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MULTICENTER, PROSPECTIVE, RANDOMIZED CONTROL NON-INFERIORITY TRIAL OF BLADDER CATHETER MANAGEMENT IN COLON SURGERY. CR-Vesical Cath I study Group

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SAX, HJM, DA, LML, wrote and edited the paper. All authors: SAX, HJM, DA, VH, MM, CTA, PMA, DS, GC, NLl, LML have reviewed the paper, revising it critically for intellectual content. Each author has participated sufficiently in the work of reviewing and approving the study as written.

-CONFLICT OF INTEREST DISCLOSURE

The authors have no conflicts of interest to declare

-CONSENT FOR PUBLICATION

Not applicable.

-ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved by our center's local ethic committee. (CEIC 2019/306)

All patients included in the study were informed of the surgical technique used as well as its risks and possible complications. They provided specific informed consent to undergo the surgery.

-CLINICAL TRIAL REGISTRATIONS

The study is registered in Clinical trials with the registration code **NCT04070898**

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ABSTRACT

Aim: Perioperative bladder catheterization is a controversial issue. Most current recommendations are based on data from open surgery extrapolated to Enhanced Recovery After Surgery (ERAS) or Fast-Track programs ranging between 24-48 hours. The aim of this study is to provide a rationale for reducing catheterization time while at the same time avoiding acute urine retention (AUR), in patients undergoing scheduled laparoscopic colon surgery.

Method: Multicenter, prospective, controlled, randomized non-inferiority study of bladder catheter management in patients undergoing scheduled laparoscopic colon surgery, randomized into two groups: experimental (with catheter removal immediately after surgery) and control (with catheter removal 24 hours post-surgery). The main outcome will be the development of AUR, and secondary outcomes the development of urinary infection within the first 30 days and hospital stay. Demographic, surgical and pathological variables will also be evaluated, especially the development of adverse effects assessed according to the Clavien scale and the Comprehensive Complication Index (CCI). Following the literature, we assume an incidence of AUR of 11% and a margin of non-inferiority (delta) of 8%, and estimate that a sample size of 208 patients per group will be required (with an estimated 10% of losses per group).

Conclusions: The bladder catheter can be removed immediately after scheduled laparoscopic colon surgery, without increasing acute urine retention. This measure offers the benefits of earlier mobilization and reduces catheter-related morbidity.

Trial registration: ClinicalTrials.gov Identifier: NCT04070898. Registration nº Ethical and Clinical Research Committee, Parc Taulí University Hospital: ID 2019/306

Keywords: Laparoscopic colon, bladder catheter, acute urine retention

What does this paper add to the literature?'

Although the Enhanced Recovery After Surgery (ERAS) and Fast-Track programs guidelines recommend the withdrawal of the bladder catheter at 24 hours or 2-3 days, we believe that it can be withdrawn earlier, at the completion of surgery. Without increasing acute urine retention, this strategy allows early mobilization and reduces catheter-related morbidity such as urine infection

INTRODUCTION

Perioperative bladder catheterization may be recommended for surgical reasons, for hemodynamic control, or due to personal preferences. As the procedure is not complication-free [1] an evidence-based approach is required.

The optimal duration of bladder catheterization in hospitalized patients remains controversial. In colorectal surgery, the duration traditionally proposed (albeit with limited evidence, based primarily on open surgery data) is five days, with a range of 3 to 10 days [2]. This practice substantially lengthens hospital stay and is associated with an increased risk of complications; for example, urinary infections have been reported in 42-60% of cases [3].

The introduction of the Enhanced Recovery After Surgery (ERAS) and Fast-Track programs [4,5] in minimally invasive surgery has shown that the practices (implemented above all due to force of habit) were in fact mistaken, and the recommended duration of bladder catheterization has now been shortened. This strategy has reduced the incidence of urinary tract infections without significantly increasing acute urine retention (AUR).

Currently, European international guidelines recommend limiting bladder catheterization to a period of 24-48 hours after scheduled colon and rectal interventions. Exceptions are resections of the middle and lower rectum (with extensive perineal and rectal dissection) which require longer periods of catheterization depending on the clinical indications [6].

The clinical guidelines of the ASCRS (American Society of Colon and Rectal Surgeons) and the SAGES (Society of American Gastrointestinal and Endoscopic Surgeons) [5] are even more restrictive with respect to the use of bladder catheterization in elective surgery of the colon or upper rectum; they recommend catheter withdrawal within 24 hours, and state that at 48 hours the risk of postoperative urinary tract infection has doubled [7].

At present there are no reliable studies in the literature that give clear guidance on the question of the timing of UC withdrawal. We have already mentioned that the ERAS guides [4,5] give some recommendations, though these are based on inconclusive studies. It is not known whether

laparoscopy in colorectal surgery favors early withdrawal, or whether in colon surgery the UC can be removed immediately after the intervention.

HYPOTHESIS AND OBJECTIVES

Hypothesis

Although the ERAS guidelines recommend the withdrawal of the bladder catheter at 24 hours or 2-3 days, we believe that it can be withdrawn earlier, at the completion of surgery. Without increasing AUR, this strategy allows early mobilization and reduces catheter-related morbidity such as urine infection.

Objectives

Primary: The main study outcome is the assessment of the degree of AUR after bladder catheter removal in colon surgery in the two study groups: control (with withdrawal at 24 h) and experimental (with withdrawal at the end of the surgery). AUR is defined as the need for bladder catheter replacement due to inability to urinate eight hours after the withdrawal, or inability to urinate with clinical symptoms suggestive of urgency. AUR will not be considered if less than 400cc of urine is obtained after catheter replacement, in which case the catheter can be withdrawn again. If a second catheterization is required, regardless of the amount of urine the catheter will be kept in place and the case will be considered as AUR.

Secondary: Secondary outcomes are the decrease in incidence of urinary tract infections within the first 30 days in both groups, and reductions in hospital stay and catheter-related morbidity. Urine culture samples will be collected if the patient presents clinical symptoms suggestive of urinary tract infection (persistent symptoms lasting at least 24 hours): dysuria, urinary frequency, urgency, suprapubic pain, hematuria or testicular pain. Urinary tract infection will be defined if there are more than 104 colonies per ml in men or 105 colonies per ml in women produced by one or two microorganisms in the urine culture.

METHODS/DESIGN

Study design

This prospective, multicenter, controlled, randomized, non-inferiority study of bladder catheter management in scheduled laparoscopic colon surgery has been designed in accordance with the standards of the SPIRIT statement [8].

Recruitment and scope of the study

Patients will be recruited from colorectal surgery units of eight hospitals participating in the study. The same criteria will be applied at all units.

Inclusion criteria

Any patient aged over 18, undergoing scheduled laparoscopic colon and upper rectum surgery in which the peritoneal reflection has not been opened, with a surgical time below 180 minutes, and who agrees to participate in the study and provides signed informed consent will be included. Patients must have a previous anesthetic assessment of ASA I-III and an international prostate symptom score (IPSS) below 20 with/without alpha-blocker treatment for high blood pressure.

Exclusion criteria

Open surgery or conversion to open surgery (defined as any intervention that requires removal of laparoscopic material and conversion to traditional open surgery [9]); administration of epidural anesthesia or ASA IV; preoperative diagnosis of urinary tract infections (more than three episodes/year documented by urine culture, or two urinary tract infections in the last six months); moderate-severe prostate clinical symptoms (IPSS> 20); in men, the presence of positive urine culture in preoperative tests; in women, clinical symptoms of urine infection with positive urine culture. Previous history of AUR, presence of a permanent bladder or ureteral catheter and intermittent self-catheterization will also be grounds for exclusion. Men who have undergone prostatic obstruction surgery (HOLEP, TURP, Millin's or prostate vaporization) will not be included; nor will patients with a history of treatment for urological tumor (prostate

cancer, bladder tumor, ureteral or renal tumor) or urethral stricture, enterovesical fistula or previous pelvic surgery. Other reasons for exclusion will be urinary incontinence or neurogenic bladder; chronic renal failure with creatinine levels above 2 mg/dL (including terminal renal failure or dialysis); emergency surgery, pregnancy, previous pelvic radiotherapy or the administration of > 2,000ml of saline solution during the operation.

Study withdrawal criteria

The following criteria for withdrawal from the study will be applied: the difficulty/impossibility of intraoperative catheterization, urethral bleeding/hematuria after traumatic catheterization or the need for suprapubic cystostomy placement; active antibiotic treatment due to urinary tract infection at the time of surgery; need for intraoperative ureteral catheter placement; need for 24-hour diuresis monitoring by bladder catheterization, combination with other surgeries (hysterectomy, prostatectomy, etc.), Clavien post-surgical complication score > 2 (requiring longer than expected catheterization); intraoperative urinary tract injury or the need for epidural anesthesia in the immediate postoperative period.

The preoperative evaluation in males will include administration of the IPSS questionnaire and a urine culture. Patients with a positive result will be excluded from the study. Medication for high blood pressure will also be evaluated. In women, a urine culture will be performed in the case of clinical symptoms of urine infection.

Ethics, informed consent and legal considerations

Patients who meet the inclusion criteria, understand the nature study, agree to participate and sign the informed consent documentation will enter the randomization process. In this informed consent document, we give the background about the study. We inform the patient about a research study in which you are being invited to participate. That the study has been approved by a clinical research ethics committee. It is voluntary participation. We explain the Objective of the study, the study design, study activities, risks and discomforts arising from the participation in the study, possible benefits, personal data protection, future use of data, contact

in case of doubt or If during the participation in the study they have any questions or need more information, to contact with the principal investigator of the study.

The study was approved by the Clinical Research Ethics Committee of Parc Tauli University Hospital (2019-306) and is registered as ClinicalTrials.gov ID NCT04070898.

The processing, communication and transfer of personal data of all participants will comply with the provisions of the 1999 Spanish Personal Data Protection Act. In accordance with this legislation, patients have the right to access, modify and withdraw their data. To exercise these rights, they should contact the doctor in charge of the study.

The data collected for the study will be identified by means of a code, and only the main researcher of the study and his/her co-workers will be able to relate these data to patients' medical histories. Patients' identities will not be disclosed to any person except in the case of medical urgency or legal requirement. Access to personal information will be restricted to the main researcher and his/her co-workers, the Clinical Research Ethics Committee and personnel authorized by the promoter when they need to check the study data and procedures, but maintaining the confidentiality of these data in accordance with current legislation at all times. The data will be managed across the study centers by XOLOMON TREE, S.L, with the preservation of data protection in accordance with the legislation. Version 3 of this protocol.

Description of the randomization

Patients who meet the inclusion criteria and none of exclusion criteria will be entered in the online database created by XOLOMON TREE, S.L. Once compliance with the inclusion and exclusion criteria and the signature and date of the informed consent documentation have been confirmed, the database, associated with a computer program, will generate the randomization. Patients will be assigned to the control group and the intervention group in a 1: 1 ratio using simple rather than stratified block randomization.

Follow-up (Fig 1, flow chart)

All patients scheduled for laparoscopic colon surgery and who meet the inclusion criteria of the study will undergo preoperative assessment. Female patients will be randomized at the time of surgery, while male patients will complete the IPSS questionnaire and undergo a urine culture. Male patients with IPSS values bellow 19 and negative urine culture will be recruited for the study and randomized at the time of surgery.

Study outcomes

The main outcome will be the development of acute urinary retention. Secondary outcomes will be the development of urinary infection within the first 30 days, and hospital stay.

Other variables analysed will be age, sex, body mass index, the diagnosis and procedure performed, the use of neoadjuvant chemotherapy, the need for conversion to laparoscopy, creation of a stoma, surgical time, type and length of anesthesia, intraoperative bleeding defined in cubic centimeters (measure of the amount of blood collected by the suction system after subtracting the saline serum) , development and type of postoperative complications according to the Clavien scale [10,11] and the Comprehensive Complication Index (CCI) [12,13], Days of admission, the need for re-admission due to AUR or UTI within 30 days after surgery, or administration of saline solution (in milliliters) during surgery will also be assessed.

Sample size

Following the literature, and assuming an AUR rate of 11% and a margin of non-inferiority (delta) of 8%, a sample size of 416 patients is required (208 patients per group with an estimated 10% of losses per group). To achieve this predetermined sample size and to increase the external validity of the study, a multicenter design will be applied involving Spanish hospitals that perform laparoscopic colorectal surgery.

Statistical analysis

The data analysis will be performed using the IBM 21 SPSS Statistics Editor program and will be conducted in a blind manner by independent researchers. The intention-to-treat analysis will

include all randomized patients. The per protocol analysis will include all patients with catheter withdrawal at 24 hours (control group), and all patients in the in whom the catheter will be removed at the end of surgery (intervention group).

Quantitative variables will be described using the mean and standard deviation when the distribution is considered normal; otherwise, the median, interquartile range will be used. Categorical variables will be described in absolute numbers and in percentages. The statistical analysis of the quantitative variables, with independent groups, will be carried out using the parametric Student t test or the non-parametric Mann-Whitney test. The Pearson's chi-square test will be used for the analysis of the categorical variables. The variables will be recorded in an online database which will be managed by the data administrator via the different hospitals.

DISCUSSION

There is an important trade-off to consider between withdrawing the UC early, and thus raising the risk of AUR, and leaving it in place, thus raising the risk of UTI. This dilemma was reflected in the randomized study by Beneoist et al [3] who compared UC removal on postoperative day (PO) 1 versus PO 5 in rectal surgery. AUR appeared in 14% of PO 1 versus 7% of PO 5, but the figures for UTI were 12% and 40% respectively. As we have stated at the beginning there are no reliable studies in the literature that give clear guidance on the question of the timing of UC withdrawal. Early removal of the bladder catheter after colon resection is essential for improving mobilization and for achieving satisfactory postoperative recovery. However, there is a risk of acute urine retention (AUR).

Normal bladder capacity ranges between 400 and 600 ml [14]. Acute urinary retention is understood as the inability to empty a full bladder; it is common after anesthesia and surgery, though its incidence varies widely (5-70%)[15], depending on the type of surgery, the surgical technique and the time of postoperative catheter removal [1617]. Bladder catheterization in AUR is recommended when the bladder volume is greater than 600 ml for a minimum of two hours [18], that is, slightly above the maximum recommended volume in the adult population [19].

The diagnosis of AUR is often arbitrary, and its true incidence is unknown due to the lack of uniform criteria for its definition (14). A mean incidence of 11% is accepted, though in colorectal surgery it varies widely from 1% to 52% [20]. Potential risk factors for the development of AUR are not only advanced age due to progressive neuronal degeneration, or male sex due to benign prostatic hypertrophy, but also the presence of concomitant neurological diseases such as stroke, poliomyelitis, or multiple sclerosis, or diabetic and alcohol-related neuropathy [21]. Administration of anticholinergic drugs such as atropine in the perioperative period blocks detrusor muscle contractions and causes bladder hypotonia, favoring the development of urine retention [1]. It has also been reported that the administration of more than 750 ml of intravenous fluids during the perioperative period doubles or triples the risk of urine

retention [22]; this is because bladder overdistension, especially in patients undergoing spinal anesthesia, eliminates the perception of bladder filling and the urination reflex is not restored even after bladder catheterization.

The vagal response to the pain caused by an excessively distended bladder may trigger vomiting, bradycardia, hypertension, arrhythmia or even asystole [23]. A common adverse effect of bladder catheter maintenance is urinary tract infection. Our group recently carried out a survey of hospitals in our geographical setting, Catalonia, to compile data regarding catheter withdrawal practices post-surgery. Forty-three of the 45 hospitals contacted responded (a response rate of 95.6%), 41 of which reported performing colon surgery. The volume of colon surgeries per year was directly related to the size of the hospital. Most hospitals (27/41, 65.9%) reported withdrawing the catheter at 24 h; twelve hospitals (29.3%, a non-negligible proportion) reported withdrawal between days 2 and 3. In general, the larger the hospital, the earlier the catheter is withdrawn.

In the continuous improvement of the care process, there is a clear need to shorten the duration of catheterization. As a relatively basic step in the surgical procedures, the decision regarding when to withdraw the catheter has been paid little attention and has been left largely to the discretion of individual surgeons. We believe that catheter removal is possible immediately after scheduled laparoscopic colon surgery, without causing an increase in acute urine retention. This practice offers the benefits of earlier mobilization, reduces catheter-related morbidity, and allows prompt discharge.

The aim of the present study is to establish an ideal balance between the reduction in urinary tract infection and the risk of AUR, providing a higher degree of evidence than that currently available [24]. ~~Our previous experience in others multicenter, prospective, randomized trials support the achievements of the study objectives [25,26,27].~~

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Figure legend

Figure 1: Trial flow chart. IPSS: International Prostate Symptom Score

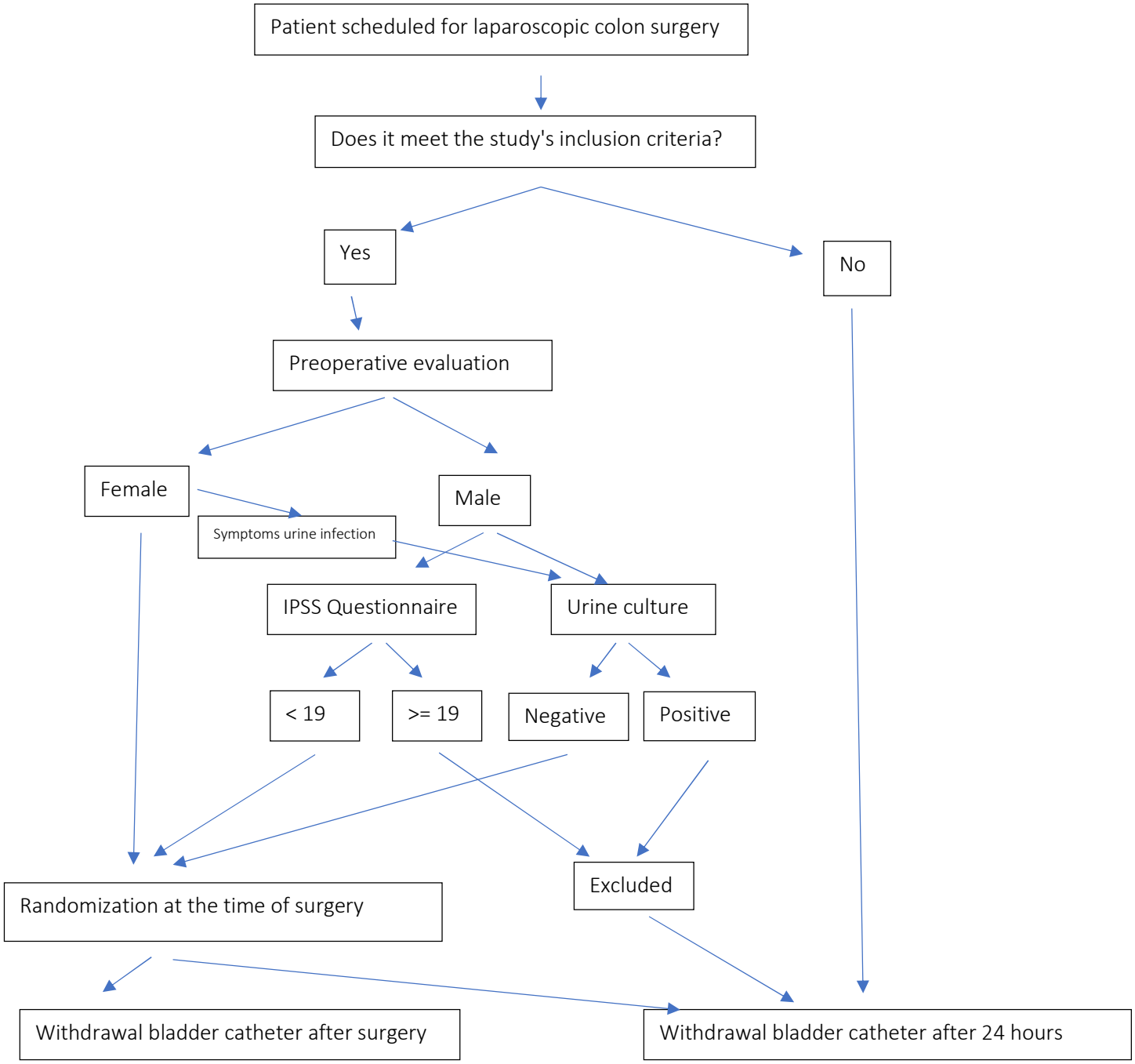

Fig 1: Trial flow chart

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