Study Protocol

RETention of urine **A**fter **IN**guinal hernia **E**lective **R**epair

(RETAINER study I)

Project Lead: Irish Surgical Research Collaborative (ISRC)

UK Lead Collaborator: NOSTRA

Italian Lead Collaborator: ItSurg

Declarations

Funding: Grants were received from the European Hernia Society and the British Hernia Society. Support (statistical and software) was provided by the Royal College of Surgeons of Ireland.

Conflicts of interest/Competing interests: Nil

Ethics approval: Ethical approval was received for the pilot study and granted to complete the research outlined in this protocol

Consent to participate: Patients in the pilot study consented to participate

Availability of data and material: Available upon reasonable request

Authors' contributions: Each of the named authors in the steering group contributed significantly to protocol design and writing

Keywords: Protocol, Inguinal hernia, Urinary retention, POUR, postoperative

Contents

Protocol Summary

General Information	
Short Title	RETAINER Study
Full Title	**RET**ention of urine **A**fter **IN**guinal hernia **E**lective **R**epair Audit
Study Information RETAINER 1	
Indication	To investigate the rate of acute urinary retention in patients following elective inguinal hernia repair
Design	Observational Audit
Primary Outcome	• The rate of urinary retention requiring catheterisation post elective inguinal hernia (IH) repair
Secondary Outcome	• Subgroup analysis - rates of post-operative urinary retention (POUR) following laparoscopic versus open repair and spinal versus general anaesthesia • Identification of preoperative risk factors marking patients at risk of POUR following IH repair • Assessment of impact of POUR on length of stay, cost analysis
Study Timelines RETAINER 1	
Time Period	March 2021 – August 2021** In light of COVID-19 pandemic a pragmatic approach to the data collection period is possible. The authors suggest a **minimum data collection period of 4 weeks** however flexibility will be supported
Main Study Period	12 week block** (minimum 4weeks preferred)
Follow up duration	1 week
Data Submission	Last date for data submission 1st August 2021
Data Analysis	September 2021
Results Available	November 2021
Paper submission	November 2021

Abstract

Purpose: Post-operative urinary retention (POUR) is a well-recognised complication of inguinal hernia repair (IHR). The magnitude of the problem is unclear, and contradictory evidence surrounds postulated risk factors. POUR risks patient distress, catheter-complications and a financial and logistical burden to services. Separately, in the field of IHR, there has been a lack of research into patients' perceptions of surgical 'success'. Our aim is to perform a two-phase, multi-centre prospective study to:

1. Assess the rate, risk factors and impact related to POUR post IH repair.
2. Develop and validate a patient reported outcome measure (PROM) for inguinal hernia repair.

Methods: RETAINER 1: We propose a 12-week prospective study with voluntary international participation. All patients undergoing elective IH repair (minimally-invasive/open) will be eligible. Standardized data collection will include patient and perioperative factors. Primary outcome will be development of POUR, defined as the need for insertion of a urinary catheter as determined by the treating clinician. Secondary outcomes will be identification of factors predisposing to POUR and the impact of POUR.

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Conclusions: Using an international multi-centre collaborative approach will produce the necessary volume of patients, whilst capturing inter-centre variability, to accurately reflect POUR rates and allow analysis of risk factors. This patient pool will provide an excellent opportunity to develop a PROM using appropriate qualitative methodology.

RETAINER I

An Audit of Acute Urinary Retention Post Elective Inguinal Hernia Repair

Introduction

Post-operative urinary retention (POUR) anecdotally occurs in a significant proportion of male patients following inguinal hernia repair. This has a potentially detrimental effect on both patients and services, due to the need for urinary catheterisation and admission.

The international literature reports an extremely wide range (0.4% - 41.6%) of rates of acute urinary retention following inguinal hernia repair [1-10]. Potential peri-operative risk factors postulated from a mixture of prospective and retrospective studies are the choice of a laparoscopic approach [8,5], the use of spinal anaesthesia [11,12], bilateral inguinal hernia repair [2,1], increased duration of operative time [2], increased volume of perioperative fluids [13], use of specific anaesthetic agents [13], and increased use of narcotic analgesia [3]. Contradictory evidence surrounds many proposed risk factors, however, with some authors finding no statistically significant correlation of POUR with open versus laparoscopic approach [1], with choice of anaesthesia [1], with performance of synchronous bilateral IH repair [3], or with volume of intra-operative fluids infused [3]. Some studies have assessed patient related risk factors and identified increased BMI [2] and increased patient age [2,1] as being associated with higher rates of POUR. Again, some dispute exists, notably surrounding whether or not an existing diagnosis of benign prostatic hyperplasia (BPH) increases the risk of POUR [1,3].

Whilst urinary catheterisation may be considered a minor intervention, it is far from inconsequential. The need for insertion of a catheter can cause patients

significant distress, prolong their hospital stay, restrict mobilisation [14] and risk complications. A recent prospective multi-centre trial assessing outcomes of short-term catheterisation of hospitalised patients (catheter indwelling for ≤3 days in 76%) found that one or more catheter-related complication were described by 57% (1184/2076) of patients at 30 day follow up [15]. Catheter associated UTIs (CAUTIs) are amongst the most common hospital acquired infections reported globally [16-19], have been described as the most common identifiable source of secondary blood-stream infection in the hospital setting [20], and are associated with the culture of rising numbers of resistant organisms [21]. Common non-infectious complications of short-term urinary catheters include blockage, leakage and haematuria [22]. More concerningly, accidental removal, urethral stricture or erosion (3.4% - 16.7%) [22] and iatrogenic trauma during insertion (0.3-3%) [23-25] may occur, causing significant morbidity with potentially life-long consequences for the patient.

Furthermore, urinary retention following inguinal hernia repair has a significant impact on hospital services. Elective inguinal hernia repair is typically planned as a day-case procedure. The development of acute urinary retention in a patient mandates placement of a urinary catheter. This generally requires admission to hospital, with the alternative being catheter training with short-interval follow-up by specialist services. Undiagnosed or later evolving POUR may require Emergency Department attendance and/or admission in the early post-operative days. All scenarios pose a significant financial and logistical burden to hospital services. Post-operative urinary retention has been identified as the cause for unplanned admission in 20-25% of ambulatory general surgical procedures [26],[27]. Whilst there is a lack of published data on the economic impact of this in the context of individual health systems, it inevitably distorts the internationally anticipated 36-65% cost saving expected with performing hernia repair as day-case surgery [28]. Should a complication of catheterisation occur, costs are greatly amplified; US evidence suggests that total costs incurred in the management of a catheter associated UTI exceed $1,000 [29]

and estimates of €3,846 - €9,064 per patient for the management of iatrogenic urethral trauma in Ireland have been declared [30,24].

Rationale and hypothesis

Post-operative urinary retention following elective inguinal hernia repair may have a significant impact on patient morbidity and a high cost to healthcare services. Rates of POUR have not been formally evaluated in a global context, it is unclear what effect the surgical approach and choice of anaesthesia have on the incidence of POUR, and no risk stratification system is in place to preoperatively identify patients most likely to experience this complication.

Our hypothesis is that POUR is a significant complication of IH repair in Ireland/UK and internationally, in both its incidence and its consequences. We propose that a prospective audit of this will assess the magnitude of the problem, and may identify patient and surgical factors increasing its incidence. Such findings would have potential to inform future research, which may explore ways to minimise and manage the complication of POUR in high-risk patient groups.

Objectives

- To identify the rate of post-operative urinary retention (POUR) in male patients undergoing elective inguinal hernia (IH) repair in participating centres internationally.

- To assess preoperatively the International Prostate Symptom Score (IPSS) in this patient cohort, and where possible, to record a pre-operative post-void residual volume (PVR) in these patients, and to assess correlation of these variables with POUR.

- To record the surgical approach to hernia repair, the anaesthetic approach used, including record of all anaesthetic drugs used intraoperatively, and the post-operative analgesic regimen on the ward, to assess correlation of these variables with POUR.

- To examine the impact of POUR on patient morbidity and on hospital services (secondary aims).

- To record pain scores following inguinal hernia repair on discharge as a secondary outcome measure.

Design and Methods

- A multicentre multinational prospective cohort study is proposed.
- Any hospital providing elective inguinal hernia repair as part of a general surgical service will be eligible to enrol patients. A named surgical consultant / attending will act as the local principal investigator. Local data collection will be managed by surgical trainees / residents at each participating centre. The study will be registered and approved by each participating hospital's audit committee or ethics committee as appropriate.

- <u>Patient eligibility</u>

    - Patients 18 years or over undergoing elective inguinal hernia repair by any surgical approach are eligible for entry into this study.
    - Patients with a long-term indwelling catheter and those who routinely perform self-catheterisation to empty their bladder, those with any form of urinary diversion, those undergoing emergency operations and those unwilling or unable to consent to participation are to be excluded.

- Projected numbers
    - We aim to enrol a minimum of 25 centres in this study.
    - We propose a 12-week data collection period* (In light of COVID-19 pandemic a pragmatic approach to the data collection period is possible. The authors suggest a minimum data collection period of 4 weeks however flexibility will be supported).
    - The study is powered based on an incidence of urinary retention of 5%. This would require n=600 participants to find a difference. With a conservative estimate of 2 inguinal hernia repairs per site per week, we predict patient enrolment of 600 (Mean 2 patients x 25 centres x 12 weeks).

- Contingency
    - Upon enrolment, centres will submit their local hernia figures for the previous week.
    - Interim data analysis of primary outcome per centre will be performed at 4 weeks and extension of study period or recruitment of further centres arranged if required.
    - We acknowledge the potential impact of the global SARS-CoV-2 on target figures, and have identified a 16-week data collection period to allow extension of the intended 12 weeks in the instance of inadequate patient recruitment.

- Study phases
    - Pilot: a three-week pilot study has been undertaken in University Hospital Limerick in 2019. This has ensured feasibility and validated data collection techniques, with minor improvements made to data collection form following same. COMPLETED.

- RETAINER I: The study will run over a minimum 12-week study period per centre, with three 4-week blocks of data collection. Centres may add an additional 4-week block, extending the study period to 16 weeks if inadequate recruitment at 12 weeks.

Outcome Measures

Primary

The definition of the primary endpoint is the rate of post-operative urinary retention (POUR) following elective inguinal hernia in male patients, where POUR is defined as the need for insertion of a urinary catheter as determined by the treating clinician.

Secondary

- Pre-operative
  - Patient demographics.
  - Preoperative urological medications or urological diagnosis.
  - International Prostate Symptom Score (IPSS) of patient.
  - 1 or more post-void residual measurement (PVR) of patient where logistically feasible.

- Intra-operative
  - Surgical approach – laparoscopic versus open
  - Unilateral versus bilateral hernia repair
  - Anaesthetic approach: Local/Spinal/General
  - Anaesthetic agents used

- Perioperative fluid volume infused
- Duration of surgery

- Post-operative
  - Analgesia administered on ward
  - Time to voiding
  - Need for urinary catheter insertion
  - If catheter inserted, outcome – morbidity and service burden
  - Pain score on discharge and at 1-week telephone follow up.

Data collection

Variables to be collected:

- Pre-operative
  - Patient age
  - Patient BMI
  - ASA grade
  - Preoperative medications for the treatment of bladder outlet obstruction or overactive bladder, or the use of alpha-blockers or medications with anticholinergic effect for other indications.
  - History of relevant urological diagnosis (benign prostatic hyperplasia/prostate cancer/urethral stricture/bladder neck stenosis/detrusor underactivity/detrusor overactivity) or of relevant urological procedure (radical prostatectomy/ transurethral prostatectomy / bladder neck or urethral surgery / pelvic radiotherapy)
  - History of previous episode of acute urinary retention, and if so, whether spontaneous or provoked by C2H5OH, urinary tract infection (UTI) or constipation
  - Pre-operative International Prostate Symptom Score (IPSS) of patient

- Pre-operative post-void residual measurement (PVR) of patient where logistically feasible
- Day bowels last opened

- <u>Intra-operative</u>
  - Surgical approach – laparoscopic versus open
  - Unilateral versus bilateral hernia repair
  - Involvement of bladder in hernia
  - Anaesthetic approach: Local/Spinal/General anaesthesia
  - Anaesthetic agents used
    - Systemic: Glycopyrronium, diazepam, pentobarbital, propofol, isoflurane, methoxyflurane, halothane, muscle relaxants
    - Spinal: Anaesthetic and opioid use
    - Local: agent of choice, with/without adrenaline
  - Perioperative analgesics
  - Perioperative fluid volume infused
  - Duration of surgery
  - Intraoperative complications (recognised injury to bladder, ureter, nerves or bowel)
  - Mesh used and type

- <u>Post-operative</u>
  - Time to voiding
  - Need for urinary catheter insertion prior to discharge
  - Time of catheter insertion (hours post-operative)
  - Indication for catheter insertion as assessed by the treating clinician:
    - Failure to resume normal voiding on the day of surgery as clinically determined
    - Inability to void despite the urge to do so
    - Suprapubic pain deemed secondary to failure to void
    - A palpable bladder
    - An ultrasound bladder scan volume of >600ml

- Presentation to ED with urinary retention within 72 hours of surgery

- If urinary retention, outcome:
    - Method of decompressing the bladder (urethral catheter, self-intermittent catheter, suprapubic catheter)
    - Number of catheterisation attempts
    - Residual volume of urine
    - Digital rectal exam findings
    - Overnight admission
    - Timing of trial without catheter (TWOC)
    - Whether or not TWOC was successful
    - Alterations to medications (addition of alpha-blocker or 5-alpha reductase inhibitor; cessation of beta-3 agonist or anti-cholinergic)
    - Outcome if first TWOC unsuccessful
    - Complications: Acute kidney injury, urinary tract infection, accidental catheter removal with balloon inflated, pain/bladder spasm
    - Whether an inpatient urology consultation was sought
    - Whether inpatient urological intervention was required
    - Whether patient was discharged with a urinary catheter in-situ
    - Whether patient was taught self-intermittent catheterisation whilst an inpatient
- Estimated cost analysis of the POUR (catheter and associated equipment, length of stay X cost of local hospital bed), cost of additional medications

Data Collection Methods

- Data will be collected in REDCap, hosted by the Royal College of Surgeons (RCSI), Dublin Ireland. It will be the responsibility of the local principal investigator (PI) to ensure that the data are password protected and kept on a secure local server. The REDCap database will be pseudonymised. However, a separate password-protected key document, including patient hospital identifier, will be kept by the local lead investigator for a period of 30 days to allow for outcome follow-up.

- Data collection points:
    - Each hospital site should identify all theatres where procedures are being performed. All consultant surgeons and anaesthetists involved in procedures should give prior consent for data collection.
    - Patient identification: patients should be identified in advance of admission from elective operating lists.
    - Pre-operative data: these should be collected from the patients' medical records. Patients should be asked in clinic / at preoperative assessment or on admission to the day ward to complete the IPSS questionnaire. Where feasible, a post-void residual measurement (PVR) should be recorded with a bladder scanner.
    - Operative data: these should be recorded by the operating surgeon or one of the assistants participating in the operation.
    - Post-operative data: All patients should be followed for 1 week post-operatively. Patients in whom a catheter was inserted for retention should be followed for 30 days. Local arrangements should be made

      but these include monitoring paper and electronic records, monitoring outpatient or ED attendance and reviewing results (e.g. catheter urine specimens) where relevant.

- There should be regular local audit to ensure all eligible local patients are being enrolled and that data collection is as complete as possible.

- Validation of dataset:
  - The supervising consultant(s) will be required to submit the total number of elective inguinal hernia repairs performed in male adult patients at their institution during the 12-14 week study period, as reported by the institution's coding department, to be able to identify the number of cases captured in the audit.

- Data collation:
  - Data will be submitted centrally via REDCAP hosted on Royal College of Surgeons of Ireland (RCSI) servers with all patient identifiers removed, and unique study ID used for each patient only. A local key, kept securely in a password protected document by the local lead investigator, will link patient identifier to study ID and be maintained for 30 days to allow input of short-term follow up data. This will then be destroyed, or, if the patient has consented to participation in RETAINER II, maintained until completion of this phase.
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Statistical analysis

- The statistical data from this study will be reported in accordance with the guidelines set by the STROBE (Strengthening of the Reporting of Observational Studies in Epidemiology) consensus statement [31]. Data will be analysed by RCSI statisticians. Data will be analysed in clinically relevant categories with Chi squared analysis used to detect differences between groups.

- All data will be anonymised prior to analysis. Binary logistic regression modelling will be used. Multivariable models will be built to produce odds ratios (OR) to account for the impact of predictive variables when assessing outcomes. The OR represents the odds of post-operative urinary retention occurring. Variable selection will be based upon those which are statistically significant at univariate analysis, and those which are significant clinically but not statistically.

Authorship for RETAINER I

- A collaborative authorship model, using The National Research Collaborative & Association of Surgeons in Training Collaborative Consensus Group Guidelines will be used.
- Preparation of a manuscript for publication will be performed by a writing committee.
- Collaborators contributing to the running of the study will be listed as 'PubMed' citable authors as part of the RETAINER study group.
- There will be a lead trainee for each site, who will be responsible for submitting the names of all authors from that site to the collaborative.
- There should be at least one consultant surgeon who agrees to act as a PI for each site.
- It is the local PI's responsibility to ensure validity of the submitted dataset.

Definitions

The following definitions will be used for this study:

- Post-Operative Urinary Retention: In the absence of a universally accepted definition[13] POUR will be defined in this study as the need for insertion of a urinary catheter as determined by the treating clinician

- American Society of Anaesthesiologists (ASA) physical status classification system is a system for assessing the fitness of patients before surgery. These are:
    - 1. A normal healthy patient
    - 2. A patient with mild systemic disease
    - 3. A patient with severe systemic disease
    - 4. A patient with severe systemic disease that is a constant threat to life
    - 5. A moribund patient who is not expected to survive without the operation

- Method of operation:
    - Laparoscopic
        - Transabdominal preperitoneal (TAPP) **repair**
        - Totally extraperitoneal (**TEP**) **repair**
    - Laparoscopic converted to open: procedure attempted laparoscopically with necessitation of conversion to an open procedure.
    - Open procedure: performed as a planned open procedure

- Duration of procedure:
    - Time from first skin incision to final skin closure.

- 30-day post-catheterisation complications – complications occurring within 30 days from the date of catheter insertion including:
    - (CAUTI): A UTI in a patient who had an indwelling urinary catheter in place at the time of, or within 48 hours prior to infection onset.
    - Urinary tract infection (1) A culture of pure organisms >100,000 cfu/ml from a catheter specimen of urine in a symptomatic patient (elevated inflammatory markers or pyrexia in the absence of a more likely source, suprapubic pain, frequency/dysuria (if catheter removed). (2) Urine dipstick positive for nitrites along with leukocytes +/- blood/protein in a symptomatic patient (ideally this should be correlated with a positive urine culture).

    - Traumatic catheterisation (2 or more failed attempts at catheterisation, clearly visible haematuria or clots immediately post catheterisation, inflation of balloon in urethra, urethral injury diagnosed by a urologist)
- Unplanned Admission – need for overnight admission of a patient planned for ambulatory (day-case) surgery.
- Re-attendance due POUR: attendance at ED / Surgical Assessment Unit / Day Ward within 72 hours of surgery due to inability to void requiring insertion of urinary catheter, whether or not admitted
- Readmission is defined as any admission following discharge necessitating an overnight stay.
- Length of stay: calculated from the date of admission to the date of discharge.

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