**Official Title:**

# THE ROLE OF MECHANICAL BOWEL PREPARATION IN LAPAROSCOPIC RIGHT HEMICOLECTOMY WITH TOTALLY INTRACORPOREAL ANASTOMOSIS FOR COLON CANCER:

# A RANDOMIZED CONTROLLED TRIAL

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# LIST OF ABBREVIATIONS

| Abbreviations | English |
|---|---|
| MBP | Mechanical Bowel Preparation |

# INTRODUCTION

Surgery remains the cornerstone in the management of colon cancer, with the role of minimally invasive approaches becoming increasingly prominent. Among these, laparoscopic right hemicolectomy with totally intracorporeal anastomosis has been demonstrated to be safe and effective, without increasing the risk of intraoperative events or anastomotic complications. Moreover, it facilitates earlier recovery of bowel function and reduces the length of hospital stay [1-4]. Consequently, this technique has gradually become an inevitable trend worldwide, including in Vietnam.

The role of mechanical bowel preparation (MBP) alone in colorectal surgery remains controversial and has not been clearly established. Theoretically, MBP is intended to reduce intraluminal bowel contents, thereby decreasing the risk of surgical site infection and anastomotic complications. However, previous randomized controlled trials have failed to confirm these benefits[5-8]. Notably, these studies were conducted in patients undergoing extracorporeal anastomosis (via laparoscopic-assisted or open surgery), where the anastomosis can be directly controlled manually, thus significantly reducing the risk of fecal contamination of the operative field and peritoneal cavity.

In the current context, where totally intracorporeal anastomosis is increasingly adopted, MBP may play a role in reducing intraoperative fecal contamination within the abdominal cavity, lowering the risk of surgical site infection, and avoiding prolongation of anastomotic construction time and overall operative duration.

Therefore, this study was conducted to address the following question: Does mechanical bowel preparation reduce intraoperative events, postoperative complications, and facilitate faster recovery in patients undergoing laparoscopic right hemicolectomy with totally intracorporeal anastomosis?

## STUDY OBJECTIVES

To compare early outcomes of laparoscopic right hemicolectomy for colon cancer with totally intracorporeal anastomosis, with or without mechanical bowel preparation (MBP) via:

1. Comparing intraoperative adverse events (intra-abdominal fecal contamination), postoperative complications (anastomotic leak, postoperative ileus, ***surgical site infection***, and medical complications such as fluid–electrolyte imbalance), and 30-day postoperative mortality between patients with and without MBP.
2. Comparing operative outcomes (anastomotic construction time and total operative time) and postoperative recovery (time to first flatus, time to first bowel movement, and length of postoperative hospital stay) between the two groups.

# LITERATURE REVIEW

## 1.1 Colon cancer

### 1.1.1 Overview

Colon cancer is one of the most common malignancies of the gastrointestinal tract. More than 90% of colon cancers originate from glandular epithelial cells of the colonic mucosa (adenocarcinoma). Other less common histological types include neuroendocrine tumors, squamous cell carcinoma, spindle cell carcinoma, and undifferentiated carcinoma.

According to GLOBOCAN 2020 data, colorectal cancer ranks third in incidence and second in mortality worldwide [9]. ]. In Vietnam, colorectal cancer ranks fourth in men and second in women in terms of both incidence and cancer-related mortality [10]. Furthermore, a recent study has projected that by 2025, colorectal cancer will become the second most common cancer in Vietnam for both sexes combined [11].

### 1.1.2 TNM staging of colon cancer

Based on data obtained from imaging modalities, accurate disease staging is mandatory prior to making treatment decisions. Comprehensive staging should include assessment of the extent of primary tumor invasion, the presence of regional lymph node metastases, and distant metastases.

For decades, the TNM classification system developed by the American Joint Committee on Cancer (AJCC) has been widely adopted and accepted worldwide for evaluating cancer progression in general, and colorectal cancer in particular. In this system, T (tumor) refers to the primary tumor, N (regional nodes) to regional lymph node involvement, and M (metastasis) to distant metastasis [12].

Since its introduction, the TNM classification has become a universal language among clinicians globally and serves as a fundamental framework for prognostic assessment and the development of treatment strategies in oncology..

Based on the TNM classification, the American Joint Committee on Cancer 8th edition defines stages of colon cancer as follows: Stage I includes tumors invading the submucosa or muscularis propria (T1–T2) without regional lymph node metastasis (N0); Stage II includes tumors invading the subserosa, pericolic tissues not covered by peritoneum, or penetrating the visceral peritoneum (T3–T4) without regional lymph node metastasis (N0); Stage III includes tumors with regional lymph node involvement regardless of the depth of tumor invasion (N1 or higher); and Stage IV includes tumors with distant metastasis (M1) [12]. Accurate staging plays a critical role in prognostic assessment. In general, more advanced disease stages are associated with poorer outcomes.

| | | | |
|---|---|---|---|
| T3-4a<br>T2-3<br>T1-2 | N1 / N1c<br>N2a<br>N2b | M0<br>M0<br>M0 | IIIB |
| T4a<br>T3-4a<br>T4b | N2a<br>N2b<br>N1-2 | M0<br>M0<br>M0 | IIIC |
| T bất kỳ | N bất kỳ | M1a | IVA |
| T bất kỳ | N bất kỳ | M1b | IVB |
| T bất kỳ | N bất kỳ | M1c | IVC |

In addition to the core TNM components, supplementary prefixes may be applied depending on the timing and context of staging. These include: c (clinical assessment), based on clinical and imaging data obtained prior to treatment; p (pathological staging), based on histopathological findings following surgical resection; y (post-treatment or restaging), indicating assessment after neoadjuvant therapy (e.g., chemotherapy or radiotherapy); r (recurrence), used for staging

recurrent disease after a disease-free interval; and a (autopsy), based on findings from postmortem examination.

## 1.2 Laparoscopic right hemicolectomy / extended right hemicolectomy with totally intracorporeal anastomosis

### 1.2.1 Surgical techniques

From a technical perspective, according to Marco Milone, intracorporeal colonic anastomosis offers several advantages [2]. First, the tumor-bearing colon does not require extensive mobilization for exteriorization, but only sufficient mobilization to allow intracorporeal anastomosis. Second, performing the anastomosis intracorporeally reduces exposure of digestive contents to the surgical wound, thereby decreasing the risk of surgical site infection. Third, the formation of intra-abdominal adhesions may be minimized due to reduced manual manipulation of the peritoneal cavity. Fourth, the length of the extraction incision can be reduced by up to 50%, as it is used solely for specimen retrieval rather than anastomotic construction, thereby reducing postoperative pain and wound-related complications. Finally, intracorporeal anastomosis under direct laparoscopic visualization eliminates the risk of anastomotic torsion associated with the limited operative field in extracorporeal techniques.

However, Milone also highlighted several challenges associated with intracorporeal anastomosis [2]. First, adequate bowel preparation is required to minimize intra-abdominal fecal contamination. Second, surgeons must possess advanced laparoscopic skills to perform intracorporeal suturing. Third, prolonged anastomotic construction time may increase the risk of anastomotic-related complications. Fourth, operative costs may increase, as intracorporeal overlap techniques often require more stapling devices compared with

functional end-to-end anastomosis. In our study, we identified an additional challenge: for small colonic lesions, manual palpation during extracorporeal anastomosis facilitates accurate localization and determination of safe resection margins. This is more difficult when operating laparoscopically and often necessitates intraoperative colonoscopy, thereby prolonging operative time.

Regarding operative time, previous studies have reported conflicting results. Studies by Vignali[1] and Achilli [13] demonstrated significantly longer operative times in the intracorporeal anastomosis group, whereas studies by Allaix [3], Widmar [14], và Malczak [4] found no significant difference. In our study, total operative time did not differ significantly between the two groups (145.9 ± 32.0 minutes vs. 138.7 ± 43.2 minutes, $p = 0.04$), although anastomotic construction time was significantly longer in the intracorporeal group (33.6 ± 6.1 minutes vs. 24.4 ± 6.1 minutes, $p < 0.001$). Intracorporeal anastomosis requires less extensive colonic mobilization, thereby shortening the resection phase. This reduction may offset the longer anastomotic construction time, resulting in no overall difference in total operative duration. Furthermore, both operative and anastomotic times are highly dependent on surgeon experience. As these were among our initial cases of intracorporeal anastomosis, these times may decrease as the surgical team progresses along the learning curve.

In terms of postoperative recovery, numerous studies have demonstrated that intracorporeal anastomosis is associated with faster recovery of bowel function and shorter hospital stay. A meta-analysis by Milone in 2018, including 1,862 patients undergoing laparoscopic right hemicolectomy, showed that intracorporeal anastomosis significantly reduced time to first flatus, time to first bowel movement, and length of hospital stay compared with extracorporeal

anastomosis[2]. These findings have been consistently confirmed in randomized controlled trials by Vignali[1], Allaix[3], Widmar[14], và Malczak[4]. Notably, Vignali et al. also reported a markedly lower rate of postoperative ileus in the intracorporeal group (3.3% vs. 23.3%) [1]. This may be explained by reduced bowel manipulation and traction during intracorporeal procedures. Additionally, longer extraction incisions in extracorporeal anastomosis may increase postoperative pain, analgesic requirements, and consequently the risk of ileus due to reduced mobilization and opioid-related effects.

Regarding long-term outcomes, with a median follow-up of 40.0 months in our study, no significant differences were observed between the two groups in terms of distant metastasis or cancer-related mortality. These findings are consistent with previous studies. However, our study has several limitations inherent to its retrospective design, including potential selection bias and differences in baseline characteristics between groups. Furthermore, postoperative pain, incision length, and surgical costs were not evaluated. Future prospective randomized controlled trials with comprehensive outcome assessment are needed to more accurately evaluate the advantages and limitations of these two techniques.

### 1.2.2 Current Evidence

Worldwide, the earliest studies comparing intracorporeal and extracorporeal anastomosis in laparoscopic right hemicolectomy were conducted around 2009. Hellan et al. performed a prospective study comparing 23 patients undergoing intracorporeal anastomosis with 57 patients undergoing extracorporeal anastomosis[15]. Initial results demonstrated no significant differences in early postoperative outcomes between the two groups. However,

intracorporeal anastomosis was associated with a shorter incision and a potential reduction in wound-related complications.

Over the subsequent decade, numerous retrospective and prospective studies have compared early postoperative outcomes between these two techniques in laparoscopic right hemicolectomy, although results remain somewhat inconsistent. Some authors have reported that intracorporeal anastomosis reduces length of hospital stay and improves postoperative recovery[1,3].

Randomized controlled trials have also demonstrated several advantages of intracorporeal over extracorporeal anastomosis. Mari et al. reported significantly lower postoperative levels of inflammatory markers, including interleukin-6 and C-reactive protein, in patients undergoing intracorporeal anastomosis [16]. Similarly, Vignali et al. demonstrated improved postoperative recovery in the intracorporeal group compared with the extracorporeal group [1]. Studies by Allaix et al. [3] and Bollo et al. [17] further showed that intracorporeal anastomosis was associated with better recovery of gastrointestinal function, lower rates of postoperative ileus, and reduced postoperative pain.

Recent meta-analyses and systematic reviews have consistently suggested that intracorporeal anastomosis offers superior postoperative recovery compared with extracorporeal techniques. Analyses by Wu et al. (2016) [18] , Milone (2018) [2], and Emile (2019)[19] demonstrated that intracorporeal anastomosis is associated with improved postoperative recovery, lower rates of surgical site infection, and reduced incidence of incisional hernia. Furthermore, patients undergoing intracorporeal anastomosis tend to experience faster return to normal physiological function, less wound pain,

shorter incision length, and significantly reduced hospital stay compared with those undergoing extracorporeal anastomosis.

In Vietnam, there remains a relative paucity of studies comparing intracorporeal and extracorporeal anastomosis in laparoscopic colectomy in general, and right hemicolectomy in particular. Le Huy Luu reported a review highlighting the advantages of intracorporeal anastomosis over extracorporeal techniques in laparoscopic colectomy for cancer, as well as the challenges in adopting this technique in Vietnam [20]. Dao Van Cam (2019)[21] conducted an initial study demonstrating that intracorporeal anastomosis in laparoscopic colectomy is safe and feasible; however, this study did not include a direct comparison with extracorporeal anastomosis.

# STUDY SUBJECTS AND METHODS

## 1.3 Study design

A single-center randomized controlled trial.

## 1.4 Study setting and duration

The study was conducted from April 2025 to April 2028 at University Medical Center Ho Chi Minh City.

## 1.5 Study population

### 1.6 Target population

Patients undergoing right hemicolectomy or extended right hemicolectomy for colon cancer with totally intracorporeal anastomosis.

### 1.7 Study population

Patients undergoing right hemicolectomy or extended right hemicolectomy for colon cancer with totally intracorporeal anastomosis at University Medical Center Ho Chi Minh City between April 1, 2025 and April 1, 2028.

## 1.8 Eligibilitiy criteria

#### 1.8.1 Inclusion criteria

- Patients aged ≥18 years.
- Patients with colon cancer stage I–III according to the TNM classification.
- Patients undergoing right hemicolectomy or extended right hemicolectomy for colon cancer with totally intracorporeal anastomosis at University Medical Center Ho Chi Minh City.
- Postoperative histopathology confirming adenocarcinoma.

#### 1.8.2 Exclusion criteria

- Patients undergoing emergency surgery.

- Patients with contraindications to mechanical bowel preparation (e.g., bowel obstruction, subobstruction, bowel perforation, or peritumoral abscess).
- Patients with contraindications to laparoscopic surgery (American Society of Anesthesiologists (ASA) physical status IV or V) or contraindications to intracorporeal anastomosis (e.g., bowel obstruction, subobstruction, bowel perforation, or peritumoral abscess).
- Patients with distant metastasis at the time of surgery (stage IV according to the TNM classification).
- Patients with recurrent colon cancer after prior surgery.
- Patients with synchronous primary malignancies in organs other than the colon.
- Patients undergoing palliative surgery or surgery for tumor-related complications (non-curative intent).
- Patients lost to follow-up or unable to be contacted.

**1.9 Sample size calculation**

All patients were allocated into two groups:

- Group I: with mechanical bowel preparation (MBP) before surgery.
- Group II: without mechanical bowel preparation before surgery.

The sample size was determined based on the primary outcome of the study, which was the rate of anastomotic leakage. The sample size for comparing two proportions was calculated using the following formula:

$$n = \frac{\left[Z_{(1-\alpha/2)}\sqrt{2p^*(1-p^*)} + Z_{(1-\beta)}\sqrt{p_1(1-p_1)+p_2(1-p_2)}\right]^2}{(p_1-p_2)^2}$$

-

Where:

- $n$: minimum sample size required for each group.
- $\alpha$: type I error probability; with α = 0.05, $Z_{(1-\alpha/2)} = 1.96$.

- $\beta$: type II error probability; with β = 0.20, $Z_{(1-\beta)} = 0.84$
- p1: rate of surgical site infection in Group I, according to Ozawa et al.[22], p1=0,045
- p2: rate of surgical site infection in Group I, according to Ozawa et al.[22], p2=0,313
- p* = (p1 + p2)/2 = 0,18
- Substituting these values into the formula yielded a required sample size of n ≥ 32.
- To account for potential dropout and loss to follow-up, an additional 15% of participants will be recruited. Therefore, the total sample size is increased from 64 to 74 patients.

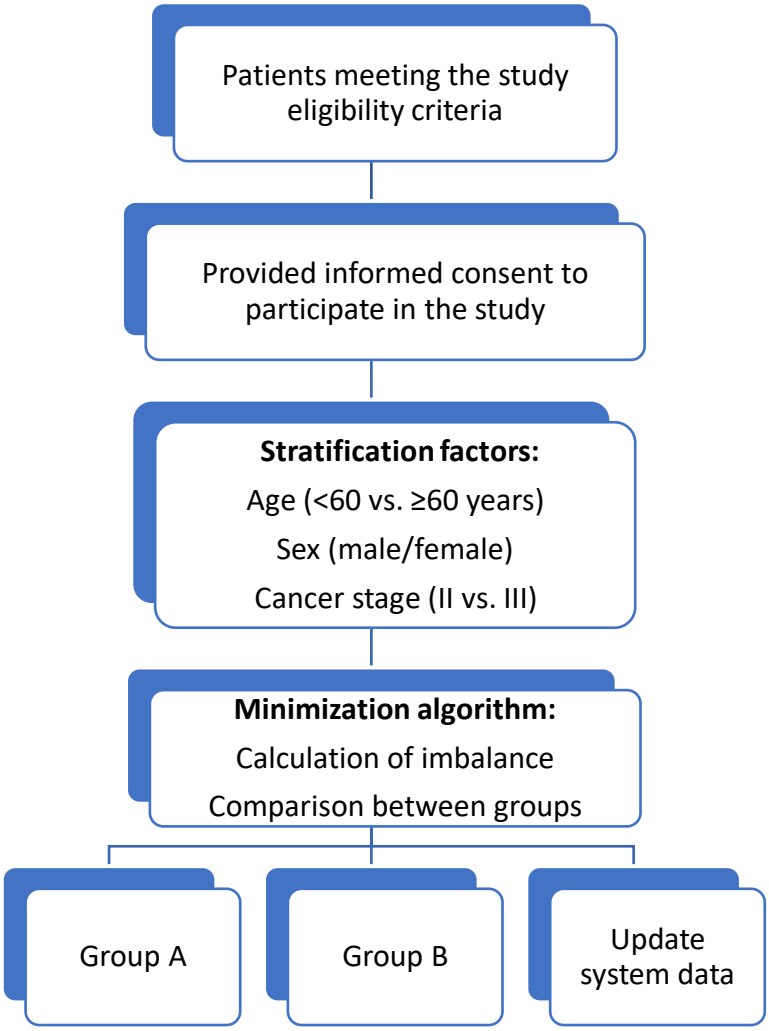
## 1.10 Randomization, Allocation Concealment, and Blinding

Participants were randomly assigned in a 1:1 ratio to either the mechanical bowel preparation (MBP) group or the no mechanical bowel preparation group. Randomization was performed using a centralized, web-based platform employing a minimization algorithm to ensure balance between groups with respect to age (≤60 vs >60 years), sex, and tumor stage (stage II vs III).

Allocation concealment was maintained through the web-based system, which generated group assignments only after patient enrollment. The allocation sequence was not accessible to the investigators involved in patient recruitment or surgical procedures. Group assignments were available exclusively to designated research personnel responsible for preoperative preparation.

Blinding was implemented at the level of the operating surgeons (investigators). Due to the nature of the intervention, participants were aware of their assigned group. However, the surgeons performing the procedures were not informed of the allocation prior to surgery. Standardized perioperative management protocols were applied to all participants to minimize potential bias.

Complete blinding of the operating surgeons may not be fully guaranteed due to intraoperative findings; however, allocation concealment and protocol standardization were strictly maintained to reduce the risk of bias. Whenever feasible, postoperative outcomes were assessed using predefined objective criteria, and outcome assessors not involved in the surgical procedures were kept blinded to group allocation.




### 1.11 Definition of variables

- Age: Continuous variable, expressed in years, calculated at the time of surgery.
- Sex: Binary variable (male/female).

- ASA score: Patient physical status classified according to the American Society of Anesthesiologists, ranging from I to IV [23].
- Body mass index (BMI): Continuous variable (kg/m²), calculated as body weight (kg) divided by the square of height (m²), measured at the time of surgery. Classified according to WHO criteria for Asian populations.
- Preoperative laboratory parameters: Hemoglobin, albumin, sodium, potassium, magnesium, phosphate, and bicarbonate levels measured within 3 days prior to surgery.
- Postoperative laboratory parameters: Hemoglobin, albumin, procalcitonin, sodium, potassium, magnesium, phosphate, and bicarbonate levels measured after surgery.
- Comorbidities: Categorical variable, including hypertension, diabetes mellitus, cardiovascular diseases (atrial fibrillation, coronary stent, prior myocardial infarction, chronic ischemic heart disease), chronic obstructive pulmonary disease, bronchial asthma, cirrhosis, chronic kidney disease, and Cushing syndrome.
- Tumor location: Categorical variable determined by preoperative abdominopelvic computed tomography (CT), including cecum, ascending colon, hepatic flexure, and transverse colon.
- Tumor size: Continuous variable (cm), defined as the largest dimension (length, width, or height) measured on preoperative CT imaging.
- Tumor differentiation: Histopathological grading (well, moderately, or poorly differentiated).
- Cancer stage: TNM staging according to the American Joint Committee on Cancer 8th edition[12], dựa vào hình chụp cắt lớp vi tính bụng chậu trước phẫu thuật.
- Preoperative fasting time (solid food): Continuous variable (hours), calculated from the last intake of solid food before surgery to the start of surgery.

- Preoperative fasting time (liquids): Continuous variable (hours), calculated from the last intake of liquids before surgery to the start of surgery.
- Operative time: Continuous variable (minutes), measured from skin incision to completion of skin closure, as recorded in the operative report and medical records.
- Anastomotic construction time: Continuous variable (minutes), measured from completion of bowel resection to completion of the anastomosis, as recorded in the operative report.
- Degree of fecal contamination: Categorical variable, classified as distant from the anastomosis / at the anastomosis / none.
- Bowel condition: Categorical variable, classified as solid stool / liquid stool / clean bowel.
- Intraoperative blood loss: Continuous variable (mL), recorded in the operative report.
- Intraoperative adverse events: Categorical variable, including organ injury (organs other than the colon) and intra-abdominal fecal contamination, as recorded in the operative report. Intra-abdominal fecal contamination is defined as gross spillage of intestinal contents into the peritoneal cavity beyond the bowel mucosa, confirmed and documented by the operating surgeon.
- Postoperative complications (Clavien–Dindo classification): Postoperative complications were graded according to the Clavien–Dindo classification system, ranging from Grade I to Grade V [24].
- -Surgical site infection (SSI): Categorical variable. In this study, the term surgical site infection includes superficial SSI, deep SSI, and organ/space SSI, as defined by the Centers for Disease Control and Prevention.[25]. All cases of infection involving the skin and subcutaneous tissue occurring within 30 days after surgery, with at least one of the following findings: purulent discharge from the incision, positive wound culture, wound opening or drainage requiring suture removal or packing, together with signs of inflammation (swelling,

warmth, redness, pain), or a diagnosis of superficial surgical site infection by the surgeon, were classified as superficial SSI.

- All cases of infection involving the fascial and muscle layers of the incision occurring within 30–90 days after surgery, with at least one of the following findings: purulent discharge, positive wound culture, wound opening or drainage, or spontaneous wound dehiscence, together with symptoms such as localized tenderness or fever >38°C, or a diagnosis of deep SSI by the surgeon, were classified as deep SSI.
- All cases of infection involving organs or body spaces occurring within 30–90 days after surgery, with at least one of the following findings: purulent drainage from a drain placed in the organ/space, positive culture from drainage fluid, or evidence of abscess or infection on clinical examination, histopathology, or imaging, and meeting the diagnostic criteria for intra-abdominal infection, were classified as organ/space SSI.
- According to Centers for Disease Control and Prevention criteria, intra-abdominal infection was diagnosed if at least one of the following was present: (1) evidence of abscess or infection on clinical or histopathological examination; (2) positive culture from intra-abdominal fluid or drainage; or (3) at least two of the following clinical features: fever >38°C, hypotension, nausea, vomiting, abdominal pain, elevated liver enzymes (transaminases), or jaundice, together with at least one of the following: Gram stain demonstrating bacteria in intra-abdominal fluid/drainage, or imaging findings consistent with intra-abdominal infection.
- Wound dehiscence: Categorical variable, defined as separation of the abdominal fascia at the incision site, with or without evisceration.
- Bleeding (wound/intra-abdominal/gastrointestinal): Categorical variable, defined as bleeding from the surgical wound, abdominal cavity, or gastrointestinal tract requiring procedural or surgical intervention (e.g., hemostatic suturing or reoperation).

- Postoperative electrolyte imbalance: Categorical variable, defined as the presence of any of the following abnormalities: hypokalemia (serum potassium ≤3.5 mmol/L), hyperkalemia (≥5.5 mmol/L), hyponatremia (serum sodium ≤130 mmol/L), hypernatremia (≥150 mmol/L), hypomagnesemia (≤0.50 mmol/L), hypophosphatemia (≤0.80 mmol/L), metabolic acidosis (serum bicarbonate ≤22 mmol/L), or metabolic alkalosis (≥30 mmol/L).
- [26].
- Length of postoperative hospital stay: Continuous variable (days), calculated from the date of surgery (postoperative day 0) to discharge.
- Time to first flatus: Continuous variable (days), calculated from the date of surgery to the first passage of flatus.
- Time to first bowel movement: Continuous variable (days), calculated from the date of surgery to the first defecation.
- 30-day postoperative mortality: Proportion of patients who died from any cause within 30 days after surgery.

**1.12 Study procedure**

All patients diagnosed with colon cancer at University Medical Center Ho Chi Minh City who, after multidisciplinary team discussion, were indicated for right hemicolectomy or extended right hemicolectomy and met the study inclusion criteria were approached by a member of the research team. Patients were provided with detailed information regarding the surgical procedure and study participation.

If the patient agreed to participate, written informed consent for both the surgical procedure and study participation was obtained from the patient and their legal representative. Patients were then randomly assigned by a member of the research team, using a lottery method, to one of two groups: with or without mechanical bowel preparation (MBP) prior to surgery.

## 1.13 Preoperative investigastions

All patients included in the study underwent laboratory testing, including complete blood count, serum albumin, procalcitonin, creatinine, and serum electrolytes (sodium, potassium, magnesium, phosphate, and bicarbonate). These investigations were performed within 3 days prior to surgery.

### 1.13.1 Mechanical bowel preparation

On the day before surgery, all patients were allowed solid food until 22:00 and fasted thereafter until surgery. On the day of surgery, patients were allowed to drink water ad libitum and received 400 mL of 12.5% maltodextrin solution every 4 hours until 2 hours before surgery.

On the evening prior to surgery, patients in the mechanical bowel preparation (MBP) group received 3 liters of water mixed with three sachets of Coliet (Medisun Pharmaceutical Joint Stock Company; each sachet containing macrogol 4000 64 g, sodium bicarbonate 1.68 g, sodium sulfate 5.7 g, sodium chloride 1.46 g, potassium chloride 0.75 g, and sodium saccharin as excipient) for bowel preparation. The MBP protocol was approved and implemented at University Medical Center Ho Chi Minh City.

### 1.13.2 Laparoscopic right hemicolectomy with totally intracorporeal anastomosis

All procedures were performed by members of the research team.

***a). Patient positioning and trocar placement***

Patients underwent general anesthesia with endotracheal intubation and were placed in the supine position, with arms and legs adducted, in a 20–30° Trendelenburg position and 20–30° left tilt. Five trocars were inserted as follows: a 10-mm port at the umbilicus, a 12-mm port in the left subcostal region, and three 5-mm ports in the left flank, right iliac fossa, and right flank.

***b). Colonic mobilization***

The surgeon explored the abdominal cavity to assess tumor characteristics, including the extent of tumor invasion, regional lymph node involvement, evidence of distant metastasis, and tumor-related complications. The terminal ileum, appendix, and cecum were mobilized from the posterior abdominal wall. The right ureter and gonadal vessels were identified and preserved. The ascending colon and right mesocolon were further mobilized from the posterior abdominal wall, as well as from the duodenum and pancreatic head.

The greater omentum was divided to mobilize the transverse colon from the greater curvature of the stomach. The transverse colon, hepatic flexure, and corresponding mesocolon were mobilized from the posterior gastric wall, duodenal frame, and abdominal wall.

***c). Vascular ligation***

The ileocolic vessels and right colic vessels (if present) were ligated at their origin, with lymphadenectomy performed at the root of the ileocolic artery. Complete mesocolic excision (CME) was carried out.

For tumors of the cecum and ascending colon, the right branch of the middle colic vessels was ligated, and lymphadenectomy was performed at the origin of the middle colic trunk. For tumors of the hepatic flexure and transverse colon, the middle colic vessels were ligated at their origin, with lymphadenectomy performed at the root of the middle colic artery.

***d). Bowel resection***

The terminal ileum was transected approximately 20 cm proximal to the ileocecal valve, and the transverse colon was transected at least 10 cm distal to the tumor using an endoscopic linear stapler. The resected ileocolic specimen was placed in a specimen retrieval bag. Hemostasis was carefully ensured, and the operative field was irrigated with 0.9% saline solution.

***e). Intracorporeal anastomosis, mesenteric closure, and abdominal drainage***

The terminal ileum and transverse colon were positioned side by side in an isoperistaltic orientation. Small enterotomies (5–10 mm in diameter) were created on the antimesenteric borders of both the ileum and transverse colon using monopolar electrocautery. A side-to-side ileocolic anastomosis was constructed using an endoscopic linear stapler. The common enterotomy was closed with a continuous suture using polydioxanone (PDS) 3-0 or 4-0, followed by reinforcement with interrupted PDS 3-0 or 4-0 sutures.

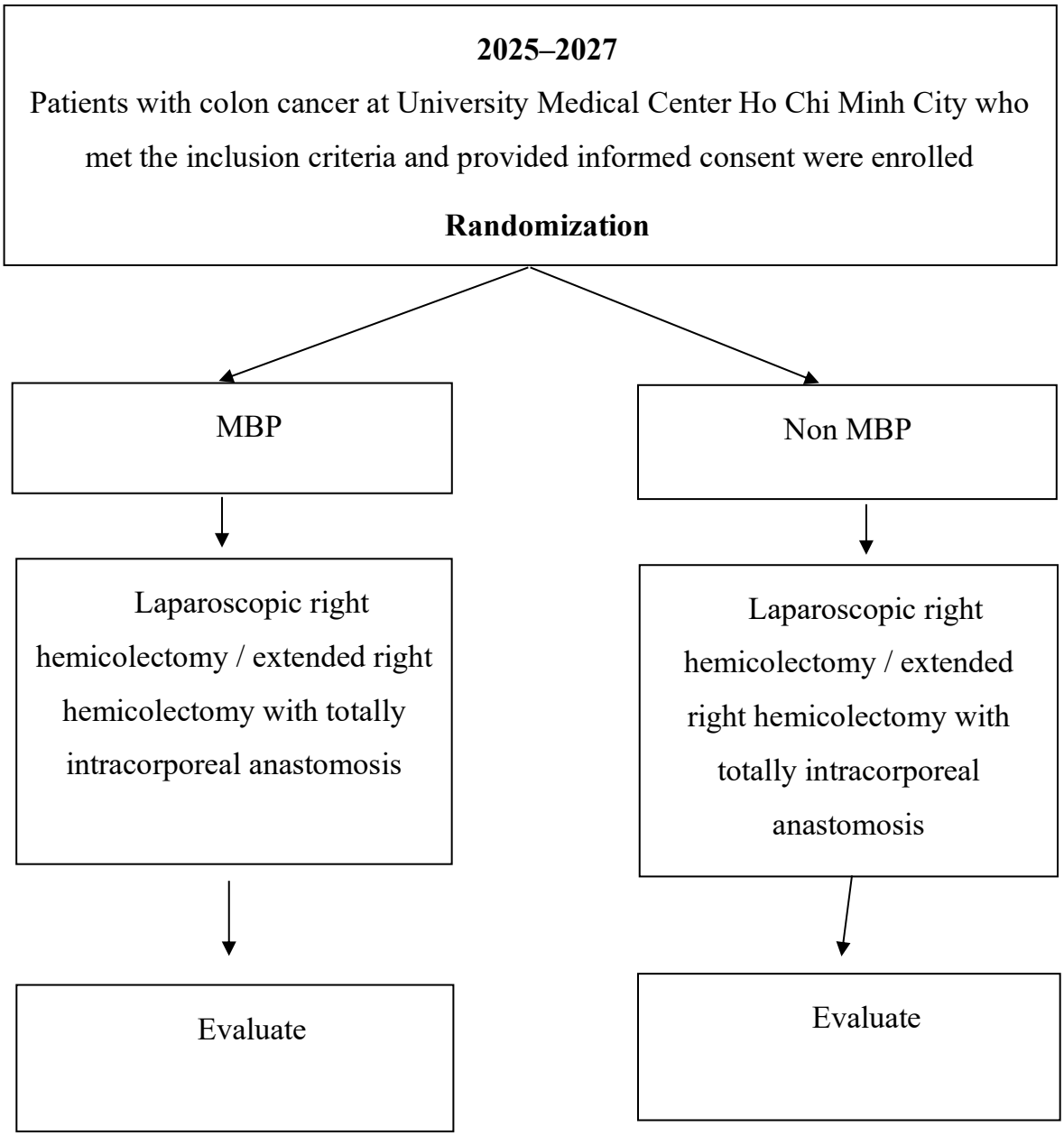
The mesenteric defect at the ileocolic anastomosis was closed with a continuous PDS 3-0 or 4-0 suture. A 16-Fr drain was placed in the right paracolic gutter and exteriorized through the right flank.

***f). Specimen extraction***

The colonic specimen was extracted within a retrieval bag through a suprapubic transverse incision measuring 5–10 cm. The peritoneum at the incision site was closed with continuous polyglactin 3-0 sutures. The rectus muscle was approximated with interrupted polyglactin 3-0 sutures. The anterior rectus sheath at the suprapubic incision was closed with continuous polyglactin 1 sutures. Fascial defects at the 10-mm and 12-mm trocar sites were closed with polyglactin 1 sutures.

The suprapubic incision was irrigated with 100 mL of 0.9% saline solution. The skin was closed with interrupted nylon 3-0 sutures

**Figure 1.** Study protocol



### 1.14 Postoperative care and assessment

Patients were allowed oral intake of water and a liquid diet within 24 hours after surgery, provided there were no contraindications (e.g., postoperative ileus, bowel obstruction, or persistent vomiting).

Routine laboratory tests, including complete blood count, serum albumin, procalcitonin, creatinine, and electrolytes, as well as abdominal ultrasound, were performed on postoperative day 2 and repeated every 48 hours.

Wound dressings were changed every 24 hours starting from postoperative day 2. Samples of suprapubic wound discharge and drain fluid were collected for culture on postoperative day 3.

### 1.15 Data analysis

All data were collected, processed, and analyzed using Microsoft Excel and SPSS software. Continuous variables were compared using the Student's t-test when normally distributed and the Mann–Whitney U test when non-normally distributed. Categorical variables were analyzed using the chi-square test or Fisher's exact test, as appropriate.

Logistic regression analysis was performed to identify independent risk factors. A p-value of $<0.05$ was considered statistically significant.

### 1.16 Ethical considerations

This study was approved by the Institutional Review Board of University of Medicine and Pharmacy at Ho Chi Minh City.

Participants had the right to withdraw from the study at any time without any impact on their medical care. All patient information was kept strictly confidential in accordance with regulations of the Ministry of Health

## EXPECTED RESULTS

Objective 1: To compare intraoperative adverse events (intra-abdominal fecal contamination), postoperative complications (anastomotic leak, postoperative ileus, deep surgical site infection, superficial surgical site infection, and medical complications), and 30-day postoperative mortality between patients with and without mechanical bowel preparation (MBP).

Objective 2: To compare operative outcomes (anastomotic construction time and total operative time) and postoperative recovery (time to first flatus, time to first bowel movement, and length of postoperative hospital stay) between patients with and without MBP.

The expected results will be presented in tables and figures as follows:

**Table 3.1**: Baseline clinical and laboratory characteristics of patients

| Patient characteristics | n or Mean ± SD | Percentage (%) |
|---|---|---|
| Age | | |
| Sex | | |
| BMI | | |
| ASA score | | |
| Comorbidities:<br>• Cardiovascular disease<br>• Diabetes mellitus<br>• Respiratory disease (COPD, asthma)<br>• Cirrhosis<br>• Chronic kidney disease<br>• Cushing syndrome | | |
| Pre-operative hemoglobin, albumin, sodium, potassium, magnesium, phosphate, and bicarbonate levels | | |

| | | |
|---|---|---|
| Post-operative hemoglobin, albumin, sodium, potassium, magnesium, phosphate, and bicarbonate levels | | |
| Tumor location<br>• Cecum<br>• Ascending colon<br>• Hepatic flexure<br>• Transverse colon | | |
| Maximum tumor size (mm) | | |
| Tumor differentiation | | |

**Table 3.2**: Surgical outcomes

| | |
|---|---|
| Surgical outcomes | |
| Preoperative fasting time for solid food (hours) | |
| Preoperative fasting time for liquid food (hours) | |
| Operating time (minutes) | |
| Anastomotic construction time (minutes) | |
| Intraoperative blood loss (mL) | |
| Intraoperative adverse events<br>• Organ injury<br>• Intra-abdominal fecal contamination | |
| Time to first flatus (days) | |
| Time to first bowel movement (days) | |
| Length of postoperative hospital stay (days) | |
| **Postoperative complications**<br>• Superficial surgical site infection | |

| | |
|---|---|
| • Deep surgical site infection<br>• Organ/space surgical site infection<br>• Anastomotic leak<br>• Intra-abdominal bleeding<br>• Gastrointestinal bleeding<br>• Gastrointestinal fistula<br>• Abdominal wound dehiscence<br>• Fluid–electrolyte imbalance<br>• … | |
| Clavien–Dindo classification of postoperative complications | |
| 30-day postoperative mortality rate | |

**References**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