Randomised Controlled Trial

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Multicentre, prospective, randomized controlled non-inferiority trial of bladder catheter management in short-duration, minimally invasive colon surgery (The Vesicalcath I-Study)

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Background: Urinary catheterizationis a routine practice during major surgery to aid fluid resuscitation and monitor hemodynamic stability. However, the optimal duration for catheter retention remains controversial due to associated complications like acute urinary retention (AUR) and urinary tract infections (UTIs). This study evaluates whether immediate catheter removal after laparoscopic colectomy and upper rectal surgery is non-inferior to the conventional 24-hour removal protocol in terms of safety and efficacy.
Materials and methods: This prospective, multicentre, randomised, controlled non-inferiority trial compared two catheter management protocols in patients undergoing elective minimally invasive colon and upper rectal surgery, with Enhanced Recovery After Surgery (ERAS) protocols, short operative time (<180 minutes), and restricted fluid administration (<2000 mL). Patients were recruited from six Spanish public hospitals. The sample size was calculated based on an expected postoperative AUR rate of 11%, a non-inferiority margin of 8%, a unilateral alpha risk of 0.05, and a beta risk of 0.2. Accounting for an anticipated dropout rate of 10%, a total of 416 patients (208 per group) were required.
Results: Between February 2020 and October 2024, 804 patients scheduled for laparoscopic or robotic colectomy were randomized. After applying eligibility criteria, 218 were included in the control group and 197 in the experimental group. The incidence of AUR was 3.4% (14/415): 1.8% in the 24-hour group vs. 5.1% in the immediate removal group. The absolute difference was 3.48% (one-sided 95% confidence interval [CI] upper bound: 7.18%), meeting the pre-specified non-inferiority margin of 8%. The UTI rate was 0.5% (95% CI: -1.39% to 1.29%). No significant differences were observed between groups in secondary outcomes, though higher AUR rates were observed in left-sided resections with immediate removal.
Conclusion: Immediate urinary catheter removal after laparoscopic colon and upper rectal surgery is a safe and non-inferior alternative to the standard 24-hour protocol in selected patients. These findings support its implementation within ERAS programs. A possible increased AUR rate in left-sided resections was observed and should be further explored in future studies.

Keywords: acute urine retention, bladder catheter, laparoscopic colon

Introduction

Urinary catheterization is routinely employed in major surgery to monitor urine output, guide fluid management, and assess hemodynamic stability[1]. Normal bladder capacity ranges from 400 to 600 mL[2], with the first urge to void at approximately 150 mL and a sensation of fullness at around 300 mL[3]. Postoperative acute urinary retention (AUR), defined as the inability to void after surgery and anesthesia, has a highly variable reported incidence (5%–70%) due to heterogeneous diagnostic criteria.

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Catheter reinsertion is generally indicated when bladder volume exceeds 600 mL for at least 2 hours[4], slightly above the recommended adult threshold[5]. Evidence regarding urinary catheter use in laparoscopic colorectal surgery is limited, and current guidelines are largely based on data from open procedures, often failing to incorporate Enhanced Recovery After Surgery (ERAS) principles. Consequently, adherence to early catheter removal remains suboptimal – ranging from 47% to 68% in colon surgery and 34%–70% in rectal surgery[6]. Prolonged catheterization increases the risk of bacteriuria by 3%–8% per day[7], and although progression to bacteremia is rare (<5%), catheter-associated infections can triple hospital mortality[8,9].

Beyond infectious risks, prolonged catheter use may cause pain, restricted mobility, and local complications such as skin lesions, ulceration, or urethral injury, emphasizing the need for strict indications and minimal duration[10]. While early removal facilitates mobilization and aligns with ERAS protocols[11], traditional colorectal practices – based on outdated evidence from open surgery – often involved catheterization for up to 5 days, increasing hospital stay and urinary tract infection (UTI) rates (42%–60%)[12]. The adoption of ERAS and Fast-Track protocols in minimally invasive surgery has challenged these practices, supporting shorter catheterization durations without a significant increase in AUR[13,14]. Current European and American guidelines recommend catheter removal within 24–48 hours in elective colorectal surgery, except in selected rectal procedures[13–15]. Notably, catheterization beyond 48 hours has been associated with a significantly increased risk of UTI[16]. A 2020 regional survey in Catalonia revealed that although most centers adhere to the 24-hour recommendation, only a small minority implement immediate postoperative removal[17].

This study hypothesizes that, in laparoscopic colon and upper rectal surgery, immediate urinary catheter removal at the end of the procedure is non-inferior to the standard 24-hour protocol in terms of AUR and UTI incidence. The primary objective is to compare AUR rates between the immediate removal group and the 24-hour group. Secondary objectives include four comparing UTI rates, evaluating whether early removal reduces hospital stay and catheter-related morbidity, and identifying risk factors for AUR in the immediate removal group through univariate and multivariate analysis.

This manuscript adheres to the TITAN 2025 guidelines for transparent reporting of artificial intelligence use in scientific writing, and the completed TITAN-Guideline-Checklist-2025 is submitted as supplementary material[18].

HIGHLIGHTS

- This study is the largest prospective, multicenter, randomized controlled trial evaluating immediate vs. 24-hour urinary catheter removal after laparoscopic colectomy and upper rectal surgery.
- Immediate postoperative catheter removal demonstrated non-inferiority compared to the conventional 24-hour protocol, with a low overall incidence of acute urinary retention of 3.4% and urinary tract infections of 0.5%.
- The rigorous patient selection criteria and standardized methodology ensured robust internal validity, providing high-quality evidence supporting early catheter removal in line with Enhanced Recovery After Surgery (ERAS) protocols.
- Findings from this trial have the potential to significantly influence international ERAS guidelines by establishing immediate catheter removal as a safe and effective practice in laparoscopic colorectal surgery.
- Despite strict inclusion and exclusion criteria, the study achieved successful recruitment across multiple centers, highlighting the feasibility and general applicability of immediate catheter removal within specialized surgical units.

Materials and methods

Study design

The present was designed following the standards of the SPIRIT statement[19] and the CONSORT extension for non-inferiority trials[20]. It is a prospective, multicenter, randomized, controlled, non-inferiority study (CR-Vesicalcath I) comparing two urinary catheter management strategies in elective colon and upper rectal surgery (without peritoneal reflection opening) performed laparoscopically or robotically[21,22]. The study protocol, patient information sheet, and informed consent were approved by the Ethics and Clinical Research Committee of our Hospital and conducted in compliance with the seventh revision of the Declaration of Helsinki[23]

Study population and participants

This multicenter study involved six colorectal surgery units from secondary and tertiary hospitals within the Spanish Public Health System. All participating surgeons were colorectal specialists. All patients scheduled for elective laparoscopic or robotic surgery of the colon or upper rectum who met inclusion criteria and had none of the exclusion or withdrawal criteria were consecutively enrolled (Fig. 1).

Inclusion criteria: Age >18 years, scheduled elective surgery of colon and upper rectum without opening peritoneal reflection, laparoscopic or robotic approach, ASA classification I–III, ability to understand the study, provide informed consent, and agree to participate, International Prostate Symptom Score (IPSS) <20.

Exclusion criteria: ASA IV classification, open surgery or total coloproctectomy, epidural analgesia, recurrent preoperative UTIs (≥3 episodes/year or ≥2 episodes in the last 6 months), moderate-to-severe prostatic symptoms (IPSS ≥20) or history of AUR, permanent urinary catheterization, ureteral catheter or intermittent self-catheterization, history of obstructive prostatic surgery, urological tumors, urethral strictures, enterovesical fistula, or prior pelvic surgery, urinary incontinence or neurogenic bladder, chronic renal failure (creatinine >2 mg/dL), emergency surgery, pregnancy, pelvic radiotherapy.

Withdrawal or Study Termination Criteria: pathological urinary sediment (≥50–100 leukocytes/field), difficulty or impossibility of intraoperative catheterization, urethral bleeding/hematuria or requirement for suprapubic cystostomy, active antibiotic treatment for UTI at the time of surgery, conversion to open surgery, need for a ureteral catheter or urine output monitoring >24 hours, simultaneous combination with other surgeries, postoperative complications Clavien-Dindo >II, urinary tract injury, immediate need for epidural analgesia, surgical time >180 minutes, intraoperative fluid administration >2000 mL.

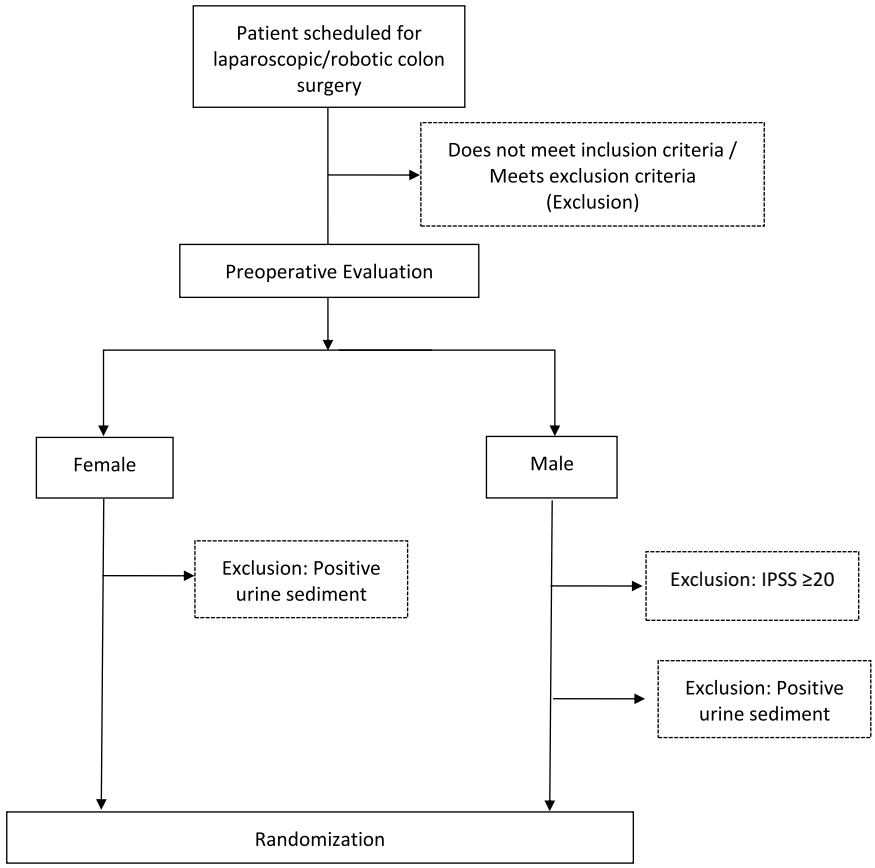

Figure 1. Flowchart of the CR-Vesicalcath I Study protocol.

Intervention

Urinary catheterization was performed after induction of general anesthesia by the operating room surgical nurse, under strict sterile conditions, to ensure patient comfort and standardize procedural conditions. A sterile, water-based lubricant without lidocaine was used during all catheterizations.

Control group: urinary catheterization was maintained for 24 hours postoperatively.

Experimental group: the urinary catheter was removed immediately at the end of surgery.

Postoperative monitoring was carried out in the surgical ward following a brief stay in the post-anesthesia care unit, in accordance with ERAS protocols. Suspected urinary retention was initially identified by nursing staff based on predefined criteria (e.g. failure to void within 8 hours or symptoms of urgency). Catheter reinsertion was performed under aseptic conditions and immediately reported to the surgical team, who confirmed the diagnosis and authorized reinsertion when appropriate. Each event was documented in both the case report form and the patient's medical record, according to the study's predefined criteria for postoperative AUR.

A flowchart (Fig. 2) was developed following the CONSORT criteria to track all included, excluded, randomized, and withdrawn patients[20].

Study variables

Primary outcome: The primary endpoint was postoperative AUR, defined as the need for urinary catheter reinsertion due to failure to achieve spontaneous voiding within 8 hours after removal or due to clinical symptoms suggestive of urgency. AUR was only confirmed when the drained urine volume was ≥400 mL. In cases of suspected AUR, catheter reinsertion was performed based on predefined clinical criteria (e.g. inability to void, suprapubic discomfort, palpable bladder, or low urine output), but final decisions were made using clinical judgment by the surgical team. This clinical definition was adopted to ensure consistency across participating centers and to avoid reliance on bladder ultrasound, which may not be uniformly available or standardized. If a second catheterization was required, the catheter was left in place, and the event was registered as AUR[8,24–28].

Secondary outcomes: UTI within 30 days, defined by a urine culture with $>10^4$ CFU/mL in males or $>10^5$ CFU/mL in females, hospital length of stay (days), demographic and clinical variables: sex, age, body mass index (BMI), medication for benign prostatic hyperplasia (BPH), comorbidities (diabetes, neurological diseases), diagnosis, type of procedure, surgical approach (laparoscopy/robotic), conversion to open surgery, stoma creation, duration of surgery and anesthesia, intraoperative fluid administration, and intraoperative blood loss, postoperative complications

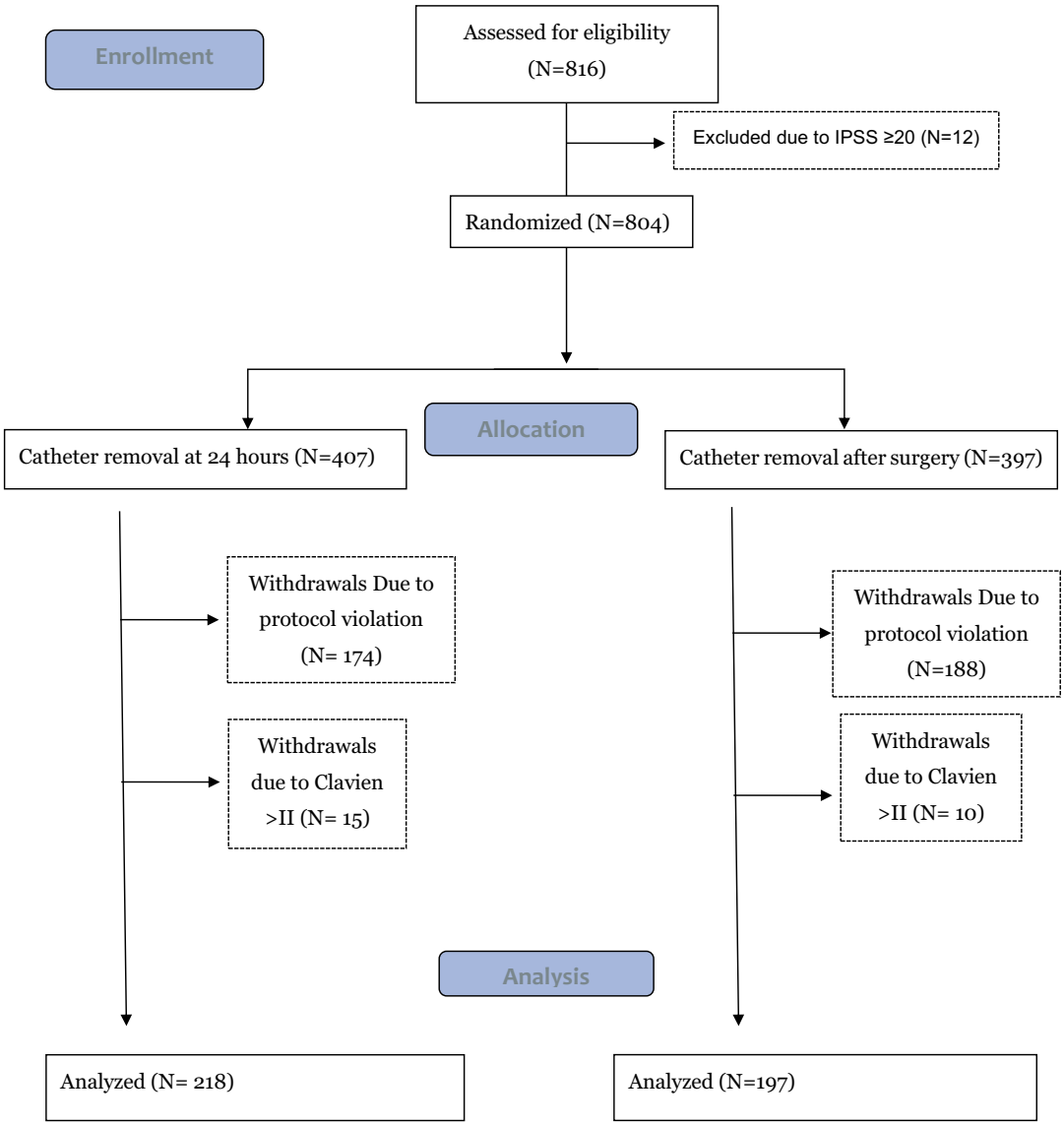

Figure 2. CONSORT flow diagram.

(graded according to the Clavien-Dindo classification[29] and Comprehensive Complication Index [CCI][30]); readmissions due to AUR or UTI, TNM staging.

Sample size determination and non-inferiority delta margin

Based on prospective studies with similar designs, we estimated a postoperative AUR incidence of approximately 11%. Accordingly, we defined an 8% non-inferiority margin, which was considered clinically acceptable. This led to an expected AUR range of 2%–19%, aligning with previously reported data from authors such as Eriksen[6], Coyle[11], and Stubbs[31]. With a one-sided alpha risk of 0.05 and a beta risk of 0.2, the required sample size was calculated as 416 patients (208 per group), accounting for a 10% dropout rate.

The non-inferiority margin was set at 8% based on clinical and statistical reasoning. Historical rates of AUR after laparoscopic colectomy range between 3% and 10% in the literature. A margin of 8% was considered clinically acceptable, preserving the majority of the comparator's safety profile while allowing for a feasible sample size. This approach aligns with current methodological recommendations, including those by Taylor *et al*[32], which emphasize that non-inferiority margins should be justified based on preserved clinical effect, biological plausibility, and real-world clinical acceptability.

Randomization and allocation

Patients meeting the inclusion criteria were randomly assigned into two groups: control group and experimental group.

Randomization was conducted centrally and computer-generated using a 1:1 allocation ratio (without block stratification) via the online data collection system developed by Xolomon©.

Recruitment, blinding, and monitoring procedures

All patients fulfilling the eligibility criteria during outpatient consultations at the participating hospitals were included and randomized through an online system. Data collection and verification were performed using a digital case report form managed by Xolomon©. Data integrity was ensured through periodic quality control checks and centralized monitoring.

Statistical analysis

To evaluate the primary endpoint (AUR non-inferiority), a one-sided 95% confidence interval (CI) was calculated for the proportion of patients without AUR. Continuous variables were described using means and standard deviations or medians and interquartile ranges (IQRs). Categorical variables were presented as frequencies and percentages. Between-group comparisons were performed using the Student's *t*-test for parametric data and the Mann–Whitney *U* test for non-parametric data. Categorical variables were analyzed using the Chi-square test or Fisher's exact test, with $P < 0.05$ considered statistically significant. Statistical analyses were conducted using SPSS version 29.

A per-protocol (PP) analysis was chosen, as withdrawal criteria could impact the primary outcome (AUR) and diminish the clinical relevance of an intention-to-treat (ITT) analysis. The study continued until the required sample size was achieved for PP analysis.

Results

Patient flow and recruitment

From February 2020 to October 2024, a total of 816 patients were evaluated in outpatient clinics at participating hospitals as candidates for laparoscopic/robotic colectomy for localized colon and upper rectal disease. Based on inclusion criteria, 804 patients were randomized, as 12 patients were directly excluded due to previously undiagnosed moderate-to-severe prostatic symptoms (IPSS ≥20) detected in the preoperative assessment.

During the study, 387 patients met the criteria for withdrawal or study completion (Fig. 2). A total of 362 patients were excluded due to one or more protocol deviations, with the most common reason being a prolonged surgical duration exceeding three hours (255 cases, 58%). The remaining reasons are detailed in Table 1. An additional 25 patients were withdrawn due to postoperative morbidity classified as Clavien-Dindo grade >II. Most cases were Clavien IIIa ($N = 12$, 48%) and Clavien IIIb ($N = 11$, 44%) (Supplemental Digital Content Table 1, available at: http://links.lww.com/JS9/E613).

Table 1

Reasons for protocol deviations

Reason for study withdrawal or termination per protocol	*N* (patients)
Surgeries exceeding 180 minutes	255
Opening of the peritoneal reflection and/or association with other procedures	61
Prolongation of catheterization for urine output monitoring	62
Conversion to open surgery	26
Presence of pathological sediments	17
Need for postoperative epidural anesthesia	12
Intraoperative fluid administration >2000 mL	7
Intraoperative difficulty/impossibility of catheterization	3
Urethral bleeding/hematuria following traumatic catheterization	3
Active antibiotic treatment for urinary tract infection (UTI)	1
Intraoperative urinary tract injury	1

As detailed in the study flow diagram (Fig. 2), a total of 415 patients were analyzed per protocol (218 in the control group and 197 in the experimental group). The distribution of included patients per center is detailed in Supplemental Digital Content Table 2, available at: http://links.lww.com/JS9/E614.

Baseline data

The analysis of demographic and preoperative variables (Table 2) revealed that 229 patients (55.2%) were female, with a median age of 69 years in both groups. There were no significant differences in height, weight, BMI, or IPSS values. The overall prevalence of comorbidities was 18.8%, with a slightly higher incidence of diabetes and prior stroke in the control group.

Primary outcome analysis

The incidence of AUR was 3.4% (14 out of 415 patients). Specifically, in the 24-hour catheter removal group, 4 out of 218 patients (1.8%) experienced AUR, compared to 10 out of 197 patients (5.1%) in the postoperative catheter removal group. The non-inferiority criteria were met with a difference of 3.48 % and one-sided 95% CI upper bound of 7.18%, which was below the non-inferiority margin of 8% points (Fig. 3). In both groups, catheter reinsertion was performed exclusively in patients meeting the predefined AUR criteria. No patients required straight catheterization without a confirmed diagnosis of AUR, and all others achieved spontaneous voiding postoperatively. The characteristics of patients with postoperative AUR are detailed in Supplemental Digital Content Table 3, available at: http://links.lww.com/JS9/E615.

Secondary outcome analysis

Pre- and intraoperative variables

According to Table 3, the predominant diagnosis was colon malignancy, 385 out of 415 (85.8%), compared to benign conditions, 59 out of 415 (14.2%). The most commonly performed surgical procedure was laparoscopic/robotic right hemicolectomy, 220 out of 415 (53%), followed by laparoscopic/robotic sigmoidectomy, 131 out of 415 (31.6%). Surgical duration was comparable between groups, with a median operative time of 160 minutes, after excluding cases exceeding 180 minutes from the analysis. However, a statistically significant but clinically irrelevant difference was observed in intraoperative fluid administration (median of 1000 mL; $P = 0.044$).

Postoperative morbidity variables

The median number of postoperative complications was 115 (27.7%). The CCI median was 8.7 in both groups, but with a higher IQR in the experimental group (3.5 vs. 12.2). A detailed analysis of morbidity using the Clavien-Dindo classification showed that most complications were Grade I (70%, $N = 114$), followed by Grade II (30%, $N = 50$). The absence of major complications was due to their exclusion per protocol.

Table 2

Demographic/preoperative variables

Variable	Total (*N* = 415)	Catheter removal at 24 hours (*N* = 218)	Catheter removal after IQ (*N* = 197)	*P*-value	Difference (95% CI)
Sex					
Male	186 (44.8%)	99	87	0.84	–
Female	229 (55.2%)	119 (54.6%)	110 (55.8%)		
Age, median (IQR) (years)	69 (18)	69 (18)	69 (16)	0.88	–
IPSS, median (IQR)	4.5 (8)	5 (8)	4 (7)	0.75	–
Height, median (IQR) (m)	1.6 (0.1)	1.6 (0.1)	1.64 (0.1)	0.75	–
Weight, median (IQR) (Kg)	71.25 (17.3)	71 (17.3)	72 (19.5)	0.64	–
BMI, median (IQR)	26.7 (5.8)	27 (5.6)	26.5 (6.6)	0.64	–
Comorbidities (N, %)	78 (18.8%)	45 (20.6%)	33 (16.8%)	0.32	5.89 (–3.08 to 14.86)
Diabetes	63 (15.2%)	36 (16.5%)	27 (13.7%)		
Prior stroke	8 (1.9%)	6 (2.8%)	2 (1%)		
Other neurological diseases	1 (0.2%)		1 (0.5%)		
Parkinson	4 (1%)	2 (0.9%)	2 (1%)		
BPH medication (*N*, %)	29 (7%)	13 (6%)	16 (8.1%)	0.44	–2.5 (–7.81 to 2.82)

IQR, interquartile range.

The incidence of UTIs was very low in both groups. Only one UTI event occurred in the control group (0.46%) and one in the experimental group (0.5%), resulting in a global incidence of 0.5% (2/415 patients). No statistically significant difference was observed between groups ($P > 0.99$), and the 95% CI for the difference in proportions ranged from -1.39% to 1.29%.

As for length of hospital stay, the median duration was 3 days (interquartile range: 1) in both groups, with no significant difference ($P = 0.809$). These findings suggest that immediate catheter removal does not adversely affect short-term recovery or prolong hospitalization when implemented within an ERAS protocol.

A subgroup analysis of AUR by surgical location (Supplemental Digital Content Table 4, available at: http://links.lww.com/JS9/E616) showed no statistically significant difference between right- and left-sided colectomies overall ($P = 0.27$). However, in left-sided surgeries, AUR was more frequent in the immediate removal group (9.1% vs. 1.1%, $P = 0.024$), suggesting a potential increased risk in these patients, which warrants further investigation.

Mortality was observed in one patient (Supplemental Digital Content Table 1, available at: http://links.lww.com/JS9/E613). The remaining adverse events are detailed in Supplemental Digital Content Table 5, available at: http://links.lww.com/JS9/E617.

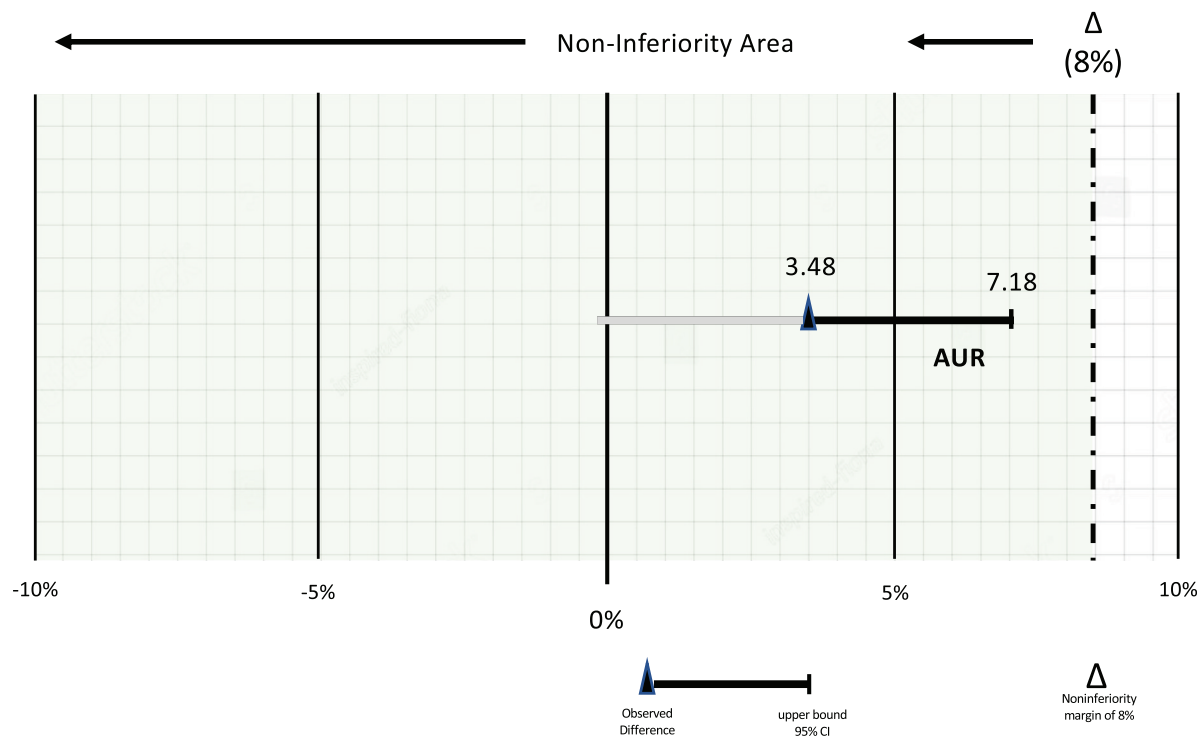

Figure 3. One-sided 95% confidence interval for acute urinary retention (AUR).

Table 3

Pre-/intraoperative variables

Variable	Total (*N* = 415)	Catheter removal at 24 hours (*N* = 218)	Catheter removal after IQ (*N* = 197)	*P*-value	Difference (95% CI)
Diagnoses (*N*, %)					
Colon adenoma	35 (8.4%)	17 (7.8%)	18 (9.1%)	0.86	
Diverticular disease	16 (3.9%)	8 (3.7%)	8 (4%)	–	
Chronic inflammatory bowel disease	8 (1.9%)	4 (1.9%)	4 (2%)		
Malignant colon neoplasm	356 (85.8%)	189 (86.7%)	167 (84.8%)		
Procedure (*N*, %)					
Laparoscopic subtotal colectomy	1 (0.2%)	–	1 (0.5%)	0.37	
Laparoscopic total colectomy	1 (0.2%)	1 (0.5%)	–	–	
Extended laparoscopic right hemicolectomy	24 (5.8%)	11 (5%)	13 (6.6%)		
Laparoscopic right hemicolectomy	220 (53%)	114 (52.3%)	106 (53.8%)		
Laparoscopic left hemicolectomy	32 (7.7%)	19 (8.7%)	13 (6.6%)		
Laparoscopic high anterior resection of the rectum	6 (1.4%)	1 (0.5%)	5 (2.5%)		
Laparoscopic sigmoidectomy	131 (31.6%)	72 (33%)	59 (29.9%)		
Stoma creation					
Yes	2	1	1	–	
No	389	205	184		–0.06 (1.37[a]–1.48)
Surgical intervention					
Surgery time, median (IQR) (minutes)	160 (40)	160 (40)	160 (40)	0.73	
Anesthesia time, mean (SD) (minutes)	226,9 (47,2)	227.5 (48)	226.2 (46.6)	0.68	
Intraoperative fluid, median (IQR) (ml)	1000 (500)	1000 (550)	1000 (500)	0.04	
Intraoperative bleeding, median (IQR) (cm^3)	50 (75)	50 (25)	50 (70)	0.17	
TNM (N, %)					
T1	65 (15.7%)	39 (17.9%)	26 (13.2%)	0.44	
T2	78 (18.8%)	38 (17.4%)	40 (20.3%)		
T3	184 (44.3%)	95 (43.6%)	89 (45.2%)		
T4	40 (9.6%)	24 (11%)	16 (8.1%)		
N0	273 (65.8%)	141 (64.7%)	132 (67%)	0.75	
N1	86 (20.7%)	49 (22.5%)	37 (18.8%)		
N2	32 (7.7%)	17 (7.8%)	15 (7.6%)		
M0	378 (91.1%)	198 (90.8%)	180 (91.4%)	0.56	
M1	12 (2.9%)	8 (3.7%)	4 (2%)	–	

Discusion

Urinary catheterization is a traditional procedure in colon and upper rectal surgery, inherited from the era of open surgery. However, the introduction of Fast-Track protocols and minimally invasive surgery has led to a reconsideration of both its indication and the duration of its use[13,33,34]. Prolonged catheterization is associated with preventable adverse effects; therefore, minimizing catheter dwell time could reduce complications such as UTIs and catheter-related discomfort.

A review of the literature highlights the significant difficulty in establishing uniform criteria for defining AUR. As early as 2009, Baldini *et al*[1] warned about the heterogeneity in definitions, with over 15 different approaches described. Currently, most studies are retrospective and single-center, combining colonic and rectal resections and even mixing open and laparoscopic surgery. This has resulted in a high degree of variability in the available evidence, with no consensus on the temporal or volumetric threshold considered pathological.

Although AUR can be diagnosed clinically or by ultrasound, the latter poses limitations in multicenter trials due to varying access to equipment and operator expertise. Therefore, a pragmatic clinical definition was adopted, recognizing the variability in existing criteria. While some authors (Patel[8], Tam[24], Zmora[26]) define AUR as no voiding within 8 hours, others (Eriksen[6], Alyami[9]) use 6 hours as the cutoff. After reviewing these studies, an 8-hour threshold was selected by consensus.

Recatheterization was performed only when voiding failed or symptoms of urgency persisted, and AUR was confirmed when the drained volume exceeded 400 mL, a threshold supported by prior literature and clinical guidelines[24–28].

Moreover, there is a scarcity of literature addressing urinary catheterization in the context of laparoscopic colon surgery, as many guidelines are based on open surgery data without adequately incorporating the ERAS model. This lack of specific evidence complicates the extrapolation of findings for clinical decision-making, even though most experts recognize the benefits of early catheter removal.

The relatively low incidence of AUR in our study may be explained, in part, by the use of a pragmatic clinical definition and standardized reinsertion threshold (≥400 mL). Unlike studies that rely on ultrasound-based post-void residual estimation, methods that may overestimate the diagnosis and lack a clear consensus on cutoff values[6,8,9]. Our approach prioritized clinical applicability and consistency across centers, avoiding dependence on imaging tools that may not be practical in routine practice."

Given this context, our study aimed to demonstrate that it is feasible to reduce urinary catheterization time to the minimum necessary without compromising patient safety. To achieve this, rigorous inclusion, exclusion, and catheter removal criteria were

established to minimize biases that could influence the results beyond the duration of catheterization. Patients undergoing elective laparoscopic colon and upper rectal surgery were included, while those in whom the peritoneal reflection was opened or who had received pelvic radiotherapy were excluded to avoid bias related to potential autonomic nerve injury during pelvic dissection[35].

Additionally, BPH is a well-recognized risk factor for postoperative AUR. Therefore, patients with moderate to severe symptoms (IPSS ≥20) were excluded. This selection resulted in a mean IPSS of less than 7, which partly explains the low AUR rates observed.

Furthermore, patients with active UTIs, those in whom catheterization was not feasible without complications, and those requiring conversion to open surgery or combined surgical procedures were withdrawn from the study. Surgical duration was also considered, and surgeries exceeding three hours were excluded, as prolonged operative times are associated with greater procedural complexity, higher intraoperative fluid administration, and consequently, an increased risk of AUR[1,3,4,9]. In this regard, cases with intraoperative fluid administration exceeding 2 L were also excluded, as intensive fluid therapy may lead to bladder overdistension at a time when bladder contractility is diminished[28].

As we previously mentioned, to quantify the magnitude of the problem in our setting, a survey was conducted among surgical units in public hospitals in Catalonia. The results showed that, although 85.4% of hospitals adhered to ERAS protocol recommendations, only 65.9% removed the catheter at 24 hours, evidencing a discrepancy between the guidelines and clinical practice, particularly in smaller centers[17].

While the adjusted sample size target was 208 patients per group to account for a 10% dropout rate, the final PP population included 218 patients in the control group and 197 in the experimental group. As the minimum required sample size per group was 189 to maintain 80% power, the study remained adequately powered despite this slight deviation. The difference in group sizes reflects the natural imbalance of patient inclusion in a real-world multicentre trial without fixed block sizes, and does not compromise the statistical robustness of the results

While the study was initially designed to allow both ITT and PP analyses, a number of patients were withdrawn intraoperatively due to predefined criteria – particularly prolonged surgical time – which precluded consistent data collection and follow-up. As a result, only the PP population was available for final analysis. We acknowledge this as a limitation, particularly in the context of non-inferiority trial design, and emphasize the need for future trials to assess the applicability of immediate catheter removal strategies in more complex or extended procedures.

Randomization was performed centrally to ensure better concealment of allocation and balance the distribution of patients among centers, despite this method potentially introducing logistical challenges and delays. Cluster randomization was not chosen, as although it facilitates faster enrollment, it carries a higher risk of bias and imbalance, as previous studies have pointed out[36,37].

One of the most debated aspects of the study was the definition of AUR. While it has been shown that physical examination alone can be inaccurate in up to 46%–54% of cases, our study prioritized clinical relevance, defining AUR as the inability to void, accompanied by a post-catheterization residual volume of ≥400 mL[12]. Ultrasound was not used for diagnosis due to the lack of consensus on the volumetric threshold and its tendency to overestimate the incidence, complicating its application in routine clinical practice.

Following an extensive review of the literature to define the non-inferiority margin (see Supplemental Digital Content Table 6, available at: http://links.lww.com/JS9/E618), we extrapolated from the most comparable prospective studies an approximate 11% incidence of postoperative AUR. Based on this, we defined an 8% non-inferiority margin, yielding a clinically acceptable AUR range of 2%–19%, consistent with findings reported by Eriksen[6], Coyle[11], and Stubbs[31].

The primary objective of this study was to demonstrate the non-inferiority of immediate urinary catheter removal compared to the standard 24-hour protocol. The results showed an overall AUR incidence of 3.4% (1.8% in the control group vs. 5.1% in the experimental group), with an absolute risk difference of 3.48% and a one-sided 95% CI upper bound of 7.18%, remaining within the pre-defined 8% non-inferiority margin. Although the incidence of AUR was higher in the immediate removal group, this difference was not clinically significant. In fact, both rates were considerably lower than those reported in previous studies, which range from 9% to over 30%, even with delayed catheter removal strategies (Supplemental Digital Content Table 6, available at: http://links.lww.com/JS9/E618)[11,25,38]. These findings support that immediate catheter removal after minimally invasive colon surgery is a safe and non-inferior alternative to standard timing, with a low complication rate in real-world practice.

While the study was designed to include both right- and left-sided colectomies without pelvic dissection, a post hoc analysis revealed a higher AUR incidence in left-sided surgeries with immediate catheter removal. These findings, though not conclusive due to limited sample size and lack of statistical power, raise an important hypothesis for future research.

As secondary outcomes, both the UTI rate and hospital length of stay showed no significant differences between groups. UTI incidence was exceptionally low in both arms (0.5%), much lower than the rates commonly reported in the literature, which often exceed 10% and may reach up to 42% in the context of prolonged catheterization[12].

Additionally, the median hospital stay was 3 days in both groups, with no statistical difference observed. These findings further support the safety of immediate catheter removal in enhanced recovery protocols.

The identification of risk factors for AUR and UTI was prespecified as a secondary objective of this study. However, the low number of events observed – 14 cases of AUR and 2 cases of UTI – precluded the possibility of conducting a valid multivariate analysis with sufficient power. Although previous research has indicated that variables such as male sex, older age, and preexisting lower urinary tract symptoms may increase the risk of urinary complications, our findings were not adequate to test these associations. Future studies with larger populations will be necessary to explore these risk profiles in depth and support personalized urinary catheter management in the context of enhanced recovery protocols.

This study has several limitations. The prolonged recruitment period and the exclusion of 255 patients were largely due to the strict inclusion, exclusion, and withdrawal criteria, particularly the restriction to procedures with operative times under 180 minutes. While this enhanced internal validity, it limits external generalizability to broader patient populations. Although the

predefined non-inferiority margin was statistically met, the total number of AUR events in both groups was low. This reduces the statistical power to detect small differences and limits the robustness of the non-inferiority conclusion. Nevertheless, the very low absolute incidence of AUR in the early catheter removal group reinforces the clinical relevance of the finding: even with immediate removal, urinary retention remained rare. These results suggest that immediate catheter removal can be considered safe and feasible in appropriately selected patients. Patient-reported outcomes related to catheter-associated discomfort or urgency perception were not collected, which may restrict the evaluation of patient-centered recovery within the ERAS framework. Although subgroup analyses suggest a potentially higher AUR rate in left-sided colectomies with immediate catheter removal, these findings are exploratory and the study was not powered to detect differences by surgical laterality. Finally, the applicability of these results is limited to selected patients undergoing elective laparoscopic colectomy without urological comorbidities or intraoperative complications. Further validation is needed in higher-risk and more diverse populations.

In light of our findings, the following key learning points and conclusions may help inform clinical practice and future guideline development: (1) Immediate urinary catheter removal is safe and feasible after laparoscopic colon and upper rectal surgery in carefully selected patients. (2) AUR remains infrequent and within the pre-defined non-inferiority margin (P = 0.1, 95% CI: 0.22–7.18). (3) UTIs were exceptionally rare, favoring shorter catheter duration. (4) Early removal facilitates mobilization and discharge, thereby enhancing adherence to ERAS protocols and improving recovery. (5) Patient selection is essential, particularly in left-sided resections, where AUR risk may be slightly increased. These findings support immediate catheter removal as a safe, non-inferior alternative to the traditional 24-hour protocol, especially in experienced centers managing enhanced recovery pathways. Moreover, this non-inferiority result marks a step forward in the pursuit of ambulatory major colon surgery, facilitating early discharge and optimizing resource utilization in high-efficiency surgical programs.

Future lines of research are proposed to evaluate the real incidence of nerve injury in laparoscopic/robotic rectal surgery after pelvic dissection (CR-Vesicalcath II project) and to determine whether patients undergoing longer surgeries could also benefit from early catheter removal. These studies will be necessary to broaden the external validity of the results and to establish standardized protocols for the management of urinary catheterization in colorectal surgery[4,6,7,9,11].

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Ethical approval

The study protocol and the patient information and informed consent documents were approved by the institutional review boards of all the centers participating in the trial.

Consent

Written informed consent was obtained from the patient for publication and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

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Author contributions

X.S.A. and J.H. drafted the manuscript. X.S.A. and J. H. conceived and designed the study. X.S.A., J.H., N.L.L.P., S. D.R., J.M.R.M., C.C., A.C., J.F., M.M., V.P.R., and A.G. were responsible for data acquisition. X.S.A. and J.H. were responsible for analysis. X.S.A. and J.H. have access to the data. X.S. A. and J.H. interpreted the data. X.S.A. and J.H. critically reviewed the manuscript for important intellectual content. All authors agree to be accountable for all aspects of the work and for ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved.

Conflicts of interest disclosure

The authors have no conflicts of interest to report.

Research registration unique identifying number (UIN)

The study was registered with ClinicalTrials.gov (ID: Clinical Trials.gov ID NCT04070898).

Guarantor

Prof. Xavier Serra-Aracil.

Provenance and peer review

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Data availability statement

The study data is available in the federated and multidisciplinary data repository of Catalan universities, CERCA research centers, and other research entities: CORA.RDR. This repository complies with the FAIR principles (ensure that data is findable, accessible, interoperable, and reusable) and follows the EOSC (European Open Science Cloud) guidelines. The dataset related to this study has been published in the dataverse (own space within the repository) of the Institut d'Investigació i Innovació Parc Taulí, the institution to which the first author of the publication is affiliated. The dataset is available at: https://doi.org/10.34810/data2088. The set of data deposited contains a database with all the clinical data from the study, a codebook that describes the variables of the study presented in the database file and a "readme" with all the descriptions, explanations, and

Approval from the Clinical Research Ethics Committees (CEIC)

Approval was obtained from the Clinical Research Ethics Committees (CEIC) of all participating hospitals, with the CEIC of the Parc Taulí University Hospital (PTUH) as a reference point (ID: Vesicalcath I 2019/306).

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TITAN 2025 Compliance

This manuscript complies with the TITAN 2025 guidelines for the transparent reporting of artificial intelligence use in scientific writing. ChatGPT-4.0 (OpenAI) was used exclusively to assist with English grammar and language refinement during manuscript drafting and revision. The authors take full responsibility for the content. The completed TITAN-Guideline-Checklist-2025 is submitted as supplementary material.

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