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Clinical Efficacy Observation of Jing Ethnic Group's Self-Proposed Formula Combined with Burning Mugwort on Patients after Cholecystectomy for Gallstones

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Abstract

Objective: To explore the clinical efficacy of the Jing ethnic group's self-proposed formula combined with burning mugwort on patients after cholecystectomy for gallstones. **Methods:** Sixty-four patients with gallstones who received inpatient treatment at the Hepatobiliary Surgery Department of Fangchenggang Traditional Chinese Medicine Hospital from November 2022 to November 2023 were selected and randomly divided into a control group and an observation group. The treatment group was treated with the Jing ethnic group's self-proposed formula combined with burning mugwort, while the control group was treated with ursodeoxycholic acid tablets. The liver function indicators, therapeutic effect, safety evaluation, and quality of life of the two groups were compared. **Results:** After treatment, compared with the control group, the ALT, AST, and TBIL levels of the treatment group changed, but the differences were not statistically significant ($P > 0.05$). Within-group comparisons showed that the ALT, AST, and TBIL levels of the observation group significantly decreased after treatment, with statistically significant differences ($P < 0.001$). The same trend was observed in the control group, with statistically significant differences ($P < 0.001$). The overall effective rate of the treatment group was higher than that of the control group ($P < 0.05$). During the treatment process and follow-up period, there were no statistically significant differences in adverse reactions between the two groups ($P > 0.05$). After treatment, compared with the control group, the scores for psychological, physiological, social-cultural, and environmental aspects of the treatment group

increased significantly, with statistically significant differences ($P < 0.05$). Within-group comparisons showed that the scores for psychological, physiological, social-cultural, and environmental aspects of the observation group increased significantly after treatment, with statistically significant differences ($P < 0.001$). The same trend was observed in the control group, with statistically significant differences ($P < 0.001$). **Conclusion:** The Jing ethnic group's self-proposed formula combined with burning mugwort can improve the therapeutic effect and quality of life of patients after cholecystectomy for gallstones without causing adverse reactions.

Keywords

Jing Ethnic Medicine, Burning Mugwort, Post-Cholecystectomy for Gallstones, Quality of Life

1. Introduction

Laparoscopic cholecystectomy is a common minimally invasive surgery in clinical practice, often used for the treatment of gallbladder polyps and gallstones, with relatively significant effects. Postoperative gastrointestinal dysfunction is a common complication, primarily characterized by delayed transmission of gastrointestinal contents, weakened or absent bowel sounds, accompanied by symptoms such as defecation and flatulence disorders and even abdominal distension. If patients do not receive timely and effective intervention, it may further develop into postoperative intestinal obstruction, or even induce serious cardiovascular and cerebrovascular complications, leading to a significant decline in the patient's quality of life [1]. The pathophysiological mechanisms underlying gastrointestinal dysfunction after cholecystectomy for gallbladder stones are complex and involve multiple factors. Firstly, the surgery itself can cause damage to the intestinal nerves and muscle tissues, affecting the normal peristaltic function of the intestines. Secondly, postoperative fasting and the use of anesthetic drugs can also suppress intestinal motility, leading to reduced gastrointestinal motility. Additionally, the inflammatory mediators released and changes in immune function due to the postoperative stress response may also impact intestinal function. These factors collectively contribute to the occurrence and progression of postoperative gastrointestinal dysfunction.

At present, clinical interventions for patients who have undergone cholecystectomy mainly consist of routine nursing measures. While these measures can accelerate intestinal peristalsis to some extent, their clinical effectiveness is suboptimal, often failing to adequately alleviate the postoperative symptoms experienced by patients [2]. Therefore, it is particularly important to seek more effective treatment methods. Jing ethnic medicine, one of our ethnic minority medicines, has certain insights into the treatment of patients after cholecystectomy for gallstones. Due to factors such as fasting before and after surgery and surgical trauma,

patients often suffer from qi and blood deficiency. Therefore, clinical interventions can adopt principles such as unblocking meridians, regulating qi, and promoting blood circulation [3]. Burning mugwort is a characteristic external therapy of the Jing ethnic group, which stimulates acupoints using the warming and heat effects of mugwort and transmits these effects through meridians to the affected area, thereby achieving the effects of regulating qi, strengthening the spleen, and harmonizing the stomach [4]. In recent years, some studies have preliminarily demonstrated the efficacy and safety of the custom formula of the Jing ethnic group combined with moxibustion (burning mugwort) in the treatment of various diseases. However, research on its application in patients who have undergone cholecystectomy for gallbladder stones is relatively scarce, and the specific therapeutic effects and mechanisms of action require further investigation. Based on this, the present study selected 64 patients who had undergone cholecystectomy for gallbladder stones, aiming to explore the effects of the Jing ethnic group's custom formula combined with moxibustion on these patients. This study aims to provide new treatment ideas and methods for clinical practice. The results are reported as follows.

2. Clinical Data and Methods

2.1. Case Selection

Sixty-four patients with gallstones who received inpatient treatment at the Hepatobiliary Surgery Department of Fangchenggang Traditional Chinese Medicine Hospital from November 2022 to November 2023 were selected. This study was approved by the Ethics Committee of Fangchenggang Traditional Chinese Medicine Hospital, and informed consent was obtained from all subjects when they were conscious.

2.1.1. Inclusion Criteria

(1) Patients who met the diagnostic criteria of the "Expert Consensus on the Surgical Treatment of Benign Gallbladder Diseases (2021 Edition)."

(2) Patients who underwent laparoscopic cholecystectomy and had successful surgery.

(3) Patients with normal preoperative blood routine and normal heart, liver, and kidney functions.

(4) All patients and their families understood and signed the informed consent form.

2.1.2. Exclusion Criteria

(1) Patients with a history of abdominal surgery.

(2) Patients who entered the intensive care unit postoperatively.

(3) Patients with severe mental illness or cognitive impairment.

2.2. Case Grouping

A total of 64 eligible patients who met the diagnostic criteria for gallbladder stones

and were admitted to the ward were enrolled in this study. According to the principles of randomization and controlled trials in prospective clinical research, all subjects were randomly divided into two groups: the treatment group (32 cases) received the custom formula of the Jing ethnic group combined with moxibustion therapy, and the control group (32 cases) received ursodeoxycholic acid tablets. During the study, 4 cases were excluded due to patient loss to follow-up or withdrawal (3 cases from the treatment group and 1 case from the control group). Therefore, the actual number of cases included in the study was 60 (treatment group, n = 29; control group, n = 31).

2.3. Treatment Protocol

All patients received conventional medication and treatment based on their condition.

Control Group Protocol

On top of the "basic treatment protocol," patients in the control group were given ursodeoxycholic acid tablets (manufacturer: Sichuan Difite Pharmaceutical Co., Ltd.; batch number: National Drug Approval No. Z21021236). The dosage was 8 - 10 mg/kg per day, divided into two doses taken during breakfast and dinner, and continued for 6 months.

Treatment Group Protocol

In addition to the "basic treatment protocol," the treatment group received the Jing ethnic group's self-proposed formula combined with burning mugwort.

The composition and dosage of the Jing ethnic group's self-proposed formula are as follows: Chuan Bieshe 12 g, Cheqiancao 12 g, Huashi 18 g, Chuanmuxiang 12 g, Huangqin 18 g, Binglang 12 g, Wuyao 12 g, Tiankui zi 12 g, Qumai 12 g, Lanqian 12 g. The decoction was prepared at 200 ml per dose, three times daily, for a duration of 6 months.

Burning mugwort: Moxibustion was performed at the following acupoints: Heart Shu (HT15), Tai Xi (KI3), Neiguan (PC6), Waiguan (SJ5), Lieque (LU7), Tai Yuan (LU9), Zusanli (ST36), Qimen (LR14), and Guangming (GB37). Afterward, moxibustion was applied to Baihui (GV20) and Ashi points. Each session lasted 15 to 30 minutes.

Both groups were treated continuously for 6 months and then underwent reexamination and efficacy assessment, with a 4-month follow-up.

2.4. Observation Indicators

2.4.1. General Information

Before the start of the clinical trial, general information of all subjects was collected, including basic information such as name, gender, ethnicity, weight, age, occupation, height, and treatment-related information such as family history, past medical history, allergy history, and medication history.

2.4.2. Clinical Indicators

Blood samples (whole blood and serum) were collected from patients before and

after treatment and sent to the hospital laboratory for liver function tests. The main liver function indicators were alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total bilirubin (TBIL).

Therapeutic effect was evaluated based on the following criteria:

Clinical efficacy: disappearance of biliary colic and other symptoms, no stones present (effective);

Relief of biliary colic and other symptoms, residual stones present (improved);

No change in symptoms or signs (ineffective). The overall effective rate = effective rate + improved rate.

2.4.3. Safety Indicators

(1) Vital signs monitoring: blood pressure, heart rate, body temperature, and respiration were monitored.

(2) Blood, urine, and stool tests were conducted twice weekly during the clinical trial and follow-up periods, and liver and kidney function tests were conducted monthly.

2.4.4. Quality of Life Assessment

The Simplified Comfort Status Scale was used to assess the quality of life of both groups before and after treatment. This scale includes four dimensions: physiological, psychological, social-cultural, and environmental, with a total of 28 items, where higher scores indicate better comfort [5].

2.5. Safety Evaluation

This included observing adverse symptoms, signs, and laboratory test results during the clinical trial, recording the handling process and methods, and evaluating their safety.

2.6. Statistical Methods

Data were analyzed using SPSS 23.0 statistical software. Independent t-tests and chi-square tests were used to calculate intergroup differences, with $P < 0.05$ indicating statistical significance. PCA analysis of bile endogenous metabolites was performed using SIMCA software, importing relative peak area data of metabolites and observing sample distribution in the standardized PCA model. Bile endogenous metabolites were identified using the LECO-Fiehn Rtx5 database, with identification results considered reliable if the match score was greater than 800 (maximum 1000).

3. Results

3.1. Comparison of Baseline Characteristics between the Two Groups at Admission

There were no significant differences in gender, age, body mass index (BMI), disease duration, and TCM syndrome score between the two groups before treatment ($P > 0.05$), indicating comparability. See Table 1.

Table 1. Comparison of baseline characteristics at admission between the two groups ($\overline{x} \pm S$).

Parameter	Treatment Group (n = 29)	Control Group (n = 31)	t-value	P-value
Age (years)	51.15 ± 1.25	51.17 ± 1.18	0.99	0.32
Gender (male/female)	27(93.1%)/2(6.9%)	29(93.5%)/2(6.5%)	0.16	0.73
BMI (kg/m^2)	25.0 ± 0.89	25.7 ± 0.88	0.75	0.46
Disease Duration (months)	19.39 ± 4.52	19.87 ± 4.13	0.72	0.48
Syndrome Score (points)	13.35 ± 3.38	13.27 ± 3.24	0.68	0.50

3.2. Comparison of Liver Function Tests before and after Treatment between the Two Groups

Inter-group Comparison: Before treatment, there were no statistically significant differences in ALT, AST, and TBIL between the two groups (P > 0.05). After treatment, compared with the control group, the ALT, AST, and TBIL levels in the treatment group showed changes, but these differences were not statistically significant (P > 0.05). Intra-group Comparison: Compared with before treatment, the ALT, AST, and TBIL levels in the observation group significantly decreased after treatment, with statistically significant differences (P < 0.001). The same trend was observed in the control group, with statistically significant differences (P < 0.001). See Table 2.

Table 2. Comparison of liver function tests before and after treatment between the two groups ($\overline{x} \pm S$).

Group	N	ALT(U/L)		AST(U/L)		TBIL (umol/L)	
		Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Treatment Group	29	121.60 ± 25.30	44.63 ± 10.95★★	132.62 ± 9.56	48.46 ± 6.57★★	96.12 ± 8.97	44.48 ± 4.84★★
Control Group	31	123.81 ± 38.00	42.23 ± 20.74★★	133.18 ± 9.73	48.55 ± 6.90★★	86.46 ± 7.18	44.31. ± 4.42★★

Note: Compared with pre-treatment, ★★P < 0.001.

3.3. Efficacy Evaluation

The overall effective rate of the treatment group was higher than that of the control group (P < 0.05). See Table 3.

Table 3. Comparison of therapeutic effects between the two groups.

Group	Markedly Effective	Effective	Ineffective	Overall Effective Rate (%)
Treatment Group (n = 29)	14	11	4	86.21
Control Group (n = 31)	17	7	7	77.42

3.4. Safety Observation

During the treatment process and follow-up period, routine examinations were conducted for both groups, including electrocardiograms (ECGs), liver and kidney function tests, urinalysis, complete blood counts (CBCs), and stool tests. No significant abnormalities were observed in any of these tests.

For the recording and observation of adverse reactions, 2 cases (6.89%) of nausea and vomiting occurred in the treatment group, which were found to be caused by taking the medication on an empty stomach. These symptoms resolved after switching to post-meal administration. In the control group, 3 cases (9.68%) of abnormal bowel movements were reported, but these symptoms were tolerable for the patients. There were no statistically significant differences in adverse reactions between the two groups ($P > 0.05$).

3.5. Comparison of Quality of Life between the Two Groups

Inter-group Comparison:

Before treatment, there were no statistically significant differences in the quality of life scores for psychological, physiological, social-cultural, and environmental aspects between the two groups ($P > 0.05$). After treatment, compared with the control group, the scores for psychological, physiological, social-cultural, and environmental aspects in the treatment group increased significantly, with statistically significant differences ($P < 0.05$). Intra-group Comparison: Compared with before treatment, the scores for psychological, physiological, social-cultural, and environmental aspects in the observation group increased significantly after treatment, with statistically significant differences ($P < 0.001$). The same trend was observed in the control group, with statistically significant differences ($P < 0.001$). See Table 4.

Table 4. Comparison of quality of life scores before and after treatment between the two groups (Scores).

Group	N	Physiological		Psychological		Social-Cultural		Environmental	
		Pre	Post	Pre	Post	Pre	Post	Pre	Post
Treatment Group	29	11.43 ± 3.29	30.99 ± 2.31**	18.35 ± 3.24	34.96 ± 3.43**	17.13 ± 3.30	26.33 ± 2.27**	7.51 ± 1.28	15.12 ± 1.31**
Control Group	31	11.46 ± 3.26	26.48 ± 2.36**	18.37 ± 3.26	28.46 ± 3.40**	17.15 ± 3.26	22.62 ± 2.29**	7.50 ± 1.27	12.61 ± 1.29**

Note: Compared with before treatment, ** indicates a statistically significant difference ($P < 0.001$).

4. Discussion

4.1. Analysis of Baseline Data

In this study, the baseline data of all subjects, including gender, age, body mass index (BMI), and disease duration, were statistically analyzed. It was found that in both the treatment group and the control group, the incidence was higher among females (approximately 93.1% in the treatment group and 93.5% in the

control group), with the majority being middle-aged and elderly individuals. The BMI was generally in the range of 23 - 24 kg/m^2, and the disease duration was mostly 1 - 2 years. The reasons for this may include the higher work and life pressures faced by women in this age group, particularly those in menopause or perimenopause, leading to emotional distress and inappropriate diet, which can disrupt the smooth flow of qi and blood, eventually resulting in illness. Additionally, obesity is associated with conditions such as hyperlipidemia, which are risk factors for primary biliary cholangitis, suggesting that middle-aged and elderly women with a higher BMI are more prone to developing gallstones. Therefore, they should be prioritized for screening and intervention in clinical settings.

4.2. Analysis of Liver Function Test Results

Ursodeoxycholic acid (UDCA) is recognized as a standard treatment for gallstones after cholecystectomy, effectively removing harmful substances from the body, relieving symptoms, promoting the excretion of bile acids, and reducing the absorption of bile acids in the liver, thus protecting the stability of liver cell membranes and achieving therapeutic goals. However, with further research, it has been found that about 40% of patients treated with UDCA show poor response, and prolonged use of UDCA can still lead to liver function abnormalities and continued histological deterioration.

In this study, the inter-group comparison showed that before treatment, there were no statistically significant differences in ALT, AST, and TBIL levels between the two groups ($P > 0.05$). After treatment, compared with the control group, the ALT, AST, and TBIL levels in the treatment group showed changes, but these differences were not statistically significant ($P > 0.05$). In the intra-group comparison, compared with before treatment, the ALT, AST, and TBIL levels in the observation group significantly decreased after treatment, with statistically significant differences ($P < 0.001$). The same trend was observed in the control group, with statistically significant differences ($P < 0.001$). This suggests that the Jing ethnic group's self-proposed formula has anti-inflammatory and hepatoprotective effects, which may be due to the properties of herbs like Chuan Bieshe and Cheqiancao. Modern pharmacological studies have shown that these herbs have hepatoprotective and nephroprotective effects, antibacterial and antiviral properties, protect cell membranes, have anti-inflammatory and antioxidant functions, and enhance immunity.

4.3. Safety Analysis

During the treatment process and follow-up period, routine examinations were conducted for both groups, including electrocardiograms (ECGs), liver and kidney function tests, urinalysis, complete blood counts (CBCs), and stool tests. No significant abnormalities were observed in any of these tests. For the recording and observation of adverse reactions, 3 cases (4.17%) of nausea and vomiting occurred in the treatment group, which were found to be caused by taking the

medication on an empty stomach. These symptoms resolved after switching to post-meal administration. In the control group, 5 cases (7.14%) of abnormal bowel movements were reported, mainly characterized by increased bowel movements (2 - 3 times/day) and loose stools, but these symptoms were tolerable for the patients. There were no statistically significant differences in adverse reactions between the two groups ($P > 0.05$). This indicates that the Jing ethnic group's self-proposed formula combined with burning mugwort for treating post-cholecystectomy gallstones has minimal adverse reactions and high safety.

4.4. Comparison of Quality of Life during Follow-Up

With the continuous improvement in living standards, people are no longer solely focused on the improvement of physical symptoms but also on mental and physical health. Therefore, this study introduced the observation of quality of life. The results showed that before treatment, there were no statistically significant differences in the quality of life scores for psychological, physiological, social-cultural, and environmental aspects between the two groups ($P > 0.05$). After treatment, compared with the control group, the scores for psychological, physiological, social-cultural, and environmental aspects in the treatment group increased significantly, with statistically significant differences ($P < 0.05$). In the intra-group comparison, compared with before treatment, the scores for psychological, physiological, social-cultural, and environmental aspects in the observation group increased significantly after treatment, with statistically significant differences ($P < 0.001$). The same trend was observed in the control group, with statistically significant differences ($P < 0.001$). This suggests that the Jing ethnic group's self-proposed formula has a more pronounced effect on improving quality of life, which may be related to the lower incidence of stone recurrence observed in patients using the formula combined with burning mugwort. However, these results are still under statistical analysis and require further research.

5. Conclusions

The results of this study demonstrate that the custom formula of the Jing ethnic group combined with moxibustion therapy has significant clinical efficacy in treating patients who have undergone cholecystectomy for gallbladder stones. This treatment can effectively improve liver function indicators and enhance the quality of life of patients, with a high level of safety. These findings provide strong support for further exploration and promotion of Jing ethnic medicine in the treatment of post-cholecystectomy patients.

Despite the achievements of this study, several issues require further investigation. The current study has a relatively short follow-up period. Future research should conduct longer-term follow-ups to evaluate the long-term effects and potential side effects of the treatment involving the Jing ethnic group's custom formula combined with moxibustion. While the pharmacological effects of the custom formula have been preliminarily explored, the specific molecular mechanisms

and pathways of action need further research to better understand the treatment's effectiveness. Future multicenter studies should be conducted to validate the treatment effects under different regional and medical conditions, thereby enhancing the external validity of the research.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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