Trials

STUDY PROTOCOL

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A study of intersphincteric resection rate following robotic-assisted total mesorectal excision versus laparoscopic-assisted total mesorectal excision for patients with middle and low rectal cancer: study protocol for a multicenter randomized clinical trial

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Abstract

Introduction Robotic-assisted complete mesorectal excision (RATME) is increasingly being used by colorectal surgeons. Most surgeons consider RATME a safe method, and believe it can facilitate total mesorectal excision (TME) in rectal cancer, and may potentially have advantages over intersphincteric resection (ISR) and anus preservation. Therefore, this trial was designed to investigate whether RATME has technical advantages and can increase the ISR rate compared with laparoscopic-assisted TME (LATME) in patients with middle and low rectal cancer.

Methods and analysis This is a multicenter, superiority, randomized controlled trial designed to compare RATME and LATME in middle and low rectal cancer. The primary endpoint is the ISR rate. The secondary endpoints are coloanal anastomosis (CAA) rate, conversion to open surgery, conversion to transanal TME (TaTME), abdominoperineal resection (APR) rate, postoperative morbidity and mortality within 30 days, pathological outcomes, long-term survival outcomes, functional outcomes, and quality of life. In addition, certain measurements will be conducted to ensure quality and safety, including centralized photography review and semiannual assessment.

Discussion This trial will clarify if RATME improves ISR and promotes anus preservation in patients with mid- and low-rectal cancer. Furthermore, this trial will provide evidence on the optimal treatment strategies for RATME and LATME in patients with mid- and low-rectal cancer regarding improved operational safety.

Trial registration ClinicalTrials.gov NCT06105203. Registered on October 27, 2023.

Keywords Total mesorectal excision, Rectal cancer, Intersphincteric resection, Laparoscopy, Robot

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Background

To date, total mesorectal excision (TME) for middle and low rectal cancers remains technically challenging. Surgeons may encounter limited vision and operating space in low anterior resection in patients with a narrow pelvis. These problems may result in poor-quality mesorectal excision, unexpected surgical injuries, or conversion to laparotomy. In extreme cases, these complications may further lead to conversion to abdominoperineal resection (APR) and reduce the anus-preserving rate. Robotic techniques with three-dimensional vision and flexible robotic arms can improve surgical quality in proctectomy [1–4]. Nevertheless, these conclusions are not convincing as they were primarily derived from cohort studies. Several retrospective studies have indicated that RATME can significantly reduce the need for a transanal resection approach, which may reflect its technical advantages in lower rectal cancer [5, 6]. However, few studies have discussed its advantages in the field of intersphincteric resection (ISR) and anus-preserving surgery, which may also be improved by robotic surgery, as the three-dimensional vision and flexible robotic arms have been indicated to improve surgical quality and facilitate pelvic resection in proctectomy [7, 8]. Herein, we present the protocol for a multicenter, randomized, controlled trial designed to determine the advantages of RATME in achieving ISR and preserving the anus compared to laparoscopy-assisted total mesorectal excision (LATME) in middle and low rectal cancers.

Method

Study design

This is a multicenter, prospective, superiority, double-arm, open-label, parallel, randomized controlled trial. We followed the standardized program intervention: Standard Protocol Item Recommendations for Interventional Trials (SPIRIT) [9].

Population

The target population of this study is patients with middle and low rectal cancer.

The inclusion criteria are as follows: [1] patients aged 18–90 years, diagnosed with rectal cancer by pathological biopsy; [2] no distal metastasis, as confirmed by abdominal contrast-enhanced and chest computed tomography (CT) (or positron emission tomography [PET]-CT); [3] preoperative rectal nuclear magnetic resonance (MR) results confirming that the distal margin of the tumor is below the peritoneal reflux and at least 1 cm above the intersphincteric groove; [4] tumors located above the hiatus of the levator ani muscle were evaluated by MR as cT1-3, cN0-1, M0, and MRF (-), and tumors located below the hiatus of the levator ani muscle must be evaluated by MR as cT1-2, cN0-1, M0, and MRF (-); after neoadjuvant treatment, the tumor above the hiatus of the levator ani muscle was staged ycT3NxM0 or below, and the tumor below the hiatus of the levator ani muscle was staged ycT2NxM0; and lastly, [5] the patient underwent LATME surgery or RATME surgery.

The exclusion criteria are as follows: [1] multiple primary cancers; [2] history of open surgery; [3] no preoperative MR evaluation, and/or incomplete evaluation of tumor clinical staging; [4] patients with rectal cancer who received endoscopic resection and required subsequent transabdominal resection; [5] pregnancy; [6] concomitant inflammatory bowel disease; [7] patients with preoperative complete intestinal obstruction or requiring emergency surgery; [8] preoperative evaluation indicating that the patient may require combined organ resection; [9] recently received treatment for other malignant tumors; [10] Bordeaux type IV low rectal cancer [10]; and [11] preoperative pathological results indicating pathological types as signet ring cell carcinoma, mucinous adenocarcinoma, undifferentiated carcinoma, or poorly differentiated carcinoma.

The exit criteria include [1] refusal to undergo surgical treatment after randomization; [2] open surgery was performed for treatment after randomization; and [3] patient request to withdraw from the study at any time during the entire study process after randomization.

It may take 4 years to complete the enrollment of patients. The follow-up duration will be 3 years. The duration of the entire study (including the establishment of the study, recruitment, follow-up, and data analysis) may be 7 years. The primary outcome will be analyzed after the last enrolled patient has completed a 1-month follow-up. Survival data will be analyzed after the last patient has completed the 3-year follow-up. The research will commence in the First Hospital of Jilin University in January 2024 and will soon be extended to other hospitals.

Blinding and randomization

After enrollment, the patients will be randomized into the LATME and RATME groups (Fig. 1). Stratified randomization will be performed using a computer according to the following factors: research center, sex, tumor size (> 5 cm or < 5 cm), BMI (> 28 kg/m^2 or < 28 kg/m^2), and treatment with neoadjuvant radiochemotherapy. The randomization ratio of RATME to LATME is 1:1. In this trial, allocation cannot be blinded to the researcher because the researcher completes the procedure. Similarly, patients cannot be blinded because they know the allocation when browsing medical records. In addition, patients are not necessarily blinded because blinding patients will not affect the primary outcomes. However,

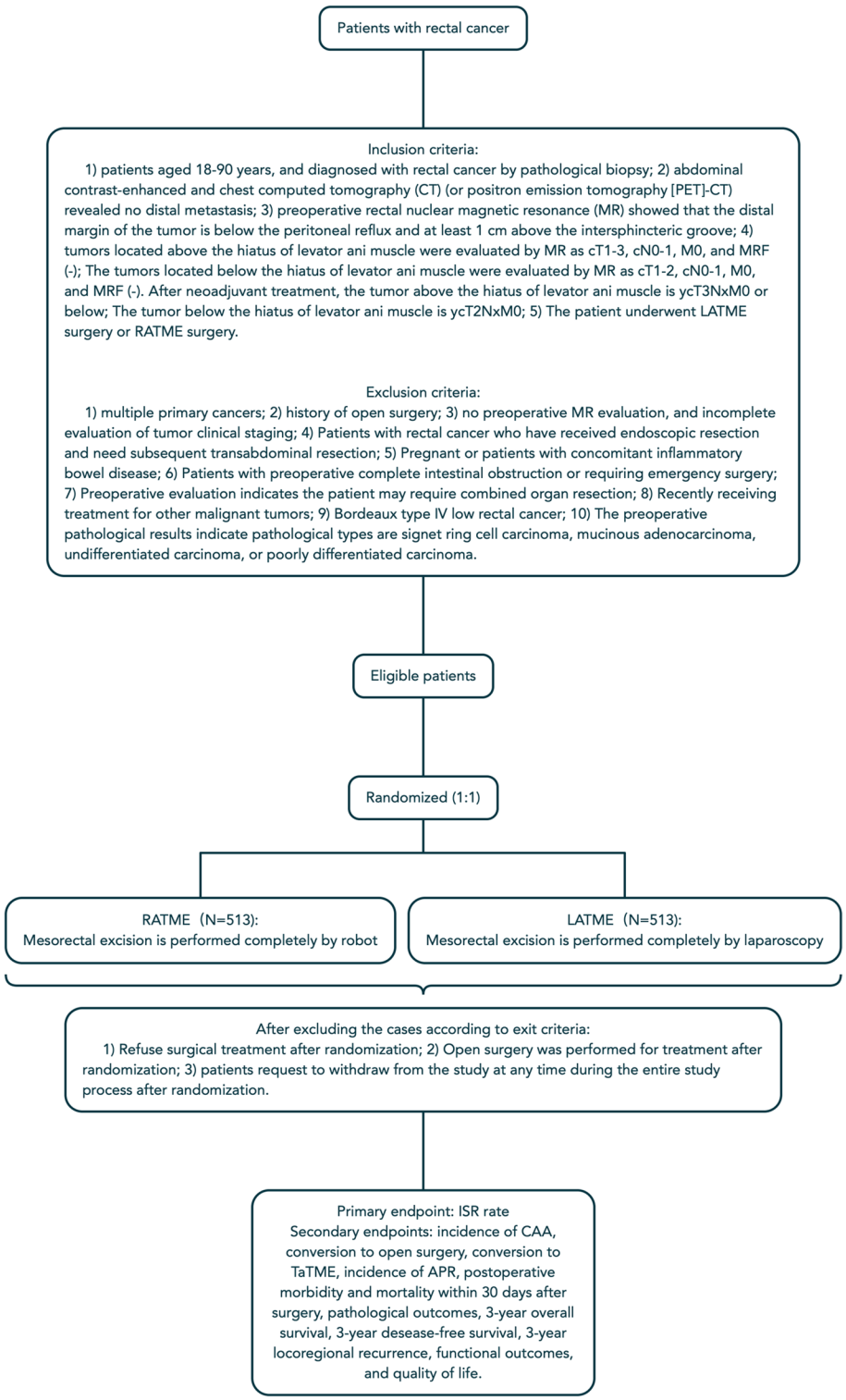

Fig. 1 Flow diagram of subject enrollment

the senior pathologists of each participating center and data analysts are blinded to the allocation.

Surgical procedure

In this study, the enrolled patients will undergo RATME or LATME. All surgeons will be required to conduct high ligation of the inferior mesenteric artery and D3 lymph node dissection. Splenic flexure mobilization should be performed if there is tension at the anastomosis site. In cases where preoperative assessment suggests the potential presence of metastasis in the lateral lymph nodes, it is recommended to include lateral lymph node dissection as part of the surgical procedure. There is no limitation on the preventive stoma and the use of transabdominal or transanal drainage tubes.

ISR will be determined by the surgeon during the operation. The location of distal resection margin needs to be recorded if it is below the hiatus of the levator ani muscle (above the dentate line, at the dentate line, between the dentate line and intersphincteric groove, or at the intersphincteric groove). Further, the subtypes of ISR will also be recorded according to the location of the distal resection margin (partial ISR at the dentate line, subtotal ISR between the dentate line and intersphincteric groove, and total ISR at the intersphincteric groove).

All mesorectal excision procedures should be completed via the transabdominal approach in both groups. If it cannot be completed according to the allocated plan, conversion to the open or transanal TME (TaTME) will be required. TaTME is performed in the presence of an imaging system and endoscopic instruments in the transanal approach. Conversion during surgery is determined according to technical reasons, adverse events, and surgical quality and safety considerations.

The above information will be recorded in CRF.

Endpoints and data collection

The primary endpoint of this study is the ISR rate. The ISR was defined according to the definition provided by a Japanese study group [11]. ISR at the intersphincteric groove is defined as total ISR; subtotal ISR is between the dentate line and intersphincteric groove; and partial ISR is at the dentate line.

Secondary outcomes included coloanal anastomosis (CAA), conversion to open surgery, conversion to TaTME, incidence of APR, postoperative morbidity and mortality within 30 days after surgery, pathological outcomes, 3-year overall survival (OS), 3-year disease-free survival (DFS), 3-year locoregional recurrence (LR), functional outcomes, and quality of life (3-year urinary function, sexual function, defecation function, and comprehensive quality of life).

Data will be collected within 2 weeks before the operation. Information on sex, age, medical history, preoperative radiotherapy or chemotherapy, laboratory test results, American Society of Anesthesiologists (ASA) status, body mass index (BMI), rectal MR results, and the pelvic meridian index will all be recorded. Operative data including operating time, lateral lymph node dissection, method of specimen extraction (via the abdomen or anus), anastomosis method (no anastomosis, circular stapler or handsewn, end-to-end or end-to-side, intracorporeal or extracorporeal), preventive stoma, and stoma site (ileum or colon) will also be recorded. Finally, postoperative data, including readmission rate within 30 days after discharge, length of postoperative hospital stay, and hospitalization cost, will be recorded as well. This trial will also grade the difficulty of surgery according to the grading scale in Table 1. A grade below 6 indicates a low risk of surgical difficulty, whereas a grade of ≥ 6 indicates a high risk of difficulty [12]. In addition, surgeons are instructed to complete the Surgery Task Load Index. This index comprises six subscales addressing mental, physical, and temporal demands, task complexity, situation, and distractions. All questions are rated on a 20-point scale (0 = low, 20 = high) [13].

Definitions and grades

CAA was defined as an anastomosis of the distal colon and surgical anal canal; in CAA, the distal resection margin is located below the hiatus of the levator ani muscle. Conversion to open surgery is defined as an abdominal incision larger than necessary for specimen retrieval extraction. Conversion to TaTME is defined as a TME that could not be completed via the transabdominal approach and had to instead be completed by a transanal approach with the help of an imaging system and endoscopic instruments. It should be noted that if the TME is completely performed via the transabdominal approach, simply dissecting the internal sphincter and intersphincteric space or finishing the coloanal anastomosis via the transanal approach will not be classified as TaTME.

The pathological outcomes included macroscopic completeness of resection, CRM positivity rate, distal

Table 1 Grading scale for surgical difficulty

Items	Points
Duration of surgery > 300 min	3
Conversion to open procedure	3
Use of transanal dissection	2
Postoperative hospital stay > 15 days	2
Blood loss > 200 ml	1
Morbidity (grade II and III)	1

resection margin (DRM) positivity rate, tumor volume, number of lymph nodes, and pathological TNM stage. The macroscopic completeness of resection is classified into complete, nearly complete, and incomplete, following the standard of Nagtegaal et al. [14]. CRM will also be evaluated according to previously reported methods [15]. CRM positivity is defined as tumor cells within 1 mm from the CRM by microscopy. The distance to the CRM is defined as the shortest distance between the tumor and CRM. The distance to the DRM is defined as the shortest length between the tumor and the DRM. DRM positivity is defined as a distal margin within 1 mm of the tumor. Tumor volume was evaluated according to the pathological report and calculated by multiplying the length, width, and thickness of the tumor following formalin fixation. The pathological TNM classification was determined according to the American Joint Committee on Cancer (AJCC) Cancer Staging Manual, 8th edition.

The operating time is defined as the time from cutting to suturing the skin, or finishing the enterostomy. The definition for 30-day morbidity is intraoperative adverse events and postoperative complications within 30 days. Possible intraoperative adverse events include intraoperative bleeding (> 200 ml), pelvic vascular and nerve injury, vascular injury in other parts, digestive tract injury, ureteral injury, and anastomotic defects. Pelvic vascular nerve injury is defined as bleeding during dissection of the vascular nerve bundle that requires energy instruments to halt the bleeding. Vascular injury in other parts is defined as rupture and active bleeding of the branches of the inferior mesenteric artery, inferior mesenteric vein, genitourinary vessels, or iliac vessels. Digestive tract injury is defined as damage to at least the serous layer of the intestine. In addition, ureteral injury is defined as damage to the ureteral smooth muscle layer that requires suturing or implantation of a ureteral stent. Anastomotic defects are defined as incomplete anastomosis rings. Furthermore, the 30-day postoperative complications will be evaluated according to the Clavien–Dindo classification [16]. DFS is defined as the time from randomization to the discovery of locoregional recurrence, distant metastasis, or death. LR is defined as tumor recurrence (assessed by PET-CT, enhanced CT, or MRI) at the surgical site and confirmed by pathological biopsy or surgery. Distant metastasis refers to metastasis in the lung, liver, bone, or other regions outside the surgical site, confirmed using enhanced CT, MRI, or PET-CT. OS is defined as the time from randomization to death for any reason.

Postoperative treatment

Postoperative treatment will be performed according to the treatment plans in different medical centers. Postoperative adjuvant chemotherapy will be determined by pathological results and follows the National Comprehensive Cancer Network guidelines for rectal cancer.

Follow-up

The total follow-up duration has been set at 3 years, and the follow-up time must comply with the guidelines in Table 2. The measures to assess at follow-up include CA19-9, CEA, CT, magnetic resonance imaging (MRI), colonoscopy, or radionuclide scanning. For patients with LR or distant metastasis, follow-up should last at least 3 years after recurrence or until death.

The 30-day postoperative complications will be evaluated by daily ward rounds, outpatient services, telephone calls, or questionnaires. Mortality and complications of Clavien–Dindo grade III or higher will be included in the analysis. Postoperative complications to be included for analysis in the statistics are intra-abdominal hemorrhage, gastrointestinal bleeding, anastomotic leakage, chylous fistula, surgical site infection, intra-abdominal infections, wound infection, intestinal obstruction, postoperative diarrhea, pulmonary infection, urinary tract infection, cardiovascular accident, cerebral vascular accident, and thrombotic disease.

Questionnaires will be administered to the patients at 1, 3, 6, 12, 24, and 36 months postoperatively. All urinary (International Consultation on Incontinence Questionnaire—Short Form and one prostate function), sexual (International Index of Erectile Function-5), and defecation functions (Low Anterior Resection Syndrome score) will be evaluated.

Quality assurance

Qualifications of the research center: All surgeons must have performed a minimum of 30 LATME and 30 RATME procedures for rectal cancer annually. The Trial Steering Group (TSG) will evaluate unedited videos of six consecutive cases (three LATME and three RATME) before a surgeon can participate in the trial. Surgeons meeting these surgical quality criteria will be eligible for the trial, with evaluation conducted using the Delphi method.

Photos of the surgical site and specimen: the photo of distal resection line in ISR will be needed. After completing anterior rectal resection and lymph node dissection, the surgeons will also need to take photos of the surgical site, including the pelvis and root of the inferior mesenteric artery. Surgeons should also obtain photographs of the specimens (anterior and posterior sides of the mesorectum, proximal and distal margins before formalin fixation). The quality of mesenteric excision will be evaluated by senior pathologists in each center as complete, nearly complete, or incomplete. Pathologists will be blinded

Table 2 Schedule of enrollment, invervention, and assessments

	Study period										
	Enrollment	**Allocation**	**Post-allocation**								
Timepoint Items	—2 weeks	0	Surgery	1 month	3 months	6 months	12 months	18 months	24 months	30 months	36 months
Enrollment:											
Eligibility screen	X										
Informed consent	X										
Allocation		X									
Interventions:											
RATME			X								
LATME			X								
Assessments:											
ISR			X								
Operative data [a]			X								
Pathological data [b]			X								
Morbidity and mortality [c]				X							
Postoperative function [d]				X	X	X	X		X		X
Survival data [e]				X	X	X	X	X	X	X	X

[a] Operative data includes CAA, APR, conversion to open, conversion to TaTME, and grading for surgical difficult

[b] Pathological data includes CRM positivity, DRM positivity, CRM distance, DRM distance, tumor volume, pT stage, pN stage, pTNM stage, number of harvested lymph nodes, number of metastatic lymph nodes

[c] Morbidity and mortality includes complications and death within 30 days after operation

[d] Postoperative function includes urinary function, sexual function, defecation function, and comprehensive quality of life

[e] Survival data includes 3-year overall survival , 3-year desease-free survival, and 3-year locoregional recurrence

to the allocation. In addition, the medical center must record the reasons for not retaining the above photos. Participating centers are required to retain surgical videos for each operation. These videos and photos will be reviewed by the Trial Steering Group (TSG) to assess the acceptability of surgical quality and conversions.

Participating centers

Five tertiary medical centers will participate in this study. These medical centers are the First Hospital of Jilin University, Jilin Provincial Tumor Hospital, Daping Hospital and the Research Institute of Surgery of the Third Military Medical University, the Second Affiliated Hospital of Dalian Medical University, and the Tumor Hospital of Harbin Medical University. Other medical centers will join the study in the future. The coordinating centers will be responsible for enrolling eligible patients and administering the assigned interventions. Additionally, they will assist in collecting perioperative data, uploading this data to the database, and collaborating with and supporting the work of the Project Management Group (PMG) and the TSG.

Project audit

The PMG comprises the principal investigator, project manager, statisticians, and other key team members responsible for the day-to-day oversight of the trial. Each coordinating center must have at least one representative in the PMG. The PMG convenes bi-monthly to assess trial progress, address emerging issues, and ensure strict adherence to the trial protocol.

The TSG includes the trial sponsor, colorectal surgery experts, methodologists, and patient representatives. Tasked with providing comprehensive supervision, the TSG ensures that the trial adheres to high standards of clinical practice.

The Data and Safety Monitoring Board (DSMB), composed of senior colorectal surgeons, ethicists, and statisticians, functions independently to monitor trial safety and efficacy. The DSMB conducts periodic reviews of interim data and offers recommendations on whether to continue, modify, or terminate the trial.

Both the TSG and DSMB are established before the trial commences and convene regularly, including a pre-study meeting and biannual gatherings during the trial. Given the established efficacy of LATME and RATME in rectal cancer surgery, there are no predefined termination parameters for the overall project, and interim analyses are not included in the study protocol.

The DSMB evaluates the trial's safety and quality, considering adverse events, pathological outcomes, and participant attrition. Medical centers exceeding specified thresholds—for instance, postoperative morbidity and mortality rates above 50%, incomplete mesorectal resection rates over 10%, or dropout rates exceeding 20%—will undergo scrutiny by the DSMB. In cases where satisfactory justifications are not provided by the principal investigator, the DSMB may recommend to the TSG the cessation of further enrollment at the implicated medical center.

Sample size calculation

This study is a superiority trial. The sample size calculation is based on the ISR rate. According to previous reports and data from our center [17, 18], the ISR rates of the control (LATME) and intervention groups (RATME) are estimated as 5% and 10%, respectively. The superiority margin ratio between the intervention and control groups is set to 1.02. The patients will be randomly assigned to the LATME and RATME groups in a 1:1 ratio. Thus, with a significance level of 2.5%, a one-sided test, and 80% power calculated using the PASS 15 software, 461 people in the control group and 461 in the intervention group will be required. Assuming a dropout rate of 10%, an estimated 513 people are needed in each group.

Statistical analysis

Continuous variables will be described as the mean ± SD or median (Q1, Q3). The classification data will be presented as *N* (%). The analysis of primary outcomes will be conducted based on the mITT. In mITT analysis, patients will be analyzed according to their allocation plan after randomization, even if they undergo the other treatment. However, patients who meet the exit criteria after randomization will be excluded from the mITT analysis. In addition, this study will conduct the as-treated analysis (ATA). In ATA, the analysis is carried out according to the treatment received by the patients. All hypothesis tests are bilateral, with a significance level of 5%.

In analyzing primary and secondary outcomes, we will compare the risk differences between the two groups before and after adjustment. Logistic regression will be used to adjust for factors affecting the ISR rate (medical center, sex, T stage, BMI, tumor height, and preoperative concurrent chemoradiotherapy). The locoregional recurrence rate, DFS, and OS within 3 years will be compared using the log-rank test and Kaplan–Meier curve. Exploratory analysis of the prognostic effects of various baseline factors on DFS and OS will be performed using multivariate Cox regression. We will further consider using sensitivity analysis to explain the impact of missing data on the overall results. We will also conduct a subgroup analysis to explore surgical results in different situations. Subgroups will be set according to medical center, sex,

age, ASA, T stage, BMI, tumor height, and preoperative concurrent chemoradiotherapy.

Data management and missing data

Data storage and backup will be managed in the secure online database, which will track all changes to the data and retain a history for each variable. Data will be encoded to protect patient privacy. All data will be entered by trained research assistants. Double data entry will be adopted to ensure accuracy. Discrepancies and missing data will be reported back to participating centers to be clarified by the local investigator.

Ethics and dissemination

This trial has been approved by the Ethics Review Committee of the First Hospital of Jilin University (23K163-001). Protocol modifications will be reviewed by the Ethics Review Committee and communicated to all participating centers. Further, the trial has been registered on ClinicalTrials.gov website, NCT06105203. This trial follows the principles of the Declaration of Helsinki. All eligible patients will be informed of the study's purpose, procedures, potential benefits, and risks. Informed consent will be obtained by the principal investigator or their sub-investigators.

We will analyze the primary outcomes and write an initial paper after a 1-month follow-up of the last enrolled patients. Subsequent studies will be completed after the 3-year follow-up period. The findings will be presented internally at scientific conferences. The feasibility results are intended for publication in journals. People who have made significant contributions to this trial will be listed as co-authors.

Protocol amendments

In the case of substantial protocol amendments, the TSG will communicate these changes to the sponsor and funder and inform the relevant medical centers. A revised protocol copy will be provided to the PI for inclusion in the Investigator Site File. Any departures from the protocol will be diligently recorded using a breach report form. Additionally, the protocol will be swiftly revised in the clinical trial registry to ensure transparency and accuracy in trial documentation.

Patient and public involvement

While there is no public or patient involvement in the trial's design, the TSG will incorporate two patient representatives. One patient representative has undergone RATME procedure, while the other has experienced LATME procedure. Their valuable perspectives as individuals with firsthand experience will enrich the TSG's discussions and decision-making processes related to the trial.

Confidentiality

Participants will be assigned a unique code to ensure that the participants' anonymity is maintained. Documents containing personal information will be stored separately from assessment data in locked cabinets. Nobody except for the principal investigator (PI) and authorized research assistants will have access to the dataset, unless there is an institutional or regulatory requirement. The fully anonymized experimental data will be stored on secure servers of the Jilin University First Hospital and will be preserved for at least 5 years after study close-out.

Discussion

A significant number of prior studies have been conducted to compare RATME and LATME [1, 2, 19]. In terms of specimen quality and positive CRM rate, most studies indicate that RATME is not inferior to LATME. Furthermore, there is evidence to indicate that RATME may be associated with a lower conversion rate compared with LATME [18]. However, few studies have discussed its advantages in the field of ISR and anus-preserving surgery, which may also be improved by robotic surgery, as the three-dimensional vision and flexible robotic arms have been indicated to improve surgical quality in proctectomy [7, 8]. The REAL study previously compared RATME and LATME and found that the proportion of abdominal perineal resection was lower in the RATME group, implying that the RATME may increase the ISR resection rate, thereby increasing the anus preservation rate [17]. However, the REAL study primarily concerned 3-year locoregional recurrence. As a result, its findings on ISR should be interpreted carefully.

The primary endpoint in this study was the ISR rate. We defined ISR clearly in this study based on a prior Japanese study [20]. To minimize misunderstanding, our study will explicitly distinguish between ISR and CAA. CAA is defined as an anastomosis of the distal colon and surgical anal canal. In CAA anastomosis, the resection line of the distal margin is located in the surgical anal canal, below the upper level of the levator ani muscle. In ISR, the resection line of the distal margin is in the anatomical canal from the dentate line to the intersphincteric groove; thus, ISR was included in the CAA. The distal resection line above the dentate line will be characterized as CAA rather than partial ISR.

Our study eliminates the clinical T4 rectal cancer above the hiatus of the levator ani muscle and clinical T3/4 rectal cancer under the hiatus of the levator ani muscle. Cases in which an external anal sphincter or levator ani muscle invasion is suspected will be excluded.

Furthermore, preoperative pathological classification of signet ring cell carcinoma, mucinous adenocarcinoma, undifferentiated carcinoma, or poorly differentiated carcinoma will also be excluded. This is because ISR may not achieve R0 resection and may be associated with higher risk of locoregional recurrence in these cases; as such, APR should be performed [21, 22]. As the aim of this study is to determine the advantages of RATME over LATME in terms of obtaining ISR and preserving the anus, we eliminated the cases in which APR was preferable. This experiment did not provide a clear quantitative criterion for the maximal tumor height to the anus due to variances in patient height and pelvic size. Instead, the distal margin of the tumor must be below the peritoneal reflux. This is significant in clinical practice. We believe that the outcomes of this trial will clarify if the RATME improves ISR and promotes preservation of the anus in patients with mid- and low-rectal cancer.

Trial status

The present study protocol version number is v1.1.1 and was written on July 27, 2023. Recruitment has not yet begun. The recruitment will begin in January 2024 and will be completed in January 2028.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-024-08561-4.

Additional file 1: SPIRIT checklist for Trials.

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Authors' contributions
Yuchen Guo and Quan Wang designed the study; Yuchen Guo and Liang He wrote the initial trial protocol and drafted the manuscript. Quan Wang, Weidong Tong, Zhaocheng Chi, Shuangyi Ren, and Binbin Cui are principal investigators and revised the manuscript. Yuchen Guo and Liang He acted as trial managers and were involved in data collection. All authors have read and approved the final manuscript.

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Data availability
Not applicable.

Declarations

Ethics approval and consent to participate
This trial has been approved by the Ethics Review Committee of the First Hospital of Jilin University (23K163-001). Informed consent will be obtained from patients before enrollment.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no completing interests.

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