J Acupunct Meridian Stud 2013;■■(■):■■–■■

Available online at www.sciencedirect.com

Journal of Acupuncture and Meridian Studies

journal homepage: www.jams-kpi.com

RESEARCH ARTICLE

Direct Moxibustion to Treat Spleen *Qi* and *Yang* Deficiency Fatigue: A Pilot Study

Tracy L. Thorne [1,*,4], Doug A. Hanes [1], Heather Wild [2], Agatha Colbert [3]

[1] *NCNM, Helfgott Institute, 2220 SW 1st Avenue, Portland, OR 97201, USA*
[2] *Rentrek, 4749 NE 79th Avenue, Portland, OR 97218, USA*
[3] *6240 A1A South Unit 403, St. Augustine, FL 32080, USA*

Available online ■ ■ ■

Received: Dec 11, 2012
Revised: Mar 12, 2013
Accepted: Mar 21, 2013

KEYWORDS
direct moxibustion;
moxa;
moxibustion;
okyu;
tonnetskyu;
Sawada

Abstract
Background: Direct moxibustion (*tonnetsukyu*) is commonly used in Japanese Meridian Therapy (JMT) acupuncture. Limited research suggests that indirect moxibustion may be beneficial for treating fatigue, but no studies to evaluate direct moxibustion have been conducted in the United States.
Objectives: To assess patient safety and tolerability, explore the usefulness of four outcome measures [Flinders Fatigue Scale (FFS), SF-36, skin conductance (SC) at the Source acupoints (*Yuan*) and heart rate variability (HRV)] and to obtain preliminary data on the effectiveness of a specific dosing regimen of direct moxibustion for patients with spleen *qi* and *yang* deficiency fatigue (SQYDF).
Design: and setting: A pre- to poststudy comparison was conducted at the National College of Natural Medicine.
Patients: Eleven female volunteers aged 25—60 years were enrolled.
Intervention: Three to five rice grain to thread-sized moxa cones were burned on 11 acupuncture points, once per week for 8 weeks.
Results: Eight participants completed the study. The most common adverse events (AEs) were temporary worsening of fatigue (27 reports in 7 participants), lightheadedness (9 reports) and headache (7 reports). Symptomatic improvement was seen on the SF-36 Energy/Fatigue scale ($p = 0.003$), the SF-36 Social Function scale ($p = 0.008$) and the FFS ($p = 0.014$). SC at acupoints showed no consistent diagnostic baseline meridian patterns among participants. Usable HRV data from four participants showed an improved low frequency/high frequency (LF/HF) ratio in three of the four.

* Corresponding author. NCNM, Helfgott Institute, Helfgott, 2220 SW 1st Avenue, Portland, OR 97201, USA.
E-mail: tracy@tracythorne.net (T.L. Thorne).
[4] Clinic address: 3641 SE 28th Avenue, Portland, OR 97202, USA.

pISSN 2005-2901 eISSN 2093-8152
http://dx.doi.org/10.1016/j.jams.2013.04.003

Please cite this article in press as: Thorne TL, et al., Direct Moxibustion to Treat Spleen *Qi* and *Yang* Deficiency Fatigue: A Pilot Study, Journal of Acupuncture and Meridian Studies (2013), http://dx.doi.org/10.1016/j.jams.2013.04.003

Conclusions: Direct moxibustion is safe and tolerable in patients with SQYDF. The FFS and SF-36 are useful outcome measures for evaluating the effects of direct moxibustion. HRV may also be a useful objective outcome measure. SC measurements did not correlate with SQYDF diagnosis or with symptomatic improvement in this small patient sample.

1. Introduction

Moxibustion is an essential treatment modality in traditional Chinese medicine, with roots that may be older than the use of acupuncture needles. A survey of classical medical literature reveals centuries of writing on the clinical application and benefits of at least 20 different forms of moxibustion [1].

Despite the long appreciated clinical benefits of moxibustion, its use appears to be undervalued in the US. As reasons for not utilizing moxibustion therapy, practitioners cite time commitment, exposure to smoke and the lack of US malpractice insurance coverage for some forms of moxibustion (direct) [2]. In contrast to the US, the use of moxibustion for a myriad of diseases and conditions is still widespread in East Asia. In Japan, which separates licensures for acupuncture and moxibustion, a common form of moxibustion is called tonnetsukyu ("scarring", "penetrating" or okyu) [3]. Practitioners form tiny moxa cones weighing approximately 1 mg and ranging in size from a "rice grain" to a "thread" [4]. The cone is placed on the skin, with either a drop of water or ointment as a barrier, and burned down to the skin. In Japan, the species of moxa used for moxibustion is *Artemisia princeps*, which is refined and aged for long periods of time. The resulting grade of moxa produces less smoke and odor and combusts at a lower temperature than other grades of moxa [5]. A well known moxa treatment in Japan was developed by Sawada Ken in the early 20th century, after years of studying moxibustion in Korea. Called *taikyoku* (*Ch. taiji*), this treatment utilizes a core set of acupoints with modifications based on the clinical presentation of the patient [6–8]. Fukaya Isaburo is another modern moxibustionist who introduced the practice of placing a bamboo tube over burning moxa cones, to provide deeper penetration of the therapeutic stimulus [9].

Though some clinical research on direct moxibustion has been conducted in Japan and Korea, the few articles available in English are basic science studies [10,11]. Research on moxibustion in China has primarily investigated the use of indirect moxa (moxa poles, moxa on the needle, and moxa cones placed on various mediums such as garlic, ginger or aconite) [12]. One clinician, Guang-Rong Li, is investigating direct moxa, but unlike the technique used in our study the cones are much larger and the dose he proposes involves intentional blistering and suppuration [13]. A paucity of moxa research is available in the US, with no published studies of the direct moxibustion technique.

Clinically, moxibustion is frequently used to treat fatigue from spleen *qi* and *yang* deficiency. This is a common diagnosis in Western acupuncture clinics due to the unhealthy effects of modern diet and lifestyle [14], and closely aligns with the common complaint of fatigue seen in many biomedical clinics [15]. At the acupuncture and naturopathic clinics of the National College of Natural Medicine (NCNM), the diagnosis of fatigue and malaise describes the most common chief complaint. Evidence from a systematic review of 40 moxibustion studies and a single study utilizing both moxa and psychological intervention, supports the use of indirect moxibustion for treating patients with the western medical diagnosis chronic fatigue syndrome (CFS) [12,16]. However, few previous studies have assessed moxibustion as a sole intervention for fatigue and no studies have evaluated the use of direct moxibustion for treating spleen *qi* and *yang* deficiency fatigue (SQYDF). In addition, no previous study has specifically addressed patient tolerance and adverse events (AEs) associated with direct moxibustion.

Given the lack of available published research on direct moxibustion for SQYDF, minimal reporting on patient tolerability or AEs and the current reluctance to utilize direct moxibustion in the US, we set out to test a methodological approach for conducting a human study utilizing the combined Sawada/Fukaya protocol-technique to treat the common clinical complaint of fatigue.

Our goal was to answer the following questions:

- Can patients with SQYDF be recruited and retained in an 8-week clinical trial of direct moxibustion?
- Is the direct moxibustion technique safe and tolerable in US participants?
- What experience do patients report when direct moxibustion is applied?
- Will a standardized *taikyoku* direct moxibustion protocol administered once per week for 8 weeks provide symptomatic improvement in patients with SQYDF?
- Do the outcome measures SF-36 and Flinders Fatigue Scale (FFS) characterize symptomatic change associated with direct moxibustion treatments?
- Is there a consistent skin conductance (SC) pattern among the 24 Source acupoints in patients diagnosed with SQYDF?
- Do SC patterns at the 24 Source acupoints change as a result of eight direct moxibustion treatments?
- Will heart rate variability (HRV) change as a result of a series of direct moxibustion treatments in this participant sample?

2. Methods

The study was approved by the NCNM Institutional Review Board. Both genders were recruited from the local community utilizing posters at businesses and libraries and postings on the NCNM website. All participants signed an

Please cite this article in press as: Thorne TL, et al., Direct Moxibustion to Treat Spleen *Qi* and *Yang* Deficiency Fatigue: A Pilot Study, Journal of Acupuncture and Meridian Studies (2013), http://dx.doi.org/10.1016/j.jams.2013.04.003

informed consent. There was no compensation for participation in the study. The study was conducted between March and August 2011 at NCNM's Helfgott Research Institute.

2.1. Inclusion and exclusion

Telephone screening and in-person physical examination determined whether potential participants met the following symptomatic criteria: complaints of fatigue, lack of energy/strength/vitality, lack of concentration, a feeling of being cold, and loose stools. Physical examination inclusion criteria were: findings of a puffy, pale, swollen or scalloped tongue, palpatory coolness in the lower abdomen, or weakness in the area of acupoints CV12—CV6, and a spleen deficient pulse pattern. The pulse analysis utilized is known as "pulse strength comparison," and is typical of Japanese Meridian Therapy (JMT) acupuncture [17]. The abdominal diagnosis (fukushin) utilized is also derived from JMT, which refers to the abdominal reflex zones from chapter 16 of the classical Chinese medical text the Nan Jing. Tongue diagnosis was used according to Traditional Chinese Medicine (TCM) practice. Excluded were individuals who had an acute or chronic illness including CFS, those diagnosed with Epstein-Barr or Lyme disease, or chronic parasitic diseases, or those on psychotropic drugs. Also excluded were individuals who had experienced acupuncture or moxa treatments during the previous 6 months and those whose physical examination suggested multiple TCM diagnoses that confounded a primary diagnosis of spleen *qi* and/or *yang* deficiency (e.g., pronounced blood stagnation or *qi* stagnation that resulted in heat signs).

2.2. Moxibustion test screening session

The direct moxibustion intervention was described to potential participants as follows: "Direct moxibustion involves burning a small amount of the dried leaves of a plant at acupuncture points on the skin. The moxa is placed on a smear of protective ointment, then lit with an incense stick and snuffed out. People who receive moxibustion report a warming sensation at the site, though sometimes they report a momentary stinging sensation.". Potential participants were then asked if they would be willing to experience a test session of moxibustion. The acupuncturist who performed the screening, had been licensed for 6 years for clinical evaluations and treatments, and had been trained in both TCM and JMT. She first demonstrated direct moxibustion on herself at the left LI11 acupoint using a transparent test tube over the moxa, so that the participant could observe the burning moxa cone. Participants then received a test direct moxa treatment at four non-acupuncture skin sites (lower arm, abdomen, shin and back). If after the test session they were willing to initiate the 8-week course of treatment, they were enrolled in the study.

2.3. Intervention

For 8 sequential weeks, on the same day, at approximately the same time of day, participants received direct moxibustion as a sole intervention for SQYDF. During the first

Figure 1 Bamboo boards, jointed bamboo tube and one length of pre-rolled moxa.

three treatments, three moxa cones (rice grain to thread size) were burned at each of 11 acupoints. For treatments 4—8, five moxa cones were burned at each acupoint. Acupoints were treated in the following order: left TE4 (back of the wrist on the crease), CV12 (midway between the navel and sternum), bilateral ST36 (just below the knee), GV12 (below the spinous process of T3), bilateral BL20 (at the level of the 11th thoracic vertebra on the back), bilateral BL23 (at the level of the 3rd lumbar vertebra on the back), and bilateral LI11 (at the lateral elbow). The low back points were administered in a cross-cross pattern (R BL20, L BL23, L BL20, R BL23). Acupoint location was determined by using the standard point location definitions and palpation of the site for skin texture changes (moisture, tension, depression).

The moxa was pre-rolled using two bamboo boards (11 $\times$ 8 cm) (Fig. 1). A small amount of "purple cloud ointment" (*Shiunko*) was first placed on the skin. *Shiunko* contains *dang gui* (*Angelica sinensis*), *zi cao gen* (*Lithospermum spp.*), sesame oil, and beeswax. The width of the Shiunko smear was slightly larger than the circumference of the tiny moxa cone (approximately 0.5—2 mm). The cone was lit with incense (Seiun Joss sticks) and then covered over with a jointed bamboo tube (diameter of 13—14 mm, approximately 3 cm to one joint in bamboo, 7 cm for the opposite end) (Fig. 2). The tube remained on the skin until the moxa stopped burning (about 2—3 seconds). The remaining ash was flattened and left in place. Additional moxa cones were stacked on top of this until the desired number of cones had been burned. Initially, the short end of the bamboo tube was

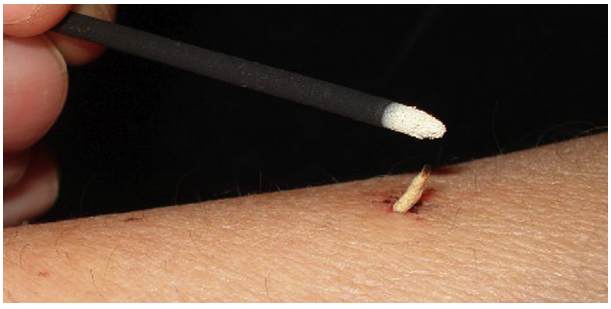

Figure 2 Rice grain cone of moxa on Shiunko cream.

Please cite this article in press as: Thorne TL, et al., Direct Moxibustion to Treat Spleen *Qi* and *Yang* Deficiency Fatigue: A Pilot Study, Journal of Acupuncture and Meridian Studies (2013), http://dx.doi.org/10.1016/j.jams.2013.04.003

placed over the lit moxa cone. If the participant reported a muted sensation of heat, then the long end of the tube was used to allow for more oxygen and thereby increase the felt heat. This modification was recorded in the participant's file.

Research determining the most efficacious dose of "felt heat" from moxibustion is limited [18,19]. Clinically, practitioners vary in their recommended degree of felt heat required to deliver an effective dose of direct moxibustion, which ranges from the patient not needing to feel anything, to a required sensation of "hot". In this study, a specific range of sensations was described to the participant, which spanned feeling "at least some sense of warmth" to a "zip" or "sting" that "should last only momentarily" with each cone. If the participant perceived the stimulus to be outside of this range, then she was urged to tell the practitioner, so that the cone density, size, end of tube, or how quickly the bamboo tube covered the burning moxa, could be modified. The acupuncturist repeatedly checked with participants to ensure that they were in the "dosage range."

One acupuncturist (TT) performed all moxibustion treatments. At each treatment, she first reviewed any AEs reported by the participant from a prespecified symptom checklist. The checklist was developed from a systematic review of AEs associated with moxibustion [20]. Each treatment took approximately 15 minutes. Each study visit lasted a total of 30 minutes.

2.4. Outcome measures

Two subjective and two objective outcome measures were evaluated for their usefulness in a future clinical trial. The FFS and the SF-36 were administered at baseline and study completion. SC measurements at the 24 Source acupoints were obtained at each study visit and electrocardiographic (ECG) readings for HRV were obtained at baseline and study completion.

2.4.1. The FFS

The FFS [21] is a 7-item scale that measures various characteristics of fatigue experienced over the past 2 weeks. The items tap into commonly reported themes of how problematic fatigue is, the consequences of fatigue, frequency, severity, and patients' perception of fatigue's association with sleep. Six items are presented in Likert format, with responses ranging from 0 (not at all) to 4 (extremely). Total fatigue scores range from 0 to 31, with higher scores indicating greater fatigue. A clear description of the term "fatigue" is provided in the initial instructions to the scale.

2.4.2. The short form SF-36

The short form SF-36 [22] is a self-administered, 36-item questionnaire that measures health-related quality of life in eight domains: physical functioning, limitations due to physical problems, bodily pain, general health, vitality, social functioning, limitations due to emotional problems, and mental health. Each domain is scored separately from 0 (worst score) to 100 (best score). Two summary scores (Physical Function and Mental Health Summary) can be calculated from information obtained in the 8 domains.

2.4.3. Skin conductance

SC at the 24 Source points (Yuan) on the wrists and ankles was obtained with the AcuGraph 3 Digital Meridian Imaging System (Miridia Technology, Inc, Meridian, ID 83646, USA). This system, which consists of software, an electronic control unit, and a probe set (ground and probe), electrically measures galvanic skin resistance. The software then calculates and reports the conductance at each measured point in normalized units (nu). The system was chosen because of its proven single operator reliability ($r = 0.86$) for measuring conductance at the Source acupoints [23].

2.4.4. HRV

HRV data was used to assess possible autonomic nervous system changes associated with the stimulation of acupoints [24]. Electrocardiograph interbeat intervals were acquired with the J & J Engineering I-330-C2+ 12 channel biofeedback system (J & J Engineering, Inc, Poulsbo, WA, USA). At baseline and 1 week after completing the final moxibustion treatment, participants were instrumented with the ECG leads of the system while 6 minutes of data were collected. The middle 5 minutes of data were analyzed for total variability and low frequency/high frequency ratio (LF/HF). The HRV software provided by Biomedical Signal Analysis Group, Department of Applied Physics, University of Kuopio, Kuopio, Finland was used to interpret the J & J signals.

2.5. Statistical analysis

For this exploratory study, we used descriptive statistics to summarize recruitment, retention, and compliance, and to document AEs. Pre- to post-symptomatic changes were analyzed with paired *t* tests in order to test for significance of changes over the course of the trial. Limited HRV data were analyzed for effect size relative to standard deviation. A post-study anonymous survey was used to assess participant satisfaction. Analysis of SC data for individual Source points and left-right averages was conducted, using repeated measures ANOVA, to determine significant differences at any time points, and linear regression on time point, and to test for consistent changes across time. *Yin—yang*, left—right, and upper—lower difference data, once computed from data on appropriate Source points, were assessed with simple *t* tests in order to test the significance of changes from the beginning to the end of the trial. Although analysis of SC data involved a large number of tests, the goal was largely to describe outcomes, since it was quickly apparent that trends did not support hypothesized effects. All analyses were carried out using SPSS v. 19.

3. Results

During a 3-month recruitment period, 26 individuals responded to posted advertisements. Initial history and physical examination screenings yielded 13 females who met the SQYDF diagnostic criteria. Twelve completed an in-person screening, which included tongue, pulse and abdominal examination and a test moxibustion session. One individual declined to initiate the series of treatments due to feeling unwell the day after her test session. She believed

Please cite this article in press as: Thorne TL, et al., Direct Moxibustion to Treat Spleen *Qi* and *Yang* Deficiency Fatigue: A Pilot Study, Journal of Acupuncture and Meridian Studies (2013), http://dx.doi.org/10.1016/j.jams.2013.04.003

Table 1 SF-36 and Flinders Fatigue Scale symptomatic outcome measures.

SF-36 Sub-scale	Pre*	Post*	*p*
Physical function	63.3 (25.5)	73.3 (21.8)	0.198
Role of physical function	40.3 (30.5)	59.0 (28.3)	0.041
Bodily pain	61.8 (26.6)	73.7 (21.0)	0.021
General health	44.4 (20.5)	45.8 (20.6)	0.408
Vitality	23.9 (9.3)	43.1 (13.9)	0.003‡
Social function	33.3 (24.2)	64.6 (23.8)	0.008†
Role-emotional	62.5 (23.0)	64.4 (19.4)	0.758
Mental Health	52.9 (16.7)	58.7 (14.3)	0.021
Flinders Fatigue	26.1 (4.0)	17.9 (7.7)	0.014†

* All entries are mean (standard deviation).
† Statistically significant ($p < 0.05$).
‡ Significant after Bonferroni adjustment ($p < 0.005$).

the fluorescent lights in the lab or the moxibustion may have been the cause. Eleven female participants, aged 25—60 years, were ultimately enrolled. Eight enrollees completed seven of the required eight moxibustion treatments to be considered completers. Three were withdrawn: one because she sought additional acupuncture for an unrelated symptom, the second because of a self-perceived allergic reaction and the third because of a desire to pursue homeopathy for a different physical complaint.

The moxibustion treatment was generally well tolerated among study participants. AEs were minimal; seven of 11 participants had at least one temporary episode of worsening of fatigue. For all participants (completers and non-completers), the most frequently occurring AEs were temporary worsening of fatigue ($n = 27$ occurrences among 7 participants); lightheadedness occurred on nine occasions among three participants; headache occurred seven times among five participants. A complete list of AEs reported by participants is shown in Table 1.

In an anonymous follow-up questionnaire, respondents reported experiencing the treatments as "very relaxing" or "relaxing" and all who responded expressed willingness to participate in a future moxibustion study.

3.1. Symptomatic outcomes

One goal of this study was to determine the usefulness of two questionnaires (FFS and the SF-36 pre-post) in patients with SQYDF. Paired *t* tests for pre- to-post intervention changes yielded compelling results for the Vitality ($p = 0.003$) and Social Function ($p = 0.008$) subscales of the SF-36, as well as for FFS ($p = 0.014$). Changes in scores on the Role-Physical, Bodily Pain, and Mental Health subscales of the SF-36 also showed large effects and yielded significance values <0.05 (Table 2). Due to the large number of tests, only the change in the Vitality subscale can be considered significant, after an appropriate Bonferroni adjustment (Bonferroni corrected alpha = 0.005).

3.2. Physiological outcomes

Mean SC at baseline of the 24 acupoints for the 13 participants who met the diagnostic criteria for SQYDF at baseline, was 38 nu, on a scale of 0—200. At final assessment for the eight completers, it was 52 nu. SC readings at the 24 Source acupoints showed no consistent diagnostic meridian patterns among participants at baseline. There was also no consistent change among the meridian patterns over the 8-week course of the study. Overall, a wide variation in SC readings between visits and among participants was observed. Regression coefficients for time of measurement were negative for most of these. Neither regression nor repeated measures ANOVA showed significant effects of time point on SC readings.

Due to technical difficulties, pre- and post-intervention HRV data were available for only four of the eight study completers. Three of these four participants showed improvement in LF/HF ratios between pre- and post-intervention measurement, with the LF/HF ratio reduced at the end of the trial. The mean change in LF/HF was equal

Table 2 Adverse events reported.

	Number of participants	Number of reports
Symptom (from checklist)		
Reddening of skin at site of moxa application that lasted >24 h	2	6
Blistering at site of moxa applications	1	1
Itching sensations	3	4
Discomfort due to the smoke or the smell of incense and moxa	1	2
Worsening of fatigue	7	27
Stomach upset or nausea	3	4
Headache	5	7
Frequent urination	2	2
Burn at site of moxa application	1	1
Lightheadedness	3	9
Easy bruising	3	4
Feeling ill at ease	3	5
Cough	2	2
Blurred vision	2	4
Dizziness	2	2
Change in sexual drive	3	5
Body pain	4	5
Skin rash	0	0
Other participant-reported symptoms, not on checklist		
Poor sleep	1	6
Increased energy	1	3
Increased thirst	1	3
Emotional, moody	2	2
Night sweats	2	2
Constipation	1	2
"Brain ache"	1	1
Hot flash	1	1
Labored breathing	1	1
Epigastric low chest pain	1	1
Urgent bowel movement	1	1
Lack of coordination	1	1
"Brain fog"	1	1
Numb face while driving	1	1

Please cite this article in press as: Thorne TL, et al., Direct Moxibustion to Treat Spleen *Qi* and *Yang* Deficiency Fatigue: A Pilot Study, Journal of Acupuncture and Meridian Studies (2013), http://dx.doi.org/10.1016/j.jams.2013.04.003

to −0.91, relative to a standard deviation of 3.11. After log transformation of LF/HF scores, these figures become: mean change = −0.78; standard deviation = 1.34.

4. Discussion

Our objectives in conducting this feasibility study were to evaluate our methodology and answer the preliminary questions listed in the introduction. Our results indicated adequate recruitment, retention and compliance and good participant tolerability for the direct moxibustion treatments. The dosing regimen of direct moxibustion (11 acupoints treated once per week for 8 weeks within the established range of felt experience) provided significant symptomatic improvement in fatigue as measured by the SF-36 vitality scale and near significant improvement as measured by the FFS and the SF-36 Social Function Scale. In addition to the small sample size, a possible reason for the FFS results not reaching significance might be a less than optimal dosing regimen. Although we obtained improvement with the dosing regimen we chose, it is possible that participants would have benefitted even more if more acupoints were treated, more moxa cones burned at each site, more frequent treatments (perhaps twice per week) or more total treatments (12 rather than 8 sessions) were provided. Furthermore, all participants received a standardized treatment protocol. Individualizing the protocol as in clinical practice, might have resulted in added improvement. Finally, direct moxibustion was the sole intervention in this study. Participants may have needed additional intervention (i.e., needle acupuncture) to further reduce their longstanding fatigue.

The HRV data are not sufficient to yield statistical significance, especially since HRV data cannot usually be assumed to be normally or log-normally distributed [25], but calculations did reveal promising effect sizes that, if replicated in a larger study, could yield significant results. Thus, the limited data obtained are consistent with our belief that moxibustion treatment (like acupuncture) leads to improved parasympathetic activity, as measured by HRV.

Changes in SC measurements at acupoints are used in clinical practice as an aid to meridian diagnosis and to guide acupuncture treatment options. The SC readings at the 24 Source acupoints in our SQYDF patients sample yielded inconclusive results. Yu et al observed that individuals with tiredness had significantly lower SC than non-tired individuals and that the decrease in SC correlates with the degree of tiredness [26]. In our sample of SQYDF patients, the average SC was low at baseline (38 nu), compared to findings reported in a large patient sample. Chamberlin et al analyzed first visit data on 6069 females who were seen by one of 311 experienced AcuGraph users [27]. The average SC readings of the 24 Source acupoints in a subgroup of females aged 31 to 50 years, was 86 nu. Although these patients had a variety of undescribed health complaints, their mean baseline SC readings are substantially higher than those found in our sample. SC increased from 38 nu to 52 nu over the 8-week treatment in our sample. Because of large variations in the changes between individuals, however, the increase among the eight completers was not significant (paired t test of average SC at first and final session; $p = 0.16$).

Other than low mean baseline SC recordings that appeared to correspond to symptomatic fatigue, we observed no consistent SC patterns relative to an acupuncture meridian diagnosis or to an organ (*zang fu*) diagnosis of SQYDF. Nor did changes over the course of the study in the individual acupoint SC, or patterns among the 24 acupoints, correlate with the symptomatic improvement reported by our participants. Our findings are dissimilar, however, to results reported in a related study. Ahn et al found that measures of dispersion (Gini and SD) in SC decreased over 8 weeks of needle acupuncture treatment (2 sessions per week), reflecting improved balance among the acupuncture meridians[28]. In our study, the mean right—left, *yin—yang*, and upper-lower differences all showed mean increases in SD over the course of the trial. These results suggest either that future studies will require more precise methods for measurement of SC, or that the SC recordings may be ill-suited to the evaluation of moxibustion therapy in patients with SQYDF.

5. Conclusions

In this small pilot study, burning small moxa cones directly on the skin in the modified Sawada/Fukuya protocol-technique is safe and tolerable for SQYDF patients when administered by an experienced practitioner. The FFS and SF-36 were useful outcome measures for assessing symptomatic change in patients with SQYDF. A larger study is needed to explore this further. The LF/HF ratio of HRV may have promise as a physiological outcome measure for studying the effects of direct moxibustion. SC at the 24 Source acupoints did not show a consistent diagnostic pattern in patients with SQYDF and changes in SC over the 8-week treatment period did not correlate with symptomatic improvement. The use of SC as an objective outcome may not be appropriate in this patient population.

Acknowledgments

We would like to thank Steve Chamberlin, BS, Kristin Sparrow, MD, Mitesh Master, MSOM, Bob Quinn, DAOM, Shalini Mukherjee, PhD, and Suzanne Chi, MSOM for their assistance in developing the clinical protocol and suggestions for data analysis.

References

1. Wilcox L. *Moxibustion: The Power of Mugwort Fire*. Blue Poppy Press; 2008:7—12.
2. Wheeler J, Coppock B, Chen C. Does the burning of moxa (*Artemisia vulgaris*) in traditional Chinese medicine constitute a health hazard? *Acupunct Med*. 2009;27:16—20.
3. Okada K, Kawakita K. Analgesic action of acupuncture and moxibustion: a review of unique approaches in Japan. *Evid Based Complement Alternat Med*. 2009;6:11—17.
4. Birch S, Ida J. *Japanese Acupuncture: A Clinical Guide*. Brookline: Paradigm Publications; 1998:111—122.
5. Craig J, Young M. How does moxa work? Part 1: an investigation of temperature effects. *NAJOM*. 2011;18:3—6.
6. Obaidey E. Taikyoku therapy-Sawada style treatment strategy. *NAJOM*. 1996;3:12—14.
7. Mizutani J. Practical moxibustion therapy. *NAJOM*. 2009;19:82—88.

Please cite this article in press as: Thorne TL, et al., Direct Moxibustion to Treat Spleen *Qi* and *Yang* Deficiency Fatigue: A Pilot Study, Journal of Acupuncture and Meridian Studies (2013), http://dx.doi.org/10.1016/j.jams.2013.04.003

8. Manaka Y, Itaya K, Birch S. *Chasing the Dragon's Tail*. Brookline: Paradigm Publications; 1995:177.
9. Hideo S. The Fukaya multiple-grain moxibustion technique. *NAJOM*. 2009;18:11—13.
10. Yi SH. Thermal properties of direct and indirect moxibustion. *J Acupunct Meridian Stud*. 2009;2:273—279.
11. Kogure M, Mimura N, Ikemoto H, Ishikawa S, Nakanishi-Ueda T, Sunagawa M, et al. *J Acupunct Meridian Stud*. 2012;5:29—33.
12. Wang T, Zhang Q, Xue X, Young A. A systematic review of acupuncture and moxibustion treatment for chronic fatigue syndrome in China. *Am J Chin Med*. 2008;36:1—24.
13. Li G- R. *Clinical Moxibustion Therapy*. Beijing: Peoples Medical Publishing House; 2007.
14. Maciocia G. *The Foundations of Chinese Medicine: A Comprehensive Text for Acupuncturists and Herbalists*. Edinburgh, London, Madrid, Melbourne, New York, Tokyo: Churchill Livingstone; 1989.
15. Fuhrer R, Wessely S. The epidemiology of fatigue and depression: a French primary-care study. *Psychol Med*. 1995;25:895—905.
16. Guo J. Chronic fatigue syndrome treated by acupuncture and moxibustion in combination with psychological approaches in 310 cases. *J Trad Chin Med*. 2007;27:92—95.
17. Shudo D. *Japanese Classical Acupuncture: Introduction to Meridian Therapy*. Seattle: Eastland Press; 1990:45—77.
18. Chen R, Chen M, Xiong J, Chi Z, Zhou M, Su T, et al. Is there difference between the effects of two-dose stimulation for knee osteoarthritis in the treatment of heat-sensitive moxibustion? *Evid Based Complement Alternat Med*. 2012;2012:696498.
19. Kim SY, Yi SH, Cho JH, Yin CS, Lee H, Park HJ. Heat stimulation on the skin for medical treatment: can it be controlled? *J Altern Complement Med*. 2011;17:497—504.
20. Park J, Lee S, Lee S, Ernst E. Adverse events of moxibustion: a systematic review. *Complement Ther Med*. 2010;18(5):215—223.
21. Gradisar M, Lack L, Richards H, Harris J, Gallasch J, Boundy M, et al. The flinders fatigue scale: preliminary psychometric properties and clinical sensitivity of a new scale for measuring daytime fatigue associated with insomnia. *J Clin Sleep Med*. 2007;3:722—728.
22. Brazier JE, Harper R, Jones NM, O'Cathain A, Thomas KJ, Usherwood T, et al. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. *BMJ*. 1992;305:160—164.
23. Mist SD, Aickin M, Kalnins P, Cleaver J, Batchelor R, Thorne T, et al. Reliability of AcuGraph system for measuring skin conductance at acupoints. *Acupunct Med*. 2011;29:221—226.
24. Lee S, Lee MS, Lee JY, Lee SW, Leong SY, Ernst E. Acupuncture and heart rate variability: a systematic review. *Auton Neurosci*. 2010;155:5—13.
25. Mukherjee S, Yadav R, Yung I, Zajdel DP, Oken BS. Sensitivity to mental effort and test-retest reliability of heart rate variability measures in healthy seniors. *Clin Neurophysiol*. 2011;122:2059—2066.
26. Yu HM, Chang HH, Liou SY, Li SF, Hou MM, Chen MF. The correlation between skin electrical conductance and the score of qi vacuity. *Am J Chin Med*. 1998;26:283—290.
27. Chamberlin S, Colbert AP, Larsen A. Skin conductance at 24 Source (Yuan) acupoints in 8637 patients: influence of age, gender and time of day. *J Acupunct Meridian Stud*. 2011;4:14—23.
28. Ahn AC, Schnyer R, Conboy L, Laufer MR, Wayne PM. Electrodermal measures of Jing-Well points and their clinical relevance in endometriosis-related chronic pelvic pain. *J Altern Complement Med*. 2009;15:1293—1305.

Please cite this article in press as: Thorne TL, et al., Direct Moxibustion to Treat Spleen *Qi* and *Yang* Deficiency Fatigue: A Pilot Study, Journal of Acupuncture and Meridian Studies (2013), http://dx.doi.org/10.1016/j.jams.2013.04.003