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Safety And Efficacy of Using Ureteral Access Sheath in Flexible Ureteroscopy Surgery

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ABSTRACT

Background: The ureteral access sheath (UAS) is widely employed in flexible ureteroscopy (FURS) because of its high stone-free rate and low intrarenal pressure. However, it may damage the ureteral wall and raise surgical costs. Therefore, we wanted to assess the safety and efficiency of FURS with and without UAS in treating renal stones.

Objectives: This research aimed to assess the safety and useful efficacy of applying a ureteral access sheath (AS) in the operation of flexible ureteroscopy (fURS) for stone removal, concentrating on results such as complications, operation duration, and stone-free rate.

Patients and methods: Between August 2021 and August 2023, this prospective, randomized trial was carried out at Badr Hospital, and Demerdash Hospital. Patients were randomly assigned to two groups (flexible URS with AS: 66 patients and fURS without AS: 62 patients) and evaluated before and after surgery, including laboratory testing and imaging. Possible procedure-related hazards, including unsuccessful stone access, discomfort, bleeding, and infection, were monitored.

Results: Preoperative stone results and demographic factors were similar in the 2 groups ($p > 0.05$ for all). However, the no sheath group's operation time was lower (79.4 ± 15.3 minutes compared to 90.4 ± 16.7 minutes in the group that using access sheath, $p=0.008$). Both groups experienced similar rates of intraoperative complications, such as hemorrhage, ureteric damage, operation termination, and unsuccessful access ($p > 0.05$). There was no significant change in the mean residual stone size (2.7 ± 3.5 mm vs. 3.1±3.1 mm, $p=0.687$) or the postoperative results of stone-free rates (78.8% vs. 71.0%, $p=0.305$).

Conclusions: According to the current study, flexible URS without an access sheath may provide a practical and equally effective alternative for treating renal and upper ureteric stones.

Keywords: Ureteral access sheath, flexible Ureteroscopy surgery, ureteric stones.

INTRODUCTION

About 10% to 12% of people worldwide suffer from kidney stones, also known as urinary tract stone disease, which is a widespread disorder with rising incidence and prevalence [1, 2]. Treatment options for this problem comprise percutaneous nephrolithotomy, extracorporeal shock wave lithotripsy, and ureteroscopy [3]. Because of its excellent success rates and fewer difficulties than other choices, flexible ureteroscopy (fURS) has been more popular in recent years due to technological developments [4, 5].

Nowadays, flexible URS is widely used to treat upper ureteral and renal calculi, either with or without the implantation of an access sheath (AS) [6]. In addition to making it easier to insert and remove the ureteroscope, the double-layered, tube-like access sheath may also lower intrarenal pressure during procedure, which could potentially lessen postoperative problems [7, 8].

According to a number of studies, applying an AS during fURS may increase stone free rate (SFR), shorten the operating time, and may lower the incidence of complications [9, 10]. Those findings are not always true, though, since other research indicates that there may not be a substantial difference in SFR and operating time. Some even speculate that using since may raise the risk of ureteral damage and other problems [11, 12].

The use of AS during fURS is controversial, hence there is constant discussion about it. Therefore, it is essential to carry out a comprehensive comparative analysis to assess the advantages and disadvantages of utilizing an AS during fURS. SFR, surgery efficiency, operation time, and complications were the main focus of the current study, which compared flexible URS with and without AS insertion. This will give urologists important information for clinical practice decision-making and aid in a better understanding of the efficacy and safety of both approaches.

PATIENTS AND METHODS

Study Design: From August 2021 to August 2023, Badr Hospital, and Demerdash hospital participated in this prospective, randomized comparative study.

Inclusion criteria: Adult patients with normal renal function tests and a solitary renal stone or upper ureteric stone not larger than 2.5 cm in diameter.

Exclusion criteria: Ureteral stricture, multiple stone formation, age < 20 years, staghorn stones, numerous kidney stones, and renal or ureteric stones greater than 2.5 cm in diameter, congenital kidney anomalies, abnormal coagulation parameters, complicated UTI, renal or

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ureteric stones larger than 2.5 cm in diameter, and prior urinary transplant or diversion.

Randomization and groups: Participants were randomly designed into two groups: Group A had flexible ureteroscopy using a ureteric access sheath, whereas group B underwent versatile ureteroscopy that doesn't require an access sheath.

Data collection: In-depth medical, surgical, and personal histories were acquired, along with general and local physical examinations and laboratory testing such as coagulation profiles, liver and kidney function tests, complete blood counts (CBCs), urinalysis, and urine culture. Every subject had CT-UT, abdominal and pelvic ultrasonography, and kidney, ureter, and KUB.

Procedure and Follow-up: 48 hours before to surgery, patients with +ve urine cultures received the proper prophylactic antibiotic treatment, which continued after surgery. During the procedure, urinary tract imaging/illumination equipment that is single-use (i.e., disposable) was used for a maximum of four hours. One week following the operation, non-contrast CTUT was used to evaluate the patients. Patients with remaining stones less than 4 mm were classified as "stone-free." The same urologist assessed all preoperative and postoperative CT-UT scans. Failure to get access to the stone, discomfort, hemorrhage, infection, perforation, high temperature, extravasation, and persistent stone were the hazards of the procedure.

Ethical approval: Helwan University Faculty of Medicine's Ethical Committee gave its approval to the study protocol (IRB: 48-2023). After receiving comprehensive information regarding the study's possible hazards and benefits, remuneration details, and the possibility to withdraw at any time, all participants gave their informed consents. The hospitals where the study was carried out granted their administrative consent. Throughout its implementation, the study complied with the Helsinki Declaration.

Statistical analysis

The statistical analyses were carried out using SPSS software (Version 26). Descriptive statistics were computed, such as means and standard deviations for quantitative variables and frequency counts for qualitative variables. The Chi-square test was performed to compare categorical variables between groups. The Student's t-test was used to compare mean values between groups.

RESULTS

Demographic characteristics: The demographic characteristics of the two groups were summarized in figure (1). The sheath (n=66) and no sheath (n=62) groups did not differ substantially in terms of gender distribution (male: 63.5% vs. 58.1%, female: 36.4% vs. 41.8% respectively, p=0.648) or age (mean age 43.8 ± 10.7 vs. 42.6 ± 11.7 years respectively, p=0.709). Furthermore, the mean BMI of the two groups was similar (29.1 ± 2.3 vs. 28.7 ± 2.8 kg/m², p=0.570).

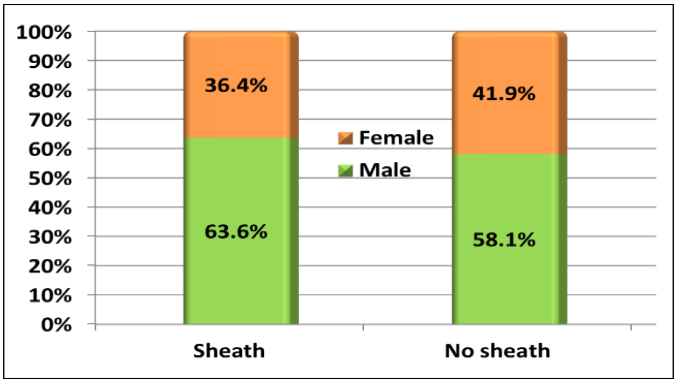

Figure (1): Demographic characteristics.

Preoperative stone radiography: The preoperative radiographic characteristics of the renal stones were listed in figure (2). The average stone sizes in the two groups were comparable (16.8 ± 2.9 mm vs. 16.5 ± 1.9 mm, p=0.616). There was no significant difference in the distribution of stone locations between the right and left sides (p=0.942) or between sites in the kidney and upper ureter (p=0.974). The stone opacity did not significantly differ between the two groups (p=0.665).

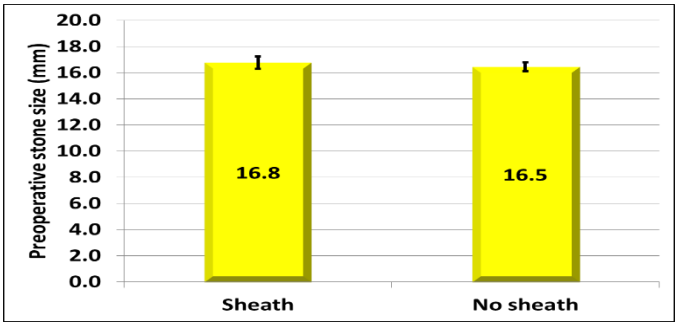

Figure (2): Preoperative stone radiological findings.

Operation Duration: Compared to the sheath group, the no sheath group's operation time was considerably lower (Average time: 79.4±15.2 minutes versus 90.4±16.7 minutes, p=0.008).

Intraoperative complications: The intraoperative problems from the study are shown in figure (3). In terms of bleeding (15.3% vs. 6.5%, p=0.428), ureteric injury (21.2% vs. 9.7%, p=0.305), surgery termination (9.1% vs.

3.2%, p=0.614), and unsuccessful access (21.3% vs. 12.9%, p=0.379), there was no significant difference between the two groups.

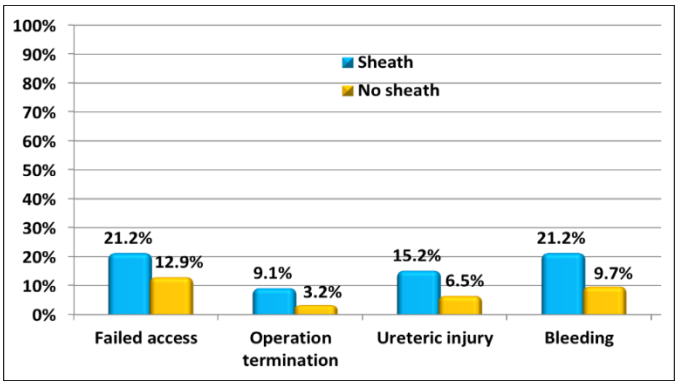

Figure (3): Intraoperative complications.

Radiological results associated with postoperative stones: Figure (4) summarized the radiological results associated with postoperative stones. Between the sheath and no using sheath groups, the mean residual stone size did not differ significantly (2.7 ± 3.6 mm vs. 3.1 ± 3.1 mm, p=0.687). With 78.9% in the sheath group and 71.0% in the no sheath group, the stone-free rate was comparable between the two groups (p=0.305).

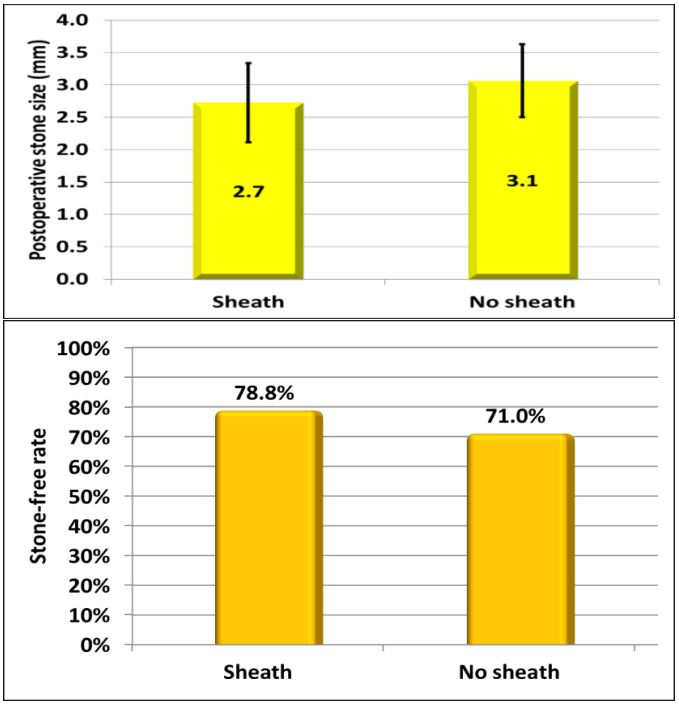

Figure (4): Postoperative stone radiological findings.

DISCUSSION

The goal of the current study was to assess the results of fURS for the treatment of renal or upper ureteric stones with and without the implantation of an AS. SFR, operation duration, surgical efficiency, and the frequency and type of intraoperative and postoperative complications were the main parameters in this investigation. The preoperative radiological aspects of the stones and two groups demographic attributes did not differ significantly, according to our data. This equivalency is crucial because it validates the validity of juxtaposition of the two groups and attests to the efficacy of the randomization procedure.

According to our research, the group that did not use AS had a substantially lower operation time. **Lima *et al.*** [13] showed that, in line with our findings, patients treated with flexible-URS without AS had shorter operation times than those treated with AS (41.2 ± 22.2 vs. 54.8 ± 25.8; p<0.001).

Similarly, **Berquet *et al.*** [6] and **Traxer *et al.*** [9] demonstrated a correlation between the use of AS and extended operational times. This conclusion was further corroborated by the results of **Cristallo *et al.*** [14] who showed that the treated group without AS had a significantly shorter operational time than the AS group (p=0.010). However, in terms of operating time, **Pardalidis *et al.*** [15] emphasized that fURS with AS were more successful than those without AS. Also, In terms of operation time, **Huang *et al.*** [10] comprehensive review and meta-analysis revealed no appreciable difference between the two approaches (Mean difference, MD = 4.08, 95% confidence interval: from -15.08 to 23.26, p = 0.68). Numerous factors, like variations in surgical technique, the intricacy of the stones, and patient-specific traits, could be to blame for this disparity. This disparity thus emphasizes the significance of a customized approach to patient care.

The sheath group experienced somewhat more intraoperative problems, however there was no statistically significant change. These results are consistent with those of **Traxer *et al.*** [9] who demonstrated that the AS's intraoperative problems and non-AS groups did not differ significantly.

This conclusion is also supported by a pooled analysis of other study [10]. **Wang *et al.*** [17] on the other hand, found that patients treated with AS had a noticeably greater risk of intraoperative complications than those who did not. This disparity could be clarified by the fact that Wang's study only included youngsters as patients.

One important indicator of the procedure's efficacy is the stone free rate, which did not significantly differ between the two groups in our study. This result is consistent with a number of earlier studies that found no significant effect of AS usage on SFR [6, 15-19]. However, other research with contradictory findings, such as **L'esperance *et al.*** [20] and **Traxer *et al.*** [9] who discovered a substantial difference in SFR between the 2 groups. Using AS was linked to a two-fold greater risk of SFR than non-AS, according to **L'esperance *et al.*** [20]**.** The AS group's SFR, however, was lower than the non-AS group's, which was 40%, according to **Traxer *et al.*** [9]**.**

Finally, integrating these studies revealed that the two groups' SFRs did not differ significantly [10]. It should be mentioned that a variety of other factors, including location, stone composition, and surgical skill, may also have an impact on stone clearance [21].

The 2 groups did not vary statistically significantly in terms of postoperative problems. Similar postoperative complication rates are also seen across groups with and without an AS by **Geraghty *et al.*** [16], **Berquet *et al.*** [6] and **Kourambas *et al.*** [19]**.** This study implied that there was no increase in postoperative complications when an AS is used, even though there was a slightly greater risk of intraoperative complications. Similarly, when AS was implanted during retrograde intrarenal surgery (RIRS), **Bozzini *et al.*** [22] demonstrated that it was not linked to an increased risk of ureteral damage.

Although those limitations, our research offered important new information on the flexible URS technique for treating renal and upper ureteric stones. For certain individuals, without an access sheath, flexible ureteroscopy could be a good option because to the reduced operation duration, comparable stone free rate, and lack of complications. We must, however, also recognize the advantages of access sheaths that have been shown in previous research, such as enhancing irrigation flow and enabling repeated ureteroscope passes, which may be especially helpful in situations involving bigger or more complicated stones [23]. As a result, the application of an access sheath ought to be tailored to the particular patient and the properties of the stone.

LIMITATIONS

Although these remarkable findings, our study had many difficulties. First of all, the small sample size of the study might have restricted how widely the results could be used. Second, because this was a single-center study, the findings might not be generalizable due to possible variations in regional practice patterns and patient demographics. Therefore, higher sample numbers in future multicenter research might be helpful to validate our findings. The absence of long-term follow-up to evaluate outcomes such as stone recurrence and changes in renal function was another significant drawback of our experiment. There is undoubtedly a need for more research on these long term effects. Although it was not examined in our study, the kinds and dimensions of access sheaths may also have an effect on results, which might be a topic for further investigation.

CONCLUSION

The current study concluded that flexible URS without using access sheath may be a viable and equally effective alternative for the treatment of renal and upper ureteric stones. To confirm these results and provide more accurate suggestions for this strategy. It is essential to do more research with a larger sample size and longer follow-up periods.

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Conflict of Interest: Nil.

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