Participants

Eligible patients were males and females aged ≥18 years diagnosed with bladder urothelial carcinoma and scheduled for intravesical BCG or chemotherapy instillation. The exclusion criteria were as follows:

- Prior diagnosis of anxiety or psychiatric disorder
- History of urethral trauma associated with catheterization.
- Diagnosis of dementia

Of the 200 initially screened patients, 21 were excluded: 11 due to anxiety, seven due to previous urethral trauma, and three due to dementia. In total,179 patients were included in the final analysis.

Randomization and Blinding

An assistant head nurse performed randomization using a computer-based program(www.randomizer.org; simple randomization, 1:1 ratio). The participants were 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 was concealed using the sealed envelope method, which was managed by the nurse. Both the participants and outcome assessors were blinded to group allocation. The randomization process is illustrated in the CONSORT flow diagram (**Figure 1**).

Intervention

Intravesical drug instillations were 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.

Prior to catheterization, a 2% lidocaine gel was administered to the urethra via the external meatus. After a 1-minute wait, the appropriate catheter was inserted, and the pre-prepared BCG or chemotherapeutic agent was instilled into the bladder. The catheter was removed immediately after drug administration.

Outcome Assessment

Measurement of Pain and Anxiety

Pain and anxiety assessments were conducted immediately after catheterization by a second research nurse using standardized questionnaires.

- Pain was measured using the visual analog scale (VAS), ranging from 0 ("no pain") to 10 ("worst imaginable pain"). According to the WHO Health Organization pain classification:
    - <3 = mild pain
    - 3–6 = moderate pain
    - 6 = severe pain
- Anxiety was evaluated by using the Beck Anxiety Inventory (BAI):
    - 8–15: mild anxiety
    - 16–25: moderate anxiety
    - 26–63: severe anxiety

Complication Monitoring

All patients were monitored 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 ($>10^5$ CFU/mL) accompanied by symptoms such as urinary frequency, which was defined based on significant bacterial growth in urine culture ($>10^5$ CFU/mL) along with symptoms consistent with prostatitis (e.g., pelvic pain, dysuria, and nocturia). Macroscopic hematuria was defined as visible blood in urine.

All adverse events were recorded by a urologist, and the groups were compared in terms of pain, anxiety, and complication rates.

Statistical Analysis

All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables are expressed as mean ± standard deviation (SD) or median with interquartile range (IQR), and categorical variables are expressed as frequency and percentage. Normality was assessed using the Shapiro–Wilk test

and Q–Q plots, while homogeneity of variances was evaluated using Levene's test.Nonparametric tests were applied when parametric assumptions were not met. Group comparisons were conducted using one-way ANOVA or the Kruskal–Wallis test, as appropriate. Categorical variables were compared using the chi-squared test or Fisher's exact test. Independent predictors of the VAS pain scores were identified using multiple linear regression analysis, adjusting for age, sex, catheter type, anxiety, and complications. Ordinal logistic regression was performed to evaluate the factors influencing anxiety severity. Results are presented as odds ratios (ORs) with 95% confidence intervals (CIs). Statistical significance was defined as a two-sided p-value of < 0.05.