A Retrospective Cohort Study on the Safety and Clinical Efficacy of an Anastomotic Technique for Ileocecal Valve Function Reconstruction During Laparoscopic Right Hemicolectomy for Colon Cancer

(Observational Clinical Study Protocol)

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1. Background

With changes in dietary habits and lifestyle, colorectal cancer has become the fourth leading cause of cancer-related death worldwide, with a higher incidence in males than females. The disease is increasingly showing trends of higher incidence and younger onset [1–2]. In China, the incidence of colorectal cancer is growing at an annual rate of approximately 2% [3], posing a significant burden on the healthcare system and society. Currently, surgical resection remains the primary treatment for colorectal cancer. With the advancement of minimally invasive surgery (MIS), the safety and efficacy of laparoscopic colorectal cancer resection have been widely validated and adopted [4].

However, the optimal technique for bowel anastomosis remains a subject of debate. Some studies suggest that totally laparoscopic anastomosis better aligns with the principles of MIS and oncological clearance compared to extracorporeal anastomosis [5]. Nevertheless, the complexity, longer operative time, and the requirement for highly experienced surgeons limit its widespread application. Furthermore, there is ongoing debate over side-to-side versus end-to-side anastomosis. Some literature reports suggest that side-to-side anastomosis may be associated with a higher incidence of postoperative bowel obstruction [6].

On one hand, advances in anatomical understanding—particularly the development of the mesocolic plane theory—and improvements in surgical instruments have significantly extended patient survival and reduced recurrence rates. On the other hand, patients' expectations regarding postoperative quality of life are also increasing. Since the anastomotic technique is closely linked to postoperative bowel function and complications, there is a growing clinical demand to optimize bowel reconstruction in a way that preserves or restores physiological function while ensuring oncologic radicality.

The ileocecal valve (ICV) functions as a sphincteric structure separating the small and large intestines. It regulates the passage of intestinal contents under the influence of hormonal and neural control [7]. Some scholars propose that the concept of the "ileocecal region" better reflects the physiological role of this anatomical structure [8]. For tumors located in the ascending colon or proximal hepatic flexure, resection often includes removal of the ICV and part of the terminal ileum. Current anastomotic techniques rarely address reconstruction of the ICV or its potential impact on postoperative gastrointestinal function.

Existing studies suggest that preserving the ICV during extended right hemicolectomy is both safe and feasible without compromising oncologic outcomes, while also promoting faster bowel function recovery [9]. Although this is a promising direction,

many patients, due to tumor location, still require resection of the ICV, leading to several clinical challenges.

The concept of ICV reconstruction was first proposed by Kellogg in 1918 [10]. Subsequent animal studies demonstrated that ICV reconstruction improved weight gain, prevented reflux, and enhanced nutritional status, indicating potential clinical benefits [11]. Clinically, ICV reconstruction has been applied in pediatric patients with congenital ileocecal valve atresia and in patients undergoing ICV resection for non-malignant reasons, yielding satisfactory results. However, the long-term outcomes remain controversial [12–13].

In patients undergoing right hemicolectomy, removal of the ICV compromises the natural bacterial barrier, allowing colonic bacteria to migrate into the terminal ileum and even the proximal small intestine. Under certain conditions, this can lead to small intestinal bacterial overgrowth (SIBO), manifesting as abdominal distension, diarrhea, and severe malabsorption of bile acids, vitamin B12, fatty acids, and other nutrients [14].

Our research team previously established an animal model using a "Roll-Intussuscepted Sleeve Embedding" (RISE) anastomosis technique, which showed improved outcomes compared to conventional anastomosis. Rats in the RISE group experienced faster weight gain, earlier stool formation, and restoration of gut microbiota closer to preoperative levels.

Based on these findings, reconstructing the function of the ICV during laparoscopic right hemicolectomy may offer a solution to the aforementioned clinical problems. However, to date, no studies have systematically evaluated the clinical efficacy or safety of ICV reconstruction in right hemicolectomy for colon cancer. Therefore, this retrospective cohort study aims to assess the safety, feasibility, and clinical outcomes of an anastomotic technique designed to reconstruct ICV function, with the goal of improving postoperative recovery and quality of life for patients.

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2. Objectives

This is a retrospective study that systematically collects data from patients who have undergone laparoscopic radical right hemicolectomy for colon cancer in our department. Patients are categorized into two groups based on the type of anastomosis: the conventional anastomosis group and the ileocecal valve function reconstruction group. This study aims to investigate the impact of ileocecal valve (ICV) function reconstruction on postoperative complications and bowel function recovery in patients following right hemicolectomy.

The outcomes of interest include anastomotic leakage, anastomotic bleeding, anastomotic stenosis, wound infection, time to first flatus, time to first defecation, time to stool formation, incidence of postoperative diarrhea, and Bristol Stool Form Scale classification.

Primary Objective

To evaluate the safety and feasibility of an anastomotic technique designed to reconstruct ileocecal valve function during laparoscopic right hemicolectomy.

Secondary Objective

To evaluate the clinical efficacy of ileocecal valve function reconstruction in laparoscopic right hemicolectomy, focusing on postoperative recovery of bowel function and reduction in gastrointestinal complications.

3. Study Design

3.1 Overall Study Design

This study is a retrospective cohort study. Clinical data will be collected and analyzed from patients who underwent laparoscopic radical right hemicolectomy for colon cancer in our department. Patients will be categorized into two groups based on the type of anastomosis: the conventional anastomosis group and the ileocecal valve reconstruction group.

3.2 Study Setting and Population

This is a single-center observational study. All clinical data are derived from patients who have previously undergone laparoscopic radical right hemicolectomy in the Department of General Surgery.
Patients will be grouped according to the type of anastomosis (exposure factor):

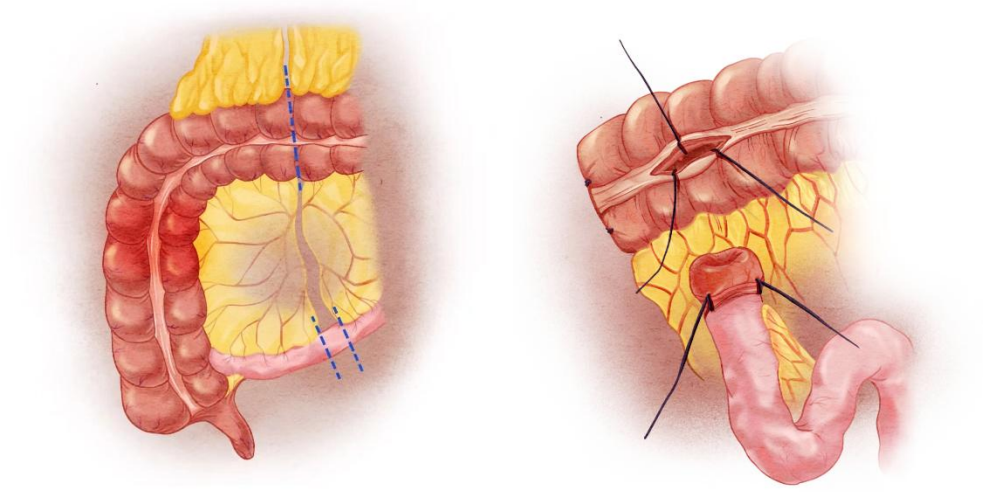
Conventional Anastomosis Group:
Conventional anastomosis is defined as follows: After transecting the intestine 10 cm proximal to the ileocecal valve and 10 cm distal to the tumor using a linear stapler, the specimen is removed. The stapled ends are disinfected with alcohol. A side-to-side ileocolic anastomosis is performed using a linear stapler. The common enterotomy is closed with additional reinforcement sutures (3-0 absorbable sutures). Anastomotic integrity, patency, and blood supply are verified to ensure no leakage.

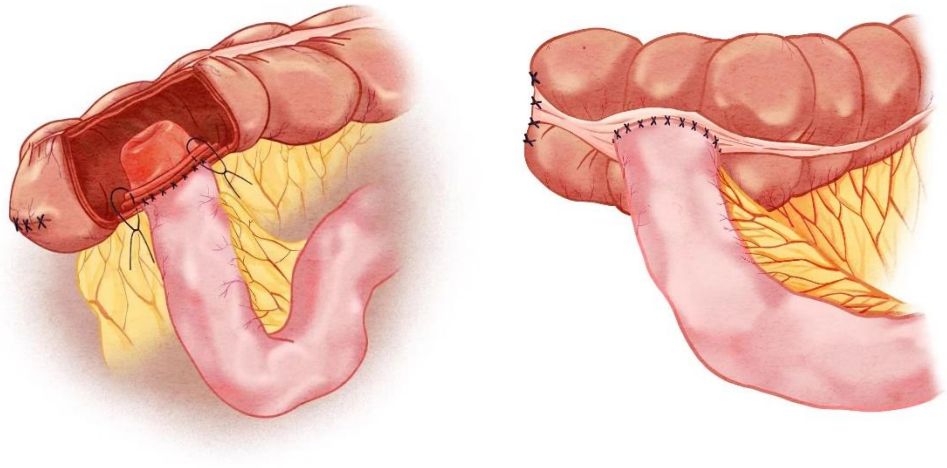
Ileocecal Valve Reconstruction Group (RISE Anastomosis):

This study focuses on a novel anastomotic technique aimed at reconstructing ileocecal valve function, based on literature review and accumulated surgical experience. The method is referred to as Revolute Insert Side-End Ileocecal Valve Reconstruction (RISE-ICVR), or simply the RISE Anastomosis. This technique is designed to recreate the physiological valve structure that separates the bacterial-rich colon from the relatively sterile small intestine, adhering to the principle that "form determines function."

Surgical steps include:

1. After resecting the tumor and relevant bowel segments within oncological safety margins, the terminal ileum is everted at three equidistant points using 3-0 sutures to form an "artificial ileocecal valve."
2. A longitudinal incision of approximately 2 cm is made in the colonic wall, about 2 cm from the stapled colon end, along the taenia coli.
3. After confirming that there is no mesenteric twisting, the ileal stump is inserted into the colonic incision. Three anchoring sutures are placed between the midpoint of each ileal suture and the colonic wall.
4. A barbed suture is then used to continuously suture the ileal stump to the colonic wall, creating a sleeve-like embedded anastomosis while simultaneously closing the mesenteric defect between the bowel segments.





This technique complies with the technical standards outlined in the "Expert Consensus on Digestive Tract Reconstruction After Colorectal Resection." All patients underwent standard laparoscopic radical right hemicolectomy.

3.2.1 Inclusion Criteria

Participants must meet all of the following criteria:

1. Aged between 18 and 80 years;
2. American Society of Anesthesiologists (ASA) physical status score of ≤3;
3. First-time diagnosis of colon cancer located in the appendix, cecum, ascending colon, hepatic flexure, or the right one-third of the transverse colon, including patients requiring additional surgery based on post-endoscopic pathological findings;
4. No history of other gastrointestinal diseases (except for benign conditions such as intestinal polyps or gallstones);
5. Complete and accessible clinical data.

3.2.2 Exclusion Criteria

Participants will be excluded if they meet any of the following conditions:

1. Concurrent diagnosis of other malignant tumors;
2. Presence of infectious diseases or autoimmune diseases (e.g., Crohn’s disease);
3. Surgical plan changes resulting in the ileocecal valve not being included in the resection;
4. Incomplete or missing clinical data.

3.3 Sample Size

This is a retrospective cohort study. Based on screening of the hospital's electronic medical records and application of the predefined inclusion and exclusion criteria, a total of 50 patients were included. Among them, 30 patients underwent conventional anastomosis and 20 patients underwent ileocecal valve reconstruction. All surgeries and follow-up were conducted in the Department of General Surgery, Second Affiliated Hospital of Army Medical University.

3.4 Study Factors and Observation Indicators

Clinical data will be collected from patients undergoing laparoscopic right hemicolectomy in the Department of General Surgery, Second Affiliated Hospital of Army Medical University, starting from the date of ethics committee approval.
Observation Indicators:

Surgical Safety and Feasibility:
Successful completion of surgery without anastomotic leakage, anastomotic bleeding, or stenosis.
No severe perioperative complications.

Intraoperative Indicators:
Total operative time
Anastomosis time
Intraoperative blood loss
Intraoperative blood transfusion volume
Incision length
Proximal and distal resection margins
Total number of lymph nodes harvested
Number of positive lymph nodes

Postoperative Indicators:
Postoperative complications within 30 days
Postoperative inflammatory markers
Time to first flatus
Time to first bowel movement
Time to first ambulation
Time to formed stool
Length of hospital stay
Reoperation rate
Readmission rate
Mortality rate
Bristol Stool Form Scale (BSFS) score
Defecation frequency

Urgency frequency
Incidence of fecal incontinence

Follow-up Indicators:
Anastomotic healing status
Gastrointestinal contrast imaging (e.g., iodine-based contrast, upper GI barium meal)
Colonoscopy findings

Metabolic parameters:
blood glucose, lipid profile, glycated hemoglobin (HbA1c), and other physiological indicators

3.5 Data Collection Method

All clinical data are obtained from the hospital's electronic medical record (EMR) system. A dedicated research coordinator is responsible for data extraction and verification.

3.6 Study Endpoints

Primary Endpoint:
Postoperative complications within 30 days, specifically anastomotic leakage, anastomotic bleeding, and anastomotic stenosis.

Secondary Endpoints:
Time to first flatus
Time to first bowel movement
Time to formed stool

3.7 Data Management and Statistical Analysis

Statistical analyses will be performed using SPSS version 22.0.Categorical variables will be expressed as n (%) and compared using the Chi-square (χ^2) test.Continuous variables will be tested for normality using the Shapiro-Wilk test (S-W test). Data conforming to normal distribution will be presented as mean ± standard deviation ($\bar{x} \pm s$), and comparisons between groups will be performed using the t-test.A P-value < 0.05 will be considered statistically significant.

4. Study-Related Costs

4.1 Budget

This is a retrospective cohort study. Data collection and analysis do not require dedicated funding.

4.2 Funding Source

None.

4.3 Financial Burden to Participants

All patients included in this study have completed surgery and were discharged prior to study initiation. This study involves retrospective data analysis only and will impose no additional financial burden on participants.

5. Quality Control

This study will be led by a senior chief physician with extensive clinical and research experience. All other team members have completed Good Clinical Practice (GCP) training and will be responsible for patient observation, data recording, and data management. The overall quality of the study will be strictly controlled and ensured throughout the research process.

6. Ethical Principles and Requirements

This clinical study will adhere to the ethical principles outlined in the Declaration of Helsinki (World Medical Association) and comply with the "Administrative Measures for Ethical Review of Life Science and Medical Research Involving Humans" issued by the People's Republic of China.

Key ethical considerations include:

Informed Consent:

Before the study begins, the study protocol will be reviewed and approved by the Ethics Committee. If this study is not granted exemption from informed consent, the investigator has the responsibility to fully inform each participant and/or their legal representative about the study's purpose, procedures, and potential risks before enrollment.

Written informed consent will be obtained from all participants. Participation is entirely voluntary, and subjects may refuse to participate or withdraw from the study at any time without discrimination, penalty, or impact on their standard medical care or legal rights.

Privacy and Confidentiality Protection:

Investigators will take strict measures to protect the privacy and confidentiality of participants' personal information. All study data will be stored securely at the Second Affiliated Hospital of Army Medical University.

Exceptions to privacy protection will apply only in circumstances required by law or regulation, allowing study-related personnel, regulatory authorities, or ethics committees to review individual participant data when necessary for study oversight.

Risk Control and Compensation for Research-Related Harm:
The research team commits to minimizing risk and will provide appropriate protection for vulnerable populations if involved. Any research-related injury will be addressed according to applicable laws and regulations.

Data Protection Measures:
To safeguard personal data confidentiality, measures will include:
Removal or anonymization of identifiable information in study reports
Access restrictions for identifiable data
Use of data encryption and anonymization procedures where applicable
Ensuring that any publication or presentation of study results will not reveal individual participant identities

The research team hereby solemnly pledges to make every effort, within the limits permitted by law, to protect participants' personal privacy and data confidentiality.

7. Study Timeline

June 2024 – August 2024:
Strictly collect patient medical records according to the inclusion and exclusion criteria. Complete clinical data collection and preliminary data analysis.

September 2024 – December 2024:
Complete statistical analysis of the collected data. The principal investigator and core research team will review the results, organize manuscript preparation, and summarize the findings for publication and further improvement suggestions.

8. Study Team Members

8.1 On-Site Study Team Members

Name	Department	Title	Institution	Role in Study	GCP Training Date	Contact Number
Weidong Xiao	General Surgery	Chief Physician	Xinqiao Hospital	Principal Investigator	April 2017	+86-13996390860
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Kun Yu	General Surgery	Resident Physician	Xinqiao Hospital	Data Collection and Manuscript Preparation	None	+86-15826050221