

**Official Title:**

Impact of Ureterorenoscope Diameter on Technical Outcomes, Procedural Difficulty, and Surgeon Stress: A Comparative Study

**NCT Number:**

NCT06935500

**Protocol Version:** Version 1.0

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**1. Background and Rationale**

Ureterorenoscopy (URS) is widely used in the management of ureteral stones due to its high success rates and favorable safety profile. Technological advancements have enabled the use of thin-caliber ureteroscopes, which may facilitate atraumatic ureteral access and reduce the need for dilation. However, the impact of ureteroscope diameter on technical outcomes and surgeon-related factors such as procedural difficulty and intraoperative stress remains unclear.

In addition to traditional surgical outcomes, the psychological burden experienced by the surgeon during technically demanding procedures has gained increasing attention. Therefore, this study aims to evaluate both technical and surgeon-related outcomes associated with different ureteroscope calibers.

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**2. Objectives****Primary Objective**

To evaluate the impact of ureterorenoscope diameter on intraoperative surgeon stress during ureterorenoscopy.

**Secondary Objectives**

- To compare technical outcomes between thin-caliber and standard-caliber ureteroscopes
- To evaluate procedural difficulty
- To assess perioperative outcomes including:
  - Stone-free rate (SFR)
  - Ureteral injury (Traxer classification)
  - Balloon dilation requirement
  - JJ stent placement
  - Postoperative complications (Clavien–Dindo classification)

### **3. Study Design**

This study was designed as a **prospective, randomized, single-center clinical trial**. The study was approved by the local ethics committee (Decision No: 14, Protocol No: 2025/74) and prospectively registered at ClinicalTrials.gov (Identifier: NCT06935500). Participants were enrolled between March 2025 and December 2025 and randomly assigned in a 1:1 ratio using a simple randomization method.

### **4. Study Population**

#### **Inclusion Criteria**

- Patients scheduled for ureterorenoscopy due to ureteral stones
- Age  $\geq 18$  years
- Provision of written informed consent

#### **Exclusion Criteria**

- Emergency surgery
  - Bilateral ureteral stones
  - Pre-existing double-J stent
  - Radiolucent stones not adequately evaluated on imaging
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## **5. Interventions**

Participants were randomized into two groups:

- **Group 1:** 4.5–6.5 Fr semirigid ureteroscope (thin-caliber)
- **Group 2:** 8–9.8 Fr semirigid ureteroscope (standard-caliber)

All procedures were performed under spinal anesthesia using a holmium:YAG laser system. Ureteral dilation and JJ stent placement were performed when clinically indicated.

## **6. Outcome Measures**

### **Primary Outcome**

- Occurrence of stress-related procedures (defined as  $\Delta\text{STAI-TX1} > 0$ )

### **Secondary Outcomes**

- Stone-free rate at 1 month
- Operative time
- Balloon dilation requirement
- Ureteral injury (Traxer classification)
- JJ stent placement

- Postoperative complications (Clavien–Dindo classification)

## **7. Assessment of Surgeon Stress**

Surgeon stress was assessed using the **State–Trait Anxiety Inventory (STAI-TX1)**. The 20-item state anxiety scale was administered immediately before and after each procedure by an independent investigator. An increase in postoperative STAI-TX1 score compared to preoperative score ( $\Delta\text{STAI-TX1} > 0$ ) was defined as a stress-related procedure.

## **8. Data Collection**

Collected variables included:

- Demographics (age, sex, BMI)
- Stone characteristics (size, location, side)
- Operative time
- Perioperative outcomes
- STAI-TX1 scores

## **9. Statistical Analysis (SAP)**

Statistical analyses were performed using SPSS (version 20.0; IBM, Armonk, NY).

- Continuous variables: Student's t-test or Mann–Whitney U test
- Categorical variables: Chi-square or Fisher's Exact test
- Significance level:  $p < 0.05$

Sample size was calculated using G\*Power (v3.1). Based on prior SFR data, 65 patients per group were required (power 95%, alpha 0.05). Multivariable logistic regression analysis was performed to identify independent predictors of stress-related procedures.

Variables included:

- Ureteroscope caliber
- Stone size
- Stone location
- Operative time

Adjusted odds ratios (aOR) with 95% confidence intervals were calculated. Model calibration was assessed using the Hosmer–Lemeshow test.

## **10. Ethics**

The study was approved by the Aydın Adnan Menderes University Ethics Committee (Decision No: 14, Protocol No: 2025/74). All participants provided written informed consent. The study was conducted in accordance with the Declaration of Helsinki.

## **11. Protocol Amendments**

No protocol amendments were made prior to submission.