The Value of Bowel Sounds in Evaluating Postoperative Intestinal Function Recovery in Colorectal Cancer Patients: A Prospective Cohort Study

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Protocol Summary

Project Title	**The Value of Bowel Sounds in Evaluating Postoperative Intestinal Function Recovery in Colorectal Cancer Patients**
Study Objective	This study enrolls patients scheduled to undergo curative surgery for colorectal cancer. Bowel sounds will be assessed preoperatively and postoperatively. By comparing intraoperative variables, the incidence of perioperative complications, reoperation rates, and postoperative outcomes—including time to first flatus, resumption of oral intake, and occurrence of intestinal obstruction—this study aims to investigate the association between perioperative bowel sounds and postoperative recovery, and provide evidence-based support for the clinical application of bowel sound monitoring. Supplementary Definitions ***Perioperative Period*** Encompasses the entire process from preoperative preparation to 30 days postoperatively, including the preoperative, intraoperative, and postoperative phases. ***Postoperative Ileus (POI):*** Refers to a temporary impairment or cessation of intestinal motility following abdominal surgery, caused by neural, inflammatory, or other non-mechanical factors, resulting in ineffective passage of intestinal contents or intolerance to oral intake. ***Characteristics of Bowel Sounds*** Refers to the key acoustic features of bowel sounds, including frequency, duration, energy, spectral centroid (SC), spectral bandwidth (SBW), sub-band energy, short-time Fourier transform (STFT), number of effective bowel sounds per minute (number/min), energy of effective bowel sounds per minute (energy/min), and the ratio of effective bowel sounds to total monitoring time (EBS ratio).

Study Design	This study is designed as a prospective, single-center cohort trial.
Sample Size	172
Case Selection	*Inclusion Criteria* (1) Aged 18–80 years, with histopathologically confirmed colorectal adenocarcinoma (WHO 2022 classification).; (2) No restriction on prior neoadjuvant or other antitumor treatments (e.g., chemoradiotherapy, targeted therapy, immunotherapy); (3) Patient and/or family members are able to understand and voluntarily participate in the study, providing written informed consent; (4) Patient can communicate effectively with the investigators and is willing to comply with all study requirements, including follow-up and postoperative management.
	Exclusion Criteria (1) Significant organ dysfunction indicating inability to tolerate surgery or excessively high perioperative risk, including but not limited to: Severe cardiac dysfunction: NYHA class ≥ III; Severe hepatic dysfunction: MELD score > 12; Severe renal dysfunction: eGFR < 30 mL/(min·1.73 m²) (CKD stage 4–5) or end-stage renal disease requiring dialysis; Severe pulmonary dysfunction: resting PaO_2 < 60 mmHg on room air or presence of other respiratory failure signs (e.g., requiring long-term oxygen therapy or mechanical ventilation). (2) Participation in another clinical study within 4 weeks prior to enrollment or ongoing participation. (3) Emergency surgery required due to intestinal obstruction, perforation, or other acute conditions after admission.

	(4) Severe psychiatric disorders preventing cooperation with perioperative management or follow-up. (5) Pregnant or breastfeeding women. (6) Other clinical or laboratory abnormalities judged by the investigator as unsuitable for study participation. *Withdrawal Criteria* 1) Patients who voluntarily request to withdraw from the study after enrollment. 2) Patients with concurrent non-tumor conditions that prevent continuation of the treatment protocol. 3) Patients unable to complete the planned study procedures for any reason after enrollment.
Intervention Measures	Undergoing Curative Surgery for Colorectal Cancer
Outcome Measures	**Primary Outcome Measure:** Occurrence of postoperative ileus (POI) in patients. Secondary Outcome Measures： 1) **Perioperative Complications within 30 Days Postoperatively:** Incidence of complications such as anastomotic leak/dehiscence, anastomotic bleeding, ischemic bowel necrosis, intra-abdominal infection, intra-abdominal hemorrhage, early postoperative intestinal obstruction, postoperative ileus, pulmonary infection, and other complications, as well as any reoperation resulting from these events. The severity of complications will be graded using the Classification of Surgical Complications.； 2) **Intraoperative Parameters:** Surgical duration, intraoperative blood loss, surgical approach, and intraoperative complications.；

	3) **Bowel Sound Characteristics:** Assessment of bowel sound features over 5-minute recordings at 2 h, 6 h, 12 h, 24 h, 36 h, 48 h, 60 h, 72 h, 84 h, and 96 h postoperatively. 4) **Postoperative Recovery Indicators:** Postoperative pain scores (VAS) on days 1–3, time to first flatus, time to first intake of liquid food, time to first defecation, length of postoperative hospital stay, and total hospitalization costs.
Statistical Analysis	All statistical analyses will be performed using R software (version 4.2.2, http://www.R-project.org, The R Foundation) and SPSS. Continuous variables will be expressed as mean ± standard deviation (SD), while categorical variables will be presented as frequency and percentage (%). Group comparisons will be conducted using t-tests, chi-square tests, or Fisher's exact tests, depending on the type and distribution of the data. To explore the relationship between bowel sound characteristics and postoperative outcomes, univariate and multivariate logistic regression and linear regression models will be applied to control for potential confounding factors. The predictive performance of the models will be evaluated using receiver operating characteristic (ROC) curves and the area under the curve (AUC). All statistical tests will be two-sided, and a p-value < 0.05 will be considered statistically significant.
Study Duration	From October 2025 to July 2026

1. Research Background

Colorectal cancer (CRC) is the third most common malignancy worldwide and the second leading cause of cancer-related mortality. In recent years, both the incidence and mortality of CRC in China have shown a significant upward trend. With population aging and lifestyle changes, the disease is increasingly affecting younger individuals, with the proportion of patients under 40 years of age steadily rising. Treatment strategies vary according to disease stage; however, for most cases amenable to primary resection, surgical intervention remains the cornerstone of therapy.

With the widespread implementation of enhanced recovery after surgery (ERAS) protocols, postoperative rehabilitation has been substantially improved through optimization of preoperative, intraoperative, and postoperative management strategies, such as shortened preoperative fasting, the use of laparoscopic techniques, and early postoperative oral intake, thereby facilitating accelerated recovery and earlier discharge. Following curative surgery for colorectal cancer, patients commonly experience reduced or transiently absent intestinal motility due to surgical manipulation and the effects of anesthesia, with gradual return to normal function over several days. Early postoperative feeding has been shown to promote the recovery of gastrointestinal function.

However, a subset of patients may exhibit delayed recovery of bowel function, characterized by diminished bowel sound activity, prolonged time to first flatus, and often accompanied by abdominal distension. Postoperative ileus (POI) is one of the most common causes of delayed postoperative gastrointestinal recovery and typically presents as transient suppression of gastrointestinal motility. When the duration exceeds the expected physiological range, potential pathological conditions, such as early postoperative small bowel obstruction (EPSBO), should be considered. In such circumstances, oral intake may exacerbate ileus and even precipitate

intestinal obstruction. Therefore, timely differentiation and accurate diagnosis of the patient's postoperative gastrointestinal status are of critical importance.

Abdominal auscultation, as a noninvasive diagnostic technique, has a history spanning several centuries. In 1905, Cannon was the first to report systematic investigations of abdominal auscultation, proposing that regular bowel sounds are generated by intestinal peristalsis. Subsequent studies have demonstrated that bowel sounds vary by anatomical location: sounds originating from the small intestine are typically high-pitched, high-amplitude, and frequent, whereas colonic sounds are lower in frequency, weaker in amplitude, and less frequent. Postoperatively, the recovery of gastrointestinal motility differs among segments, with the small intestine recovering first, followed by the stomach and the colon.

Abdominal auscultation has been widely used as an adjunctive tool in the evaluation of conditions such as intestinal obstruction and ileus, owing to its immediacy and convenience, and is commonly applied in patients with delayed postoperative gastrointestinal recovery. However, the reliability of auscultation-based assessment remains controversial due to the inherent subjectivity in clinicians' descriptions of bowel sounds. A prospective study by Felder et al. demonstrated low sensitivity (22%–32%) of manual auscultation in distinguishing healthy from diseased individuals, along with low positive predictive values (23%–44%). Similarly, Thomas et al. conducted a prospective study examining the relationship between auscultated bowel sounds and postoperative oral tolerance and flatus, finding no significant correlation between bowel sounds and postoperative abdominal distension, flatus, defecation, or tolerance of oral intake.

Therefore, bowel sound monitoring devices, which objectively detect and analyze bowel sounds, have emerged as important adjunctive tools for postoperative bowel sound assessment. These systems enable precise quantification of acoustic features such as frequency, amplitude, and energy. Currently, both domestic and

international researchers have begun to explore the use of bowel sound monitoring systems in the diagnosis and management of gastrointestinal disorders. Preliminary small-sample studies suggest that such systems hold substantial clinical potential in the precision management of intestinal obstruction, the diagnosis of functional gastrointestinal disorders, and the prediction of acute gastrointestinal injury in critically ill patients.

Nevertheless, progress in bowel sound monitoring technology has been relatively slow, primarily due to several challenges: (1) the weak and highly stochastic nature of bowel sound signals; (2) substantial interference from environmental and internal physiological noise; and (3) dynamic fluctuations in bowel sounds related to individual physiological states, with marked interindividual variability. To address these challenges, our center has independently developed a highly intelligent, digital bowel sound monitoring system based on a distributed, multichannel, real-time acquisition framework. This system enables simultaneous collection of bowel sound signals from different abdominal regions, while concurrently recording heart sounds and ambient noise as reference signals for noise suppression, followed by centralized classification and recognition of bowel sounds. Through this approach, bowel sound signals can be accurately extracted in complex acoustic environments, significantly improving the accuracy of feature detection, parameter computation, and classification algorithms, while also assisting clinicians with synchronized auscultation.

At present, our center has conducted multiple iterations of the bowel sound monitoring device, completing optimized denoising and detection algorithms that enable accurate extraction of bowel sound signals in complex environments. Furthermore, we have implemented a bowel sound recognition algorithm that integrates an attention-based Broadcasting Residual Neural Network (Broadcasting ResNet) with a Dual-Path Recurrent Neural Network (Dual-Path RNN). This

algorithm is capable of extracting time–frequency features of bowel sounds, thereby supporting the auxiliary diagnosis of various intestinal disorders.

In summary, there is an urgent need for a high-quality, prospective clinical trial to investigate the predictive value of bowel sounds for postoperative gastrointestinal functional recovery using a digital bowel sound monitoring system. Such a study would facilitate the clinical translation of this technology and assist clinicians in the diagnosis and intervention of postoperative intestinal obstruction.

2. Study Objectives

Primary Objective: To evaluate the clinical value of a bowel sound monitoring device in predicting the occurrence of postoperative ileus (POI) in patients undergoing curative surgery for colorectal cancer, and to validate its effectiveness as an adjunctive diagnostic and predictive tool.

Secondary Objective:To investigate the association between perioperative bowel sound characteristics and postoperative recovery following curative surgery for colorectal cancer.

2.1. Study Design

This study is designed as a prospective, single-center cohort study. A total of 172 patients are planned to be enrolled.

2.2. Study Procedures

2.2.1. General Information

Based on the predefined eligibility criteria (including inclusion and exclusion criteria), patients scheduled to undergo curative surgery for colorectal cancer will be selected as study participants. All patients who meet the inclusion criteria and provide written informed consent will be enrolled in this study.

2.3. Methods

2.3.1 Perioperative Period:

The perioperative period is defined as the interval from the initiation of preoperative preparation to 30 days after surgery, encompassing the preoperative, intraoperative, and postoperative phases.

2.3.2. Postoperative Ileus (POI):

Postoperative ileus refers to a transient reduction or cessation of intestinal motility following abdominal surgery, caused by neural, inflammatory, or other non-mechanical factors, resulting in ineffective passage of intestinal contents or intolerance to oral intake.

2.3.3. Characteristics of Bowel Sounds:

Bowel sound characteristics denote the key acoustic features of bowel sounds, including frequency, duration, energy, spectral centroid (SC), spectral bandwidth (SBW), sub-band energy, short-time Fourier transform (STFT), number of effective bowel sounds per minute (number/min), energy of effective bowel sounds per minute (energy/min), and the ratio of effective bowel sounds to total monitoring time (EBS ratio).

2.4. Surgical Procedure：

All patients will undergo laparoscopic complete mesocolic excision (CME). In addition to resection of the primary tumor, proximal and distal resection margins of at least 5 cm will be obtained. To maximize lymph node harvest, the feeding vessels will be ligated at their origin. The specific surgical approach will be determined based on tumor location, disease stage, and intraoperative findings, with the aim of ensuring oncologic radicality while preserving intestinal blood supply and function to the greatest extent possible.

2.4.1. Right hemicolectomy

For lesions located in the cecum or ascending colon, right hemicolectomy with ileocolic anastomosis is performed. The resection margins include approximately 10 cm proximal to the ileocecal valve and the proximal transverse colon.

First, the ileocolic artery is identified and ligated at a high level adjacent to the duodenum, with careful dissection and protection of the duodenum. Subsequently, the mesentery is dissected along the retroperitoneal plane to identify the right branches of the middle colic artery and vein, which are ligated at their origins. The mesocolon and marginal vessels of the transverse colon are then divided, followed by division of the mesentery near the predetermined transection point of the terminal ileum. The lesser omentum is opened, the transverse colon is mobilized, and mobilization of the hepatic flexure is completed. Finally, the diseased bowel segment is resected, and anastomosis is performed according to the surgeon's preference.

For lesions involving the hepatic flexure, an extended right hemicolectomy may be required depending on tumor location. The anatomical resection margins for extended right hemicolectomy range from the terminal ileum to the distal transverse colon. The operative steps are similar to those of standard right hemicolectomy, with ligation of the middle colic artery, complete opening of the lesser omentum, and mobilization of the splenic flexure to create a tension-free anastomosis. The colon and mesentery are resected according to the delineated vascular supply.

2.4.2. Left hemicolectomy

For tumors located at the splenic flexure and proximal descending colon, left hemicolectomy with transverse colon–sigmoid colon anastomosis is performed. The extent of mesenteric resection includes the bowel from the distal transverse colon to the descending colon.

The inferior mesenteric vein is ligated near the ligament of Treitz. Depending on the extent of the lesion, a decision is made whether to preserve the sigmoid colon or to ligate the left colic artery at its origin. Complete mobilization of the splenic flexure is performed, and the proximal and distal transection lines are determined by the vascular supply of the resected bowel and the required oncologic margins. In procedures preserving the superior rectal artery, high ligation of the left colic artery

and the left branch of the middle colic artery is required to ensure adequate blood supply to the remaining sigmoid colon, while achieving clearance of the primary tumor and regional lymph nodes within 10 cm of the tumor-bearing colon and mesentery.

For procedures requiring high ligation at the origin of the inferior mesenteric artery, particular attention is paid to protecting the left ureter during ligation, and additional ligation of the inferior mesenteric vein may be performed if necessary. The resection range includes the entire left colon from the distal transverse colon to the upper rectum, and reconstruction is typically achieved by transverse colon–rectal anastomosis.

2.4.3. Rectectomy

For rectal lesions, total mesorectal excision (TME) with colorectal anastomosis is performed. The resection range includes the involved segment of the rectum and the proximal sigmoid colon.

First, the sigmoid colon is placed under traction to facilitate identification of the origin of the inferior mesenteric artery (IMA). The mesentery is approached from medial to lateral, with incision of the peritoneal envelope at the root of the rectosigmoid mesentery and extension toward the IMA origin. Dissection is then carried out laterally along the loose connective tissue plane between the undersurface of the sigmoid mesocolon and the retroperitoneum, allowing identification of the left ureter and the left gonadal vein. The inferior mesenteric vessels are ligated at their origin, and dissection is continued beneath the sigmoid and left mesocolon.

Subsequently, the splenic flexure is mobilized from the transverse colon side and the left paracolic gutter, after which attention is turned to the rectal dissection. Following the principles of total mesorectal excision, the loose connective tissue fibers are dissected circumferentially down to the level of the coccygeal tip, the Waldeyer’s fascia is divided, and dissection proceeds until the upper portion of the

levator ani muscles is reached. Bilateral dissection is carried out in a similar manner down to the pelvic floor. Careful anterior dissection is performed along the plane between the rectum and the seminal vesicles/prostate in male patients or the vagina in female patients.

The rectum is then elevated out of the pelvis and shifted to the left, and a 45-mm linear stapler is used to transect the rectum. After rectal transection, a low colorectal anastomosis is constructed using a stapling device, and the integrity of the anastomosis is assessed. Depending on the patient's clinical condition, a diverting loop ileostomy may be considered.

2.5. Observation Indicators

2.5.1. Baseline Characteristics:

Including sex, age, body mass index (BMI), medical history, surgical history, tumor characteristics (primary tumor location and TNM stage), ASA score, history of neoadjuvant therapy, as well as the number, mean energy, and mean duration of bowel sounds recorded during a 5-minute preoperative assessment.

2.5.2. Intraoperative Parameters:

Including operative time, intraoperative blood loss, surgical approach, and intraoperative complications.;

2.5.3. Postoperative Recovery Indicators:

Postoperative pain scores (VAS) on postoperative days 1–3, time to first flatus, time to first intake of liquid diet, time to first defecation, length of postoperative hospital stay, and total hospitalization costs;

2.5.4. Characteristics of Intestinal Obstruction:

Bowel Sound Features:Five-minute bowel sound recordings obtained at 2 h, 6 h, 12 h, 24 h, 36 h, 48 h, 60 h, 72 h, 84 h, and 96 h postoperatively.

2.5.5. Perioperative Complications and Reoperation Rate:

The incidence of complications within 30 days postoperatively, including

anastomotic leak/dehiscence, anastomotic bleeding, ischemic bowel necrosis, intra-abdominal infection, intra-abdominal hemorrhage, early postoperative intestinal obstruction, postoperative ileus, pulmonary infection, and other complications, as well as any reoperations resulting from these events. The severity of complications will be graded using the Classification of Surgical Complications.

2.6. Statistical Analysis

All statistical analyses will be conducted using R software (version 4.2.2, http://www.R-project.org, The R Foundation) and SPSS. Continuous variables will be expressed as mean ± standard deviation (SD), while categorical variables will be presented as frequencies and percentages (%). Between-group comparisons will be performed using the t-test, chi-square test, or Fisher's exact test, as appropriate based on data type and distribution. To investigate the association between bowel sound characteristics and postoperative recovery, univariate and multivariate logistic regression and linear regression models will be applied to control for potential confounding factors. The diagnostic performance of the predictive models will be evaluated using receiver operating characteristic (ROC) curves and the area under the curve (AUC). All statistical tests will be two-sided, and a p-value < 0.05 will be considered statistically significant.

3. **Case Selection**

3.1. Inclusion Criteria

(1) Aged 18 - 80 years, with histopathologically confirmed colorectal adenocarcinoma (WHO 2022 classification).;

(2) No restriction on prior neoadjuvant or other antitumor treatments (e.g., chemoradiotherapy, targeted therapy, immunotherapy);

(3) Patient and/or family members are able to understand and voluntarily participate in the study, providing written informed consent;

(4) Patient can communicate effectively with the investigators and is willing to comply with all study requirements, including follow-up and postoperative management.

3.2. Exclusion Criteria

(1) Significant organ dysfunction indicating inability to tolerate surgery or excessively high perioperative risk, including but not limited to:

Severe cardiac dysfunction: NYHA class ⩾ III;

Severe hepatic dysfunction: MELD score > 12;

Severe renal dysfunction: eGFR < 30 mL/(min·1.73 m²) (CKD stage 4–5) or end-stage renal disease requiring dialysis;

Severe pulmonary dysfunction: resting PaO_2 < 60 mmHg on room air or presence of other respiratory failure signs (e.g., requiring long-term oxygen therapy or mechanical ventilation).

(2) Participation in another clinical study within 4 weeks prior to enrollment or ongoing participation.

(3) Emergency surgery required due to intestinal obstruction, perforation, or other acute conditions after admission.

(4) Severe psychiatric disorders preventing cooperation with perioperative management or follow-up.

(5) Pregnant or breastfeeding women.

(6) Other clinical or laboratory abnormalities judged by the investigator as unsuitable for study participation.

3.3. Withdrawal Criteria

1) Patients who voluntarily request to withdraw from the study after enrollment.

2) Patients with concurrent non-tumor conditions that prevent continuation of the treatment protocol.

3) Patients unable to complete the planned study procedures for any reason after

enrollment.

4. Research Methods and Technical Framework

4.1. Sample Size Calculation

As the primary aim of this study is to investigate the relationship between bowel sounds and postoperative ileus (POI), the incidence of POI is used as the basis for sample size estimation. Our center has previously conducted a small-sample retrospective study that included 34 patients undergoing curative colorectal cancer surgery, all of whom underwent postoperative bowel sound assessment. Among these patients, 4 developed postoperative ileus, while the remaining patients experienced normal recovery of bowel function.

Based on a case allocation ratio of 1:8, a two-sided significance level of $\alpha = 0.05$, and a statistical power $(1-\beta)$ of 80%, a non-inferiority study design was adopted. Sample size calculation for a two-sample t-test was performed using PASS version 15.0. After accounting for an anticipated dropout rate of 10%, the total sample size was determined to be 116 patients. The sample size may be appropriately increased if deemed necessary upon further methodological justification.

4.2. Study Implementation

4.2.1. Blinding

To minimize information bias, the assessors responsible for the diagnosis and management of postoperative ileus are independent from the investigators conducting this study. Data analysis will be performed using anonymized group codes to ensure blinded analysis.

4.2.2. Preoperative Evaluation and Management

All patients with colorectal cancer are required to undergo multidisciplinary

team (MDT) discussion. Treatment strategies will be formulated in accordance with the *2024 Chinese Society of Clinical Oncology (CSCO) Guidelines for the Diagnosis and Treatment of Colorectal Cancer*. For patients receiving neoadjuvant therapy, surgery will be scheduled 6–8 weeks after completion of the final cycle of neoadjuvant treatment. Preoperatively, all patients will complete routine laboratory tests and imaging evaluations.

4.2.3. Monitoring Procedures

- On the day before surgery, bowel sounds will be recorded for 5 minutes using a highly intelligent digital bowel sound monitoring device, with simultaneous manual auscultation. General medical history will be obtained, and relevant precautions will be explained to the participants.
- On the day of surgery, the research team will implement the planned anesthesia and surgical procedures. Standard intraoperative monitoring of vital signs will be performed, and intraoperative parameters will be recorded.
- At 2 h, 6 h, 12 h, 24 h, 36 h, 48 h, 60 h, 72 h, 84 h, and 96 h postoperatively, bowel sounds will be collected using the digital bowel sound monitoring device. Postoperative outcomes, including time to first defecation, time to first flatus, and pain scores on the visual analog scale (VAS), will also be recorded.

4.2.4 Discharge Criteria

Patients may be considered for discharge when the following criteria are met:

- Stable general condition with recovery of normal diet and bowel function;
- Normal body temperature with no signs of fever;
- No abnormal findings on abdominal physical examination;
- Relevant laboratory parameters returned to, or approaching, normal ranges.

5. Observation Items and Assessment Time Points

5.1. Primary Outcome Measure: Occurrence of postoperative ileus (POI) after

surgery.

5.2. Secondary Outcome Measures:

5.2.1 Postoperative Complications within 30 Days:

Incidence of complications such as anastomotic leak/dehiscence, anastomotic bleeding, ischemic bowel necrosis, intra-abdominal infection, intra-abdominal hemorrhage, early postoperative intestinal obstruction, postoperative ileus, pulmonary infection, and other complications, as well as reoperations resulting from these events. The severity of complications will be graded using the Classification of Surgical Complications.

5.2.2. Intraoperative Parameters:

Operative time, intraoperative blood loss, surgical approach, and intraoperative complications.

5.2.3. Bowel Sound Characteristics:

Five-minute bowel sound recordings obtained at 2 h, 6 h, 12 h, 24 h, 36 h, 48 h, 60 h, 72 h, 84 h, and 96 h postoperatively, with corresponding acoustic feature analyses.

5.2.4. Postoperative Recovery Indicators:

Postoperative pain scores (VAS) on postoperative days 1–3, time to first flatus, time to first intake of a liquid diet, time to first defecation, length of postoperative hospital stay, and total hospitalization costs.

5.3. Data Collection

All study-related data will be recorded in a timely, accurate, and detailed manner in the Case Report Form (CRF). Investigators are required to enter information strictly in accordance with the study protocol. Monitors appointed by the study center will review the completeness and accuracy of the CRFs and provide guidance for any necessary corrections or additions. Completed CRFs will be submitted by regional monitors for data processing. One copy will be retained at the

study center, while another will be kept as part of the monitor's working documentation. All data will be entered into the database by professional medical data managers. Each participating site must designate a qualified individual responsible for completing the CRFs; a case will be considered valid only after signature confirmation by the site principal investigator. The coordinating center, together with collaborating institutions, will regularly verify and collect CRFs. All data entered into the database will undergo systematic validation to ensure complete consistency with the source documents, and all calculated results must be traceable. After text data entry, corrections may only be made through manual verification. Once data entry is completed, the database will be locked, and any subsequent modifications will require joint written approval from the clinical research leader, the study statistician, and the data manager. The research team is currently refining an internet-based electronic data capture and management system (ResMan system, URL: http://www.medresman.org.cn/login.aspx; currently under review). In the later phase of the study, this system may be used to record and transmit all clinical data directly to a central database, thereby reducing paper-based data entry, lowering costs, and minimizing transcription errors.

6. Criteria for Efficacy Evaluation

All patients who are successfully enrolled and complete at least one bowel sound data acquisition will be included in the Full Analysis Set (FAS) for analysis of the primary outcome. Patients who strictly adhere to the study protocol and complete all scheduled assessments will be included in the Per-Protocol Set (PPS) for sensitivity analyses to verify the robustness and consistency of the study findings. Although this study is observational in design, the definition of analysis populations draws on the intention-to-treat (ITT) and per-protocol (PP) analytical frameworks

commonly used in interventional studies to clarify data handling strategies.

Missing data will be addressed using the conditional forward likelihood optimization (CFLO) method or multiple imputation, with the aim of minimizing potential bias.

After enrollment of 86 eligible patients, an interim analysis will be conducted and organized by the coordinating center, with results communicated to all participating sites. The interim analysis will include: (1) overall enrollment progress and projected study completion timeline; (2) distribution of cases with protocol adherence and deviations; (3) assessment of data completeness, accuracy, and timeliness across centers; and (4) preliminary analysis of the primary outcome measure. The coordinating office will compile the statistical results and present them at regular coordination meetings. Based on the interim analysis, the study protocol may be modified if necessary, or early termination of the study may be considered following appropriate scientific and ethical evaluation.

7. Adverse Event Monitoring

1. Definition of Adverse Events

An adverse event (AE) is any unfavorable health condition or clinical abnormality occurring in a participant during the study period, which may be related to the treatment of intestinal obstruction but not necessarily directly caused by the bowel sound monitoring device. Specific examples include, but are not limited to:

1) AEs occurring during bowel sound monitoring (e.g., local discomfort, allergic reactions, anxiety).
2) Complications related to intestinal obstruction treatment (e.g., severe infection, anastomotic leakage, ischemic bowel necrosis).
3) Adverse reactions due to underlying diseases, postoperative treatments, or other medications.

4) Post-recovery functional impairments or decreased quality of life.

2. Classification of Adverse Events

1) Mild AEs: Symptoms are minor, do not affect daily activities, and do not require special treatment;

2) Moderate AEs: Symptoms have a noticeable impact, may require symptomatic treatment or short-term intervention, and may limit certain activities without necessitating hospitalization;

3) Severe AEs: Symptoms seriously affect health or life, requiring urgent treatment or hospitalizatio;

4) Fatal AEs: Directly result in the participant's death from any cause.

3. Recording and Observation

During the study, all participants' health conditions will be closely monitored:

1) Admission Assessment: Record detailed medical history, prior surgeries, and medication or allergy history to identify potential AE risk factors.

2) In-Hospital Monitoring: Regularly check vital signs (heart rate, blood pressure, temperature) and document any abnormal symptoms or signs.

3) Follow-Up: After discharge, conduct regular follow-up visits to assess recovery, document complications and treatments, and perform additional tests if necessar.

4. Evaluation of Adverse Events

All recorded AEs will be evaluated by the study team for:

1) Severity: Classified according to the defined AE categories (mild, moderate, severe, fatal).

2) Management and Outcome: Document interventions and outcomes (recovery, sequelae, death).

5. Reporting of Adverse Events

1) Initial Reporting: AEs must be recorded in the CRF and submitted to the Data

Monitoring Committee (DMC) within 24 hours for preliminary assessment.

2) Regular Reporting: Monthly study progress reports will include detailed AE information, analysis of their relation to treatment, and any necessary adjustments to therapy.

3) Serious Adverse Event (SAE) Reporting: Any SAE must be reported to the Ethics Committee and relevant regulatory authorities within 24 hours, including detailed description, management, outcome, and possible causality.

6. Management and Response to Adverse Events

1) Event Management: The study team will adjust treatment according to AE severity. Severe AEs or major complications may require temporary suspension or termination of treatment, with additional care or referral as needed.

2) Emergency Measures: For life-threatening or fatal AEs, immediate emergency interventions will be provided, with interventions tailored to the participant's condition.

7. Data Analysis and Summary

All AEs will be included in the statistical analysis. The study team will evaluate the incidence of postoperative complications, the distribution of different types of AEs, and the effectiveness of various management approaches. The results will ultimately help assess the safety of mesenteric defect closure and its impact on postoperative complications.

8. Quality Control and Assurance

The principal investigators have received Good Clinical Practice (GCP) training and passed the assessment. The study team has established a comprehensive management system to ensure strict adherence to the study protocol and accurate, complete, and timely data entry. Prior to study initiation, all researchers at participating sites will be trained on the clinical study protocol to ensure full

understanding of study requirements and procedures.

Site investigators are responsible for maintaining research quality at their units, strictly enforcing inclusion and exclusion criteria, and ensuring that all CRFs are fully completed and signed by the person filling them out. Study monitors will review CRFs every six months, supervising their completion, verification, and signature. All study data must have objective supporting evidence; fabrication of data is strictly prohibited.Relevant source documents include medical records (CRFs, informed consent forms, patient background surveys, symptoms and signs, treatment plans, etc.), examination reports (pathology, imaging results), and laboratory test data (biochemistry, urinalysis, tumor markers, etc.). Researchers must retain these clinical study materials for five years after study completion.

For surgical quality control, unedited intraoperative videos must be preserved and backed up to a central archive within one year. High-resolution surgical photographs (≥8 megapixels) are required after mesenteric defect closure.

9. Data Safety Monitoring

The clinical study will develop a data safety monitoring plan proportional to the level of risk. All AEs will be recorded in detail, appropriately managed, and followed until resolved or the patient's condition stabilizes. SAEs and unexpected events will be reported promptly to the Ethics Committee, regulatory authorities, the sponsor, and the relevant oversight bodies. Principal investigators will periodically review cumulative AE data and, if necessary, convene investigator meetings to evaluate the study's risk–benefit profile.

10. Ethics of Clinical Research

This clinical study will be conducted in strict accordance with the World Medical Association Declaration of Helsinki and relevant regulations. Prior to study

initiation at any participating institution, approval must be obtained from the Ethics Committee (each site may accept the approval of a central or recognized ethics committee). Upon study completion, a written report must be submitted to the Ethics Committee.

Before enrolling participants, investigators must fully explain the study details according to the informed consent form (ICF) and allow sufficient time for participants to consider and voluntarily decide whether to sign the ICF. If protocol amendments or newly available information potentially affecting continued participation arise during the study, the ICF must be revised accordingly. Participants must be informed of the changes and asked whether they agree to sign the updated ICF. Refusal to sign the revised ICF will be considered a withdrawal from the study.The ICF will be issued in two copies: the original will be retained by the study center, and a copy will be given to the participant. Any modifications to the ICF must be approved by the Ethics Committee before implementation. Participants who have signed the previous version of the ICF and have not yet completed the study must sign the updated ICF before continuing participation. Both old and new versions of the ICF will be retained as source documents.In all case report forms, statistical analyses, study reports, and adverse event reports, patient-identifiable information must not be disclosed. All participants will be identified by assigned codes and initials to ensure confidentiality.