Cairo University

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CAIRO UNIVERSITY - FACULTY OF MEDICINE

Faculty of Medicine, Cairo University Postgraduate Research Protocol Template

(Please read carefully provided guidance documents for a comprehensive understanding and proper formulation of your thesis protocol and required forms)

1. Study

a- Proposed Study Title: **A comparative study between the Usage of Flexible and Navigable Suction Ureteral Access Sheath (FANS) versus Traditional Access sheath in RIRS : Randomized controlled trial .**

b- Degree: Master's degree

c- Date of Registration of MSc or MD: September 2024

2. Candidate

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4. Scientific committee approval

(Was it scientifically approved by the department?) Yes
Date of approval:

5. Background and Rationale:

Urinary calculus is a worldwide urological disease, with a prevalence ranging from 1% to 13% in different regions [1]. Currently, the main therapeutic methods beyond conservative treatment for renal calculi include extracorporeal shock wave lithotripsy (ESWL) and minimally invasive endoscopic surgical methods, including percutaneous nephrolithotomy (PCNL) and retrograde intrarenal surgery (RIRS). Treatment plans depend on the characteristics of calculi, patient factors, surgeon experience and the condition of medical centers [2].

Technological advancements in RIRS have been numerous in recent years, with the introduction of single-use flexible ureteroscopes and higher-power lasers being the most notable. High intrarenal pressure (IRP) can lead to pyelovenous backflow and infection from transient bacteraemia, particularly during laser lithotripsy. Another major concern is the retention of residual fragments (RFs), which are pieces that are hidden from view because of the snow-globe effect [3].

Therefore, in order to facilitate the clearance of RF and enhance the overall performance of RIRS, a variety of adjuncts have been developed, including pressure sensors to regulate IRP, a direct in-scope vacuum technique to aspirate dust, and stone retrieval devices that utilize suction technologies [4].

These objectives are all designed to achieve the triumvirate of successful RIRS: a high stone-free rate (SFR), minimal ancillary interventions, and minimal complications—the ultimate goal of all RIRS surgeons [5].

The ureteral access sheath (UAS) has been used in RIRS to reduce IRP and hence infectious complications, as well as to improve drainage, stone clearance, and intraoperative vision, thus shortening operative time. However, there still remains some debate over the ideal UAS size – too large risks injuring the ureteral mucosa and causing ischaemia, while too small defeats its purpose of improving drainage [6].

The addition of suction to a traditional UAS resulted in the conception of suction ureteral access sheath (SUAS). As demonstrated in clinical studies, the SUAS has the potential to reduce intrarenal temperature and pressure, thus reducing infectious complications and improving SFR [7, 8].

Nevertheless, the SUAS continues to exhibit certain constraints [9]. If it is positioned below the uretero-pelvic junction (UPJ), as is the case with the traditional UAS, the application of suction results in the collapse of the proximal ureteral mucosa. This reduces the calibre of the narrow UPJ and impedes the aspiration of RF by acting as a functional valve to block the opening of the UAS. Despite being positioned across the UPJ, it is incapable of overcoming acute angles or reaching distant calyces to facilitate the complete aspiration of particulate that has settled in dependent calyces [10].

A flexible-tip SUAS, also known as the flexible and navigable suction UAS (FANS), was developed as a natural evolution. This SUAS could be navigated using the flexible scope. FANS can be securely maneuvered into individual calyces under fluoroscopic guidance to remove fragments and dust more thoroughly and targeted through suctioning [11].

6. Objectives:

This study aims to compare the results between using FANS and conventional UAS regarding SFR and postoperative complications.

7. Study Design:

- Descriptive: - Survey (cross sectional) ☐
  - Qualitative ☐

- Analytic: - Observational: - Case-control study ☐
  - Cross sectional analytic study ☐
  - Cohort (Longitudinal) study ☐

- Experimental: - Randomized controlled Trial ■ Phase:
  - Non-randomized clinical trial ☐
  - Animal study ☐
  - Cellular study ☐

- Others: Please describe:

8. Study Methods

- **Population of study:**

Adults ≥14 years old, undergoing RIRS using flexible ureteroscope with renal, upper ureteric stones less than 2 cm.

- **Study location:**

The study will be conducted in Cairo University Hospitals.

- **Inclusion criteria:**
  - Age ≥14 years old in patients not known to have stone forming medical conditions.
  - Renal stones diameter of ≤2 cm confirmed by CT with all types of configurations (branching & non-branching).
  - Non - recurrent cases of previous renal surgeries with normal renal anatomy.
  - Patients with non – infected urine analysis.

- **Exclusion criteria:**
  - Patients with abnormal urinary tract anatomy (such as horseshoe kidney or ileal conduit).
  - Pre – stented ureters (with DJs).
  - Patients with medical conditions promoting stone formation (hyperparathyroidism – gout).
  - Patients with history of stones on the same side with previous surgical intervention.
  - Patients with e-GFR < 90 ml / min.
  - Patients with uncontrolled urinary tract infection.
  - Patients with health or other factors that are absolute contraindications to RIRS.
  - Patients who are unable to understand or complete trial documentation.

- **Randomization and blindness:**

An online randomization program (http://www.randomizer.org) will be used to generate a random list and each patient's code will be kept in an opaque sealed envelope. Patients will be randomly allocated with 1:1 allocation ratio into two groups in a parallel manner:

- **Group I (n=40):** Patients will undergo FANS.
- **Group II (n=40):** Patients will undergo traditional UAS as a control group.

This study will be open label due to different techniques used.

- **Methodology in details:**
  - **Preoperative:**
    - Patient demographics.
    - History includes personal, medical and surgical

- Complaint, history of present illness.
- Laboratory Investigations such as: CBC, serum chemistry, coagulation profile, urine analysis, urine culture, Hba1C
- Radiological investigations (NCCTUT, plain kub identifying stone characteristics (number and location of stones, maximum stone diameter, characteristics, and density) Stone density will be measured with Hounsfield units on computed tomography (CT) scan. Stone size will be assessed as the largest diameter.)

- **Operative:**
  - **FANS technique**

After the successful induction of anesthesia, the lithotomy position will be adopted. Ureteroscopy will be used with the aid of a safety guidewire to evaluate the condition of the ureter. The serial dilation of the ureter using ureteral dilators up to 14 Fr . The FANS will be then inserted into the ureter under the guidance of the safety guidewire. The FANS tip will be positioned in the renal pelvis or calyces near the location of the stone.

The FANS will be connected to a vacuum device, and the negative pressure will be applied. The actual intraoperative negative pressure value will be adjusted by the urologist through a pressure adjustment vent as needed. The irrigation volume was set using peristaltic pumps. Lithotripsy will be conducted using the holmium: yttrium aluminum garnet laser applying the dusting technique of laser lithotripsy. During lithotripsy, the FANS will allow us to retrieve most of the fragmented stone particles by application of the suction pressure. All cases will be stented using JJ stents with the suitable size.

  - **Traditional UAS technique:**

The method of anesthesia, patient positioning, ureteral dilation, and lithotripsy were the same as those used in the FANS group.

For the traditional UAS group, the end of the UAS will be positioned underneath the ureteropelvic junction (UPJ). The irrigation volume is applied using peristaltic pumps. The dusting technique of laser lithotripsy will be applied to the stones.

All cases will be stented using JJ stents with the suitable size.

- **Postoperative:**

Postoperative follow-up will be performed for 1 week, 6 weeks, 12 weeks after surgery to assess for RF, any post operative complications.

1 week follow-up will be in the form of a physical examination, bedside ultrasound , urine analysis, urine culture.

The 6-week follow-up will be in the form of NCCTUT, KUB , urine analysis ..

12 weeks follow-up will be in the form of NCCTUT, urine analysis , urine culture.

SFR is defined as the absence of a single residual fragments (RF) > 2 mm on unenhanced CT scan.

Postoperative complications will be assessed systematically through:

- History
- Examination (vital instability, fever, tenderness, hematuria, etc)
- Investigations (hemoglobin drop, perinephric hematoma or extravasation, large residuals requiring ancillary procedures).

- **Intervention:**

☐ Diagnostic intervention (please describe):

■ Therapeutic intervention (please describe): FANS and conventional UAS regarding SFR and postoperative complications

☐ No intervention

- **Does the research involve?**

  ■ Human participants

  ☐ Biological samples/Tissues

  ☐ Identifiable private data/Information

- **Type of consent of study participants:**

  ■ Written consent

  ☐ Oral consent

  ☐ No consent needed (Please justify)

- **Confidentiality of data:**

We will minimize or eliminate the collection of personally identifiable information that can be used to distinguish or trace an individual's identity and collected data access will be restricted to the participating investigators only .

9. Study outcomes:

- **Primary outcome:**
  - Stone-free rate (SFR).

- **Secondary outcome parameters**
  - Operating time.
  - Length of hospital stay.
  - Auxiliary procedures (ESWL – URS or FURS)

- Complications (using the clavien – dindo grading system).

10. Sample size

The sample size calculation was performed using G.power 3.1.9.2 (Universitat Kiel, Germany). The sample size was calculated according to the prevalence of initial stone-free rate (SFR) was 81.3% with FANS and was 49.4% with traditional UAS according to a previous study [9]. Based on the following considerations: 0.05 α error and 80% power of the study, allocation ration 1:1. Six cases were added to each group to overcome dropout. Therefore, 40 patients will be recruited in each group.

11. Statistical analysis

Statistical analysis will be done by SPSS v26 (IBM Inc., Chicago, IL, USA). Shapiro-Wilks test and histograms will be used to evaluate the normality of the distribution of data. Quantitative parametric variables will be presented as mean and standard deviation (SD) and compared between the two groups utilizing unpaired Student's T- test. Quantitative non-parametric data will be presented as median and interquartile range (IQR) and will be analyzed by Mann Whitney-test. Qualitative variables will be presented as frequency and percentage (%) and will be analyzed utilizing the Chi-square test or Fisher's exact test when appropriate. A two tailed P value < 0.05 will be considered statistically significant.

12- Source of funding: (Please include source of funding even if self funding)

- Faculty of Medicine, Cairo University ☐
- Other sources: ☐

  Please specify: None

13- Time plan:

- When to start? The study will be started immediately after thesis registration
- When expected to finish? Expected time to finish within 6 to 24 months according to the availability of cases
- When to publish? Within 12 months after completion

14- References:

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3. **Gauhar V, Chai CA, Chew BH, Singh A, Castellani D, Tailly T, et al.** RIRS with disposable or reusable scopes: does it make a difference? Results from the multicenter FLEXOR study. Ther Adv Urol. 2023;15(8):175-628.

4. **Geavlete P, Multescu R, Mares C, Buzescu B, Iordache V and Geavlete B**. Retrograde intrarenal surgery for lithiasis using suctioning devices: A shift in paradigm? J Clin Med. 2024;13(9):841-956.

5. **Abozaid M, Elsherif E, Elserafy F, Abobakr I and Selim M**. Preoperative prediction of flexible ureteroscopy outcome in the treatment of renal calculi. Afr J Urol. 2025;31(1):11-98.

6. **Yu Y, Chen Y, Zhou X, Li X, Liu W, Cheng X, et al.** Comparison of novel flexible and traditional ureteral access sheath in retrograde intrarenal surgery. World J Urol. 2024;42(1):7-9.

7. **Gauhar V, Traxer O, Castellani D, Ragoori D, Heng CT, Chew BH, et al.** A feasibility study on clinical utility, efficacy and limitations of 2 types of flexible and navigable suction ureteral access sheaths in retrograde intrarenal surgery for renal stones. Urology. 2023;178(5):173-9.

8. **Solano C, Chicaud M, Kutchukian S, Candela L, Corrales M, Panthier F, et al.** Optimizing outcomes in flexible ureteroscopy: A narrative review of suction techniques. J Clin Med. 2023;12(8):541-685.

9. **Zhu W, Liu S, Cao J, Wang H, Liang H, Jiang K, et al.** Tip bendable suction ureteral access sheath versus traditional sheath in retrograde intrarenal stone surgery: an international multicentre, randomized, parallel group, superiority study. EClinicalMedicine. 2024;74(5):514-758.

10. **Wang L, Zhou Z, Gao P, Yang Y, Ding Q and Wu Z**. Comparison of traditional and suctioning ureteral access sheath during retrograde intrarenal surgery in the treatment of renal calculi. Langenbecks Arch Surg. 2024;409(1):81.

11. **Ong CSH, Somani BK, Chew BH, Fong KY, Bin Hamri S, Sridharan V, et al.** Multicentre study comparing outcomes of RIRS using traditional suction ureteral access sheath (SUAS) and flexible and navigable suction UAS (FANS). J Clin Urol. 2024;6(1):205-341.

1- Please fill in all the included sections and don't delete any part of the template
2- For choice brackets, please just use the fill in function in word