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UROLITHIASIS

Measurement and comparison of intrarenal pressures during retrograde intrarenal surgery using novel flexible ureteroscopes with integrated direct in-scope suction: An experimental *ex vivo* study

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Introduction To evaluate the intrarenal pressure parameters of the 9.2 Fr (5.1 Fr working channel) and 7.5 Fr (3.6 Fr working channel) flexible ureteroscopes with direct-in-scope suction (DISS) in an *ex vivo* experimental setting.

Material and methods We performed an experimental study using an ex vivo porcine model using two DISS single-use digital videoureteroscopes: a 7.5 Fr PU3033AH and 9.2 Fr PU400A (Pusen, Zhuhai, China). Intrarenal pressures (IRPs) were measured with an automated irrigation pump set at 40, 60, 80, 100 mmHg, manual hand pumping and gravity fed-irrigation, with suction applied continuously and intermittently at 3-second intervals.

Results Higher IRPs were documented when the 9.2 Fr flexible ureteroscope was used compared to the 7.5 Fr scope, regardless of the irrigation setup. The highest IRP (45 mmHg) was documented with the 9.2 Fr scope, using manual pump irrigation and intermittent pumping with no suction. In contrast, the lowest IRP was reported with the 7.5 Fr scope and the automated pump at 40 mmHg. The pressure difference following 1second of suctioning was more pronounced with 9.2 Fr compared to 7.5 Fr. The 9.2 Fr ureteroscope with the 5.1 Fr working channel resulted in significantly shorter time to regain the initial IRP.

Conclusions For the first time in experimental studies we noted that irrigation through a wider 5.1 Fr working channel raises the baseline IRP faster than the classic 3.6 Fr working channel. Although these findings should be further investigated in a clinical setting, they should be taken into consideration to select the optimal strategy, to keep IRP at safe levels, and avoid complications.

Key Words: DISS ‹› RIRS ‹› suction ‹› intrarenal pressures ‹› basic research

INTRODUCTION

Retrograde intrarenal surgery (RIRS) is considered a first line treatment option for renal stones smaller than 2 cm [1]. Flexible ureteroscopy is likewise accepted as a first line treatment technique for certain low risk upper tract urinary tumors [2]. As indications of flexible ureteroscopy expand to more complex case scenarios, optimal vision by increasing the irrigation flow during the procedure is a must [3, 4]. Maneuvers to improve irrigation inflow include pressurized irrigation bags, rising height of gravity irrigation drainage, roller pump from a mechanical irrigation, and either hand or foot-activated syringe-based manual pumps [3, 5, 6]. However, if irrigation inflow outweighs the outflow, this might lead to complications as a consequence of raised intrarenal pressure (IRP) [5, 6]. These complications might include pyelovenous backflow, rupture of the collecting system, postoperative sepsis, urinoma, intraoperative bleeding obscuring vision, renal tissue damage, etc. [5–8].

Several options have been proposed as suction tools to increase the outflow during RIRS and decrease IRP. Suction via different modalities has proved to be beneficial to reduce IRP [9–12]. One of these suction techniques is the direct in-scope suction (DISS) (7,8). DISS has proved *in vitro* and clinically to remove dust and relocate stones fragments up to 4 mm in diameter, thus improving vision during FURS [8, 13–16].

The aim of the current study was to evaluate the intrarenal pressure parameters of the 9.2 Fr (5.1 Fr working channel) and 7.5 Fr (3.6 Fr working channel) flexible ureteroscopes with DISS in an *ex vivo* experimental setting.

MATERIAL AND METHODS

Study design

We performed an experimental study using an *ex vivo* porcine model. A unilateral upper urinary tract including kidney and ureter were freshly harvested from a female pig from slaughter. The pig was not sacrificed for the study purpose. The experimental set-up included a standard surgical vacuum regulator (Air Liquide, Paris, France), either manual or automated fluid irrigation pumps, arterial pressure monitoring sets, a pressure monitor, and a DISS, either the PU3033AH or the PU400A (ZhuHai Pusen Medical Technology Co, Ltd, Zhuhai, China). The vacuum regulator was set at 100 mmHg and connected to the ureteroscope through a silicone tube. Depending on the trials, a standard irrigation system (Cook Medical, Indiana, USA), a manual irrigation pump (Cook Medical, Indiana, USA), or an Endomat select UP 210 automatic irrigation pump (Karl Storz Se & Co. Tuttlingen, Germany) was used. A Medicath disposable pressure transducer (Medicath LTD, Guangdong, China) was connected to a pressure monitor (Vista 120, Drägerwerk AG & Co., Lübeck, Germany). Calibration of pressure sets was performed prior to the start of the experiment. Pressure sets were fixed at the level of an operating theater table. Before the start of the experiment calibration was performed to avoid any potential biases.

Two pressure transducers sets were connected to the 20G venous catheters introduced from the upper and lower calyces of the porcine kidney under endoscopic vision (Figure 1). As a result, simultaneously 2 measurements were performed. Flexible ureteroscopes were advanced in the upper, lower calyx and in the renal pelvis. The first group of trials was performed with the 7.5 Fr DISS single-use flexible ureteroscope, and the 9.2 Fr DISS was used for the second group of trials. The suction was activated once the ureteroscopes were placed in the middle of the upper and lower calyces or in the pelvis.

Evaluated ureteroscopes

In our study 2 recently introduced DISS single-use digital flexible ureteroscopes, the PU3033AH and PU400A, were evaluated. Both scopes are equipped with dual led light system, integrated straight working channel and innovative handle design stated to reduce the possible hand fatigue during RIRS procedure. The unique characteristic of these scopes is the integrated direct in-scope suction. For both devices continuous or intermittent suction can be easily achieved by the operating surgeon just by pressing the suction button, with no need for additional assistance. The 7.5 Fr flexible ureteroscope (PU3033AH) features a 3.6 Fr working channel width, while a 5.1 Fr working channel is available on 9.2 Fr scope (PU400A).

Figure 1. *Experimental setup. Black arrows – arterial catheterization system connected to 18 Gauge intravenous catheters placed in the lower and upper calyx; yellow arrow – irrigation system connected to the irrigation canula; red arrow – aspiration canula; green arrow – pressure monitor.*

Evaluated parameters

For each scope, trials were performed with an empty working channel. Intrarenal pressures were measured with an automated irrigation pump set at 40, 60, 80, 100 mmHg, manual hand pumping, and gravity irrigation setups. When the manual pump was used, both continuous and intermittent pumping were performed. In the trials with continuous manual pumping, the pump was pressed continuously with the same force till it was completely empty and reactivated once it was completely refilled, while intermittent pumping was done every 3 seconds as measured by a chronometer. In all trials, two 3-litre irrigation bags were placed 100 cm above the operating table [17]. The suction was only activated once a stable IRP was reached with the irrigation mode "off". Thereafter the suction was activated for up to 3 seconds or till a zero IRP was reached. The level of pressure reduction and the time for IRP recovery were recorded by a separate researcher. For each trial, three measurements were performed.

Statistical analysis

SPSS v25 software (IBM Statistics, NY, USA) was used for the descriptive statistical analysis. The Mann-Whitney test was used for non-parametric variables. Statistical significance was defined as $p < 0.05$.

Bioethical standards

Due to the nature of the study, approval from the bioethics committee was not required.

RESULTS

In total, 7 sets of trials, 4 with an automated pump, 2 with a manual irrigation pump, and 1 with a gravity irrigation, were performed. No differences in IRPs from the 2 pressures transducers were reported when the flexible scopes were placed in the upper, lower calyces, and renal pelvis. Higher IRPs were documented when the 9.2 Fr flexible ureteroscope was used compared to the 7.5 Fr scope, regardless of the irrigation setup. The highest IRP was documented with the 9.2 Fr scope using manual pump irrigation and mild intermittent pumping with no suction. By contrast, the lowest IRP was reported with the 7.5 Fr DISS scope and the automated pump at 40 mmHg.

A dramatic IRP decrease to 0–6 mmHg was reported only after 1 second of active suctioning, whereas 2 seconds of active suctioning resulted in the complete collapse of the collecting system reaching zero IRP for all settings with 9.2 Fr DISS. When suctioning was stopped, it took between 8 and 14 seconds to regain the initial IRPs. Similar IRP recovery time between 8 and 9 seconds was reported with an automated pump set at 100 mmHg, gravity irrigation, and manual pump irrigation, even though the initial IRP with manual pump irrigation was higher (Table 1).

For the tests with the 7.5 Fr DISS, the maximum IRP was recorded with intermittent manual pumping, at levels up to 26 mmHg. An incremental decrease in IRP was documented with active suction. However, the decline of the IRP was less pronounced compared to that shown when using the 9.2 Fr DISS scope. After 1 second of suction activation, IRP of 7 mmHg were recorded for higher irrigation pressure settings (gravity and manual pump irrigation and automated pump irrigation with 80 and 100 mmHg settings), and IRP of 3 mmHg was noted after 2 seconds of suctioning. The collecting system was completely collapsed reaching zero IRP after 3 seconds of suctioning (Table 2). The comparison of the IRP differences after 1 second of suctioning with the 9.2 Fr and the 7.5 Fr scopes revealed a statistically significant decrease with all irrigation settings was registered with the 9.2 Fr scope (Table 3). Nonetheless, the 9.2 Fr ureteroscope with the wider working channel resulted in significantly shorter time to regain the initial IRP.

DISCUSSION

DISS has shown to be effective in improving SFR, maximizing efficacy and minimizing infective complications in various clinical and experimental studies for retrograde intrarenal surgery [9, 13, 16, 18, 19]. The current study used an *ex vivo* porcine model to compare the IRPs using two DISS single-use digital videoureteroscopes: the PU3033AH, a 7.5 Fr digital ureteroscope with a 3.6 Fr working channel, and the PU400A, a 9.2 Fr digital ureteroscope with a 5.1 Fr working channel. The IRPs were measured with an automated irrigation pump set at 40, 60, 80, 100 mmHg, manual hand pumping and gravity fed-irrigation, with suction applied continuously and intermittently at 3-second intervals. In our experimental study using we noted that wider working channel diameter of 5.1 Fr recorded a higher baseline IRP compared to the 3.6 Fr working channel, but the drop in IRP was also significantly faster. The feature of integrated suction is a key element to regulate the flow and hence control the IRP. A practical application of our finding is that in clinical practice when using this scope without an ureteral access sheath (UAS), intermittent suc-

Table 1. *Intrarenal pressure change with 9.2 Fr direct-in-scope suction single-use flexible ureteroscope*

Parameters	Intrarenal pressure				
	No suction	Active suction 1 sec.	Active suction 2 sec.	Pressure recovery 1 sec. suction	Pressure recovery 2 sec. suction
Automated pump pressure (mmHg)					
100	36	4	0	8 sec	9 sec
80	29	3	0	10 sec	11 sec
60	20	0	0	12 sec	13 sec
40	12	0	0	14 sec	14 sec
Gravity irrigation	25	4	0	11 sec	12 sec
Manual pump irrigation					
Mild continuous pumping	42	6	0	8 sec	9 sec
Mild intermittent pumping	45	6	0	9 sec	9 sec

* Pressures measured in mm Hg

Table 2. *Intrarenal pressure change with 7.5 Fr direct-in-scope single-use flexible ureteroscope*

Parameters	Intrarenal pressure*						
	No suction	Active suction 1 sec.	Active suction 2 sec.	Active suction 3 sec.	Pressure recovery 1 sec. suction	Pressure recovery 2 sec. suction	Pressure recovery 3 sec. suction
Automated pump (mm Hg)							
100	20	7	3	0	10 sec	12 sec	12 sec
80	16	7	3	0	12 sec	14 sec	14 sec
60	12	3	0	0	14 sec	16 sec	16 sec
40	7	2	0	0	16 sec	18 sec	18 sec
Gravity irrigation	16	7	3	0	12 sec	14 sec	14 sec
Manual pump irrigation							
Mild continuous pumping	22	7	3	0	10 sec	11 sec	11 sec
Mild intermittent pumping	26	7	3	0	12 sec	12 sec	12 sec

* Pressures measured in mmHg

Table 3. *Decline and incline of intrarenal pressure after 1 second of suction activation*

	9.2 Fr scope	7.5 Fr scope	p
Δ pressure (mm Hg)			
100 mmHg	32	13	**0.043**
80 mmHg	26	9	**0.043**
60 mmHg	20	9	**0.043**
40 mmHg	12	5	**0.043**
Gravity	21	9	**0.043**
Manual continuous	36	15	**0.034**
Manual intermittent	39	19	**0.025**
Time to pressure recovery (seconds)			
100 mmHg	8	10	**0.043**
80 mmHg	10	12	**0.043**
60 mmHg	12	14	**0.043**
40 mmHg	14	16	0.068
Gravity	10	12	**0.043**
Manual continuous	8	10	**0.034**
Manual intermittent	9	12	**0.025**

Δ – Difference of pressures (starting pressure – the pressure registered 1 sec. following active suction)
Bolded are the statistically significant outcomes

tioning with a large 9.2 Fr diameter DISS scope may out perform in removal of dust volumes compared to 7.5 Fr DISS scope with a rapid restoration of IRP, making the procedure safe to use even in the absence of UAS. The possible collapse of the system that has been reported during suction may be minimized if the irrigation and suction is well balanced. While these may be postulated for the 5.1 Fr working channel, these effects have already been described when performing DISS in the multicentric prospective clinical study by Nedbal et al. [16]. The latter study evaluated the 7.5 Fr PU3033AH DISS regarding maneuverability, suction quality, visibility and clinical efficiency, resulting in very positive outcomes [16]. Nonetheless, to our knowledge no evaluation has been published to date on IRP management with the 7.5 Fr PU3033AH and 9.2 Fr PU400A DISS scopes, nor any clinical nor preclinical comparison of both scopes. Likewise, the data regarding physics under the mechanism of action of both DISS ureteroscopes and what can one expect from them structurally remains unknown.

Gauhar et al. introduced in 2022 for the first time the direct in-scope suction technique that any urologist could simply build in the operating theater and attach it to any flexible ureteroscope [8]. One theoretical advantage of both the PU3033AH and the PU400A, with DISS directly integrated in the scope is that no time needs to be wasted on producing any additional add-ons modification, as these are in-built in the scope. Whether these DISS scopes are cost-effective in comparison with the DISS technique proposed by Gauhar et al. [8] should be further evaluated. Perhaps, one disadvantage of the PU3033AH and the DISS technique introduced by Gauhar et al. [8] on any ureteroscope with a 3.6 Fr working channel was the small size of the working channel which limited the suction efficiency as proved in our tests.

In the initial clinical assessment published by Nedbal et al. [16], all surgeons evaluated positively the PU3033AH DISS 7.5 Fr digital ureteroscope. Comparisons of the proposed DISS technique between the PU3033AH and the PU400A DISS ureteroscopes from the perspective of users' subjective satisfaction would be also necessary.

All the proposed suction accessories and devices have proved to increase the outflow during RIRS and decrease IRP. These include a catheter-type system, ureteral access sheaths with suction, modified scopes with a vacuum accessory connected, and direct in scope suction (DISS) option [8, 11, 18]. Such suction devices during flexible ureteroscopy have proved to improve surgical outcomes, stone-free rate and visibility, and therefore decrease operative time and complications [16, 20]. Clinical and preclinical comparisons of the efficiency and effectivity amongst the different techniques would also provide useful data for endourologists.

In our trials, no differences were reported between the measurements between the different cavities of the porcine kidney; upper and lower calyces. That may be due to the small kidney size of the pig. In clinical scenarios, this may differ from case to case due to anatomical differences, which would need further assessment.

A limitation of the study is that the model was an ex vivo porcine kidney, and the reduced tissue compliance was not considered in the measurements taken. Yet, human and porcine kidney show similar characteristics for IRP as has been reported by Lildal et al. and in pelvic function studies [21–23]. Likewise, measurements were taken with the working channel unoccupied by any instruments such as endo-baskets or the laser fiber, which might need to be considered, especially as it is the usual clinical practice while activating suction. Nevertheless, this study provides important data on how the IRP may change depending on the scope diameter and the diameter of the working channel, and it may be useful as a starting point for further preclinical and clinical studies.

CONCLUSIONS

For the first time in experimental studies, we noted that irrigation through a wider 5.1 Fr working channel raises the baseline IRP faster than the classic 3.6 Fr working channel. Although these findings should be further investigated in a clinical setting, they should be taken into consideration, to select the optimal strategy, to keep IRP at safe levels and avoid complications.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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ETHICS APPROVAL STATEMENT

The ethical approval was not required.

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