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How the type and size of urinary catheters affect pain and complications during bladder immunotherapy and chemotherapy treatments

Submission date
06/10/2025

Recruitment status
No longer recruiting

Registration date
08/10/2025

Overall study status
Completed

Last Edited
08/10/2025

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study explores whether the type and size of urinary catheters affect how comfortable patients feel during bladder treatments for non-muscle-invasive bladder cancer (NMIBC). These treatments involve putting medicine, such as BCG or chemotherapy, directly into the bladder through a catheter. Although this is a common procedure, many patients experience pain or anxiety during catheterization.

Who can participate?
Adult patients (men and women aged 18 years or older) with bladder urothelial carcinoma.

What does the study involve?
Participants were randomly assigned to one of four groups, depending on the type and size of catheter used:
12 French (Fr) Foley catheter
8 Fr Foley catheter
12 Fr TAK (silicone) catheter
8 Fr TAK (silicone) catheter
All treatments were performed by a urologist. Before catheter insertion, a 2% lidocaine gel was applied to reduce discomfort. After a short wait, the assigned catheter was inserted, and the bladder medicine was given. The catheter was removed immediately after the drug was instilled. Pain and anxiety were measured right after the procedure using standard scales. Patients were also followed for one week to record any side effects, such as bleeding, infection, or catheter-related injury.

What are the possible benefits and risks of participating?
The study aims to identify which catheter type and size causes less pain and anxiety and leads to fewer complications, helping doctors choose the most comfortable and safest option for future bladder treatments.

There are minimal risks. Possible mild discomfort may occur during catheterization, but no serious or long-term complications are expected.

Where is the study run from?
Lokman Hekim University, Türkiye.

When is the study starting and how long is it expected to run for?
December 2023 to March 2025

Who is funding the study?
Lokman Hekim University, Türkiye.

Who is the main contact?
Dr Ferec Efendioğlu, Gülhane Training and Research Hospital, Department of Urology, ferec.efendioglu@gulhane.edu.tr, ferecefendiyev@mail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of catheter type and size on patient comfort and complications in intravesical BCG and chemotherapy administration: a randomized prospective pilot study

Study objectives
To evaluate whether catheter type and size influence patient-reported pain, anxiety, and adverse events during intravesical therapy, recognizing that intravesical instillation of Bacillus Calmette-Guérin (BCG) or chemotherapeutic agents requires urethral catheterization, which may cause pain, anxiety, and complications.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/12/2023, Scientific Research Ethics Committee of Lokman Hekim University (Söğütözü, 9 Eylül Cd No:6, Ankara, 06530, Türkiye; +90-444 8 548; info@lokmanhekim.edu.tr), ref: Approval Code: 2023232, date: 2023/241

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Laboratory, Training facility/simulation, University/medical school/dental school

Study type(s)
Quality of life, Safety, Efficacy

Participant information sheet
Not available web format,please use contact details to reguest a participant information sheet

Health condition(s) or problem(s) studied
Patients diagnosed with non-muscle-invasive bladder cancer (NMIBC) who are receiving intravesical instillation of Bacillus Calmette–Guérin (BCG) or chemotherapeutic agents as part of their standard treatment.

Interventions
Participants
Eligible patients will be males and females aged ≥18 years diagnosed with bladder urothelial carcinoma and scheduled for intravesical BCG or chemotherapy instillation.

Randomization and Blinding
An assistant head nurse will perform randomization using a computer-based program (www.randomizer.org; simple randomization, 1:1 ratio). The participants will be randomly allocated into four groups:
• Group 1: 12 Fr Foley catheter

• Group 2: 8 Fr Foley catheter
• Group 3: 12 Fr TAK catheter
• Group 4: 8 Fr TAK catheter
The allocation sequence will be concealed using the sealed envelope method, which will be managed by the nurse. Both the participants and outcome assessors will be blinded to group allocation. The randomization process will be illustrated in the CONSORT flow diagram.

Intervention
Intravesical drug instillations will be performed by a urologist using either a rubber Foley catheter (Rüsch) or a silicone catheter (TAK) (Homecath), with sizes of 8 Fr or 12 Fr, as per group assignment.
Before catheterization, a 2% lidocaine gel will be administered to the urethra via the external meatus. After a 1-minute wait, the appropriate catheter will be inserted, and the pre-prepared BCG or chemotherapeutic agent will be instilled into the bladder. The catheter will be removed immediately after drug administration.

Statistical Analysis
All statistical analyses will be performed using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables will be expressed as mean ± standard deviation (SD) or median with interquartile range (IQR), and categorical variables will be expressed as frequency and percentage. Normality will be assessed using the Shapiro–Wilk test and Q–Q plots, while homogeneity of variances will be evaluated using Levene's test. Nonparametric tests will be applied when parametric assumptions are not met.
Group comparisons will be conducted using one-way ANOVA or the Kruskal–Wallis test, as appropriate. Categorical variables will be compared using the chi-squared test or Fisher's exact test. Independent predictors of the VAS pain scores will be identified using multiple linear regression analysis, adjusting for age, sex, catheter type, anxiety, and complications. Ordinal logistic regression will be performed to evaluate the factors influencing anxiety severity. Results will be presented as odds ratios (ORs) with 95% confidence intervals (CIs). Statistical significance will be defined as a two-sided p-value of < 0.05.
Participants (continued)

Intervention Type
Procedure/Surgery

Primary outcome measure
The following tools were used immediately after catheterization:
1. Anxiety was measured using the Anxiety: Beck Anxiety Inventory (BAI) questionnaire
2. Pain was measured using the Visual Analog Scale (VAS), ranging from 0 ("no pain") to 10 ("worst imaginable pain")

Secondary outcome measures
Complications were measured by a urologist who recorded all adverse events for one week post-procedure for complications (e.g., macroscopic hematuria, urinary tract infection, and catheter-induced trauma-false route). Dysuria was defined as painful urination in the absence of bacterial growth in urine culture. Cystitis was defined as the presence of significant bacterial growth in urine culture (>105 CFU/mL), accompanied by symptoms such as urinary frequency, which was defined based on significant bacterial growth in urine culture (>105 CFU/mL) along with symptoms consistent with prostatitis (e.g., pelvic pain, dysuria, and nocturia). Macroscopic hematuria was defined as the presence of visible blood in the urine.

Overall study start date
01/12/2023

Completion date
12/03/2025

Eligibility

Key inclusion criteria
1. Patients diagnosed with non-muscle-invasive bladder cancer (NMIBC)
2. Receiving intravesical instillation of Bacillus Calmette–Guérin (BCG) or chemotherapeutic agents as part of their standard treatment

Participant type(s)
Patient

Age group
Mixed

Lower age limit
20 Years

Upper age limit
97 Years

Sex
Both

Target number of participants
200

Total final enrolment
179

Key exclusion criteria
1. Prior diagnosis of anxiety or psychiatric disorder
2. History of urethral trauma associated with catheterization
3. Diagnosis of dementia

Date of first enrolment
12/12/2023

Date of final enrolment
12/03/2025

Locations

Countries of recruitment
Türkiye

Study participating centre
Lokman Hekim University
Söğütözü, 9 Eylül Cd No:6
Aankara
Türkiye
06530

Sponsor information

Organisation
Lokman Hekim Üniversitesi

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Sponsor type
University/education

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ROR
https://ror.org/04v8ap992

Funder(s)

Funder type
University/education

Funder Name
Lokman Hekim Üniversitesi

Results and Publications

Publication and dissemination plan

The results of this research will be published in scientific journals and presented at medical conferences so that doctors and patients can benefit from the findings.
The results will also be added to the ISRCTN and ClinicalTrials.gov websites within one year after the study finishes.

Intention to publish date
12/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ferec Efendioğlu, Gülhane Training and Research Hospital, Department of Urology, ferec.efendioglu@gulhane.edu.tr, ferecefendiyev@mail.com.

Description:
De-identified individual participant data (IPD) that support the findings of this study will be made available to qualified researchers upon reasonable request. The shared dataset will include variables related to patient demographics, catheter type and size, pain scores (VAS), anxiety scores (BAI), and recorded complications.

Data will be anonymized in accordance with data protection regulations (GDPR and national ethics guidelines).
No information that could identify a participant will be shared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			08/10/2025	No	No