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ORIGINAL PAPER

Sheathed flexible retrograde intrarenal surgery without safety guide wire for upper urinary tract stones

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Summary ***Objectives: To assess the success rate and intraoperative complications of flexible ureterorenoscopy (f-URS) in patients with upper urinary tract (UUT) stones using a ureteral access sheath (UAS) without a safety guide wire (SGW).***

Patients and methods: Between April 2010 and March 2022, 464 renal units in patients with renal stones with and without concomitant ureteral stones (UUT), underwent ureterorenoscopy by one surgeon, and UAS was used in all of them. The primary endpoint was the stone-free rate (SFR). SFR was defined as no residual fragments at all. The following characteristics were examined: age, sex, laterality, renal/ureteral stones, stone diameter, SFR, Hounsfield unit, auxiliary procedures, double-J stent insertion, and intraoperative complications. This study was retrospective, with all the data recorded prospectively. Patients with residual stones were scheduled for the 2nd RIRS. The Clavien-Dindo classification was used to report complications.

Results: The mean patient age was 52.9 years. The mean stone size was 13.1 mm. Lower pole, upper and middle calyces, renal pelvis and ureteral stones were found in 51.5% (239), 34.9% (162), 18.3% (85) and 46.9% (218) of cases, respectively. The mean diameter was 8.1 mm, 8 mm, 12.5 mm and 8.1 mm for the lower pole, upper and middle calyces, renal pelvis and ureteral stones, respectively. The single- and second-session SFRs were 90% and 100%, respectively. The mean number of procedures per renal unit was 1.1. Ureteral double-J stents were inserted in 45.7% (212) of patients. In 96 cases, a stent was placed before surgery. Postoperative complications were minor, with no avulsion or perforation of the ureters; readmission and insertion of a DJ stent occurred in one patient. Ureteral stricture developed in one patient (0.2%) and needed treatment with laser ureterotomy.

Conclusions: f-URS is a safe and effective mode of surgical management of renal and simultaneous renal and ureteral calculi using the ureteral access sheath without a safety guide wire. A guide wire should not be routinely used in these cases.

KEY WORDS: RIRS; Retrograde intrarenal surgery; Safety guide wire; Ureteral access sheath; Renal stones; Ureteroscopy.

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INTRODUCTION

Nephrolithiasis is a common disease in Asia with a rate of 1-5% (1).

For decades, it was advised to have a *safety guide wire* (SGW) present during ureteroscopy to ease the management of possible complications (2, 3). With the development of small flexible ureteroscopes and the improvement of laser lithotripsy, ureteroscopy has become the standard of care for treating urolithiasis less than 2 cm (4, 5). Should we still use the SGW? Does the use of a *ureteral access sheath* (UAS) alter the results or increase the complications?

The goal of this study was to assess the success rate of *flexible ureterorenoscopy* (f-URS) in patients with renal stones with or without ureteral stones using UAS without a safety guide wire. To our knowledge, there are no articles discussing the use of UASs without guide wires present in *upper urinary tract* (UUT) stones.

PATIENTS AND METHODS

Between April 2010 and March 2022, 464 renal units in patients with renal stones with and without concomitant ureteral stones, underwent ureterorenoscopy by one surgeon, and UAS was used in all of them. A guide wire was used just to place the UAS and during insertion of ureteral double-J stent. No SGW was used inside or outside the UAS during the operation. The UAS was always placed below the ureteral stone and moved up to the middle or proximal ureter for renal stone treatment.

All the patients were included in the study after they matched our inclusion criteria.

The inclusion criteria were as follows:

1. Upper tract stones, renal stones with or without ureteral stones.
2. The same flexible ureteroscope (flexible uretero-renoscope FLEX- X2s (*Karl Stortz & Co. KG, Tuttlingen, Germany)* was used.
3. The Holmium YAG LASER energy was used (fibres 272 µ, 200 µ and 230 µ).
4. The LASER generator Sphinx Jr 30 watt (*LISA Laser Products GmbH, Germany*) or Mega Plus 15 Watt (*Richard Wolf GmbH, Knittlingen, Germay*) or Luminis 120 watt (*Luminis, Yokneam, Israel*) was used.
4. A ureteral access sheath (*Flexor ureteral access sheath 12/14F, 28, 35, 45 cm; FUS- Cook Medical, Bloomington, IN, USA*) was used.
5. All data recorded.
6. Adults aged 18 years and older.

No conflict of interest declared.

The exclusion criteria were as follows:
1. Using other flexible ureteroscopes.
2. Comorbidities that interfered with the completion of the study included severe. systemic disease, congestive heart failure, pregnancy, and severe chronic lung disease.
2. Missed data.
3. No or other access sheath used.
4. Patients with non-compliant ureters.
5. Using rigid ureteroscope.

The primary endpoint was the *stone-free rate* (SFR). Stone-free status was defined as no residual fragments at all. At the end of the operation, a triple test was done for all the calyces, using a plain abdominal radiograph of the kidneys, ureter and bladder, using the scope and the C-arm while injecting contrast intraoperatively as a retrograde pyelography and screening every calyx using the endoscope and simultaneously following the anatomy on the C-arm screen.
We evaluated 464 consecutive renal units that underwent f-URS for UUT stones (Table 1).
In all patients, the following characteristics were examined: age, sex, laterality, renal/ureteral stones, stone diameter, Hounsfield unit, stone-free rate, auxiliary procedures per renal unit, double-J stent insertion, length of hospital stay, and any perioperative complications. Stone-free status was defined as complete stone removal.
This study was retrospective, and all the data (demographic data, stone characteristics, operative and postoperative data) were recorded prospectively.
Postoperative follow-up was scheduled at one month later with renal scan DTPA, urine culture, and renal function. Patients with residual stones were scheduled for a 2nd RIRS (retrograde intrarenal surgery).
The Clavien-Dindo classification was used to report complications (6).

Results

The mean patient age was 52.9 years. The mean maximum stone diameter was 13.1 mm. Lower pole, upper and middle calyces, and renal pelvis stones were in 51.5% (239), 34.9% (162), and 18.3% (85), respectively. Ureteral stones were associated to renal stones in 46.9% (218) of cases. The mean diameter was 8.1 mm, 8 mm, 12.5 mm and 8.1 mm of the lower pole, upper and middle calyces, renal pelvis and ureteral stones, respectively.

Table 1.
Patient demographics and stone characteristics.

Patients	423
Gender M/F	266/157
Renal units (Kidney +/- Ureter)	464
Male	0.63
Age (years)	52.9
Hounsfield unit	880.1
Mean Maximum Stone Diameter (mm)	13.1
Lateralization R/L	210/254

Table 2.
Renal and Ureteral Stone Location and Diameter.

	No	%	Total Stone Diameter (mm)
Renal and ureter	464	100	13.1
Lower pole	239	51.5	8.1
Upper and middle calyx	159	34.3	8
Renal pelvis	85	18.3	12.5
Upper ureter	98	21.1	8.9
Middle ureter	46	9.9	7.3
Lower ureter	74	15.9	7.4

Table 3.
Stone-free rate/auxiliary F-URS.

	No	%
Renal units	464	100
SF- 1ST Session	418	90
SF- 2nd Session	464	100
Auxiliary F-URS	46	9.9
Laser frequency (HZ)	31.3	**
Energy (Joule)	0.54	**

SF = Stone Free; F-URS = Flexible Ureteroscopy; HZ = Hertz.

Table 4.
Complications.

	No	%
Renal units	464	100
Renal colic needs IM/IV* treatment	13	2.8
Haematuria	1	0.2
Insetion of stent due to pain	1	0.2
Fever	2	0.4
Ureteral stricture	1	0.2
Ureteral avulsion	0	0
Ureteral Perforation	0	0
Clavien- Dindo classification I	16	3.4
Clavien- Dindo classification III	2	0.4
Clavien- Dindo classification II, IV, V	0	0

*IM = Intramuscular, IV = Intravenous.

The renal and ureteral stone characteristics are shown in Table 2.
As shown in Table 3, the single-session SFR was 90% (418/464), and the two-stage procedure SFR was 100%. The mean number of procedures per renal unit was 1.1.
Ureteral double-J stents were inserted 45.7% (212) postoperatively. In 96 cases, a stent was placed before surgery. The mean hospital stay was one day.
Intra- and postoperative complications were minor, as shown in Table 4.
There was no avulsion of the ureters, no need for conversion to open surgery, no ureteral perforation; there was readmission and insertion of an a-DJ stent in one patient (0.2%).
In the follow up ureteral stricture developed in one patient that needed treatment with laser ureterotomy (0.2%).

Discussion

RIRS is a safe and valuable alternative option for the management of renal stones. It is a well-established procedure under constant evolution with advances in technique and technology. It has gained worldwide popularity due to its minimal invasiveness and satisfactory outcomes (7).

With the development of small flexible ureteroscopes and the improvement of laser lithotripsy, ureteroscopy has become the standard of care for treating urolithiasis less than 2 cm (4, 5). The *stone-free rate* (SFR) is higher in percutaneous nephrolithotomy-PCNL, but RIRS is also an option for large renal stones larger than 2.5 cm with low morbidity (8). Ho et al. published their review highlighting the expanding role of URS for the management of more complex stones and patients with good outcomes (9).

Advances in flexible ureteroscope design and accessory instrumentation and new LASER generators have allowed for more challenging cases to be treated ureteroscopically.

A safety guide wire is still used during ureteroscopy or RIRS to ease the management of possible complications (2, 3). There is a belief that the use of a safety guide wire could help when prompt stent placement is needed in the event of a major ureteral perforation or bleeding precluding continuing URS (3, 10).

Patel et al. showed that the flexible ureteroscope itself could be used as a safe guide wire and that working without SGW facilitates access, scope manipulation and stone basketing. There is less friction passing the ureteroscope alongside a guide wire (11).

In their retrospective study, Johnson et al. treated renal stones with wireless and sheathless flexible URS. There were no false passages or ureteral perforations secondary to ureteroscope placement (12). *Eandi et al.* also reported no intraoperative complications related to lack of a safety wire in semirigid and flexible URS for the treatment of urolithiasis (13).

Using the UAS makes it easier to enter and exit the ureter, renal pelvis and calyces during the operation and even more so when handling large stones.

Moran and Bratslavsky studied a single urologist's experience with flexible ureteroscopic laser lithotripsy without the use of an SGW, and the stone-free rate was 96% (326/340) for those who did not use an SGW compared to a contemporary, large single-centre experience with eleven treating urologists (Table 5).

There were no complications in the group without a safety wire secondary to loss of upper tract access (14).

Ulvik et al. compared the results of URS for the treatment of ureteral stones at two different hospitals where the SGW was either routinely used or omitted. Both groups had 500 patients each. Pre-treatment stone status differed in many aspects between groups. There was no significant difference in the overall intraoperative complication rates at the two hospitals. The overall stone-free rates were 77.1% and 85.9% with and without the SGW, respectively ($p = 0.001$). A significant increase in the number of patients (14 patients, 3.4%) with post-endoscopic ureteral stenosis was found at the hospital where the SGW was routinely used compared to the hospital where an SGW was omitted (six patients, 1.2%), $p = 0.039$ (15).

UAS was not routinely used in the different studies dealing with wireless f-URS, so it is hard to make a comparison between these series (11-13, 16-17). In the Moran and Bratslavsky comparative study, there was no information about the UAS (14).

Molina et al., in their review, showed a lack of relevant data supporting the use of SGW during retrograde URS (18).

Eandi et al. concluded that the presence of a safety guide wire adjacent to the endoscope inhibits passage of the ureteroscope in an *in vitro* animal model.

Technologic advancements in ureteroscope design and use of the holmium laser lithotrite minimize ureteral trauma and obviate the need for routine use of a safety wire during ureteroscopy (13).

Dutta et al., in their article titled "*Death of the Safety Guide Wire*", concluded that a safety guide wire served an important function in providing safer percutaneous and ureteroscopic procedures during the initial endourological history score. However, the decrease in the size of today's ureteroscopes coupled with the advent of effective ureteral access sheaths and the evolution of endoscopic percutaneous renal access has largely eliminated the need for safety guide wires in both ureteroscopic and percutaneous procedures.

They argued that what was once a "*help*" had become an inhibitor and a nuisance, as recent studies have shown that the safety guide wire increases the resistance to passage of the ureteroscope (19). To our knowledge, there are no articles dealing with the use of UAS without guide wires present in upper urinary tract stones. Table 5 summarizes some of the results of this study compared to other studies and shows that this study had the greatest number of cases with UAS and without SGW simultaneously, with success similar to other studies and no major complications.

The uniqueness of the current study is that similar components were used in all the patients.

In all patients we used UAS without SGW, a holmium LASER, fibres (200 µ, 230 µ and 272 µ) with the same ureteroscope (Karl-Stortz flex-x2s), access sheaths (12/14 28, 35, or 45 cm) from the same company, and the same surgeon.

We showed that f-URS was successful in 90% of cases in

Table 5.
Current study/other series.

	SGW	No.	Mean renal stone diameter (mm)	Mean ureteral stone diameter (mm)	SFR (%)	UAS (n)	Ureteral perforation	Ureteral avulsion
Patel et al. (11)	No	268	12	**	N/A	40	0	0
Eandi et al. (13)	No	322	N/A	N/A	N/A	0	0	0
Moran & Bratslavsky (14)	No	340	N/A	N/A	96	N/A	0	0
Ulvik et al. [15]	No	500	N/A	8.8	85.9	1	6	1
	Yes	480	N/A	7.9	77.1	158	11	1
Dickstein et al. (16)	No	270	9.1	**	88.9	0	0	0
Current study	No	464	8.8	8.1	90	464	0	0

SGW: safety guide wire; SFR: stone-free rate; UAS: ureteral access sheath.

a single session and 100% in the second session. The mean number of procedures per renal unit was 1.1. According to the Clavien-Dindo classification, no major complications were observed.
We achieved good results, although there were more lower pole stones (239/464).

Conclusions

f-URS is a safe and effective mode of surgical management of renal and simultaneous renal and ureteral calculi using the ureteral access sheath without a safety guide wire.
A guide wire should not be routinely used in these cases.

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