Are Flexible-Tip Suction Ureteral Access Sheaths An Improvement Compared To The Traditional Ureteral Access Sheaths In f-URS? – Initial Experience

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ABSTRACT

Introduction and objectives. Flexible ureterorenoscopy (f-URS) gained a lot of field in treating reno-ureteral lithiasis, especially with the advancement of the available technology, like the bendable tip suction ureteral access sheaths, improving the outcomes and decreasing the complications' risk. This study is aimed to analyze the initial experience from a tertiary care center of urological surgery department on the effectiveness and safety of the ClearPetra® suction-sheath, compared to the traditional UAS, in the context of FURS as minimally invasive treatment of pyelocaliceal system (PCS) lithiasis.

Material and methods. The study was conducted on a retrospective manner on two study groups comprising 15 patients with similar stone burden, each undergoing f-URS for PCS stones, first group using bendable tip suctioning ureteral access sheath and the other one using a standard conventional ureteral access sheath. Patients' and lithiasis characteristics, f-URS-related parameters, SFR and complications were gathered into a database for comparison and statistical assessment of the differences.

Results. The two study groups were quite comparable, regarding the age, sex, stone location, and stone burden. The total operative time and laser time showed to be lower for the first study group, with a mean value of 51,78 minutes versus 65 minutes, in the second group with traditional UAS, 23,28 minutes versus 32,8 minutes, respectively. The SFR was improved in the first group, with flexible tip suctioning UAS, of 86.6% versus 80% in the standard UAS group, with no case of SIRS versus two cases in the second group.

Conclusion. Compared to traditional ureteral access sheaths, using a bendable tip suctioning ureteral access sheath for f-URS seems to be superior in the immediate SFR on one month after surgery, showing shorter operative time, and apparently less infectious complications.

Keywords: flexible ureteroscopy, flexible-tip suctioning ureteral access sheath, SFR, SIRS, stone free rate

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INTRODUCTION

Flexible ureteroscopy (FURS) is frequently employed for the identification and removal of kidney stones, serving as an example of a natural orifice surgical procedure [1]. The intervention is particularly useful for low volume calculi located in the ureter or kidney and may be preferred in cases where other methods, such as extracorporeal shock wave lithotripsy (ESWL), semirigid ureteroscopy, or percutaneous nephrolithotomy (PCNL), may be more difficult, less effective or considered to have more possible complications. This aspect is even more important considering the relatively high prevalence of urinary lithiasis worldwide, currently between 1 and 13%, with regional variability [2,3].

According to the EAU (European Association of Urology) guidelines, FURS is currently the therapeutic option of choice for kidney stones with a maximum diameter of less than 20 mm, simultaneously serving as an effective alternative in the case of kidney stones larger than 20 mm, especially when PCNL is contraindicated [4-6].

Although the efficiency of FURS is undeniable and the technique requires low invasiveness, patients can still develop a series of complications, among which the most fearful one is the urosepsis caused by stone-colonizing bacteria and bacterial endotoxins in combination with the positive pressure of the irrigation fluid used. Therefore, the use of the ureteral access sheath (UAS) - which significantly reduces the intrarenal pressure during the intervention - leads to the improvement of the safety of FURS, improving the surgical visibility and possibly also the stone clearance rate [1,4]. In addition, the reduction of intrarenal pressure also reduces the risk of local occurrence of hematomas [7].

Suction ureteral access sheaths (S-UAS) represent a category that has been intensively studied in recent years, with superior results compared to traditional UAS (T-UAS), in terms of effectiveness (higher stone-free rate - SFR - on the first day and one month postoperatively, shorter operative time) and safety (lower rates of fever, urosepsis and overall complications) [1,2,4,5]. The incidence of SIRS (Systemic Inflammatory Response Syndrome) is also relatively low among patients using S-UAS compared to T-UAS [1]. Although these results present a new perspective, robust high volume comparative data between S-UAS and T-UAS are lacking, and further studies in this direction are needed.

This study is aimed to analyze the initial experience from a tertiary care center of urological surgery department on the effectiveness and safety of the ClearPetra® suction-sheath, compared to the traditional UAS, in the context of FURS as minimally invasive treatment of pyelocaliceal system (PCS) lithiasis.

MATERIALS AND METHODS

We conducted a retrospective study in our tertiary care urology clinic of „Prof. Dr. Th. Burghele" Clinical Hospital, between 1st of June and 20th of December 2023, revising the medical records of the first 15 patients for whom F-URS for renal lithiasis with bendable tip ClearPetra® S-UAS has been performed. Another study group consisting on the same number of patients with F-URS with T-UAS performed was created from the medical records of the clinic in order to have a similar stone burden before the surgery to the group. All these f-URS procedures were performed by a single surgeon, experienced in semirigid ureteroscopy, F-URS and PCNL. Patients' characteristics (demographics), surgery related parameters, complication rates in terms of SIRS and sepsis and SFR were gathered into a database. The first study group was represented by the ClearPetra® S-UAS F-URS group, while the second group by the T-UAS F-URS group (same producer, same model T-UAS). A comparison was made between the two study groups regarding the patients' demographics, preoperative data, several operative parameters, success, and complication rate.

Although the EAU Guidelines on urolithiasis still recommend the type of surgical treatment based on the stone largest diameter [9], the stone burden of each patient is assessed in our department with calculated volume on the pre-operative contrast enhanced or non-contrast CT used to establish the treatment conduit and for planning and staging the surgical intervention. Therefore, all the cases had the lithiasis volume calculated on the images obtained from the pre-op CT scan, expressed in cubic centimeters (cc).

All cases were performed under general anesthesia with Oro-tracheal intubation, with the patient

placed in the lithotomy position. All cases had previously mounted JJ stent before the f-URS procedure and the semirigid ureteroscopy under guidewire was performed at the beginning of the surgery for all cases to ensure direct visualization of the ureter and passive dilation to assess and to facilitate the insertion of the ureteral access sheath (UAS). The same manufacturer and model single-use digital chip-on-the-tip flexible ureteroscope was used for all cases, while the laser lithotripsy was performed with one Ho: Yag High Power Laser (HPL) 150W device, all cases with 200 microns multiple usage fibers. Standard technique implied gravitational pressure of the washing saline of 40 cm H20 and laser powers not exceeding 24W in total power and cognitive measuring of the intrarenal temperature. Following the surgery, JJ stent was inserted in all cases under fluoroscopic guidance. Al l these elements are probably very useful in eliminating bias regarding surgeon and technical equipment used. Final stone free status was assessed with non-contrast abdomen and pelvis computed tomography (CT) 1 months after the surgery. Successful surgery in terms of stone free rate was defined as the absence of renal and/or ureteral lithiasis larger than 2 mm on the follow-up CT. Data gathering and statistical analysis were performed by using Microsoft Excel® work packages.

RESULTS

According to the assessed characteristics, the two study groups were quite similar, with comparable age, sex, stone location and stone burden. The most important element that was matched was the total stone burden of each patient, as illustrated below.

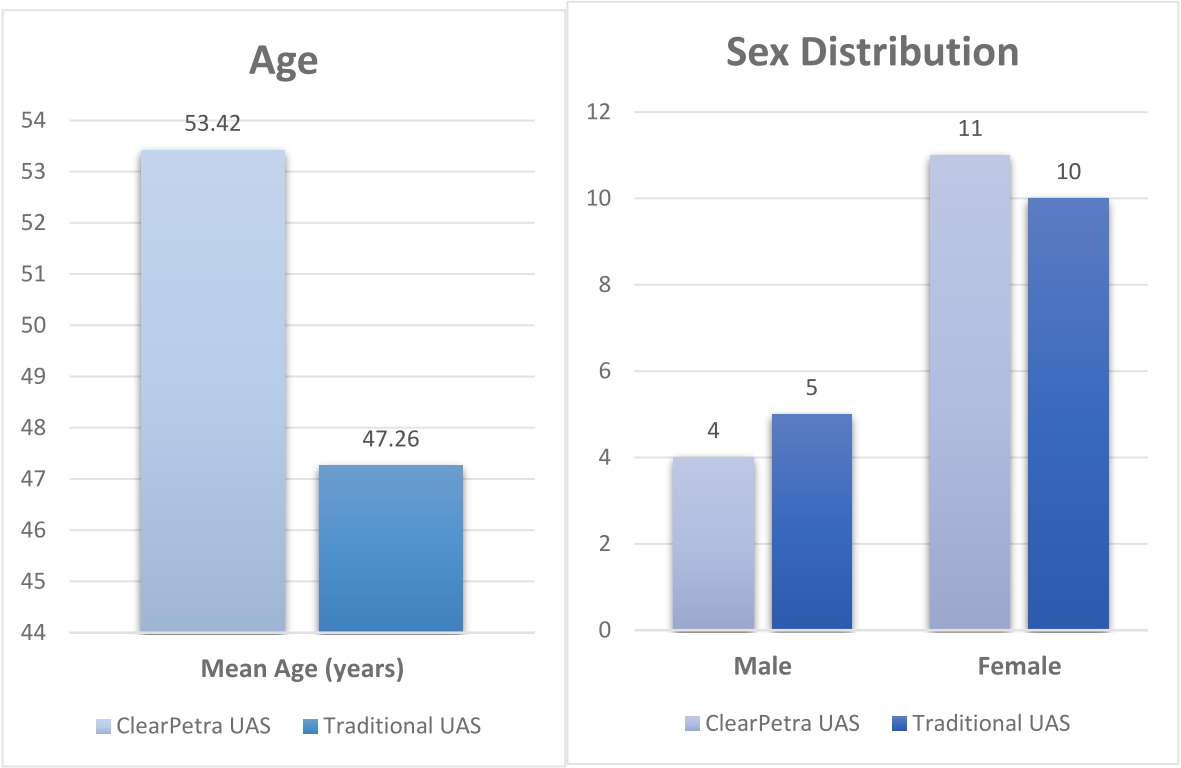
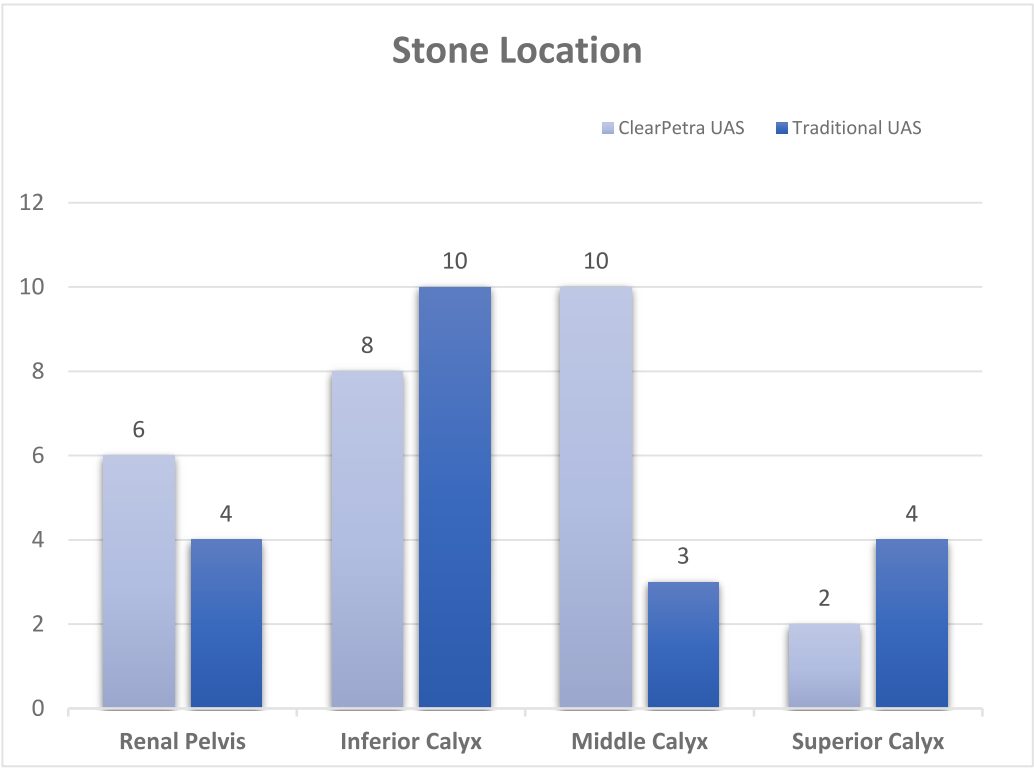


Fig. 1 – Demographics of the two study groups



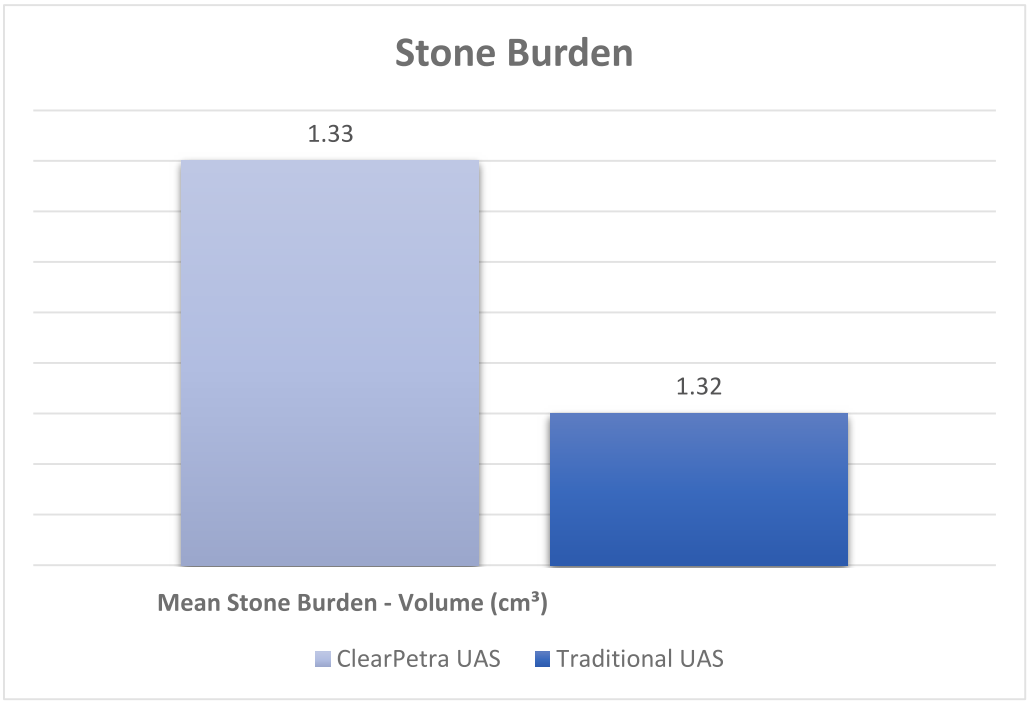


Fig. 2 – Stone location and stone burden for the two studied groups.

In terms of stone burden, the volume was similar for both groups – 1,33 cc for the ClearPetra® S-UAS group (CP-UAS), and 1,32 cc for the T-UAS group (T-UAS). The most prevalent stone location in the CP-UAS was the mid-calyx (38,46%), followed by inferior-calyx (30,77%), while for the T-UAS – inferior-calyx (47,62%), and superior-calyx and renal pelvis (19,05%), respectively.

The caliber of the UAS for the CP-UAS was 12/14 CH for all the 15 cases performed, while in the T-UAS 11/13 CH was used in 10 cases, 10/12 CH in one case and 12/14 CH in four cases.

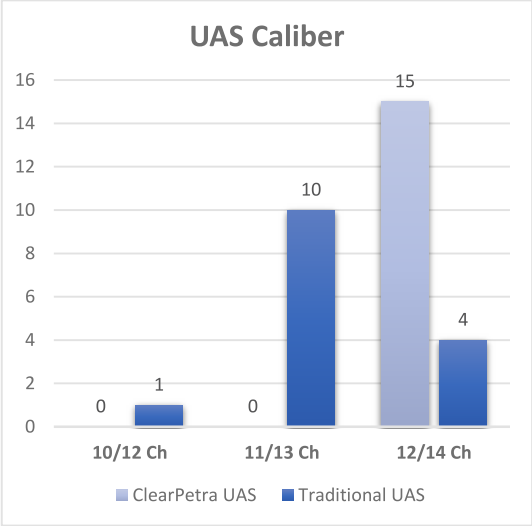


Fig. 3 – Size of the ureteral access sheaths used for both groups.

Intraoperative parameters were assessed, and the results showed the following:

Regarding the total operative time, measured from the beginning of the urethral access until the Foley urethro-vesical catheter was mounted, the T-UAS revealed a mean value of 65 minutes, while the CP-UAS showed a significantly shorter time of 51,78 minutes.

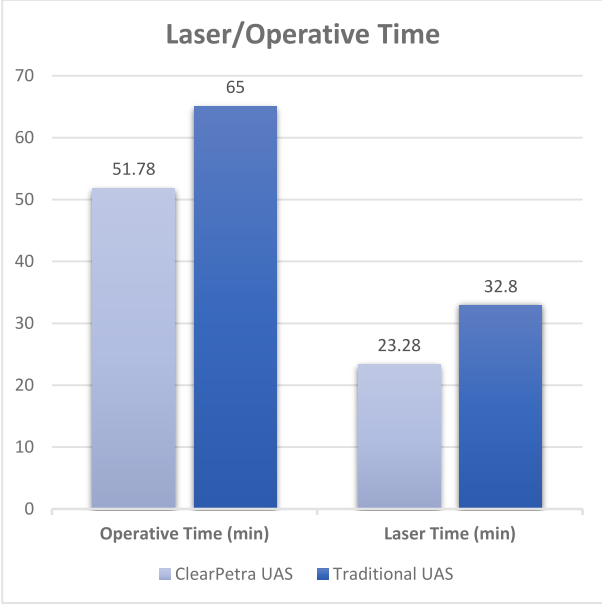


Fig. 4 – Total operative time and laser lithotripsy time for the two studied groups.

The mean lasing time value was also lower for the CP-UAS compared to T-UAS, with 23,28 minutes versus 32,8 minutes. Worth mentioning that the percentage of laser time from the total operative time was higher for the T-UAS when compared to the CP-UAS, 44.96% versus 50,46%, like illustrated below.

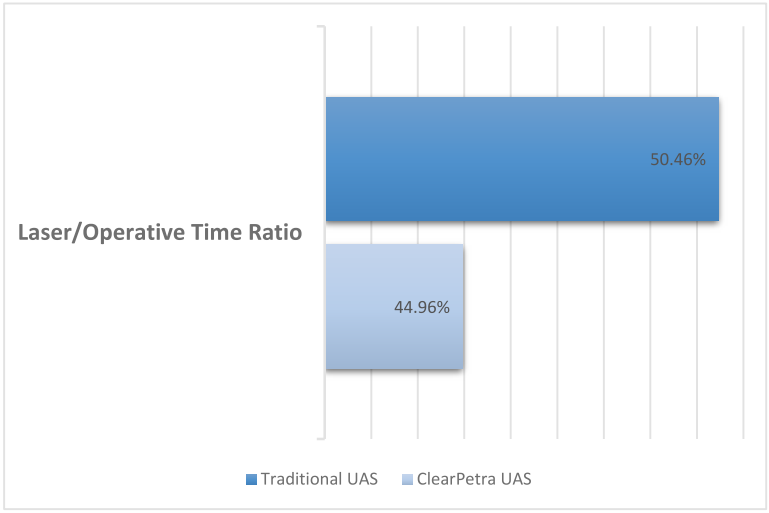
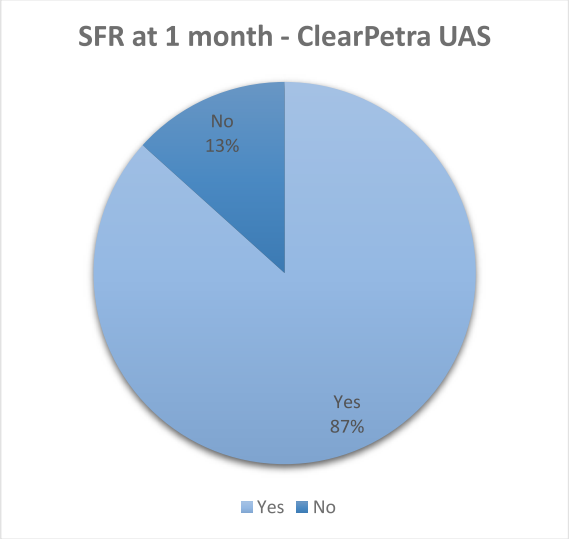


Fig. 5 – The ratio between laser and total operative time in the two groups.

The possible rationale behind this might be that according to the stone density, macroscopic aspect and laser settings, combined with the active suctioning on the bendable tip of the UAS, the amount of time needed to perform the laser lithotripsy might eventually drop, probably due to the clearer view and aspiration of small fragments, that the operator does not need to "pop-corn" at the end of the surgery. Moreover, all the small size residual fragments might be actively aspirated afterwards when retracting the scope out of the UAS, hence diminishing the need for basketing.

Comparing the stone free rate between the two-groups at one month after the surgery, it's been revealed that it is slightly higher for the CP-UAS, 86,67% versus 80%.



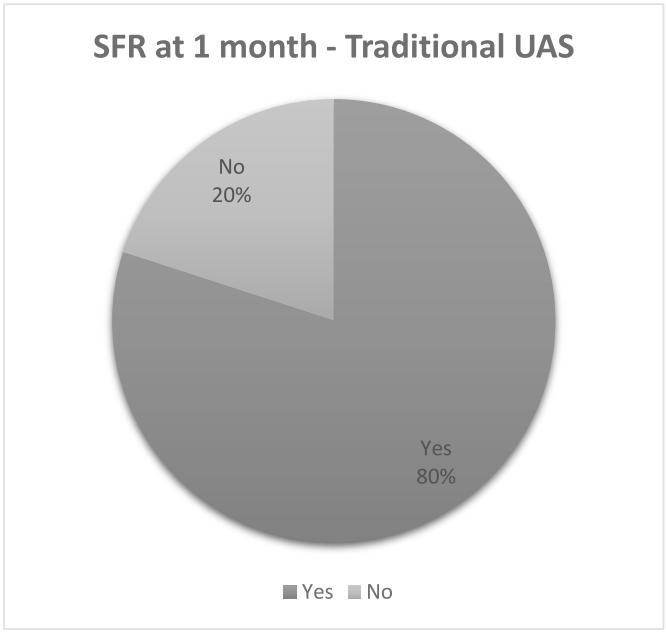


Fig. 6 – SFR for the two groups at the first 1-month evaluation.

In terms of complications, for this study we only looked after the SIRS and septic complications, the results showing no case of sepsis in neither of the groups studied. However, we noted 2 cases of SIRS defined as fever and mild leukocytosis in the first pre-operative day in the T-UAS and none in the CP-UAS.

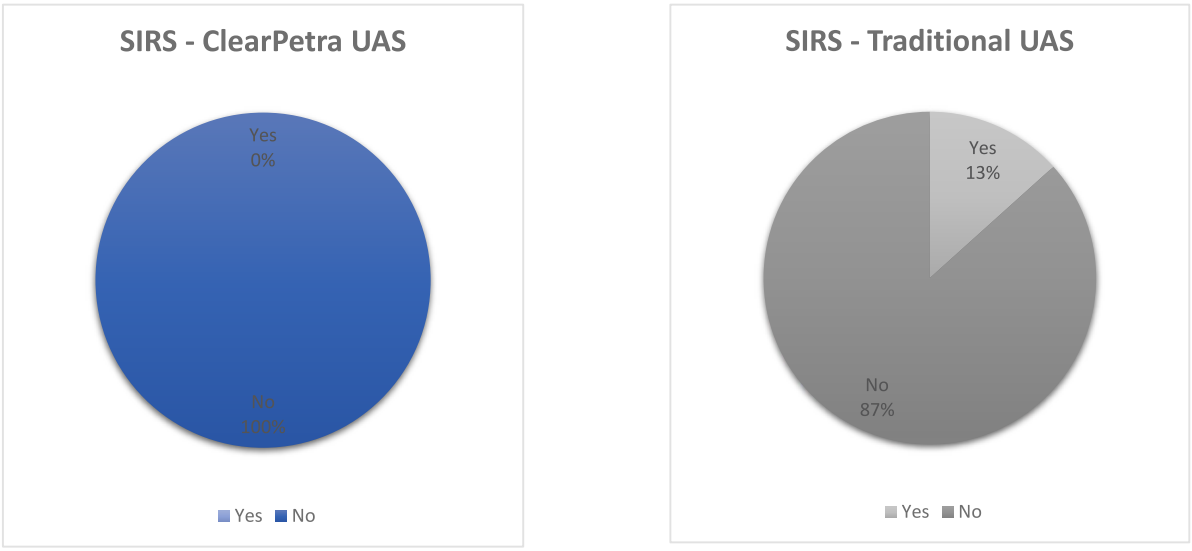


Fig. 7 – Occurrence of SIRS in both studied groups.

A possible explanation for that might be the lower irrigation fluid pressure for the active aspiration bendable tip CP-UAS, that maintains somehow negative pressures inside the pyelocaliceal system during the laser lithotripsy, thus improving vision, clearing stone fragments and also working on lowering the temperature of the irrigation fluid inside the pyelocaliceal system during the procedure.

All the obtained and discussed results as summarized in the table below:

	ClearPetra UAS		Traditional UAS	
Number of Patients	15		15	
Mean Age (years)	53.42		47.26	
Sex Distribution				
Male	4	26.67%	5	33.33%
Female	11	73.33%	10	66.67%
UAS Caliber				
10/12 Ch	0	0.00%	1	6.67%
11/13 Ch	0	0.00%	10	66.67%
12/14 Ch	15	100.00%	4	26.67%
Stone Location				
Renal Pelvis	6	23.08%	4	19.05%
Inferior Calyx	8	30.77%	10	47.62%
Middle Calyx	10	38.46%	3	14.29%
Superior Calyx	2	7.69%	4	19.05%
Mean Stone Burden (Volume - cm^3)	1.33		1.32	
Operative Time (min)	51.78		65	
Laser Time (min)	23.28		32.8	
Laser/Operative Time Ratio	44.96%		50.46%	
SIRS				
Yes	0	0.00%	2	13.33%
No	15	100.00%	13	86.67%
SFR at 1 month				
Yes	13	86.67%	12	80.00%
No	2	13.33%	3	20.00%

Table 1 – Comparison between the assessed parameters in the CP-UAS and T-UAS groups.

DISCUSSION

The operative time of CP-UAS was shorter than that of T-UAS, which was similar to the results reported by Zhu et al. and Zhang et al [2, 4]. The difference in total operative time can probably be attributed to clearer surgical view field which enables faster lithotripsy and better immediate active fragments clearance ability of the bendable tip suctioning sheath. In addition, decreased need for basketing or pop-corn lasing could shorten the overall surgical time.

The occurrence of SIRS was only present in the T-UAS group. Zhu et al. also revealed that, the incidence of fever was significantly lower than that in the traditional UAS group [4], while Qian et al. reported a lower incidence of postoperative fever or systemic inflammatory response syndrome in suctioning UAS group [1]. Thus, infectious complications after RIRS may be directly related to intrarenal pressure. Furthermore, too much saline irrigation pressure or insufficient release of pressure through drainage may result in increased PCS pressure, which may lead to renal damage, favorizing pyelo-venous reflux, infection spread, urosepsis or even sepsis shock [14]. By using suctioning-UAS you can adjust suction in the renal collecting system to theoretically retain lower pressure, which may reduce the risk of infectious complications or SIRS. In addition to the fluid in the renal collecting system, infectious stone fragments, blood clots, bacterial endotoxin and pus can also be suctioned through NTFS-UAS, which can reduce the risk of bacteria being absorbed in the systemic circulation.

Although the obtained results are encouraging and they tend to concur with the scarcely published literature on this topic [1, 2, 4, 6, 8, 10-14], our current study has several limitations. First, it is a retrospective case matching study on a limited number, and potential patient selection bias cannot be fully eliminated.

However, we are just considering this the initial experience, as this particular type of access sheath came on our country's market in the 3rd trimester of the last year. Due to these limitations, a stricter designed prospective randomized controlled study on a large number of cases is recommendable.

So far, from the surgeon's point of view, its main advantages would be the clearer view, this resulting in no frequent need for surge in the washing fluid pressure, faster operating time, lower risks of infectious complications, urothelial mucosal damage, possibly less fluoroscopy time, assuming it will be a game changer for flexible ureteroscopy especially in high volume stones.

CONCLUSION

Compared to T-UAS, using a bendable tip suctioning ureteral access sheath for f-URS seems to be superior in the immediate SFR on 1 month after surgery, also showing shorter operative time, and apparently less infectious complications. Of course, further prospective randomized studies ought to be conducted to confirm these results.

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