Effectiveness of Xinglouchengqi decoction on constipation in patients with acute ischemic stroke: a randomized controlled trial

Chen Pei, Jiang Lan, Geng Hualei, Han Xiao, Xu Yinping, Chen Yan, Guo Jinbin, Wu Shuang, Wang Yahui, Yan Ruyu, Ren Yi, Zou Yihuai

METHODS: A total of 317 eligible patients were recruited and randomized to the XLCQ group (211 patients) or the control group (106 patients). In addition to conventional standard medical care and rehabilitation, participants in the XLCQ group received XLCQ decoction, while the control group received clysis therapy using glycerin enemas or lactulose oral solution. Both groups were given treatment for 3 to 6 d, during which they received daily visits to record defecation features and accompanying symptoms. Neurological assessments using the National Institutes of Health Stroke Scale (NIHSS) were conducted before and 1 month after treatment.

RESULTS: Patients in the XLCQ group had lower aggregate constipation scores compared with the control group on day 3 and 5 ($P < 0.05$). Spontaneous bowel movements tended to reappear more rapidly after taking the XLCQ decoction than after conventional laxative treatment. Both the average aggregate constipation score and the time taken to achieve spontaneous bowel movements showed positive correlations with NIHSS scores before and 1 month after treatment ($P < 0.01$).

CONCLUSION: Treatment with XLCQ decoction effectively alleviated the overall symptoms of constipation in acute ischemic stroke patients. The status of bowel movements in acute ischemic stroke can reflect the severity of neurological impairment and predict neurological outcomes at 1 month.

Keywords: Stroke; Constipation; Xinglouchengqi decoction; Randomized controlled trial
INTRODUCTION

Stroke is the second leading cause of death in the world.1 Although the incidence, prevalence, and mortality rates of stroke have tended to decline from 1990 to 2013, there has been a global increase in overall stroke burden in terms of the absolute numbers of patients who are affected by or remain disabled from stroke.2,3 Constipation is one of the most common medical complications among stroke patients,4 negatively affecting their quality of life. Incidence of constipation varies according to different studies, but has been reported to be as high as 79.4%.5 A large population-based study in Denmark, involving 13,721 acute stroke patients, revealed that constipation was ranked third (6.8%) among in-hospital medical complications, following urinary tract infections (15.4%) and pneumonia (9.0%).6 The frequent occurrence of constipation in stroke patients may be caused by immobility, lack of consciousness, insufficient water and nutrition intake, mood disturbances, the use of a bedpan for defecation, or medication side effects, among other reasons.7-9 The influence of constipation in stroke patients is not limited to the gastrointestinal system. Stroke patients with constipation have a significantly prolonged colon transit time, higher prevalence of dysphagia, and a worse functional status when compared with stroke patients without constipation.7 The development of constipation is also associated with longer lengths of hospitalization and poorer outcomes.6,8 Currently, frequently used treatments include dietary adjustments, laxatives, prokinetic agents, and enemas, but evidence supporting their use remains scarce.9 Xinglouchengqi (XLCQ) decoction, a type of Chinese herbal medicine, has been widely used in China for more than 30 years. It was tailored for stroke patients in the Traditional Chinese Medicine (TCM) syndrome of phlegm-heat and fu-organ excess, which is featured with constipation. The decoction is made up of five Chinese herbs, and is simple and cheap to prepare. Chinese medicine practitioners have conducted many related preclinical and clinical investigations of XLCQ since Wang Yongyan, an academic of the China Academy of Chinese Medical Sciences, first published his experience of the clinical applications of XLCQ decoction in 1986.10 However, rigorous studies in this field remain lacking. The present study was designed as a multi-center large-sample clinical trial to investigate the effectiveness and safety of XLCQ decoction, providing a new approach for the treatment of constipation in acute ischemic stroke patients. The role that bowel movements play in the treatment of acute ischemic stroke was also explored, highlighting the importance of retaining normal bowel movements.

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Figure 1 Study flowchart
XLCQ: Xinglouchengqi.

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METHODS

Study design
This study was designed as a prospective, multi-center, randomized controlled trial. Eligible participants were randomly assigned to the XLCQ group or the control group at a ratio of 2:1. Subjects in the XLCQ group received XLCQ decoction while those in the control group received conventional laxative treatment. Both groups were otherwise treated with standard medical care and rehabilitation. The duration of treatment and observation varied from 3 to 6 d, depending on the time it took for the patient to regain complete spontaneous bowel movements. A flow diagram of the study process is given in Figure 1.

The study design followed the Declaration of Helsinki principles. The research ethics committees of Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine, and all other participating hospitals, approved the study protocol. The trial was registered in the Chinese Clinical Trial Registry (identifier: ChiCTR-TRC-14005146) and the study protocol was published.11

Subjects
Subjects were screened and recruited from May 2014 to December 2016 in (a) Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine, (b) Dongzhimen Hospital Eastern affiliated to Beijing University of Chinese Medicine, (c) Beijing Pinggu Hospital of TCM, (d) Beijing Huairou Hospital of TCM, (e) Beijing Changping Hospital of TCM, (f) Hospital affiliated to Changzhi Academy of Chinese Medical Sciences. All participants signed written informed consents before randomization.

Diagnostic criteria
According to the Chinese Guideline for Diagnosis and Management of Acute Ischemic Stroke 2010,12 the diagnostic criteria for acute ischemic stroke were as follows: (a) acute onset; (b) focal neurological deficits (a minority of patients have overall neurological deficits); (c) clinical symptoms and signs lasting for several hours; (d) exclusion of cerebral hemorrhage and other related diseases using computed tomography or magnetic resonance imaging; and (e) responsible infarct lesions in the brain confirmed by computed tomography or magnetic resonance imaging.

The main diagnostic criteria for the TCM syndrome of phlegm-heat and fu-organ excess were as follows:13 (a) dry, hard stools or difficult bowel movements; (b) yellow slimy fur on the tongue; and (c) a string-like, slippery pulse. Furthermore, patients displaying this syndrome often complain of a dry mouth, thirst, abdominal distension, halitosis, and poor appetite and so on.

Inclusion and exclusion criteria
All participants met the following inclusion criteria: they (a) met the diagnostic criteria for acute ischemic stroke; (b) met the diagnostic criteria for TCM syndrome of phlegm-heat and fu-organ excess; (c) were within 14 d from the onset of the present stroke episode; (d) were over 18 years old; (e) volunteered to take part and signed written informed consent; (f) had not participated in other clinical trials in the past 3 months; and (g) were compliant to continue throughout the entire study process.

Patients were excluded if they met any of the following criteria: (a) lacunar infarction or transient ischemic attack; (b) stroke caused by brain tumors, brain trauma, or hematologic diseases; (c) cerebral embolism; (d) severe primary disease of the cardiovascular system, liver, kidney, or hematologic system, or immunodeficiency diseases, tumors, psychoses, serious cognitive impairment, or significant abnormality of the liver or renal function; (e) pregnant or lactating women; (f) allergic constitution; or (g) had taken any medicine in the previous 4 weeks that was known to impair vital organs.

Sample size
Because there were no published rates of XLCQ decoction for the amelioration of constipation in stroke patients, we used the overall response rate for stroke instead.10 In light of previous studies, response rates of 0.856 for XLCQ decoction and 0.71 for the control group were assumed.10,14,15 The alpha and beta levels were set at 0.05 and 0.10, respectively. With a group sample ratio of 2, the required sample size was calculated to be 200 in the XLCQ group and 100 in the control group. The expected dropout rate was no more than 20%, so the final target sample size was enlarged to 360, to be divided into 240 and 120.

Randomization and allocation concealment
After written informed consents were obtained, subjects were randomly assigned to the XLCQ group or control group using a computer-generated randomization sequence at a ratio of 2:1. A block size of six was designed, with four subjects in the XLCQ group and two in the control group. The principal researcher from each hospital did not take direct part in recruitment, but maintained records of the assignments. Other researchers were able to see the corresponding allocations from the principal researcher after written informed consent had been obtained.

Blinding
Because the Chinese herbal decoction was totally different from the glycerin enema and the lactulose oral solution, it was almost impossible to blind the participants. Both the researchers and participants were therefore informed of the group allocation, but the assessors and statistician were blinded to group allocation.

Treatments
Patients in both groups received conventional standard medical care and rehabilitation. In addition, partici-
pents randomized to the XLCQ group received the XLCQ decoction, composed of Dahuang (Radix et Rhizoma Rhei Palmatii) 10 g, Dannanxing (Rhizoma Aris- aematis Cum Bile) 6 g, Gualou (Fructus et Semen Trichosanthis) 30 g, Mangxiao (Natrii Sulphatis) 10 g, Qianghuo (Rhizoma et Radix Notopterygii) 6 g. Participants were instructed to take 100 mL of the decoction twice daily. In the control group, clysis was performed using glycerin enemas (40 mL, once daily) or oral administration of lactulose oral solution (Duphalac; 15 mL containing 10 g lactulose, once daily) purchased from Abbott Healthcare Products B.V. (Olst, Netherlands). Individual differences were taken into account, and the treatment course varied from 3 to 6 d until the participant regained complete spontaneous bowel movements.

Outcome measures
During the treatment period, patients were visited and observed each day. If the patients defeated that day, the level of urgency and the level of difficulty in passing stools, the defecation time, and the consistency of the stools would be recorded. Each feature had a score of 0, 2, or 4, with the lower score correlating with a better situation. Additionally, it was recorded whether patients had the following symptoms: abdominal pain, abdominal distention, dizziness, fatigue, annoyance and irritability, apathy, hypomnesis, aprosexia, slow reaction time, bitter taste in the mouth, poor appetite, or sacrococcygeal pain. Each of the symptoms was given a score of 0.5. The total constipation score was calculated by adding the scores of the features and the scores of the accompanying symptoms. Observations were terminated once the patients regained spontaneous bowel movement, after 3 to 6 d of treatment.

Additionally, the severity of neurological impairment was assessed before and 1 month after treatment using the National Institutes of Health Stroke Scale (NIHSS).

Statistical analysis
Data analysis was conducted using SPSS 20.0 (IBM Corp., released 2011. IBM SPSS Statistics for Windows, Version 20.0., Armonk, NY, USA). To compare the efficacy of the two therapies, comparisons between the two groups were performed. For continuous variables, presented as mean ± standard deviation (x̄ ± s), a t-test (if normally distributed) or non-parametric test (if not normally distributed) was used. χ² test was applied for categorical variables. Bivariate correlation analyses were conducted to figure out the relationship between two indicators. Values of P < 0.05 were considered statistically significant.

RESULTS

Patient recruitment and comparison of patient characteristics
Each acute ischemic stroke patient that was enrolled in the inpatient department was screened. After obtaining written informed consent, 317 patients were randomized to either the XLCQ group (211 patients) or the control group (106 patients). Of these patients, one patient was enrolled mistakenly and 12 patients had protocol noncompliance issues. Therefore, a total of 304 patients (205 in the XLCQ group and 99 in the control group) completed the study. Statistical analyses were carried out on these patients. The dropout rates of the XLCQ group (2.84%) and the control group (6.60%) were not significantly different (P > 0.05).

There was no significant difference in gender, age, course of the disease, or NIHSS score between the two groups (P > 0.05). A comparison of patient characteristics between the two groups at baseline is shown in Table 1.

Comparison of the defecation rates in the two groups
Daily visits to each patient during the course of treatment allowed researchers to record whether the patients defeated or not. Every patient received treatment and observation for the first 3 d, and the treatment and daily visits were terminated once spontaneous bowel movements were regained. Thus, the number of patients observed in both groups continuously varied from day 4. On the first day of treatment, a larger percentage of patients in the control group defeated compared with the XLCQ group (P < 0.01). However, this finding was transient, and there were no statistical differences in defecation rates between the two groups for the following 5 d (Table 2, Figure 2A).

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Comparison of patient characteristics between the two groups (x̄ ± s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>XLCQ group (n = 211)</td>
</tr>
<tr>
<td>Gender (n)</td>
<td>Male</td>
</tr>
<tr>
<td></td>
<td>Female</td>
</tr>
<tr>
<td>Age (years)</td>
<td>65.7±10.1</td>
</tr>
<tr>
<td>Disease duration (days)</td>
<td>2.6±3.5</td>
</tr>
<tr>
<td>NIHSS score before treatment</td>
<td>7.2±4.5</td>
</tr>
</tbody>
</table>

Notes: XLCQ group received 100 mL of XLCQ decoction twice daily. The control group was treated with glycerin enemas (40 mL, once daily) or lactulose oral solution (Duphalac; 15 mL containing 10 g lactulose, once daily). Treatment duration varied from 3 to 6 d until the participant regained complete spontaneous bowel movements. XLCQ: Xinglouchengqi.
Comparison of time taken to regain spontaneous bowel movements

We also compared how many days it took for patients to regain spontaneous bowel movements between the two groups. Compared with the control group, the average time consumed to regain spontaneous bowel movement seemed to be shorter, and the percentage of patients who regained bowel movements at 3 to 5 d to be higher in the XLCQ group than the control group. However, there were no significant differences between the two groups (P > 0.05; Table 3, Figure 2B).

Comparison of the number of accompanying symptoms

We recorded 12 accompanying symptoms, including abdominal pain, abdominal distention, dizziness and so forth. For the first 3 d, the average number of accompanying symptoms in the XLCQ group seemed to be higher than in the control group. From the fourth day, patients in the control group began to have more accompanying symptoms than the XLCQ group. However, there were no significant differences between the two groups (P > 0.05; Table 4, Figure 2C).

Comparison of aggregate constipation scores

The aggregate constipation score was calculated by adding the scores of all of the defecation features to the scores of the accompanying symptoms. In the XLCQ group, the aggregate constipation scores on days 3 and 5 were significantly lower than in the control group (P < 0.05; Table 5, Figure 2D).

Table 2 Comparison of defecation rates between the two groups (number of patients who defecated/number of patients observed, %)

<table>
<thead>
<tr>
<th>Group</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>XLCQ group</td>
<td>51/205 (24.88)%</td>
<td>121/205 (59.02)</td>
<td>143/205 (69.76)</td>
<td>121/184 (65.76)</td>
<td>104/145 (71.72)</td>
<td>66/118 (55.93)</td>
</tr>
<tr>
<td>Control group</td>
<td>42/99 (42.42)</td>
<td>55/99 (55.56)</td>
<td>59/99 (59.60)</td>
<td>63/89 (70.79)</td>
<td>54/73 (73.97)</td>
<td>38/60 (63.33)</td>
</tr>
</tbody>
</table>

Notes: XLCQ group received 100 mL of XLCQ decoction twice daily. The control group was treated with glycerin enemas (100 mL, once daily) or lactulose oral solution (Duphalac; 15 mL containing 10 g lactulose, once daily). Treatment duration varied from 3 to 6 d until the participant regained complete spontaneous bowel movements. XLCQ: Xinglouchengqi. *P < 0.01 XLCQ group vs the control group.

Table 3 Comparison of the time taken to regain spontaneous bowel movements

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Average (d)</th>
<th>3 d [n (%)]</th>
<th>4 d [n (%)]</th>
<th>5 d [n (%)]</th>
<th>6 d [n (%)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>XLCQ</td>
<td>205</td>
<td>5.2±1.1</td>
<td>21 (10.24)</td>
<td>39 (19.02)</td>
<td>27 (13.17)</td>
<td>118 (57.56)</td>
</tr>
<tr>
<td>Control</td>
<td>99</td>
<td>5.2±1.1</td>
<td>10 (10.10)</td>
<td>16 (16.16)</td>
<td>13 (13.13)</td>
<td>60 (60.61)</td>
</tr>
</tbody>
</table>

Notes: XLCQ group received 100 mL of XLCQ decoction twice daily. The control group was treated with glycerin enemas (40 mL, once daily) or lactulose oral solution (Duphalac; 15 mL containing 10 g lactulose, once daily). Treatment duration varied from 3 to 6 d until the participant regained complete spontaneous bowel movements. XLCQ: Xinglouchengqi.

Correlations between average aggregate constipation scores, time taken to regain spontaneous bowel movements, and NIHSS scores

Significant correlations (all P values < 0.01) were observed between average aggregate constipation scores, time taken to regain spontaneous bowel movements, and NIHSS scores before and 1 month after treatment (Table 6, Figure 3).

Comparison of safety and adverse events

There were no significant differences in routine blood, liver, and renal function tests before and after treatment. One patient in the XLCQ group experienced abdominal pain after administration of the decoction. However, the pain was moderate in severity and may have been caused by the drug or by constipation itself. No serious adverse events were reported.

DISCUSSION

The present clinical trial focused on constipation, a common complication in stroke patients, using a detailed multi-perspective observation of defecation features and 12 accompanying symptoms. Results revealed that the XLCQ decoction could effectively alleviate the overall symptoms of constipation in acute ischemic stroke patients, as shown by the lower aggregate constipation scores compared with the control group (Table 5, Figure 2D). Furthermore, it may take less time for patients to regain spontaneous bowel movements.

Table 4 Comparison of the numbers of accompanying symptoms between the two groups (n ± x ±t)

<table>
<thead>
<tr>
<th>Group</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>XLCQ</td>
<td>4.2±2.7</td>
<td>3.9±2.4</td>
<td>3.2±2.3</td>
<td>2.2±2.1</td>
<td>2.0±2.0</td>
<td>2.2±2.1</td>
</tr>
<tr>
<td>Control group</td>
<td>3.9±3.0</td>
<td>3.5±2.3</td>
<td>3.1±2.7</td>
<td>2.4±2.3</td>
<td>2.4±2.5</td>
<td>2.7±2.7</td>
</tr>
</tbody>
</table>

Notes: XLCQ group received 100 mL of XLCQ decoction twice daily. The control group was treated with glycerin enemas (40 mL, once daily) or lactulose oral solution (Duphalac; 15 mL containing 10 g lactulose, once daily). Treatment duration varied from 3 to 6 d until the participant regained complete spontaneous bowel movements. XLCQ: Xinglouchengqi.

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movements after taking the XLCQ decoction compared with conventional laxative treatment (Table 3, Figure 2B). Importantly, both the average aggregate constipation scores and the time taken to regain spontaneous bowel movements were positively correlated with NIHSS scores before and 1 month after treatment (Table 6 and Figure 3). These results confirm that the status of bowel movements can reflect the severity of neurological impairment, and can predict neurological outcomes at 1 month. However, in the XLCQ group, the average defecation rate on day 1 was lower (Table 2, Figure 2A) and the numbers of accompanying symptoms during the first 3 d seemed higher (Table 4, Figure 2C), suggesting that conventional laxative treatment has a better immediate effect than the XLCQ decoction.

TCM has been practiced in China for thousands of years and vast experience has been accumulated. According to TCM theory, strokes result from a deficiency of visceral function, disharmony of Yin and Yang, and disorder of Qi and blood. The combination of these pathogenic factors is detrimental to the brain and may simultaneously impact bowel movements; disturbed bowel function can in turn intensify existing pathogenic factors and produce new ones. From a holistic viewpoint, pathogenic factors can be eliminated through relaxation of the bowels, and relief of neurological and bowel malfunction will follow.

**Table 5** Comparison of aggregate constipation scores between the two groups (\(\bar{x} \pm s\))

<table>
<thead>
<tr>
<th>Group</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>XLCQ</td>
<td>8±4</td>
<td>9±4</td>
<td>7±4</td>
<td>6±4</td>
<td>5±3</td>
<td>5±3</td>
</tr>
<tr>
<td>Control</td>
<td>8±4</td>
<td>8±4</td>
<td>8±4</td>
<td>7±4</td>
<td>7±4</td>
<td>6±4</td>
</tr>
</tbody>
</table>

Notes: XLCQ group received 100 mL of XLCQ decoction twice daily. The control group was treated with glycerin enemas (40 mL, once daily) or lactulose oral solution (Duphalac; 15 mL containing 10 g lactulose, once daily). Treatment duration varied from 3 to 6 d until the participant regained complete spontaneous bowel movements. XLCQ: Xinglouchengqi. *P* < 0.05 XLCQ group vs the control group.

Figure 2 Effect of the two therapies on constipation and related symptoms

A: comparison of the defecation rates in the two groups. A higher percentage of patients defecated in the control group than in the XLCQ group on the first day of receiving treatment (\(P < 0.01\)); B: comparison of the time taken to regain spontaneous bowel movements; C: comparison of the number of accompanying symptoms; D: comparison of the aggregate constipation scores. The scores of days 3 and 5 were significantly different between the two groups (\(P < 0.05\)). XLCQ: Xinglouchengqi.
Chinese herbs: Gualou (Fructus et Semen Trichosanthis) helps to remove heat and phlegm; Dannanxing (Rhizoma Arisaematis Cum Bile) can tranquilize endogenous wind, clear heat and resolve phlegm; Dahuang (Radix et Rhizoma Rhei Palmati) and Mangxiao (Nalrii Sulfa) can effectively relax the bowels, leading the pathogenic factors a way out; Qianghuo (Rhizoma et Radix Notopterygii) helps to ascend the Yang Qi. Working as a whole, XLCQ decoction removes heat-phlegm and relaxes the bowels, regulating body Qi activity and restoring Yin-Yang harmony. The decoction is representative in the TCM treatment of stroke and has been widely used in clinical practice. Although the exact mechanism behind XLCQ decoction’s action is not yet known, its effectiveness in improving constipation overall is significant.

The interactions between gut microbiota and stroke have recently attracted much attention, and progress in this field is flourishing. It has been revealed that, through generating trimethylamine N-oxide (TMAO), gut microbes contribute to platelet hyperreactivity and enhanced thrombosis (such as stroke) potential. After a stroke occurs, acute brain lesions cause gut microbiota dysbiosis, which in turn affects neuroinflammatory

<table>
<thead>
<tr>
<th>Item</th>
<th>Average aggregate constipation score</th>
<th>Time consumed to gain spontaneous bowel movement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>r value</td>
<td>P value</td>
</tr>
<tr>
<td>NIHSS (before treatment)</td>
<td>0.33</td>
<td>0.00</td>
</tr>
<tr>
<td>NIHSS (1-month)</td>
<td>0.33</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Notes: NIHSS: National Institutes of Health Stroke Scale.

Figure 3 Correlations between average aggregate constipation scores, time consumed to regain spontaneous bowel movements, and NIHSS scores

Both the average aggregate constipation score and the time taken to regain spontaneous bowel movements were positively correlated with the NIHSS score before and 1 month after treatment (P < 0.01). A: correlation between average aggregate constipation scores and the NIHSS scores before treatment; B: correlation between time consumed to regain spontaneous (days) and NIHSS scores before treatment; C: correlation between average aggregate constipation scores and the NIHSS scores 1-month after treatment; D: correlation between time consumed to regain spontaneous (days) and NIHSS scores 1-month after treatment.
and functional outcomes after brain injury.\(^7\) Additionally, translocation and dissemination of selective strains of bacteria originating from the host gut microbiota to peripheral tissues is promoted after stroke, which is an important source of post-stroke infection.\(^8\) Intestinal γδ T cells have been shown to play a key role in the effect of commensal gut bacteria on ischemic stroke outcome.\(^9\) Therefore, gut microbiota may be a potential therapeutic target for stroke and/or for complications after cerebral ischemia.\(^10\) Taken together, these results suggest that the XLCQ decoction may benefit stroke patients through the regulation of gut microbiota. In addition, gut microbiota richness and composition, enterotypes, and bacterial growth rates can be reflected in stool consistency.\(^11\) Although gut microbiota were not investigated here, the present study conducted a detailed analysis of defecation-related symptoms, laying the foundation for future studies.

Previous studies have reported that Chinese herbal medicine is beneficial for functional constipation;\(^12\) however, English-language publications about Chinese herbal treatments of post-stroke constipation can hardly be searched. One limitation concerning our results is that participants and researchers were not blinded to the group assignment. The XLCQ decoction has obvious differences from the control treatments in appearance, taste, and smell, and almost all Chinese people have some basic knowledge of Chinese herbal medicine. These inherent problems make it almost impossible to blind patients. The only benefit is that both therapies are commonly used and well received in TCM hospitals in China. Patients are usually unsure about which therapy is better, and they consequently do not have a personal preference.

In conclusion, the XLCQ decoction is safe and can effectively alleviate the overall symptoms of constipation in acute ischemic stroke patients. The status of bowel movements in acute ischemic stroke reflects the severity of neurological impairments and predicts neurological outcomes at 1 month. Future studies could be conducted to investigate the therapeutic mechanisms of the XLCQ decoction.

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### REFERENCES


