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Development of Acupuncture and Moxibustion Protocol in a Clinical Trial for Irritable Bowel Syndrome

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Abstract

Traditional Chinese medicine encompasses many different practices, most notably acupuncture and moxibustion. Traditionally, these modalities are used in combination to augment treatment but seldom are they tested together in clinical studies. Numerous acupuncture studies have been conducted in Asia, Europe, and the United States but there have been few randomized controlled trials utilizing moxibustion outside of East Asia. Limited studies have described the use of a moxibustion control or placebo procedure. The methods for developing an acupuncture and moxibustion protocol used in a randomized controlled trial for irritable bowel syndrome, diarrhea predominant in adults are described here. Our approach conformed to the scientific rigor for a clinical trial and was consistent to the foundations of traditional Chinese medicine.

Keywords

acupuncture; irritable bowel syndrome; moxibustion

1. Introduction

Irritable bowel syndrome (IBS) is a functional gastrointestinal (GI) disorder characterized by abdominal pain or discomfort associated with alterations in bowel habit [1]. It is accompanied by symptoms such as bloating, mucus in the stool, urgency, and incomplete bowel movements. IBS is classified by the predominant stool pattern: IBS with constipation (IBS-C), IBS with diarrhea (IBS-D), IBS-mixed (IBS-M), or unsubtyped IBS (IBS-U). An acupuncture and moxibustion protocol was developed as part of a symptom management research study for IBS-D in accordance with STRICTA (Standards for Reporting Interventions in Clinical Trials of Acupuncture) guidelines [2].

Acupuncture coupled with moxibustion is a common practice of traditional Chinese medicine (TCM). Moxibustion is the traditional method of burning the dried leaves of the plant, mugwort (*Artemisia vulgaris*) to stimulate acupuncture points. The effects of

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moxibustion are associated with properties from burning the dried herb, including the thermal stimulation [3]. The types of moxibustion include direct and indirect. Direct moxibustion refers to the use of moxa cones or small cone shaped amounts of moxa placed directly on the skin. Indirect moxibustion may utilize moxa cones insulated from the skin with a substance such as ginger or salt or small round balls of moxa placed atop the needle. The more common indirect method is pole moxibustion; moxa compressed and rolled into a cylindrical shaped stick, held above the point.

In the United States and Europe, moxibustion became more popular for its use with breech presentation of babies [4]. Most of these studies used either observation or usual care as a control. One study described the use of a sham moxibustion intervention [5]. To date, there have been a limited number of randomized controlled trials (RCTs) utilizing moxibustion outside of Asia. Trials using moxibustion for IBS [6] and other GI disorders like ulcerative colitis [7] have mostly all originated in China or Korea. These trials compared active control groups and were complicated with methodological issues of blinding and sample size. Of the RCTs conducted, only a few have described the use of a placebo moxibustion procedure.

2. Materials and methods

2.1. Materials

The study was a 24-week three-arm, prospective, parallel groups controlled trial of 171 men and women diagnosed with IBS-D based on the Rome III diagnostic criteria for functional GI disorders [1]. The primary objective of the study was to test a symptom management strategy to reduce abdominal pain and IBS secondary symptoms (bloating, gas, and stool consistency) as measured from a daily self-reported symptom diary and weekly clinical global impression scale [8] during 8 weeks of treatment and follow-up phases. The patients were randomized to one of three groups: standard acupuncture/moxibustion, individualized acupuncture/moxibustion, and sham acupuncture/placebo moxa (control group). Eligibility criteria were selected to identify men and women diagnosed with IBS-D and experiencing recurrent abdominal pain/discomfort. Exclusion criteria included those with other IBS subtypes (IBS-C, IBS-M, IBS-U); history of lactose intolerance; coexisting GI, gynecological, or urological conditions; and abdominal surgery < 6 months prior to study entry. Individuals taking the following medications were also excluded: iron supplements, antibiotics, narcotics, cholestyramine, colchicine, antispasmodics, or benzodiazepines > 3 days a week. Individuals receiving acupuncture currently or < 6 months prior to enrollment, as well as those with a history of receiving moxibustion were excluded as they may have recalled heat sensation. The study was registered with ClinicalTrials.gov, number NCT00945074.

2.2. Procedure

During the development of the study design, an expert panel of three senior licensed and nationally certified acupuncturists reviewed both classical and modern Chinese medicine textbook literature available in English on the topic of GI symptoms [9–11]. The panel considered available acupuncture and moxibustion studies for the treatment of IBS [12,13]. The panel also held focus groups with IBS patients and reviewed the IBS symptom patterns

and syndrome differentiation. From that, the panel developed a list of eight primary TCM diagnoses clinically seen in IBS patients (Table 1). The panel delineated the bowel movement and stool characteristics according to TCM textbooks. They also noted other symptoms used for TCM pattern differentiation and treatment principles for each diagnosis. The panel reviewed point selections for all the diagnoses and arrived by consensus at a standard protocol that would benefit the main complaints associated with IBS. Using this framework and the results of our previous pilot study [14], a set of “core points” for the individualized arm was developed. For each TCM diagnosis, a list of acupuncture points corresponding to each specific diagnosis was determined (Table 1). The rationale for this tailored protocol was to treat a generalized imbalance of the organ systems and the patient’s specific symptoms. In determining the moxibustion protocol for the standard and individualized protocols, the same rationale of point selection was followed because its function was to provide point stimulation, and move and smooth the flow of qi among the channels and organ systems.

All of the patients were evaluated weekly by a diagnostic acupuncturist (DA), with at least 5 years of experience, who provided a TCM diagnosis and point prescription to be used at each week’s treatment session. The DA was not told to which treatment group the patient was randomized. The DA selected points from a list of acupuncture points corresponding to the patient’s specific TCM diagnosis, with a minimum of two needles and maximum of six needles. The DA also determined the needling method; either a reinforcing/tonification or reducing method. The reinforcing method was performed by inserting the needle at the appropriate depth (according to the classic text) [9] while the patient inhaled. After insertion of the needle, it was rotated nine times gently and slowly with small amplitude in a clockwise direction. The reducing method was performed by inserting the needle when the patient exhaled and it was rotated six times with large and forceful amplitude in a counterclockwise direction.

Treatment protocol fidelity was further addressed by the inclusion of a study facilitator (SF). The SF’s role was to ensure subject safety and methodical facilitation of the treatment protocol, timing and sequencing of points, monitor blinding procedures and documentation of treatment sessions. Dialogue was scripted so that all subjects received the same level of information and interaction.

After the DA filled out the point prescription on a card, it was handed directly to the unblinded SF who transcribed it to a point verification form for the treating acupuncturist (TA), and filed the original prescription card in an envelope. The actual needling of the prescribed treatment was administered by a TA with at least 2 years’ experience. Prior to the start of the study, the TAs received an acupuncture point location training session, including a protocol manual of true and sham point locations, and passed a written and practical exam on both true and sham acupuncture locations. The DA’s clinical notes were kept in a separate filing cabinet so the TA had no access, to protect blinding. The TA did not discuss, prescribe, or suggest any points with the DA.

All patients were blindfolded during treatment sessions and the interaction between the patients and TA was kept to a minimum. Any questions or comments were directed to the SF who remained present during all the treatment sessions.

2.3. Protocols

All three groups received 12 treatment sessions following a schedule of twice weekly sessions for 4 weeks followed by once a week for 4 weeks, and two nontreatment follow-up sessions at Week 12 and Week 24. All protocols were carried out by state licensed and nationally certified acupuncturists. Sterile, single use, disposable needles (Seirin® J type No. 2, 0.18 mm × 30 mm) and pure moxa sticks (Pure Moxa Rolls for Mild Moxibustion®; China National Medicines and Health Products, Beijing, China) were utilized (based on the preliminary study and our prior acupuncture studies). Anterior points were needled first in the supine position and retained for 15 minutes. Once the needles were removed, anterior moxibustion proceeded. Then, the patient moved into a prone position and the posterior points were needled and retained for 15 minutes, followed by posterior moxibustion. All sessions were monitored and timed by the SF to ensure protocol fidelity.

2.4. Standard acupuncture/moxibustion

The standard set of points consisted of 14 needles (Table 2). Needles were inserted at the appropriate depth (according to the classic text) [9] with a de qi sensation [15] and the reinforcing/tonification method was followed for all standard patients. After the needles were removed, the moxibustion treatment began. The moxa stick was lit on one end and held vertically to the skin. The protocol followed the classic text *Chinese Acupuncture and Moxibustion* [9]: 2–3 cm over the traditional point, clockwise circular motion directly over the point for a period of 2 minutes for each point, while the area of the point became pink.

2.5. Individualized acupuncture/moxibustion

A tailored process was used as elected in other individualized acupuncture RCTs [16,17]. The individualized arm consisted of eight core points (Table 3) along with the DA-selected points from a list of additional acupuncture points corresponding to the patient's specific TCM diagnosis, with a minimum of two and maximum of six needles (Table 1). Thus, the protocol was tailored specifically for the patient's unique diagnosis according to the symptoms reported at each weekly DA session. The total number of needles could not exceed 14 to be comparable to the same number of needles used in the standard and sham groups. The needles were inserted at the appropriate depth (according to the classic text) [9] with a de qi sensation, and the technique was either reinforcing/tonification or reducing according to the DA's prescription. The moxibustion procedure was the same as described in the standard.

2.6. Sham acupuncture/placebo moxa (control group)

The sham control consisted of 14 sham points that were 2–3 cm away from the traditional true acupuncture point location and not on a meridian. The needles were inserted with a shallow depth of 1–2 mm, with no de qi sensation or stimulation. The sham points were as

anatomically specific and precise as the true acupuncture protocol and locations were described and diagrammed in a detailed manner in a procedure manual.

The technique of placebo moxa involved the same type of moxa stick used in the standard and individualized arms. It was lit and held approximately 20 cm above and 2–3 cm away from the traditional location for a period of 2 minutes for each point. This allowed for the smell of the moxa and same time attention as the standard and individualized treatments. Specific diligence was made on the part of the treating acupuncturist to not generate a heat sensation. The TA placed his/her hand close to the patient's skin to check that no heat was felt. The credibility of our control condition was tested in our prior studies funded by the National Institutes of Health that used true and sham acupuncture and true and placebo moxibustion, in which the groups did not significantly differ on the credibility questions when tested with a two-sample median test.

2.7. Anticipated results

It was important that patients randomized to the control group perceived their experience to be as valuable as that of patients in the active standard and individualized treatment groups. A lack of perceived value in the control group could have led to differential attrition across the groups. While the use of acupuncture controls generates debate, numerous studies have researched sham conditions of acupuncture [18]. In our study, patients received sham acupuncture using superficial needling at nonacupuncture points according to previously established procedures [19,20]. Only a few studies have described the use of placebo moxibustion procedures and studies involving moxibustion have been plagued with devising appropriate placebo controls. Experiential cues accompanying acupuncture and moxibustion may impart significant but transient placebo responses [21]. Therefore, we believed that the best methodological approach was to expose control patients to sham acupuncture and placebo moxa that was indistinguishable from true acupuncture and moxibustion. An important concern in designing this study was the selection of procedures that would maximize experimental control over nonspecific confounding factors. The description of an acupuncture and moxibustion protocol here provides the detail necessary for demonstrating TCM protocols that mimic real clinical practice in the confines of an RCT.

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References

1. Drossman, DA. Rome III: The Functional Gastrointestinal Disorders. 3rd. McLean, VA: Degnon Associates; 2006.
2. MacPherson H, Altman DG, Hammerschlag R, Youping L, Taixiang W, White A, et al. Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): Extending the CONSORT Statement. PLoS Med. 2010; 7:e1000261. [PubMed: 20543992]
3. Pach D, Brinkhaus B, Willich SN. Moxa sticks: thermal properties and possible implications for clinical trials. Complement Ther Med. 2009; 17:243–246. [PubMed: 19632553]

4. Coyle ME, Smith CA, Peat B. Cephalic version by moxibustion for breech presentation. Cochrane Database Syst Rev. 2012; 16:CD003928.
5. Vas J, Aranda JM, Barón M, Perea-Milla E, Méndez C, Ramírez C, et al. Correcting non cephalic presentation with moxibustion: study protocol for a multi-centre randomised controlled trial in general practice. BMC Complement Altern Med. 2008; 8:22. [PubMed: 18495031]
6. Tang B, Zhang J, Yang Z, Lu Y, Xu Q, Chen X, Lin J. Moxibustion for diarrhea-predominant irritable bowel syndrome: a systematic review and meta-analysis of randomized controlled trials. Evid Based Complement Alternat Med. 2016; 2016:5105108. [PubMed: 27293460]
7. Lee DH, Kim JI, Lee MS, Choi TY, Choi SM, Ernst E. Moxibustion for ulcerative colitis: a systematic review and meta-analysis. BMC Gastroenterol. 2010; 10:36. [PubMed: 20374658]
8. Guy W. Clinical global impression scale The ECDEU Assessment Manual for Psychopharmacology-Revised Volume DHEW Publ No ADM. 1976:218–222.
9. Beijing College of Traditional Chinese Medicine, Shanghai and Nanjing College of Traditional Chinese Medicine. Chinese Acupuncture & Moxibustion. Beijing, China: Foreign Languages Press; 1987.
10. Maciocia, G. Diagnosis in Chinese Medicine: A Comprehensive Guide. Edinburgh: Elsevier Churchill Livingstone; 2004.
11. Ross, J. Acupuncture Point Combinations: The Key to Clinical Success. Edinburgh: Churchill Livingstone; 1995.
12. Lim B, Manheimer E, Lao L, Ziea E, Wisniewski J, Liu J, et al. Acupuncture for treatment of irritable bowel syndrome. Cochrane Database Syst Rev. 2006; 18:CD00511.
13. Schneider A, Enck P, Streitberger K, Weiland C, Bagheri S, Witte S, et al. Acupuncture treatment in irritable bowel syndrome. Gut. 2006; 55:649–654. [PubMed: 16150852]
14. Anastasi JK, McMahon DJ, Kim GH. Symptom management for irritable bowel syndrome: a pilot randomized controlled trial of acupuncture/moxibustion. Gastroenterol Nurs. 2009; 32:243–255. [PubMed: 19696601]
15. Langevin HM, Churchill DL, Fox JR, Badger GJ, Garra BS, Krag MH. Biomechanical response to acupuncture needling in humans. J Appl Physiol. 2001; 91:2471–2478. [PubMed: 11717207]
16. Nir Y, Huang MI, Schnyer R, Chen B, Manber R. Acupuncture for postmenopausal hot flashes. Maturitas. 2007; 56:383–395. [PubMed: 17182200]
17. Kalish LA, Buczynski B, Connell P, Gemmel A, Goertz C, Macklin EA, et al. Stop Hypertension with the Acupuncture Research Program (SHARP): clinical trial design and screening results. Controlled Clinical Trials. 2004; 25:76–103. [PubMed: 14980754]
18. Marx BL, Milley R, Cantor DG, Ackerman DL, Hammerschlag R. AcuTrials : an online database of randomized controlled trials and systematic reviews of acupuncture. BMC Complement Altern Med. 2013; 13:181. [PubMed: 23866767]
19. Birch S, Hammerschlag R, Trinh K, Zaslawski C. The nonspecific effects of acupuncture treatment: when and how to control for them. Clin Acupunct Orient Med. 2002; 3:20–25.
20. Hammerschlag R. Methodological and ethical issues in clinical trials of acupuncture. J Altern Complement Med. 1998; 4:159–171. [PubMed: 9628206]
21. Langevin HM, Wayne PM, MacPherson H, Schnyer R, Milley RM, Napadow V, et al. Paradoxes in acupuncture research: strategies for moving forward. Evid Based Complement Alternat Med. 2011; 2011:180805. [PubMed: 20976074]

Table 1

TCM diagnoses of IBS-D and associated acupuncture points.

Primary TCM diagnosis associated with IBS-D symptoms	Additional acupuncture points (minimum of 2, maximum of 6 selected)
Spleen and stomach qi deficiency	SP3, SP5, SP6, SP7, SP8, SP9, SP15, ST21, ST22, ST23, ST36, ST37, ST39, ST43, PC6, LI10, BL16, BL21, BL22, BL24, BL26, BL57, BL58
Spleen qi deficiency with damp	SP5, SP6, SP7, SP8, SP9, ST21, ST22, ST23, ST36, ST37, ST40, ST43, CV9, BL21, BL22, BL24, BL26, BL57, BL58
Spleen yang deficiency	KI3, KI16, SP3, SP5, SP7, SP8, SP9, ST23, ST37, ST39, LI4, BL22, BL24, BL57, BL58
Kidney yang deficiency	KI3, KI7, KI16, CV4, ST36, SP6, LI4, GB25, BL22, BL24, BL26, BL57, BL58,GV4
Liver qi stagnation	LV2, LV3, LV13, LV14, LI4, LI10, LI11, ST21, ST22, ST36, GB25, GB34, PC6, SP5, SP6, BL16, BL19, BL21, BL26, BL27, BL57, BL58
Retention of cold damp	CV4, CV9, ST21, ST36, ST37, ST40, SP6, SP9, SP15, LV13, KI16, BL21, BL22, BL26, BL57, BL58, GV4
Retention of damp heat	LV2, LV3, LV5, LV8, LI10, LI11, SP6, SP9, GB34, GB41, ST21, ST37, ST38, ST40, ST44, GV4, CV 3, KI7, KI8, BL19, BL21, BL22, BL26, BL27, BL57, BL58
Retention of food	CV 9, CV10, PC6, LV3, LI4, LI11, KI7, SP5, SP15, ST21, ST36, ST37, ST43, ST44, BL21, BL24

BL = urinary bladder; CV = conception vessel; GB = gallbladder; GV = governing vessel; IBS-D = irritable bowel syndrome with diarrhea; KI = kidney; LI = large intestine; LV = liver; PC = pericardium; SP = spleen; ST = stomach; TCM = traditional Chinese medicine.

Table 2

Standard acupuncture points and moxibustion protocol for irritable bowel syndrome with diarrhea.

CV 6	Needle & moxa
CV 12	Needle & moxa
ST 25	Needle & moxa
SP 4	Needle only
BL 18	Needle only
BL 20	Needle & moxa
BL 23	Needle & moxa
BL 25	Needle & moxa

BL = urinary bladder; CV = conception vessel; SP = spleen; ST = stomach.

Table 3

Individualized acupuncture and moxibustion protocol of core points for irritable bowel syndrome with diarrhea.

CV 12	Needle & moxa
ST 25	Needle & moxa
CV 6	Needle & moxa
BL 23	Needle & moxa
BL 25	Needle & moxa

BL = urinary bladder; CV = conception vessel; ST = stomach.