

Original Article

Effects of TCM external scalding therapy on spleen-stomach deficiency cold stomachache and inflammatory indexes

Yunyi Ye¹, Lingling Xu², Yingyue Sheng²

¹Disease Prevention Centre with Prominent TCM Characteristics, Affiliated Hospital of Jiangnan University, Wuxi 214000, Jiangsu, China; ²Department of Gastroenterology, Affiliated Hospital of Jiangnan University, Wuxi 214122, Jiangsu, China

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Abstract: Objective: To determine the efficacy and safety of traditional Chinese medicine (TCM) external scalding therapy on spleen-stomach deficiency cold stomachache. Methods: The medical records of 98 patients with spleen-stomach deficiency cold stomachache treated in the Affiliated Hospital of Jiangnan University from January 2019 to January 2020 were collected and analyzed retrospectively. Among them, 52 patients treated with western medicine were assigned to the control group, while the other 46 patients treated additionally with TCM external scalding therapy were assigned to the observation group. The two groups were compared in terms of serum gastrin (GAS), inflammatory factors and visual analogue scale (VAS) score, adverse reaction rate and symptom remission time. Results: After treatment, the observation group showed a significantly lower GAS level than the control group ($P<0.05$), along with significantly lower serum levels of tumor necrosis factor- α (TNF- α), interleukin-1 β (IL-1 β) and interleukin-6 (IL-6) than the control group (all $P<0.05$). The observation group demonstrated significantly lower VAS score than the control group ($P<0.05$). The observation group experienced notably shorter remission time of dull epigastric pain, epigastric distension, fatigue and belching and acid reflux than the control group (all $P<0.05$), and a significantly lower incidence of adverse reactions was found in the observation group than that in the control group ($P<0.05$). Multivariate analysis revealed that history of alcoholism and treatment method were independent risk factors affecting patient outcomes (all $P<0.05$). Conclusion: TCM external scalding therapy has shown effectiveness in treating spleen-stomach deficiency cold stomachache. It alleviates stomachache symptoms and also reduces the occurrence of adverse reactions and inflammation, holding great potential for widespread adoption in clinical practice.

Keywords: External scalding therapy, traditional Chinese medicine, spleen-stomach deficiency cold stomachache, multivariate analysis

Introduction

Epigastric pain, also recognized as functional dyspepsia and upper abdominal pain, is one of the most common clinical symptoms encountered in internal medicine practices of traditional Chinese medicine (TCM) [1]. Notable changes in past decades has largely attributed to improved living standards, heightened mental stress, irregular eating patterns, and a lifestyle that compromises adequate rest and relaxation, collectively imposing a significant strain on the gastrointestinal system, leading to recurrent stomach pain that adversely affects indi-

viduals' study, work, and overall quality of life [2]. Moreover, the summertime habit of seeking relief through the use of air conditioning and the consumption of cold beverages, though momentarily satisfying, can over time heighten the gastrointestinal tract's vulnerability to negative impacts. In the long run, the Yang energy will inevitably be weakened, resulting in endogenous asthenia cold, and cold stagnation in the middle energizer, disease recurrence and chronic illness [3]. According to modern literature research [4], there are many pathological conditions of Yang deficiency in chronic diseases, so patients with epigastric pain of spleen-

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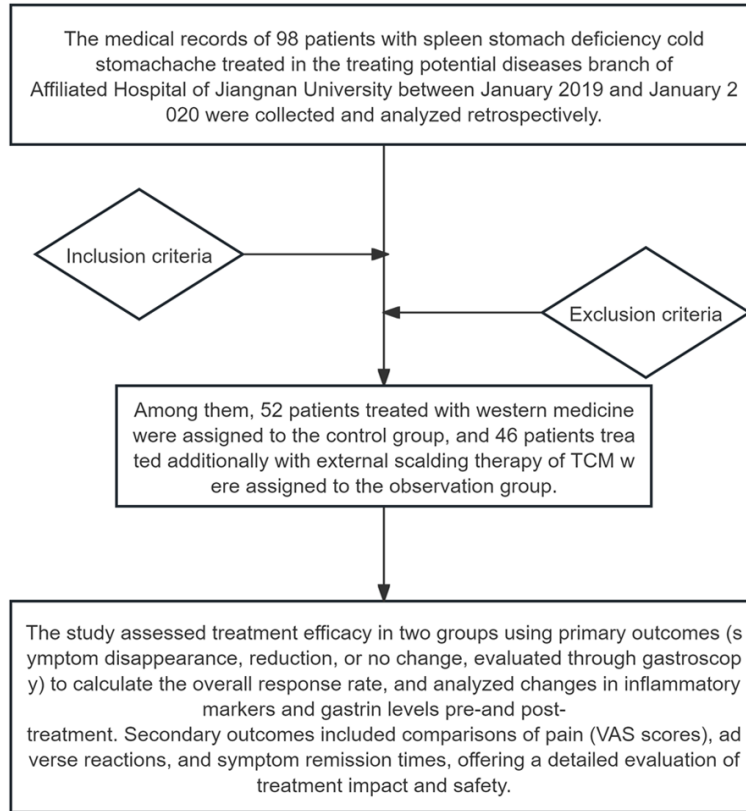


Figure 1. Study flow chart.

stomach deficiency and cold syndrome are relatively common in clinical scenarios.

The pathogenesis of epigastric pain in modern medicine still remains elusive. It is believed to be related to a combination of factors, such as abnormal secretion of gastrointestinal hormones, gastrointestinal dysfunction, digestive tract hypersensitivity, and mental psychology [5]. Treatment primarily focuses on symptom relief, through acid inhibitors, gastrointestinal prokinetic agents, digestants and antidepressants; However, recurrence post-treatment is common [6]. The holistic concept of TCM encapsulates its treatment philosophy, rendering TCM's strategies towards managing this condition noteworthy for research [7]. External scalding therapy, a distinctive modality within TCM, combines drug therapy and thermotherapy. It involves the application of a medicinally infused concoction, tailored through syndrome differentiation, directly onto the affected area that allows for the transdermal absorption of the concoction's active ingredients, aiming at syndrome-specific intervention [8]. Thermotherapy, on the other hand, can accelerate the

local metabolism and increase the oxygen consumption of tissues by promoting the congestion of skin and mucosa and increasing the permeability of capillaries, thus speeding up the reflux of lymph and blood, reducing blood viscosity and muscle tension, and effectively relieving muscle spasm and pain [9].

Despite the widespread application of external scalding therapy in treating various conditions, including upper abdominal pain, research on its effectiveness and mechanisms specific to spleen-stomach deficiency cold stomachache remains sparse. Therefore, this study employs a rigorous research design and an appropriate sample size to systematically evaluate the efficacy and safety of TCM external scalding therapy in treating spleen-stomach deficiency cold stomachache to

provide scientific evidence and new treatment perspectives in this field.

Methods and data

Clinical data

The medical records of 98 patients with spleen-stomach deficiency cold stomachache treated in the Affiliated Hospital of Jiangnan University from January 2019 to January 2020 were collected and analyzed retrospectively. Among them, 52 patients treated with western medicine were assigned to the control group, and the other 46 patients treated additionally with external scalding therapy were assigned to the observation group. This study was conducted with the approval of the Medical Ethics Committee of Affiliated Hospital of Jiangnan University (LL0848 (A)). The study research flowchart is shown in **Figure 1**.

Inclusion and exclusion criteria

Inclusion criteria: Patients meeting the relevant diagnostic criteria of stomachache in Practical

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Internal Medicine and Standards for Diagnosis [10] and Curative Effect of Chinese Medical Symptom [11]; patients with spleen-stomach deficiency cold stomachache. The main symptoms: faint stomach pain, preference for warmth and pressure, aggravating symptoms on an empty stomach, and vomiting clear fluids; secondary symptoms: loose stool, limb weakness and mental fatigue. The tongue and pulse manifestations included a pale tongue, a white and thin tongue coating, and a weak pulse. All the included patients displayed some degree of liver Qi stagnation.

Exclusion criteria: Patients with stomach diseases such as gastrointestinal bleeding; patients with pyloric obstruction, perforation, or gastric neurosis; patients with a history of digestive tract diseases or surgery; patients who had been treated with non-steroidal drugs; patients with digestive system diseases such as diseases of the liver, gallbladder and pancreas; patients with severe dysfunction or insufficiency of the liver or kidney; patients with malignant tumors; patients with mental illness or cognitive impairment; patients who were allergic to the drugs adopted in this study or had contraindications; pregnant women; lactating women.

Therapeutic regimen

According to the therapeutic regimen, patients in both groups were orally treated with 20 mg omeprazole enteric-coated tablets (Shandong New Time Pharmaceutical Co., Ltd., State Food and Drug Administration (SFDA) approval number: H20044871), twice a day, for 4 weeks. Additionally, a reasonable diet plan was developed for each patient according to the condition. This diet was structured to provide comprehensive nutrition, ensuring a balanced intake of various nutrients without exceeding recommended amounts. In addition, the dietary regimen emphasized easily digestible, light foods, prioritizing fruits and vegetables high in fiber and vitamins. The dietary principles included consuming multiple smaller meals throughout the day, avoiding overeating, increasing water intake, and avoiding spicy, cold, and other irritating foods.

On the basis of the treatment in the control group, patients in the observation group were

additionally treated with TCM external scalding therapy. Specifically, 30 g galangal, 20 g rhizomacorydalis, 20 g Sichuan pepper, 10 g cinnamon, 10 g cablin potchouli herb, 10 g common monkshood root, 10 g Chinese angelica root, and 10 g nutgrass galingale rhizome were mixed, ground, and then placed into a cotton bag, which was sealed and boiled in water. When the temperature reached 70-80°C, the bag was taken out, and gently moved back and forth over the patient's epigastric area. Initially, to prevent skin damage, the bag was applied with a technique of lifting and replacing at higher temperatures. As the temperature decreased, the bag could be left in prolonged contact with the skin. Each session of scalding therapy lasted approximately 30 minutes, and the treatment was administered once every 12 days. The efficacy of the treatment was compared between the two groups after a 3-week treatment period.

Data collection

Patient data was collected from electronic medical records, including age, gender, BMI, course of disease, smoking history, history of alcoholism, education level, race, average monthly family income, clinical efficacy, VAS score, adverse reaction incidence, and symptom remission time. Prior to treatment and after 3 weeks' treatment, enzyme-linked immunosorbent assay (ELISA) was conducted to measure serum levels of gastrin (GAS), tumor necrosis factor-alpha (TNF- α), interleukin-1 beta (IL-1 β), and interleukin-6 (IL-6) between both groups of patients. It should be noted that all indicators involved in this study are part of the routine diagnostic repertoire at the Affiliated Hospital of Jiangnan University.

Outcome measures

Primary outcome measures: The clinical efficacy on the two groups was compared according to the following criteria: markedly effective (complete symptom resolution and gastroscopic evidence of inflammation resolution), effective (symptom alleviation and reduced inflammation on gastroscopy), and ineffective (no symptom relief or reduction in inflammation as per gastroscopy). Overall response rate = (number of markedly effective cases + number of

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Table 1. Baseline data

Factors	Control group (n=52)	Observation group (n=46)	P value
Age			0.464
≥40 years old	29	29	
<40 years old	23	17	
Gender			0.609
Male	29	28	
Female	23	18	
BMI			0.715
≥25 kg/m ²	13	13	
<25 kg/m ²	39	33	
Course of disease			0.373
≥1 year	25	18	
<1 year	27	28	
Smoking history			0.609
Yes	29	28	
No	23	18	
History of alcoholism			0.586
Yes	4	5	
No	48	41	
Education level			0.392
≥ Senior high school	37	29	
< Senior high school	15	17	
Ethnicity			0.838
The Han nationality	47	41	
Others	5	5	
Average monthly family income			0.357
≥4000 Yuan	24	17	
<4000 Yuan	28	29	

Note: BMI: Body mass index.

effective cases)/the total number of cases × 100%. The changes in inflammatory markers and GAS levels were compared between the two patient groups before and after treatment. Before initiating the treatment and after a 3-week treatment period, blood samples were collected from both patient groups. By performing ELISA on the serum samples collected before treatment and after a 3-week treatment period, the levels of GAS, TNF- α , IL-1 β , and IL-6 in both patient groups were quantified, allowing for the evaluation of any changes or differences in these biomarkers.

Secondary outcome measures: The clinical data of two groups were compared. The two groups were compared in visual analogue scale (VAS) scores before and after treatment,

adverse reaction rate and symptom remission time.

Statistical analyses

The data were processed using SPSS 26.0 software. The distribution of data was analyzed using the K-S test. Measurement data with normal distribution were presented as mean \pm standard deviation (Mean \pm SD). The independent sample t-test was used to compare between the two groups, while the paired t-test was used for within-group comparisons, and the results were expressed using t-values. Non-normally distributed data were analyzed using non-parametric tests, and the results were expressed using Z-values. The comparison of counting data was conducted using χ^2 test. Logistic regression analysis was conducted to analyze the risk factors affecting patient outcomes. P<0.05 indicated a notable difference.

Results

Comparison of clinical data

According to inter-group comparison of clinical data, the observation and control groups were comparable in clinical data (all P>0.05, **Table 1**).

Comparison of clinical efficacy between two groups

The evaluation of clinical efficacy demonstrated that the control group had a significantly lower overall response rate compared to the observation group, suggesting a superior effectiveness of the treatment in the observation group (P<0.05, **Table 2**).

Comparison of changes in inflammatory indexes between two groups of patients

The levels of inflammatory markers TNF- α , IL-1 β , and IL-6 were measured in both groups.

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Table 2. Evaluation of clinical efficacy

Group	Markedly effective	Effective	Ineffective	Overall response
Control group (n=52)	30	20	2	50 (96.15%)
Observation group (n=46)	10	26	10	36 (78.26%)
χ^2 value	13.061	3.196	7.272	7.272
P value	<0.001	0.073	0.007	0.007

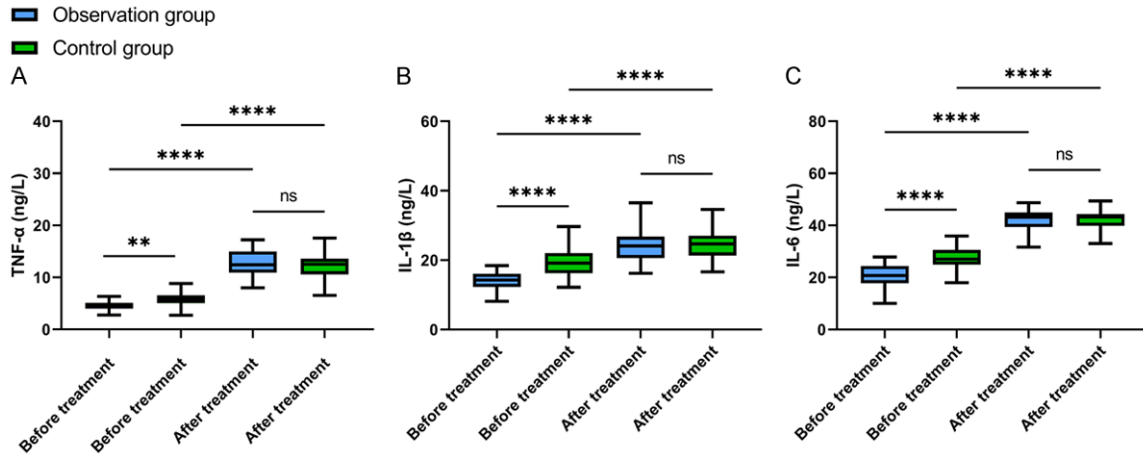


Figure 2. Changes of inflammatory indexes in patients before and after treatment. A. Changes of TNF- α level in patients before and after treatment; B. Changes of IL-1 β level in patients before and after treatment; C. Changes of IL-6 level in patients before and after treatment. Notes: TNF- α : Tumor necrosis factor- α ; IL-1 β : Interleukin-1 β ; IL-6: interleukin-6; nsP<0.05, **P<0.01, ****P<0.0001.

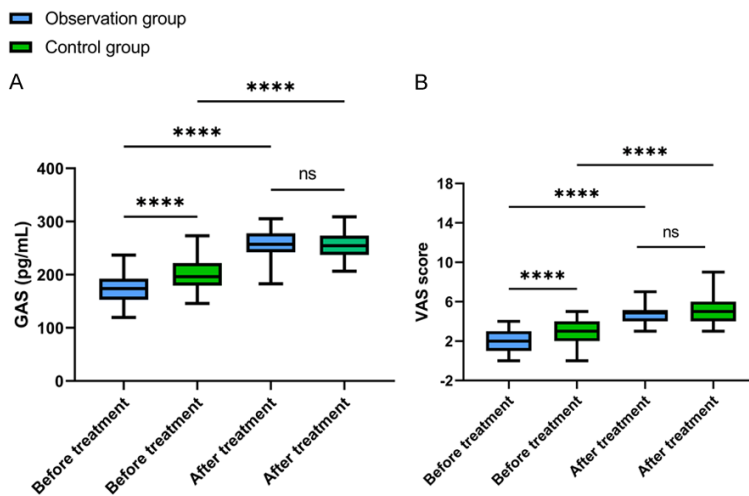


Figure 3. Changes of GAS level and VAS score in patients before and after treatment. A. Changes of GAS level in patients before and after treatment; B. Changes of VAS scores in patients before and after treatment. Notes: GAS: Gastrin; VAS: Visual analogue scale; nsP<0.05, ****P<0.0001.

Before treatment, there was no significant difference in these levels between the groups (P>0.05, **Figure 2**). However, post-treatment, both groups showed a significant reduction in

these inflammatory markers, with the observation group exhibiting more pronounced reductions compared to the control group (all P<0.05, **Figure 2**).

Comparison of changes in GAS level and VAS score between two groups of patients

According to the comparison of GAS level and VAS score between the two groups before and after therapy, the two groups were not greatly different in the GAS level and VAS score (all P>0.05, **Figure 3**) before treatment; however, after the treatment, the GAS level and VAS score of the two groups decreased notably (P<0.05, **Figure 3**), with notably lower GAS level and VAS score in the observation group than those in the control group (both P<0.05, **Figure 3**).

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Table 3. Adverse reactions

Group	Nausea	Rash	Headache	Vomiting	Total incidence rate
Control group (n=52)	3	2	3	3	11 (23.91)
Observation group (n=46)	1	0	1	1	3 (5.77)
χ^2 value	0.805	1.806	0.805	0.805	6.562
P value	0.369	0.179	0.369	0.369	0.010

Table 4. Comparison of symptom remission time between the two groups of patients

Group	Dull epigastric pain (d)	Epigastric distension (d)	Belching and acid reflux (d)	Fatigue (d)
Control group (n=52)	9.02±2.69	9.43±3.1	6.11±1.14	10.41±2.75
Observation group (n=46)	11.08±2.53	12.54±2.89	8.25±1.33	14.98±2.9
T value	3.900	5.134	8.514	7.967
P value	0.001	<0.001	<0.001	<0.001

Comparison of adverse reactions between two groups of patients

The comparison of the incidence of adverse events between the two groups revealed a notably higher incidence of adverse reactions in the control group than that in the observation group ($P < 0.05$, **Table 3**).

Comparison of symptom remission time between two groups of patients

After treatment, the observation group experienced notably shorter remission time of dull epigastric pain, epigastric distension, fatigue and belching and acid reflux than the control group (all $P < 0.05$, **Table 4**).

Risk factor analysis

Patients who responded well to the treatment were included in the good prognosis group (n=86), while those who did not respond or responded poorly were included in the poor prognosis group (n=12). Risk factors affecting patient prognosis were analyzed. Univariate analysis revealed age, smoking history, history of alcoholism, and treatment method as risk factors influencing patient outcomes (**Table 5**). Subsequently, multivariate analysis was performed on these variables (**Table 6**), and found that history of alcoholism and treatment method were independent risk factors affecting patient outcomes (**Table 7**).

Discussion

The etiology of stomach pain encompasses both acute and chronic conditions such as gas-

tritis, peptic gastric ulcers, and duodenal ulcers, classified under the broader term of epigastric pain in TCM [12]. TCM delineates five distinct syndromic classifications for stomachache: spleen-stomach deficiency cold, invasion by cold pathogens, food stagnation, blood stasis, and liver-Qi stagnation, with spleen-stomach deficiency cold being particularly prevalent [13]. TCM views the spleen and stomach as crucial organs for digestion and assimilation, highlighting that overwork, irregular eating habits, or excessive consumption of cold and spicy foods can impair the Yang energy of these organs. This impairment manifests as a deficiency-cold condition in the middle jiao (energizer), compromising the functions of spleen transportation and stomach reception, thereby leading to epigastric pain. Spleen deficiency may also result in dampness accumulation, characterized by symptoms such as loose stools, stomach acidity, fatigue, and a general sense of weakness; a deficiency in the spleen and stomach's Yang Qi may render the extremities particularly prone to coldness. In contrast, modern medicine primarily attributes stomach pain to bacterial infections, treating it with medications like amoxicillin, aspirin, and rabeprazole. Although these drugs can alleviate symptoms, they do not address the underlying issue of long-term gastric mucosal damage [14]. However, recent research on the integration of TCM and Western medicine has shown promising synergistic effects in mitigating clinical symptoms in patients, offering a more holistic approach to treatment.

Considering the underlying causes and mechanisms of spleen-stomach deficiency cold type

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Table 5. Univariate analysis of factors affecting patient prognosis

Factors	Poor prognosis (n=12)	Good prognosis (n=86)	P value
Age			0.015
≥40 years old (n=58)	11	47	
<40 years old (n=40)	1	39	
Gender			0.990
Male (n=57)	7	50	
Female (n=41)	5	36	
BMI			0.205
≥25 kg/m ² (n=26)	5	21	
<25 kg/m ² (n=72)	7	65	
Course of disease			0.090
≥1 year (n=43)	8	35	
<1 year (n=55)	4	51	
Smoking history			0.012
Yes (n=57)	11	46	
No (n=41)	1	40	
History of alcoholism			<0.001
Yes (n=9)	7	2	
No (n=89)	5	84	
Treatment method			0.025
Western medicine (n=52)	10	42	
External scalding therapy + Western medicine (n=46)	2	44	
Average monthly family income			0.541
≥4000 Yuan (n=41)	6	35	
<4000 Yuan (n=57)	6	51	

Table 6. Value assignment

	0	1
Age	<40 years old	≥40 years old
Smoking history	No	Yes
History of alcoholism	No	Yes
Treatment method	External scalding therapy + Western medicine	Western medicine
Prognosis	Good	Poor

Table 7. Multivariate analysis of factors affecting patient prognosis

	B	S.E.	Wals	Sig.	Exp (B)	95% C.I. of the EXP (B)	
						Lower limit	Upper limit
Age	1.63	1.181	1.905	0.168	5.105	0.504	51.705
Smoking history	2.435	1.426	2.916	0.088	11.419	0.698	186.883
History of alcoholism	3.961	1.286	9.486	0.002	52.486	4.222	652.549
Treatment method	2.73	1.324	4.255	0.039	15.335	1.146	205.245

epigastric pain, the primary treatment strategies focus on warming the middle jiao to fortify the deficiency, enhancing spleen function and aiding the stomach, alongside utilizing warmth to alleviate pain [15-17]. Nonetheless, all par-

ticipants in this study also exhibited varying degrees of liver Qi obstruction and Qi stagnation, warranting the inclusion of TCM scalding therapy as a supplementary treatment approach. TCM scalding therapy, an external treat-

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ment modality, involves the application of heated substances or objects to specific body parts or acupoints. Through gentle, slow movements, the combined effect of the medication's potency and heat penetrates the meridians and blood vessels via surface pores, thereby warming meridians, clearing blockages, dispelling cold, alleviating pain, removing blood stasis, and reducing swelling [18, 19]. Comparative analyses revealed that the observation group exhibited a significantly higher overall response rate compared to the control group, alongside markedly reduced levels of GAS and lower VAS scores post-treatment. Furthermore, symptoms such as dull epigastric pain, bloating, fatigue, and symptoms of belching and acid reflux subsided more rapidly in the observation group than in the control group. These findings suggest that integrating TCM scalding therapy with conventional Western medicine not only enhances clinical outcomes but also effectively mitigates pain symptoms, underscoring the therapeutic potential of this holistic treatment approach.

TNF- α , IL-1 β , and IL-6 are identified as key pro-inflammatory cytokines, synthesized and released by macrophages, lymphocytes, and vascular endothelial cells [20]. Elevation in these cytokine level signifies the extensive release of inflammatory mediators in individuals experiencing stomach pain, potentially exacerbating the condition [21, 22]. The study's analysis demonstrated a more pronounced reduction in the serum concentrations of TNF- α , IL-1 β , and IL-6 in the observation group post-treatment compared to the control group, indicating the efficacy of TCM scalding therapy in diminishing serum inflammatory markers in patients. This therapeutic effect is attributed to the selected TCM formulation, which incorporates components such as Chinese angelica root and Rhizoma Corydalis for their blood circulation enhancing and stasis resolving properties, along with promoting Qi flow and pain relief. Ingredients like galangal, Sichuan pepper, and cinnamon are recognized for their roles in warming meridians, improving circulation, and dispelling cold and stagnation. Cablin patchouli herb is noted for its dampness eliminating and stomach regulating capabilities; common monkshood root is esteemed for treating conditions associated with wind-cold-dampness arthralgia, vomiting, diarrhea, cold

limbs, and weak pulse. Through scalding therapy, the application of heated medicinal substances directly over the stomach area expands gastric capillaries, boosts peripheral circulation, facilitates the removal of inflammatory agents, reduces nerve root inflammation, and thereby alleviates stomach pain symptoms [23, 24]. Moreover, this study also assessed the frequency of adverse reactions of two groups, revealing a significantly lower overall incidence of adverse reactions in the observation group compared to the control group, underscoring the safety and reduced risk of side effects associated with TCM scalding therapy.

The study has confirmed the benefits of TCM external scalding therapy on enhancing the efficacy and reducing the inflammatory index in patients with spleen-stomach deficiency cold stomachache. However, it is important to note some limitations in this study. Firstly, being a single-center study with a small sample size, there is a possibility of deviations in result analysis. Secondly, considering that patients with stomachache are prone to relapse, the effect of external scalding therapy of TCM on recurrence remains unclear. Therefore, future research should aim to conduct more experiments to enhance the robustness of the findings.

In conclusion, TCM external scalding therapy has shown effectiveness in treating spleen-stomach deficiency cold stomachache. This therapy not only significantly alleviates stomachache symptoms but also reduces the occurrence of adverse reactions and inflammation. Therefore, it holds great potential for widespread adoption in clinical practice.

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Disclosure of conflict of interest

None.

Address correspondence to: Yingyue Sheng, Department of Gastroenterology, Affiliated Hospital of Jiangnan University, No. 1000, Hefeng Road, Binhu District, Wuxi 214122, Jiangsu, China. E-mail: shengyingyue001@163.com

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