

Clinical study on *Amomum villosum* Lour extract in the treatment of functional dyspepsia due to deficiency of spleen and stomach.

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Abstract

Objective: To investigate clinical significance of *Amomum villosum* Lour extract for the treatment of functional dyspepsia resulting from deficiency of spleen and stomach.

Methods: From February 11, 2016 to January 5, 2017, 88 cases of functional dyspepsia in our hospital were selected as the objects and randomly divided into two groups (control group and observation group). The control group took mosapride treatment while the observation group was treated with extract of *Amomum villosum* Lour. The clinical effects, TCM symptoms, quality of life and adverse events of the two groups were observed. **Results:** In the observation group, the total effective rate (95.45%) was significantly higher compared with that of the control group (77.27%) of statistical significance, $P < 0.05$; the TCM syndrome scores 9.65 ± 1.08 and the score of life quality 86.89 ± 2.47 after treatment were better than those of the control group, $P < 0.05$; and there was no significant difference in adverse events between the two groups with no serious consequences, $P > 0.05$. **Conclusion:** the extract of *Amomum villosum* Lour can be used to treat functional dyspepsia caused by deficiency of spleen and stomach with definite effects of security and it can effectively alleviate the suffering of patients, help disease control and improve the quality of life.

Keywords: Functional dyspepsia, Extract of *Amomum villosum* Lour, Deficiency of spleen and stomach.

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Introduction

Functional dyspepsia refers to such related symptoms of hypopepsia as postprandial fullness discomfort, upper abdominal pain or epigastric burning sensation but no suspicious lesions will be seen through the means of ultrasound, biochemical examination and endoscope [1], thus it cannot be explained as an organic disease. The disease, linking with age to some degree, is featured with long course and easy relapse, exerting serious impacts on life and work of the patients. It is included in stuffiness of stomach by Chinese medicine with the deficiency of the spleen and stomach more commonly seen which can be treated by conventional western medicine with certain yet not very idea results. The purpose of this study is to investigate the clinical significance of *Amomum villosum* Lour extract for the treatment of functional dyspepsia resulting from deficiency of spleen and stomach.

Data and Methods

Data

From February 11, 2016 to January 5, 2017, 88 cases of functional dyspepsia due to deficiency of spleen and stomach treated in our hospital were selected as the objects and

randomly divided into two groups (44 cases in each group) with informed consent of all the patients and their families to join in the study.

Control group: There were 26 males and 18 females at the age of 41-70, 56.17 ± 3.90 on average, and with the disease course of 2.15 ± 0.87 years.

Observation group: There were 24 males and 20 females at the age of 42-69, 56.03 ± 3.78 on average, and with the disease course of 2.28 ± 0.95 years.

Criteria of TCM diagnosis: Stomach fullness or faint stomachache; predilection for pressure and warmth, worse illness condition after suffering from coldness or tiredness, much more painful feeling under an empty stomach; lack of warmth in the extremities, lassitude and anorexia, thin sloppy stool, fatigued limbs and spit clear water.

Inclusion criteria: The patients at the age of 41 or older with no organic disease and subject to symptoms like early satiety, postprandial fullness discomfort and upper abdominal pain.

Exclusion criteria: Patients with serious organs diseases of heart, liver, kidney or lung; patients with diseases of the blood system or immune system; patients at the state of pregnancy and lactation; patients with mental disorder or confusion;

patients with a history of drug abuse or chronic alcoholics; patients with endocrine system diseases like diabetes mellitus and connective tissue disease; overlap syndrome patients with the first manifestation of irritable bowel syndrome and gastroesophageal reflux disease.

Methods

The control group was treated with conventional western medicine at the dosage of 5 mg/times, three times a day, oral before meals for one month.

The patients in the observation group were given the extract of *Amomum villosum* Lour at the dosage of 5 ml/times (the equivalent of 6 grams of medicinal materials of *Amomum villosum* Lour), three times a day for a constant month.

Observation index

The clinical effects, TCM symptoms, quality of life and adverse events were observed before and after treatment in the two groups.

The TCM syndromes involved twelve items, namely noisy stomach, nausea and vomiting, abdominal distention, belching, eating less epigastric pain, hiccup, fatigue, throat pain, chest tightness, loose stool, body weight drowsiness, short yellow urine with 4 as the highest score and 0 the lowest for each item, The lower, the better.

The quality of life was evaluated by means of Quality of Life Questionnaire (GQOL-74), including physiological, psychological and social function and material life of the patients with 100 as the highest score, with higher, the better.

Criteria for efficacy

Cure: the related symptoms and signs basically disappeared after treatment and the TCM score decreased by more than 95%.

Markedly effective: symptoms and signs were significantly improved and the TCM score improved by an extent from 70% to 95%.

Effective: symptoms and signs were relieved and the TCM score decreased by 30% to 70%.

Table 2. Comparison of the TCM score and quality of life score between two groups.

Items	Cases	TCM score		Quality of life score	
		Before treatment	After treatment	Before treatment	After treatment
Observation group	44	28.93 ± 2.76	9.65 ± 1.08	65.71 ± 4.81	86.89 ± 2.47
Control group	44	29.47 ± 3.03	17.34 ± 1.61	66.09 ± 4.56	77.11 ± 3.08
t	/	0.87	26.31	0.38	16.43
P	/	0.38	0.01	0.70	0.01

Invalid: the failure of meeting the above standards.

The total effective rate= the total rate-invalid rate in the 2 groups [2].

Statistical analysis

Count data including TCM syndrome score and quality of life score were detected by t test and measurement data including the total effective rate and the rate of adverse events by chi-square test on SPSS 21.0 software for statistical analysis. $p < 0.05$ suggested that the difference had statistical significance.

Results

Comparison of clinical effects between two groups

The study showed that the total effective rate of the observation group was 95.45%, significantly higher than that of the control group, $p < 0.05$ (Table 1).

Table 1. Comparison of the total effective rate between two groups.

Items	Cases	Cure	Markedly effective	Effective	Invalid	Total effective rate
Observation group	44	14	13	15	2	95.45
Control group	44	8	14	12	10	77.27
χ^2	/	2.18	0.05	0.48	6.18	6.18
P	/	0.14	0.82	0.49	0.01	0.01

Comparison of change in traditional Chinese medicine clinical symptoms and quality of life before and after treatment between two groups

The analysis showed that there was no significant difference in TCM syndrome score and life quality score before treatment between the two groups, $P > 0.05$; after treatment, the TCM score of the observation group ($9.65 \pm 1.08\%$) was lower than that of the control group and the quality of life score ($86.89 \pm 2.47\%$) was higher than that of the control group, $P < 0.05$ (Table 2).

Comparison of adverse events between two groups

No serious consequences have been found in either group in terms of adverse events and the adverse event rate of the observation group was 4.55%, lower than that of the control group but of no significant difference, $P > 0.05$ (Table 3).

Table 3. Comparison of the rate of adverse events in the two groups.

Items	Cases	Nausea	Stomach upset	Headache	Adverse events rate
Observation group	44	1	1	0	4.55
Control group	44	2	1	1	9.09
x ²	/	0.35	0.00	1.01	0.72
P	/	0.56	1.00	0.31	0.40

Discussion

Functional dyspepsia due to deficiency of the spleen and stomach is one of common functional gastrointestinal disorders and the patients are usually subject to such symptoms as early satiety and abdominal distension [3]. The pathogenesis of this disease remains to be established and in clinical trials it is often given western medicine treatment of gastric motility to promote gastric emptying and relieve relevant symptoms [4]. Meanwhile proton pump inhibitor would be used to inhibit the secretion of gastric acid and further control of the disease. The result, however, is not even satisfactory enough.

In addition to the influence in quality of life, functional dyspepsia due to the deficiency of spleen and stomach may also cause economic pressure and increase mental burden for the patients [5]. Chinese medicine believes that this disease is mainly due to the fact that people's stomach is hurt by improper diet and labor as well as tiredness lead to the injury of spleen. The following insufficiency of the function in qi transportation [6-9] will directly cause the weakness of the spleen and stomach followed by indigestion. In addition, those with long illness and deficiency are usually subject to the weakness of spleen and stomach, which is mainly treated with Chinese medicine of Decoction of Cyperus and *Amomum* with Six Noble Ingredients. *Fructus amomi* is the mature fruit of *Semen amomi* Longiligula with the function of removing dampness by means of aromatics [10,11]. *Amomum villosum* Lour is produced in Yangchun of Guangdong province and it can be used as a flavoring accessory. Besides it also has the effect of warming spleen and stopping diarrhea, stimulating the appetite and removing the dampness, regulating the flow of vital energy and removing obstruction to it and miscarriage prevention. Its nature is warm and flavor is pungent, able to treat vomiting and diarrhea, stomach deficiency and fetal irritability [12]. The extract of this medicine mainly contains components of borneol, acetic acid, borneol, limonene and camphor, as many as twenty-six substances included. Research and analysis on its biological activity and pharmacological action have been made in multi-angles in clinical practices [13-16] and the results found that the extract of *Amomum*

villosum Lour can enhance gastrointestinal motility and gastric emptying. Besides it also enables to increase the contents of motilin and has certain choleric effect in inducing the secretion of bile [17,18]. Its action intensity is to certain degree dependent on its drug dose, conducive to the secretion of digestive juice and discharge of internal gas in digestive tract [19].

The results of this study showed in the observation group, the total effective rate (95.45%) was significantly higher compared with that of the control group (77.27%) of statistical significance, $P < 0.05$; the TCM syndrome scores (9.65 ± 1.08) and the score of life quality (86.89 ± 2.47) after treatment were better than those of the control group, $P < 0.05$; and in terms of adverse events, no serious consequence was seen in both groups, the rate of adverse event of the observation group was 4.55%, lower than that of the control group of no significant difference, $P > 0.05$. Xie and his colleagues [20] applied in their research the extract of *Amomum villosum* Lour for the treatment of functional dyspepsia caused by deficiency of stomach and spleen and achieved similar results, which further demonstrates the application of this treatment method is effective.

In conclusion, the extract of *Amomum villosum* Lour has high clinical value in the treatment of functional dyspepsia caused by deficiency of stomach and spleen, which can effectively control the disease, help to improve the quality of life and reduce the pain of patients. It is worthy of further promotion with high security and low risk of adverse events.

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