CLINICAL EXPERIENCE

The Therapeutic Effect of Xiaopi-I (消痞I号) on Functional Dyspepsia

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ABSTRACT  Objective: To observe the therapeutic efficacy of Xiaopi-I (消痞I号) on functional dyspepsia and its effects on gastric emptying. Methods: A total of 134 patients with functional dyspepsia were randomly assigned to 2 groups. The patients in the Xiaopi-I group (66 cases) and the Domperidone group (68 cases) were given Xiaopi-I granules and Domperidone 10 mg, 3 times a day, respectively. Another 20 healthy volunteers were chosen as the negative control group. The severity scores of the symptoms, as well as the gastric emptying, were detected before and after 4-week treatment by barium strip-trial meal. Results: During therapy, 6 cases from the Xiaopi-I group and 8 cases from the Domperidone group were lost to follow, and 120 cases finally finished the study. Statistical differences were observed from both groups in terms of the symptoms of postprandial fullness, early satiety, epigastric pain, and epigastric burning after 4-week treatment (P<0.01). The symptomatic severity scores of the Xiaopi-I group before and after the treatment were 7.48±1.64 and 2.16±1.26, respectively (P<0.01). Gastric emptying rates were also improved in the patients with delayed gastric emptying, and the effective rates were 91.3% and 75.8% in the Xiaopi-I and Domperidone groups, respectively. No obvious adverse effects were found from both groups. Conclusion: Xiaopi-I was an effective and safe agent in the treatment of functional dyspepsia and was worth of further development in clinical.

KEYWORDS functional dyspepsia, Xiaopi-I, barium strip-trial meal, Chinese medicine

Functional dyspepsia (FD) refers to a group of symptoms, including postprandial fullness, early satiety, epigastric pain, and epigastric burning, which are considered by most physicians to originate from the gastroduodenal region if standard investigations do not provide an explanation for symptoms. The incidence rate as epidemiological research reported in China is from 0.82% to 5.67%, and the proportions of the patients from internal medicine clinics and digestive clinics are 10.1% and 34.3%, respectively. Rome III criteria classified FD into postprandial distress syndrome (PDS) and epigastric pain syndrome (EPS). Of note, the Rome III criteria of FD have yet to be validated in clinical trials. Song, et al explored that the delaying of gastric emptying was the main mechanism for FD according to Rome III criteria. Due to the complicated pathophysiology of FD, the most appropriate therapeutic targets to the symptoms have not been defined yet; thus, searching for an effective treatment option is considerably necessary.

The long-time practice proves that Chinese herbs could improve the gastric motility and relieve certain symptoms associated with FD. Xiaopi-I (消痞I号), a kind of traditional formulae developed by the cooperation of Department of Gastroenterology and Traditional Chinese Medicine from Shengjing Hospital of China Medical University, had been proven a significant therapeutic method against gastric motility in clinical practice. Furthermore, previous researches found that Xiaopi-I could improve the gastric emptying and intestinal pulling of mice, and thus acted as promotion of gastrointestinal motility. Zhu, et al concluded the reasonable prescription composition of Xiaopi-I by screening the original agent with the orthogonal t value method and identified its pharmacodynamic action by animal experiments. This research mainly observed the therapeutic effect of the reasonable combination of Xiaopi-I on symptom improvement and gastric emptying.

METHODS

Inclusion Criteria

The diagnostic criteria were based on the Rome
III criteria. All subjects aged from 18 to 65 years old, who complained of at least one of the symptoms (early satiety, epigastric pain, epigastric burning, and postprandial fullness), which had been lasting for more than 6 months and becoming more severe for the recent 3 months, were enrolled.

Exclusion Criteria

The exclusion criteria included: history of carcinoma or ulcer by the examination of gastroscope, barium meal, and ultrasound; prior treatment with medications included anticholinesterases, spasmolysis or other gastrointestinal promotion, evidence of acute or serious medical conditions that could mask the effect of the trial medication was disallowed; in addition, psychinosis, or allergic to the two drugs, pregnant or breastfeeding women, and those of childbearing age who were not using contraception method were excluded.

Grouping and Treatment

A total of 134 eligible patients fulfilling Rome III criteria from the digestive clinic were randomized into 2 groups by a random number table. The Xiaopi-I group included 22 males and 44 females, aging between 26 and 58 years, with FD duration 2–10 years, and the Domperidone group included 29 males and 39 females, aging between 30 and 63 years, with FD duration 2–15 years. The patients were recruited from January 2008 to July 2009 in Shengjing Hospital. The baselines were comparable between the two groups. Another 20 healthy volunteers were recruited as the negative control group.

The Xiaopi-I prescription was made into granules composed of Rhizoma Atratylodis Macrocephalae 10 g, Fructus Amomi 15 g, Fructus Aurantii Immaturus 12 g, etc. (Huarun Sanjui Pharmaceutical Co., Ltd., Shenzhen, China: 0806021). Xiaopi-I and Domperidone (Xi'an Janssen Pharmaceutical Ltd., Xi'an, China: 080107126), 10 mg 3 times per day, were given to the two groups for 4 weeks, respectively.

Observation of the Symptomatic Severity Scores

For the assessment of FD symptoms, the criterion included 4 levels according to the severity: 0: without symptoms; 1: mild symptoms that are totally bearable; 2: severe symptoms that frequently interfere daily life and work, but are still bearable; 3: unbeatable severe symptoms.8

Detection of Gastric Emptying

Gastric emptying was detected before and after treatment by ingestion of barium strip-trial meal. The barium strip (provided by Aerospace Industry for National Defense Medical Research Institute) was 10 mm × 1 mm. The standard meal was the rice pudding sold in market. All subjects who did not take any kind of gastrointestinal promoting drugs for at least 72 h, and fasted diet for more than 12 h, took the standard meals mixed with 20 strips at 8:00 a.m., and finished the meals within about 20 min. Erect abdominal X-ray test was taken 5 h later, and the number of the strips in stomach was counted. The duration of gastric emptying exceeding more than twice standard deviation was defined as delayed gastric emptying.

Efficacy Assessment

The symptomatic severity scores were recorded before and after treatment for the efficacy assessment. The therapeutic responses were instituted according to Guiding Principles for the Clinical Research on New Drugs of Tradtional Chinese Medicines8 that included the following: remarkable: both symptoms and physical signs are improved significantly, and the descent of total points are more than 75%; effective: both symptoms and physical signs are improved, and the descent of total points are more than 50%, but less than 75%; ineffective: both symptoms and physical signs are not improved, or even aggregated, and the descent of total points are less than 50%. The rate of total symptomatic improvement (RTSI) = (severity scores before treatment – severity scores after treatment)/severity scores before treatment × 100%. Effective rate = (remarkable cases + effective cases)/60 × 100%. Residual rate = residual strips in stomach/20 × 100%.

Statistical Analysis

All data were presented as mean ± standard deviation and tested using SPSS 13.0 software. T-test was used to compute the difference between the two sample mean, χ² test with counting data, and Ridit test was used to compare the clinical efficacy between groups. P<0.05 was recognized as having statistical significance.