ACUPUNCTURE RESEARCH

Efficacy of Electroacupuncture in the Treatment of Functional Constipation: A Randomized Controlled Pilot Trial

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ABSTRACT **Objective**: To evaluate the efficacy and safety of electroacupuncture at Tianshu (ST25) for patients with functional constipation (FC). **Methods**: Ninety-six patients with FC were randomized to receive deep needling on bilateral ST25 (group A, 48 cases) or shallow needling on bilateral ST25 (group B, 48 cases) with electroacupuncture once daily for 4 weeks. The proportion of patients with four or more complete spontaneous bowel movements (CSBMs) per week, and scores of constipation symptoms and satisfaction with treatment were compared between two groups. Safety was also assessed. **Results**: The proportion of patients with four or more CSBMs per week was 52.1% in group A, significantly higher than 25.0% in group B during the 4-week treatment (P<0.05). The constipation symptom score of patients were significantly improved in group A as compared with group B at week 2–4 (P<0.05). Patients in group A were more satisfied with their treatment compared with those in group B at week 1–4 (P<0.05). Five patients in group A felt significant pain and discomfort. No other adverse reaction was observed in both groups. **Conclusion**: Using electroacupuncture at ST25 to treat patients with FC is effectively, and deep needling had more stable effect than shallow needling.

KEYWORDS electroacupuncture, functional constipation, Tianshu, Chinese medicine, randomized controlled trial

Constipation is a common gastrointestinal complaint in clinical practice. It affects 12%–19% of Americans,[1] 14% of Asian,[2] and up to 27% of the general population depending on demographic factors, sampling, and definition.[3] Constipation severely reduces patients' quality of life (QOL) and results in frequent visits to physicians, particularly by women and older patients.[4,5] Physicians and patients usually have different conceptions of constipation. Based on different symptoms, constipation is divided into two syndromes by Rome Ⅲ criteria, i.e., functional constipation (FC) and constipation-predominant irritable bowel syndrome (IBS).[6] Recognizing that patients refer to a variety of symptoms when they consider themselves to be constipated, Rome Ⅲ criteria define FC by the presence of two or more of the following six symptoms, i.e., infrequent bowel habits (less than 3 stools/week), hard stools, excessive straining, a sense of anorectal blockage, or the use of manual maneuvers during evacuation, and a sense of incomplete evacuation after defecation.[3]

In recent years, various treatments for FC have emerged. Increasing physical activity and fiber and fluid intake are often recommended as the first choice of treatment, although the scientific evidence for such treatments is scarce.[7,8]

There was evidence to support the effectiveness of many available treatments for FC such as lactulose, polyethylene glycol,[9-12] biofeedback training (patients are taught relaxation and defecation techniques), and surgery in severe cases.[13,14] However, studies have reported that conventional dose of laxatives can significantly induce drug resistance, drug dependency, or severe adverse events in patients with FC.[15] This has led to high patients' dissatisfaction and frustration with current treatments for FC.[16,17] Therefore, they seek help from complementary and alternative medicines.[18]

Acupuncture is a very important form of Chinese medicine, which is a 3000-year-old holistic system. Advantages of acupuncture include low cost and minimally invasive with low incidence of adverse reaction. Acupuncture has been used in China for thousands of years to treat a variety of

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gastrointestinal problems.[19] Body acupuncture and auricular acupuncture are the most commonly used therapies for chronic constipation.[20-23] Over the past 10 years, there were more than 50 clinical reports on acupuncture treatment of FC. Although the conclusions of researches support the clinical value of acupuncture, the quality and quantity of the evidence is still not fully convincing. On basis of pre-clinical experience summarization, we carried out a single-center, prospective, randomized controlled trial to evaluate the efficacy and safety of electroacupuncture at Tianshu (ST25) on QOL of patients with FC.

METHODS

Inclusion Criteria

Patients were included if they (1) met the Rome Ⅲ diagnostic criteria for FC;[3] (2) were 18–75 years old; and (3) signed the written informed consent.

Exclusion Criteria

Patients were excluded if they (1) had constipation caused by IBS, inflammation, endocrine and metabolic diseases and drugs; (2) had constipation complicated with abdominal aortic aneurysm, abnormal liver and spleen enlargement, intestinal paralysis, incomplete intestinal obstruction, and abdominal tuberculosis; (3) were pregnant or nursing; (4) had severe heart diseases, liver, kidney and other organ damages; or (5) had a cardiac pacemaker.

Participants

Patients were recruited from the Acupuncture and Moxibustion Clinic in West China Hospital of Sichuan University between October 2007 and February 2009. According to sample size calculation formula, this study included 96 patients, and all of them were Han ethnic.

Case Selection

The base line assessment on the eligible patients was completed one week before the treatment. To reduce the influence of laxatives that might be taken by patients before the trial, we prescribed a comfort drug capsule filled with starch instead of purgative three times a day, so that patients had a washout period. Patients enrolled in the study all had experience of ineffective drug therapy for many times, and lost confidence in medication. They were randomly assigned into the group A and group B (48 cases in each group, Figure 1).

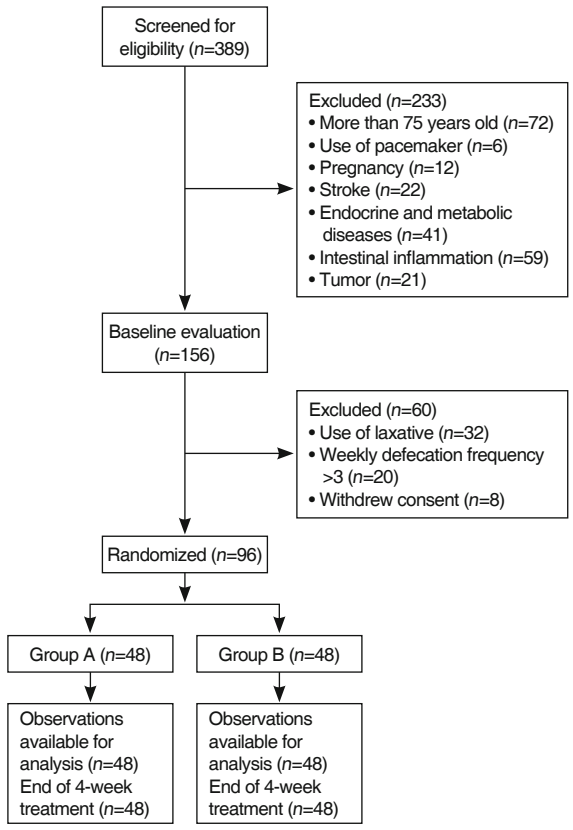

Figure 1. Flow of Participants through the Study

Assignment

All subjects were randomized by an independent investigator using central randomization. Therefore, the variability of variables such as age, gender, disease duration and constipation symptom score (CSS) before treatment was reduced to a minimum.

Treatment

Patients in group A received electroacupuncture treatment of deep needling on bilateral ST25, which locates at the crossing of clavicle midline and umbilical horizontal line bilaterally. The 75-mm-long filiform needles (No. 28) were rapidly inserted into the skin, and slowly deepened perpendicularly until penetrating peritoneum, then retained without lifting, thrusting, swirling and rotating manipulation. (The standard of breaking through the peritoneum: manipulators felt a sense of puncturing; patients felt obvious pulling pain simultaneously; and the needling depth was about 45 mm). Needles at bilateral ST25 were connected to Han's electroacupuncture apparatus (LH202H, Shanghai Huayi Medical Instrument Factory, Shanghai, China). The frequency of electrical stimulation was 2/15 Hz. Stimulation intensity was gradually increased until slight vibration of abdominal muscles was observed and

patients felt mild pain. Needles were retained for 30 min without manipulation. All manipulations were same as the electroacupuncture deep-needling protocol. Patients in group B received the same electroacupuncture treatment as group A except that the length of acupuncture needles were 10 mm and the depth of needling was at approximately 5 mm. Acupuncture was operated by two registered acupuncturists, who had been trained for 4 years and had at least 5-year clinical experience in acupuncture treatment. All patients in the two groups received electroacupuncture treatment once daily, 5 times a week, continuously for 4 weeks.

Ethics

This trial was approved by Medical Ethics Committee of West China Hospital of Sichuan University (No. 2006BAI1205), and complied with the recent principles of the Declaration of Helsinki (World Medical Association, 2000).

Outcome Measures

During the trial, patients recorded in daily diaries the complete spontaneous bowel movements (CSBMs), date and time of intake of the relevant aperient medicine, and change of the diet and exercise.

The primary efficacy end point was the proportion of patients with, on average, four or more CSBMs per week during the 4-week treatment; and the proportion of patients with an average increase of two or more CSBMs per week as compared with the baseline number.

The main secondary efficacy end point was CSS assessed patients' constipation symptoms at baseline and at week 1, 2, 3 and 4.[22] About eight constipation-related symptoms were recorded and scored by patients, including straining, endless sensation of defecation, stool consistency, bowel sound, abdominal pain, abdominal bloating, diarrhea and fecal incontinence. Scores ranged from 0 (symptoms absent) to 4 (symptoms very severe). Moreover, the patient's satisfaction with treatment was assessed at week 1, 2, 3 and 4 with the use of a 5-point scoring scale completed by patients, ranging from "not at all" (4 points) to "extremely satisfactory" (0 point).

To evaluate the safety of electroacupuncture, adverse reactions such as diarrhea, abdominal pain, fainting during acupuncture treatment, hematoma, and infection in abdominal cavity, were monitored during the treatment and 1 week after treatment.

Statistical Analysis

Statistical analysis of the data was performed using SPSS 12.0. Data were expressed as mean ± standard deviation ($\bar{x} \pm s$) or percentage. Continuous data in normal distribution were analyzed using analysis of variance and *t*-test with Dunnett's adjustment for multiple comparisons; data in abnormal distribution was analyzed using Kruskal-Wallis test; categorical data was analyzed using *Chi*-square test. $P<0.05$ was considered to be statistically significant.

RESULTS

Baseline Characteristics of Patients in Two Groups

From October 2007 to February 2009, all patients had good compliance with the treatment. Patients in group A were 21–75 years old with disease duration of 1–28 years; while in group B were 26–71 years old and 1–22 years, respectively. There was no significant difference in baseline characteristics between two groups ($P>0.05$, Table 1).

Comparison of CSBMs between Two Groups

As shown in Table 2, the percentage of patients with four or more CSBMs per week was significantly higher in group A, as compared with group B ($P<0.05$). Over 4 weeks, the percentage of patients with an increase of two or more CSBMs per week in group A was 75.0%, more than 33.3% in group B ($P<0.05$). The average number of CSBMs per week and change from baseline over the 4-week period were significantly improved in group A, as compared with group B ($P<0.05$).

Comparison of CSS between Two Groups

As shown in Table 3, CSS of patients in both

Table 1. Baseline Characteristics of Patients in Two Groups

Group	Case	Sex [Case (%)]		Age (Year, $\bar{x} \pm s$)	Disease duration (Year, $\bar{x} \pm s$)	CSS (Score, $\bar{x} \pm s$)
		Female	Male			
A	48	38 (79.2)	10 (20.8)	48.85 ± 13.30	7.65 ± 6.48	11.77 ± 3.01
B	48	42 (87.5)	6 (12.5)	45.25 ± 11.28	8.48 ± 5.76	11.31 ± 2.30

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Table 2. Comparison of CSBMs between Two Groups

Group	Case	≥4 CSBMs per week [Case (%)]	Increase of ≥2 CSBMs per week [Case (%)]	Number of CSBMs		
				Baseline	Week 1–4	Change from baseline
A	48	25 (52.1)*	36 (75.0)*	1.65	4.18*	2.53*
B	48	12 (25.0)	16 (33.3)	1.75	3.35	1.60

Note: *P<0.05, compared with group B

Table 3. Comparisons of CSS and Patients' Satisfaction Score with Treatment between Two Groups (Score, $\bar{x} \pm s$)

Group	Case	Time	CSS	Change from baseline of CSS	Satisfaction
A	48	Baseline	11.77 ± 3.01	—	—
		Week 1	8.21 ± 2.54*	–3.56 ± 2.97△	2.08 ± 0.54△
		Week 2	6.81 ± 2.62*△	–4.96 ± 2.96△	1.88 ± 0.67△
		Week 3	6.13 ± 2.36*△	–5.65 ± 2.92△	1.73 ± 0.84△
		Week 4	5.15 ± 2.33*△	–6.63 ± 2.98△	1.35 ± 0.84△
B	48	Baseline	11.31 ± 2.30	—	—
		Week 1	8.90 ± 2.67*	–2.42 ± 2.00	2.56 ± 0.68
		Week 2	8.44 ± 2.61*	–2.88 ± 2.33	2.44 ± 0.68
		Week 3	8.00 ± 2.67*	–3.29 ± 2.80	2.56 ± 0.74
		Week 4	7.81 ± 3.10*	–3.46 ± 3.22	2.48 ± 0.68

Notes: *P<0.05, compared with baseline; △P<0.05, compared with group B

groups were significantly reduced from baseline to week 1–4 (P<0.05). Compared with patients in group B, patients in group A had significant improvements in CSS at week 2–4 and change from baseline of CSS at week 1–4 (P<0.05).

Comparison of Patients' Satisfaction Score with Treatment between Two Groups

Patients' satisfaction score with treatment was significantly improved in group A as compared with group B at week 1–4 (P<0.05, Table 3).

Adverse Reactions

Five patients in group A felt significant pain and discomfort. There were no other adverse reactions such as diarrhea, abdominal pain, fainting during acupuncture treatment, hematoma, or infection in abdominal cavity in both groups.

DISCUSSION

In this randomized controlled trial, the proportion of patients with four or more CSBMs per week was significantly higher in group A than in group B during the 4-week treatment. This primary end point is considered to be clinically meaningful, since it combines a subjective measure of the completeness of evacuation with an objective measure of the number of CSBMs and reflects the relief of chronic constipation.

The increase of 2.53 CSBMs per week among patients in group A was in contrast to an increase of 1.60 CSBMs per week in group B. In a clinical trial that used the same definition of CSBMs, the increase from baseline was 2.2 and 2.5 CSBMs per week with the use of 2 and 4 mg of prucalopride once daily, respectively, as compared with an increase of 0.8 CSBMs with the use of placebo.[22]

Our trial also demonstrated that electroacupuncture at ST25 significantly improved patients' perception of the severity of constipation and satisfaction with treatment. Patients in group A showed more benefit in the CSS and satisfaction score than patients in group B.

Although the deep needling with electroacupuncture had more stable effect and produced faster effect than the shallow needling, deep needling on ST25 made five patients feel significant pain and discomfort, as patients often fear acupuncture especially after more than ten times of continuous deep needling treatment.

There are some limitations in this trial. As blind method was not adopted in acupuncture operator in this trial, the method which minimized the bias of measurement consisted of two doctors specially operating in the two groups, respectively, and another doctor who did not know grouping evaluating the therapeutic effect.

Since the research institute belongs to Western medical center, the patients enrolled in the study all had experience of ineffective therapy in other hospitals for many times, however, they did not fill in the evaluation indexes actively, which may produce memory bias.

The current results was similar to previous acupuncture studies that carried out electroacupuncture at Zhigou (SJ6) for constipations.[23-25] Acupuncture groups had statistical differences in improving symptoms of constipations and increasing frequency of defecation compared with multiple control groups; the therapeutic effect consistently last from the end of the treatment to a 3-month follow-up.

Based on the results of this trial, it is concluded that electroacupuncture at ST25 can produce continuous clinical benefits. Deep needling had more stable effect than shallow needling. The therapeutic scheme was easy to operate and it can be considered to be efficacious in the FC treatment.

Conflict of Interest

The authors declare that they have no conflict of interests.

Author Contributions

Xue QM drafted the manuscript; Lu JQ collected the data; Wang CW and Xue QM performed the statistical analysis; Li N and Liu ZS participated in the design of the study and explanation of the data. All authors have read and approved the final manuscript.

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