Abdominal Acupuncture for Gastrointestinal Function Recovery After Gynecologic Laparoscopic Surgery: A Randomized Clinical Trial

Guangdong Provincial Hospital of Chinese Medicine,

Guangzhou University of Chinese Medicine

Clinical sites:

Guangdong Provincial Hospital of Chinese Medicine

Data Management and Statistical Centers:

Guangzhou University of Chinese Medicine

Date of Document:

Dec 20, 2023

Confidentiality Statement

This document constitutes the intellectual property of the investigator. The information contained herein is strictly confidential and is provided solely for review by the sponsor, the investigator, potential investigators, the appropriate ethics committees, institutional review boards, and other governmental regulatory authorities. No disclosure of this information is permitted without the prior written authorization of the investigator who developed the protocol, except where disclosure is required for obtaining informed consent from potential study participants.

Table of Contents

1. Study Contact and Organization

1.1 Study Contacts

Principal Investigator for study,

Professor Yi Chen.

Guangdong Provincial Hospital of Chinese Medicine,111 Dade Road, Yuexiu District,

Guangzhou City, Guangdong Province, 510120, China

Email address: chen_yi2024@163.com.

1.2 Investigators

Yi Chen, Professor, supervisor and implementer of abdominal acupuncture scheme

Meng-yao Han, PhD, Experimental management and implementation, data collection, result evaluation, abdominal acupuncture plan design

Jia-xin Feng, MM, Implementation of experiment

Si-qi Yang, MM, Implementation of experiment

Wen-yuan Zhu, MM, Implementation of experiment

Rui-qi Zhao, PhD, Outcome evaluation and data collection

2. Study Design

2.1 Study Overview

To investigate the clinical efficacy of abdominal acupuncture in promoting gastrointestinal functional recovery following gynecologic laparoscopic hysterectomy, with the aim of reducing postoperative complications, enhancing postoperative quality of life, and providing a safe, convenient, and effective therapeutic strategy for clinical practice.

2.2 Background

Postoperative gastrointestinal dysfunction (POGD), commonly referred to as postoperative ileus (POI), is a well-recognized complication[1]。Contemporary studies indicate that POI typically persists for 3–5 days and is characterized by transient impairment of gastrointestinal tract (GIT) function following abdominal surgery. Its pathological manifestations primarily involve mucosal injury, disruption of barrier integrity, and impaired gastrointestinal motility. Clinically, patients may present with a wide spectrum of symptoms, including nausea, vomiting, abdominal pain, diarrhea, defecatory difficulties, and diminished or absent bowel sounds[2,3].

The pathogenesis of this condition is multifactorial, encompassing surgical techniques and manipulation, disturbances of internal homeostasis, alterations in blood perfusion, anesthetic and analgesic regimens, inflammatory responses, and neuroendocrine mechanisms. In addition, unique physiological characteristics in gynecologic patients, unfavorable psychological states, and surgical positioning further elevate the risk of POGD, underscoring the critical importance of prevention and management[4–11]。Current Western medical approaches comprise supportive measures (such as enemas and fluid replacement), pharmacotherapy (e.g., metoclopramide hydrochloride, mosapride), endoscopic interventions, gastrointestinal pacing devices, and surgical

procedures. However, drug-related adverse effects—including somnolence, agitation, and paradoxical gastrointestinal symptoms—remain prevalent, while invasive procedures carry inherent risks and may even exacerbate gastrointestinal dysfunction. In contrast, traditional Chinese medicine (TCM) has demonstrated encouraging outcomes in the management of POGD. Treatment modalities include oral herbal preparations, acupuncture, moxibustion, herbal enemas, and acupoint injections. These therapies, mainly employed as adjunctive interventions, offer the advantages of individualized pattern-based treatment, clear therapeutic efficacy, high safety, and relatively low cost. Nonetheless, challenges persist, such as reliance on practitioner experience, methodological limitations in clinical research, lack of standardized diagnostic criteria, incomplete elucidation of therapeutic mechanisms, and insufficient safety evaluation. At present, studies specifically targeting gastrointestinal dysfunction after gynecologic laparoscopy remain scarce, and greater attention should be given to the potential of TCM-based strategies to enhance patients' overall postoperative quality of life by leveraging their simplicity, accessibility, and cost-effectiveness.

Abdominal acupuncture, as both an inheritance and an innovation of traditional acupuncture, has been increasingly applied in clinical settings due to its broad indications, minimal discomfort, stable efficacy, and rapid onset of action[12–14]. It operates primarily through the stimulation of specific abdominal acupoints, thereby harmonizing congenital and acquired Qi to restore physiological balance. Among various approaches, Bo's abdominal acupuncture is most widely utilized. By capitalizing on the therapeutic advantages of abdominal acupoints, this technique

enhances gastrointestinal peristalsis, facilitates gastric emptying, accelerates the recovery of gastrointestinal hormones, and ultimately promotes restoration of gastrointestinal function. Compared with conventional Chinese and Western medical interventions, abdominal acupuncture offers fewer adverse effects, technical simplicity, reduced financial burden, and an ability to avoid the unpleasant sensations of soreness, numbness, distension, or pain associated with traditional body acupuncture, thus highlighting its unique clinical value. This study is therefore designed to investigate the impact of abdominal acupuncture on gastrointestinal functional recovery and long-term quality of life in patients undergoing gynecologic laparoscopic hysterectomy, with the ultimate aim of providing a safer, simpler, and more effective therapeutic modality for the management of postoperative gastrointestinal dysfunction.

2.3 Study Objective

To explore the clinical efficacy and safety of abdominal acupuncture therapy in promoting gastrointestinal function recovery after gynecological laparoscopic surgery.

2.4 Methodology

2.4.1 Trial Design

This study was conducted as a single-center, randomized, controlled clinical trial in China. Ethical approval was obtained from the Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine (Approval No. YF2023-435-01), and written informed consent was secured from all participants.

2.4.2 Patients

2.4.2.1 Patient Selection

Between December 2023 and December 2024, patients admitted to the Department of Gynecology at the Dade Road Branch of Guangdong Provincial Hospital of Chinese Medicine who underwent laparoscopic total hysterectomy, met the inclusion criteria, voluntarily agreed to participate, and signed the informed consent form provided by the investigators were enrolled in the study.

2.4.2.2 Diagnostic Criteria of Western Medicine

The diagnostic criteria for postoperative gastrointestinal dysfunction were established according to the *Expert consensus on prevention and treatment of postoperative gastrointestinal dysfunction*[15]:

(1) Nausea or vomiting;

(2) Inability to tolerate solid or semi-liquid food within 24 hours after surgery;

(3) Absence of flatus or defecation within 24 hours postoperatively;

(4) Abdominal distension;

(5) Radiological evidence of POI.

A diagnosis can be established if any two of the above five criteria are present.

2.4.2.3 Inclusion Criteria

(1) Female patients who underwent gynecologic laparoscopic total hysterectomy under general anesthesia;

(2) Age between 18 and 65 years;

(3) Surgical duration ranging from 0.5 to 4.5 hours;

(4) Anesthesia duration ranging from 1 to 5 hours;

(5) Willingness to receive acupuncture therapy without a history of adverse reactions such as needle syncope;

(6) Provision of signed informed consent.

2.4.2.4 Exclusion Criteria

(1) Patients with comorbid conditions that may affect gastrointestinal function, including intestinal obstruction or space-occupying lesions of the digestive system;

(2) Patients with severe systemic diseases, including hepatic or renal failure, cardiovascular or cerebrovascular disorders, infectious diseases such as HIV/AIDS, or severe psychiatric illness;

(3) Individuals with a history of adverse reactions to acupuncture, including needle syncope;

(4) Patients with local skin damage, rashes, or ulcers at the proposed acupoint sites;

(5) Patients concurrently enrolled in other clinical studies.

2.4.2.5 Dropout Criteria

(1) Patients who develop subcutaneous hematoma, skin damage, or rash at the primary acupoint sites during the trial, rendering acupuncture infeasible;

(2) Patients who fail to comply with the prescribed treatment protocol or have incomplete data.

2.4.2.6 Withdrawal Criteria

(1) Patients who voluntarily request withdrawal from the clinical trial;

(2) Patients lost to follow-up due to subjective or objective reasons.

2.4.2.7 Criteria for Termination of Participation

(1) Patients experiencing moderate to severe adverse reactions to acupuncture (e.g., needle syncope), or those unwilling to continue treatment;

(2) Patients who develop serious adverse events or complications that preclude continuation of the study;

(3) Patients who present with severe gastrointestinal dysfunction during the trial requiring alternative therapeutic interventions.

2.4.3 Trial Flow

2.4.3.1 Screening Visit

Patients will be screened according to inclusion and exclusion criteria, eligible patients will be required to provide written informed consent and enter the baseline visit. Randomization will be performed before baseline assessment.

2.4.3.2 Baseline Visit

The investigators provided participants with postoperative recovery education and collected data on demographic information, clinical characteristics, assessment scales, and routine examinations.

2.4.3.3 Abdominal acupuncture treatment

The initial abdominal acupuncture treatment was performed 4–6 hours after surgery, followed by one session daily from postoperative day 1 through day 4, yielding a total of five sessions per treatment course. Throughout the treatment period and thereafter, patients' clinical conditions were systematically recorded and evaluated, with concurrent monitoring of adverse events and concomitant medication use.

2.4.3.4 Aftertreatment Visit

On the 14th day following the final treatment, a quality-of-life assessment was conducted, and individualized recommendations were provided based on the patient's current condition.

2.4.3.5 Patient Withdrawals

Patients may leave the study at their own discretion, and the investigator may determine if the patients withdraw from the trial due to violation of the trial protocol or the occurrence of a serious adverse event. Figure l shows the flow diagram of the trial.

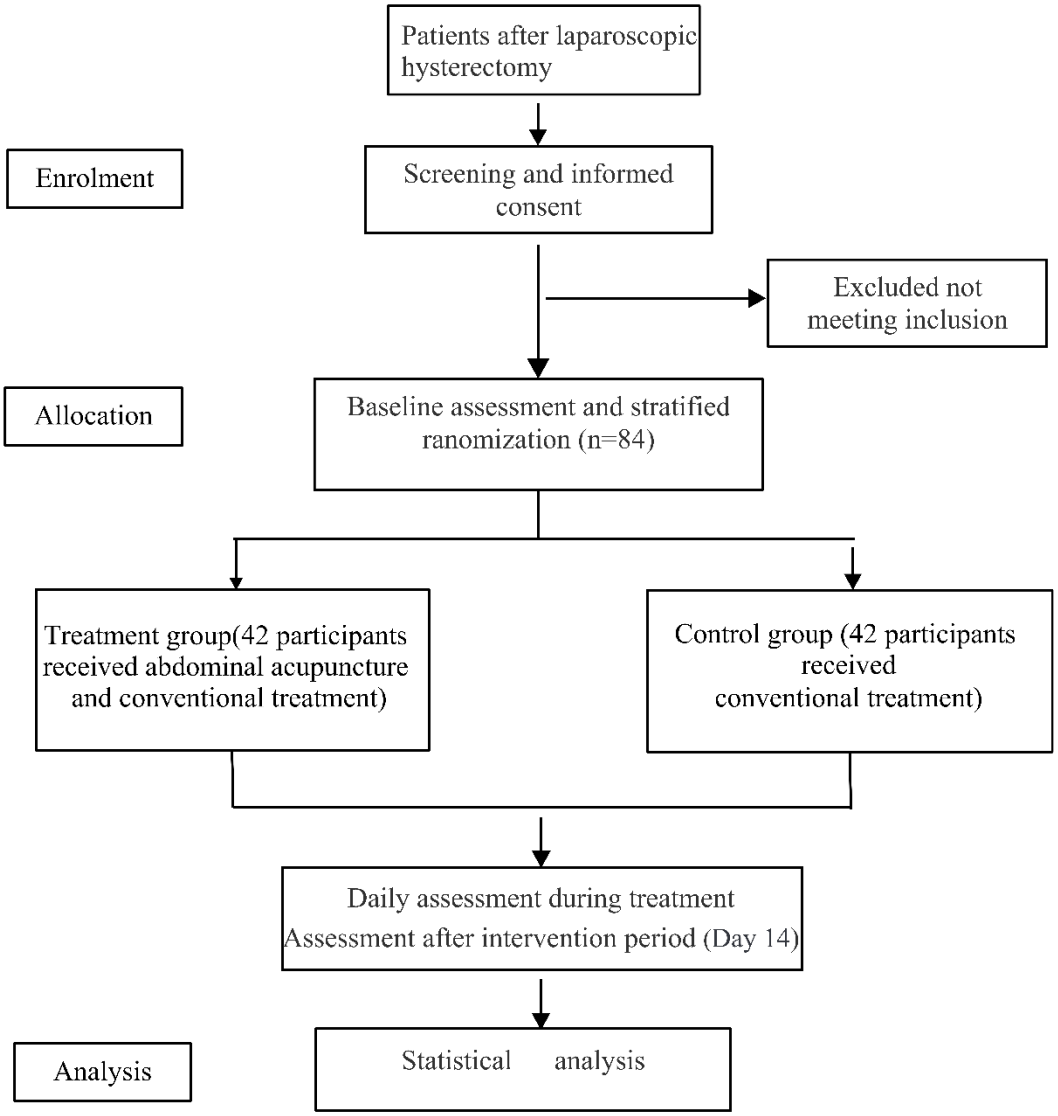


Figure 1 Flow chart

2.4.4 Sample Size

This study was designed as a randomized controlled trial, with the treatment group receiving abdominal acupuncture and the control group receiving conventional therapy. The primary outcome measure was the time to first postoperative flatus. Based on published literature, the mean ± standard deviation of the time to first flatus in the control group was 37.60 ± 4.11

hours. It was anticipated that abdominal acupuncture would reduce this time by approximately 8.1 hours. Assuming a two-sided $\alpha = 0.05$ and a statistical power of 90%, the sample size was

$$n = \frac{2\left(z_\alpha + z_\beta\right)^2 * \sigma^2}{\delta^2}$$

calculated using the standard formula:

The required sample size was determined to be 33 participants per group. With a 1:1 randomization ratio, both the abdominal acupuncture group and the control group required 33 participants each. Allowing for a potential 15% dropout or loss to follow-up, the minimum enrollment target was set at 38 participants per group, resulting in a total sample size of no fewer than 76 participants.

2.4.5 Randomization

Randomization was performed using SPSS version 26.0. To ensure reproducibility of the randomization process, a Random Number Seed was first applied, followed by the generation of random numbers using the UNIFORM(Max) function. These random numbers were then used to assign participants into groups, and a randomization table was created accordingly. During clinical implementation, participants were allocated sequentially according to their order of enrollment by matching them to the corresponding numbers in the randomization table, and the designated treatment protocol was applied. In this study, the intervention group received abdominal acupuncture, while the control group received standard care.

3. Interventions

3.1 Basic treatment

The standardized postoperative management protocol consists of the following components:

(1) Early oral intake: patients may commence a liquid diet 6 hours after surgery, advance to a semi-liquid diet following the passage of flatus, and transition to a regular diet after bowel movement.

(2) Early mobilization: patients are encouraged to turn in bed and initiate physical activity as early as 6 hours postoperatively, and to ambulate as soon as their condition permits.

(3) Adequate fluid supplementation.

(4) Maintenance of fluid–electrolyte and acid–base balance.

(5) Prophylactic antibiotic therapy to prevent infection.

(6) Early removal of urinary catheters, drainage tubes, and other indwelling devices.

(7) Postoperative analgesia: implementation of a multimodal pain management strategy.

(8) In critically ill patients, supplemental oxygen and continuous electrocardiographic monitoring are required.

Note: During routine management, any interventions potentially impairing gastrointestinal function—such as prokinetic agents, enemas, or traditional herbal therapies—are strictly contraindicated.

3.2 Abdominal acupuncture treatment

3.2.1 Instrument Selection

Acupuncture needles were supplied by HanYi (Changchun Aikang Medical Equipment Co., Ltd., Production License No. Jiyao Device Manufacturing Xu 20150075), with specifications of 1.5 cun (0.30 mm × 40 mm) and 2.0 cun (0.30 mm × 50 mm).

3.2.2 Acupoint Selection

Acupoint selection for abdominal acupuncture was based on Abdominal Acupuncture Therapy[14]:

Primary points: Zhongwan (CV12), Xiawan (CV10), Qihai (CV6), Guanyuan (CV4), and bilateral Daheng (SP15).

Secondary points: bilateral Huaroomen (ST24) and Wailling (ST26).

3.2.3 Point Localization

Point localization was standardized according to the *National Standard of the People's Republic of China (GB/T 12346-2021): Nomenclature and Location of Acupuncture Points*. The anatomical positions include: Zhongwan (CV12), Xiawan (CV10), Qihai (CV6), Guanyuan (CV4), Daheng (SP15), Huaroomen (ST24), and Wailling (ST26) (Figure 2).

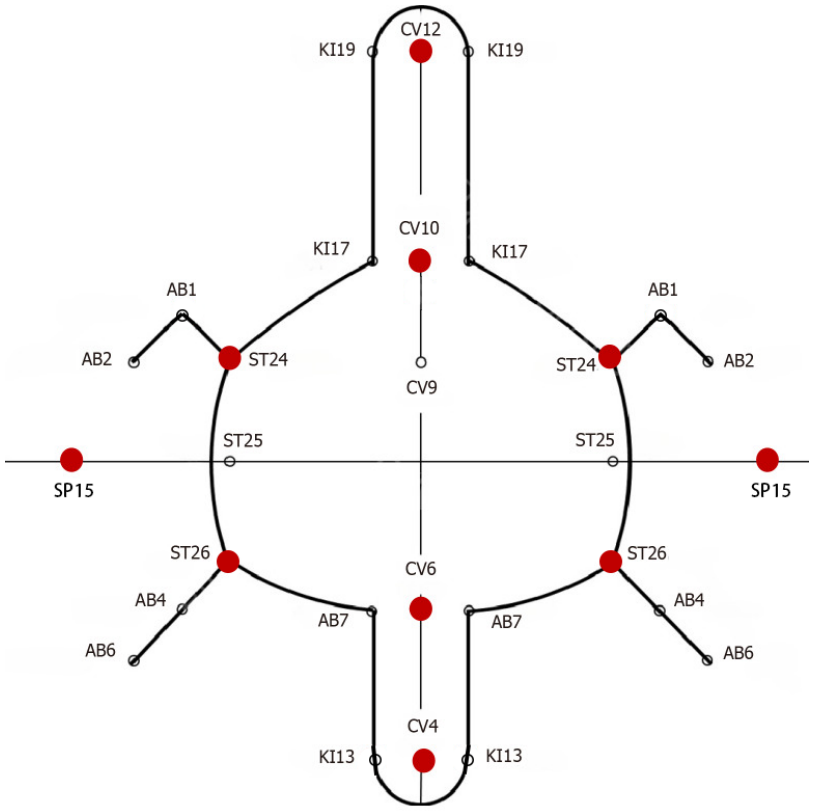


Figure 2 Abdominal divine turtle diagram and selected acupoints.

The acupoints marked with red dots indicate the sites selected for treatment in this study.

3.2.4 Procedure

Patients were placed in the supine position with the abdominal region fully exposed. Acupoint selection and needling techniques followed the standards outlined in *Abdominal Acupuncture Therapy*. For localization: the distance from the umbilicus (CV8) to Zhongting (CV16) was defined as 8 cun above the navel; from the umbilicus to the pubic symphysis was defined as 5 cun below the navel; and the transverse distance from the umbilicus to the lateral abdominal margin was defined as 6 cun. All acupoints were measured precisely with a straight ruler and proportionally located. After strict hand hygiene and aseptic preparation of the acupoint sites,

routine skin disinfection was performed. Disposable sterile acupuncture needles were inserted perpendicularly. Care was taken to ensure minimal or no pain during insertion. Needle manipulation employed gentle rotational techniques without lifting or thrusting. Primary acupoints were needled to the *Di level* (deep layer, at the base of subcutaneous fat or on the fascia, insertion depth approximately 1.0–1.5 cun), primarily for treating visceral disorders. Secondary acupoints were needled to the *Ren level* (intermediate layer, within the mid-fat tissue, insertion depth approximately 0.5–1.0 cun), predominantly for stimulating peripheral systems. Needle depth was adjusted according to body habitus, and patients were not required to experience the typical deqi sensations of soreness, numbness, distension, or heaviness.

Needles were retained for 30 minutes, during which an infrared therapeutic lamp was applied for concurrent warming therapy. After treatment, needles were withdrawn carefully, and sterile cotton was applied with gentle compression at the insertion sites to prevent bleeding.

Note*:* Needling was avoided directly at surgical incisions. In such cases, acupoints were either slightly displaced for adjusted localization or omitted as appropriate.

3.2.5 Treatment Course

The first abdominal acupuncture session was performed 4–6 hours postoperatively. From postoperative Day 1 through Day 4, one session was administered daily, with a total of five sessions constituting a complete treatment course. Clinical condition was carefully documented and evaluated throughout and following the treatment period.

4. Outcome Measurements

4.1 General Parameters

Collected variables included age, body mass index (BMI), intraoperative blood loss, operative duration, and length of postoperative hospitalization.

4.2 Safety Parameters

Laboratory and clinical assessments—including complete blood count, electrocardiography, and liver function tests—were performed preoperatively (upon admission), on the day of surgery before treatment, and on postoperative Day 5.

Adverse events related to acupuncture were monitored during treatment, such as syncope, needle breakage, bending or retention, palpitations, and excessive perspiration.

4.3 Efficacy Parameters

4.3.1 Clinical efficacy indices

- **Recovery of gastrointestinal motility** including time to first postoperative passage of flatus (recorded to the exact hour and minute), time to first postoperative bowel movement (recorded precisely), and restoration of bowel sounds.
- **Incidence of postoperative gastrointestinal dysfunction** related complications: including abdominal distension or pain, nausea, vomiting, and diarrhea.

All the above parameters were observed starting on the day of surgery and continued to be

recorded daily until the fifth postoperative day or discharge, whichever came first.

4.3.2 Laboratory Parameters

Inflammatory markers included C-reactive protein (CRP), serum interleukin-6 (IL-6), serum tumor necrosis factor-α (TNF-α), and the systemic immune-inflammation index [SII, SII = (platelet count × neutrophil count) / lymphocyte count].

Each parameter was assessed once preoperatively, on the day of surgery prior to treatment, and on postoperative Day 5.

4.3.3 Relevant Assessment Scales

- **Pain assessment**: The Visual analogue scale (VAS) was applied (Appendix 1). Abdominal pain scores were recorded before and after treatment on the day of surgery (5 days after surgery).
- **Gastrointestinal symptom assessment** Symptom scoring was based on the Perioperative Clinical Evaluation Standards for Gastrointestinal Motility (Guangdong Provincial Standard, Appendix 2). Scores were documented daily from the day of surgery (before treatment) through postoperative Days 1–5, according to observed gastrointestinal function.
- **Quality of life assessment** The Gastrointestinal Quality of Life Index (GIQLI) was employed (Appendix 3). Assessments were performed on the day of surgery prior to treatment, on postoperative Day 5, and again on Day 14 following the final treatment session.

5. Adverse Events and Management

If adverse reactions occurred during the trial—such as needle stagnation, syncope, breakage, hematoma, or infection—investigators promptly managed the event, ensured patient safety, reassured the participant with an explanation, and documented the details in the case report form.

6. Ethical Principle

This clinical trial was reviewed and approved by the Ethics Committee of Guangdong Provincial Hospital of Traditional Chinese Medicine prior to participant enrollment (Approval No. YF-2023-435-01). The study was conducted in full compliance with the principles of the Declaration of Helsinki.

7. Statistical Analysis

Data were organized and managed using Microsoft Excel to establish a primary database, which was subsequently converted into an SPSS 26.0 database for statistical analysis. The Shapiro–Wilk test was employed to assess the normality of continuous variables. According to data distribution, descriptive statistics were presented as mean ± standard deviation (SD) for normally distributed variables, and as median with interquartile range [P_{25}, P_{75}] for non-normally distributed variables. Between-group comparisons of normally distributed data were performed using independent-samples t tests, while within-group pre- and post-treatment comparisons were conducted using paired t tests. For non-normally distributed data, the Mann–Whitney U test was applied for between-group comparisons, and the Wilcoxon signed-rank test for within-group comparisons.

Categorical variables were expressed as frequencies (n) and percentages (%), with between-group comparisons analyzed using the chi-square test or Fisher's exact test, as appropriate. Repeated measures analysis of variance (ANOVA) was applied for comparisons across multiple time points between groups. All statistical analyses were two-tailed, and a P value of less than 0.05 was considered statistically significant.

8. References

1. Buchanan L, Tuma F. Postoperative Ileus. In: *StatPearls*. StatPearls Publishing; 2025. Accessed September 24, 2025. http://www.ncbi.nlm.nih.gov/books/NBK560780/

2. Boeckxstaens GE, de Jonge WJ. Neuroimmune mechanisms in postoperative ileus. *Gut*. 2009;58(9):1300-1311. doi:10.1136/gut.2008.169250

3. Yu S, Kerolus K, Jin Z, Bajrami S, Denoya P, Bergese SD. Multidisciplinary Postoperative Ileus Management: A Narrative Review. *Medicina (Kaunas)*. 2025;61(8):1344. doi:10.3390/medicina61081344

4. Mythen MGM. Postoperative gastrointestinal tract dysfunction: an overview of causes and management strategies. *Cleve Clin J Med*. 2009;76 Suppl 4:S66-71. doi:10.3949/ccjm.76.s4.11

5. Kehlet H. Surgical Stress Response: Does Endoscopic Surgery Confer an Advantage? *World J Surg*. 1999;23(8):801-807. doi:10.1007/s002689900583

6. Bragg D, El-Sharkawy AM, Psaltis E, Maxwell-Armstrong CA, Lobo DN. Postoperative ileus: Recent developments in pathophysiology and management. *Clinical Nutrition*. 2015;34(3):367-376. doi:10.1016/j.clnu.2015.01.016

7. Cailotto C, Costes LMM, van der Vliet J, et al. Neuroanatomical evidence demonstrating the existence of the vagal anti-inflammatory reflex in the intestine: The vagal anti-inflammatory reflex. *Neurogastroenterology & Motility*. 2012;24(2):191-e93. doi:10.1111/j.1365-2982.2011.01824.x

8. Schietroma M, Carlei F, Cecilia EM, et al. A Prospective Randomized Study of Systemic Inflammation and Immune Response After Laparoscopic Nissen Fundoplication Performed With Standard and Low-pressure Pneumoperitoneum. *Surgical Laparoscopy, Endoscopy & Percutaneous Techniques*. 2013;23(2):189-196. doi:10.1097/SLE.0b013e3182827e51

9. Mazzotta E, Villalobos-Hernandez EC, Fiorda-Diaz J, Harzman A, Christofi FL. Postoperative Ileus and Postoperative Gastrointestinal Tract Dysfunction: Pathogenic Mechanisms and Novel Treatment Strategies Beyond Colorectal Enhanced Recovery After Surgery Protocols. *Frontiers in Pharmacology*. 2020;11. Accessed September 28, 2023. https://www.frontiersin.org/articles/10.3389/fphar.2020.583422

10. Holte K, Kehlet H. Postoperative ileus: a preventable event. *BJS (British Journal of Surgery)*. 2000;87(11):1480-1493. doi:10.1046/j.1365-2168.2000.01595.x

11. Shariat Moharari R, Motalebi M, Najafi A, et al. Magnesium Can Decrease Postoperative Physiological Ileus and Postoperative Pain in Major non Laparoscopic Gastrointestinal Surgeries: A Randomized Controlled Trial. *Anesth Pain Med*. 2013;4(1):e12750. doi:10.5812/aapm.12750

12. Lv SG, Liu H, Du J, et al. [Effect of Bo's abdominal acupuncture as adjunctive therapy on rheumatoid arthritis and ESR, RF and CRP levels]. *Zhongguo Zhen Jiu*. 2021;41(9):999-1002. doi:10.13703/j.0255-2930.20200721-k0008

13. Zhan J, Ai Y, Zhan L, et al. Effect of abdominal acupuncture combined with routine rehabilitation training on shoulder-hand syndrome after stroke: A randomized controlled trial. *Integr Med Res*. 2022;11(2):100805. doi:10.1016/j.imr.2021.100805

14. Discussion on the mechanisms of BO's abdominal acupuncture therapy. *World Journal of Acupuncture - Moxibustion*. 2013;23(4):52-59. doi:10.1016/S1003-5257(14)60013-1

15. Li S, Liu K X, Deng X M, et al. Expert consensus on prevention and treatment of postoperative gastrointestinal dysfunction[J]. International Journal of Anesthesiology and Resuscitation, 2021, 42(11): 1133-42.

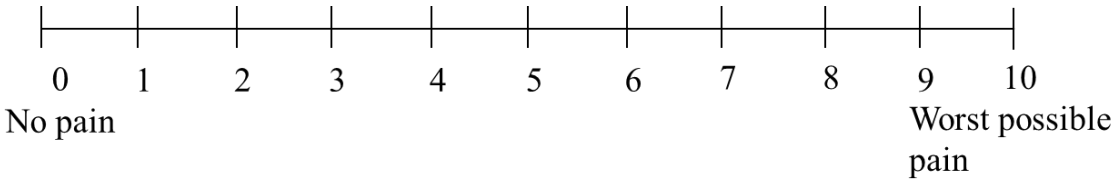
Appendix 1

Visual Analogue Scale (VAS)

□Not Assessed

□Assessed: Score:

□No pain (0) □Mild pain (1-3) □Moderate pain (4-6) □Severe pain (7-10)



Appendix 2

Gastrointestinal symptom rating scale

Observation items	Symptom grading
Anal exhaustion	☐ 15 points: Present ☐ 0 points: Absent Postoperative exhaust time:
Defecation	☐ 15 points: Present ☐ 0 points: Absent Postoperative defecation time:
Abdominal distension/pain	☐ 10 points: No distension or pain ☐5 points: Mild distension or discomfort ☐ 0 points: Intolerable distension or pain
Bowel Sounds	☐ 10 points: Normal ☐ 5 points: Reduced ☐ 0 points: Absent
Nausea	☐ 10 points: No nausea ☐ 5 points: No nausea at rest, mild nausea upon activity ☐ 0 points (i) Intermittent nausea at rest ☐ 0 points (ii) Persistent nausea at rest with aggravation during activity
Vomiting	☐ 10 points: None ☐ 5 points: 1–2 episodes/day ☐ 0 points (i) 3–5 episodes/day； 0 points (ii) ≥6 episodes/day
Diarrhea	☐ 10 points: None ☐ 5 points: 1–2 episodes/day ☐ 0 points (i) 3–5 episodes/day； 0 points (ii) ≥6 episodes/day
Surgical Incision	☐ 10 points: Well-approximated, without redness, swelling, or pain ☐ 0 points: Redness, swelling, heat, pain, fat liquefaction, or wound dehiscence
Body Temperature	℃ ☐ 10 points: ≤37.5℃ ☐ 5 points: 37.5–39℃ ☐ 0 points: ≥39℃ (Record highest temperature of the day)
7:00-9:00	Time: ___ h ___ min /☐10 points ☐5 points ☐0 points ☐Not recorded
11:00-13:00	Time: ___ h ___ min /☐10 points ☐5 points ☐0 points ☐Not recorded
17:00-19:00	Time: ___ h ___ min /☐10 points ☐5 points ☐0 points ☐Not recorded
Time of first tolerance to food	Semi-liquid diet ☐ None ☐ Yes: ___ h ___ min Solid diet ☐ None ☐ Yes: ___ h ___ min

Appendix 3

Gastrointestinal Quality of Life Index

Please mark √ in the box corresponding to the option that best applies to you, for example: ☑ E.

Scoring Criteria: A = 0 points, B = 1 point, C = 2 points, D = 3 points, E = 4 points.

The sum of all item scores constitutes the GIQLI total score.

Total Score:_____

1. During the past week, how often have you experienced abdominal pain (frequency and severity)?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

2. During the past week, how often have you experienced a sense of gastric (epigastric) fullness or distension?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

3. During the past week, how often have you experienced abdominal bloating (excessive gas in the abdomen)?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

4. During the past week, how frequently have you passed flatus?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

5. During the past week, how often have you experienced belching (release of gastric gas through the mouth)?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

6. During the past week, how often have you noticed bowel sounds (audible abdominal gurgling)?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

7. During the past week, how often have you experienced excessive bowel movements?

☐ A. Very pronounced ☐ B. Pronounced ☐ C. Moderate ☐ D. Slight ☐ E. No change

8. During the past week, how often have you lacked appetite during meals?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

9. During the past week, how often did you have to avoid certain preferred foods due to illness?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

10. During the past week, how well were you able to cope with and manage daily life stress?

☐ A. Very poor ☐ B. Poor ☐ C. Fair ☐ D. Good ☐ E. Excellent

11. During the past week, how often have you felt sad because of your illness?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

12. During the past week, how often have you felt tense or fearful because of your illness?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

13. During the past week, how often have you felt dissatisfied with your life?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

14. During the past week, how often have you felt discouraged because of your illness?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

15. During the past week, how often have you felt fatigued?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

16. During the past week, how often have you felt unwell?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

17. During the past week, how frequently have you experienced insomnia at night?

☐ A. Every night ☐ B. 5–6 nights per week ☐ C. 3–4 nights per week ☐ D. 1–2 nights per week £ E. Never

18. Do you feel that your appearance has changed due to illness (e.g., pallor, weight loss)?

☐ A. Very evident ☐ B. Evident ☐ C. Moderate ☐ D. Slight ☐ E. No change

19. To what extent has your physical strength declined?

☐ A. Very evident ☐ B. Evident ☐ C. Moderate ☐ D. Slight ☐ E. No change

20. To what extent has your endurance decreased?

☐ A. Very evident ☐ B. Evident ☐ C. Moderate ☐ D. Slight ☐ E. No change

21. To what extent has your overall health deteriorated?

☐ A. Very evident ☐ B. Evident ☐ C. Moderate ☐ D. Slight ☐ E. No change

22. During the past week, to what extent has your illness interfered with daily work (including household tasks or study)?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Not at all

23. During the past week, to what extent has your illness interfered with leisure activities?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Not at all

24. During the past week, how much distress have you experienced due to treatment?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Not at all

25. To what extent has your illness affected your relationships with family and friends?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

26. To what extent has your sexual life been restricted?

☐ A. Very evident ☐ B. Evident ☐ C. Moderate ☐ D. Slight ☐ E. No change

27. During the past week, how often have you experienced regurgitation (return of food or fluid from the stomach to the mouth)?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

28. During the past week, how often has your eating speed been restricted?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

29. During the past week, how often have you experienced difficulty swallowing food?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

30. During the past week, how often have you experienced a sudden urge to defecate?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

31. During the past week, how often have you experienced diarrhea?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

32. During the past week, how often have you experienced constipation?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

33. During the past week, how often have you experienced nausea?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

34. During the past week, how often have you noticed blood in your stool?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

35. During the past week, how often have you experienced heartburn (a burning sensation in the stomach or chest)?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never

36. During the past week, how often have you experienced fecal incontinence?

☐ A. All the time ☐ B. Most of the time ☐ C. Sometimes ☐ D. Occasionally ☐ E. Never