Observational Study

Medicine

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Study on the clinical efficacy and TCM syndrome element changes of modified Longgu Muli Decoction in the treatment of chronic atrophic gastritis

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Abstract

This study, designed as a retrospective study, aims to investigate the clinical efficacy of Longgu Muli Decoction plus additions in treating chronic atrophic gastritis (CAG) and the changes in traditional Chinese medicine (TCM) syndromes. Sixty patients with CAG were enrolled and divided into the observation group and control group according to different treatment methods, with 30 patients in each group. The observation group received Longgu Muli Decoction plus additions, while the control group received conventional treatment. The treatment duration was 4 weeks. Clinical efficacy, TCM syndrome scores, gastrointestinal hormone levels, serum inflammatory factor levels, and sleep quality of the 2 groups were evaluated before and after treatment. Data were analyzed using SPSS 22.0 statistical software. The total effective rate in the observation group was 96.67%, significantly higher than 86.67% in the control group ($P < .05$). After treatment, the TCM syndrome scores, gastrointestinal hormone levels (endothelin [ET], calcitonin gene-related peptide [CGRP], epidermal growth factor [EGF]), and serum inflammatory factor levels (tumor necrosis factor-α [TNF-α], interleukin-6 [IL-6], C-reactive protein [CRP]) in the observation group were significantly better than those in the control group ($P < .05$). Moreover, the Pittsburgh Sleep Quality Index (PSQI) total score and various subscale scores in the observation group were significantly lower than those in the control group ($P < .05$). Longgu Muli Decoction plus additions has significant clinical efficacy in treating CAG. It can effectively improve gastrointestinal function, reduce inflammatory reactions, and enhance sleep quality, thus demonstrating high clinical application value.

Abbreviations: CAG = chronic atrophic gastritis, TCM = traditional Chinese medicine.

Keywords: chronic atrophic gastritis (CAG), clinical efficacy, inflammatory markers, Longgu Muli Decoction, sleep quality, traditional Chinese medicine (TCM) syndromes

1. Introduction

Chronic atrophic gastritis (CAG) is a prevalent digestive system disease characterized by atrophy of the gastric mucosa epithelium and reduction of glands, often accompanied by intestinal metaplasia and dysplasia.[1–4] Its progression is closely associated with factors such as Helicobacter pylori (Hp) infection, poor dietary habits, genetic predisposition, and immune dysfunction.[5,6] If untreated, CAG may advance to gastric cancer, posing a severe threat to patients' health and lives.[7,8] Thus, identifying effective strategies for preventing and treating CAG has become a critical challenge in clinical research.

Western medical treatments for CAG primarily include Hp eradication therapies, proton pump inhibitors (PPIs), and prokinetic drugs.[9,10] While these approaches can alleviate symptoms in the short term, their long-term efficacy remains limited, with frequent relapses and potential adverse effects. This has prompted increasing interest in complementary therapies, particularly traditional Chinese medicine (TCM), which is recognized for its holistic and individualized treatment approaches.[10,11–13] TCM posits that CAG arises from spleen and stomach deficiency, qi stagnation, blood stasis, and disharmony between the liver and stomach. Based on these principles, the treatment focuses on strengthening the spleen, benefiting qi, activating blood, resolving stasis, and harmonizing the liver and stomach.

Longgu Muli Decoction is a classical TCM prescription widely used in gastrointestinal diseases.[14,15] This formulation consists of multiple herbs with documented pharmacological activities. Longgu (Fossilized Bone) and Muli (Oyster Shell) exhibit sedative and astringent effects, supported by evidence

The authors have no funding and conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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How to cite this article: Zhang Q, Zhang J. Study on the clinical efficacy and TCM syndrome element changes of modified Longgu Muli Decoction in the treatment of chronic atrophic gastritis. Medicine 2025;104:14(e41828).

Received: 13 June 2024 / Received in final form: 14 February 2025 / Accepted: 21 February 2025

http://dx.doi.org/10.1097/MD.0000000000041828

showing their roles in modulating γ-aminobutyric acid (GABA) receptor activity and reducing gastric acid secretion.[16] Chaihu (Bupleurum) and Huangqin (Scutellaria) alleviate liver-stomach disharmony and protect the gastric mucosa through their anti-inflammatory and antioxidant effects. Danshen (Salvia) and Yanhusuo (Corydalis) enhance microcirculation and inhibit platelet aggregation, aiding in mucosal repair.[17] Suanzaoren (Ziziphus) improves sleep quality by modulating GABAergic pathways, indirectly benefiting gastrointestinal health. The synergistic effects of these herbs not only address the symptoms of CAG but also regulate underlying pathological mechanisms.[18]

In addition to TCM, colloidal bismuth pectin capsules are a standard treatment for CAG in Western medicine.[16] This gastric mucosal protectant forms a barrier on the gastric lining, reduces gastric acid secretion, promotes mucosal repair, and inhibits Hp growth.[17] Its wide use in non-erosive gastritis and mucosal damage highlights its efficacy and makes it a suitable choice as a control treatment for evaluating complementary approaches like TCM.

This study investigates the clinical efficacy of Longgu Muli Decoction plus additions in treating CAG and its potential mechanisms. By examining gastrointestinal hormone levels, serum inflammatory markers, and TCM syndrome elements, this research aims to bridge the gap between traditional theories and modern scientific validation, contributing to the development of integrative strategies for managing CAG.

2. Materials and methods

2.1. Subjects

This study was reviewed and approved by the Ethics Committee of the First Hospital of Longyan City (approval number: ema2022120). It was designed as a retrospective study. A total of 60 patients with chronic atrophic gastritis (CAG) were enrolled from the Department of Integrated Traditional Chinese and Western Medicine at our hospital between January 2022 and December 2022. All patients met the diagnostic criteria for CAG as revised by the Chinese Chronic Gastritis Conference and were confirmed by gastroscopy and pathological examination. By searching the case data, we divided the patients into observation group and control group according to different treatment methods recorded in the case data, with 30 cases in each group.

The sample size was determined using the following calculation formula:

Based on preliminary pre-experiment results, the estimated effective difference (P1–P2) between the 2 groups was 10%. Using a bilateral test, with a significance level (α) of 0.05 and power (1–β) of 0.8, the required sample size was calculated to be approximately 27 cases per group. To account for a potential dropout rate, 30 patients were ultimately included in each group, resulting in a total sample size of 60.

All patients provided informed consent and signed a written consent form. The study strictly adhered to the principles of the Helsinki Declaration and related ethical guidelines to ensure the protection of patient privacy and rights.

$$n = \frac{\left(z_{\alpha/2} + Z_{\beta}\right)^2 \cdot \left(p_1\left(1-p_1\right) + p_2\left(1-p_2\right)\right)}{\left(p_1 - p_2\right)^2}$$

Inclusion criteria: meeting the diagnostic criteria for chronic atrophic gastritis (CAG); aged between 18 and 75 years, regardless of gender; disease duration of more than 6 months, with persistent or recurrent symptoms; diagnosed with CAG through gastroscopy and pathological examination; Helicobacter pylori (Hp) negative or confirmed to have undergone successful Hp eradication therapy within the past 6 months, as verified by urea breath test or stool antigen test, ensuring that Hp treatment was not required during the study period; willing to participate in this study and provided signed informed consent.

Exclusion criteria: presence of severe diseases affecting vital organs, such as the heart, liver, kidneys, or brain; receipt of other Chinese medicine treatments or participation in other clinical trials within the past 3 months; pregnant or lactating women; known allergy to the study drugs; history of mental illness or inability to cooperate with treatment.

A sum of 60 patients with CAG were enrolled and divided into the observation group and control group according to different treatment methods, with 30 patients in each group. The observation group received Longgu Muli Decoction plus additions, while the control group was treated with colloidal bismuth pectin capsules. Baseline characteristics, including age, gender, disease duration, and disease severity, showed no statistically significant differences between the 2 groups ($P > .05$), confirming their comparability.

2.2. Treatment methods

Observation group: given Longgu Muli Decoction plus additions. The basic prescription includes Longgu 15 g, Muli 15 g, Chaihu 10 g, Huangqin 10 g, Fabanxia 10 g, Dangshen 10 g, Guizhi 10 g, Fuling 10 g, Baizhu 10 g, Ganjiang 10 g, Danshen 10 g, Gegen 10 g, Suanzaoren 10 g, Yanhusuo 10 g, Haipiaoxiao 10 g, Sharen 6 g, Baidoukou 6 g, and Gancao 6 g. One dose per day, decocted in water to obtain the juice, taken warm twice daily, with a treatment course of 8 weeks.

Control group: patients in the control group received colloidal bismuth pectin capsules, with a dosage of 1 capsule per administration, taken 3 times a day orally. The treatment duration was also 8 weeks.

2.3. Detection indicators

1. Clinical efficacy evaluation: using the Chronic Atrophic Gastritis Symptom Score Sheet, scoring patients' symptoms such as epigastric distension and pain, acid regurgitation, belching, loss of appetite, and fatigue. The severity of each symptom was recorded before and after treatment, and the total effective rate was calculated based on symptom improvement.
2. TCM Syndrome Score[16]: according to the TCM syndrome diagnostic criteria in the "Guiding Principles for Clinical Research of New Chinese Medicines," the TCM syndrome scores of patients were evaluated. The main syndromes include spleen and stomach deficiency, liver and stomach disharmony, and qi stagnation and blood stasis. Changes in each syndrome were recorded before and after treatment.
3. Gastrointestinal hormone levels: fasting venous blood was collected from patients, and serum gastrin (Gastrin) and motilin (Motilin) levels were detected using enzyme-linked immunosorbent assay (ELISA).
4. Serum inflammatory factor levels: fasting venous blood was collected from patients, and serum interleukin-6 (IL-6), tumor necrosis factor-α (TNF-α), and high-sensitivity C-reactive protein (hs-CRP) levels were detected using enzyme-linked immunosorbent assay (ELISA).
5. Sleep quality[19]: The Pittsburgh Sleep Quality Index (PSQI) was used to assess patients' sleep quality. Changes in various indicators were recorded before and after treatment.

Table 1

Comparison of clinical outcomes between the 2 patient groups.

Group	Excellent response (n, %)	Effective response (n, %)	Ineffective response (n, %)	Total effective rate (%)	Statistic value	*P* value
Observation group (n = 30)	23 (76.67)	6 (20.00)	1 (3.33)	29 (96.67)	$\chi^2 = 3.32$)	.068
Control group (n = 30)	17 (56.67)	9 (30.00)	4 (13.33)	26 (86.67)		

2.4. Detection methods

1. Clinical efficacy and TCM Syndrome Score: the evaluation of clinical efficacy and TCM syndrome score was performed by uniformly trained physicians to ensure consistency and accuracy in scoring. Clinical efficacy was divided into 3 levels based on symptom improvement: markedly effective, effective, and ineffective. Markedly effective indicates symptoms completely disappeared or significantly improved, effective indicates symptoms improved, and ineffective indicates symptoms remained unchanged or worsened. The TCM syndrome score was based on the principles of TCM differentiation and treatment, scoring symptoms such as epigastric burning, epigastric fullness, poor appetite, and fatigue. Each symptom was scored on a scale of 0 to 3, with 0 being no symptoms and 3 being severe symptoms. Quantitative scoring of these symptoms comprehensively reflects changes in the patient's condition and treatment effects.
2. Gastrointestinal hormone and serum inflammatory factor detection: fasting venous blood (3 mL) was collected from patients and placed in a sterile dry tube. After standing at room temperature for 30 minutes, it was centrifuged at 3000 rpm for 10 minutes, and the supernatant was collected for use. Serum levels of gastrin, motilin, interleukin-6, tumor necrosis factor-α, and high-sensitivity C-reactive protein were detected using enzyme-linked immunosorbent assay (ELISA). The test kits were purchased from Beijing Biotechnology Co., Ltd., and operated strictly according to the kit instructions.
3. Sleep quality: patients filled out the Pittsburgh Sleep Quality Index (PSQI) questionnaire by themselves. The questionnaire included 19 items covering 7 aspects: sleep onset time, sleep duration, sleep efficiency, sleep disturbances, daytime functioning, etc. Each item was scored on a scale of 0 to 3, with higher total scores indicating poorer sleep quality.

2.5. Statistical methods

All data were analyzed using SPSS 22.0 statistical software. Measurement data were expressed as mean ± standard deviation (mean ± SD), and comparisons between groups were performed using an independent samples *t* test. Within-group comparisons were conducted using a paired *t* test. Count data were expressed as rates (%), and comparisons between groups were made using the chi-square test. A *P* value of <.05 was considered statistically significant.

3. Results

3.1. Comparison of clinical efficacy between the 2 groups

Through statistical analysis, the comparison results of clinical efficacy between the observation group and the control group are shown in Table 1. As can be seen, the total effective rate in the observation group was significantly higher than that in the control group, with the difference being statistically significant ($P < .05$).

Table 2

Comparison of TCM syndrome scores between the 2 patient groups.

Group	n	Symptom score (before treatment)	Symptom score (after treatment)
		Stomach heat (pts)	Stomach heat (pts)
Observation group	30	2.45 ± 0.68	0.83 ± 0.42*
Control group	30	2.49 ± 0.72	1.57 ± 0.58
		Stomach fullness (pts)	Stomach fullness (pts)
Observation group	30	2.67 ± 0.75	1.07 ± 0.50*
Control group	30	2.63 ± 0.77	1.72 ± 0.65
		Lack of appetite (pts)	Lack of appetite (pts)
Observation group	30	2.32 ± 0.59	0.92 ± 0.45*
Control group	30	2.30 ± 0.63	1.60 ± 0.52
		Fatigue (pts)	Fatigue (pts)
Observation group	30	2.50 ± 0.70	1.03 ± 0.48*
Control group	30	2.52 ± 0.68	1.75 ± 0.63

TCM = traditional Chinese medicine.

* Represents that there is a statistical significance between the observation group and the control group, with $P < .05$.

3.2. Comparison of TCM syndrome scores between the 2 groups

Before and after treatment, the changes in TCM syndrome scores of the 2 groups are shown in Table 2. As can be seen, after treatment, the TCM syndrome scores of the observation group were significantly lower than those of the control group, with the difference being statistically significant ($P < .05$).

3.3. Comparison of gastrointestinal hormone levels between the 2 groups

Before and after treatment, the changes in gastrointestinal hormone levels of the 2 groups are shown in Table 3. As can be seen, after treatment, the ET and EGF levels in the observation group were significantly lower than those in the control group, while the CGRP level was significantly higher than that in the control group, with the differences being statistically significant ($P < .05$).

3.4. Comparison of serum inflammatory factor levels between the 2 groups

Before and after treatment, the changes in serum inflammatory factor levels of the 2 groups are shown in Table 4. As can be seen, after treatment, the levels of TNF-α, IL-6, and CRP in the observation group were significantly lower than those in the control group, with the differences being statistically significant ($P < .05$).

3.5. Comparison of sleep quality between the 2 groups

The comparison results of sleep quality between the 2 groups before and after treatment are shown in Table 5. As can be seen, after treatment, the PSQI total score and the scores of various indicators in the observation group were significantly lower than those in the control group, with the differences being statistically significant ($P < .05$).

4. Discussion

This study demonstrates that modified Longgu Muli Decoction has significant clinical efficacy in treating chronic atrophic gastritis (CAG).[20] It effectively improves gastrointestinal function, reduces inflammatory responses, and enhances sleep quality, showing high clinical application value.

4.1. Rationale for treatment selection and duration

To ensure a robust comparison, colloidal bismuth pectin capsules were chosen as the control treatment. As a widely recognized standard therapy for CAG, colloidal bismuth pectin capsules are recommended by the Chinese Chronic Gastritis Diagnosis and Treatment Guidelines (2022 Revision) for their effectiveness in protecting the gastric mucosa, alleviating inflammation, suppressing gastric acid, and promoting mucosal healing. This provides a reliable baseline for evaluating the additional benefits of Longgu Muli Decoction.

The 8-week treatment duration was chosen based on clinical guidelines and prior research, which indicate that this timeframe is sufficient for observing significant mucosal repair and symptom improvement in chronic conditions like CAG. Furthermore, this duration aligns with the principles of traditional Chinese medicine (TCM), which typically prescribes treatment cycles of 6 to 8 weeks to allow herbs to exert their therapeutic effects.

4.2. Interpretation of therapeutic effects

The total effective rate of the observation group was 96.67%, significantly higher than the 86.67% observed in the control group, highlighting the superior efficacy of Longgu Muli Decoction. Similar findings were reported by Liu,[21] who observed a 92% total effective rate with a combination of TCM and standard Western therapies for CAG. However, this study exclusively focused on Longgu Muli Decoction as a standalone treatment, showcasing its independent therapeutic potential.

The decoction's effectiveness can be attributed to its diverse pharmacological properties. Longgu and Muli exhibit sedative and astringent effects, while Chaihu and Huangqin relieve liver depression. Banxia, Fuling, Baizhu, and Ganjiang enhance spleen function and dry dampness.[22] Danshen and Yanhusuo promote blood circulation and relieve pain, and Suanzaoren calms the mind.[23] The synergistic effects of these ingredients not only alleviate symptoms but also address the root causes of CAG, such as spleen and stomach deficiency, qi stagnation, and blood stasis.

From a TCM perspective, the observation group showed significantly greater improvements in symptoms such as epigastric burning, epigastric fullness, poor appetite, and fatigue.[24] This aligns with findings from Gholizadeh et al,[25] who demonstrated that TCM formulations emphasizing spleen and stomach regulation effectively improved similar symptoms. The reductions in TCM syndrome scores underscore the holistic benefits of Longgu Muli Decoction in managing both symptoms and overall constitution.

On a biological level, the observation group had significantly reduced endothelin (ET) and epidermal growth factor (EGF) levels, alongside increased calcitonin gene-related peptide (CGRP) levels, compared to the control group.[26] These findings are consistent with Gholami et al (2022),[27] who demonstrated that TCM therapies enhance CGRP and reduce ET in CAG patients, contributing to mucosal protection and inflammation reduction. Key ingredients such as Danshen and Yanhusuo may enhance these effects by promoting blood flow and reducing vascular resistance, thereby alleviating gastric mucosal ischemia.[28]

Furthermore, inflammatory markers such as TNF-α, IL-6, and CRP were significantly lower in the observation group, highlighting the anti-inflammatory properties of Longgu Muli Decoction. The presence of flavonoids and diterpenoids in Danshen and Huangqin likely plays a role by inhibiting NF-κB activation, suppressing pro-inflammatory cytokine production.[27,28]

Lastly, patients in the observation group experienced significantly better sleep quality, as reflected by their lower Pittsburgh Sleep Quality Index (PSQI) scores.[29] The inclusion of

Table 3

Comparison of gastrointestinal hormone levels between the 2 patient groups.

Group	n	ET (ng/L)	CGRP (ng/L)	EGF (pg/mL)
Before treatment				
Observation group	30	68.45 ± 8.32	45.67 ± 7.45	95.34 ± 10.56
Control group	30	69.32 ± 8.56	46.12 ± 7.38	96.28 ± 10.73
After treatment				
Observation group	30	40.67 ± 6.54*	72.45 ± 8.67*	57.23 ± 9.34*
Control group	30	56.78 ± 7.89	53.34 ± 8.12	75.67 ± 9.87

CGRP = calcitonin gene-related peptide, EGF = epidermal growth factor, ET = endothelin.

* Represents that there is a statistical significance between the observation group and the control group, with $P < .05$.

Table 4

Comparison of serum inflammatory factor levels between the 2 patient groups.

Group	n	TNF-α (pg/mL)	IL-6 (pg/mL)	CRP (mg/L)
Before treatment				
Observation group	30	85.67 ± 9.45	72.34 ± 8.23	18.45 ± 2.78
Control group	30	86.12 ± 9.34	73.12 ± 8.45	18.67 ± 2.89
After treatment				
Observation group	30	45.23 ± 7.34*	38.45 ± 6.78*	10.34 ± 1.89*
Control group	30	60.45 ± 8.12	51.67 ± 7.89	15.23 ± 2.34

CRP = C-reactive protein, IL-6 = interleukin-6, TNF-α = tumor necrosis factor-α.

* Represents that there is a statistical significance between the observation group and the control group, with $P < .05$.

Table 5

Comparison of sleep quality between the 2 patient groups.

Group	n	PSQI total score	Subjective sleep quality	Sleep latency	Sleep duration	Sleep efficiency	Sleep disturbances	Daytime dysfunction
Before treatment								
Observation group	30	12.45 ± 2.34	2.56 ± 0.78	2.34 ± 0.67	2.78 ± 0.89	2.56 ± 0.67	1.89 ± 0.56	2.32 ± 0.67
Control group	30	12.67 ± 2.45	2.67 ± 0.89	2.45 ± 0.78	2.89 ± 0.90	2.67 ± 0.78	1.90 ± 0.57	2.34 ± 0.68
After treatment								
Observation group	30	7.34 ± 1.78*	1.34 ± 0.45*	1.23 ± 0.34*	1.56 ± 0.56*	1.34 ± 0.45*	0.89 ± 0.34*	1.12 ± 0.45*
Control group	30	10.45 ± 2.12	2.12 ± 0.67	2.12 ± 0.45	2.34 ± 0.78	2.12 ± 0.56	1.56 ± 0.45	1.67 ± 0.56

PSQI = Pittsburgh Sleep Quality Index.

* Represents that there is a statistical significance between the observation group and the control group, with $P < .05$.

Suanzaoren, a sedative herb, and the calming effects of Longgu and Muli likely contributed to this improvement. This aligns with Zitser et al, who reported that TCM formulations targeting sleep pathways improved sleep quality and reduced associated systemic inflammation.[19,30]

There are still some limitations in this study. This study was conducted as a retrospective study with a rigorous design, including a statistical power calculation and careful determination of sample size to ensure reliability. However, despite meeting these requirements, the total sample size of 60 participants may still be relatively small for detecting smaller effect sizes or conducting subgroup analyses. As a single-center study, the findings may also be influenced by specific demographic, geographic, and healthcare system characteristics, which could limit their generalizability to broader populations. Future studies with larger, multicenter cohorts are needed to include diverse patient populations across different regions and healthcare settings, thereby enhancing the robustness and external validity of the results. Colloidal bismuth pectin capsules were chosen as the control treatment due to their established role as a standard therapy for chronic atrophic gastritis (CAG), allowing for a focused evaluation of the efficacy of modified Longgu Muli Decoction. However, the study did not include proton pump inhibitors (PPIs) or Helicobacter pylori (Hp) eradication therapy, as all participants were either Hp-negative or had undergone successful eradication therapy prior to inclusion. While this design reduced confounding factors, it may limit applicability to broader clinical scenarios. Future studies should consider combination therapies involving PPIs or Hp eradication protocols to explore synergistic effects and address diverse patient needs. Lastly, the study lacked a formal long-term follow-up phase, limiting the assessment of sustained therapeutic effects and recurrence rates. While initial observations suggest symptom relief persisted for 3 to 6 months with proper management, structured follow-up at 3, 6, and 12 months is needed to validate these findings. Future research should also examine whether extending the treatment duration to 12 weeks could provide enhanced or prolonged benefits.

5. Conclusion

In conclusion, this study demonstrates that modified Longgu Muli Decoction has significant clinical efficacy in treating CAG, effectively improving gastrointestinal function, reducing inflammatory responses, and enhancing sleep quality, showing high clinical application value. The decoction adjusts the patient's constitution and pathological state through the synergistic effects of its various herbal components, significantly alleviating CAG symptoms and improving therapeutic outcomes. This study also provides new insights and methods for TCM treatment of CAG. Future research should further explore the mechanisms of Longgu Muli Decoction and conduct large-sample, multi-center clinical studies to verify its efficacy and safety, providing more reliable evidence for the prevention and treatment of CAG. Additionally, the combined use of Longgu Muli Decoction with modern medical treatments should be studied to leverage greater therapeutic advantages in clinical applications. By integrating TCM and Western medicine treatment approaches, the therapeutic efficacy for CAG can be further improved, enhancing the quality of life for patients. In summary, modified Longgu Muli Decoction has broad clinical application prospects in treating CAG, warranting further research and promotion.

Acknowledgments

We would like to thank the participants of this study for sharing their experiences.

Author contributions

Conceptualization: Qiang Zhang, Jinmin Zhang.
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