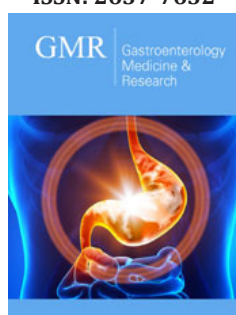


Investigating the Influence of Early Gastric Discomfort Symptoms on Life Quality and the Interventional Effects of a Stomach-Protecting Formula

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Abstract

To investigate the effect of a gastric protective formula on relieving early gastric discomfort and improving the quality of life. 99 participants diagnosed with early gastric discomfort were recruited in a single arm trial for one week. 2g/sachet product was consumed once or twice a day during the trial. Quality of life and severity of symptoms were monitored by questionnaires based on the Pittsburgh Sleep Quality Index (PSQI), SF-36 health survey, Zung Self-Rating Anxiety Scale (SAS) and self-rating scale for gastric discomfort. Early gastric discomfort imposed a direct impact on mental state, emotional anxiety, sleep disorders, memory and thinking, accounting for 62%, 48%, 40% and 25% of participants, respectively. Results demonstrated the relief on stomach bloating, acid reflux, belching, acute gastric pain, and heartburn after intervention, representing improvement of 72% ($P < 0.01$), 65% ($P < 0.01$), 64% ($P < 0.05$), 50% ($P < 0.05$), respectively. 83% of subjects with positive results responded that symptoms could be relieved within 60 minutes. Quality of life could be improved in different levels which is varied with each individual. This stomach-protecting formula had a rapid improvement on symptoms and quality of life. Hence, it could be considered as a good alternative choice for the patients with early gastric discomfort.

Keywords: Early gastric discomfort; Self-rating scale; Stomach protecting formula; Quality of life

Introduction

Globally prevalent Gastroesophageal Reflux Disease (GERD) is a chronic disease of digestive system with clinical symptoms including stomach burning, acid reflux and heartburn. It brings severely negative impact on daily life, even worsening other chronic disease [1]. The prevalence of GERD in western countries is 10-20% according to epidemiology and health statistics. The incidence of GERD in China increases continuously, now as high as 12.5% [2]. Even More people suffer from early gastric discomfort symptoms (acid reflux, stomach burning, gastroesophageal reflux, bloating, nausea and vomiting, stomach pain, one or more symptom), which shared the same diagnostic criteria with GERD. Due to the lower frequency and less severity, most people just ignore it instead of seeking for medical treatment [1,3,4]. Hence, a nutritious and healthy food, which could rapidly neutralize gastric acid, heal ulcers and relieve symptoms, is in urgent need. Gastro-AD soy protein powder is derived from ferments of soy by *Lactobacillus delbrueckii subsp.*, which can significantly alleviate stomach symptoms such as heartburn and stomach pain [5,6]. *In vitro* studies indicated that dietary fibers (resistant starch) can effectively protect rats from gastric mucosal damage caused by alcohol [7,8]. And it has been verified by Traditional Chinese Medicine (TCM) and *in vivo* studies that *Heridium erinaceus* can afford obvious prevention or therapeutic effect on chronic gastric mucosal damage [9]. A stomach-protecting instant powder based on three functional ingredients mentioned above has been launched in Chinese market. In this study, questionnaire survey, based on the self-rating scale for gastric discomfort, PSQI, SF-36, and SAS for quality of life, was designed and performed [10-12]. The effects of this stomach-protecting formula on the symptoms and the quality of life were investigated by comparing pre-intervention and post-intervention scales [13,14].

Material and Methods

Ethical Declaration

This study was a single arm trial approved by China Ethics Committee of Registering Clinical trials (Approved Number: ChiECRCT20200130). This study was registered in Chinese Clinical Trial Registry Center (Registration Number: ChiCTR2000032741).

Entry criteria

Diagnosis of GERD requires a combination of symptom judgment and endoscopy inspection. Among the symptoms of gastric discomfort (acid reflux, stomach burning, gastroesophageal reflux, bloating, nausea and vomiting, stomach pain, etc.), most patients didn't have large areas of erosion. Endoscopy is not suitable for patients with early gastric discomfort as an initial diagnosis [1]. This study was based on the classification criteria of the self-assessment scale for gastric discomfort.

Inclusion criteria

- A. Diagnosed with gastric discomfort (one or more symptoms of gastric burning, gastroesophageal reflux, bloating, nausea and vomiting, and stomach pain)
- B. Lasted more than 1 month, average ≥ 3 times a week
- C. Aged 18 years or older

Exclusion criteria:

- a) Pregnant or lactating
- b) Gastrointestinal bleeding, gastrointestinal tumors or surgery
- c) Under medications, and others who are not suitable for testing

Study design and operations

Subjects involved took samples once or twice a day for one week (7 days) on an empty stomach (more than half an hour before or after meals) or under circumstance of stomach upset. Products for test were provided by Sirio pharma Co., LTD., (Production License Number: SC10644050700110) as foil sachets. The contents per sachet (2g) contained 500mg Gastro-AD soybean protein powder; 500mg water-soluble dietary fiber (resistant dextrin), and 10mg *Hericum erinaceus* powder. According to the Asia-Pacific consensus on the management of gastroesophageal reflux disease and Consensus on the diagnosis and treatment of gastroesophageal reflux disease with integrated traditional Chinese and western medicine, questionnaire for self-rating scale of early gastric discomfort was made below [10,15]:

1. Symptoms were divided into 7 types, such as bloating, acid reflux, belching, and other types
2. In the light of severity, scores recorded from 1 to 10, and 0 represented no obvious symptoms

The questionnaire for the quality of life covered related dimensions referred to sleep quality PSQI, health survey SF-36 and

anxiety self-assessment SAS. Mental state, emotional anxiety, sleep disorders and memory and thinking were included. Adverse events were monitored on the whole time with a local professional doctor standing by for emergency.

Statistical analysis

Continuous data was showed as the mean \pm standard deviation, which was tested by Shapiro-Wilk firstly, t test for normal distributed data, and Mann Whitney U test for non-normal distributed data, with $P < 0.05$ representing significant difference, and $P < 0.01$ indicating extremely significant difference [16].

Results

Participants

Of 99 participants involved in this study, 14 dropped out for personal reasons, 85 completed the whole test. 33 females and 52 males aged from 18 to 75 years old, accounting for 39%, 61% of the gender distribution respectively. As for age distribution, Table 1 provided more details. During the whole test, no adverse events were reported.

Table 1: Age distribution of subjects.

Age Range (years)	Number	Proportion
18-30	41	48%
31-50	32	38%
51-75	12	14%
Total	85	100%

Improvement in quality of life

Stomach discomfort has a large negative impact on patients' quality of life. Data from the recruited subjects indicates that early stomach discomfort had a direct impact on mental state, emotional anxiety, sleep disorders, and memory and thinking, accounting for 62%, 48%, 40% and 25% respectively. Only 9% of them had no complaint. After a week intervention, all indicators for quality of life were improved to some extent (Table 2).

Table 2: Influence of gastric disorder on quality of life.

Quality of life	Before Intervention	After Intervention
	Cases (proportion)	Improved (proportion)
Mental status	53(62%)	33(62%)
Anxiety	41(48%)	25(61%)
Sleep disorder	34(40%)	25(74%)
Memory & thinking	21(25%)	14(67%)
Others	15(8%)	8(53%)
No effects	8(9%)	-

Relief in stomach discomfort

In the pre-intervention, Bloating, acid reflux and belching, accounting for 72%, 58% and 33%, respectively. By using

the stomach-protecting formula, these annoying symptoms participants complained showed a downtrend. Bloating and acid reflux were relieved significantly ($P<0.01$, Table 3), belching and acute stomach pain were also alleviated ($P<0.05$, Table 3). Other

symptoms, such as vomiting, heartburn and halitosis got a relief in the post-intervention, while not statistically difference are found (Table 3).

Table 3: Scores on symptoms based on the self-rating scale.

Symptoms	Cases (proportion)	Pre-Intervention	Post-Intervention	Valid/total	Efficiency
bloating	61(72%)	5.72±1.79	3.95±1.86**	44/61	72%
Acid reflux	49(58%)	4.98±2.22	3.25±1.71**	32/49	65%
Belching	28(33%)	5.25±2.39	3.64±2.41*	18/28	64%
Nausea and vomiting	21(25%)	4.48±2.48	3.29±1.83	10/21	48%
Acute stomach pain	20(24%)	4.60±2.65	2.75±2.14*	10/20	50%
Heartburn	20(24%)	4.00±2.05	3.10±1.70	13/20	65%
Halitosis	17(20%)	4.88±2.61	3.88±1.11	7/17	41%
Others	11(13%)	4.36±2.46	2.73±2.26	4/11	36%

Note: * $P<0.05$, ** $P<0.01$

Effectual time

For a product solution, it is of great value if the symptoms of consumers could be addressed timely. In this study, 63% subjects

claimed that the product helped them to feel better in 30 minutes, and 83% subjects responded positively in 60 minutes (Table 4). These results suggested that products were effective in relieving symptoms of stomach upset quickly.

Table 4: Effectual time of intervention.

Period	Proportion
5min	15%
30min	48%
1h	20%
>1h	17%
Total	100%

Discussion

The common medical treatment for GERD patients are oral acid inhibitors, gastric motility drugs, or surgical treatment [17,18]. However, the relevant therapy is complicated, easy to relapse, with high costs and a long course of treatment [1]. Oral acid inhibitors and gastric motility drugs could neutralize or empty gastric acid instantly, but these drugs will also change the physiological environment of stomach, affecting the absorption of nutrients. In contrast, in the opinion of traditional Chinese medicine, "Nourishing the stomach" is the key point to protect stomach. Therefore in China, a compound derived from medicinal and edible materials is often used to relieve symptoms gradually. Fermented soybean protein powder neutralizes gastric acid and inactivates pepsin; [5] resistant starch can resist the digestion of amylase and glycosidase; [7] and mixing both of them can increase the viscosity of gastric juice and reduce the frequency and amount of gastric juice reflux. *Hericum*

erinaceus has long been used in nourishing and protecting the stomach recorded by Traditional Chinese medicine. Latest studies have verified that *Hericum erinaceus* polysaccharide promotes the secretion of anti-inflammatory cytokines by activating dendritic cells in human peripheral blood mononuclear cells and regulating the immune response of TH1, to the purpose of protecting the gastric mucosa [9].

It was suggested that patients with GERD should control their weight. Overweight people should exercise and avoid eating at night or before going to bed [1,19]. Chocolate, caffeine, alcohol, acidic or spicy foods are not recommended [1]. In modern society, people often have a tight pattern of work and life, and irregular habits such as staying up late and overtime, irregular diets, and intemperance uptake of irritant substances (such as alcohol, spicy food and drugs), leading to the digestive system "burden" [20,21]. Nowadays, people with stomach acid reflux, heartburn, flatulence

and other gastric discomforts are increasing. In this test, 48% people aged from 18 to 30 years old are in novice period or rising period. They often work overtime and have irregular diets. We demonstrated that symptoms of gastric discomfort are becoming more diverse and the patients are getting younger. It has been proved that gastric discomfort is directly relevant to the quality of life. During the intervention, with the relief of symptoms, mental state, memory and thinking can be improved, meanwhile anxiety and sleep disorders could also be alleviated significantly [13,14,22]. In this study, we confirmed it with a stomach-protecting formula. 4 of the symptoms were relieved by more than 60%, up to 72%; 83% of the people involved in the study showed positive effects within 60 minutes. This study demonstrated that formula with fermented soybean protein powder, resistant starch and *Hericium erinaceus* powder as the main functional materials can alleviate the symptoms of early stomach discomfort quickly and effectively and improve the quality of life.

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