

# Observation on the Therapeutic Effect of Modified Major Bupleurum Decoction in Treating Elderly Patients with Type 2 Diabetes Mellitus Complicated by Constipation

Yaru Zhou

Lianyungang Hospital of Traditional Chinese Medicine, Lianyungang 222000, Jiangsu, China

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**Abstract:** *Objective:* To observe the clinical effect of modified Major Bupleurum Decoction in treating elderly patients with type 2 diabetes mellitus (T2DM) complicated by constipation, particularly its role in alleviating constipation symptoms. *Methods:* A clinical study was conducted on 60 elderly patients with T2DM complicated by constipation who were hospitalized in the geriatrics department of our hospital from January 2024 to December 2025. The patients were divided into groups based on the order of their visits. The control group (n = 30) received Western medicine treatment, while the treatment group (n = 30) received a combination of Western medicine and modified Major Bupleurum Decoction. Differences in traditional Chinese medicine (TCM) syndrome scores, constipation scale scores, glycemic and lipid metabolism indicators, treatment efficacy, and the incidence of adverse reactions were compared between the two groups before and after treatment. *Results:* Compared with the control group, the treatment group showed a significant reduction in TCM syndrome scores and CCS scores after treatment, along with an increase in treatment efficacy, with statistically significant differences ( $p < 0.05$ ). Compared with the control group, the treatment group also demonstrated a significant reduction in glycemic and lipid metabolism indicators after treatment, with statistically significant differences ( $p < 0.05$ ). *Conclusion:* Modified Major Bupleurum Decoction can actively improve constipation symptoms in elderly patients with T2DM complicated by constipation, with a definite therapeutic effect. Additionally, it exerts a certain auxiliary regulatory effect on the glycemic and lipid metabolism health of patients.

**Keywords:** Elderly patients; Type 2 diabetes mellitus; Functional constipation; Modified Major Bupleurum Decoction

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## 1. Introduction

Type 2 diabetes mellitus (T2DM), as a common chronic metabolic disease in clinical practice, has a complex pathogenesis and a high incidence rate among the elderly population. It can damage the functional health of multi-

ple organ systems through long-term blood glucose fluctuations after onset, exacerbating the impact of the disease on patients' health<sup>[1]</sup>.

Gastrointestinal dysfunction, a common manifestation of digestive system dysfunction in elderly T2DM patients, primarily presents as functional constipation. Blood glucose fluctuations can cause nerve and functional damage to the human anorectal structure, thereby exacerbating constipation symptoms. Prolonged constipation not only affects patients' quality of life but also increases the risk of hemorrhagic stroke in patients with comorbid hypertension. Therefore, it is crucial to alleviate constipation symptoms in relevant patients<sup>[2,3]</sup>.

Based on a summary of previous treatment experiences for elderly T2DM patients with constipation, while the use of laxatives can provide some relief from constipation, it fails to address the root cause. Combining other therapeutic techniques may optimize the actual treatment outcomes for patients<sup>[4]</sup>. Therefore, to observe the clinical effects of modified Dachaihu Decoction on elderly T2DM patients with constipation and its role in alleviating constipation symptoms, a study was conducted, with details as follows.

## 2. Materials and methods

### 2.1. Clinical data

Sixty elderly patients with T2DM and constipation who were hospitalized in the geriatrics department of our hospital from January 2024 to December 2025 were selected for this clinical study. They were divided into a control group and a treatment group based on the order of admission, with 30 patients in each group.

In the control group, the gender ratio (male/female) was 17/13, with ages ranging from 67 to 86 years ( $76.54 \pm 5.12$  years), a T2DM duration of 2 to 11 years ( $6.58 \pm 1.04$  years), and a constipation duration of 3 to 9 weeks ( $6.12 \pm 0.73$  weeks). In the treatment group, the gender ratio (male/female) was 16/14, with ages ranging from 68 to 84 years ( $76.28 \pm 5.07$  years), a T2DM duration of 3 to 9 years ( $6.25 \pm 1.02$  years), and a constipation duration of 3 to 10 weeks ( $6.51 \pm 1.08$  weeks). There were no statistically significant differences in gender ratio, age, or disease duration between the groups ( $p > 0.05$ ), indicating comparability.

#### 2.1.1. Inclusion criteria

- (1) Meeting the clinical diagnostic criteria for T2DM and functional constipation;
- (2) Traditional Chinese medicine (TCM) syndrome differentiation indicating liver-stomach heat stagnation syndrome;
- (3) Age  $> 65$  years, with intact cognitive and language communication abilities and clear expression of autonomous will;
- (4) No history of stroke or mobility impairment, capable of cooperating with clinical treatment.

#### 2.1.2. Exclusion criteria

- (1) Definite gastrointestinal organic lesions;
- (2) Presence of alternating constipation and diarrhea symptoms within the previous 12 weeks;
- (3) Comorbid severe liver, kidney, or other organ diseases or diabetic complications;
- (4) Comorbid psychiatric disorders;
- (5) Allergic constitution or a clear history of allergy to the study drugs;
- (6) Comorbid psychiatric disorders (repeated for emphasis, should be removed in actual text);

(7) Withdrawal or active exit from the study during the research period.

## 2.2. Methods

All patients received constipation treatment based on individualized blood glucose control, treatment of underlying diseases, and health guidance on lifestyle factors such as diet and exercise.

### 2.2.1. Control group

Western medicine treatment.

(1) Lactulose

Administered orally with warm water before meals, 15 mL per dose, for 14 consecutive days of treatment;

(2) Glycerin enema

If the patient has not defecated for three consecutive days during treatment, glycerin enema should be administered through the anus for bowel evacuation.

### 2.2.2. Treatment group

(1) Western medicine treatment was the same as that in the control group;

(2) Modified Dachaihu Decoction treatment

The decoction consisted of 24 g of *Bupleurum*, 15 g of White Peony Root, 12 g of *Scutellaria*, and 10 g each of *Pinellia*, Immature Bitter Orange, Ginger, and Jujube, along with 5 g of Raw Rhubarb. The herbs were decocted twice over a gentle flame to obtain 400 mL of juice, which was taken in the morning and evening, one dose per day, for 14 consecutive days of treatment. If the stool was dry and hard, 20 g of *Scrophularia* and 12 g of *Rehmannia* could be added; if defecation was weak, 20 g each of *Codonopsis* and *Astragalus* could be added.

## 2.3. Observation indicators

(1) TCM syndrome scores

Based on the syndromes related to diabetes with liver-stomach heat stagnation and functional constipation, the main symptoms (dry stool, difficult defecation) and secondary symptoms (abdominal distension, red face and bitter mouth) were evaluated before and after treatment. The main symptom scores ranged from 0 to 6 points, and the secondary symptom scores ranged from 0 to 3 points. Higher scores indicated more severe syndrome manifestations<sup>[5]</sup>.

(2) Constipation scale scores

The Cleveland Constipation Scale (CCS) was used for evaluation, including eight items such as defecation frequency, abdominal pain, difficult defecation, and incomplete evacuation. The total score ranged from 0 to 30 points. A score  $\geq 15$  indicated constipation, with higher scores indicating more severe constipation<sup>[6]</sup>.

(3) Glucose and lipid metabolism indicators

Fasting peripheral venous blood samples and postprandial 2-hour peripheral venous blood samples were collected. The clinical laboratory performed tests for fasting blood glucose (FBG), postprandial 2-hour blood glucose (2hPG), total cholesterol (TC), triglycerides (TG), and low-density lipoprotein cholesterol (LDL-C) as needed.

(4) Treatment effectiveness rate

Based on the improvement in constipation symptoms and TCM syndrome scores after treatment, the treatment effect was evaluated as follows: markedly effective (constipation symptoms disappeared or significantly improved after treatment, with a total TCM syndrome score reduction of  $\geq 70\%$  compared to before treatment), effective (constipation symptoms improved after treatment, with a total TCM syndrome score reduction of  $\geq 30\%$  compared to before treatment), and ineffective (not meeting the above evaluation criteria). The total effectiveness rate = (markedly effective + effective) / n  $\times$  100%.

(5) Incidence of adverse reactions

The total incidence of drug-related adverse reactions in each group was statistically analyzed, including dizziness, nausea, gastrointestinal reactions, and skin reactions.

### 2.4. Statistical methods

Data were analyzed using SPSS 25.0 statistical software. Count data were expressed as [number (%)], and constituent ratio data were tested using the  $\chi^2$  test. Measurement data conforming to a normal distribution were expressed as ( $\bar{x} \pm s$ ), with independent sample *t*-tests used for intergroup comparisons and paired *t*-tests used for intragroup comparisons. A *p*-value < 0.05 indicated a statistically significant difference.

## 3. Results

### 3.1. Comparison of TCM syndrome scores

There was no statistically significant difference in TCM syndrome scores between the groups before treatment (*p* > 0.05). After treatment, the scores for dry stool, difficult defecation, abdominal distension, and red face and bitter mouth decreased compared to before treatment, with the treatment group having lower scores than the control group (*p* < 0.05), as shown in Table 1.

Table 1. Comparison of TCM syndrome scores ( $\bar{x} \pm s$ )

Group/n	Dry stool (score)		Difficult defecation (score)		Abdominal distension (score)		Facial flushing and bitter taste (score)	
	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment
Control group / 30	4.35 $\pm$ 0.32	2.47 $\pm$ 0.41*	4.28 $\pm$ 0.35	2.42 $\pm$ 0.21*	1.87 $\pm$ 0.38	1.17 $\pm$ 0.22*	1.82 $\pm$ 0.28	1.02 $\pm$ 0.23*
Treatment group / 30	4.28 $\pm$ 0.38	1.52 $\pm$ 0.25*	4.31 $\pm$ 0.32	1.45 $\pm$ 0.18*	1.89 $\pm$ 0.36	0.79 $\pm$ 0.18*	1.84 $\pm$ 0.31	0.85 $\pm$ 0.22*
<i>t</i>	0.772	10.836	0.356	19.209	0.209	7.322	0.262	2.926
<i>p</i>	0.443	< 0.001	0.730	< 0.001	0.835	< 0.001	0.794	0.005

Note: A statistically significant difference was observed compared to before treatment, \**p* < 0.05.

### 3.2. Comparison of constipation scale scores

There was no statistically significant difference in CCS scores between the two groups before treatment (*p* > 0.05). After treatment, CCS scores in both groups decreased compared with those before treatment, and the scores in the treatment group were lower than those in the control group (*p* < 0.05). See Table 2.

**Table 2.** Comparison of constipation scale scores ( $\bar{x} \pm s$ )

Group (n)	Before treatment (points)	After 7 days of treatment (points)	After 14 days of treatment (points)
Control group / 30	14.24 ± 2.78	10.85 ± 2.21*	9.15 ± 1.79*
Treatment group / 30	14.21 ± 2.83	9.24 ± 2.15*	7.21 ± 1.25*
<i>t</i>	0.041	2.860	4.867
<i>p</i>	0.967	0.006	< 0.001

Note: A statistically significant difference was observed compared to pre-treatment values, \* $p < 0.05$ .

### 3.3. Comparison of glycemic and lipid metabolism indicators

There was no statistically significant difference in glycemic and lipid metabolism indicators between the groups before treatment ( $p > 0.05$ ). After treatment, FBG, 2hPG, TC, TG, and LDL-C levels decreased compared to pre-treatment values, with the treatment group showing lower levels than the control group ( $p < 0.05$ ). See **Table 3** and **4**.

**Table 3.** Comparison of glycemic and lipid metabolism indicators (FBG and 2hPG) ( $\bar{x} \pm s$ )

Group / n	FBG (mmol/L)		2hPG (mmol/L)	
	Before treatment	After treatment	Before treatment	After treatment
Control group / 30	12.85 ± 2.21	8.97 ± 2.24*	15.72 ± 3.45	11.45 ± 2.87*
Treatment group / 30	12.94 ± 2.16	7.05 ± 1.65*	15.68 ± 3.52	9.15 ± 2.15*
<i>t</i>	0.159	3.779	0.044	3.513
<i>p</i>	0.874	< 0.001	0.965	0.001

**Table 4.** Comparison of glycemic and lipid metabolism indicators (TC, TG and LDL-C) ( $\bar{x} \pm s$ )

Group (n)	TC (mmol/L)		TG (mmol/L)		LDL-C (mmol/L)	
	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment
Control group (n = 30)	5.98 ± 1.24	5.45 ± 0.79	4.79 ± 1.25	4.05 ± 0.82*	3.41 ± 0.97	3.02 ± 0.67*
Treatment group (n = 30)	6.01 ± 1.26	4.97 ± 0.62*	4.81 ± 1.22	3.24 ± 0.78*	3.43 ± 0.92	2.34 ± 0.58*
<i>t</i>	0.093	2.618	0.063	3.920	0.082	4.203
<i>p</i>	0.926	0.011	0.950	< 0.001	0.935	< 0.001

Note: There is a statistically significant difference compared to before treatment, \* $p < 0.05$ .

### 3.4. Comparison of treatment effectiveness rate and incidence of adverse reactions

There was no statistically significant difference in the incidence of drug-related adverse reactions between the groups ( $p > 0.05$ ). The treatment effectiveness rate in the treatment group was higher than that in the control group ( $p < 0.05$ ). See **Table 5**.

**Table 5.** Comparison of treatment effectiveness rate and incidence of adverse reactions (n, %)

Group (n)	Treatment effectiveness rate	Adverse reaction incidence rate
Control group (30)	25 (83.33)	1 (3.33)
Treatment group (40)	30 (100.00)	3 (10.00)
$\chi^2$	5.455	1.071
$p$	0.019	0.301

## 4. Discussion

Digestive system diseases, as a category where traditional Chinese medicine (TCM) demonstrates significant therapeutic advantages, have shown definite clinical efficacy in treating various types of diseases. After conducting a syndrome differentiation analysis of the symptoms and pathogenesis in patients with type 2 diabetes mellitus (T2DM) complicated by constipation, it is considered that their condition falls within the scope of “diabetes” and “constipation”. Based on diabetes, the pathogenesis of “fullness in the middle and internal heat” leads to internal dryness and heat accumulation, as well as impaired large intestine function. Alternatively, diabetes can cause damage to both Qi and Yin, internal retention of damp turbidity, or blood stasis obstructing the collaterals, resulting in insufficient intestinal lubrication as the primary pathogenic mechanism of constipation. The primary pathological sites are the gastrointestinal tract, which can also affect the lungs, spleen, liver, and kidneys. Therefore, a differential treatment approach can be adopted, utilizing methods such as clearing heat and promoting blood circulation, soothing the liver and relieving depression, and strengthening the spleen and harmonizing the stomach [7].

Major Bupleurum Decoction, originating from Treatise on Febrile Diseases, has the effects of purging heat and promoting bowel movement, as well as soothing the liver and regulating Qi. The formula uses *bupleurum* as the principal herb, which can soothe the liver and relieve depression, clear heat, and elevate Yang. *Rhubarb*, *scutellaria*, and immature bitter orange serve as the deputy herbs, which can clear heat and reduce fire, dry dampness, and break Qi to eliminate accumulation. Supplemented with white peony root to soften and restrain the liver and suppress liver Yang, and *pinellia* to dry dampness and resolve phlegm, eliminate fullness, the overall formula, through the combined effects of its individual herbs, can regulate the functions of the stomach, intestines, spleen, liver, and other organs, address the pathogenic mechanisms, and enhance the efficacy of laxatives in alleviating constipation symptoms in patients [8,9]. These conclusions are consistent with the findings of this study. Compared with the control group, the treatment group showed reduced TCM syndrome scores and CCS scores after treatment, along with an increased treatment efficacy, with statistically significant differences ( $p < 0.05$ ).

Moreover, this study indicates that, compared with the control group, the treatment group demonstrated reduced glycemic and lipid metabolism indicators after treatment, with statistically significant differences ( $p < 0.05$ ). Analysis suggests that the biological polysaccharides and poly glycosides contained in bupleurum in Major Bupleurum Decoction have a certain regulatory effect on human lipid metabolism levels and possess anti-inflammatory properties. The biological components in *scutellaria* can inhibit the activity of inflammatory cytokines, while those in immature bitter orange significantly improve human lipid metabolism and glucose tolerance. Therefore, under the combined effects of these components, they can assist in promoting the improvement of glycemic and lipid metabolism health in patients after treatment and optimize the clinical treatment outcomes of T2DM [10].

## 5. Conclusion

In summary, the treatment with modified Major Bupleurum Decoction can actively improve constipation symptoms in elderly patients with T2DM complicated by constipation, with definite therapeutic effects, and also has a certain auxiliary regulatory effect on the glycemic and lipid metabolism health of patients.

## Disclosure statement

The author declares no conflict of interest.

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