

BMJ Open Effect of intermittent urethral catheter clamping combined with active urination training (ICCAUT) strategy on postoperative urinary dysfunction after radical rectal cancer surgery: single-centre randomised controlled trial (ICCAUT -1) study protocol

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ABSTRACT

Background Urinary catheter placement is routinely performed after proctectomy. However, there is uncertainty regarding the need for bladder training before catheter removal. This trial aims to examine the effect of intermittent catheter clamping combined with active urination training (ICCAUT) on urinary retention and secondary catheterisation after proctectomy.

Methods and analysis Eligible patients will be randomly assigned in a 1:1 ratio to either the ICCAUT group or the free-drainage (FD) group. In the ICCAUT group, patients will undergo intermittent clamping of the urinary catheter combined with active urination training before its removal, whereas the patients in the FD group will not receive any specific training. The urinary catheter will be removed on postoperative day 2 in both groups after emptying the bladder. The primary end point is the incidence of urinary tract infection. Secondary end points include urinary tract infection, time to first urination after catheter removal, catheter-related bladder discomfort syndrome, postoperative morbidity and mortality and urinary function within 30 days.

Ethics and dissemination This trial was approved by the Ethics Review Committee of the First Hospital of Jilin University (24K047-001). Written informed consent will be obtained before performing any study procedures. All primary and secondary outcomes will be reported in peer-reviewed publications and at conference presentations.

Trial registration number The trial was registered at ClinicalTrials.gov website, [NCT06241703](https://clinicaltrials.gov/ct2/show/study/NCT06241703).

BACKGROUND

Urinary catheterisation is a common procedure in gastrointestinal surgery. In upper gastrointestinal surgery, where there is no surgical manipulation of the pelvic organs, the catheter is typically removed within 2 days after surgery and urinary retention is

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study proposed a new urinary catheter management strategy called intermittent catheter clamping combined with active urination training (ICCAUT) strategy, which combines intermittent catheterisation clamp with active urination training.
- ⇒ This study aims to investigate the effectiveness of the ICCAUT strategy in addressing urinary retention following proctectomy.
- ⇒ This study is designed as a randomised controlled trial.
- ⇒ The study's applicability to different surgical contexts or broader populations may be constrained by its single-centre design and focused patient selection criteria.
- ⇒ We set the indwelling time of urinary catheters at 48 hours to reduce the potential impact on urinary function. This differs somewhat from the recommendation in the ERAS (Enhanced Recovery After Surgery) guideline for upper rectal resection. However, it is necessary to control the bias and evaluate the effectiveness of the ICCAUT strategy.

rarely observed. However, in rectal surgery, the root of the inferior mesenteric artery is divided to clear the third-station lymph nodes, and the mesorectum is divided from the pelvic cavity. During this process, there is a possibility of damage to the superior hypogastric and pelvic plexuses. Injury to these nerves, along with other potential factors during the perioperative period, leads to an increased incidence of postoperative urinary retention and the need for secondary catheterisation.^{1 2} Therefore,

reducing postoperative urinary retention and the rate of secondary catheterisation are important clinical concerns.

Bladder training^{3–6} is one of the most commonly used methods to reduce urinary retention in clinical practice. A clinical study conducted by Williamson in 1982 found that intermittent clamping of the catheter before its removal potentially shortened the time required for recovery of bladder function in patients.⁷ During this procedure, the catheter was clamped, and after 3 hours, it was opened to allow urine to drain through the catheter. This process was repeated several times. Bladder training is widely used in various departments of clinical practice. Current research has confirmed that bladder training can be used as a treatment for bladder overactivity, to reduce urinary frequency and to relieve urinary incontinence.^{8–10} However, the effectiveness of bladder training in reducing postoperative urinary retention remains controversial.

A recent systematic review published in Cochrane suggested that compared with direct catheter removal, bladder training by intermittent clamping of the catheter may not effectively reduce the rate of secondary catheterisation in patients.¹¹ However, there are a limited number of randomised controlled trials (RCTs) on bladder training using intermittent catheter clamping. The quality of these RCTs is inconsistent, with issues such as insufficient sample size calculation, inadequate controls for confounding factors and low statistical power of the study design, raising concerns about the quality and credibility of the research and making it difficult to obtain reliable clinical evidence.^{12–15}

In actual clinical practice, especially for patients undergoing lower rectal surgery, many centres still perform bladder training through intermittent catheter clamping to reduce the incidence of urinary retention and the rate of secondary catheterisation. As stated by Muge *et al* in 2020, more research is required to determine the impact of postoperative bladder training on urinary retention.¹⁶ To add high-quality evidence in this field, we design two RCTs—the ICCAUT-1 trial and the ICCAUT-2 trial. We aim to investigate the effect of intermittent catheter clamping combined with active urination training, which we call the ICCAUT strategy, on postoperative urinary dysfunction (ICCAUT-1 trial) and secondary catheterisation (ICCAUT-2 trial). Here, we introduce the ICCAUT-1 trial, which aims to investigate the effect of the ICCAUT strategy on urinary dysfunction after minimally invasive rectal surgery.

METHODS

Study design

This is a single-centre, prospective, two-arm, parallel-group, randomised controlled study. We will follow the standardised programme intervention Standard Protocol Item Recommendations for Interventional Trials.¹⁷

Objective

The primary objective of this study is to investigate the impact of the ICCAUT strategy, which comprises intermittent catheter clamping and active urination training, on urinary dysfunction in patients undergoing laparoscopic or robot-assisted proctectomy. The secondary objective of this study is to investigate whether the ICCAUT strategy is associated with an increased risk of postoperative urinary tract infection.

Setting and population

The patients will be recruited from the Department of Gastrocolorectal Surgery, General Surgery Center of the First Hospital of Jilin University, located in Changchun, Jilin Province, China.

Study participants will be patients with rectal cancer who require low anterior resection (LAR) or abdominoperineal resection (APR).

Inclusion criteria

1. Patients with a confirmed preoperative diagnosis of rectal cancer.
2. Patients with tumours located below the rectosigmoid junction, as determined by preoperative CT or rectal MRI.
3. Patients undergoing laparoscopic or robotic-assisted LAR or APR for rectal cancer.

Exclusion criteria

1. History of abdominal surgery involving the rectum, sigmoid colon, left hemicolectomy, bladder resection or partial resection, prostate surgery or hysterectomy.
2. History of urethral injury, cranial surgery, spinal surgery, stroke with limb dysfunction or Parkinson's disease.
3. Inability to urinate through the urethra preoperatively due to various reasons (eg, ureteral puncture or ureterostomy).
4. Presence of urinary tract infection preoperatively.
5. Previously diagnosed with bladder overactivity syndrome, urinary retention or voiding dysfunction or diabetic bladder disease.
6. Concomitant resection of other pelvic organs was performed during surgery, including the bladder, prostate, uterus, cervix and vagina, except for simple adnexal resection.
7. Lateral lymph node dissection for rectal cancer.
8. Injury to the ureter, bladder or urethra during the perioperative period.
9. Preoperative renal dysfunction (serum creatinine level >133 µmol/L).
10. Emergency surgery.
11. Male patients with preoperative benign prostatic hyperplasia receive medication treatment.
12. Patients with a ureteral stent or ureteral stricture, or bilateral hydronephrosis.
13. Conversion to open surgery.

Withdrawal criteria

After randomisation, patients will be withdrawn from the trial if the following situations occur:

1. Inability to remove the urinary catheter within 5 days postoperatively due to various reasons (eg, impaired consciousness, transfer to the intensive care unit, Sequential Organ Failure Assessment score ≥ 2).
2. Secondary catheterisation was performed for reasons other than urinary retention (eg, secondary surgery, shock, rectal bladder leakage, ureteral leakage or urethral injury).
3. Patient requests to withdraw from the study at any time during the entire study process.
4. Selective $\alpha 1$ -adrenergic receptor blocker is used during the first catheterisation of the patient due to medical necessity.

Randomisation and blinding

Patients who meet the inclusion criteria will be randomly assigned to the ICCAUT group or the FD group (figure 1). Stratified randomisation will be performed based on the following two factors: (1) sex and (2) whether APR was performed. The allocation ratio of the ICCAUT and FD group will be 1:1. Randomisation will take place between 06:00 and 07:00 on the first day after the patient's surgery, before the intervention. The randomisation information will be placed in sealed envelopes and assigned to the bedside nurses before 08:00 on the first postoperative day, and bedside nurses will conduct the intervention.

In the present study, patients and bedside nurses cannot be blinded, but physicians, medical ultrasound doctors and outcomes assessors were masked to study group assignment. Patients and bedside nurses kept the group assignments confidential from the physicians and the medical ultrasound doctor. Unblinding will occur when the urinary catheter is removed for 7 days, and any instances of premature blinding will be recorded.

Intervention and procedure

The time frame of enrolment, intervention and outcome assessment is listed in table 1. On the morning of the first postoperative day, at 09:00, the nurses will perform the designated intervention procedures for the two groups of patients based on randomisation envelopes. Before the intervention, nurses will have assessed the patient's discomfort using a Catheter-Related Bladder Discomfort (CRBD) questionnaire.^{18 19} Patients in both groups will be instructed not to use selective $\alpha 1$ -adrenergic receptor blockers (such as tamsulosin) during their initial catheterisation period.

The ICCAUT strategy includes intermittent urethral catheter clamping and active urination training. For patients in the ICCAUT group, intermittent catheter clamping will be initiated at 09:00 on the first postoperative day. The catheter will be clamped for 3 hours, followed by a 5-min release, which is one cycle. Each time the catheter is released, we will encourage the patients to actively initiate urination to facilitate complete bladder

emptying. The next cycle will begin after the cycle is completed. Catheter training is to conclude at 22:00 on the first postoperative day, and the catheter is left open during the night. At 06:00 on the second postoperative day, another cycle of training will be performed, with the catheter removed at 09:00 after the bladder is empty. During the training period, if the patient experiences a strong urge to urinate before the 3-hour clamping time is over, the clamping can be released in advance for 5 min, allowing the patient to proceed to the next cycle of bladder training.

For patients in the free draining group, no intervention will be performed on the catheter during this period. The catheter will be removed at 09:00 on postoperative day two.

Before the catheter is removed in both groups on the second postoperative day, nurses will perform another assessment of CRBD using a questionnaire and collected urine samples for urinalysis and urine culture. Additionally, patients in the ICCAUT group will be required to complete a self-assessment form regarding the quality of bladder training prior to the first catheter removal. The catheter will be removed in both groups after the bladder is empty. After catheter removal, the time to the first void after catheter removal and the volume of the first voided urine will be recorded for both groups.

Immediately after the first void, a bladder ultrasound will be performed to assess the residual volume of urine by a designated ultrasound physician. After catheter removal, the need for secondary catheterisation will be observed in the following 7 days. For patients requiring secondary catheterisation, the time to the second catheterisation after catheter removal, the volume of urine drained during the second catheterisation, the catheterisation method and the reasons for the second catheterisation will be documented.

The International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) score and International Prostate Symptom Score (IPSS) (excluding patients who undergo secondary catheterisation) will be recorded before the operation and on the second day after the first catheter removal for both groups. Furthermore, any complications occurring within 30 days after surgery and the Clavien-Dindo classification were documented.

Staff nurses are strictly trained to follow the study protocol. Patients are fully informed and instructed to meet the study requirements. Any interventions that deviate from the research protocol will be recorded and addressed in the per-protocol (PP) analysis set and the as-treated (AT) analysis set.

End points and definitions

The primary end point of this study is a composite end point. It consists of incomplete bladder emptying after the first voiding following catheter removal or the need for secondary catheterisation due to urinary retention. In this study, we define this composite end point as urinary dysfunction for convenience.

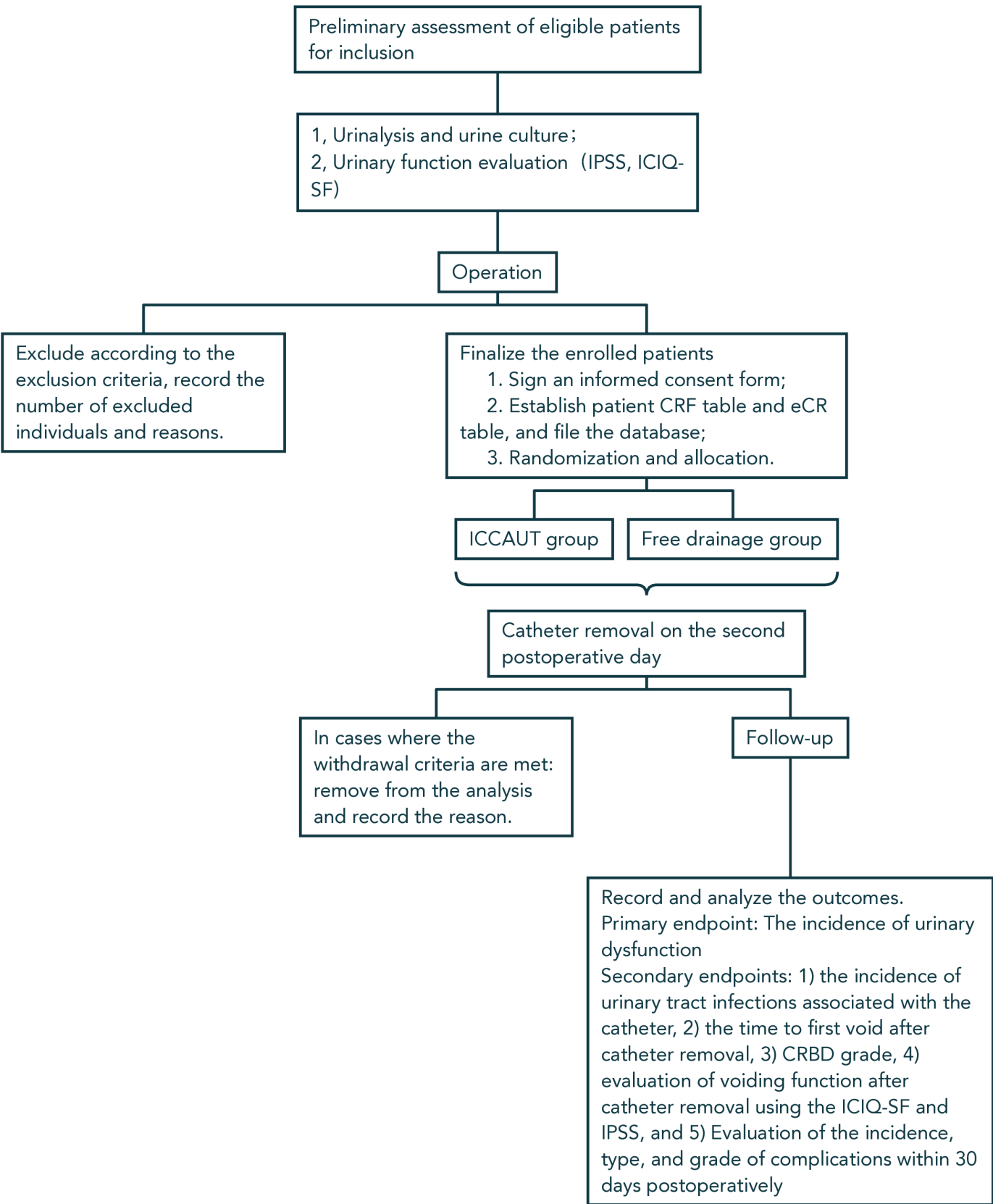


Figure 1 Inclusion flow diagram for study participants. CRBD, Catheter-Related Bladder Discomfort; ICCAUT, intermittent catheter clamping combined with active urination training; ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form; IPSS, International Prostate Symptom Score; CRF, case report form; eCR, electronic case report.

Table 1 Enrolment, intervention and outcome assessment

Items	Study period				
	Enrolment	Time points	Enrolment	Operation and randomisation	Post-randomisation
	-1 week	0	Before catheter removal	After catheter removal	1 month
Enrolment:					
Eligibility screening	X	X			
Informed consent	X	X			
Data collection					
Allocation					
Interventions:					
ICCAUT			X		
Free drainage			X		
Assessments:					
Secondary catheterisation				X	
Data on catheter removal				X	
Catheter-related bladder discomfort			X		
Self-assessment form on the quality of bladder training			X		
Urinalysis and urine culture	X		X		
Urinary function	X			X	
Morbidity and mortality				X	
ICCAUT, intermittent catheter clamping combined with active urination training.					

Incomplete bladder emptying is defined as a bladder residual urine volume greater than 100 mL after the first voiding.^{20–24} The bladder residual urine volume after the first voiding will be estimated immediately by bladder ultrasound using the formula: Bladder volume = anterior-posterior diameter × superior-inferior diameter × left-right diameter × 0.52.

The criteria for determining the need for secondary catheterisation due to difficulty voiding are as follows: (1) If a patient is unable to void within 10 hours after catheter removal, percussion indicates that the upper border of the bladder is above the pubic bone, and bedside bladder ultrasound estimates a residual bladder volume greater than 200 mL or (2) although the patient can void after catheter removal, they continue to feel lower abdominal distension after multiple voiding episodes. Percussion shows that the upper border of the bladder is above the pubic bone after voiding, and bedside bladder ultrasound estimates a residual bladder volume greater than 200 mL.

In the assessment of the primary end point, if a patient undergoes secondary catheterisation and does not meet the withdrawal criteria, but the urine output after the secondary catheterisation is less than 100 mL, such patients will not be classified as having urinary dysfunction. They will be included in the modified intention-to-treat population but will not be considered as meeting the primary end point.

The secondary end points of this study are as follows: (1) the incidence of urinary tract infections associated with the catheter, (2) the time to first void after catheter removal, (3) CRBD grade, (4) evaluation of voiding function after catheter removal using the ICIQ-SF and IPSS, (5) evaluation of the incidence, type and grade of complications within 30 days postoperatively and (6) incidence rate of residual urine volume greater than 200 mL after the first voiding.

To diagnose a urinary tract infection, the following criteria must be met simultaneously: (1) urinalysis indicating a bacterial count above the upper limit of normal and (2) positive urine culture (growth of one or two uropathogens at $\geq 10^5$ colony-forming units per millilitre, and except for contaminants, ie, α -haemolytic streptococci, *Lactobacillus* sp, *Corynebacteria*, *Gardnerella* sp or coagulase-negative staphylococci).^{25 26}

The time to first voiding after catheter removal refers to the duration, measured in hours, from the moment the catheter was removed until the patient spontaneously voids for the first time.

Complications that occur within 30 days after the operation will be evaluated and documented according to the Clavien-Dindo classification.²⁷ Complications of grade II or higher were analysed. These complications cover a variety of possibilities, including, but not limited to, intra-abdominal bleeding, gastrointestinal bleeding, anastomotic leakage, chyle leakage, surgical site infections, intestinal obstruction, postoperative diarrhoea, pulmonary infection, urinary tract infection, cardiovascular events, cerebrovascular events and thrombotic events.

Follow-up

On discharge, the patients will be scheduled for a follow-up visit 1 month after surgery. During this visit, the doctor collects information about any complications that occur within the first month after surgery, noting their respective Clavien–Dindo grades. Additionally, IPSS and ICIQ-SF scores will be assessed to evaluate the patient's voiding function at the 1 month mark after surgery. During the 30-day follow-up period, observations will be made through hospital monitoring, outpatient visits, phone calls and questionnaires.

Data and safety monitoring

This study established a Data and Safety Monitoring Board (DSMB) that comprises experienced surgeons, ethicists and statistical analysts. The members of the DSMB are independent of the trial and have no competing interests that could influence the study. Their primary role will be to receive and review safety data from the trial.

The DSMB will closely monitor the occurrence of adverse events and assess any potential bias in their distribution among the different groups. They will conduct regular evaluations, typically every 6 months after the study begins, and may also convene for interim evaluations if necessary. These evaluations encompass various aspects, including recording primary and secondary end points, adverse events and participant dropout rates.

To maintain confidentiality, DSMB members are strictly prohibited from sharing sensitive information outside the DSMB except with the Trial Steering Committee (TSC). This will ensure the integrity and security of the data and will protect the privacy of the participants.

Although the study does not have predefined stopping parameters for the entire project, the DSMB will have a crucial role in evaluating urological safety indicators associated with the intervention methods. If the DSMB identifies significant deviations from current national standards in terms of urological safety during regular evaluations, it will provide written recommendations to the TSC. These recommendations may include proposed modifications to the trial protocol, re-evaluation of case quality or even temporarily suspending or terminating the enrolment of participants in the clinical trial.

Sample size calculation

This trial determined the sample size based on the post-operative urinary dysfunction rate. The estimated rate in the FD group was approximately 59.3% based on the current literature and data from our centre. By contrast, the ICCAUT group was estimated to have a urinary dysfunction rate of approximately 44.7%.²⁸

To achieve a balanced comparison, patients were randomly assigned to two groups in a 1:1 ratio. α was set at 0.05, and the power ($1-\beta$) was set at 80%. Using PASS 15 software for the calculation, a sample size of 180 patients was required for both groups. Considering a potential dropout rate of 10%, the final sample size needed was 200 patients in both the ICCAUT and FD group.

Statistical analysis

A primary outcome comparison analysis will be conducted based on the 'modified intention-to-treat (mITT)' population. The mITT analysis will include patients who were not treated according to the randomisation measures but were not excluded based on the withdrawal criteria. If a patient meets the withdrawal criteria after randomisation, they will be excluded, and their data will not be included in the statistical analysis. In the mITT analysis, patients randomised to the ICCAUT group who did not receive ICCAUT strategy will still be analysed as part of the ICCAUT group. Similarly, patients randomised to the FD group who received bladder training will still be analysed as part of the FD group. Cases whose drained urine volume is <100 mL after re-catheterisation will not be considered as meeting the primary end point and will not be classified as positive events. In this situation, these cases will be included in the analysis as negative events.

This study will also perform a PP analysis and an AT analysis. In the PP analysis, only those cases that strictly adhere to the assigned treatment protocols and randomisation will be included in the analysis. Patients who did not receive treatment according to the randomly assigned protocol will be excluded from the PP analysis. Patients who did not undergo catheter removal on the second postoperative day and those who did not strictly undergo bladder training as planned will also be excluded from the PP analysis. In the AT analysis, patients will be analysed based on the treatment they actually receive rather than the treatment assigned by randomisation. In the AT analysis, patients who received at least one round of ICCAUT will be classified into the ICCAUT group, whereas those who did not receive training were classified into the FD group.

Categorical variables will be summarised using counts and percentages for the analysis of primary end points. The primary end points between the two groups will be compared without multivariate adjustment. Relative risk and 95% CI will be used to describe the differences between groups. In addition, logistic regression will be used to adjust for potential factors that can influence urinary dysfunction, such as tumour height, body mass index (BMI), age and operating time. Adjusted differences between groups will be described using odds ratios (ORs) and 95% CI.

In the analysis of secondary end points, continuous variables will be described using mean \pm SD or median (IQR), while categorical variables will be presented as counts and percentages. A sensitivity analysis will be performed to assess the impact of missing data on the overall results.

Subgroup analyses will explore differences in urinary dysfunction rates between the two groups within different subgroups. Subgroups will be stratified by sex (male; female), age (≤ 65 years; >65 years), ASA classification (\leq II; \geq III), BMI (≥ 28 kg/m²; <28 kg/m²), the height of the tumour (above peritoneal reflection; below peritoneal reflection), operating time (≤ 180 min; >180 min), neoadjuvant therapy (combined neoadjuvant

chemoradiotherapy; no neoadjuvant chemoradiotherapy) and surgical methods (LAR, APR, transanal total mesorectal excision, Bacon surgery, intersphincteric resection, and coloanal anastomosis operation). Univariate and multivariate analyses will be performed using logistic regression. Effect sizes are expressed as OR with the corresponding 95% CI. The p value for interactions within the subgroups will also be calculated. Additionally, exploratory subgroup analyses will be conducted for key secondary end points such as urinary tract infections.

All hypothesis tests will be two-sided, and a significance level of 5% will be used. The analysis and manuscript preparation will be based on the results obtained at the 1 month follow-up for all enrolled patients.

Data management and missing data

Data storage and backup will be managed in a secure online database that tracks all changes in the data and retains a history for each variable. Data will be encoded to protect patient privacy. Data managers will include a Clinical Research Coordinator (CRC) and two trained research assistants with no competing interests in this trial. Data collection will be conducted daily by the CRC to verify and collect patient enrolment, withdrawal, primary end point and secondary end point measurements. Two trained research assistants will record the data. Double data entry will be adopted to ensure accuracy. The missing data for the primary outcome were expected to be small and were designed to be treated as censored data and be not imputed in the trial plan.

Ethics and dissemination

This trial was approved by the Ethics Review Committee of the First Hospital of Jilin University (24K047-001) and has been registered in ClinicalTrials.gov (NCT06241703). All eligible participants and/or their legal surrogates will be fully informed of the potential risks and benefits of the intervention for each group. Only patients who provide their written informed consent will be enrolled. A participant consent form is provided in the online supplemental material.

The enrolment may last for 2 years. We will analyse the primary outcomes and write the paper after a 1-month follow-up of the last enrolled patients. All primary and secondary outcomes will be reported. People who have made significant contributions to this trial will be listed as coauthors.

Confidentiality

Except for data managers and DSMB, there will be no access to the dataset unless there is an institutional or regulatory requirement. Except for the TSC, the DSMB members are not allowed to share confidential information with anyone other than the DSMB. Fully anonymised experimental data were stored on secure servers at Jilin University First Hospital.

Trial status

The version of this study protocol is v1.1.2, November 30, 2024. Recruitment has begun in March 20, 2024, and will be completed in February, 2026.

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