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Clinical trial

Efficacy and safety of different doses of moxibustion for irritable bowel syndrome: A randomised controlled pilot trial

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ABSTRACT

Introduction: Moxibustion therapy has been used in oriental medicine for symptoms of irritable bowel syndrome such as diarrhoea and constipation. This study aimed to evaluate the efficacy and safety of different doses of moxibustion for irritable bowel syndrome (IBS).

Methods: This study was conducted at Semyung Korean Medical Hospital, Chungbuk, Republic of Korea. Twenty-four patients (12 males, 12 females) aged 18–30 years who were diagnosed with IBS using the Rome III criteria were included. trial In this triple blind randomised controlled trial patients were allocated to receive either 3-cone moxibustion or 1-cone moxibustion. Moxa was applied to Guan Yuan (CV4) for 20 min. The Bowel Symptom Severity Scale (BSSS) score was used as the primary outcome measure; the Irritable Bowel Syndrome Severity Scale – Korean Version (IBSSS-K) score, heart rate variability (HRV), visceral sensitivity questionnaire, and a pattern identification questionnaire were secondary outcome measures.

Results: There was a significant difference in IBSSS-K scores after moxibustion in both the 3CMG (score: before: 217.50 ± 79.95, after: 137.42 ± 68.70, $p = 0.021$) and 1CMG groups (score: before: 217.67 ± 98.77, after: 112.25 ± 71.11, $p = 0.006$). There were no significant differences in the BSSS scores, IBSSS-K scores, Qi stagnation questionnaire scores, or cold-heat pattern questionnaire scores, between the two groups.

Conclusions: Different doses of moxibustion resulted in similar efficacy levels for the treatment of IBS. These preliminary findings suggest that moxibustion therapy may be effective and can be safe in improving the symptoms of IBS.

1. Introduction

Irritable bowel syndrome (IBS) is a common functional gastrointestinal (GI) disorder characterised by abdominal pain, changes in bowel habit, distention, and abnormal stools. Although the exact mechanisms of IBS GI symptoms have not yet been elucidated, visceral hypersensitivity and GI motility disorders are the main pathological causes [2–6].

According to the Rome III criteria, patients diagnosed with IBS repeatedly experience abdominal pain or discomfort (an uncomfortable sensation not described as pain) at least 3 times per month over the 3 months prior to the diagnosis. Patients have either a) stool with fluffy pieces and ragged edges or that is mushy, watery, or entirely liquid (Bristol Stool Chart Scale 6–7) ≥25% or b) stool with separate hard lumps similar to nuts that are hard to pass or sausage-shaped but lumpy (Bristol Stool Chart Scale 1–2) ≥25%.

Epidemiological surveys have shown that the worldwide occurrence of IBS is approximately 5%–15% [6]. IBS leads to significant mental stress and can be a huge financial burden for patients. However, there are currently insufficient treatment options for patients with IBS [2–6]. Therefore, an effective, rational management strategy for IBS is needed.

In clinical practice, moxibustion therapy is widely administered for IBS, diarrhoea, and abdominal pain. However, to our knowledge, there are very few well-designed studies that show moxibustion is effective for IBS. Therefore, this study aimed to evaluate the efficacy and safety of different doses of moxibustion for IBS.

Abbreviations: IBS, irritable bowel syndrome; BSSS, Bowel Symptom Severity Scale; IBSSS-K, Irritable Bowel Syndrome Severity Scale – Korean Version; HRV, heart rate variability; 3CMG, 3-cone moxa group; 1CMG, 1-cone moxa group

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2. Methods

2.1. Study design and period

This study was a subject-, assessor- and analyst-blinded, randomised, controlled clinical trial with two parallel groups. The trial was conducted at a single clinical centre (Semyung Korean Medical Hospital) from 30 June 2016 to 31 December 2016. The protocol of this study was published in the European Journal of Integrative Medicine (Volume 9, January 2017, Pages 126–130) [1].

2.2. Inclusion and exclusion criteria

2.2.1. Inclusion criteria

Inclusion criteria were as follows: (1) IBS according to Rome III; (2) age 18–30 years; (3) voluntary agreement to participate in the research; (4) for female subjects, negative urine pregnancy test results and agreement not to become pregnant during the clinical trial; (5) no diagnosis of cardiovascular disease, such as hypertension, diabetes mellitus, or hyperlipidaemia; (6) recent body temperature should not have been greater than 38.5 °C for more than 4 h; and (7) willingness to sign the institutional review board-approved consent form and agreement with both the clinical trial plan and follow-up observations.

2.2.2. Exclusion criteria

Patients with any of the following conditions were excluded because of safety concerns: (1) diagnosed cardiovascular disease; (2) high fever in the past week; (3) screening for or participation in a clinical trial within the past 30 days and were administered medication or a placebo; or (4) inappropriate subject status, as determined by a clinical trial researcher.

2.3. Clinical trial process

2.3.1. Randomisation and allocation concealment

Participants were randomised using a computerised number generator using the stratified block randomisation method in R software (R version 3. 3. 1, 2016.06.21) by a statistician with no clinical involvement in this trial. A total of 24 participants who met the eligibility criteria were allocated at a ratio of 1:1 to either the 3-cone moxa group (3CMG) or the 1-cone moxa group (1CMG). The 3CMG was treated with 3 moxa cautery cones in a moxibustion plate. The 1CMG was treated with 1 moxa cautery cone in a moxibustion plate.

The allocation was concealed in sequentially numbered, opaque, sealed envelopes containing the randomisation assignments. Allocation concealment was broken only after the participant met all selection criteria and completed the baseline assessments. The participants did not know which group they were allocated to, and the outcome assessors and data analysts were blinded to the intervention allocation.

2.3.2. Blinding

To keep the subjects blinded, we used the Dan Jeon Gu Hab moxa plate (Dongbang Medical Co. Ltd., Boryeong, Republic of Korea), which is invisible on the inside. In addition, the subjects' eyes were covered throughout the treatment. An infrared (IR) red light was used to radiate the subjects' lower legs to keep the subjects from feeling temperature differences in the abdomen. The IR radiation degree was 1 (degree range from 1 to 7), and the IR radiation area focused on the lower legs, so that it did not affect the moxibustion intervention.

The treatment and assessment were performed independently by each investigator. The outcome assessors and data analysts were blinded to the treatment allocation throughout the study.

2.3.3. Interventions

Moxa was applied to Guan Yuan (CV4) using 3-cones or 1-cone moxa placed in one moxibustion plate for 20 min. The 3 cones were located about 2 cm apart from each other. The intervention was conducted over 4 weeks, for a total of 8 sessions (2 times per week × 4 weeks). Guan Yuan (CV4) was selected because this point has been implicated in the treatment of IBS [7–13]. Charcoal moxa cones (Dongbang Medical Co. Ltd.) were used. The potential occurrence of side effects such as burns during moxibustion were explained to the subjects before the clinical trial.

2.4. Variables

The primary outcome measured was the Bowel Symptom Severity Scale (BSSS) [15–19]. The secondary outcomes measured were the Irritable Bowel Syndrome Severity Scale, Korean version (IBSSS-K) [14,20], heart rate variability (HRV), visceral sensitivity questionnaire [20], cold-heat pattern questionnaire [21], and Qi stagnation questionnaire [22]. Autonomic nerve activity, autonomic nerve balance, stress resistance, stress level, degree of fatigue, and cardiac stability were measured by HRV.

Adverse events were investigated as follows. If an adverse event occurred, an investigator would evaluate the patient at each visit and complete an 'Adverse event report' regarding the potential causality between the trial intervention and the adverse event. Patients who experienced adverse events were treated at Semyung Korean Medical Hospital. All vital signs and adverse events were measured and recorded at each visit.

2.5. Sample size and statistical analysis

Although several studies have investigated the effects of moxibustion on IBS, not enough randomised controlled trials have been performed to assess differences in the effects of moxibustion for diarrhoea-predominant IBS and constipation-predominant IBS. There are a lack of clinical trials investigating moxibustion dosage, and there are insufficient previous studies from which to base sample size calculations on. The base average difference of 4 weeks after IBSSS-K score of the intervention group and the base against the control group after 4 weeks of assuming that the average difference between the IBSSS-K score, intervention group, and assuming that the effect of the average difference between the control group will be present, the hypothesis for the primary endpoint of the trial was as follows:

H_0: $D \geq 0$ vs H_a: $D < 0$

This paper could not identify any existing Korean clinical trials, which could be used to determine the dosage of moxibustion. Miller [23] noted that a clinically significant reduction in the IBS symptom severity scale is 50. In this study, the average effective reduction in the intervention group and the control group was assumed to be 50 and the standard deviation was assumed to be 45, for a coefficient of variation of 90%. On the basis of these values, we calculated the sample size using the following formula [24]:

$$N = \frac{2(z_{1-\alpha} + z_{1-\beta})^2\sigma^2}{\delta^2}$$

If the significance level is set at 0.05, the statistical power is 0.8, and the drop out probability is 10%, the number of subjects required for this study would be 24 (12 per group).

Data were analysed by a statistician blinded to the group allocations using the Statistical Package for the Social Sciences (SPSS) V.20.0 statistical software package. Significance level was set at $p < 0.05$. Baseline characteristics and primary and secondary outcomes were analysed based on the intention-to-treat principle.

A paired *t*-test was used for within-group comparisons before and after moxibustion, and an independent *t*-test was used for between-group comparisons.

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