The effect of intermittent catheter clamping combined with active urination training (ICCAUT) on urinary dysfunction after radical resection of rectal cancer: a single-center randomized controlled trial

Clinical Study Protocol

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Content

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Content

1. Background and Rationale

Gastrointestinal surgery usually requires the placement of a urinary catheter during the operation, which is removed after the surgery. For upper gastrointestinal surgery, since there is no surgical manipulation of the pelvic and abdominal organs, the catheter is usually removed within 2 days after the operation, and urinary retention rarely occurs. However, in rectal surgery, which is performed in the pelvic cavity, the resection requires the ligation at the root of the inferior mesenteric artery to achieve the third station lymph node dissection. During this process, there is a possibility of damaging the upper hypogastric plexus and the pelvic nerve plexus. Damage to these nerves, along with other potential perioperative factors, can lead to urinary retention in patients after rectal surgery, resulting in a significantly increased rate of secondary catheterization. Therefore, reducing postoperative urinary retention and the rate of secondary catheterization is one of the clinical issues that need to be addressed.

Bladder training is a method commonly used by surgeons in clinical practice. In a clinical study conducted by Williamson in 1982, it was indicated that intermittently clamping the catheter before catheter removal may shorten the time required for patients to regain bladder function(1).In this procedure, the patient's urinary catheter is first clamped. After clamping for three hours, the catheter is released to allow the urine in the bladder to be drained through the catheter. This cycle is repeated multiple times. It is widely applied across various departments in clinical settings. Current research has confirmed that bladder training can be used as a treatment method for overactive bladder syndrome, which can reduce the frequency of urination and alleviate symptoms of urinary frequency and urgency(2,3).For patients with urinary incontinence, bladder training also has a certain therapeutic effect(4).However, the effect of bladder training on reducing urinary retention and secondary catheterization rates in patients remains debatable. A recent systematic review published in the Cochrane suggests that compared with direct catheter removal, bladder training through intermittent urethral catheter clamping may not be sufficient

to reduce the rate of secondary catheterization in patients(5).In addition, the procedure of bladder training may actually increase the rate of urinary tract infections in patients(6).At present, the number of RCT studies on bladder training through intermittent urethral catheter clamping is limited, and no advantage has been found compared to free-drainage in reducing the rate of secondary catheterization. It is worth noting that the quality of RCT trials on the impact of bladder training on post-pelvic surgery urinary retention is inconsistent, with study designs that suffer fro m inadequate basis for sample size calculation, insufficient sample sizes, and low stati stical power.Additionally, most of the relevant RCT studies have not been conducted in strict accordance with the RCT trial process and have not been registered, casting doubt on their quality and credibility, making it difficult to derive reliable clinical practice evidence from them(6-9).At present, there is no consensus among clinicians regarding this issue. Although current guidelines related to urinary catheter care tend to suggest that intermittent clamping of the urinary catheter for bladder function training cannot effectively reduce the incidence of urinary retention and may even increase the incidence of urinary tract infections in patients. However, since most of the existing relevant studies are mainly retrospective studies and lack high-quality RCT trials, the recommendations in the published guidelines regarding whether to conduct bladder training before removing the urinary catheter are all based on low-quality research evidence. In clinical practice, especially for patients after low radical resection of rectal cancer many centers still perform intermittent urethral catheter clamping for bladder training to reduce the incidence of urinary retention and the rate of secondary catheterization. In 2020, Muge et al. also published a comment in a top nursing journal, pointing out that the impact of postoperative bladder training on urinary retention still requires further research(10).Therefore, high-quality clinical studies are needed to explore the effectiveness of bladder training.

In this study, we plan to conduct intermittent clamping of the urinary catheter for patients to explore the impact of this procedure on postoperative urinary dysfunction after radical resection of rectal cancer. Unlike previous studies, on the basis of intermittent clamping of the urinary catheter, we have combined active urination

training, which means instructing patients to perform active urination movements during the intervals when the catheter is opened, to assist in the emptying of urine from the bladder. In recent years, studies have shown that active urination training to calculate the efficiency of urination can effectively predict the occurrence of urinary retention in patients(11,12).However, there are no studies on the impact of active urination training on urinary retention. Theoretically, intermittent catheter clamping combined with active urination training can simulate the normal micturition process of patients. In addition, studies have shown that active urination training can alleviate catheter-related pain in patients(13).Therefore, in this study, we combined intermittent urethral catheter clamping training with active urination training. We named this urinary catheter management strategy the ICCAUT（intermittent catheterization clamp combined with active urination training） management strategy. Currently, there are no registered RCT studies on how ICCAUT management strategies affect the postoperative urinary function of patients after radical resection of rectal cancer. Therefore, this study aims to conduct a prospective randomized controlled trial. It will explore whether the ICCAUT management strategy, compared with the free-drainage strategy, can affect postoperative urinary dysfunction in patients after proctectomy, aiming to provide high-level evidence for clinical practice.

2. Research Objectives and Endpoints

2.1 Objective

Primary Objective

This study investigated the effects of intermittent catheter clamping combined with active urination training (ICCAUT) on postoperative urinary dysfunction in patients after proctectomy.

Secondary Objective

To explore whether bladder training will increase the risk of postoperative urinary tract infections in patients after radical resection of rectal cancer.

2.2 Study Endpoint

2.2.1 Primary Study Endpoint and Definition

The primary endpoint of the study is urinary dysfunction in patients within 7 days after catheter removal. In this study, urinary dysfunction was defined as incomplete bladder emptying after the first voiding following catheter removal or an inability to urinate requiring a second catheterization.

Incomplete bladder emptying was characterized by a postvoid residual urine volume (PRUV) exceeding 100 mL (14–18).The residual urine volume in the bladder after the first urination will be estimated immediately following the first urination using bladder ultrasound. The calculation formula is: Bladder urine volume = Anteroposterior diameter * Vertical diameter * Transverse diameter * 0.52. The bladder ultrasound is performed by a fixed radiologist from the ultrasound imaging department, who is exclusively assigned to our department.

The criteria for determining whether secondary catheterization is needed due to difficulty in urination are as follows:1)The patient is unable to urinate within 10 hours after catheter removal, and percussion of the bladder upper border indicates that it is located above the pubic bone, with an estimated residual urine volume in the bladder greater than 200 ml using bedside bladder ultrasound;2)Although the patient is able to urinate after catheter removal, they still feel lower abdominal distension after multiple attempts to urinate, and percussion by the physician indicates that the bladder upper border is located above the pubic bone, with an estimated residual urine volume in the bladder greater than 200 ml using bedside bladder ultrasound.

In the assessment of the primary endpoint, if a patient undergoes secondary catheterization but does not meet the criteria for withdrawal, and if the urine volume drained after secondary catheterization is less than 100 ml, such patients will not be defined as having urinary dysfunction.

2.2.2 Secondary study endpoints and definitions.

Secondary endpoints of this study include: 1) Catheter-associated urinary tract infection status; 2) Time to first urination after catheter removal; 3) Grading assessment of catheter-related bladder discomfort (CRBD); 4) Post-catheter removal urinary function evaluation (using ICIQ-SF and IPSS scores); 5) Postoperative complications within 30 days (incidence of complications, types of complications, and grading of complications).

2.2.3 Other indicators and definitions.

Urinary tract infection is defined as an inflammatory response of the urinary epithelium to bacterial invasion. The diagnosis requires both of the following criteria to be met: 1) Urinalysis indicates a bacterial count above the normal upper limit, and 2) Positive urine culture. The time to first urination after catheter removal is defined as the time from the removal of the catheter to the patient's spontaneous urination, measured in hours. The time from the second catheterization to the removal of the urinary catheter is defined as the time interval from the first removal of the urinary catheter to the completion of catheter insertion by the nurse or suprapubic puncture by the ultrasound doctor after the clinician determines that the patient requires a second catheterization.

Complications within 30 days after surgery are assessed according to the Clavien-Dindo classification, and complications of grade II and above are recorded and analyzed. These include, but are not limited to, intraperitoneal bleeding, gastrointestinal bleeding, anastomotic leak, chylous fistula, surgical site infection (intra-abdominal infection and incisional infection), intestinal obstruction, postoperative diarrhea, pulmonary infection, urinary tract infection, cardiovascular accident, cerebrovascular accident, and thrombotic diseases.

3.Study design.

3.1 Overall study design.

Single-center, prospective, two-arm, parallel-group randomized controlled study.

3.2 Study duration.

This study plans to complete patient enrollment within one year. The postoperative follow-up period for patients is one month. The entire study, including the establishment of the study, patient recruitment, patient follow-up, and data analysis, is expected to last for two years. We will conduct the primary endpoint analysis after all patients have completed their first postoperative month follow-up. The study will begin in February 2024 at the First Hospital of Jilin University.

3.3 Trial flowchart

As shown in Figure 1.

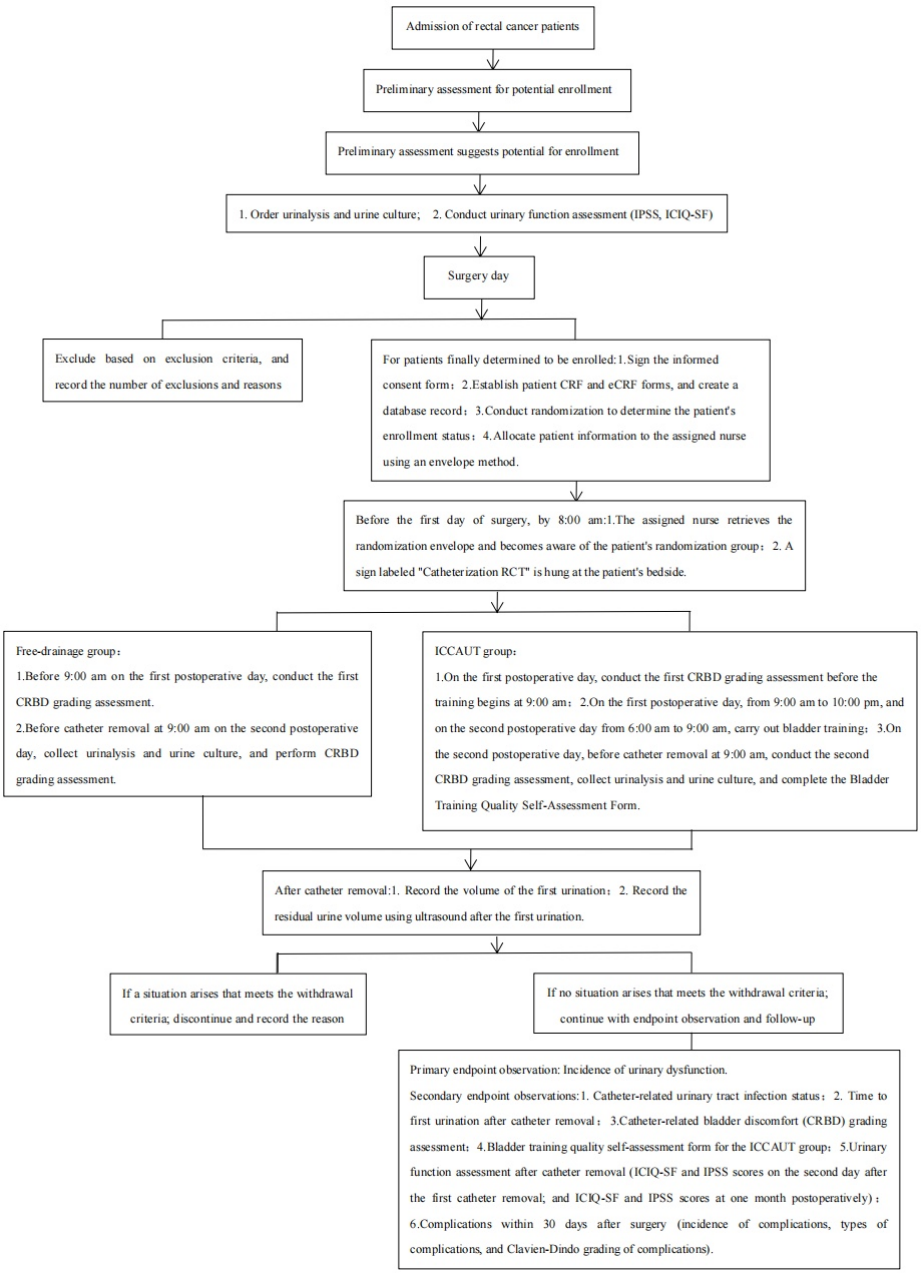

Figure 1.Trial flowchart

4. Population.

4.1 Inclusion criteria

1) Patients with a confirmed preoperative diagnosis of rectal cancer.

2) Patients with tumors located below the rectosigmoid junction, as determined by preoperative computed tomography (CT) or rectal magnetic resonance imaging

(MRI).

3) Patients undergoing laparoscopic or robotic-assisted low anterior resection or abdominoperineal resection for rectal cancer.

4.2 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 (e.g., 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.

4.3 Withdrawal criteria.

After randomization, patients will be withdrawn from the trial if any of the

following situations occur:

1) Inability to remove the urinary catheter within 5 days postoperatively due to various reasons (e.g., impaired consciousness, transfer to the intensive care unit (ICU), Sequential Organ Failure Assessment (SOFA) score ≥2, etc.).

2) Secondary catheterization was performed for reasons other than urinary retention (e.g., 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 α1-adrenergic receptor blocker is used during the first catheterization of the patient due to medical necessity.

5. Study treatment groups.

ICCAUT group（Experimental group）： Patients underwent laparoscopic or robotic rectal cancer TME surgery, and bladder function exercises were initiated through intermittent catheter clamping at 9:00 am on the first postoperative day, with the urinary catheter removed at 9:00 am on the second postoperative day.

Free-drainage group（Control group.）: Patients underwent laparoscopic or robotic rectal cancer TME surgery, with the urinary catheter kept open postoperatively, and it was removed at 9:00 am on the second postoperative day.

Physicians need to determine whether to remove the urinary catheter according to the planned date based on a comprehensive assessment of the patient's consciousness, postoperative renal function, circulatory status, and other factors. Using the Sequential Organ Failure Assessment (SOFA) score as a reference, if the patient's SOFA score is less than 2, the catheter will be removed as planned during the day on the second postoperative day. If the SOFA score is 2 or higher, the duration of catheter placement should be extended. If the catheter still cannot be removed by the fifth day due to a SOFA score of 2 or higher, the patient will be excluded according to

the withdrawal criteria. The specific situation still requires a comprehensive judgment by the physician. If the catheter is not removed as planned, the reason must be stated in the CRF form. Additionally, if a patient is suspected of having a urinary tract infection during catheter training, the clinical physician may decide to stop the catheter exercise.

5.1 Randomization and group assignment.

5.1.1 Methods for Generating Random Sequences

Patients who meet the inclusion criteria will be randomly assigned to either the bladder training group or the direct removal group. Stratified randomization will be performed based on the following three factors, with randomization information generated using R language on a computer. The stratification factors are: 1) Gender; 2) Whether undergoing abdominoperineal resection (APR). The randomization ratio between the ICCAUT group and the Free-drainage group is 1:1. The randomly assigned time is on the day when the patient returns to the ward after the operation. The randomization will be distributed to the assigned nurse via an envelope, and the bladder training will be conducted by the assigned nurse.

5.1.2 Randomization concealment.

After randomization, the group assignment information will be printed on a slip of paper and placed into an opaque envelope. Before 8:00 am on the second postoperative day, the envelope containing the group assignment information will be given to the assigned nurse, who will conduct the catheter training.

5.2 Blinding and Unblinding.

This study is blinded to the physician group, the ultrasound imaging physicians who assess bladder residual urine volume, and the data analysts. The study group requires patients and assigned nurses to keep the patient's group assignment

confidential from the assigned physicians and bladder ultrasound physicians. Since the clinical operations are performed by the assigned nurses on the patients, this study cannot blind the patients and assigned nurses. The time of unblinding is at the time of patient discharge, and any premature unblinding will be recorded. Additionally, this study is blinded to the data statisticians.

6. Study procedure

6.1 Study treatment period.

As shown in Table 1

6.1.1 Patient recruitment and randomization.

1）After admission, patients are initially assessed to determine if they meet the inclusion criteria. If they do, urinalysis and urine culture are performed. The patient's urinary function is evaluated using the International Prostate Symptom Score (IPSS) (Appendix 1) and the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) (Appendix 2), and baseline data are collected.

2）Participants will undergo laparoscopic or robotic-assisted radical resection of rectal cancer. For patients with a narrow pelvic cavity or ultra-low rectal tumors scheduled to receive low anterior resection (LAR), either transanal total mesorectal excision (TaTME) or the Turnbull-Cutait pull-through procedure combined with two-stage hand-sewn coloanal anastomosis (TCA) will be employed. The second stage of the TCA procedure will be performed 2 to 3 weeks following the initial operation. All surgeons will be required to perform high ligation of the inferior mesenteric artery (IMA) and to preserve Denonvilliers' fascia. The decision to perform APR will be based on the patient's tumor stage and the outcome of communication between the surgeon and the patient. After surgery, patients are reassessed to determine if they still meet the inclusion criteria and are checked against each exclusion criterion. If they are not excluded, they are deemed suitable for

enrollment. The patient is then informed and asked to sign the informed consent. If the patient is informed and agrees to participate, the informed consent form is signed, and randomization begins. Baseline data and surgical-related data for the enrolled patients are then collected and completed.

3）Based on stratification factors, randomization is conducted on a computer. The randomization information will be delivered to the assigned nurse via an envelope before 8:00 am on the day following surgery. The nurse will then perform the catheter operation according to the group assignment indicated in the envelope.

6.1.2 Intervention

On the day following surgery (postoperative day 1) at 9:00 am, the nurse will perform the corresponding intervention operations for patients in both groups based on the group assignment indicated in the randomization envelope. Before the intervention, both groups of patients must complete the CRBD (Catheter-Related Bladder Discomfort) grading assessment by the assigned nurse (Appendix 3). During the patient's first catheterization, the use of selective α1-adrenergic receptor blockers (such as tamsulosin) is not permitted.

1）The ICCAUT strategy included intermittent urethral catheter clamping and active urination training. In the ICCAUT group, intermittent catheter clamping was initiated at 9:00 am on the frst postoperative day. In each cycle, the catheter was clamped for 3 h, followed by a 5-min release. The next cycle began as soon as the previous cycle had been completed. Catheter training concluded at 10:00 pm on the frst postoperative day, and the catheter was left open during the night. The urinary catheter was removed on the second postoperative day, and the training did not stop until the catheter had been removed. During the training period, if the patient experienced a strong urge to urinate before the 3-h clamping time was over, the clamping could be released in advance for 5 min, allowing the patient to proceed to the next cycle of bladder training. Each time the catheter was released, the patients were encouraged to actively initiate urination to facilitate complete bladder emptying. We refer to this catheter management strategy, which involves intermittent clamping

of the catheter and active urination during the release periods, as the ICCAUT management strategy.

2）For patients in the free-draining group, no intervention was performed using a catheter during this period. The urinary catheter was removed at 9:00 am on the second postoperative day.

3） Before the urinary catheter is removed on the second day, both groups of patients must complete the CRBD (Catheter-Related Bladder Discomfort) grading assessment again by the assigned nurse (Appendix 3), and urine samples must be collected for urinalysis and urine culture. Additionally, patients in the ICCAUT group must scan a code to fill out the Bladder Training Quality Self-Assessment Form (Appendix 4) before the catheter is first removed. After the catheter is removed, the time from the first catheter removal to the first urination, as well as the volume of the first urination, should be recorded for both groups of patients.

4） Immediately after the first urination, a bladder ultrasound must be performed to assess the residual urine volume in the bladder. The bladder ultrasound is conducted by a fixed radiologist from the ultrasound imaging department, who is exclusively assigned to our department and is located in the same therapeutic area as the patient. After the urinary catheter is removed, the patient must be observed and the situation of any secondary catheterization must be recorded. The observation period is the following 7 days after first urinary catheter removal. For patients who undergo secondary catheterization, the time from the first catheter removal to the secondary catheterization, the volume of urine drained after secondary catheterization, the method of secondary catheterization, and the reason for secondary catheterization must be recorded.

5）Record the IPSS score and ICIQ-SF score of the patient on the day following the first catheter removal (excluding patients who underwent secondary catheterization). Record complications within 30 days after surgery and their Clavien-Dindo classification (Appendix 5).

6.1.3 Discharge and follow-up.

After discharge, when the patient returns for a follow-up visit one month after surgery, the physician must collect information on complications and their grading within the first postoperative month, and conduct an assessment using the one-month postoperative urinary function score form.

Table 1: Study Enrollment, Intervention, and Outcome Assessment Form

	Study phase				
	Recruitment	Surgery and randomization	Post-randomization		
Item \ Time point	Pre-randomization	0	Before catheter removal	After catheter removal	One month postoperatively
Enrollment：					
Screen suitable population	X				
Informed consent	X				
Baseline and surgery-related data collection	X	X			
Randomization		X			
Intervention：					
ICCAUT group			X		
Free-drainage group			X		
Assessment:					
Bladder residual urine volume and secondary catheterization record				X	
Record of information after catheter removal				X	
Catheter-related bladder discomfort (CRBD) grading assessment			X		
Bladder training self-assessment form			X		

Urinalysis and urine culture	X	X		
Urinary function assessment	X		X	X
Postoperative complications and grading		X	X	X

6.2 Concomitant treatment, follow-up

The total follow-up time for postoperative patients is one month. The follow-up content includes postoperative complications within 30 days, as well as the IPSS and ICIQ-SF scores at one month postoperatively.

The follow-up within the first 30 days after surgery is conducted through in-hospital observation, outpatient visits, phone calls, or questionnaires. Complications related to the surgery and their grading, as well as the solutions, are recorded during this period

The postoperative chemotherapy regimen for patients will be based on the NCCN 2023 Rectal Cancer Treatment Guidelines, which will guide the appropriate chemotherapy or systemic treatment.

6.3 Patient compliance and withdrawal

If patients refuse the randomly assigned urinary catheter management method at any time during the indwelling of the urinary catheter after random grouping and request that the operation be carried out according to another urinary catheter management method, their wishes shall be followed and they will be included in the modified intent-to-treat (mITT) analysis set. In the mITT analysis, the primary outcomes of patients will still be analyzed according to the situation of random grouping rather than the actual treatment received.After randomization, patients may withdraw from the trial at any time. If at any point during the entire study, a patient requests to withdraw, the principal investigator of the research center will communicate with the patient to avoid disrupting the balance of randomization due to withdrawal. If the patient still insists on withdrawing, their preference will be respected, and the patient will be excluded from the trial. The clinical information

related to this patient will not be included in any data analysis related to this trial.

6.4 Protocol deviations

Researchers participating in the experiment will follow the experimental requirements for the corresponding operations and data recording. Any events that deviate from the original trial protocol must be recorded with the time of occurrence and specific reasons, and any deviations from the trial protocol must be explained.

7.Evaluation

7.1 Efficacy evaluation

The efficacy evaluation methods for different interventions include, but are not limited to: postoperative assessment of symptoms and signs, postoperative ultrasound assessment of the urinary system, postoperative evaluation of urination-related parameters, postoperative urinalysis and urine culture assessment, and postoperative surveys on urination function-related questionnaires.

7.2 Safety evaluation

7.2.1 Baseline vital signs and symptoms

When conducting a safety assessment, it is first necessary to understand the baseline vital signs and symptoms of the test subjects. This includes measuring their body temperature, pulse, respiratory rate, and blood pressure, while noting any specific symptoms such as dizziness, nausea, vomiting, etc. Preoperative hematological examinations and imaging studies should be completed, along with preoperative urinalysis, urine culture, and preoperative voiding function questionnaire assessments. Additionally, the patient's medical history must be clarified and cross-checked against the trial's inclusion and exclusion criteria one by one to ensure

that the patient population has no surgical contraindications and fully meets the enrollment criteria. These baseline data will serve as reference indicators for the assessment.

7.2.2 Laboratory examinations

The continuity indicators describe the measured values of each research subject after surgery and the change values relative to the preoperative baseline. The laboratory indicators are divided into low, normal, and high according to the normal value range. Describe the situations where the values change from normal or high at baseline to low after baseline, and where the values change from normal or low at baseline to high after baseline. The low or high values after baseline are calculated using the minimum or maximum observed value after baseline. Doctors will evaluate these abnormal indicators to determine whether their abnormalities have clinical significance. Describe the proportion of "abnormal and clinically significant" among the subjects with abnormal changes.

7.2.3 Physical examination and vital signs

Physical Examination: General examination, head examination, neck examination, thorax and lung examination, heart and vascular examination, abdominal examination, spine and limbs examination, and neurological examination. Vital signs include routine blood pressure, heart rate, body temperature, etc. Statistical descriptions are provided for the measurement values of physical examination, vital signs, and weight before and after treatment relative to the baseline. Abnormal vital signs or those exceeding the normal value range are described.

8. Adverse event reporting

8.1 Adverse events

Adverse events in the study include complications and death events within 30

days after surgery. All adverse events reported spontaneously by the subjects or observed by the staff will be recorded in the database and promptly reported to the trial steering committee.

8.2 Definition of adverse events

An adverse event is defined as any untoward experience occurring in a subject during the study, regardless of whether it is considered to be related to catheter clamping. All adverse events reported spontaneously by the trial subject or observed by the investigator or their staff will be recorded.

8.3 Abnormal test results.

Abnormal test results should be evaluated to determine whether they should be reported as adverse events based on the following criteria for objective test values: 1) Test results are accompanied by symptoms; 2) Test results require medical or surgical intervention; 3) The investigator considers the test result to be an adverse event.

If none of the above criteria are met, merely repeating an abnormal test does not constitute an adverse event. Test results judged by the investigator to be erroneous do not need to be reported as adverse events.

8.4 Serious adverse events

Serious adverse events include any of the following adverse medical events: 1) Events or effects leading to death; 2) Life-threatening events; 3) Events requiring hospitalization or prolonging the hospital stay of an inpatient; 4) Events resulting in persistent or significant disability or incapacity. Upon learning of a serious adverse event that is life-threatening or leads to death, it must be reported within 7 days. Other serious adverse events must be reported within 15 days. All adverse events are followed up immediately after they occur, until the event stabilizes or improves. Depending on the specific situation, follow-up may require additional tests or medical

procedures, or further referral.

8.5 Severity assessment

The severity of adverse events will be assessed using the Clavien-Dindo classification of complications.

8.6 Causality assessment

The causality of adverse events with respect to the intervention will be subjectively assessed by the investigator.

9. Data processing and storage

Clinical research data will be recorded through the perioperative eCRF, including perioperative information, pathological data, and follow-up information. To protect patient privacy, patient identification numbers will not be disclosed to data analysts. All patients will be coded and identified using random numbers. These random numbers do not include patient initials or date of birth. Members of the trial steering committee will have a decoding list that specifies the random numbers of patients in the database and their identification numbers.

All patients who meet the inclusion criteria will be registered, including those who refuse randomization, those excluded due to exclusion criteria, and those who are withdrawn after randomization due to withdrawal criteria. Reasons for exclusion and withdrawal will be recorded.

10. Quality management

The key to the quality control of the trial lies in:

（1）Blinding quality control

The implementation of blinding in this study may affect the quality of the

research, particularly the achievement of the primary endpoint. If the trial is not blinded to surgeons, it may influence their judgment on whether the patient needs secondary catheterization based on whether bladder training was performed. If the ultrasound imaging physicians are not blinded, it may affect their assessment of residual urine volume in the bladder based on their knowledge of the patient's intervention. Therefore, blinding the randomization information from surgeons and ultrasound imaging physicians is one of the key aspects of quality control in this experiment. To this end, the study requires patients and nurses to keep the patient's group assignment confidential from surgeons and ultrasound imaging physicians. Surgeons and ultrasound physicians must also consciously adhere to the principle of not inquiring about the patient's group assignment. Any premature unblinding must be recorded, including the reason and time of unblinding.

（2）Interventional method quality control

The implementation quality of the interventional method is the second key point of quality control in this study. To address this, the study implements quality control in the following aspects:1) All assigned nurses receive training, which includes standardized procedures for clamping and unclamping the urinary catheter, as well as the standardized operation for obtaining urine routine and urine culture before catheter removal；2) After the patient signs the informed consent and is enrolled, the assigned physician is clearly informed not to provide clinical advice on whether to clamp the catheter and not to participate in any operations related to bladder training. Additionally, the trial management group communicates with the patient that if the assigned physician suggests bladder training, the patient should promptly report to the assigned nurse and the trial steering committee. The trial steering committee will then communicate again with the assigned physician and emphasize the quality control points of the trial；3) The start of training is uniformly set for 9:00 am on the first postoperative day, and the removal of the catheter is uniformly set for 9:00 am the next day. It is not recommended to advance or delay the catheter removal time. Any orders to advance or delay the catheter removal must be communicated to the trial steering committee members before execution, with reasons provided. If the trial

steering committee deems the reason valid, the order to advance or delay the catheter removal is allowed to be executed；4) Nurses need to educate and guide enrolled patients to ensure that patients in the bladder training group actively perform forceful urination during each period of unclamping to assist in urine discharge；5) Patients in the bladder training group, if unable to persist in reaching the specified catheter clamping time (less than 3 hours of catheter clamping before feeling the urge to urinate), may end a training cycle early, open the catheter for 5 minutes, and then start the next clamping training cycle；6) Before catheter removal, patients in the bladder training group must complete the Bladder Training Quality Self-Assessment Form；7) During the first catheterization, selective α1-adrenergic receptor blockers (such as tamsulosin) should not be used. If medically necessary, the patient must withdraw from the trial.

（3）Endpoint quality control

Our project team requires all levels of physicians in our department to strictly follow the bladder residual urine assessment method and the criteria for secondary catheterization as stipulated in the project research plan to calculate bladder residual urine and decide whether to perform secondary catheterization. To reduce bias in the measurement of bladder residual urine, this study implements quality control in the following two aspects: 1) A fixed radiologist is responsible for assessing bladder residual urine, and this physician has specialized in abdominal digestive and urinary system ultrasound examinations for over 10 years; 2) The ultrasound diagnosis location is set in the same therapeutic area as the patient, ensuring that patients can undergo immediate ultrasound examination after the first urination following catheter removal, avoiding the impact on the judgment of residual urine due to a long interval between urination and ultrasound examination.

To ensure the collection of primary and secondary endpoints, this study will appoint a supervisory nurse to serve as the Clinical Research Coordinator (CRC). The CRC will daily verify the patient's enrollment, withdrawal, achievement of primary endpoints, and measurement of secondary endpoints. They will remind physicians to perform relevant medical orders, nurses to execute medical orders and collect data,

and patients to fill out the required questionnaires and self-assessment forms in a timely manner. Additionally, the study will arrange for two graduate students to work with the CRC to promptly enter data into the Electronic Case Report Form (eCRF) and the database (Epidata).

（4）Regular education for healthcare personnel involved in the study.

The research group of this project will conduct regular education for all physicians and nurses involved in the study on a monthly basis. The main content of the education includes the three quality control aspects mentioned above: blinding quality control, interventional method quality control, and endpoint quality control. This ensures that physicians and nurses can strictly follow the quality control requirements of the study for related operations and ensures the quality of the intervention operations performed by nurses on enrolled patients.

11. Statistical analysis

11.1 Sample size determination

The sample size is calculated based on a differential test, with urinary dysfunction as the primary endpoint. Based on our preliminary research results, we estimate the incidence of urinary dysfunction in the bladder training group is 44.7%, and in the direct removal group, it is 59.3%. Patients are randomly assigned to the two groups in a 1:1 ratio. With a two-sided significance level α of 0.05 and a power (1-β) of 80%, the sample size was calculated using PASS 15 software. Each group, the ICCAUT group and the free-drainage group, requires 180 cases. Assuming a dropout rate of 10%, each group requires 200 cases. Therefore, this trial needs a total of 400 cases.

11.2 Analysis population

11.2.1 Full analysis set

The comparative analysis of the primary outcomes will be conducted on the basis

of the "modified intention-to-treat (mITT)". The mITT analysis will include patients who did not follow the randomly assigned measures but were not excluded according to the withdrawal criteria. In this study, if a patient meets the withdrawal criteria after randomization, this patient will be excluded, and the relevant data of this patient will not appear in the statistical analysis including the mITT analysis. In the mITT analysis, for patients randomly assigned to the bladder training group, if the catheter is directly removed without undergoing training at the end, the analysis will still be carried out according to the bladder training group; for patients randomly assigned to the direct removal group, if they receive bladder training at the end, the analysis will still be carried out according to the direct removal group. In addition, if a patient undergoes secondary catheterization, does not meet the withdrawal criteria, but the urine volume drawn after secondary catheterization is less than 100ml. We will not consider that this secondary catheterization is caused by bladder emptying disorder. In the analysis, we will not classify such patients as having urinary dysfunction. In the mITT analysis, we will still include these patients in the analysis, but instead of classifying them as end-point events (positive events), we will analyze them as negative events.

Specific possible reasons for not following the randomization procedure include: 1) The patient's urine becomes cloudy during the postoperative catheterization period, and the physician suspects a urinary tract infection, thus not recommending bladder training; 2) The patient cannot tolerate catheter clamping and refuses bladder training; 3) The patient refuses to follow the assigned procedure; 4) The nurse fails to perform the operation according to the assigned method; 5) The catheter is not removed on the second postoperative day, either earlier or later (but not beyond the fifth postoperative day). The study needs to record the specific reasons for not following the planned procedure.

11.2.2 Per-protocol analysis set

In the per-protocol analysis set (PPA), only cases that strictly follow the randomization and the assigned treatment plan will be included in the analysis. Patients who do not receive treatment according to the assigned randomization plan

will be excluded from the PPA. Excluded patients include those who did not have the catheter removed on the second postoperative day, as well as those whose bladder training was not conducted strictly according to plan.

11.2.3 As-treated analysis set

In the as-treated analysis set (ATA), we will analyze patients based on the actual treatment they received, rather than the treatment assigned by randomization. In the ATA analysis, patients who receive at least one round of bladder training are classified as the bladder training group, while those who do not receive training are classified as the direct removal group.

11.3 Efficacy analysis and statistical methods

11.3.1 Analysis of the primary endpoint

Categorical variables will be statistically analyzed and described using counts (percentages). Without multivariate adjustment, the primary endpoints of the two groups will be compared using relative risk (RR) and its 95% confidence interval (95% CI) to describe the differences between the groups. Additionally, logistic regression will be used to adjust for factors that may affect the rate of secondary catheterization (such as the relationship between the lower edge of the tumor and the peritoneal reflection, BMI, age, surgery duration, etc.). The adjusted differences between groups will be described using odds ratios (OR) and 95% CI.

11.3.2 Analysis of secondary endpoints

In the analysis of secondary endpoints, continuous variables will be described using mean ± standard deviation or median (interquartile range); categorical variables will be described using counts (percentages). We will consider using sensitivity analysis to explain the impact of missing data on overall results.

11.3.3 Subgroup analysis

We will explore differences in the rate of secondary catheterization between the two groups in different subgroups through subgroup analysis. Subgroups include Sex (male; female), age (≤65 years; >65 years), ASA classification (≤II; ≥III), BMI (≥28 kg/m²; <28 kg/m²), the relationship between the lower edge of the tumor and the peritoneal reflection (above the peritoneal reflection; below the peritoneal reflection), Operating time (≤180 mins; >180 mins), neoadjuvant therapy Yes, No), and surgical procedures (LAR surgery; APR surgery; TaTME surgery; Bacon surgery; ISR surgery; CAA surgery). Logistic regression will be used for univariate and multivariate analyses, with effect sizes represented by OR and 95% CI, and subgroup interaction P-values will be calculated. Additionally, we will conduct exploratory subgroup analyses for some key secondary endpoints, such as the incidence of urinary tract infections.

All hypothesis tests are two-sided with a significance level of 5%. We will analyze the results and write the paper after all enrolled patients have completed the one-month follow-up.

11.4 Interim analysis

This study does not include an interim analysis

11.5 Final analysis

We will conduct the primary endpoint analysis of the study after all patients have completed their first postoperative month follow-up and will publish the relevant research findings.

11.6 Data Monitoring Committee

This study establishes a Data and Safety Monitoring Board (DSMB), which is composed of senior surgeons, ethicists, and statistical analysts. The members of the DSMB are independent of this trial and have no competing interests that could

influence the trial. The DSMB will receive and review the safety data of this trial. If the DSMB believes that the number of adverse events in the trial is biased between groups, they will notify the trial steering committee.

No interim analyses are planned in this study. However, after the study begins, the DSMB will assess the study results every six months and may meet earlier for assessments. The assessment content includes the recording of primary and secondary endpoints, adverse events, and the dropout rate of study samples. Except for the trial steering committee, DSMB members must not share confidential information with anyone outside the DSMB.

The interventional methods used in this study (intermittent catheter clamping and continuous catheter opening) are common clinical strategies for managing catheters after surgical procedures and do not impose additional risks on patients. Therefore, this study does not have predefined stopping criteria. However, if the regular assessments by the DSMB reveal that the urinary system-related safety indicators due to the intervention methods are significantly worse than the current domestic standards, the DSMB will submit its recommendations in writing to the trial steering committee. This may include requests to modify the trial plan, re-evaluate the quality of cases, or even suspend or terminate patient enrollment in the clinical trial.

12. Data collection and management

12.1 Case Report Form/Electronic Data Recording

The Case Report Form (CRF) includes the following primary outcome measures: incidence of urinary dysfunction, including bladder residual urine volume after the first urination, rate of secondary catheterization, time from catheter removal to secondary catheterization (hours), method of secondary catheterization (suprapubic puncture/urethral catheterization), reasons for secondary catheterization, and urine volume drained after secondary catheterization (ml). Secondary outcome measures include: urinary tract infection status (white blood cell count in urine, bacterial

content, and positive/negative urine culture before catheter removal), time to first urination after catheter removal (hours), bladder residual urine volume after the first urination (milliliters), CRBD grading assessment, bladder training quality self-assessment form for the bladder training group, postoperative complications within 30 days (incidence of complications, types of complications, and grading of complications), and urinary function assessment on the second day after catheter removal (ICIQ-SF, IPSS score).Other collected baseline indicators include: gender, age, underlying diseases and medical history (hypertension, diabetes, cardiovascular disease, cerebrovascular disease, history of pelvic surgery), history of benign prostatic hyperplasia in males (confirmed by medical history or imaging), preoperative IPSS score, preoperative ICIQ-SF score, preoperative radiotherapy and chemotherapy status, preoperative urine routine white blood cell count, preoperative urine routine bacterial count, preoperative urine culture results, ASA, BMI, preoperative imaging assessment results (preferably rectal MRI), including the distance from the lower edge of the tumor to the anal margin, the relationship between the lower edge of the tumor and the peritoneal reflection (above/below the peritoneal reflection), clinical T staging, clinical N staging, MRF status, EMVI status, surgery duration, surgical procedures, including low anterior resection (LAR), intersphincteric resection (ISR), abdominoperineal resection (APR), transanal TME (TaTME), Bacon surgery, stoma status (ileum/colon, single/double), surgical technique (robotic/laparoscopic), and postoperative pathological conditions (pathological T staging, pathological N staging, CRM, DRM). See the CRF form for details.

12.2 Data management

Data collection will be conducted by the CRC, who will verify and collect information on patient enrollment, withdrawal, achievement of primary endpoints, and measurement of secondary endpoints daily. Two graduate students will serve as data entry personnel. The two graduate students and the CRC will jointly collect baseline data. Data entry will be performed using a dual-entry method, with one

person entering the data and another verifying it. Both paper and electronic versions of the CRF will be entered simultaneously. Baseline data will be entered on the day of surgery, information related to primary and secondary endpoints will be entered within two days of catheter removal, and pathological and other hospitalization information must be entered within one week after patient discharge. Complications within 30 days after surgery must be entered within 30 days after surgery. To protect patient privacy, all patients will be coded and identified using random numbers. These random numbers do not include patient initials or date of birth. Investigators will have a decoding list that specifies the random numbers of patients in their site's files and their patient identification numbers.

All patients who meet the inclusion criteria will be recorded. If a patient is excluded due to exclusion criteria or is withdrawn after randomization due to withdrawal criteria, this must be documented in the database.

13. Ethics and Morality

13.1 Ethics committee

Before the study begins, this trial will obtain ethical approval from the ethics committee of our hospital.

13.2 Patient information and informed consent

Eligible patients should receive personal notification from the treating surgeon and be provided with written information related to the trial. Before entering the randomization of the study, each patient must provide informed consent in accordance with the guidelines of the ethics committee. Patients will have at least 24 hours to decide whether to participate in the study and can withdraw from the study at any time without reason.

The informed consent process should be conducted by a physician of the

attending level or higher within our group. The information provided to patients during informed consent includes:1) A statement that the trial involves research;2) A full and fair explanation of the procedures to be followed;3) A full explanation of the nature, expected duration, and purpose of the research;4) A description of any risks or discomforts that the patient can reasonably expect;5) A description of any benefits that can be reasonably expected;6) A statement that patient data will be handled with care and confidentiality, and the duration of data retention (15 years);7) A statement that patient biological materials will be retained for 15 years;8) A statement about voluntary participation and withdrawal, indicating that refusal to participate in the trial involves no penalty or loss of benefits to which the patient is otherwise entitled, and that the patient may stop participating at any time without penalty or loss of benefits, in which case the patient will receive standard care of the same quality.

14. Definition of study completion

The study is considered complete when all enrolled patients have completed a one-month follow-up.

15. Trial organizational structure

This study is conducted at a single medical center—The First Hospital of Jilin University. The trial steering committee members include Quan Wang , Haiyan Hu, Jianan Sun, Yuchen Guo , and Tingting He . The Data and Safety Monitoring Board (DSMB) is composed of senior surgeons, ethicists, and statistical analysts. Each member of the DSMB is independent of this trial and has no competing interests that could influence the trial. This study has no research funding support.

16. Confidentiality and data security

During the study, only data entry personnel and the DSMB are aware of the data situation, and others cannot access the database to know specific patient data. DSMB

members can be aware of patient allocation and trial-related data. The DSMB will discuss the relevant results of the data with the trial steering committee members. Except for the trial steering committee, DSMB members must not share confidential information with anyone outside the DSMB.

For decisions and recommendations formed through discussions by the DSMB, the DSMB will submit these recommendations in writing to the trial steering committee. Additionally, the CRC will also receive these recommendations to be discussed at the trial steering committee meeting. The content of the meeting needs to be stored and secured by the DSMB members after the meeting, so that it can be reviewed in comparison with the next report.

17. Insurance and compensation.

All enrolled patients have purchased medical commercial insurance in collaboration with our hospital and an insurance company before surgery. The insurance will compensate for surgery-related complications and surgery-related deaths.

18. Publication statement

The data will not be published before the collection of primary outcomes is completed. We will conduct the primary endpoint analysis of the study after all patients have completed their first postoperative month follow-up and will publish the relevant research findings. The order of authors will be arranged from highest to lowest based on the number of enrolled cases.

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Appendix 1: IPSS Score		
Symptom	**Question**	**Score**
Incomplete Emptying	Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0: None
		1: Less than 1 time in 5
		2: Less than half the time
		3: About half the time
		4: More than half the time
		5: Almost always
Frequency	Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0: None
		1: Less than 1 time in 5
		2: Less than half the time
		3: About half the time
		4: More than half the time
		5: Almost always
Intermittency	Over the past month, how often have you found you stopped and started again several times when you urinated?	0: None
		1: Less than 1 time in 5
		2: Less than half the time
		3: About half the time
		4: More than half the time
		5: Almost always
Urgency	Over the past month, how difficult have you found it to postpone urination?	0: None
		1: Less than 1 time in 5
		2: Less than half the time
		3: About half the time
		4: More than half the time
		5: Almost always
Weak Stream	Over the past month, how often have you had a weak urinary stream?	0: None
		1: Less than 1 time in 5
		2: Less than half the time
		3: About half the time
		4: More than half the time
		5: Almost always
Straining	Over the past month, how often have you had to push or strain to begin urination?	0: None
		1: Less than 1 time in 5
		2: Less than half the time
		3: About half the time
		4: More than half the time
		5: Almost always
Nocturia	Over the past month, how many times did you typically get up at night to urinate?	0: None
		1: 1 time
		2: 2 times
		3: 3 times
		4: 4 times

		5: 5 or more times
1.Total Score Calculation: Sum the scores of the above 7 items. The total score ranges from 0 to 35. ①Mild symptoms: 0 - 7 ②Moderate symptoms: 8 - 19 ③Severe symptoms: 20 - 35		

Appendix 2: ICIQ-SF Score

International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI SF)

1.Please write in your date of birth: _

2.Are you (check one): □ Female □ Male

3.How often do you leak urine? Check one box.

0 □ Never
1 □ About once a week or less often
2 □ Two or three times a week
3 □ About once a day
4 □ Several times a day
5 □ All the time

4.We would like to know how much urine you think leaks. How much urine do you usually leak (whether you wear protection or not)? Check one box.

0 □ None
2 □ A small amount
4 □ A moderate amount
6 □ A large amount

5.Overall, how much does leaking urine interfere with your everyday life? Please circle a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

Not at all A great deal

ICIQ score: Sum scores 3 + 4 + 5

6.When does urine leak? Please check all that apply to you.

□ Never – urine does not leak
□ Leaks before you can get to the bathroom
□ Leaks when you cough or sneeze
□ Leaks when you are asleep
□ Leaks when you are physically active / exercising
□ Leaks when you have finished urinating and are dressed
□ Leaks for no obvious reason
□ Leaks all the time

Appendix 3: CRBD Grading Assessment

Grading	Symptoms
Grade 0	No discomfort at all
Grade 1	Only informed of urethral discomfort when asked and it is tolerable.
Grade 2	The patient actively informed of urgency, dysuria and lower abdominal distension, but without behavioral response
Grade 3	The patient actively informed of urgency, dysuria and lower abdominal distension, accompanied by behavioral responses (such as severe restlessness, limb movement, attempting to remove the catheter), requiring medical staff to restrain and multiple caregivers to watch.

Appendix 4: Bladder Training Quality Self-Assessment Form

1.Total number of times the catheter was clamped?
2.Did you feel the urge to urinate each time during the clamping training?
□ Every time； □ More than half of the times; □ Less than half of the times; □ Never
3.Were you able to hold for 3 hours before releasing the catheter?
□ Every time； □ More than half of the times; □ Less than half of the times; □ Never
4.Did you cooperate with the urination action after releasing the catheter?
□ Every time； □ More than half of the times; □ Less than half of the times; □ Never

Appendix 5: Postoperative Complications Clavien-Dindo System Grading.

Grading		Definition
I		Postoperative complications that do not require drug, surgical, endoscopic, or radiological intervention, but include drug therapy such as anti-emetics, antipyretics, analgesics, diuretics, electrolytes, physiotherapy, and also include incisional infections that are opened at the bedside;
II		Requires drug therapy, excluding patients who only received Grade I medication, incisional infections requiring antibiotic treatment, and includes blood transfusions and total parenteral nutrition
III		Requires surgical, endoscopic, or radiological intervention
	IIIa	Does not require general anesthesia
	IIIb	Requires general anesthesia
IV		Life-threatening complications (including central nervous system complications) requiring IC (intermediate care) or ICU management
	IVa	Organ failure (including dialysis)
	IVb	Multi-organ failure
V		Death

The effect of intermittent catheter clamping combined with active urination training (ICCAUT) on urinary dysfunction after radical resection of rectal cancer: a single-center randomized controlled trial

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Department: Gastrocolorectal Surgery, General Surgery Center

Version number： V 2.0

Version date： January 5, 2025

Content

1. Background and Rationale

Gastrointestinal surgery usually requires the placement of a urinary catheter during the operation, which is removed after the surgery. For upper gastrointestinal surgery, since there is no surgical manipulation of the pelvic and abdominal organs, the catheter is usually removed within 2 days after the operation, and urinary retention rarely occurs. However, in rectal surgery, which is performed in the pelvic cavity, the resection requires the ligation at the root of the inferior mesenteric artery to achieve the third station lymph node dissection. During this process, there is a possibility of damaging the upper hypogastric plexus and the pelvic nerve plexus. Damage to these nerves, along with other potential perioperative factors, can lead to urinary retention in patients after rectal surgery, resulting in a significantly increased rate of secondary catheterization. Therefore, reducing postoperative urinary retention and the rate of secondary catheterization is one of the clinical issues that need to be addressed.

Bladder training is a method commonly used by surgeons in clinical practice. In a clinical study conducted by Williamson in 1982, it was indicated that intermittently clamping the catheter before catheter removal may shorten the time required for patients to regain bladder function(1).In this procedure, the patient's urinary catheter is first clamped. After clamping for three hours, the catheter is released to allow the urine in the bladder to be drained through the catheter. This cycle is repeated multiple times. It is widely applied across various departments in clinical settings. Current research has confirmed that bladder training can be used as a treatment method for overactive bladder syndrome, which can reduce the frequency of urination and alleviate symptoms of urinary frequency and urgency(2,3).For patients with urinary incontinence, bladder training also has a certain therapeutic effect(4).However, the effect of bladder training on reducing urinary retention and secondary catheterization rates in patients remains debatable. A recent systematic review published in the Cochrane suggests that compared with direct catheter removal, bladder training through intermittent urethral catheter clamping may not be sufficient

to reduce the rate of secondary catheterization in patients(5).In addition, the procedure of bladder training may actually increase the rate of urinary tract infections in patients(6).At present, the number of RCT studies on bladder training through intermittent urethral catheter clamping is limited, and no advantage has been found compared to free-drainage in reducing the rate of secondary catheterization. It is worth noting that the quality of RCT trials on the impact of bladder training on post-pelvic surgery urinary retention is inconsistent, with study designs that suffer fro m inadequate basis for sample size calculation, insufficient sample sizes, and low stati stical power.Additionally, most of the relevant RCT studies have not been conducted in strict accordance with the RCT trial process and have not been registered, casting doubt on their quality and credibility, making it difficult to derive reliable clinical practice evidence from them(6-9).At present, there is no consensus among clinicians regarding this issue. Although current guidelines related to urinary catheter care tend to suggest that intermittent clamping of the urinary catheter for bladder function training cannot effectively reduce the incidence of urinary retention and may even increase the incidence of urinary tract infections in patients. However, since most of the existing relevant studies are mainly retrospective studies and lack high-quality RCT trials, the recommendations in the published guidelines regarding whether to conduct bladder training before removing the urinary catheter are all based on low-quality research evidence. In clinical practice, especially for patients after low radical resection of rectal cancer many centers still perform intermittent urethral catheter clamping for bladder training to reduce the incidence of urinary retention and the rate of secondary catheterization. In 2020, Muge et al. also published a comment in a top nursing journal, pointing out that the impact of postoperative bladder training on urinary retention still requires further research(10).Therefore, high-quality clinical studies are needed to explore the effectiveness of bladder training.

In this study, we plan to conduct intermittent clamping of the urinary catheter for patients to explore the impact of this procedure on postoperative urinary dysfunction after radical resection of rectal cancer. Unlike previous studies, on the basis of intermittent clamping of the urinary catheter, we have combined active urination

training, which means instructing patients to perform active urination movements during the intervals when the catheter is opened, to assist in the emptying of urine from the bladder. In recent years, studies have shown that active urination training to calculate the efficiency of urination can effectively predict the occurrence of urinary retention in patients(11,12). However, there are no studies on the impact of active urination training on urinary retention. Theoretically, intermittent catheter clamping combined with active urination training can simulate the normal micturition process of patients. In addition, studies have shown that active urination training can alleviate catheter-related pain in patients(13).Therefore, in this study, we combined intermittent urethral catheter clamping training with active urination training. We named this urinary catheter management strategy the ICCAUT（intermittent catheterization clamp combined with active urination training） management strategy. Currently, there are no registered RCT studies on how ICCAUT management strategies affect the postoperative urinary function of patients after radical resection of rectal cancer. Therefore, this study aims to conduct a prospective randomized controlled trial. It will explore whether the ICCAUT management strategy, compared with the free-drainage strategy, can affect postoperative urinary dysfunction in patients after proctectomy, aiming to provide high-level evidence for clinical practice.

2. Research Objectives and Endpoints

2.1 Objective

Primary Objective

This study investigated the effects of intermittent catheter clamping combined with active urination training (ICCAUT) on postoperative urinary dysfunction in patients after proctectomy.

Secondary Objective

To explore whether bladder training will increase the risk of postoperative urinary tract infections in patients after radical resection of rectal cancer.

2.2 Study Endpoint

2.2.1 Primary Study Endpoint and Definition

The primary endpoint of the study is urinary dysfunction in patients within 7 days after catheter removal. In this study, urinary dysfunction was defined as incomplete bladder emptying after the first voiding following catheter removal or an inability to urinate requiring a second catheterization.

Incomplete bladder emptying was characterized by a postvoid residual urine volume (PRUV) exceeding 100 mL (14–18).The residual urine volume in the bladder after the first urination will be estimated immediately following the first urination using bladder ultrasound. The calculation formula is: Bladder urine volume = Anteroposterior diameter * Vertical diameter * Transverse diameter * 0.52. The bladder ultrasound is performed by a fixed radiologist from the ultrasound imaging department, who is exclusively assigned to our department.

The criteria for determining whether secondary catheterization is needed due to difficulty in urination are as follows: 1)The patient is unable to urinate within 10 hours after catheter removal, and percussion of the bladder upper border indicates that it is located above the pubic bone, with an estimated residual urine volume in the bladder greater than 200 ml using bedside bladder ultrasound; 2)Although the patient is able to urinate after catheter removal, they still feel lower abdominal distension after multiple attempts to urinate, and percussion by the physician indicates that the bladder upper border is located above the pubic bone, with an estimated residual urine volume in the bladder greater than 200 ml using bedside bladder ultrasound.

In the determination of the primary endpoint, patients who undergo secondary catheterization for reasons other than urinary retention will also be recorded as primary endpoint events, but sensitivity analysis shall be conducted on these patients in the sensitivity analysis. The specific analysis method is described in the section on sensitivity analysis of the primary endpoint in the statistical analysis. Such events may include the following scenarios:

1) The patient requests secondary catheterization due to urgent urination or intense bloating, but the urine volume withdrawn after secondary catheterization does not exceed 100 ml;

2) The patient requires secondary catheterization due to disease-related factors (such as secondary surgery, urethral injury, shock, altered consciousness, intestinal obstruction, hemorrhage, transfer to ICU, SOFA score ≥2, etc.).

2.2.2 Secondary study endpoints and definitions.

Secondary endpoints of this study include: 1) Catheter-associated urinary tract infection status; 2) Time to first urination after catheter removal; 3) Grading assessment of catheter-related bladder discomfort (CRBD); 4) Post-catheter removal urinary function evaluation (using ICIQ-SF and IPSS scores); 5) Postoperative complications within 30 days (incidence of complications, types of complications, and grading of complications); 6) Incidence of residual urine volume greater than 200 milliliters after the first urination.

2.2.3 Other indicators and definitions.

Urinary tract infection is defined as an inflammatory response of the urinary epithelium to bacterial invasion. The diagnosis requires both of the following criteria to be met: 1) Urinalysis indicates a bacterial count above the normal upper limit, and 2) Positive urine culture. The time to first urination after catheter removal is defined as the time from the removal of the catheter to the patient's spontaneous urination, measured in hours. The time from the second catheterization to the removal of the urinary catheter is defined as the time interval from the first removal of the urinary catheter to the completion of catheter insertion by the nurse or suprapubic puncture by the ultrasound doctor after the clinician determines that the patient requires a second catheterization.

Complications within 30 days after surgery are assessed according to the Clavien-Dindo classification, and complications of grade II and above are recorded and analyzed. These include, but are not limited to, intraperitoneal bleeding,

gastrointestinal bleeding, anastomotic leak, chylous fistula, surgical site infection (intra-abdominal infection and incisional infection), intestinal obstruction, postoperative diarrhea, pulmonary infection, urinary tract infection, cardiovascular accident, cerebrovascular accident, and thrombotic diseases.

3.Study design.

3.1 Overall study design.

Single-center, prospective, two-arm, parallel-group randomized controlled study.

3.2 Study duration.

This study plans to complete patient enrollment within one year. The postoperative follow-up period for patients is one month. The entire study, including the establishment of the study, patient recruitment, patient follow-up, and data analysis, is expected to last for two years. We will conduct the primary endpoint analysis after all patients have completed their first postoperative month follow-up. The study will begin in February 2024 at the First Hospital of Jilin University.

3.3 Trial flowchart

As shown in Figure 1.

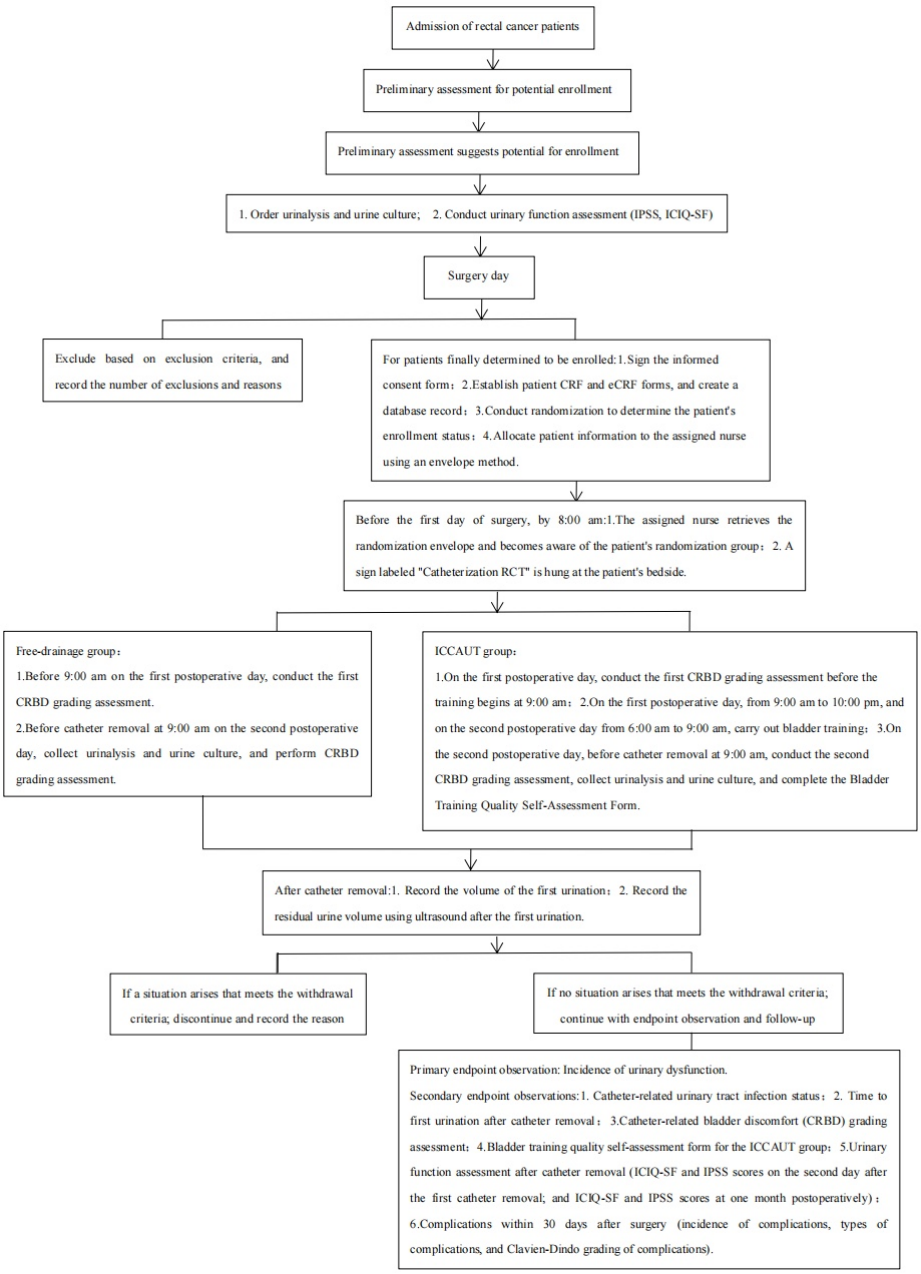

Figure 1 Trial flowchart

4. Population.

4.1 Inclusion criteria

1) Patients with a confirmed preoperative diagnosis of rectal cancer;

2) Preoperative colon CT or rectal MR confirms that the lower edge of the tumor is located in the rectum (including the rectal and anal canal regions) below the

rectosigmoid junction (12 cm from the anal verge);

3) Patients undergoing laparoscopic or robotic-assisted low anterior resection or abdominoperineal resection for rectal cancer.

4.2 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 (e.g., 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.

5. Study treatment groups.

ICCAUT group (Experimental group): Patients underwent laparoscopic or robotic rectal cancer TME surgery, and bladder function exercises were initiated through intermittent catheter clamping at 9:00 am on the first postoperative day, with the urinary catheter removed at 9:00 am on the second postoperative day.

Free-drainage group (Control group): Patients underwent laparoscopic or robotic rectal cancer TME surgery, with the urinary catheter kept open postoperatively, and it was removed at 9:00 am on the second postoperative day.

Physicians need to determine whether to remove the urinary catheter according to the planned date based on a comprehensive assessment of the patient's consciousness, postoperative renal function, circulatory status, and other factors. Using the Sequential Organ Failure Assessment (SOFA) score as a reference, if the patient's SOFA score is less than 2, the catheter will be removed as planned during the day on the second postoperative day. If the SOFA score is 2 or higher, the duration of catheter placement should be extended. The specific situation still requires a comprehensive judgment by the physician. If the catheter is not removed as planned, the reason must be stated in the CRF form. Additionally, if a patient is suspected of having a urinary tract infection during catheter training, the clinical physician may decide to stop the catheter exercise.

5.1 Randomization and group assignment.

5.1.1 Methods for Generating Random Sequences

Patients who meet the inclusion criteria will be randomly assigned to either the bladder training group or the direct removal group. Stratified randomization will be performed based on the following three factors, with randomization information generated using R language on a computer. The stratification factors are: 1) Gender; 2) Whether undergoing abdominoperineal resection (APR). The randomization ratio

between the ICCAUT group and the Free-drainage group is 1:1. A random number table manager (RNTM) (Yanhua Wu) from the Research Centre of Clinical Epidemiology (RCCE) at Jilin University First Hospital generates and preserves the random number table and allocates the randomization information. The RNTM is independent of other researchers in this trial.

5.1.2 Randomization concealment.

After the random number table is generated through R by RNTM, the random allocation information will be printed on paper strips and placed into opaque envelopes. The random number table and random allocation information will be kept by the RNTM from the RCCE. After clinical doctors and bedside nurses complete the patient screening and determine that a patient meets the inclusion criteria for enrollment, random allocation can be conducted. The random allocation will take place between 6:00 a.m. and 7:00 a.m. on the first day after the patient's surgery, before the intervention procedure. Clinical doctors and bedside nurses will submit an enrollment application to the RNTM and provide the patient's gender information and whether they have undergone an APR surgery. Based on the stratification corresponding to these two factors, the RNTM will deliver the opaque envelopes containing the random allocation information to the bedside nurse before 8:00 a.m. on the first day after surgery. The bedside nurse will then open the envelope and perform corresponding procedures on the patient according to the grouping information inside. The RNTM is independent of other personnel involved in this study, do not participate in any other clinical operations of this study, and have no knowledge of any other information about the patients.

5.2 Blinding and Unblinding.

This study is blinded to the physician group, the ultrasound imaging physicians who assess bladder residual urine volume, and the data analysts. The study group requires patients and assigned nurses to keep the patient's group assignment

confidential from the assigned physicians and bladder ultrasound physicians. Since the clinical operations are performed by the assigned nurses on the patients, this study cannot blind the patients and assigned nurses. The time of unblinding is at the time of patient discharge, and any premature unblinding will be recorded.

6. Study procedure

6.1 Study treatment period.

As shown in Table 1

6.1.1 Patient recruitment and randomization.

1）After admission, patients are initially assessed to determine if they meet the inclusion criteria. If they do, urinalysis and urine culture are performed. The patient's urinary function is evaluated using the International Prostate Symptom Score (IPSS) (Appendix 1) and the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) (Appendix 2), and baseline data are collected.

2）Participants will undergo laparoscopic or robotic-assisted radical resection of rectal cancer. For patients with a narrow pelvic cavity or ultra-low rectal tumors scheduled to receive low anterior resection (LAR), either transanal total mesorectal excision (TaTME) or the Turnbull-Cutait pull-through procedure combined with two-stage hand-sewn coloanal anastomosis (TCA) will be employed. The second stage of the TCA procedure will be performed 2 to 3 weeks following the initial operation. All surgeons will be required to perform high ligation of the inferior mesenteric artery (IMA) and to preserve Denonvilliers' fascia. The decision to perform APR will be based on the patient's tumor stage and the outcome of communication between the surgeon and the patient. After surgery, patients are reassessed to determine if they still meet the inclusion criteria and are checked against each exclusion criterion. If they are not excluded, they are deemed suitable for enrollment. The patient is then informed and asked to sign the informed consent. If

the patient is informed and agrees to participate, the informed consent form is signed, and randomization begins. Baseline data and surgical-related data for the enrolled patients are then collected and completed.

3）Based on stratification factors, randomization is conducted on a computer. The randomization information will be delivered to the assigned nurse via an envelope before 8:00 am on the day following surgery. The nurse will then perform the intervention according to the group assignment indicated in the envelope.

6.1.2 Intervention

On the day following surgery (postoperative day 1) at 9:00 am, the nurse will perform the corresponding intervention operations for patients in both groups based on the group assignment indicated in the randomization envelope. Before the intervention, both groups of patients must complete the CRBD (Catheter-Related Bladder Discomfort) grading assessment by the assigned nurse (Appendix 3). During the patient's first catheterization, the use of selective α1-adrenergic receptor blockers (such as tamsulosin) is not permitted.

1）The ICCAUT strategy included intermittent urethral catheter clamping and active urination training. In the ICCAUT group, intermittent catheter clamping was initiated at 9:00 am on the first postoperative day. In each cycle, the catheter was clamped for 3 h, followed by a 5-min release. The next cycle began as soon as the previous cycle had been completed. Catheter training concluded at 10:00 pm on the frst postoperative day, and the catheter was left open during the night. The urinary catheter was removed on the second postoperative day, and the training did not stop until the catheter had been removed. During the training period, if the patient experienced a strong urge to urinate before the 3-h clamping time was over, the clamping could be released in advance for 5 min, allowing the patient to proceed to the next cycle of bladder training. Each time the catheter was released, the patients were encouraged to actively initiate urination to facilitate complete bladder emptying. We refer to this catheter management strategy, which involves intermittent clamping of the catheter and active urination during the release periods, as the ICCAUT

management strategy.

2）For patients in the free-draining group, no intervention was performed using a catheter during this period. The urinary catheter was removed at 9:00 am on the second postoperative day.

3）Before the urinary catheter is removed on the second day, both groups of patients must complete the CRBD (Catheter-Related Bladder Discomfort) grading assessment again by the assigned nurse (Appendix 3), and urine samples must be collected for urinalysis and urine culture. Additionally, patients in the ICCAUT group must scan a code to fill out the Bladder Training Quality Self-Assessment Form (Appendix 4) before the catheter is first removed. After the catheter is removed, the time from the first catheter removal to the first urination, as well as the volume of the first urination, should be recorded for both groups of patients.

4）Immediately after the first urination, a bladder ultrasound must be performed to assess the residual urine volume in the bladder. The bladder ultrasound is conducted by a fixed radiologist from the ultrasound imaging department, who is exclusively assigned to our department and is located in the same therapeutic area as the patient. After the urinary catheter is removed, the patient must be observed and the situation of any secondary catheterization must be recorded. The observation period is the following 7 days after first urinary catheter removal. For patients who undergo secondary catheterization, the time from the first catheter removal to the secondary catheterization, the volume of urine drained after secondary catheterization, the method of secondary catheterization, and the reason for secondary catheterization must be recorded.

5）Record the IPSS score and ICIQ-SF score of the patient on the day following the first catheter removal (excluding patients who underwent secondary catheterization). Record complications within 30 days after surgery and their Clavien-Dindo classification (Appendix 5).

6.1.3 Discharge and follow-up.

After discharge, when the patient returns for a follow-up visit one month after

surgery, the physician must collect information on complications and their grading within the first postoperative month, and conduct an assessment using the one-month postoperative urinary function score form.

Table 1: Study Enrollment, Intervention, and Outcome Assessment Form

	Study phase				
	Recruitment	Surgery and randomization	Post-randomization		
Item \ Time point	Pre-randomization	0	Before catheter removal	After catheter removal	One month postoperatively
Enrollment：					
Screen suitable population	X				
Informed consent	X				
Baseline and surgery-related data collection	X	X			
Randomization		X			
Intervention：					
ICCAUT group			X		
Free-drainage group			X		
Assessment:					
Bladder residual urine volume and secondary catheterization record				X	
Record of information after catheter removal				X	
Catheter-related bladder discomfort (CRBD) grading assessment			X		
Bladder training self-assessment form			X		
Urinalysis and urine culture	X		X		

Urinary function assessment	X			X	X
Postoperative complications and grading			X	X	X

6.2 Concomitant treatment, follow-up

The total follow-up time for postoperative patients is one month. The follow-up content includes postoperative complications within 30 days, as well as the IPSS and ICIQ-SF scores at one month postoperatively.

The follow-up within the first 30 days after surgery is conducted through in-hospital observation, outpatient visits, phone calls, or questionnaires. Complications related to the surgery and their grading, as well as the solutions, are recorded during this period

The postoperative chemotherapy regimen for patients will be based on the NCCN 2023 Rectal Cancer Treatment Guidelines, which will guide the appropriate chemotherapy or systemic treatment.

6.3 Patient compliance and withdrawal

If, after randomization, a patient refuses the randomly assigned urinary catheter management method at any time during the indwelling urinary catheter period and requests to have the intervention carried out according to the other urinary catheter management method, the other urinary catheter management method shall be provided to the patient in accordance with the patient's wish. If at any time during the entire study, a patient requests to withdraw from the study, the principal investigator shall communicate with the patient to avoid disrupting the balance of the randomization due to the withdrawal. If necessary, the patient's compensation shall be increased. If the patient still insists on withdrawing from the study and refuses to allow the use of personal data in this research project, the patient shall be withdrawn from the study according to the patient's wish, and all data of this patient shall be treated as missing data. During the follow-up phase of the primary endpoint, if a

patient refuses to cooperate with the follow-up of the primary endpoint, including the follow-up of secondary catheterization and the assessment of residual urine volume, the principal investigator shall communicate with the patient and appropriately increase the compensation for the subjects to avoid the absence of the primary endpoint. If the patient stubbornly refuses to cooperate with the follow-up of the primary endpoint, the primary endpoint of the patient shall be treated as missing data, and other data shall be recorded in the database.

6.4 Protocol deviations

Researchers participating in the experiment will follow the experimental requirements for the corresponding operations and data recording. Any events that deviate from the original trial protocol must be recorded with the time of occurrence and specific reasons, and any deviations from the trial protocol must be explained.

7.Evaluation

7.1 Efficacy evaluation

The efficacy evaluation methods for different interventions include, but are not limited to: postoperative assessment of symptoms and signs, postoperative ultrasound assessment of the urinary system, postoperative evaluation of urination-related parameters, postoperative urinalysis and urine culture assessment, and postoperative surveys on urination function-related questionnaires.

7.2 Safety evaluation

7.2.1 Baseline vital signs and symptoms

When conducting a safety assessment, it is first necessary to understand the baseline vital signs and symptoms of the test subjects. This includes measuring their

body temperature, pulse, respiratory rate, and blood pressure, while noting any specific symptoms such as dizziness, nausea, vomiting, etc. Preoperative hematological examinations and imaging studies should be completed, along with preoperative urinalysis, urine culture, and preoperative voiding function questionnaire assessments. Additionally, the patient's medical history must be clarified and cross-checked against the trial's inclusion and exclusion criteria one by one to ensure that the patient population has no surgical contraindications and fully meets the enrollment criteria. These baseline data will serve as reference indicators for the assessment.

7.2.2 Laboratory examinations

The continuity indicators describe the measured values of each research subject after surgery and the change values relative to the preoperative baseline. The laboratory indicators are divided into low, normal, and high according to the normal value range. Describe the situations where the values change from normal or high at baseline to low after baseline, and where the values change from normal or low at baseline to high after baseline. The low or high values after baseline are calculated using the minimum or maximum observed value after baseline. Doctors will evaluate these abnormal indicators to determine whether their abnormalities have clinical significance. Describe the proportion of "abnormal and clinically significant" among the subjects with abnormal changes.

7.2.3 Physical examination and vital signs

Physical Examination: General examination, head examination, neck examination, thorax and lung examination, heart and vascular examination, abdominal examination, spine and limbs examination, and neurological examination. Vital signs include routine blood pressure, heart rate, body temperature, etc. Statistical descriptions are provided for the measurement values of physical examination, vital signs, and weight before and after treatment relative to the baseline. Abnormal vital signs or those exceeding the normal value range are described.

8. Adverse event reporting

8.1 Adverse events

Adverse events in the study include complications and death events within 30 days after surgery. All adverse events reported spontaneously by the subjects or observed by the staff will be recorded in the database and promptly reported to the trial steering committee.

8.2 Definition of adverse events

An adverse event is defined as any untoward experience occurring in a subject during the study, regardless of whether it is considered to be related to catheter clamping. All adverse events reported spontaneously by the trial subject or observed by the investigator or their staff will be recorded.

8.3 Abnormal test results.

Abnormal test results should be evaluated to determine whether they should be reported as adverse events based on the following criteria for objective test values: 1) Test results are accompanied by symptoms; 2) Test results require medical or surgical intervention; 3) The investigator considers the test result to be an adverse event.

If none of the above criteria are met, merely repeating an abnormal test does not constitute an adverse event. Test results judged by the investigator to be erroneous do not need to be reported as adverse events.

8.4 Serious adverse events

Serious adverse events include any of the following adverse medical events: 1) Events or effects leading to death; 2) Life-threatening events; 3) Events requiring hospitalization or prolonging the hospital stay of an inpatient; 4) Events resulting in

persistent or significant disability or incapacity. Upon learning of a serious adverse event that is life-threatening or leads to death, it must be reported within 7 days. Other serious adverse events must be reported within 15 days. All adverse events are followed up immediately after they occur, until the event stabilizes or improves. Depending on the specific situation, follow-up may require additional tests or medical procedures, or further referral.

8.5 Severity assessment

The severity of adverse events will be assessed using the Clavien-Dindo classification of complications.

8.6 Causality assessment

The causality of adverse events with respect to the intervention will be subjectively assessed by the investigator.

9. Data processing and storage

Clinical research data will be recorded through the perioperative eCRF, including perioperative information, pathological data, and follow-up information. To protect patient privacy, patient identification numbers will not be disclosed to data analysts. All patients will be coded and identified using random numbers. These random numbers do not include patient initials or date of birth. Members of the trial steering committee will have a decoding list that specifies the random numbers of patients in the database and their identification numbers.

10. Quality management

The key to the quality control of the trial lies in:

（1）Blinding quality control

The implementation of blinding in this study may affect the quality of the research, particularly the achievement of the primary endpoint. If the trial is not blinded to surgeons, it may influence their judgment on whether the patient needs secondary catheterization based on whether bladder training was performed. If the ultrasound imaging physicians are not blinded, it may affect their assessment of residual urine volume in the bladder based on their knowledge of the patient's intervention. Therefore, blinding the randomization information from surgeons and ultrasound imaging physicians is one of the key aspects of quality control in this experiment. To this end, the study requires patients and nurses to keep the patient's group assignment confidential from surgeons and ultrasound imaging physicians. Surgeons and ultrasound physicians must also consciously adhere to the principle of not inquiring about the patient's group assignment. Any premature unblinding must be recorded, including the reason and time of unblinding.

（2）Interventional method quality control

The implementation quality of the interventional method is the second key point of quality control in this study. To address this, the study implements quality control in the following aspects:1) All assigned nurses receive training, which includes standardized procedures for clamping and unclamping the urinary catheter, as well as the standardized operation for obtaining urine routine and urine culture before catheter removal；2) After the patient signs the informed consent and is enrolled, the assigned physician is clearly informed not to provide clinical advice on whether to clamp the catheter and not to participate in any operations related to bladder training. Additionally, the trial management group communicates with the patient that if the assigned physician suggests bladder training, the patient should promptly report to the assigned nurse and the trial steering committee. The trial steering committee will then communicate again with the assigned physician and emphasize the quality control points of the trial；3) The start of training is uniformly set for 9:00 am on the first postoperative day, and the removal of the catheter is uniformly set for 9:00 am the next day. It is not recommended to advance or delay the catheter removal time. Any orders to advance or delay the catheter removal must be communicated to the trial

steering committee members before execution, with reasons provided. If the trial steering committee deems the reason valid, the order to advance or delay the catheter removal is allowed to be executed；4) Nurses need to educate and guide enrolled patients to ensure that patients in the bladder training group actively perform forceful urination during each period of unclamping to assist in urine discharge；5) Patients in the bladder training group, if unable to persist in reaching the specified catheter clamping time (less than 3 hours of catheter clamping before feeling the urge to urinate), may end a training cycle early, open the catheter for 5 minutes, and then start the next clamping training cycle；6) Before catheter removal, patients in the bladder training group must complete the Bladder Training Quality Self-Assessment Form; 7) During the first catheterization of the patient, selective α1-adrenergic receptor blockers (such as Tamsulosin) should not be used. If it is necessary to use them due to the patient's condition, the reasons should be recorded; 8) Each patient enrolled in the study will be given a subject compensation of 100 yuan to increase the compliance of the enrolled patients and the success rate of follow-up.

（3）Endpoint quality control

Our project team requires all levels of physicians in our department to strictly follow the bladder residual urine assessment method and the criteria for secondary catheterization as stipulated in the project research plan to calculate bladder residual urine and decide whether to perform secondary catheterization. To reduce bias in the measurement of bladder residual urine, this study implements quality control in the following two aspects: 1) A fixed radiologist is responsible for assessing bladder residual urine, and this physician has specialized in abdominal digestive and urinary system ultrasound examinations for over 10 years; 2) The ultrasound diagnosis location is set in the same therapeutic area as the patient, ensuring that patients can undergo immediate ultrasound examination after the first urination following catheter removal, avoiding the impact on the judgment of residual urine due to a long interval between urination and ultrasound examination; 3) For patients who fail to undergo the residual urine volume assessment in a timely manner for various reasons after the first urination, a bladder ultrasound should be conducted immediately after the second

urination, and this situation should be recorded; 4) For patients whose first urination occurs after 18:00 following the removal of the urinary catheter, since the designated ultrasound physician for assessment has already left work and is unable to conduct on-site assessment, the residual urine volume assessment will be carried out by the ultrasound physician on 24-hour duty in the hospital, and this situation should be recorded.

To ensure the collection of primary and secondary endpoints, this study will appoint a supervisory nurse to serve as the Clinical Research Coordinator (CRC). The CRC will daily verify the patient's enrollment, withdrawal, achievement of primary endpoints, and measurement of secondary endpoints. They will remind physicians to perform relevant medical orders, nurses to execute medical orders and collect data, and patients to fill out the required questionnaires and self-assessment forms in a timely manner. Additionally, the study will arrange for two graduate students to work with the CRC to promptly enter data into the Electronic Case Report Form (eCRF) and the database (Epidata).

（4）Regular education for healthcare personnel involved in the study.

The research group of this project will conduct regular education for all physicians and nurses involved in the study on a monthly basis. The main content of the education includes the three quality control aspects mentioned above: blinding quality control, interventional method quality control, and endpoint quality control. This ensures that physicians and nurses can strictly follow the quality control requirements of the study for related operations and ensures the quality of the intervention operations performed by nurses on enrolled patients.

11. Statistical analysis

11.1 Sample size determination

The sample size is calculated based on a differential test, with urinary dysfunction as the primary endpoint. Based on our preliminary research results, we estimate the

incidence of urinary dysfunction in the bladder training group is 44.7%, and in the direct removal group, it is 59.3%. Patients are randomly assigned to the two groups in a 1:1 ratio. With a two-sided significance level α of 0.05 and a power (1-β) of 80%, the sample size was calculated using PASS 15 software. Each group, the ICCAUT group and the free-drainage group, requires 180 cases. Assuming a dropout rate of 10%, each group requires 200 cases. Therefore, this trial needs a total of 400 cases.

11.2 Analysis population

11.2.1 Full analysis set

The comparative analysis of the primary outcome will be conducted on the basis of the "Intention-to-Treat (ITT)" principle. The ITT analysis will include all patients who have undergone randomization. In the ITT analysis, for patients who are randomized to the bladder training group but have the urinary catheter removed directly without undergoing the training ultimately, they will still be analyzed as part of the bladder training group. For patients who are randomized to the direct catheter removal group but have received bladder training in the end, they will still be analyzed as part of the direct catheter removal group.

Specific possible reasons for not following the randomization procedure include: 1) The patient's urine becomes cloudy during the postoperative catheterization period, and the physician suspects a urinary tract infection, thus not recommending bladder training; 2) The patient cannot tolerate catheter clamping and refuses bladder training; 3) The patient refuses to follow the assigned procedure; 4) The nurse fails to perform the operation according to the assigned method; 5) The catheter is not removed on the second postoperative day, either earlier or later. The study needs to record the specific reasons for not following the planned procedure.

11.2.2 Per-protocol analysis set

In the per-protocol analysis set (PPA), only cases that strictly follow the randomization and the assigned treatment plan will be included in the analysis.

Patients who do not receive treatment according to the assigned randomization plan will be excluded from the PPA. The patients to be excluded include: 1) Patients whose urinary catheters were not removed on the second day after the operation for various reasons, either with the removal time advanced or postponed; 2) Patients who did not carry out the bladder training strictly according to the plan; 3) Patients who had to use selective α1-adrenergic receptor blockers due to their medical conditions during the first catheterization.

11.2.3 As-treated analysis set

In the as-treated analysis set (ATA), we will analyze patients based on the actual treatment they received, rather than the treatment assigned by randomization. The ATA analysis set will include all the patients in the ITT analysis set. However, in terms of grouping, in the ATA analysis, patients who receive at least one round of bladder training are classified as the bladder training group, while those who do not receive training are classified as the direct removal group.

11.3 Missing data and its handling approaches

11.3.1 Definition of Missing Data

Since the primary endpoint is a composite endpoint, if a patient fails to achieve any of the positive events within the primary endpoint (secondary catheterization or residual urine volume > 100 ml) and any of the following situations occurs: 1) the residual urine volume after the first urination following the removal of the urinary catheter is missing; or 2) the situation of secondary catheterization within 7 days after the removal of the urinary catheter is missing, the primary endpoint will be defined as missing. The possible reasons for the missing primary endpoint include: 1) loss to follow - up or death, making it impossible to know whether secondary catheterization occurs within 7 days after the removal of the urinary catheter; 2) after the removal of the urinary catheter, due to various reasons, the bladder ultrasound for assessing the residual urine volume after the first urination is not carried out in a timely manner; 3)

the patient refuses the researcher to use the data related to the patient's own micturition function.

In the case where a subject refuses the researcher to use their personal data, that is, the subject requests to withdraw the informed consent and drop out of this study midway, all the data of this patient will be treated as missing data in the ITT analysis. If the subject refuses the collection of research data after withdrawal but consents to the collection of data before withdrawal, the researcher will treat the data after withdrawal as missing values, and the data before withdrawal can be included in the analysis.

11.3.2 Methods for handling missing data

In this study, if the missing rate of the primary endpoint is less than 5%, no imputation of missing data will be done in the analysis of the primary endpoint in the ITT, PPA, and ATA sets. During the analysis of the primary outcome, missing data will be treated as censored.

If the missing rate of the primary endpoint is 5% or higher at the end of the study, the following procedures will be adopted to handle the data with missing values in any variable of the primary endpoint.

1) When the data on post-void residual urine volume (RUV) by ultrasound after the first urination is complete, and the situation of secondary catheterization within 7 days after the removal of the urinary catheter is also complete. There is no missing data.

2) When the data on post-void RUV by ultrasound after the first urination is complete, but the situation of secondary catheterization within 7 days after the removal of the urinary catheter is missing.

If the post-void RUV by ultrasound after the first urination is greater than 100 ml, handling method: The primary endpoint is reached (positive), and no imputation of missing data for secondary catheterization is performed.

If the post-void RUV by ultrasound after the first urination is less than or equal to 100 ml, handling method: Multiple imputation method is used to impute the

missing data of secondary catheterization.

3) When the data on post-void RUV by ultrasound after the first urination is missing, but the situation of secondary catheterization within 7 days after the removal of the urinary catheter is complete.

If secondary catheterization occurs within 7 days after the removal of the urinary catheter, handling method: The primary endpoint is reached (positive), and no imputation of missing data for RUV is performed.

If secondary catheterization does not occur within 7 days after the removal of the urinary catheter, and the post-void RUV by ultrasound after the second urination is not missing, handling method: The Last Observation Carried Forward (LOCF) method is used to impute the missing data of the first residual urine volume. In LOCF method, the post-void RUV after the second urination is used to impute missing data of the first post-void RUV.

If secondary catheterization does not occur within 7 days after the removal of the urinary catheter, and the post-void RUV by ultrasound after the second urination is also missing, handling method: Multiple imputation method is used to impute the missing data of the first post-void RUV.

4) When the data on post-void RUV by ultrasound after the first urination is missing, and the situation of secondary catheterization within 7 days after the removal of the urinary catheter is also missing.

If the post-void RUV by ultrasound after the second urination is not missing, handling method: The LOCF method is used to impute the missing data of the first residual urine volume. If the imputed residual urine volume is greater than 100 ml, the primary endpoint is reached (positive), and no imputation of missing data for secondary catheterization is performed; if the imputed residual urine volume is less than or equal to 100 ml, multiple imputation method is used to impute the missing data of secondary catheterization.

If the post-void RUV by ultrasound after the second urination is also missing, handling method: Multiple imputation method is used to impute the missing data of the primary endpoint. At this time, the primary endpoint is imputed as a whole

missing data, rather than imputing the RUV and secondary catheterization separately.

Through the above treatment methods, we will minimize the impact of missing data on the research results and ensure the accuracy and reliability of data analysis. The handling process of missing data in primary endpoint is shown in Figure 2.

In the analysis of secondary endpoint and subgroup analysis, we will not perform imputation of missing data.

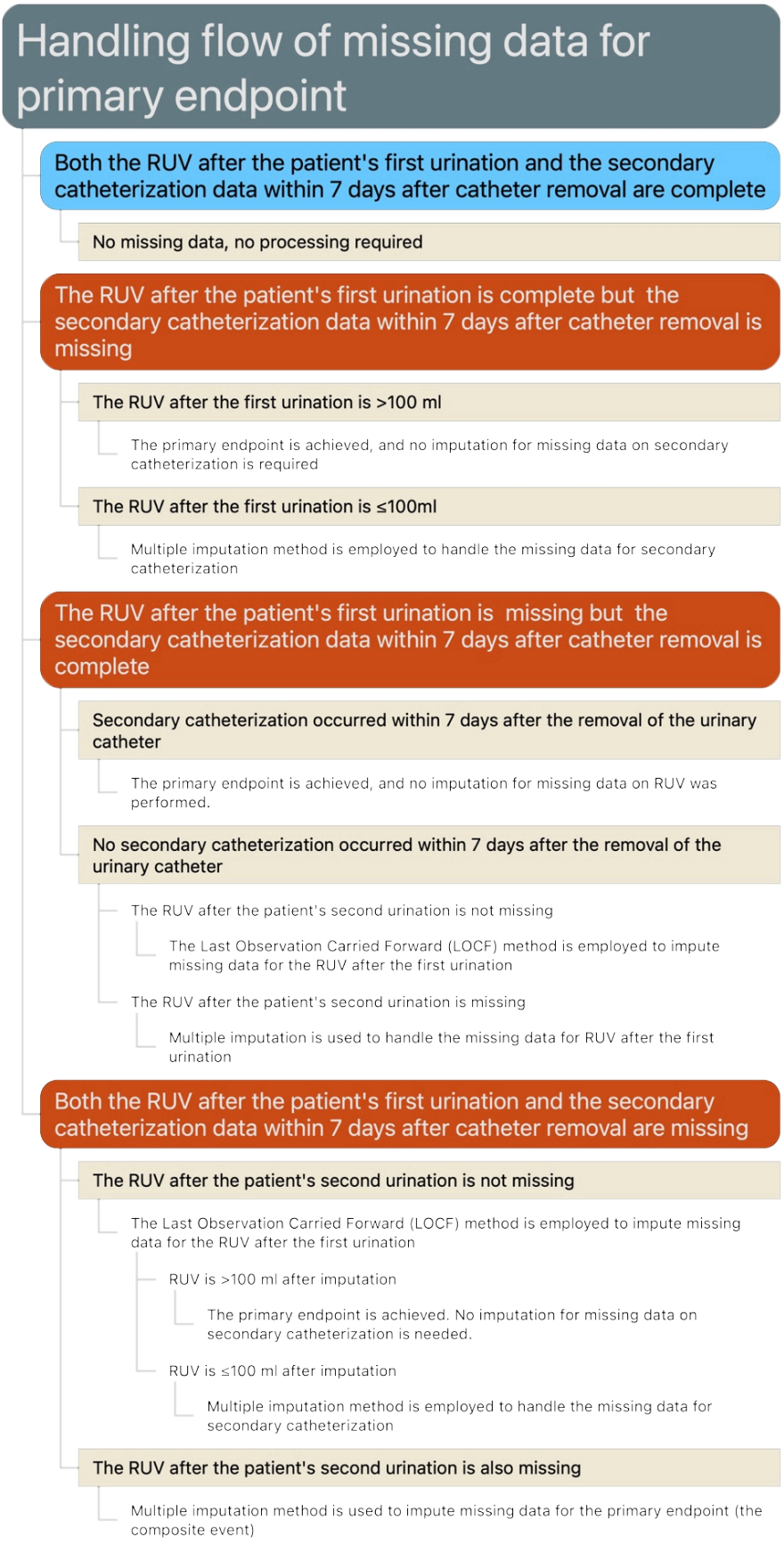

Figure 2 Imputation Scheme for Missing Data of the Primary Endpoint

11.4 Efficacy analysis and statistical methods

11.4.1 Analysis of the primary endpoint

Categorical variables will be statistically analyzed and described using counts (percentages). Without performing multivariate adjustment, the primary endpoints of the two groups will be compared in the ITT analysis set, PPA analysis set, and ATA analysis set respectively. The absolute risk differences and their 95% confidence intervals (95% CI) will be used to describe the differences between the two groups. In addition, in the PPA analysis set, the chi - square test or Fisher's exact test will be used to analyze the variables related to the primary endpoint. Multivariate logistic regression will be used to adjust for factors that may affect the primary endpoint and to analyze the independent risk factors influencing the primary endpoint. During this process, continuous variables will be converted into categorical variables. The variables used for adjustment include the patient grouping (bladder training/direct removal), tumor location (the lower border of the tumor is above the peritoneal reflection/the lower border of the tumor is below the peritoneal reflection), gender (male/female), and age (≤65 years/>65 years) in the PPA dataset. Besides the above - mentioned variables, variables with a p - value < 0.1 in the univariate analysis will also be included. The adjusted differences between groups will be described using odds ratios (OR) and 95% CI.

11.4.2 Sensitivity Analysis of the Primary Endpoint

This study will conduct sensitivity analyses on the missing cases of the primary endpoint and the positive events of the primary endpoint caused by reasons other than urinary retention. The sensitivity analyses for these two scenarios will be independently performed within the ITT analysis set.

11.4.2.1 Sensitivity Analysis of Missing Data

If the final missing rate of the primary endpoint is less than 5%, no imputation of

the primary endpoint will be carried out in the primary analysis ITT analysis set. If the final missing rate of the primary endpoint is ≥ 5%, data imputation will be performed according to the imputation scheme for missing data of the primary endpoint shown in Figure 2 within the primary analysis ITT analysis set. In the sensitivity analysis, for both of the above - mentioned situations, we will impute all missing data as either positive events or negative events, and conduct analyses for these two extreme scenarios in the ITT population.

11.4.2.2 Sensitivity Analysis of Positive Primary Endpoint Events Caused by Non - urinary Retention Reasons

In this study, some patients may undergo secondary catheterization due to reasons other than urinary retention. Such events may include the following situations: 1) The patient strongly requests secondary catheterization due to urgent urination or a strong sense of fullness, but the volume of urine drained after secondary catheterization does not exceed 100 ml; 2) The patient needs secondary catheterization due to disease - related factors (such as secondary surgery, urethral injury, shock, disturbance of consciousness, intestinal obstruction, bleeding, transfer to the ICU, SOFA score ≥2, etc.). In such cases, we still record them as positive primary endpoint events, but sensitivity analyses will be conducted for these cases.

For these patients, if 1) there is data on the post - void residual urine volume after the first urination, and the post - void residual urine volume after the first urination is > 100 ml, the primary endpoint is still considered positive, and no sensitivity analysis will be performed. If 2) there is no data on the post - void residual urine volume after the first urination, or the post - void residual urine volume after the first urination is ≤ 100 ml, a sensitivity analysis is required. In the sensitivity analysis, these patients will be treated as negative events of the primary endpoint.

11.4.3 Analysis of secondary endpoints

In the analysis of secondary endpoints, continuous variables will be described

using mean ± standard deviation or median (interquartile range); categorical variables will be described using counts (percentages). Missing values of the secondary endpoints will not be imputed, nor will sensitivity analyses be conducted for them.

11.4.4 Subgroup analysis

We will explore the differences in the primary endpoints between the two groups in different subgroups through subgroup analysis. The subgroups include gender (male; female), age (≤65 years old; > 65 years old), the relationship between the lower part of the tumor and the peritoneal reflection (above the peritoneal reflection; below the peritoneal reflection), as well as other variables that are independently related to the primary endpoint in the multivariate analysis. Logistic regression will be used for univariate and multivariate analyses, with effect sizes represented by OR and 95% CI, and subgroup interaction P-values will be calculated.

11.5 Exploratory Analysis

We will conduct an exploratory analysis of the situation of urinary tract infections. The main focus is to explore the independent related factors affecting urinary tract infections after rectal surgery. The analysis methods include univariate analysis, multivariate analysis, as well as subgroup analysis.

11.6 Interim analysis

This study does not include an interim analysis

11.7 Final analysis

We will conduct the primary endpoint analysis of the study after all patients have completed their first postoperative month follow-up and will publish the relevant research findings. The results of the exploratory analysis will be published separately as a post-hoc analysis

11.8 Data Monitoring Committee

This study establishes a Data and Safety Monitoring Board (DSMB), which is composed of senior surgeons, ethicists, and statistical analysts. The members of the DSMB are independent of this trial and have no competing interests that could influence the trial. The DSMB will receive and review the safety data of this trial. If the DSMB believes that the number of adverse events in the trial is biased between groups, they will notify the trial steering committee.

No interim analyses are planned in this study. However, after the study begins, the DSMB will assess the study results every six months and may meet earlier for assessments. The assessment content includes the recording of primary and secondary endpoints, adverse events, and the dropout rate of study samples. Except for the trial steering committee, DSMB members must not share confidential information with anyone outside the DSMB.

The interventional methods used in this study (intermittent catheter clamping and continuous catheter opening) are common clinical strategies for managing catheters after surgical procedures and do not impose additional risks on patients. Therefore, this study does not have predefined stopping criteria. However, if the regular assessments by the DSMB reveal that the urinary system-related safety indicators due to the intervention methods are significantly worse than the current domestic standards, the DSMB will submit its recommendations in writing to the trial steering committee. This may include requests to modify the trial plan, re-evaluate the quality of cases, or even suspend or terminate patient enrollment in the clinical trial.

12. Data collection and management

12.1 Case Report Form/Electronic Data Recording

The Case Report Form (CRF) includes the following primary outcome measures: incidence of urinary dysfunction, including bladder residual urine volume after the

first urination, rate of secondary catheterization, time from catheter removal to secondary catheterization (hours), method of secondary catheterization (suprapubic puncture/urethral catheterization), reasons for secondary catheterization, and urine volume drained after secondary catheterization (ml). Secondary outcome measures include: urinary tract infection status (white blood cell count in urine, bacterial content, and positive/negative urine culture before catheter removal), time to first urination after catheter removal (hours), bladder residual urine volume after the first urination (milliliters), CRBD grading assessment, bladder training quality self-assessment form for the bladder training group, postoperative complications within 30 days (incidence of complications, types of complications, and grading of complications), and urinary function assessment on the second day after catheter removal (ICIQ-SF, IPSS score).Other collected baseline indicators include: gender, age, underlying diseases and medical history (hypertension, diabetes, cardiovascular disease, cerebrovascular disease, history of pelvic surgery), history of benign prostatic hyperplasia in males (confirmed by medical history or imaging), preoperative IPSS score, preoperative ICIQ-SF score, preoperative radiotherapy and chemotherapy status, preoperative urine routine white blood cell count, preoperative urine routine bacterial count, preoperative urine culture results, ASA, BMI, preoperative imaging assessment results (preferably rectal MRI), including the distance from the lower edge of the tumor to the anal margin, the relationship between the lower edge of the tumor and the peritoneal reflection (above/below the peritoneal reflection), clinical T staging, clinical N staging, MRF status, EMVI status, surgery duration, surgical procedures, including low anterior resection (LAR), intersphincteric resection (ISR), abdominoperineal resection (APR), transanal TME (TaTME), Bacon surgery, stoma status (ileum/colon, single/double), surgical technique (robotic/laparoscopic), and postoperative pathological conditions (pathological T staging, pathological N staging, CRM, DRM). See the CRF form for details.

All patients who meet the inclusion criteria will be registered. For patients who are excluded due to the exclusion criteria, the specific reasons for exclusion need to be recorded. For the patients who eventually enter the randomization process, their

detailed information will be registered in the database. For patients who deviate from the randomized grouping for various reasons and those who deviate from the established intervention process during the intervention, the reasons for the deviation need to be recorded. All patients after randomization are required to record the relevant data completely in accordance with the content of the CRF.

12.2 Data management

Data collection will be conducted by the CRC, who will verify and collect information on patient enrollment, withdrawal, achievement of primary endpoints, and measurement of secondary endpoints daily. Two graduate students will serve as data entry personnel. The two graduate students and the CRC will jointly collect baseline data. Data entry will be performed using a dual-entry method, with one person entering the data and another verifying it. Both paper and electronic versions of the CRF will be entered simultaneously. Baseline data will be entered on the day of surgery, information related to primary and secondary endpoints will be entered within two days of catheter removal, and pathological and other hospitalization information must be entered within one week after patient discharge. Complications within 30 days after surgery must be entered within 30 days after surgery. To protect patient privacy, all patients will be coded and identified using random numbers. These random numbers do not include patient initials or date of birth. Investigators will have a decoding list that specifies the random numbers of patients in their site's files and their patient identification numbers.

13. Ethics and Morality

13.1 Ethics committee

Before the study begins, this trial will obtain ethical approval from the ethics committee of our hospital.

13.2 Patient information and informed consent

Eligible patients should receive personal notification from the treating surgeon and be provided with written information related to the trial. Before entering the randomization of the study, each patient must provide informed consent in accordance with the guidelines of the ethics committee. Patients will have at least 24 hours to decide whether to participate in the study and can withdraw from the study at any time without reason.

The informed consent process should be conducted by a physician of the attending level or higher within our group. The information provided to patients during informed consent includes:1) A statement that the trial involves research;2) A full and fair explanation of the procedures to be followed;3) A full explanation of the nature, expected duration, and purpose of the research;4) A description of any risks or discomforts that the patient can reasonably expect;5) A description of any benefits that can be reasonably expected;6) A statement that patient data will be handled with care and confidentiality, and the duration of data retention (15 years);7) A statement that patient biological materials will be retained for 15 years;8) A statement about voluntary participation and withdrawal, indicating that refusal to participate in the trial involves no penalty or loss of benefits to which the patient is otherwise entitled, and that the patient may stop participating at any time without penalty or loss of benefits, in which case the patient will receive standard care of the same quality.

14. Definition of study completion

The study is considered complete when all enrolled patients have completed a one-month follow-up.

15. Trial organizational structure

This study is conducted at a single medical center—The First Hospital of Jilin

University. The trial steering committee members include Quan Wang , Haiyan Hu, Jianan Sun, Yuchen Guo , and Tingting He . The Data and Safety Monitoring Board (DSMB) is composed of senior surgeons, ethicists, and statistical analysts. Each member of the DSMB is independent of this trial and has no competing interests that could influence the trial. This clinical trial is funded by the General Surgery Center Discipline Special Zone Project of The First Hospital of Jilin University, with the project number: 04050520005.

We did not involve patients or the public in the design of this study or in the oversight of its implementation. We also have no plans to share the data from this study with the patients who participated in the enrollment.

16. Confidentiality and data security

During the study, only data entry personnel and the DSMB are aware of the data situation, and others cannot access the database to know specific patient data. DSMB members can be aware of patient allocation and trial-related data. The DSMB will discuss the relevant results of the data with the trial steering committee members. Except for the trial steering committee, DSMB members must not share confidential information with anyone outside the DSMB.

For decisions and recommendations formed through discussions by the DSMB, the DSMB will submit these recommendations in writing to the trial steering committee. Additionally, the CRC will also receive these recommendations to be discussed at the trial steering committee meeting. The content of the meeting needs to be stored and secured by the DSMB members after the meeting, so that it can be reviewed in comparison with the next report.

17. Insurance and compensation.

All enrolled patients have purchased medical commercial insurance in

collaboration with our hospital and an insurance company before surgery. The insurance will compensate for surgery-related complications and surgery-related deaths. For each patient enrolled in the trial, an enrollment compensation of 100 yuan will be provided to enhance the patient's compliance.

18. Publication statement

The data will not be published before the collection of primary outcomes is completed. We will conduct the primary endpoint analysis of the study after all patients have completed their first postoperative month follow-up and will publish the relevant research findings. The order of authors will be arranged from highest to lowest based on the number of enrolled cases. The results of the exploratory analysis will be published separately as a post-hoc analysis after the publication of the results of the primary endpoint.

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Appendix 1: IPSS Score		
Symptom	**Question**	**Score**
Incomplete Emptying	Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0: None
		1: Less than 1 time in 5
		2: Less than half the time
		3: About half the time
		4: More than half the time
		5: Almost always
Frequency	Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0: None
		1: Less than 1 time in 5
		2: Less than half the time
		3: About half the time
		4: More than half the time
		5: Almost always
Intermittency	Over the past month, how often have you found you stopped and started again several times when you urinated?	0: None
		1: Less than 1 time in 5
		2: Less than half the time
		3: About half the time
		4: More than half the time
		5: Almost always
Urgency	Over the past month, how difficult have you found it to postpone urination?	0: None
		1: Less than 1 time in 5
		2: Less than half the time
		3: About half the time
		4: More than half the time
		5: Almost always
Weak Stream	Over the past month, how often have you had a weak urinary stream?	0: None
		1: Less than 1 time in 5
		2: Less than half the time

		3: About half the time
		4: More than half the time
		5: Almost always
Straining	Over the past month, how often have you had to push or strain to begin urination?	0: None
		1: Less than 1 time in 5
		2: Less than half the time
		3: About half the time
		4: More than half the time
		5: Almost always
Nocturia	Over the past month, how many times did you typically get up at night to urinate?	0: None
		1: 1 time
		2: 2 times
		3: 3 times
		4: 4 times
		5: 5 or more times
1.Total Score Calculation: Sum the scores of the above 7 items. The total score ranges from 0 to 35. ①Mild symptoms: 0 - 7 ②Moderate symptoms: 8 - 19 ③Severe symptoms: 20 - 35		

Appendix 2: ICIQ-SF Score

International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI SF)

1.Please write in your date of birth: _

2.Are you (check one): □ Female □ Male

3.How often do you leak urine? Check one box.

0 □ Never

1 □ About once a week or less often

2 □ Two or three times a week

3 □ About once a day

4 □ Several times a day

5 □ All the time

4.We would like to know how much urine you think leaks. How much urine do you usually leak (whether you wear protection or not)? Check one box.

0 □ None

2 □ A small amount

4 □ A moderate amount

6 □ A large amount

5.Overall, how much does leaking urine interfere with your everyday life? Please circle a number between 0 (not at all) and 10 (a great deal)

0 1 2 3 4 5 6 7 8 9 10

Not at all A great deal

ICIQ score: Sum scores 3 + 4 + 5

6.When does urine leak? Please check all that apply to you.

□ Never – urine does not leak

□ Leaks before you can get to the bathroom

□ Leaks when you cough or sneeze

□ Leaks when you are asleep

□ Leaks when you are physically active / exercising

□ Leaks when you have finished urinating and are dressed

□ Leaks for no obvious reason

□ Leaks all the time

The grading of urinary incontinence:

- Total score of 0 - 5: No urinary incontinence or mild urinary incontinence.

- Total score of 6 - 10: Moderate urinary incontinence.

- Total score of 11 and above: Severe urinary incontinence.

Appendix 3: CRBD Grading Assessment

Grading	Symptoms
Grade 0	No discomfort at all
Grade 1	Only informed of urethral discomfort when asked and it is tolerable.
Grade 2	The patient actively informed of urgency, dysuria and lower abdominal distension, but without behavioral response
Grade 3	The patient actively informed of urgency, dysuria and lower abdominal distension, accompanied by behavioral responses (such as severe restlessness, limb movement, attempting to remove the catheter), requiring medical staff to restrain and multiple caregivers to watch.

Appendix 4: Bladder Training Quality Self-Assessment Form

1.Total number of times the catheter was clamped?
2.Did you feel the urge to urinate each time during the clamping training?
□ Every time； □ More than half of the times; □ Less than half of the times; □ Never
3.Were you able to hold for 3 hours before releasing the catheter?
□ Every time； □ More than half of the times; □ Less than half of the times; □ Never
4.Did you cooperate with the urination action after releasing the catheter?
□ Every time； □ More than half of the times; □ Less than half of the times; □ Never

Appendix 5: Postoperative Complications Clavien-Dindo System Grading.

Grading		Definition
I		Postoperative complications that do not require drug, surgical, endoscopic, or radiological intervention, but include drug therapy such as anti-emetics, antipyretics, analgesics, diuretics, electrolytes, physiotherapy, and also include incisional infections that are opened at the bedside;
II		Requires drug therapy, excluding patients who only received Grade I medication, incisional infections requiring antibiotic treatment, and includes blood transfusions and total parenteral nutrition
III		Requires surgical, endoscopic, or radiological intervention
	IIIa	Does not require general anesthesia
	IIIb	Requires general anesthesia
IV		Life-threatening complications (including central nervous system complications) requiring IC (intermediate care) or ICU management
	IVa	Organ failure (including dialysis)
	IVb	Multi-organ failure
V		Death

	version 1.1.1	version 1.1.2
2.2.2 Secondary study endpoints and definitions.		The secondary study endpoint is added with 6) Incidence of residual urine volume greater than 200 milliliters after the first urination.
5.1.1 Methods for Generating Random Sequences	The randomly assigned time is on the day when the patient returns to the ward after the operation.	Random assignment will take place between 6:00 am and 7:00 am on the first postoperative day, before the intervention is carried out.
15. Trial organizational structure	This study has no research funding support.	Add a description of whether patients and the public participated in the design of this project and the supervision of project implementation. Add project funding statements.

section	version 1.1.2	version 2.0	Reasons for Revision
2.2.1 Primary Study Endpoint and Definition	In the assessment of the primary endpoint, if a patient undergoes secondary catheterization but does not meet the criteria for withdrawal, and if the urine volume drained after secondary catheterization is less than 100 ml, such patients will not be defined as having urinary dysfunction.	In the determination of the primary endpoint, patients who undergo secondary catheterization for reasons other than urinary retention will also be recorded as primary endpoint events, but sensitivity analysis shall be conducted on these patients in the sensitivity analysis. The specific analysis method is described in the section on sensitivity analysis of the primary endpoint in the statistical analysis. Such events may include the following scenarios: 1) The patient requests secondary catheterization due to urgent urination or intense bloating, but the urine volume withdrawn after secondary catheterization does not exceed 100 ml; 2) The patient requires secondary catheterization due to disease-related factors (such as secondary surgery, urethral injury, shock, altered consciousness, intestinal obstruction, hemorrhage, transfer to ICU, SOFA score ⩾2, etc.).	In the original protocol, this category of patients might include those with urinary discomfort who void multiple times or those who require secondary catheterization due to medical conditions. In the original protocol, classifying these patients as negative events may have led to an underestimation of positive events. In the revised protocol, these events are classified as positive events, and sensitivity analysis is performed to enable a more comprehensive analysis of the primary endpoint.
4.1 Inclusion criteria	2) Patients with tumors located below the rectosigmoid junction, as determined by preoperative computed tomography (CT) or rectal magnetic resonance imaging (MRI).	Preoperative colon CT or rectal MR confirms that the lower edge of the tumor is located in the rectum (including the rectal and anal canal regions) below the rectosigmoid junction (12 cm from the anal verge);	The definition of the rectosigmoid junction may vary across different literatures. The trial team of our center defines the lower boundary of the rectosigmoid junction as 12 cm from the anus. In the revised protocol, the specific length range is more clearly marked to avoid discrepancies in reading and understanding by other researchers.
4.3 Withdrawal criteria	4.3 Withdrawal criteria. After randomization, patients will be withdrawn from the trial if any of the following situations occur: 1) Inability to remove the urinary catheter within 5 days postoperatively due to various reasons (e.g., impaired consciousness, transfer to the intensive care unit (ICU), Sequential Organ Failure Assessment (SOFA) score ⩾2, etc.). 2) Secondary catheterization was performed for reasons other than urinary retention (e.g., 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 α1-adrenergic receptor blocker is used during the first catheterization of the patient due to medical necessity.	Delete the withdrawal criteria.	In this study, the mITT analysis in the original protocol excluded patients who met withdrawal criteria, which may have disrupted the trial's randomization and introduced selection bias. Therefore, the primary analysis set in the revised protocol has been changed to the ITT (Intention-to-Treat) analysis set, meaning all randomized patients are included in the analysis. The withdrawal criteria have been removed, and cases previously covered by the withdrawal criteria will be included in the sensitivity analysis.
5. Study treatment groups	…… If the SOFA score is 2 or higher, the duration of catheter placement should be extended. If the catheter still cannot be removed by the fifth day due to a SOFA score of 2 or higher, the patient will be excluded according to the withdrawal criteria. ……	Delete". If the catheter still cannot be removed by the fifth day due to a SOFA score of 2 or higher, the patient will be excluded according to the withdrawal criteria."	The revised protocol has deleted the exclusion criteria, so the description "if the urinary catheter cannot be removed due to a SOFA score ⩾2 points beyond day 5, the patient will be excluded according to the withdrawal criteria" has been removed in the new version.
5.1.1 Methods for Generating Random Sequences	Random assignment will take place between 6:00 am and 7:00 am on the first postoperative day, before the intervention is carried out. The randomization will be distributed to the assigned nurse via an envelope, and the bladder training will be conducted by the assigned nurse.	A random number table manager (RNTM) (Yanhua Wu) from the Research Centre of Clinical Epidemiology (RCCE) at Jilin University First Hospital generates and preserves the random number table and allocates the randomization information. The RNTM is independent of other researchers in this trial.	we move this description in version 1.1.2 to section "5.1.2 Randomization concealment" in version 2.0, and provide a detailed description of who generated the random number table to ensure the transparency of the protocol.
5.1.2 Randomization concealment.	After randomization, the group assignment information will be printed on a slip of paper and placed into an opaque envelope. Before 8:00 am on the second postoperative day, the envelope containing the group assignment information will be given to the assigned nurse, who will conduct the catheter training.	After the random number table is generated through R by RNTM, the random allocation information will be printed on paper strips and placed into opaque envelopes. The random number table and random allocation information will be kept by the RNTM from the RCCE. After clinical doctors and bedside nurses complete the patient screening and determine that a patient meets the inclusion criteria for enrollment, random allocation can be conducted. The random allocation will take place between 6:00 a.m. and 7:00 a.m. on the first day after the patient's surgery, before the intervention procedure. Clinical doctors and bedside nurses will submit an enrollment application to the RNTM and provide the patient's gender information and whether they have undergone an APR surgery. Based on the stratification corresponding to these two factors, the RNTM will deliver the opaque envelopes containing the random allocation information to the bedside nurse before 8:00 a.m. on the first day after surgery. The bedside nurse will then open the envelope and perform corresponding procedures on the patient according to the grouping information inside. The RNTM is independent of other personnel involved in this study, do not participate in any other clinical operations of this study, and have no knowledge of any other information about the patients.	The new protocol describes the random allocation method and concealment method in more detail, allowing other researchers to have a more detailed and clear understanding of this part of the work.
6.3 Patient compliance and withdrawal	……If the patient still insists on withdrawing, their preference will be respected, and the patient will be excluded from the trial. The clinical information related to this patient will not be included in any data analysis related to this trial.	……If the patient still insists on withdrawing from the study and refuses to allow the use of personal data in this research project, the patient shall be withdrawn from the study according to the patient's wish, and all data of this patient shall be treated as missing data. During the follow-up phase of the primary endpoint, if a patient refuses to cooperate with the follow-up of the primary endpoint, including the follow-up of secondary catheterization and the assessment of residual urine volume, the principal investigator shall communicate with the patient and appropriately increase the compensation for the subjects to avoid the absence of the primary endpoint. If the patient stubbornly refuses to cooperate with the follow-up of the primary endpoint, the primary endpoint of the patient shall be treated as missing data, and other data shall be recorded in the database.	The handling methods when patients request to withdraw from the study have been supplemented in more detail, as well as the approaches to reduce the loss to follow-up, and the principles for processing the relevant data of these patients.
9. Data processing and storage	All patients who meet the inclusion criteria will be registered, including those who refuse randomization, those excluded due to exclusion criteria, and those who are withdrawn after randomization due to withdrawal criteria. Reasons for exclusion and withdrawal will be recorded.	Delete this paragraph	This part does not fall within the scope of the content of "Data Processing and Storage." The corresponding description has been revised and added to "12.1 Case Report Form/Electronic Data Record."
10. Quality management （2） Interventional method quality control	7) During the first catheterization, selective α1-adrenergic receptor blockers (such as tamsulosin) should not be used. If medically necessary, the patient must withdraw from the trial.	7) During the first catheterization of the patient, selective α1-adrenergic receptor blockers (such as Tamsulosin) should not be used. If it is necessary to use them due to the patient's condition, the reasons should be recorded; 8) Each patient enrolled in the study will be given a subject compensation of 100 yuan to increase the compliance of the enrolled patients and the success rate of follow-up.	Patients who use α1-adrenergic receptor blockers in the new protocol will still be included in the Intention-to-Treat (ITT) analysis to avoid the impact of patient withdrawal on the balance of components after randomization. Patients who do not meet the protocol will be excluded from the Per-Protocol Analysis (PPA) set. In addition, a measure has been added to reduce the rate of loss to follow-up.
10. Quality management （3） Endpoint quality control		3) For patients who fail to undergo the residual urine volume assessment in a timely manner for various reasons after the first urination, a bladder ultrasound should be conducted immediately after the second urination, and this situation should be recorded; 4) For patients whose first urination occurs after 18:00 following the removal of the urinary catheter, since the designated ultrasound physician for assessment has already left work and is unable to conduct on-site assessment, the residual urine volume assessment will be carried out by the ultrasound physician on 24-hour duty in the hospital, and this situation should be recorded.	Measures have been added to avoid the missing of primary endpoints, as well as remedies after the primary endpoints are missing, to facilitate the subsequent processing of missing data.

11.2.1 Full analysis set	The comparative analysis of the primary outcomes will be conducted on the basis of the "modified intention-to-treat (mITT)". The mITT analysis will include patients who did not follow the randomly assigned measures but were not excluded according to the withdrawal criteria. In this study, if a patient meets the withdrawal criteria after randomization, this patient will be excluded, and the relevant data of this patient will not appear in the statistical analysis including the mITT analysis. In the mITT analysis, for patients randomly assigned to the bladder training group, if the catheter is directly removed without undergoing training at the end, the analysis will still be carried out according to the bladder training group; for patients randomly assigned to the direct removal group, if they receive bladder training at the end, the analysis will still be carried out according to the direct removal group. In addition, if a patient undergoes secondary catheterization, does not meet the withdrawal criteria, but the urine volume drawn after secondary catheterization is less than 100ml. We will not consider that this secondary catheterization is caused by bladder emptying disorder. In the analysis, we will not classify such patients as having urinary dysfunction. In the mITT analysis, we will still include these patients in the analysis, but instead of classifying them as end-point events (positive events), we will analyze them as negative events.	The comparative analysis of the primary outcome will be conducted on the basis of the "Intention-to-Treat (ITT)" principle. The ITT analysis will include all patients who have undergone randomization. In the ITT analysis, for patients who are randomized to the bladder training group but have the urinary catheter removed directly without undergoing the training ultimately, they will still be analyzed as part of the bladder training group. For patients who are randomized to the direct catheter removal group but have received bladder training in the end, they will still be analyzed as part of the direct catheter removal group.	The primary analysis set in the new version of the protocol has been changed to the Intention-to-Treat (ITT) analysis set. That is, all patients included in the randomization will be included in the analysis set, so as to prevent unnecessary patient withdrawals from disrupting the inter-group balance after randomization of the trial and introducing selection bias.
11.2.2 Per-protocol analysis set	Excluded patients include those who did not have the catheter removed on the second postoperative day, as well as those whose bladder training was not conducted strictly according to plan.	The patients to be excluded include: 1) Patients whose urinary catheters were not removed on the second day after the operation for various reasons, either with the removal time advanced or postponed; 2) Patients who did not carry out the bladder training strictly according to the plan; 3) Patients who had to use selective α1-adrenergic receptor blockers due to their medical conditions during the first catheterization.	Elaborate in more detail on the population that conforms to the per-protocol analysis set.
11.2.3 As-treated analysis set	In the ATA analysis, patients who receive at least one round of bladder training are classified as the bladder training group, while those who do not receive training are classified as the direct removal group.	The ATA analysis set will include all the patients in the ITT analysis set. However, in terms of grouping, in the ATA analysis, patients who receive at least one round of bladder training are classified as the bladder training group, while those who do not receive training are classified as the direct removal group.	Elaborate in more detail on the population of the as-treated analysis set.
11.3 Missing data and its handling approaches		Section "11.3 Missing data and its handling approaches" has been supplemented.	The missing data in the study and their handling methods have been defined in detail to prevent biases caused by unclear definitions and handling methods of the missing data during the analysis process.
11.4.1 Analysis of the primary endpoint	……Without multivariate adjustment, the primary endpoints of the two groups will be compared using relative risk (RR) and its 95% confidence interval (95% CI) to describe the differences between the groups. Additionally, logistic regression will be used to adjust for factors that may affect the rate of secondary catheterization (such as the relationship between the lower edge of the tumor and the peritoneal reflection, BMI, age, surgery duration, etc.). ……	……Without performing multivariate adjustment, the primary endpoints of the two groups will be compared in the ITT analysis set, PPA analysis set, and ATA analysis set respectively. The absolute risk differences and their 95% confidence intervals (95% CI) will be used to describe the differences between the two groups. In addition, in the PPA analysis set, the chi - square test or Fisher's exact test will be used to analyze the variables related to the primary endpoint. Multivariate logistic regression will be used to adjust for factors that may affect the primary endpoint and to analyze the independent risk factors influencing the primary endpoint. During this process, continuous variables will be converted into categorical variables. The variables used for adjustment include the patient grouping (bladder training/direct removal), tumor location (the lower border of the tumor is above the peritoneal reflection/the lower border of the tumor is below the peritoneal reflection), gender (male/female), and age (≤65 years/>65 years) in the PPA dataset. Besides the above - mentioned variables, variables with a p - value < 0.1 in the univariate analysis will also be included.……	The revised protocol employs Absolute Risk Differences to more directly reflect the absolute differences in incidence rates. The new protocol further clarifies the analysis sets for the primary endpoint and the analysis sets for the multivariate analysis of the primary endpoint. It also stipulates the criteria for variables to be included in the multivariate analysis. These measures are aimed at avoiding biases that may arise from the lack of a pre-defined statistical analysis plan.
11.4.2 Sensitivity Analysis of the Primary Endpoint		add section "11.4.2 Sensitivity Analysis of the Primary Endpoint"	Since there may be missing values for the primary endpoint or positive primary endpoint events caused by non-urinary retention reasons, sensitivity analyses are added to ensure the robustness of the analysis results.
11.4.3 Analysis of secondary endpoints	We will consider using sensitivity analysis to explain the impact of missing data on overall results.	Missing values of the secondary endpoints will not be imputed, nor will sensitivity analyses be conducted for them.	The secondary endpoints are not the main research objectives. It is clearly stated that no imputation or sensitivity analysis will be conducted for them.
11.4.4 Subgroup analysis	We will explore differences in the rate of secondary catheterization between the two groups in different subgroups through subgroup analysis. Subgroups include Sex (male; female), age (≤65 years; >65 years), ASA classification (≤II; ≥ III), BMI (≥28 kg/m²; <28 kg/m²), the relationship between the lower edge of the tumor and the peritoneal reflection (above the peritoneal reflection; below the peritoneal reflection), Operating time (≤180 mins; >180 mins), neoadjuvant therapy Yes, No), and surgical procedures (LAR surgery; APR surgery; TaTME surgery; Bacon surgery; ISR surgery; CAA surgery).	We will explore the differences in the primary endpoints between the two groups in different subgroups through subgroup analysis. The subgroups include gender (male; female), age (≤65 years old; > 65 years old), the relationship between the lower part of the tumor and the peritoneal reflection (above the peritoneal reflection; below the peritoneal reflection), as well as other variables that are independently related to the primary endpoint in the multivariate analysis.	The objectives of the subgroup analysis, the criteria for subgroup classification, and which variables are eligible for subgroup analysis have been redefined. This is to avoid conducting subgroup analysis on unnecessary variables.
	……Additionally, we will conduct exploratory subgroup analyses for some key secondary endpoints, such as the incidence of urinary tract infections. All hypothesis tests are two-sided with a significance level of 5%. We will analyze the results and write the paper after all enrolled patients have completed the one-month follow-up.	delete these statement	We move these statement to section "11.5 Exploratory Analysis"
11.5 Exploratory Analysis		add section "11.5 Exploratory Analysis"	The new protocol clarifies the target objects and analysis methods of the exploratory analysis.
11.7 Final analysis		Add the content: "The results of the exploratory analysis will be published separately as a post-hoc analysis."	The reporting time for the exploratory analysis has been supplemented.
12.1 Case Report Form/Electronic Data Recording		Add the content: "All patients who meet the inclusion criteria will be registered. For patients who are excluded due to the exclusion criteria, the specific reasons for exclusion need to be recorded. For the patients who eventually enter the randomization process, their detailed information will be registered in the database. For patients who deviate from the randomized grouping for various reasons and those who deviate from the established intervention process during the intervention, the reasons for the deviation need to be recorded. All patients after randomization are required to record the relevant data completely in accordance with the content of the CRF. "	The new research protocol clarifies the scope of data recording, as well as the principles for handling relevant data when paticipants deviate from the research protocol.
12.2 Data management	All patients who meet the inclusion criteria will be recorded. If a patient is excluded due to exclusion criteria or is withdrawn after randomization due to withdrawal criteria, this must be documented in the database.	delete this paragraph	This part does not fall within the scope of the content of the "Data Management" section. The corresponding description has been revised and added to "12.1 Case Report Form/Electronic Data Recording".
17. Insurance and compensation.		Add the content: "For each patient enrolled in the trial, an enrollment compensation of 100 yuan will be provided to enhance the patient's compliance. "	Measures to further reduce the loss to follow - up
18. Publication statement		Add the content: "The results of the exploratory analysis will be published separately as a post-hoc analysis after the publication of the results of the primary endpoint. "	The publication time and scope of the research - related results have been supplemented.
Appendix 2: ICIQ-SF Score		The grading of urinary incontinence has been supplemented: - Total score of 0 - 5: No urinary incontinence or mild urinary incontinence. - Total score of 6 - 10: Moderate urinary incontinence. - Total score of 11 and above: Severe urinary incontinence.	This is conducive to the variable transformation and grading assessment of urinary incontinence during statistical analysis.