Annals of COLOPROCTOLOGY

Original Article

Ann Coloproctol 2025;41(3):239-245
pISSN: 2287-9714 • eISSN: 2287-9722
https://doi.org/10.3393/ac.2024.00703.0100

Early urinary catheter removal in patients undergoing rectal cancer surgery: a randomized controlled trial on silodosin versus no pharmacological treatment on urinary function in the early postoperative period

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Purpose: This study aimed to evaluate the efficacy of the α1 adrenergic receptor antagonist silodosin in preventing lower urinary tract symptoms after rectal cancer surgery.

Methods: We conducted a 2-arm, double-blind, single-center randomized controlled trial. The study included 150 patients with rectal cancer who underwent radical surgery between 2019 and 2022. On the first postoperative day, the urinary catheter was removed for all patients. Of these, 100 patients were administered silodosin, while 50 patients (control group) receive placebo (glucose tablet). Urinary dysfunction (urinary retention, infection, dysuria) and other complications were monitored.

Results: Among the 150 patients, 84 (56.0%) were male and 66 (44.0%) were female. Surgical procedures included abdominoperineal resection in 33 patients, partial mesorectal excision in 45, and total mesorectal excision in 72. A laparoscopic approach was used in 69 patients, while the remaining 81 underwent open surgery. Urinary tract symptoms developed in 10 patients (6.7%): 7 (7.0%) in the silodosin group and 3 (6.0%) in the control group (P = 0.92). In the silodosin group, there was 1 case (1.0%) of urinary retention, 3 cases (3.0%) of urinary tract infection, and 3 cases (3.0%) of dysuria. In the control group, there was 1 case (2.0%) each of urinary retention, urinary tract infection, and dysuria (all P = 0.92).

Conclusion: Early urinary catheter removal on the first postoperative day was safe in both groups. The use of the oral α-antagonist silodosin did not provide additional benefits in preventing lower urinary tract symptoms in patients undergoing rectal cancer surgery.

Trial registration: ClinicalTrials.gov identifier: NCT03607370

Keywords: Rectal neoplasms; Silodosin; Low anterior resection; Proctectomy

INTRODUCTION

The use of a urinary catheter following rectal cancer surgery is a common practice [1]. While catheters are typically placed for perioperative monitoring, they are often retained postoperatively for patient convenience. However, delayed removal of the urinary catheter (beyond day 3) is associated with a higher incidence of urinary tract infections (UTIs) [2, 3]. Catheter-induced UTIs are

Received: October 6, 2024; Revised: November 24, 2024; Accepted: January 20, 2025
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linked to prolonged hospital stays, increased reoperation rates, higher morbidity, and elevated 30-day mortality rates [4–6]. Therefore, early removal of the urinary catheter (within 1–2 days) is a key component of the Enhanced Recovery After Surgery (ERAS) program, which aims to mitigate these risks [7]. However, early removal may lead to urinary retention (UR), with reported rates ranging from 5% to 30% [2, 3, 8, 9]. Balancing the risks of UTIs and UR remains a clinical challenge.

Several studies have demonstrated the efficacy of perioperative α1 adrenergic receptor antagonists in preventing UR following pelvic operations, such as varicocelectomy, inguinal herniorrhaphy, scrotal surgery, and colorectal surgery (e.g., low anterior resection) [10–12]. These agents work by relaxing the detrusor muscles, facilitating bladder emptying.

Based on this evidence, we hypothesized that early catheter removal after rectal cancer surgery, combined with the postoperative administration of the α1 adrenergic receptor antagonist silodosin, could reduce the incidence of urinary symptoms, such as UR and UTIs. This study is the first to investigate this specific approach.

METHODS

Ethics statement

The study was approved by the Vilnius Regional Bioethical Committee (No. 158200-17-930-433) and registered at ClinicalTrials.gov (identifier: NCT03607370). All patients provided written informed consent for participation in the study. All procedures were conducted in accordance with the ethical standards of the Committee on Human Experimentation of National Cancer Institute in which the experiments were done or in accord with the ethical standards of the Declaration of Helsinki.

Study design and data collection

A randomized, double-arm, double-blind clinical trial was conducted involving 150 patients with histopathologically confirmed rectal cancer who underwent radical surgery between December 2019 and January 2022. Patients were allocated in a 2:1 ratio using a computer-generated randomization schedule with random permuted blocks of 4 and 6. The randomization sequence was created using a free online tool (Sealed Envelope, Sealed Envelope Ltd; https://www.sealedenvelope.com/). Allocation designations were sequentially numbered and placed in opaque, sealed envelopes, which were opened by the investigator at the time of randomization. Due to the nature of the intervention, neither participants nor personnel were blinded to group allocation. However, the allocation was performed by a clinical trial unit nurse, and the medical staff, investigator, statistician, patient were all blinded to the allocation. Data collection and analysis were performed in a blinded manner with respect to group allocation. A total of 100 patients received the α1 adrenergic receptor antagonist silodosin (8 mg orally once daily), while 50 patients in the control group received a glucose tablet as a placebo.

The inclusion criteria were patients aged 18 years or older who provided consent, had histologically confirmed rectal cancer, and underwent total mesorectal excision (TME) or tumor-specific mesorectal excision (partial mesorectal excision, PME) with colorectal or coloanal anastomosis or abdominoperineal excision. Eligible patients had elective surgery and an American Society of Anesthesiologists (ASA) physical status classification of I to III. The exclusion criteria were as follows: patients unwilling to participate, those with a history of urinary tract disease (e.g., surgery, strictures; previous UTIs were not excluded), or those using medications for urinary flow improvement (e.g., for benign prostatic hyperplasia or urinary incontinence) were excluded. Additional exclusions included known urinary diseases (e.g., end-stage renal disease, benign prostatic hyperplasia, neurogenic bladder, malignancy), patients undergoing concomitant bladder resection or trocar cystostomy, inoperable cancer with colostomy formation only, and those undergoing combined pelvic surgery (e.g., pelvic lymph node dissection, hysterectomy, salpingo-oophorectomy, posterior vaginectomy, cystectomy, ureteral double-J stenting, ureterectomy, ureteroureterostomy, or prostatectomy) (Fig. 1).

The primary objective was to evaluate the efficacy of silodosin in preventing lower urinary tract symptoms following rectal cancer surgery. The primary endpoint was the incidence of lower urinary tract symptoms, including UR, UTI, and dysuria. Secondary endpoints included other early postoperative complications (classified using the Clavien-Dindo classification) [13], side effects of silodosin (e.g., dizziness, fainting, nasal congestion, nausea, hypotension, tachycardia, allergies), and postoperative hospital stay. postoperative UR was defined as the need for bladder catheter replacement due to the inability to urinate (empty the bladder) 8 hours after catheter removal or the inability to urinate with clinical symptoms of urgency. Retention was not considered to have occurred if less than 400 mL of urine was obtained after catheter replacement, in which case the catheter could be withdrawn again [14]. If a second catheterization was required, regardless of urine volume, the catheter was retained, and the case was classified as retention. Reoperations (Clavien-Dindo grade IIIb or higher) occurring more than 5 days after catheter removal were not considered as UR. A UTI was suspected if patients presented with clinical symptoms such as dysuria, urinary frequency, urgency, suprapubic pain, hematuria, or testicular pain. A urine sample was con-

https://doi.org/10.3393/ac.2024.00703.0100

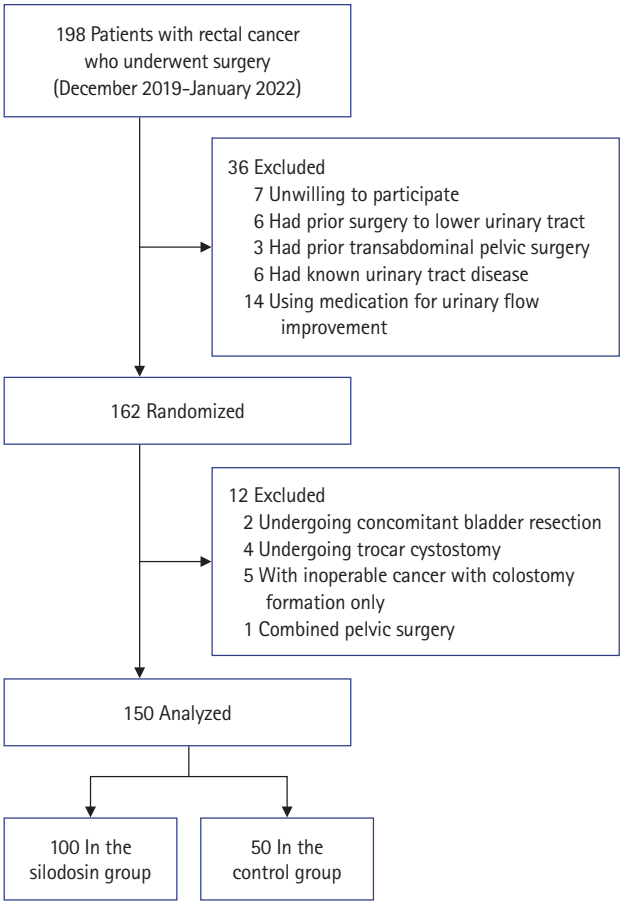

Fig. 1. CONSORT (Consolidated Standards of Reporting Trials) flowchart of the included and excluded patients.

sidered positive if the leukocyte count was ≥5 per high-power field for women or ≥1 per high-power field for men after catheter removal. Dysuria was defined as painful urination lasting more than 3 to 5 days after catheter removal. All symptoms were assessed by the investigator and documented daily.

Study procedures

Before surgery, all patients received a single intravenous dose of prophylactic antibiotics. A 16F Foley catheter was inserted using an aseptic technique after induction of general anesthesia. Catheters with a closed drainage system were maintained until the first postoperative day and removed after the first dose of silodosin (or placebo) was administered. Silodosin (8 mg) was administered for 5 consecutive days. All patients were managed according to the ERAS protocol. At the end of the procedure, patients received a transversus abdominis plane block and nonsteroidal painkillers as needed, with tramadol administered for 2 days. Drains were used for all patients and removed on day 2. Epidural or spinal analgesia was not used. One liter of normal saline was administered before or during surgery and discontinued once patients tolerated oral liquids (typically 1–2 days after surgery). Patients were encouraged to walk starting 4 hours after surgery. All participants and investigators (except data analysts) were blinded to the study allocation.

Type of procedure

Cancers involving the external anal sphincter were treated with abdominoperineal resection (APR) and end-colostomy. Low- and mid-rectal cancers were treated with low anterior resection with TME. High-rectal cancers were treated with tumor-specific mesorectal excision or PME. All patients underwent high ligation of the inferior mesenteric artery and nerve-preserving surgery.

Statistical analysis

Data were collected, calculated, and analyzed using IBM SPSS ver. 23.0 (IBM Corp). Continuous variables were presented as medians and compared using the Student t-test. Categorical variables were expressed as proportions and analyzed using the chi-square or Fisher exact test. A significance level of $P < 0.05$ was used.

Sample size calculation

Based on recent studies, the incidence of UR after rectal surgery is approximately 25% when the catheter is removed within 2 days after surgery and 10% when removed after 7 days [3, 8]. We hypothesized that the addition of an α1 adrenergic receptor antagonist and catheter removal within 2 days would result in a similar UR rate (10.0%). To detect these outcomes with α of 0.05 and β of 0.2, 100 patients were required in the experimental group. We enrolled 100 patients in the experimental group and 50 in the control group to achieve a 2:1 randomization ratio.

RESULTS

The study included 84 men (56.0%) and 66 women (44.0%), with a median age of 65 years (range, 28–94 years) and a mean body mass index of 26.6±4.9 kg/m^2. Among the participants, 47 (31.3%) had 1 or more comorbidities, with cardiovascular disease (n=18, 12.0%) and diabetes mellitus (n=19, 12.7%) being the most common. A total of 65 patients (43.3%) received neoadjuvant treatment: 51 (34.0%) underwent long-course radiotherapy combined with 5-fluorouracil and leucovorin, 9 (6.0%) received short-course radiotherapy, and 5 (3.3%) underwent chemotherapy. No statistically significant differences were observed between the groups in these baseline characteristics (Table 1).

The surgical procedures performed in both groups are summarized in Table 2. Of the 150 patients, 33 (22.0%) underwent APR, 45 (30.0%) underwent PME, and 72 (48.0%) underwent TME.

Table 1. Demographic characteristics of patients and neoadjuvant treatment

Characteristic	Total (n = 150)	Silodosin group (n = 100)	Control group (n = 50)	P-value
Sex				0.49
Male	84 (56.0)	58 (58.0)	26 (52.0)	
Female	66 (44.0)	42 (42.0)	24 (48.0)	
Age (yr)	65 (28–94)	65.5 (28–94)	63 (44–89)	0.74
Body mass index (kg/m^2)	26.6 ± 4.9	26.2 ± 4.7	27.4 ± 5.1	0.19
Comorbidity				
Cardiovascular disease	18 (12.0)	10 (10.0)	8 (16.0)	0.29
Diabetes mellitus	19 (12.7)	14 (14.0)	5 (10.0)	0.49
Pulmonary disease	7 (4.7)	6 (6.0)	1 (2.0)	0.27
Kidney disease	2 (1.3)	2 (2.0)	0 (0)	0.31
Other oncology	13 (8.7)	9 (9.0)	4 (8.0)	0.84
Neoadjuvant treatment				0.79
Chemoradiotherapy	51 (34.0)	29 (29.0)	22 (44.0)	
Radiotherapy	9 (6.0)	8 (8.0)	1 (2.0)	
Chemotherapy	5 (3.3)	2 (2.0)	3 (6.0)	

Values are presented as number (%), median (range), or mean ± standard deviation.

Table 2. Intraoperative outcomes, cancer stage by TNM staging system, and postoperative hospital stay

Variable	Total (n = 150)	Silodosin group (n = 100)	Control group (n = 50)	P-value
Distance from the tumor lower margin to anal verge (cm)				0.25
≤ 5	45 (30.0)	34 (34.0)	11 (22.0)	
> 5–10	52 (34.7)	31 (31.0)	21 (42.0)	
> 10–15	53 (35.3)	35 (35.0)	18 (36.0)	
Operative time (min)	131.0 ± 34.0	128.0 ± 31.0	138.0 ± 37.0	0.08
Blood loss (mL)	144 (30–4,200)	170 (30–4,200)	98 (30–650)	0.25
Tumor TNM stage				0.06
0	6 (4.0)	6 (6.0)	0 (0)	0.08
I	27 (18.0)	22 (22.0)	5 (10.0)	0.07
II	46 (30.7)	34 (34.0)	12 (24.0)	0.21
III	58 (38.7)	30 (30.0)	28 (56.0)	0.02*
IV	13 (8.7)	8 (8.0)	5 (10.0)	0.68
Surgical approach				< 0.001*
Laparoscopy	69 (46.0)	32 (32.0)	37 (74.0)	
Open	81 (54.0)	68 (68.0)	13 (26.0)	
Surgical procedure				0.01*
Partial mesorectal excision	45 (30.0)	32 (32.0)	13 (26.0)	
Total mesorectal excision	72 (48.0)	40 (40.0)	32 (64.0)	
Abdominoperineal resection	33 (22.0)	28 (28.0)	5 (10.0)	
Postoperative hospital stay (day)	8.0 ± 6.7 (3–51)	9.0 ± 7.0 (3–51)	7.0 ± 5.8 (4–32)	0.10

Values are presented as number (%), mean ± standard deviation, median (range), or mean ± standard deviation (range). Percentages may not total 100 due to rounding.
*P < 0.05.

Compared to the control group, the silodosin group had significantly more APR procedures (28.0% vs. 10.0%, P = 0.01) and significantly fewer TME procedures (40.0% vs. 64.0%, P = 0.01) (Table 2). A laparoscopic approach was used in 69 patients (46.0%), while the remaining 81 (54.0%) underwent open surgery. Laparoscopic procedures were performed significantly more often in the control group (32.0% vs. 74.0%, P < 0.001).

Intraoperative variables, cancer stage according to the TNM

https://doi.org/10.3393/ac.2024.00703.0100

staging system, and postoperative hospital stay are detailed in Table 2. The complications were categorized using the Clavien-Dindo classification (Table 3). Early complications developed in 49 patients (32.7%): 35 (35.0%) in the silodosin group and 14 (28.0%) in the control group (P = 0.61). Urinary tract symptoms occurred in 10 patients (6.7%): 2 (1.3%) had UR, 4 (2.7%) had UTI, and 4 (2.7%) experienced dysuria. No significant differences were observed between the groups (P = 0.92). None of the patients experienced any silodosin-related complications.

DISCUSSION

Our study revealed a relatively low incidence of lower urinary tract symptoms compared to existing literature. Although no significant differences in voiding dysfunction were observed between the groups, the silodosin group had significantly more APR procedures (28.0% vs. 10.0%, P = 0.01), while the control group had more laparoscopic procedures (40.0% vs. 64.0%, P = 0.01). APR carries an increased risk of surgical damage to the pelvic autonomic nerves during the perineal phase, potentially leading to UR due to avulsion of the pelvic splanchnic nerves from their sacral roots [15]. Therefore, this might lead to a higher incidence of UR. Moreover, minimally invasive techniques are protective against UR, which may explain the findings in the silodosin group. Changchien et al. [16], in their prospective study, concluded that UR was strongly associated with the type of surgery. The UR rate after the APR procedure was 16.7% (29 out of 174 patients), whereas it was 7.8% following anterior resection. Other researchers, such as Duchalais et al. [8], also identified APR as a significant risk factor for postoperative urinary recatheterization, with an odds ratio of 3.04 compared to the anterior resection procedure (95% confidence interval, 1.30–7.51; P < 0.05). In the COREAN (Comparison of Open Versus Laparoscopic Surgery for Mid and Low Rectal Cancer After Neoadjuvant Chemoradiotherapy) trial, the Quality of Life Questionnaire Colorectal Cancer Module (QLQ-CR38) questionnaire was used to evaluate bladder and sexual function in participants, comparing the preoperative phase to 3 months after rectal surgery [17]. The findings indicated fewer micturition problems in patients who underwent laparoscopic surgery compared to those who had open surgery (−2.583 [n = 122] vs. 4.725 [n = 129], P = 0.0002).

UR development is influenced by various risk factors, including age ≥ 50 years, male sex, lung disease, mid- or lower rectal cancer, longer operating times, and increased intraoperative fluid administration [16, 18–20]. Rectal surgery, in particular, poses a higher risk of long-term bladder dysfunction due to potential injury to the pelvic autonomic nerves and changes in bladder position after surgery [21–23].

The timing of urinary catheter removal remains a topic of debate. The ERAS guidelines recommend catheter removal on the first postoperative day for low-risk patients, while moderate- or high-risk patients may require catheterization for up to 3 days to reduce the risk of UTIs [7]. Furthermore, although the ERAS guidelines suggest using epidural or spinal anesthesia, neither was employed in our study. However, these analgesia methods could potentially increase the risk of UR, which may explain the low UR rates observed in our study.

Current discussions increasingly focus on the benefits of early catheter removal, typically between the first and second postoperative day. Benoist et al. [24] conducted a randomized controlled trial comparing the rates of UR and UTIs associated with catheter removal on the first and fifth postoperative days following rectal resection. The study included 64 patients in the first-day group and 62 in the fifth-day group. Results showed a significantly high-

Table 3. Early postoperative complications of patients included in the study

Complication	No. of patients (%)			P-value
	Total (n = 150)	Silodosin group (n = 100)	Control group (n = 50)	
Clavien-Dindo classification	49 (32.7)	35 (35.0)	14 (28.0)	0.61
I	15 (10.0)	10 (10.0)	5 (10.0)	
II	20 (13.3)	16 (16.0)	4 (8.0)	
IIIa	0 (0)	0 (0)	0 (0)	
IIIb	6 (4.0)	4 (4.0)	2 (4.0)	
IVa	6 (4.0)	3 (3.0)	3 (6.0)	
IVb	2 (1.3)	2 (2.0)	0 (0)	
Urinary tract symptom	10 (6.7)	7 (7.0)	3 (6.0)	0.92
Urinary retention	2 (1.3)	1 (1.0)	1 (2.0)	
Urinary tract infection	4 (2.7)	3 (3.0)	1 (2.0)	
Dysuria	4 (2.7)	3 (3.0)	1 (2.0)	

er UR rate in the first-day group (25% vs. 16%, P < 0.05), while the UTI rate was higher in the fifth-day group (20% vs. 42%, P < 0.05). Zmora et al. [25] categorized patients undergoing pelvic colorectal surgery into 3 groups based on the timing of catheter removal—postoperative day 1, 3, or 5. They observed an overall UR rate of 10%, with individual rates of 14.6%, 5.3%, and 10.5%, respectively (P = 0.39). The UTI rates did not show significant differences. This study also highlighted that patients with low colorectal or coloanal anastomosis were at increased risk of retention. A study from Korea found that the UR rate was not significantly influenced by the duration of urinary catheterization in patients without severe systemic or known urinary diseases [26]. The study suggested that catheters could be safely removed on postoperative day 1 to minimize UTI risks and promote early ambulation following TME or tumor-specific TME for rectal cancer. Madani et al. [10] conducted a randomized double-blind placebo-controlled study comparing the prophylactic effects of tamsulosin and placebo on postoperative UR in patients undergoing varicocelectomy, inguinal herniorrhaphy, and scrotal surgery. The UR rate in the tamsulosin group was significantly lower than in the placebo group (5.9% vs. 21.1%, P = 0.001). Another prospective, randomized, noninferiority clinical trial by Patel et al. [12] assessed the incidence of UR following major pelvic colorectal surgery with early catheter removal (postoperative day 1) using the α-antagonist prazosin versus standard catheter removal (postoperative day 3). Among 142 patients, 13 (9.2%) developed UR, with no significant difference between the early and standard removal groups (8.5% vs. 9.9%, P = 1.00). However, the UTI rate was significantly lower in the early removal group (0% vs. 11%, P = 0.01). Poylin et al. [11] reported that the preemptive perioperative use of tamsulosin significantly reduced the incidence of UR in men undergoing pelvic surgery, especially those with distal rectal cancer. In our study, we administered the medication immediately after surgery, suggesting that there is no need to initiate treatment a few days before surgery.

This study has several limitations. First, it is a single-center randomized controlled trial with a relatively small sample size, which may have limited the detection of significant differences in urinary dysfunction rates. Future trials may require at least 300 patients to demonstrate potential benefits of α-blockers. Second, randomization resulted in imbalanced groups, with the control group having more laparoscopic procedures and fewer APRs. We attempted to address this through subgroup analysis and stratification. Third, preoperative urologic function was not assessed, which could influence postoperative UR rates. Additionally, we did not use urinary function assessment questionnaires, as they are not routinely employed in our hospital due to a lack of evidence on cost-effectiveness. Finally, intraoperative documentation of autonomic nerve damage was not included, although patients undergoing combined pelvic surgery were excluded to minimize this risk. Furthermore, we acknowledge that α-adrenoblockers are not routinely recommended for treating female urinary dysfunction.

In conclusion, silodosin did not demonstrate any significant benefits compared to the control group. Conducting larger scale, multicenter, randomized controlled trials that include both preoperative and postoperative assessments of urinary function using specialized questionnaires could yield more reliable data on the effectiveness of silodosin, given the limited scope of this study.

ARTICLE INFORMATION

Conflict of interest

Audrius Dulskas is an editorial board member of this journal, but was not involved in the peer reviewer selection, evaluation, or decision process of this article. No other potential conflict of interest relevant to this article was reported.

Funding

None.

Author contributions

Conceptualization: AD, ES; Data curation: AD, ŽG, JK; Formal analysis: JK, ŽG; Visualization: AD, BB; Writing–original draft: ŽG, BB, AD, ES; Writing–review & editing: all authors. All authors read and approved the final manuscript.

Additional information

The initial results of the study were presented as a poster at the 16th Scientific and Annual Conference of the European Society of Coloproctology (ESCP) on September 21–24, 2021 (virtual). The study was also presented as an oral presentation at the International Colorectal Research Summit (iCRS) 2022 on September 4, 2022, in Seoul, Korea, and at the 17th Scientific and Annual Conference of the ESCP on September 21–23, 2022, in Dublin, Ireland.

Supplementary materials

Supplementary Video 1. Video abstract.

Supplementary materials are available from https://doi.org/10.3393/ac.2024.00703.0100.

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