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Clinical Observation on the Efficacy of Modified Bufe Decoction in Treating Functional Constipation with Qi Deficiency Pattern Based on the Theory of "Simultaneous Treatment of Lung and Intestine"

Liyun Ling, Zheng Xia*

Gastroenterology Department, Shuguang Hospital, Shanghai University of TCM (Songjiang), Shanghai 200000, China

**Corresponding author: Zheng Xia, 1204587366@qq.com*

Abstract

Objective: To observe the clinical efficacy of modified Bufe Decoction (补肺汤) in treating functional constipation (FC) with qi deficiency pattern based on the theory of "Simultaneous Treatment of Lung and Intestine", and to evaluate its effectiveness and safety. *Methods:* One hundred patients with FC and qi deficiency pattern treated at Fangta Hospital of Traditional Chinese Medicine, Songjiang District, Shanghai, were selected as the study subjects. They were randomly divided into a treatment group and a control group, with 50 patients in each group. The control group received lactulose oral solution. The treatment group received modified Bufe Decoction. The clinical efficacy, syndrome scores, and recurrence rates were observed in both groups after treatment. *Results:* After treatment, the total effective rate in the treatment group was 86.0%, significantly higher than the 74.0% in the control group ($P < 0.05$). The TCM syndrome scores in both groups decreased after treatment compared to before treatment, and the decrease was greater in the treatment group than in the control group ($P < 0.05$). *Conclusion:* Modified Bufe Decoction shows significant clinical efficacy in treating functional constipation with a qi deficiency pattern, with a high total effective rate and a low recurrence rate. It is an effective drug for treating FC.

Keywords

Functional constipation
Qi deficiency pattern
Bufe Decoction

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1. Introduction

Functional Constipation (FC) is a type of functional bowel disorder characterized mainly by difficulty defecating, reduced bowel movement frequency, or a sensation of incomplete evacuation, excluding constipation caused by organic lesions of the intestines. The prevalence of FC is currently on the rise. A large-scale multi-regional survey showed an FC prevalence of 6%, with higher rates overall in women than men and in urban areas than rural areas [1–2]. Modern medicine has certain limitations in treating FC, often showing good short-term effects but recurrence after stopping medication. Some drugs may also produce side effects and are not suitable for long-term use, leading to unsatisfactory therapeutic outcomes [3]. This study explores the clinical efficacy of Bufe Decoction in treating FC based on the theory of "Simultaneous Treatment of Lung and Intestine." The report is as follows.

2. Materials and methods

2.1. General data

One hundred and three patients diagnosed with FC and the qi deficiency pattern, who attended the Gastroenterology outpatient clinic or inpatient department of Fangta Hospital of Traditional Chinese Medicine, Songjiang District, Shanghai, between December 2023 and December 2024, were selected. Using a random number table, the 103 patients were divided into a treatment group (51 cases initially) and a control group (52 cases initially). Three cases dropped out (1 from the treatment group, 2 from the control group), resulting in 50 cases each in the final treatment and control groups. There were no statistically significant differences in the general data between the two groups ($P > 0.05$), indicating comparability. This study was approved by the hospital's medical ethics committee.

2.2. Inclusion criteria

Patients diagnosed with FC meet Western medical diagnostic criteria and TCM syndrome diagnosis criteria for the qi deficiency pattern.

* Western Diagnostic Standard: Referenced the FC diagnostic criteria in the *Rome IV Criteria* [4].

* TCM Syndrome Diagnostic Standard: Referenced the *Integrated Traditional Chinese and Western Medicine Diagnosis and Treatment Consensus for Functional Constipation (2017)* and the *Guidelines for Clinical Research of New Chinese Medicines* for diagnosing the qi deficiency pattern [5–6].

No use of other relevant medications within the past month.

Age 18 years or older, no gender restriction.

Colonoscopy ruled out organic lesions of the intestine.

All patients voluntarily participated in the study and signed informed consent forms.

2.3. Exclusion criteria

Pregnant or lactating women.

Patients with allergic constitutions or allergies to the drugs used in this study.

Patients complicated with severe diseases of vital organs (such as heart, brain, spleen, liver, kidney, etc.) or the hematopoietic system.

2.4. Treatment methods

One hundred eligible patients were randomly divided into a treatment group and a control group using a random number table, with 50 patients in each group.

(1) Control group: Lactulose oral solution. 15 ml per dose, twice daily (morning and evening).

(2) Treatment group: Modified Bufe Decoction.

Formula composition: Honey-fried *Astragali Radix* (Huangqi) 30g, *Ginseng Radix et* Rhizo*ma* (Renshen) 9g, Honey-fried *Mori Cortex* (Sangbaipi) 9g, *Rehmanniae Radix Praeparat*a (Shudihuang) 18g, *Asteris Radix* (Ziwan) 9g, *Schisandrae Chinensis Fructus* (Wuweizi) 9g, *Pruni Semen* (Yuliren) 9g, *Cistanches Herb*a (Roucongrong) 9g.

Decoction method: All medications for subjects during the treatment process were uniformly decocted into 300ml per dose, divided into two bags of 150ml each.

Administration method: One bag each, morning and evening, taken 30 minutes after meals.

2.5. Observation indicators

Based on the *Integrated Traditional Chinese and Western Medicine Diagnosis and Treatment Consensus for Functional Constipation (2017)* and the *Criteria for Diagnosis and Therapeutic Effects of Diseases and*

Syndromes in Traditional Chinese Medicine [5, 7].

Cure: After the treatment course, the main and secondary symptoms basically disappeared; efficacy index ≥ 95%.

Markedly effective: After the treatment course, main and secondary symptoms significantly improved; efficacy index 70% to <95%.

Effective: After the treatment course, main and secondary symptoms improved; efficacy index 30% to <70%.

Ineffective: After the treatment course, symptoms showed no improvement; efficacy index <30%.

Efficacy index calculation: Nimodipine method: Efficacy Index = [(Total symptom score before treatment-Total symptom score after treatment) / Total symptom score before treatment] × 100%.

Total effective rate: (Cure + Markedly Effective + Effective) / Total number of cases × 100%.

Symptom scoring system:

Included stool interval time, defecation time, stool form, and sensation of incomplete evacuation.

Primary symptoms (Max 6 points each):

Difficulty defecating: None: 0; Occasional: 2; Sometimes: 4; Frequent: 6.

Stool Frequency (days/bowel movement): 1–2: 0; 3: 2; 3–5: 4; >5: 6.

Defecation time (min): <10: 0; 10–15: 2; 15–25: 4; >25: 6.

Defecation frequency d/times: 1–2: 0 points; 3: 2 points; 3–5: 4 points; >5: 6 points

Defecation time: Less than 10min: 0 points; 10–15min: 2 points; 15–25min: 4 points; More than 25min: 6 points. (4) Stool form (B represents Bristol, international Bristol form is described as follows: Type 1: Separate hard lumps like nuts; Type 2: Sausage-shaped but lumpy; Type 3: Like a sausage but with cracks on the surface; Type 4: Like a sausage or snake, smooth and soft; Type 5: Soft blobs with clear edges; Type 6: Fluffy pieces with ragged edges, mushy stool; Type 7: Watery, no solid pieces): B:7–4: Score 0 points; B:3: Score 2 points; B:2: 4 points; B:1: Score 6 points. (5) Tenesmus or incomplete evacuation: None: 0 points; Occasionally: 2 points; Sometimes: 4 points; Frequently: 6 points. (6) Shortness of breath and fatigue: None: 0 points; After exertion: 1 point; After mild activity: 2 points; Even at rest: 3 points.

Secondary symptoms (Max 6 points each except Shortness of Breath):

Shortness of breath: None: 0; After exertion: 1; After slight activity: 2; At rest: 3.

Fatigue/Lassitude: None: 0; Occasional: 2; Sometimes: 4; Frequent: 6.

Reluctance to speak: None: 0; Occasional: 2; Sometimes: 4; Frequent: 6.

Spontaneous sweating: None: 0; Occasional: 2; Sometimes: 4; Frequent: 6.

Total score: Higher scores indicate more severe symptoms.

2.6. Statistical processing

Data analysis was performed using SPSS 24.0 software. Measurement data were expressed as mean ± standard deviation ($\bar{x}\pm s$). Inter-group comparisons were made using independent sample *t*-tests. Intra-group comparisons were made using paired *t*-tests. Count data were expressed as rates or percentages, and inter-group comparisons were made using the x^2 test. $P < 0.05$ was considered statistically significant.

3. Results

3.1. Clinical efficacy

After treatment, the total clinical effective rate in the treatment group was 86.0%, significantly higher than the 74.0% in the control group. The x^2 test yielded: $x^2 = 6.793$, $P = 0.009$. The difference in total effective rate between the two groups was statistically significant ($P < 0.05$), as shown in **Table 1**.

3.2. TCM syndrome scores

Before treatment, there was no statistically significant difference in TCM syndrome scores between the two groups ($P > 0.05$). After treatment, the TCM syndrome scores in both groups decreased significantly compared to before treatment ($P < 0.05$), and the score in the treatment group was significantly lower than that in the control group ($P < 0.05$), as shown in **Table 2**.

Table 1. Comparison of clinical efficacy between two groups (n, %)

Group	*n*	Cure	Markedly effective	Effective	Ineffective	Total effective
Treatment	50	3 (6.00)	16 (32.00)	24 (48.00)	7 (14.00)	43 (86.00)
Control	50	1 (2.00)	7 (14.00)	29 (57.90)	13 (26.00)	37 (74.00)
x^2						6.793
P						0.009

Table 2. Comparison of TCM syndrome scores between two groups (Points, $\bar{x}\pm s$)

Group	*n*	Pre-treatment score	Post-treatment score	*t*	*P*
Treatment	50	23.04 ± 3.446	8.82 ± 4.583	20.502	<0.001
Control	50	22.90 ± 3.177	12.10 ± 4.929	17.682	<0.001
t		0.211	3.446		
P		0.833	<0.001		

4. Discussion

Traditional Chinese Medicine (TCM) posits that functional constipation is primarily caused by dysfunction of the large intestine's conveyance mechanism. The key to treating this disease lies mainly in promoting bowel movement and relieving constipation. As stated in *Su Ling Wei Yun* (a TCM classic), "The lung and large intestine are exteriorly-interiorly related and share qi. Lung qi transforms essence to nourish the large intestine, making the intestines slippery and bowel movements easy...." This means the lung governs the regulation of water passages and is exteriorly-interiorly related to the large intestine. If the patient's lung qi is deficient, the water passages function poorly, leading to insufficient intestinal fluids and resulting in constipation [8]. The theory of "Simultaneous Treatment of Lung and Intestine" originates from the "exterior-interior relationship between lung and large intestine", highlighting their close physiological and pathological connection and emphasizing the importance of "simultaneous treatment" in diseases involving both organs. The normal physiological function of the large intestine relies on the dispersing and descending functions of lung qi. The lung plays a crucial role in regulating the qi dynamic and the distribution, movement, and excretion of body fluids in the large intestine. If the lung fails to descend qi, the conveyance function of the large intestine becomes dysfunctional, leading to the retention of waste in the intestines. Furthermore, the lung is the "upper source of water", assisting the spleen in transporting fluids. If the lung's dispersing and descending functions are impaired, fluids cannot move smoothly, resulting in dry, difficult-to-pass stools. Clinically, treatment should aim for both the root cause and the symptoms, addressing the root by consolidating lung and spleen qi, and managing the symptoms by enhancing the laxative effect [9].

Bufe Decoction originates from *Yong Lei Qian Fang*. Its original formula consists of Astragali Radix (Huangqi), Ginseng Radix et Rhizoma (Renshen), Schisandrae *Chinensis Fructus* (Wuweizi), *Mori Cortex* (Sangbaipi), *Rehmanniae Radix Praeparata* (Shudihuang), and *Asteris Radix* (Ziwan). It was initially used for lung deficiency causing cough, shortness of breath, and spontaneous sweating [10]. In its later application and development, its functions and indications have undergone significant changes and new uses [11]. In the formula, Huangqi and Renshen are used together to tonify qi and benefit the lung, promoting the downward conveyance function of the large intestine. Huangqi, stir-fried with honey, enhances its lung qi-warming and tonifying effect, making its nature more moistening, which benefits the intestines and can improve symptoms like abdominal distension and sensation of incomplete evacuation. Shudihuang, sweet in taste and warm in nature, aims to nourish yin and blood,

improving stool consistency. Wuweizi astringes lung qi. Sangbaipi drains the lung and promotes water movement. Ziwan warms the lung and directs qi downward. The combination of Sangbaipi and Ziwan, one dispersing and one descending, restores lung function. The research team observed in clinical practice that adding Yuliren to Bufe Decoction enhances its laxative effect, and its moistening and lubricating properties guide the promoting action of the decoction. Therefore, Roucongrong was added. It enters the kidney and large intestine meridians. The lung and kidney have a "metal-water mutual promotion" relationship, jointly supporting the large intestine. This formula primarily warms and tonifies lung qi, supplemented with moistening and lubricating herbs, avoiding excessive warmth that might generate dryness and deplete fluids. It combines tonification with purgation, tonifying without causing stagnation, aligning with the pathogenesis of FC with qi deficiency (root deficiency with branch excess) and the theoretical foundation of "Simultaneous Treatment of Lung and Intestine."

Modern research shows that Astragalus polysaccharides and Ginsenoside Rg1 activate the gap junction protein Cx43 in Interstitial Cells of Cajal (ICC), enhancing slow-wave potential conduction and promoting regular colonic peristalsis [12]. *Aster tataricus* (Ziwan) alleviates constipation symptoms by regulating neurotransmitter levels, blocking the binding of acetylcholine (Ach) to M receptors, and antagonizing Ca^{2+} influx [13]. Simultaneously, Bufe Decoction can promote the recovery of intestinal motility by regulating the secretion and redistribution of neuropeptides such as Vasoactive Intestinal Peptide (VIP), Substance P (SP), and Serotonin (5-HT) in both the lung and colon [11, 14]. This study evaluated the clinical efficacy, symptom improvement, and long-term prognosis of Bufe Decoction in treating FC. The total clinical effectiveness was significantly higher in patients treated with the decoction compared to those treated solely with Western medicine in the control group, which is consistent with previous research findings [15–16].

Functional constipation is a common clinical condition. Although it is not life-threatening, it causes significant distress to patients' work and daily life. Traditional Chinese Medicine emphasizes pattern differentiation in its treatment. Modified Bufe Decoction helps alleviate clinical symptoms in patients with FC and qi deficiency patterns, restores the conveyance function of the large intestine, reduces disease recurrence, and holistically regulates qi, blood, yin, and yang. It offers stable and lasting efficacy with minimal adverse effects, demonstrating unique advantages [17].

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Disclosure statement

The authors declare no conflict of interest.

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