Effect of Modified Sinisan on Anorectal Manometry of
the Constipation Predominant Type of Irritable Bowel Syndrome

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ABSTRACT  Objective: To explore the mechanism in patients with irritable bowel syndrome (IBS) of the
constipation predominant type and observe the therapeutic effects of Sinisan (四逆散, SNS). Methods: Forty-seven IBS patients with the constipation predominant type were randomly divided into the treated group (n=24) and the control group (n=23). Another group of 22 healthy subjects was set up for healthy control. The treated group was treated with modified SNS, and the control group was treated with Cisapride, the therapeutic course for both groups was 8 weeks. The changes of symptom scoring and anorectal manometry (the anorectal resting pressure, anal tract systolic pressure, anal tract diastolic pressure, rectal threshold feeling, maximal tolerance volume of rectum, and rectal compliance) of these two groups were recorded respectively and compared with each other. Results: Compared with the healthy control group, the rectal threshold feeling, maximal tolerance volume of rectum and rectal compliance of the treated groups got reduced significantly before treatment (P<0.05). After treatment, the symptom scoring, rectal threshold feeling and maximal tolerance volume of rectum were improved in both groups (P<0.05), and the improvement of the treated group was more significant than that of the control group (P<0.01). The total effective rate and recurrence rate of the treated group were superior to those of the control group significantly (P<0.05, P<0.01). Conclusion: SNS has good effect on IBS of the constipation predominant type.

KEY WORDS  irritable bowel syndrome, constipation-predominant type, anorectal manometry, Sinisan

Irritable bowel syndrome (IBS) of the constipation predominant type is a functional intestinal disease characterized by abdominal distress or pain, changed habit of defecation and abnormal defecation. Its pathogenesis has not been totally clarified yet. This research is to explore the mechanism of patients with IBS of the constipation predominant type through the determination of anorectal pressure via anus and better efficacy has been obtained in the study by modifying Sinisan (四逆散, SNS) and it is summarized as follows.

METHODS

Study Objective

From February 2000 to August 2003, patients who conformed to Rome diagnostic standard(1) in our clinic were included in the study. Altogether 47 patients were divided into two groups by randomly following the priority order of consultation and in the treated group were 24 patients; male 11, female 13; age 25–71 years old, 48.33±13.01 years on average; their illness course from 3 months to 4 years, 23.35±13.36 month on average. In the control group were 23 patients; male 12, female 11; age 26–69 years old, 47.70±11.39 years on average; their illness course 3 months to 4 years, 22.38±11.01 months on average. In the treated and control groups, respectively 15 and 13 cases were in the severe degree, 7 and 8 in the moderate degree, 2 and 2 in the mild degree; so the two groups were comparable. In the healthy group (no obvious anal and rectal disease, no constipation and diarrhea recently, without history of anus and rectum operation) were 22 subjects (5 healthy volunteers and the others being clinical patients who conformed to the inclusion criteria for healthy subjects); male 9, female 13; age 26–72 years old, 50.40±14.27 years on average. So the three groups were comparable in sex and age.
Treatment Methods

For the treated group, the modified SNS (Thorowax root 10 g, immature bitter orange 10 g, Aucklandia root 10 g, Spicebush root 10 g, Bighead atractylodes rhizome 20 g, White peony root 10 g, Ligusticum chuanxiong rhizome 10 g, Chinese angelica root 10 g, and Licorice 5 g water decocted) was prepared. One dose daily, which was divided into 2 portions for oral intake, 100 ml each time, 0.5 hr before meal. For the control group, with Cisapride tablet (product of Xi'an Jansen Pharmaceutical Co., Ltd., batch number: 990809) was given 10 mg each time, 3 times a day, 0.5 hr before meal. For both groups, 8 weeks were taken as one treatment course, and the therapeutic effect was evaluated after one course of treatment.

Observation Items and Examination Methods

Symptom scoring: Symptoms of abdominal distension, abdominal pain, defecation difficulty and inability to clear the bowel completely were divided into 4 grades, i.e. serious, middle, mild and none, which were respectively marked as 6, 4, 2 and 0 points.

Determination of anal and rectal pressure: The healthy group and the two treated groups before and after treatment were determined the anal and rectal pressure. Adopted were the PC Polygraf, which was to monitor via capillary liquid perfusion the gastrointestinal (GI) tract pressure device (product of the Swedish CTD-Synectics Company) and the Synectics Visceral Stimulator (SVS), a GI tract motility monitor, which is a GI tract tension detection system of the electronic barometric pressure pump. Using static determination assay (perfusion speed is 0.2 ml/min), the anal resting pressure, the anal systolic pressure, anorectal inhibitory reflects (anal diastolic pressure after 50 ml stimulation), rectum threshold feeling, the maximal tolerance volume of rectum and rectum compliance were all measured.

Standard of Therapeutic Effect

Markedly effective: TCM symptom scoring after treatment got reduced by $\geq 60\%$ compared with that before treatment and anorectal pressure determination parameter obviously improved. Effective: TCM symptom scoring after treatment lowered by $30\% - 59\%$ compared with that before treatment and anorectal pressure determination parameter improved. Ineffective: failing to reach the standard set as effective. Recurrence: Concerning those patients in whom the treatment proved markedly effective, the symptoms appeared again within 6 months after the treatment course ended and for those cases who proved the treatment effective, the symptoms got aggravated, failing to reach the standard set as effective.

Statistical Analysis

$t$ test was adopted.

RESULTS

Comparison of Efficacy of the Two Treated Groups

Of the 24 patients in the treated group, 20 (83.33%) proved the treatment to be markedly effective, 3 (12.50%) effective and 1 (4.17%) ineffective, and the total effective rate was 95.83%. Of the 23 in the control group, it was 13 (56.52%), 5 (21.74%), 5 (21.74%) respectively, and the total effective rate was 78.26%. In the treated group, the markedly effective rate, the effective rate and the total effective rate were all obviously superior to those of the control group ($P<0.05$).

Comparison of Symptom Scoring

See Table 1. The difference in symptom scoring before treatment between the two groups was not significant ($P>0.05$) and 8 weeks after treatment, the symptom scoring between the two groups was obviously reduced compared with that before treatment ($P<0.05$ or $P<0.01$), and comparison of the two treated groups before and after treatment it showed that the difference was significant ($P<0.01$).