains a practice, Listening Medicine, on the island of O'ahu, Hawai'i, where she also holds workshops on Eastern medicine. In 2016, she received her master's degree with honors in Eastern medicine from the World Medicine Institute in Honolulu, Hawai'i, where she later taught acupuncture treatment strategies, Taoist medicine and *qigong*. Elizabeth received her DAOM from Oregon College of Oriental Medicine in December 2020. Email: Elizabeth.Maximin@ocom.edu

Abstract

Objective: To examine a single case as to the effectiveness of acupuncture and medical *qigong* to reduce symptoms and control the progression of Irritant-Induced chronic obstructive pulmonary disease.

Methods: A series of 25 acupuncture and external medical *qigong* treatments were conducted over a course of two years. Data was collected through patient-reported outcomes by means of verbal rating scales from 1 to 10 with 10 being high.

Results: There was significant subjective improvement in energy levels, sleep quality, stress, sputum levels and breathing function. There was no worsening of symptoms noted.

Conclusions: By accompanying the standard western medical care for treatment of chronic obstructive pulmonary disease, acupuncture and medical *qigong* may be effective at reducing the symptoms and slowing down the progression of this condition. Further clinical studies are warranted to research acupuncture and medical *qigong* independently and as adjunct treatments for this condition.

Key words: Acupuncture, medical *qigong*, chronic obstructive pulmonary disease

Background

Biomedical

Chronic obstructive pulmonary disease (COPD) is characterized by chronic inflammation of the large airways, small bronchioles, and destruction of the lung parenchyma that create abnormalities in expiratory airflow.[1] COPD has become an increasingly important condition to address because by 2030 it is projected to be the leading cause of death worldwide.[2]

As of 2018, there were an estimated 328 million total cases of COPD, however, due to underreporting, this total may be as high as 600 million.[2,3] The economic impact of COPD in developing countries is expected to increase to $1.7 trillion by 2033.[2]

Cigarette smoke and oxidative stress are the main etiologies in COPD.[4] As a result, COPD may be preventable and treatable. E-cigarettes are devices that deliver vaporized liquid nicotine to the lungs. Although it will take decades to examine the long-term impact of e-cigarettes use on the lungs, Garcia-Arcos et al. suggest that chronic electronic cigarette exposure in mice induced features of COPD. This same study noted that e-cigarettes impaired the immune defense against bacterial and viral infections.[5] Air contamination by biomass burning is also a risk factor for COPD. Genetic variations in TNF and LTA have been associated with COPD as well.[6]

COPD can be sub-grouped into chronic bronchitis (CB) and emphysema. CB is characterized by inflammation in small airways and emphysema is characterized by the destruction of lung parenchyma.[4] Guidelines from the Global Initiative for Chronic Obstructive Lung Disease (GOLD) have stopped the categorization of COPD into CB or emphysema because clinical findings tend to show a mixture of the two categories.[7]

The severity of airflow obstruction traditionally has been classified through the post-bronchodilator FEV1 value and measured by forced expiratory volume in one second. However, current research finds there may be different phenotypes of COPD, where low initial FEV1 may be due to varying underlying etiologies. Although there is no clear consensus on how to diagnose the phenotypes, the diagnosis of COPD is moving away from FEV1 measures and leaning more toward individualized diagnoses.[7]

Worldwide, 84% of smokers live in developing countries and over 90% of COPD-related deaths occur in lower middle income countries.[2] In 2016, 15.5% of U.S. adults were cigarette smokers. The prevalence was highest in American Indians or Alaskan Natives at 31.8%. In adults 25 years and older, the prevalence of smokers was highest in persons with a GED certification (40.6%) and lowest in those with a graduate degree (4.5%). The 2018 study by Kotsiou indicates that individuals with over 10 years of education presented with lower rates of COPD and found that individuals with lower income were diagnosed with more severe grades of COPD and therefore more likely to be hospitalized.[3] Prevalence was also higher in those living below the poverty level and in LGB adults.[8]

Black patients residing in London had a lower prevalence of COPD, although it is unclear if this was due to poorer detection. In the U.S., Black COPD patients were found to have a higher mortality with increased hospital admissions.[9] When compared to other ethnicities in Hawai'i, native Hawaiians with COPD had higher rates of emergency visits as well as the greatest estimated transition to congestive heart failure.[10]

"Acupuncture is reported to be an additional treatment that helps relieve COPD symptoms by reducing bronchial immune mediated inflammation and encouraging vascular and immune regulating factors.[13]"

Asthma is a common differential diagnosis for COPD and is the most common chronic childhood disease in the US. In Hawai'i, asthma disproportionately affects Native Hawaiian children at 28% compared to Caucasian children at 17.1%.[11]

Treatment for COPD includes pharmacological interventions, which are often inhaled. There is no consistent method in which adherence to treatment is assessed in COPD. Adherence relates to the extent to which the patient can execute the prescribed therapeutic regime over time. Methods of evaluation include direct methods such as biological markers and indirect methods such as patient questionnaires.[12] Acupuncture is reported to be an additional treatment that helps relieve COPD symptoms by reducing bronchial immune mediated inflammation and encouraging vascular and immune regulating factors.[13]

East Asian Medicine

COPD in traditional Chinese medicine (TCM) is referred to as breathlessness, *chuan*, which means "to pant." *The Yellow's Emperor's Classic of Internal Medicine* states that when the Lungs are diseased there is breathlessness, sweating and pain in the shoulders and back.[14] The main etiologies of breathlessness include external pathogenic factors, irregular diet, emotional factors, overwork and chronic illness.

Wind-Cold or Wind-Heat are the prominent and often initial etiologies in breathlessness. These external pathogenic invasions create an obstruction in the Lungs, which prevents the diffusing and descending of *qi*. As a result, there is breathlessness. The pathogen can also turn into Phlegm and lodge in the Interior, further obstructing the descending function of the Lung *qi*. Phlegm in the Interior obstructs the actions of the Spleen and Stomach so that fluids are not transformed properly, increasing the likelihood of the condition becoming chronic.

The Kidneys are also involved in breathlessness as they receive *qi* from the Lungs and anchor it. Kidney deficiencies can create conditions that cause shortness of breath and coughing. Less

common causes of breathlessness are Liver-*yang* or Liver-Fire rising, which can impair the descending function of the Lung.[14]

Breathlessness can be of an excess or a deficient type. In the excess type, breathing is shallow and long, sometimes with loud wheezing sounds upon exhaling. The pulse is slippery or tight and full. In the deficient type, breathing is short and rapid and the inhale is quick with no noise. The pulse is weak.[14]

Treatments for breathlessness include acupuncture and *qigong*. The NADA protocol is a treatment for smoking cessation that includes the placement of five needles in these ear points: Sympathetic, Shenmen, Kidney, Liver and Lung.[15]

Acupuncture was noted to be superior to sham needle acupuncture at eight weeks for the treatment of 72 patients with COPD in a randomized, sham-controlled and analyst-blinded trial.[16] Another study noted acupuncture's possible positive effect on regulating inflammatory cytokines in rat models with smoke-induced COPD. In this study, HDAC2 was modulated, suggesting acupuncture's potential effect on protein structure.[17]

Theoretical foundations of *qigong* include Chinese medicine energy theory, psychoneuroimmunology, the relaxation response, meditation and epi-genetics. Energy theory denotes that humans have *qi*, a vital life energy that can be impacted by an individual's genetics and environmental factors.[18]

Sub-classifications of *qigong* include spiritual healing and medical and martial *qigong*. Medical *qigong* is either internal *qigong*, which is actively practiced by an individual for self-healing or is external *qigong*, which is passively received from another person.[18] In external medical *qigong*, the practitioner works with the patient's energy by clearing *qi* blockages or *qi* stagnation by projecting healthy *qi* circulation with a mental awareness.[19]

One 12-week protocol using internal medical *qigong* improved balanced gait and balance self-confidence in patients in 95 adults with a mean age of 68.6 years. This article also examined participants who were taught a bagua-based *qigong* protocol that includes 10 forms.[20] A meta-analysis of 10 RCTs found that internal *qigong* as described through physical actions, breathing techniques, and meditation could improve lung function, exercise capacity, and quality of life in individuals with COPD.[21]

An ancient *qigong* exercise called *wuqinxi* (WQX) was examined in both a systematic review and a meta-analysis. Research indicated that WQX could improve lung function and dyspnea symptoms of COPD patients and may also help with exercise tolerance.[22] The body of current research concerning this strong evidence needs to expand in order to further explore the value of internal and external *qigong*'s effect in therapeutic interventions.[18, 22]

Case Description

The patient seeking treatment was a 75-year-old-female of Hawaiian descent. She was raised on the Big Island of Hawai'i, where she was exposed to volcanic fumes, known as "vog." Her tonsils were removed as a child. Starting in her late teenage years and into her 20s, she had a history of respiratory issues, including asthma, bronchitis, sinusitis, a tendency to catch colds, and allergies to vog and dust.

She started smoking cigarettes when she was around 18 years of age and continued to smoke until she was 40. She had pneumonia six times in her life; the most recent episode occurred when she was 73. After one bout of pneumonia in her 30s, she developed atelectasis in which her left lower lobe collapsed and took three months to re-inflate. After being diagnosed with stage 2 throat cancer in her 60s, she was treated with radiation, which eradicated the cancer. There was suspected damage to the lung and thyroid tissue after radiation. Chemotherapy was not administered.

The patient was diagnosed with COPD at the age of 74, but the illness was not given a grade of severity. Her symptoms included a severely dry mouth, lack of saliva production, hoarse voice, unproductive cough with occasional, difficult-to-expectorate white or yellow sputum, and shortness of breath upon exertion.

The patient was prescribed beclomethasone and fexofenadine to be taken daily to help with symptoms, and she received a yearly chest x-ray to monitor progression. She was also prescribed levothyroxine for hypothyroidism, simvastatin for high cholesterol, and budesonide for irritable bowel syndrome. The patient had a bowel movement every 2-3 days and frequent urination.

The patient also had a degenerative disc disorder that affected her neck and lower back by causing musculoskeletal pain ranging from 1-5 on a verbal rating scale (VRS) of 1-10. Massage was given as a palliative treatment. She experienced arthritis in the shoulders, hands, knees and feet with symptoms of numbness, coldness and inversion of the feet. In 1998, she had an arthroscopy on the left knee. She also had macular degeneration, a hearing impairment, dry skin, and fatigue.

On a 1-10 VRS scale, she rated her stress level as 8, her energy as 3, and her sleep quality as 3. She had a 20-year history of using acupuncture to treat her ailments but had not received acupuncture for the two years prior to treatment. She had been hospitalized for the flu two months prior to treatment.

Relevant Findings

The patient's tongue was scarlet red, tender, and peeled with multiple cracks. Her pulses were superficial, rapid and slippery. The *chi* position was especially weak on both sides. Her breathing was noted as short and rapid with no wheezing.

Assessment

TCM diagnosis: KD *yin* and KD *yang* deficiency; LU *qi* and LU *yin* deficiency; KD not grasping the *qi*

The KD *yin* deficiency was indicated by her rapid pulses, red peeled tongue, poor sleep quality and constipation. The KD *yang* deficiency was evidenced by her lower back pain, knee pain, hearing loss, fatigue, frequent urination and feelings of cold. Examples of LU *qi* deficiency are bronchitis, sinusitis, a tendency to catch colds, allergies, and a cough. LU *yin* deficiency was displayed in her symptoms of dry mouth, hoarse voice, dry skin, and unproductive cough with infrequent, scanty white or yellow sputum.[23] KD not grasping the *qi* was evidenced in her shortness of breath and asthma symptoms.

Treatment

TCM Treatment Principle: Tonify KD *yin* and *yang*; Tonify LU *qi* and *yin*; Tonify KD *qi*

The patient received 25 treatments over two years, with the first five treatments completed weekly and the remaining 20 treatments completed at an average frequency of once per month.

Needles were retained for 30 minutes and inserted to moderate and superficial depths. All needles received an even method of stimulation, except for KD-3 taixi, Ren-4 guanyuan and Ren-6 qihai, which were tonified by clockwise rotations of 9 and thrusting techniques.

The first treatment used 11 needles and subsequent treatments used 16 needles. For a more gentle introduction, the first treatment needled PC-6 neiguan unilaterally on the right side only. In the next three treatments, PC-6 neiguan was needled bilaterally. During the 4th and 5th treatments, PC-6 neiguan was not needled; instead, LU-7 lieque was needled. This limited the needling to one extraordinary meridian at a time.

Additionally, all treatments only used one point on the Ren channel. In the first two treatments, Ren-6 qihai was needled. In the 3rd, 4th and 5th treatments, Ren-4 guanyuan was needled. All acupuncture points were done with 0.20 x 15 mm and 0.20 x 30 mm, spring-type, DBC Brand, Korean needles.

Table 1. Acupuncture Treatment Protocol

Point Name	Explanation for Point Selection	Number of treatments used out of 5 total
LU-5 chize	Clears Deficiency-Heat from the Lung for symptoms such as dry mouth. It is also a He-Sea point and regulates water passages and counterflow of *qi*.	5
KD-3 taixi	Treats *yin* and clears Deficiency-Heat from the pathway of its channels. It anchors the *qi* and benefits the Lung, treating Excess above and Deficiency below.	5
yintang	Powerfully calms the spirit	4
GB-20 fengchi	Regulates the *yang qi* and descends excess *yang* from the head. It affects the sensory organs, especially the eyes and benefits the neck.	4
ST-36 zusanli	Supports post-natal *qi* and fosters Original *qi*. It tonifies *qi* and nourishes Blood and *yin*.	4
Ren-4 guanyuan	Fortifies the Original *qi* and benefits the Essence. It tonifies the KD yang and KD *yin*.	3
PC-6 neiguan	Unbinds the chest, regulates *qi*, and opens the *yin* linking vessel	3
KD-27 shufu	Unbinds the chest, transforms phlegm and alleviates cough	3
ST-6 jiache	Influences the jaw and teeth and is located near the salivary glands	3
LU-7 lieque	Confluent point of the Ren channel and aides in *yin* disorders. It benefits the neck, promotes the descending function of the Lung and regulates water passages.	2
Ren-6 qihai	Fosters original *qi*, tonifies *qi* and tonifies the Kidneys	2

a. Data from Deadman, Al-Khafaji and Baker, 200724

b. Data from Kim, 201523

The patient received external medical *qigong* therapy during each of the treatments. In this type of therapy, *qi* was intentionally projected through the practitioner to the patient for the purpose of aiding the meridian systems to create healthy *qi* circulation. External medical *qigong* lasted for approximately 10 minutes during needle retention. After the needles were removed, external medical *qigong* was performed for another 10 minutes.

Note: The practitioner was trained at a Taoist lineage school called the World Medicine Institute, formerly the Tai Hsuan Foundation. The school carried a branch of the Shan Tan School from China led under the direction of the 64th Heavenly Taoist master, Chang Yi Hsiang (Lily Siou, PhD). The practitioner was trained to assist Shihfu (Master Teacher) Chang in her acupuncture and herbal medicine treatments and she observed Shihfu's use of medical *qigong* during treatment protocols. The practitioner is also a trained 2nd degree Reiki practitioner and has training in meditation techniques.

The treatment goal for this patient included clearing blockages to her Lung channels and the lung organ itself as well as to strengthen the Kidney channels. To do this, as part of each treatment, the practitioner focused *qi* over, but not touching, the acupuncture point KD-1 yongquan—a technique she had observed during her apprenticeship.

Yongquan was emphasized in the practitioners training because not only is it the first point on the Kidney channel, it is at the sole of the foot where one is taught to focus as each step is taken and planted back down to the earth in *qigong* forms. *Yongquan* is also emphasized when one is opening or closing a *qigong* form so as to return energy to its source, which is associated with the Kidney.

Additionally, PC-8 laogong is the hand pair to *yongquan*, as they are located in similar mirror positions. *Yongquan* is between the 1st and 2nd toes on the plantar aspect of the feet and *laogong* is located in between the 2nd and 3rd fingers on the palmar aspect of the hands. In this case, the practitioner emitted *qi* through her own laogong to the patient's *yongquan*.

The practitioner was taught to examine her own hands after she provided a *qigong* treatment to see if she cultivated enough *qi*. The plantar aspect of the practitioner's hands were supposed to be "speckled" with colors like white, red or brown if *qi* was activated versus having only a singular coloration. During all *qigong* treatments, the practitioner would simultaneously do internal *qigong* through slow coordinated breathing while completing external *qigong* on the patient as described.

Based on the training by her Shihfu, the treatment began as soon as the practitioner touched the patient's pulses. As she felt the rapid quality in the pulse of the patient, she would use *qi* to slow it down. As the practitioner felt the weak quality in the patient's pulses, she would use *qi* to strengthen it.

Results

Acupuncture and *qigong* showed improvements in reducing COPD-related symptoms in conjunction with standard medical care. Significant subjective improvement was noted by the patient concerning her breathing function, sputum levels, energy levels, sleep quality and stress.

Over the course of treatment on a scale of 1-10, the patient reported outcomes that were measured during each treatment: energy levels increased from 3 to 7; sleep quality increased from 3 to 8; and stress decreased from 8 to 7. These all showed improvement after five treatments over two months. These then stabilized, with consistent levels during approximately one treatment per month.

Table 2. Patient Reported Outcomes

Treatment Number	Energy levels	Sleep	Stress
1	3	3	8
2	3	8	8
3	3	3	Unknown
4	7	8	4
5	7	8	7

The patient also noted that the chest x-rays of her lungs remained clear for the two years that she received treatment. There was no worsening of any symptoms described. The patient noted a general feeling of increased wellness, relaxation, and harmony of body systems as well as feeling her lungs were clearer by the 4th treatment. The patient also noted having regular bowel movements by the 4th treatment, although this was not sustained by the 5th treatment.

Tongue and Pulse

The tongue showed a decrease in the appearance of cracks and intensity of red color. The pulses generally remained slightly rapid and slippery but increased in strength and decreased in superficial quality. The speed decreased slightly.

"It was discussed with the patient that she might also be able to reduce the exacerbation of her symptoms if she avoided dairy and greasy foods, as these can cause Phlegm that easily settles in the Lungs and obstructs breathing.[19]"

Prognosis

It was recommended that the patient continue to receive acupuncture at least once a month and to receive medical *qigong* treatments ongoing so as to prevent COPD progression as well as mitigate other comorbid factors. Due to her advanced condition, it is unlikely she will completely eradicate all her symptoms, thus eventually making palliative and prophylactic care the main protocols.

It was discussed with the patient that she might also be able to reduce the exacerbation of her symptoms if she avoided dairy and greasy foods, as these can cause Phlegm that easily settles in the Lungs and obstructs breathing.[19] Although there were no substantial dietary changes made during the course of treatment, the patient noted she made efforts to reduce sugar and refined carbohydrates and to increase her water intake.

Discussion

The two main etiologies of COPD are smoking cigarettes and exposure to toxic environmental inhalants, which can cause chronic breathlessness in future years. This case highlights the need for enhanced collaboration between educational and medical systems to promote proactive preventive measures designed to mitigate smoking at an early age. This case discussed how both of these factors may have caused the patient's COPD. Furthermore, while growing up, the patient had experienced numerous lung-related disorders, which may have modified her lung inflammation response, thus making her more susceptible to COPD as she aged.[4]

COPD mostly affects those who are less educated or who live in developing countries.[2] COPD also affects certain ethnicities more than others. This includes Hawaiians, which points to inequitable health disparities among COPD populations.[13]

Effective treatment options for COPD include pharmaceuticals, acupuncture and medical *qigong*. It is recommended that the combination of these treatments be further researched to indicate whether or not they can have a greater impact when used together compared to standard western care alone. Acupuncture has shown evidence to potentially reverse lung damage. More information is needed to determine if this holds true for both new and advanced cases of COPD.

It is important to note that the patient used acupuncture on and off for over 20 years, including during her radiation treatments, which may have been a component in stabilizing her lung health. Q*igong* as a whole has indicated potential benefits by increasing exercise tolerance in COPD patients.[21] Medical *qigong* has produced encouraging evidence that it can assist in mitigating the comorbidities of COPD and, as such, suggests the need for further research on this specific topic.

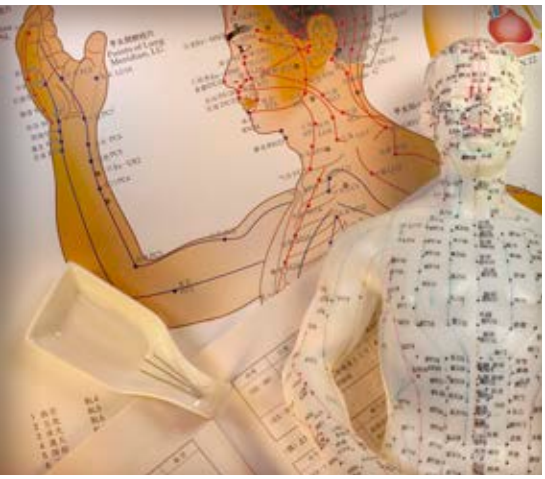
Conclusion

The case discussed here illustrates how acupuncture and medical *qigong* treatments helped a woman of Hawaiian descent in Hawaii to potentially stave off the progression of her COPD symptoms. Additional research is recommended on the use of acupuncture and medical *qigong* to aid in treatment of COPD symptoms.

References

1. Zhao Q, Meng M, Kumar R et al. The impact of COPD and smoking history on the severity of COVID-19: A systemic review and meta-analysis. *Journal of Medical Virology.* 2020;92(10):1915-1921. doi:10.1002/jmv.25889
2. Quaderi SA, Hurst JR. The unmet global burden of COPD. *Glob Health Epidemiol Genom.* 2018;3. doi:10.1017/gheg.2018.1
3. Kotsiou OS, Zouridis S, Kosmopoulos M, Gourgoulianis KI. Impact of the financial crisis on COPD burden: Greece as a case study. *European Respiratory Review.* 2018; 27(147):170106. doi:10.1183/16000617.0106-2017
4. Shi J, Li H, Yuan C, Luo M, Wei J, Liu X. Cigarette smoke-induced acquired dysfunction of cystic fibrosis transmembrane conductance regulator in the pathogenesis of chronic obstructive pulmonary disease. *Oxidative Medicine and Cellular Longevity.* 2018 (6567578) doi:https://doi.org/10.1155/2018/6567578
5. Garcia-Arcos I, Geraghty P, Baumlin N et al. Chronic electronic cigarette exposure in mice induces features of COPD in a nicotine-dependent manner. *Thorax.* 2016; 71(12):1119-1129. doi:10.1136/thoraxjnl-2015-208039
6. Reséndiz-Hernández JM, Ambrocio-Ortiz E, Pérez-Rubio G et al. TNF promoter polymorphisms are associated with genetic susceptibility in COPD secondary to tobacco smoking and biomass burning. *Int J Chron Obstruct Pulmon Dis.* 2018; 13:627-637. doi:10.2147/COPD.S147688
7. Sharma BB, Singh V. Nonsmoker COPD: Is it a reality? *Lung India.* 2017; 34(2):117-119. doi:10.4103/lungindia.lungindia_56_17
8. Jamal A. Current Cigarette Smoking Among Adults — United States, 2016. *MMWR Morb Mortal Wkly Rep.* 2018; 67. doi:10.15585/mmwr.mm6702a1
9. Gilkes A, Ashworth M, Schofield P et al. Does COPD risk vary by ethnicity? A retrospective cross-sectional study. *Int J Chron Obstruct Pulmon Dis.* 2016; 11:739-746. doi:10.2147/COPD.S96391
10. Davis J, Tam E, Taira D. Disparate rates of utilization and progression to combined heart failure and chronic obstructive pulmonary disease among Asians and pacific islanders in Hawai'i. *Hawaii J Med Public Health.* 2016; 75(8):228-234.
11. Uchima O, Grennon R. Insights in public health. *Hawaii J Med Public Health.* 2018; 77(3):68-71.

continued on page 44



Dosage: An Acupuncturist's Art Form

By Jane Grissmer, MAc, Dipl Ac (NCCAOM)

Jane Grissmer, MAc, Dipl Ac (NCCAOM) is former professor and currently adjunct faculty in the Masters of Acupuncture program at the Maryland University of Integrative Health where she served as chair of Theory Division from 2009-2017. Practicing and teaching acupuncture since 1980, she contributes clinical experience as well as ongoing scholarship in the philosophical and energetic foundations of Asian medicine. Her most recent publication is "The Geometry of Emotions: Healing Emotions through the Lens of Chinese Medicine," *The American Acupuncturist*, Winter 2015.

Abstract

This article discusses the art of dosage, or number of needles used, within a single acupuncture treatment. It explores the author's clinical experience in refining 'just the right amount' for any one patient. Over-treating or under-treating are significant in that each miss the mark and fail to optimally adjust the *qi*. Guidelines for assessing 'just the right amount' are posited and discussed: *Treat at Threshold, Discern Norm, Remember Law of Least Action*. These guidelines arise from the author's learning history in treatment observations with JR Worsley; the *Law of Least Action* as taught by Worsley and implied in the *Su Wen*; and concepts from Korean Acupuncture as taught by Peter Eckman.

Keywords: Acupuncture, dosage, treat at threshold, discern norm

Dosage is a major conversation topic among herbalists but rarely one among acupuncturists. Dosage is defined as frequency of treatment visits as well as the number of needles used per treatment. While this article focuses on dosage within an individual treatment, i.e., number of needles used, the same principles may apply in terms of treatment frequency.

When studying acupuncture with JR Worsley in England in the late 1970s, his teaching included '*The Law of Least Action*,' a principle found in homeopathy. Worsley often spoke of homeopathy in high regard as the only other natural medicine that applied the Laws of Nature in its application. He therefore included this principle in his teaching and applied it to his acupuncture treatments. The Law defined the most efficacious treatment as the one that achieved the desired outcome with the fewest needles.

The *Law of Least Action* can find a Chinese medicine parallel in the concept of a Su Wen treatment. According to Andrew Prescott, "Su Wen Ch.5 about wu-wei ('non-action') seems pretty clear; 'non-action' is surely doing only what is necessary without excess force ('wu-shi' 'non-striving'). That sounds like 'law of least action' to me."[1]

"Worsley often spoke of homeopathy in high regard as the only other natural medicine that applied the Laws of Nature in its application. He therefore included this principle in his teaching and applied it to his acupuncture treatments. The Law defined the most efficacious treatment as the one that achieved the desired outcome with the fewest needles."

In my clinical experience I have found that the number of needles used can make the difference between a treatment that heals and one that creates an aggravation or even sets the person back. In short, the Goldilocks principle of just the right amount, not too much or too little, applies. But how does one know what that is?

For years, Worsley's treatments have continued to inform me. He had an unusual ability to design an elegant treatment that met the person where they were—an amazing knack for judging this right amount. Sometimes his treatments were minimal and sometimes they applied many bilateral points. Are there principles that can guide practitioners in determining dosage?

In assessing the optimum dosage for any one patient there are three guiding principles that I teach to acupuncture students in designing their treatments: *Treat at Threshold, Discern Norm, Remember Law of Least Action.*

What is Threshold?

Threshold is "the point at which a stimulus is of sufficient intensity to begin to produce an effect."[2] Not just any effect, but an effect in acupuncture that is in 'just right' relationship between energy (*yang*) and matter (*yin*). Matter in our body is the structure: cells, organs, bones, fascia, etc. that give form to our body. Energy is the vibratory aspect or *qi* that gives movement to our body and flows within and through our form. This 'just right' or working relationship between energy and structure is the threshold the treatment needs to reach.

This dynamic interaction for each person is unique, and the clinician must find the proper calibration for that unique person. It is that sweet place where the form is receiving energy or *qi* so the *qi* can be absorbed or conducted by the form. This principle has implications for sensing effective dosage.

In any acupuncture treatment the dosage can be at the patient's threshold, which is optimal, or it can be too much (overdose) or too little (underdose). Both miss the mark of effective treatment. One can over-dose or under-dose. In either case the treatment is not as effective as it could be.

- In overdose, the number of needles and points chosen is greater than what the patient's norm or structure can conduct efficiently. There will necessarily then be an aggravation on any level of body, mind or spirit. What seemed like a good idea turns out not to be so. Treatment itself gets in the way or locks things up. One has to be particularly aware of this possibility when treating elderly because the structure or *yin* aspect of an elderly person is waning. The organs, tissues, etc. diminish in their functional capacity and are therefore less able to conduct *qi*. In this case *yang* is overriding *yin*.
- In underdose, the number of needles or points chosen do not meet the threshold of *qi* required to produce an effect on the structure or form. In this case *yang* is under-riding *yin*. This manifests characteristically with a robust, solid, dense structure and weak *qi* pulse; or often when the Spirit is inert and must be enlivened for a change to register and the points chosen do not give that result; or in a patient with very strong or excess *qi* who needs to be met with an equally strong force—as in the number of needles and points chosen. In any of these examples, the patient is left not feeling touched or engaged by the treatment.

Worsley always reached for this threshold. He never left a treatment until he saw a desired effect—and if he didn't get it, he went back to the drawing board of his assessment tools. What will give a rise to this person? What will settle this person? And how is that translated into an effective treatment?

What is Norm?

Worsley taught the concept of 'Norm' as a criterion to guide ongoing treatment. This was defined as a pulse picture with all 12 Officials registering the same quantity in volume. Very little else was offered in the early days as most patients coming for consultation were not close to Norm, and I did not have the privilege of seeing patients with him over the long term.

It was therefore music to my ears when Peter Eckman described a concept from Korean Constitutional Acupuncture in the 1990s and now in his 2014 book, *The Compleat Acupuncturist. Essentially*, "… all the Organs and their Meridians are not equally strong in a state of health, but display a pattern characteristic of that individual."[3] This became for me a description of Norm as it applies both to intensity as well as to the unique arrangement of Officials for that

individual. In my experience treating through the lens of Five Elements and Causative Factor, once the CF Official is treated appropriately all Officials register a harmonious quality as well as a pattern of arrangement of the Officials characteristic for that individual.

It became part of my practice to discern this understanding of Norm by noting when my patient reported feeling well and flourishing. Special note of their pulses was taken. If there was balance and harmony among the Officials that matched their report, I would take note of the quantity and relative balance among Officials as likely their norm. This became an imprint in my mind as to their norm and referred to in subsequent treatments. For example, in treating an excess Wood presentation, the wiry quality relaxes on all 12 Officials and the quantity on Wood reduces from +2 to +1.

Clinical evaluation then focuses on the intensity of the pulse characteristic for that individual, i.e., at what volume is reduction sufficient to produce health. Similarly in a deficient Water presentation, the deep quality rises from -2 to -1 and all Officials rise or settle evenly, with the Water in third position remaining slightly less in volume.

Norm is important especially if one sees the same patients repeatedly over time. The principle is the same as in watering plants. The right amount of water creates a strong and healthy plant but too much makes the plant soggy, so it may rot.

If treatment pushes a patient beyond their norm, they may not feel very well and may therefore suffer an aggravation. This effect has occurred in my clinic more than once. A patient I was treating reported feeling well, but when more treatment was applied she lost that sense of wellness. For example, in treating an Earth constitution, several points on Spleen and Stomach began to bring this patient from lethargy to aliveness, but with the addition of Stomach 8 she fell back into a tired state. She herself said to me, "There seems to be an optimum number of needles for me and when I go past that, it isn't so good." I knew she was correctly expressing the principle of overtreatment beyond her norm. That subtle balance of her unique *yin* to *yang* had been momentarily lost.

Law of Least Action Revisited

Worsley referred to this principle because it made sense to him, but the Law of Least Action is significant to remember in treatment dosage for another reason. *Qi* is more akin to the laws of physics than to the biomedical model. In physics one of the classic laws is known as the Law of Least Action. In essence, "Nature takes the shortest, most efficient route to accomplish things."[4] If we apply this to our acupuncture treatments, more needles than necessary can add complications to the smooth flow of *qi* and muddy the effect.

"*Qi* is more akin to the laws of physics than to the biomedical model. In physics one of the classic laws is known as the Law of Least Action."

Also, in a self-regulating and self-healing system it is important to know what wellness is and when no treatment is the best one—an application of the Law of Least Action. In a culture where many patients are constantly striving for better, it is significant to let them know that how they are right now is just right. If it is on the mark, that in itself is a powerfully effective treatment. If we can sense a normative pulse and assess the patient's reporting, we might actually be able to discern this moment.

Conclusion

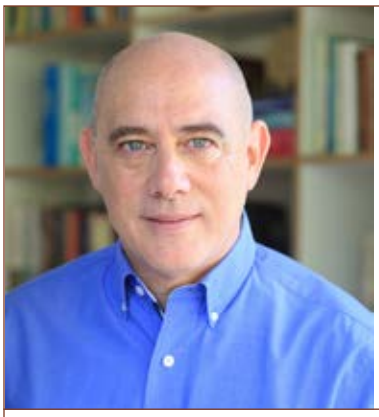
My guiding criteria are sensory inputs rather than scientific ones. The effect of *qi* intervention towards 'just the right amount' defies mechanistic indicators. The latter may be able to measure changes in quantities of *qi* but not what is optimum for any one person. To discern the latter requires the development of sensory observational skills that palpate or sense change in pulses, the patient's demeanor, working signs and symptoms, and the change in the room that occurs when the *qi* meets its threshold.

In the moment of the treatment the clinician calibrates through their senses how sensitive or reactive the patient is to the intervention. It is in this subtle domain of *qi* that lies the most reliable indicators of a treatment's effect.

Dosage is an art form. These guidelines can help a practitioner effect what is known in the classics as a Su Wen treatment: one needle that is in perfect alignment with the needs of the patient. The great physician Hua To was admired for his ability to treat patients effectively using only one or two needles. Like Hua To and like Worsley, shouldn't we all strive for the highest in our art form?

References

1. Prescott, Andrew. Email exchange, 8/13/2019.
2. Dictionary.com, 2020.
3. Eckman, Peter. The Compleat Acupuncturist. Singing Dragon, 2014, p 69.
4. Chopra, Deepak, MD. www.linkedin.com/today/post/article/01/14/14.



Interview: LifeBiotic Founder, Yair Maimon, DOM, PhD, AC

Interviewed by Eric Raymond Buckley, DOM, LAc

Yair Maimon, DOM, PhD, AC is the clinical director of Refout Integrative Medical Center, Tel Aviv, Israel. He is also president of the International Congress of Chinese Medicine in Israel (ICCM) and president of the European TCM Association. With over 30 years of clinical, academic, and research experience in the field of integrative and Chinese medicine, Dr. Maimon combines scientific research with inspiration from a deep understanding of Chinese medicine. As head of R&D at LifeBiotic Medical Research, Ltd., his outstanding and innovating reassert has led to intranational patents in herbal medicine in cancer care.

What was your motivation to start researching herbal formulas for cancer?

My answer is pretty simple. My vision and motivation in practicing Chinese medicine is to do whatever I can to relieve suffering. On this, I can say by accident, almost more than 25 years ago in 1995, while in China visiting oncology clinics, I was inspired about our ability to help cancer patients and, at the same time, address everybody's fear about treating cancer.

I realized on one hand there is a great opportunity and on the other hand there is great need to change something in our profession. When I started practicing in the '80s, I was told that Chinese medicine can treat everybody, but cancer was excluded. I was therefore surprised that in China, not only was it included, but they had remarkable results with cases, while we have less good results in the West. I was impressed at the results I was seeing from China and from the quality of life that patients had there compared to what I was seeing at the hospital that I was working in.

At that time, I was the head of the integrative medicine unit in my hospital and therefore allowed into all the departments to treat patients with acupuncture and complementary medicine. All except oncology. And when I asked why, they said because "your medicine is not evidence-based." So this was like the great resistance—at least a great excuse for resistance—that I've seen in any department. It was a challenge to me—I felt like life was kind of putting me on the spot or navigating me to this direction.

Protectival (LCS101) is the most researched TCM formula in cancer care. What brought you to invest 15 years in this research?

I realized that herbal medicine is where I was having consistent results in my clinic. Acupuncture was becoming accepted at this time, but herbal medicine was totally outcast. So what I did is the opposite to what we see in western medical research. In the normal order of medical research you find the molecule, you try it on cells, animals, slowly building up to humans until you create a viable medicine.

I did what we're all doing in the clinic—I saw results and I said, "If we have results, we can prove it; we can create an evidence base." And I realized that I had to research one formula and follow the western logic of human research, but I did it in the reverse order. I started with clinical results, moved to double blind randomized human research, and then to cases by following up with patients, animal studies, cell studies, and mechanisms.

What were the main findings of the research?

There are three features that we found in our research. One is that the formula not only kills cancer cells but kills them selectively. It kills cancer cells without affecting normal cells. And the second thing is about the protection of healthy cells. When we put chemotherapy on cancer cells and normal cells together, it kills both of them. When we added in the LCS101 (Protectival), it selectively protects the normal cells and kills the cancer cells. And I can say lastly that one of the concerns of oncology was the fear of potential interactions, so we did a lot of research combining the formula with different chemotherapies and different cells. We repeatedly we saw that there is no negative interaction, and, in fact, there is an additive effect when you use both of them.

I personally pray that the medicine of the future will combine chemotherapy (western medicine) with herbal medicine and acupuncture because I think the mutual effect will prove itself with research that shows better results and less side effects. This is actually what we are seeing today from a lot of acupuncture research as well. We are creating a much better quality of life for patients.

You have conducted research in Israel, in Europe, and in the U.S. What is the difference in the challenges between the different continents and countries?

The medical system in Israel is very open. We have Chinese medicine well-embedded within the medical system and in the hospitals. There is a lot of openness and curiosity for Chinese medicine in Israel so there was interest here. Once I finished research in one place, other places were more open. In America, we collaborated with top researchers from MD Anderson, Miami Children's Hospital, and we even got collaboration for writing our conclusive evidence with Professor David Rossinthall from Harvard Medical School.

So in America, once you show evidence, you can find collaboration. If you're coming with no evidence, you have no chance. I think that's the basic difference that I see. In Israel, even if you come with a story, there is still an openness. But in the States you need evidence to find openness. I also take inspiration from the SIO, the Society of Integrative Oncology, which I am a member of. I see how it's been developing over the last few years, with collaboration by the major hospitals that have integrative oncology centers. I can see that America is taking the lead on the integrative part.

"I personally am open to help any researcher who wants to do research in herbal medicine and oncology, to share my own path and its difficulties and how to overcome them."

America is extremely dominant in acupuncture research, and I hope and believe that we will see more herbal medicine research, although as I mentioned, the challenges in America are greater. The opportunities and the good researchers are there, so I hope we will see more collaboration. I personally am open to help any researcher who wants to do research in herbal medicine and oncology, to share my own path and its difficulties and how to overcome them.

You have been nominated recently as the President of the European TCM Association and you are also deeply involved with the U.S. TCM community. What are the differences between the two communities and what can they learn from each other?

One of my aims is to create a better unity of Chinese medicine, especially in the western world. Since I have studied in Europe, in the States, and in China, and since I'm a TCM certified practitioner, I understand the systems and I know the leaders in these countries.

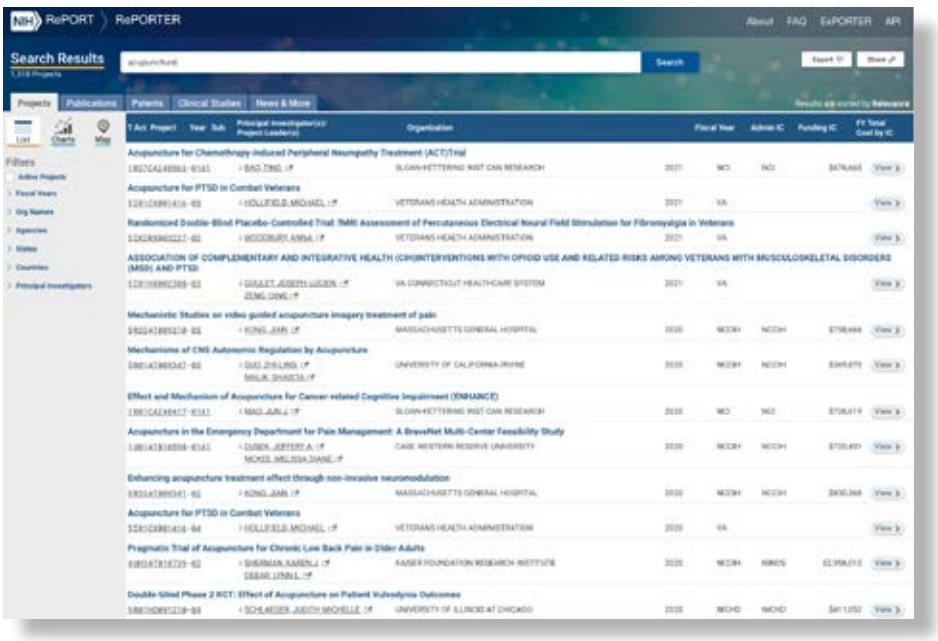
One of my biggest goals is to create better communication and exchange between Europe and America. I think Europe can learn a lot from America and vice versa. There's a great diversity of laws in Europe compared to what has been created in the States. One of my dreams is that in eastern medicine, we will have a foundational education that is recognized worldwide, so we can easily cross borders and become an international community and not so much a national community.

Eric Raymond Buckley, DOM, LAc is a staff member of Christus St. Vincent Regional Medical Center's Department of Integrative Medicine and Palliative Care, Santa Fe, New Mexico. He is a certified Oncology Acupuncture Specialist and has been a dedicated political advocate for the acupuncture profession for over 10 years.

Has the NIH Funded Acupuncture Research Projects?

By Jennifer A. M. Stone, MSOM, LAc

The federal government is funding acupuncture research. To see who's receiving funding and what projects are funded, I took a look at the NIH website that provides this information. The Research Portfolio Online Reporting Tools (RePORT) provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH-supported research. https://report.nih.gov/



One useful tool available on the RePORT website is the RePORTER (RePORT Expenditures and Results) module. RePORTER allows users to search a repository of both intramural and extramural NIH-funded research projects. Viewers can access publications and patents that result from NIH funding.

On December 17, 2020, I accessed the RePORTER tool and typed "acupuncture" into the search field. The results showed 1,318 projects currently in process that include acupuncture as a search term. To see who is getting funding and what projects are getting funded, please scroll through the results: https://reporter.nih.gov/search/QkgFgWkte0Kk189OYcpHhA/projects

HAS THE NIH FUNDED ACUPUNCTURE RESEARCH PROJECTS?

Projects that received funding include but are not limited to: research studies on humans and animals; conference grants; training grants for fellowships; planning grants; program grants; and business and technology grants. Most of the grants are awarded to universities, medical schools, research institutions and research societies. In 2019 the Society for Acupuncture Research received a $30,000 conference grant. See details: https://reporter.nih.gov/search/QkgFgWkte0Kk189OYcpHhA/project-details/9685661

In the past, but not currently, funds have been awarded to AOM schools. In these cases, the AOM school partnered with a university; research faculty from both schools teamed up and applied for the funding together.

Many institutions were awarded funding for the large *NIH Chronic Low Back Pain Study in Medicare Patients*. A good example of this is the Kaiser Foundation Research Institute project titled *Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults*. https://reporter.nih.gov/search/QkgFgWkte0Kk189OYcpHhA/project-details/10245396

Another high-profile study you might want to look at is the multi-center study led by Jeffrey Dusek at Case Western Reserve Medical School titled *Acupuncture in the Emergency Department for Pain Management: A BraveNet Multi-Center Feasibility Study*. Details can be found here: https://reporter.nih.gov/search/QkgFgWkte0Kk189OYcpHhA/project-details/10044074

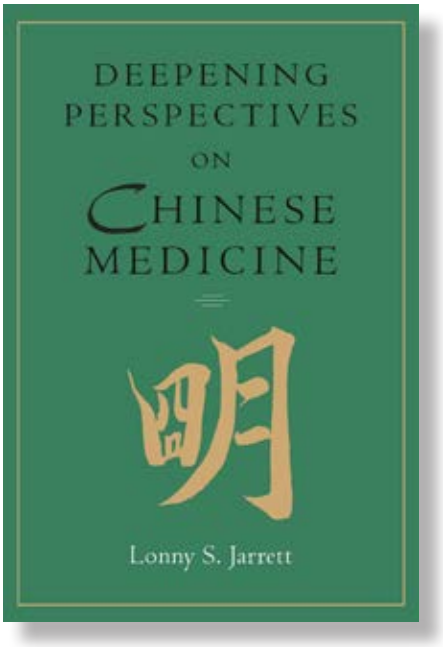
NIH funding has also been awarded for research core grants. These grants support new offices or program infrastructure at universities and research institutions and are designed to help support the research activities at the institution. Core grants are usually collaborative and involve multiple departments. A good example is Susan Dorsey's Administrative Core award received through the University of Maryland, Baltimore. Details about this project can be found here: https://reporter.nih.gov/search/QkgFgWkte0Kk189OYcpHhA/project-details/9940786

ACUPUNCTURE AND MEDICAL QIGONG TO TREAT IRRITANT-INDUCED COPD CONTINUED FROM PAGE 36

12. López-Campos JL, Quintana Gallego E, Carrasco Hernández L. Status of and strategies for improving adherence to COPD treatment. *Int J Chron Obstruct Pulmon Dis.* 2019; 14:1503-1515. doi:10.2147/COPD.S170848
13. Suzuki M, Muro S, Ando Y. A Randomized, Placebo-controlled trial of acupuncture in patients with chronic obstructive pulmonary disease (COPD): The COPD-Acupuncture Trial (CAT). *Arch Intern Med.* 2012; 17(11):878-886. doi:10.1001/aechinternmed.2012.1233
14. Maciocia G. The Practice of Chinese Medicine. Edinburgh: Churchill Livingstone/Elsevier; 2008.
15. National Acupuncture Detoxification Association. https://acudetox.com/. Accessed February 27, 2019.
16. Feng J, Wang X, Li X, Zhao D, Xu J. Acupuncture for chronic obstructive pulmonary disease (COPD). *Medicine (Baltimore).* 2016; 95(40). doi:10.1097/MD.0000000000004879
17. Li J, Wu S, Tang H et al. Long-term effects of acupuncture treatment on airway smooth muscle in a rat model of smoke-induced chronic obstructive pulmonary disease. *Acupuncture in Medicine.* 2016; 34(2):107-113. doi:10.1136/acupmed-2014-010674
18. Klein P. Qigong in cancer care: Theory, evidence-base, and practice. *Medicines(Basel).* 2017; 4(1):2. doi:10.3390/medicines4010002
19. Putiri AL, Close JR, Lilly HR, Guillaume N, Sun G-C. Qigong exercises for the management of type 2 diabetes mellitus. *Medicines (Basel).* 2017; 4(3):59. doi:10.3390/medicines4030059
20. Stahl JE, Belisle SS, Zhao W. Medical qigong for mobility and balance self-confidence in older adults. *Front Med.* 2020;7. doi:10.3389/fmed.2020.00422
21. Tong H, Liu Y, Zhu Y, Zhang B, Hu J. The therapeutic effects of qigong in patients with chronic obstructive pulmonary disease in the stable stage: A meta-analysis. *BMC Complementary and Alternative Medicine.* 2019; 19(1):239. doi:10.1186/s12906-019-2639-9
22. Yu F, Xin M, Liu N, Huang N, Lu J. The Qigong Wuqinxi for chronic obstructive pulmonary disease. *Medicine (Baltimore).* 2019;98(30). doi:10.1097/MD.0000000000016633
23. Deadman P, Al-Khafaji M, Baker K. A Manual of Acupuncture. Hove, East Sussex, England: Journal of Chinese Medicine Publications; 2011.
24. Kim HB. Handbook of Oriental Medicine. Anaheim, California: Acupuncture Media; 2015.

EFFECTIVENESS OF ACUPUNCTURE IN TREATING FOUR AUTOIMMUNE DISEASES CONTINUED FROM PAGE 16

26. Wang C et al. Acupuncture for pain relief in patients with rheumatoid arthritis: A systematic review. *Arthritis & Rheumatism.* 2008;59(9):1249-1256. doi:10.1002/art.24009
27. Lee MS et al. (2008). Acupuncture for rheumatoid arthritis: A systemic review. *Rheumatology.* 2008;47:1747-1753. doi:10.1093/rheumatology/ken330
28. Casimiro L et al. Acupuncture and electroacupuncture for the treatment of RA: Review. Cochrane Database of Systemic Reviews, 2002;3. Art No: CD003788. doi:10.1002/14651858.CD003788
29. Cabanillas JG et al. Impact of Electroacupuncture on Quality of Life for Patients with Relapsing-Remitting Multiple Sclerosis under Treatment with Immunomodulators: A randomized study. *BMC Complementary and Alternative Medicine.* 2012;12:209. https://dx.doi.org/10.1186%2F1472-6882-12-209
30. Criado MB et al. (2017). Effects of Acupuncture on Gait of Patients with Multiple Sclerosis. *The Journal of Alternative and Complementary Medicine.* 2017;23:852-857. doi: 10.1089/acm.2016.0355
31. Donnellan CP et al. Comparison of the effect of two types of acupuncture on quality of life in secondary progressive multiple sclerosis. *Clinical Rehabilitation.* 2008;22:195-205. doi: 10.1177/0269215507082738
32. Greco CM et al. Acupuncture for systemic lupus erythematosus: A pilot RCT feasibility and safety study. *University of Pittsburgh School of Medicine, Lupus.* 2008;17:1108–1116. doi:10.1177/0961203308093921.
33. Shang HX et al. (2015). Moxibustion combined with acupuncture increases tight junction protein expression in CD patients. *World Journal of Gastroenterology.* 2015;21(16):4986-4996. doi:10.3748/wjg.v21.i16.4986
34. Bao C et al. Randomized controlled trial: Moxibustion and acupuncture for treatment of CD. *World Journal of Gastroenterology.* 2014;20(30):11000-11011. doi:10.3748/wjg.v20.i31.11000
35. Bao C et al. Different brain responses to electro-acupuncture and moxibustion treatment in patients with CD. *Scientific Reports.* 2016;6:36636. doi: 10.1038/srep36636
36. Joos S et al. Acupuncture and moxibustion in the treatment of active Crohn's disease: A randomized controlled study. *Digestion.* 2004;69:131-139. doi: 10.1159/000078151
37. Cella DF et al. "Validation of the Functional Assessment of Multiple Sclerosis quality of life instrument. *Neurology,* July 1996;47(1):129-139. Doi:10.1212/WNL.47.1.129
38. Yang XY et al. Characterization of deqi sensation and acupuncture effect. *Evidence-Based Complementary and Alternative Medicine.* 2013, Article ID 319734. doi:10.1155/2013/319734
39. Zhou W et al. Significance of "Deqi" response in acupuncture treatment: Myth or reality. *Journal of Acupuncture and Meridian Studies.* 2014;7(4):86-189.
40. Vaillant AAJ, Vashisht R, Zito PM. Immediate Hypersensitivity Reactions. [Updated 2020 Sep 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK513315/
41. Carrillo JLM et al. Immune System Disorders: Hypersensitivity and Autoimmunity. 2018; IntechOpen:14-17. https://dx.doi.org/10.5772/intechopen.75794.
42. Rao RT. et al. Modeling the Sex Differences and Interindividual Variability in the Activity of the Hypothalamic-Pituitary-Adrenal Axis. *Endocrinology.* 2017;158(11):4017-4037.
43. Wang SJ et al. Regulative effect of electroacupuncture on hypothalamus-hypophysis-gonad axis in different stages of estrous cycle in rats, *Academic Journal Research (Zhen Ci Yan Jiu).* 2007;32(2):119-24. ISSN:1000-0607.
44. Chen BY. Acupuncture normalizes dysfunction of hypothalamic-pituitary-ovarian axis. *Acupuncture & Electro-Therapeutics Research*. 1997;22(2):97-108.
45. Acupuncture Continuing Education, https://www.acupuncturecontinuingeducation.com/your-one-stop-guide-to-acupuncture-needles
46. Xie YM, Xu S, Zhang CS, Xue CC. Examination of surface conditions and other physical properties of commonly used stainless steel acupuncture needles. *Acupunct Med.* 2014 Apr;32(2):146-54. doi: 10.1136/acupmed-2013-010472. Epub 2014 Feb 12. PMID:24522003; PMCID: PMC3995252.
47. Colagiuri B, Smith CA. A systematic review of the effect of expectancy on treatment responses to acupuncture. *Evidence-Based Complementary and Alternative Medicine,* vol. 2012, Article ID 857804, 12 pages, 2012. https://doi.org/10.1155/2012/857804



Sneak Preview
Expected publication date: April 2021

Deepening Perspectives on Chinese Medicine

by Lonny S. Jarrett

Reviewed by Carlos Chan Cordeiro, PhD

Deepening Perspectives on Chinese Medicine

Spirit Path Press

www.spiritpathpress.com

Expected publication date: April 2021

850 pages

ISBN: 978-0-9669916-2-8

Have you ever wondered what integral medicine primarily informed by an East Asian medical tradition might look like? *Deepening Perspectives on Chinese Medicine* by Lonny S. Jarrett is an excellent example of innovative explorations in East Asian medicine. After decades of teaching and practicing, the author elaborates a manifesto that establishes a medical practice that is congruent with integral principles as they are developing in this day and age.

Integral theory is a meta-theory, a theory of theories, an elaborate perspective on systems of systems that have been laid out since Hegel and include Henri-Louis Bergson, Alfred North Whitehead, Teillard de Chardin, Sri Aurobindo, and Jean Gebser as some of the most relevant in this field. Jarrett states:

> "Integral theory offers the potential for the emergence of a more holistic medicine that embraces the sciences of structure and function equally in better service of humanity. … Just as the synthetic nature of Chinese medicine [CM] allows it to subsume the quantitative sciences, so too does the meta-framework of integral theory allow it to subsume the complementary worldviews of East and West, induction and deduction, holism and reductionism, functional and structural perspectives, into a single, whole, unified, view."

The author also believes that as more evidence is produced to support the effectiveness of CM therapeutics, the profession often fails to address the implications of East Asian medicine's sophisticated ontology in a way that faces current postmodern challenges. The book aims to present a clear vision that is both clinically and scholarly relevant in this specific context.

Jarrett believes that East Asian medicine has the potential to bring interiority to a globalizing medical practice that looks into itself from a 15 billion-year perspective. As such, he describes the need to willingly enact the critical virtues for a much-needed radical change on a collective as well as a personal level.

Western psychology and modern philosophy can and do mesh with eastern and western philosophy and religion. In this book, East Asian medicine concepts are elaborated and interpreted within an integral and developmental context with emphasis on the subtle dimensions of the self. Outlined with a spiritual undertone that is clear and abundant in detail, Jarrett discusses the transmission of a meta-narrative of human health and development within an evolutionary context that does not dissociate from any developmental quadrants of life.

The book is divided into three main parts. Part I establishes the foundations and perspective necessary for an appreciation of medicine as a method for catalyzing development. Part II elaborates on this foundation within the context of the five-element tradition and

includes several detailed case studies on this topic. Part III presents the integral practice of Chinese medicine through an elaboration of integral theory. The relationship of states, stages, quadrants, lines, and types to the practice of integral medicine is considered here, supported by the integral perspectives of diverse authors, including Sri Aurobindo, Jean Gebser Teilhard de Chardin, Ken Wilber, and Liu Yiming as they bring their enlightenment to bear on the subject of human development.

Based on quite *sui generis* interpretations of East Asian medicine, the author attempts to elaborate a practice of medicine that is congruent with integral principles as they develop in the context of 21st-century challenges. Some conjectures could very well be challenged by peers. But as this is a medicine that is recreated at each time it is enacted, there is certainly plenty of room for more or less liberal interpretations. The kind of liberal interpretation found in this book may well lead the reader to regard it as more authentic than other traditions.

As the clinical practice of East Asian medicine expands in the wake of an increasingly globalized movement, we observe a great flourishing of professional creativity. Lonny Jarrett is the kind of teacher and writer that may rescue those dismayed by a lack of humanism and meaningfulness in their medical practices. Yet, while presenting a paradigm that is in discursive competition with existing hierarchies of discursive power, this is not for the faint of heart. I found myself at times inspired and at times challenged by Jarrett's vision but always stimulated and engaged.

The tone of the discourse woven throughout the book reflects an experiential praxis that places greater emphasis on qualitative assessments and the development of meaningful relationships between subjects in consciousness rather than the quantitative assessments of single, isolated objects. Grounded in phenomenological-sounding claims about experiential praxis that are beyond religious dogmas—because they are eventually self-evident to the aware practitioner—Jarrett sees disease from a developmental perspective that includes subtle and very subtle dimensions as they involve consciousness, free will, and choice, endeavoring to support the patient to become increasingly aware, shift perspective, and remove themselves as the source of their own and others' suffering.

Again, in the author's own words:

> "This book is about helping practitioners become exemplars of the type of change that we'd like to catalyze in our patients. For this is the basis of guiding patients to remove themselves as a source of unnecessary suffering. What I'm conveying here is a dharmic medicine predicated on the recognition of oneness. … This text is written to a very specific demographic of people. It is my feeling that practitioners of Chinese medicine are among the most sophisticated systems thinkers on the planet.
>
> Not suggesting that CM adopt integral theory as a replacement for the perennial philosophy and worldview on which it is based. Rather, explicating CM as the most substantial basis upon which the emergence of integral medicine might be based. Thus, we may appreciate the strengths of CM in this regard as well as note weaknesses that are necessarily complemented by other perspectives."

"Jarrett believes that East Asian medicine has the potential to bring interiority to a globalizing medical practice that looks into itself from a 15 billion-year perspective."

This discourse is an exemplar tradition where a psycho-analyzed, spiritualized practice is very different from many of the forms in China and East Asia. The demographic who will appreciate it the most are those who are immersed in a western modern to post-post-modern cultural background.

At some point in the path of studying Chinese medicine, etymological research can become crucial. Supported by the work of Elisabeth Rochat de la Vallé, F. Claude Larre, Heiner Fruehauf, and others, Lonny Jarrett continues to elaborate sophisticated, abundant etymological interpretations meant to be applicable in the clinical encounter between the EAM practitioner and its patient.

Deepening Perspectives on Chinese Medicine presents a narrative that is not founded on the lineage teachings of any branch of East Asian medicine, recreating myths and the etymology of ancient terms and meanings. This discussion may lead the reader to conclude that, indeed, where medicine and spirituality are merged, a liberated consciousness has everything to do with ancient Chinese medicine.

Carlos Chan Cordeiro, PhD practices East Asian medicine in Portugal. He lived for almost a decade in China and holds degrees from three Chinese universities: Nanjing TCM University (BSc TCM), China Pharmaceutical University (MSc in Clinical Pharmacy applied to Chinese medicine integrative oncology) and Tianjin TCM University (PhD in Basic Theories of CM applied to cancer treatment and network pharmacology). Carlos is HSK5-level proficient. Email: chan.cordeiro@gmail.com

Balanced Channel Therapy, acupuncture may be a successful treatment for this condition. More research using larger sample sizes is needed to determine the efficacy of using the Image and Mirror approach along with Balanced Channel Therapy treatments for this population.

References

1. How Common is Breast Cancer? American Cancer Society. [Internet]. 2020 Jan 8. [cited 2020 Sep 11].; [p. 1]. Available from: https://www.cancer.org/cancer/breast-cancer/about/how-common-is-breast-cancer.html
2. Mastectomy and Double Mastectomy [Internet]. [cited 2020Sep13]. Available from: https://www.brighamandwomens.org/surgery/surgical-oncology/resources/mastectomy
3. Beyaz SG, Ergonenc, JS, Ergonenc, T, Sonmez, OU, Erkorkmaz, JS, Altinoprak, F. Postmastectomy pain: A cross-sectional study of prevalence, pain characteristics, and effects on quality of life. *Chin Med* [Internet]. 2016 [cited 2020 Sep11]: 129(1); [p. 66-71]. doi: 10.4103/0366-6999.172589
4. Melton C. Optimal management of post-mastectomy pain syndrome [Internet]. *Clinical Pain Advisor.* 2019 [cited 2020Sep11]. Available from: https://www.clinicalpainadvisor.com/home/topics/neuropathic-pain/optimal-management-of-post-mastectomy-pain-syndrome/
5. American Society of Regional Anesthesia and Pain Medicine. Postmastectomy Pain Syndrome: Presentation and Management [Internet]. ASRA News - Postmastectomy Pain Syndrome: Presentation and Management - American Society of Regional Anesthesia and Pain Medicine. [cited 2020Sep11]. Available from: https://www.asra.com/asra-news/article/180/postmastectomy-pain-syndrome-presentation
6. Bauml J, Mao JJ, Basal C. Treatment of post-mastectomy pain syndrome with acupuncture: A case report [Internet]. *Acupunct Med* [Internet]. 2013 [cited 2020Sep12]: 32; [p 183-185]. Available from: https://pubmed.ncbi.nlm.nih.gov/24240772/
7. Cassileth BR, Zee KJV, Yeung KS, Coleton MI, Cohen S, Chan YH et al. Acupuncture in the treatment of upper-limb lymphedema [Internet]. American Cancer Society Journals. John Wiley & Sons, Ltd; 2013 [cited 2020Sep12]. Available from: https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/cncr.28093
8. Manaka Y, Itaya K, Birch S. Chasing the Dragon's Tail. Brookline, MA: Paradigm Publications; 1995. p. 17-26.
9. Schroeder S, Meyer-Hamme, Zhang, J, Apple, Friedemann, Hu, W. An acupuncture research protocol developed from historical writings by mathematical reflections: A rational individualized acupoint selection method for immediate pain relief. *Evid Based Complement Alternat Med.* 2013 Jan 29; doi: 10.1155/2013/256754. PubMed PMID: 23431334; PubMed Central PMCID: PMC3569893.
10. hrubbs, J. Conflicting nationalisms: The foundations of channel theory. *J Chin Med.* 2012; Oct,100(1):53.
11. Tan R, Rush SC. How to use this book. In: Twelve and Twelve in Acupuncture Unique Point Applications and Case Studies for Effective Pain Treatment. 2nd ed. San Diego, CA: 1991. p. 7-9.

Thank you!

JASA is here because of YOU—
our authors,
our Editorial Board,
JASA's supporting organizations & associations,
our advertisers
and our readers!

CCAOM
Council of Colleges of Acupuncture and Oriental Medicine

ACAOM
Accreditation Commission for Acupuncture & Oriental Medicine

American Society of Acupuncturists

NCCAOM
NATIONAL CERTIFICATION COMMISSION FOR ACUPUNCTURE AND ORIENTAL MEDICINE

Advertising Index

ADVERTISE in JASA

Our readership continues to grow! Please join us – you will find ad specs, deadlines and ad contract details at: www.meridiansjaom.com in the Advertising Information tab. First time ads will be discounted 15%, with a 10% discount on ads in four consecutive issues. For more information, please write to: meridiansjaom@gmail.com.

One Stop Shopping for Needles, Herbs and more!

LHASA OMS®

EVERYTHING ACUPUNCTURE™

www.LhasaOMS.com

+1 (800) 722-8775

UNRIVALED Selection

UNBEATABLE Prices

UNMATCHED Service