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Clinical Research

Electroacupuncture combined with *qibei* mixture for diarrhea-predominant irritable bowel syndrome: A randomized controlled trial

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ABSTRACT

Objective: To explore the short and long-term efficacy of combining electroacupuncture (EA) and *Qibei* mixture in the treatment of irritable bowel syndrome (IBSD).
Methods: Six hundred and forty-four patients with confirmed IBSD from the Department of Gastroenterology, the First Affiliated Hospital of Xinxiang Medical University in China, recruited from July 2012 to June 2016, were randomly divided into four groups, the EA group, *Qibei* mixture group, combination group and medication group with 161 patients in each group. The patients in the EA group were treated with EA at zúsānlǐ (足三里ST36), Gān shù (肝俞BL18), Píshù (脾俞BL20), Tàichōng (太冲LR36) and Qízhōngsìbiān (脐中四边) once daily for 4 weeks, while the patients in the *Qibei* mixture group were treated with 50 mL of *Qibei* mixture twice daily, the combination group with the above-mentioned EA and *Qibei* mixture, and the medication group with 1 tablet compound diphenoxylate twice, 3 g montmorillonite powder three times and 25 mg amitriptyline twice daily. The defecation frequencies, stool properties, accompanying symptom score, life quality score and adverse reactions were recorded pre-treatment, at the end of treatment and 6 weeks post-treatment for the four groups.
Results: Compared with pre-treatment, the defecation frequencies, stool property score and accompanying symptom score were all decreased significantly at the end of treatment in each group (all $P < 0.01$), while the scores of nine dimensions of quality of life were all increased significantly (all $P < 0.01$). The above-mentioned indices were better in the combination group than in the other groups (all $P < 0.05$). Compared with the end of treatment, no significant recurrences of the above-mentioned indices had occurred in the combination group or the EA group at 6 weeks post-treatment (both $P > 0.05$), but these indices all recurred significantly in the group given *Qibei* mixture and the medication group ($P < 0.05$). The short- and long-term total effective rates in the combination group both showed significant differences from those in the other groups ($P < 0.05$, $P < 0.01$). No serious adverse reactions occurred in the four groups.
Conclusion: EA and *Qibei* mixture can decrease defecation frequencies, improve stool properties, and alleviate accompanying symptoms to increase life quality, but the therapeutic effect of combination therapy is greater, with better reliability and long-term efficacy.

Background

Irritable bowel syndrome (IBS) is the most frequently diagnosed functional gastrointestinal disorder in primary and secondary care. It is characterized by abdominal discomfort, pain and changes in bowel habits [1]. There are a number of factors to be involved in the pathogenesis of IBS, including impaired motility and sensitivity, increased permeability, changes in the gut microbiome and alterations in the brain–gut axis [2,3]. In the Asia-Pacific region, IBS is as common as in the rest of the world, with a prevalence varying from 10% to 20%. IBS is a common problem encountered in gastroenterology, and it severely impairs quality of life [4–6]. In recent years, combined administration of intestinal peristalsis in-

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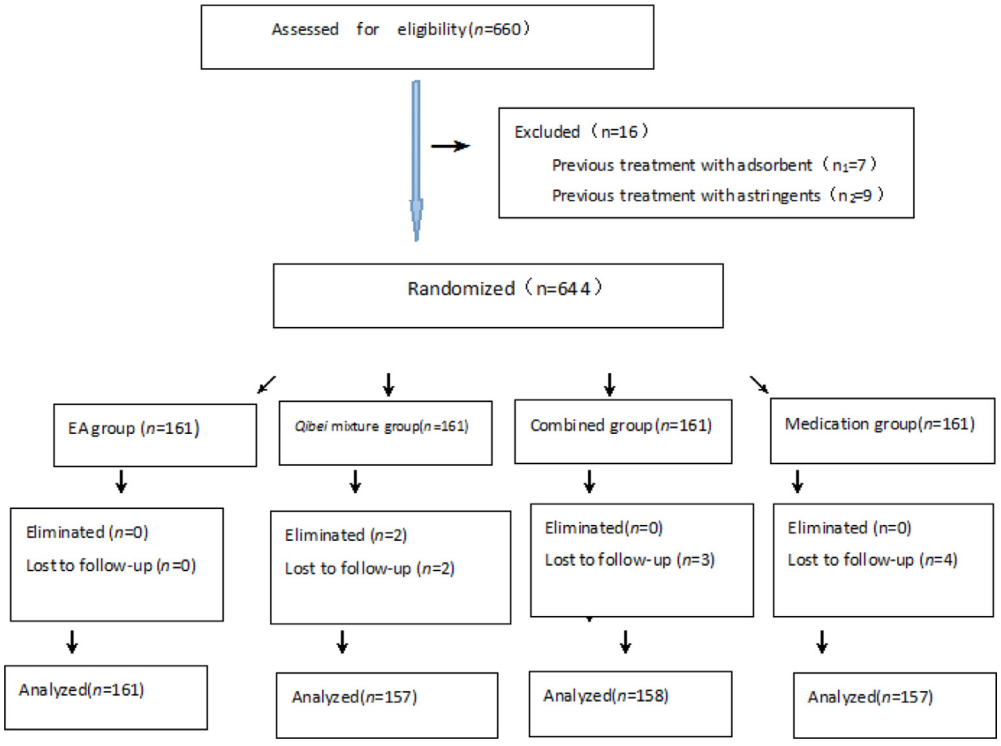

Fig. 1. Flowchart of this randomized trial.

hibitors, adsorbents, astringents, intestinal mucosa protectors and anti-depressants in the treatment of IBS have achieved a certain therapeutic effect, but with a long therapeutic course and heavy economic burden for the patient, and with a high recurrence rate after ceasing the drugs. Clinically, both acupuncture and traditional Chinese herbs have satisfactory effects on IBS, but few systematic reports are found. In this study, 644 cases of irritable bowel syndrome with diarrhea (IBSD) were treated with *Qibei* mixture, electroacupuncture (EA), EA combination with *Qibei* mixture, and western medication respectively. The defecation frequencies, stool properties, accompanying symptom score, life quality score and adverse reactions were observed at pre-treatment, the end of treatment and 60 weeks post-treatment in four groups in order to explore the clinical efficacy, safety of combining *Qibei* mixture and EA in patients with IBSD.

General datas

There were 660 cases with confirmed IBSD in out-patients or in-patients of the Department of Gastroenterology from July 2012 to June 2016, 16 of them were excluded for previous treatment with adsorbent or astringents, and the other 644 cases were randomly divided into four groups: the EA group, *Qibei* mixture group, combined group, and medication group by a randomized digital table according to the visiting order, 161 cases in each group. In the process of treatment and follow-up, 2 cases in the *Qibei* mixture group were eliminated for not taking the medicine strictly according to the research plan and 2 cases were lost to follow-up, while 3 cases in the combined group and 4 cases in the control group were lost to follow-up. Finally, there were 633 cases that were analyzed statistically. The flow diagram of this randomized trial is shown in Fig. 1. There were no significant differences among the four groups in gender, age and course of disease, degrees of disease (mild: total symptom grade $\leq$9; medium: 9 < total symptom grade $\leq$ 18; severe: total symptom grade > 18), etc. (all $P > 0.05$), as shown in Table 1. The ethical review number of the study is 2011073 by the ethics Committee of The First Affiliated Hospital of Xinxiang Medical University.

Diagnostic criteria

In accordance with the diagnostic criteria [7] for functional gastrointestinal disease, IBSD was defined as follows: the Rome criteria require the presence of abdominal pain or discomfort for at least 3 days per month in the last 3 months, along with$\geq$2 of the following: (1) Improvement with defecation. (2) Onset (of each episode of discomfort) associated with a change in frequency of defecation (more than 3 times per day). (3) Change in consistency of stool (mushy stool or watery stool).

Inclusion criteria

(1) Patients voluntarily signed the informed consent form. (2) Patients were aged between 18 and 68 years, male or female. (3) Organic lesion was excluded by endoscopy or barium enema examination within 1 month. (4) Patients did not receive drugs that could influence the outcome of the trial (for example, intestinal peristalsis inhibitor, adsorbents, or astringent) within 1 week before entering the trial.

Exclusion criteria

(1) Patients had diarrhea-like symptoms caused by various organic lesions, such as tumor, Crohn's disease, colon polyp, or tuberculosis of colon. (2) Pregnant or lactating women. (3) Patients who were hypersensitive to the test drug. (4) Cases complicated with serious primary diseases of heart, blood vessels, liver, kidney or hematopoietic system, and mental diseases.