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UROLITHIASIS

Intrarenal pressure and irrigation flow with commonly used ureteric access sheaths and instruments

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Submitted: March 25, 2015 Accepted: Sept. 1, 2015 Published on-line: Nov. 2, 2015 **Introduction** Flexible ureterorenoscopy is becoming a first-line treatment for many intrarenal stones. Ureteric access sheaths are commonly used to aid access, stone removal and reduce intrarenal pressure. We evaluated the effects of two commonly used access sheaths on irrigation flow and intrarenal pressure during flexible ureterorenoscopy. We measured the effect of scope instrumentation on flow and pressure.

Material and methods We utilized a 10/12F and 12/14F, 35 cm Re-Trace™ access sheath with a FlexX2 scope in a cadaveric porcine kidney. We evaluated the effect of four Nitinol baskets (1.3F, 1.5F, 1.9F, 2.2F), three different 200 µm laser fibres and a hand-held pump. Measurements of irrigation flow and intrarenal pressure were recorded and compared between the different sized access sheaths.

Results Flow rates varied widely between access sheaths. Without instrumentation, mean flow was 17 mls/min (10/12F access sheath), *versus* 33 mls/min (12/14F sheath) (p <0.0001). Increasing basket size produced a gradual reduction in flow and pressure in both access sheaths. Reassuringly, pressures were low overall (<40 cm H₂O). Pressures were significantly reduced when using the larger 12/14F sheath, with and without all instrumentations (p <0.0001). Hand-held pump devices have a marked effect on flow and pressure in both sheaths; with pressures rising up to 121 cm H₂O with a 10/12F sheath, *versus* 29 cm H₂O (12/14F) (p <0.0001).

Conclusions A 12/14F access sheath offered significantly improved irrigation whilst maintaining significantly lower intrarenal pressure, when compared to a 10/12F access sheath in a cadaveric porcine model. Scope instrumentation affects irrigation flow and pressure in both sized sheaths. Furthermore, there should be caution with hand-held pump devices, especially with smaller sized sheaths, as intrarenal pressure can be very high.

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INTRODUCTION

Flexible ureterorenoscopy is widely accepted as the first line treatment option for a variety of intrarenal calculi, offering a minimally invasive treatment with good stone free rates (SFR) [1]. It has also been used with large intrarenal calculi as part of multiple 'staged' procedures [2, 3]. The procedure offers minimal morbidity and is routinely performed as a day case in many centers [4]. Ureteric access sheaths were initially developed using sequentially sized, coaxial catheters to gain access to the upper urinary tract [5]. Ureteric access sheaths aid accessibility to the upper renal tract, improve irrigant flow, allow repeated intrarenal access with ease, enable stone basket extraction, improve stone free rates and maintain a lower intrarenal pressure [6–11]. Although useful, they can be difficult to insert, potentially cause ischemia of the ureteric wall and/ or ureteric wall injury limiting their universal use [12, 13]. Previous studies have suggested that larger sized ureteric access sheaths (12/14F or 14/16F) lead to improved irrigation flow and lower intrarenal pressures compared with a 10/12F sheath in a human cadaveric model [9]. Unfortunately, there was no statistical comparison between these groups. Instrumentation has been previously examined, on a plastic kidney model, and concluded that instrumentation does affect pressure and irrigation flow with a noticeable difference between different access sheaths [11].

We looked at the effect of both a 10/12F and 12/14F, 35 cm access sheaths on irrigation flow rates and intrarenal pressure based on a porcine cadaveric renal system. We examined the effect of multiple instrumentations via a flexible ureterorenoscope, in terms of flow and pressure in both sized sheaths. Our aim was to compare the irrigation flow and intrarenal pressure using the two commonly used access sheaths and the different sized baskets and laser fibers.

MATERIAL AND METHODS

Our aim was to measure the effect of different size access sheaths on renal irrigation flow rates and pressure on an *in vitro* fresh cadaveric porcine kidney model. A 6Fr cystometry pressure transducer was placed adjacent to the ureteric access sheath within the ureter. An elastic band was tightened around the ureter distally to prevent fluid leakage around the pressure transducer and access sheath. The tip of the pressure probe was placed into the renal pelvis centrally for all measurements. Pressure measurements were taken from a Sedia urodynamic machine with all measurements calibrated to atmospheric pressure (Figure 1).

We selected to use both 10/12F and 12/14F Re-TraceTM access sheaths (Coloplast, Denmark), which has been shown to have good access sheath insertion rates [14]. Using a FlexX2[™] flexible ureterorenoscope (Karl Storz, Germany), we measured the irrigation flow rates (mls/min) at the end of the access sheath and intrarenal pressure (cm H₀O) at the renal pelvis during standard flexible ureteroscopy. Once a set time interval for the system to fill and pressure to normalize had been reached; measurements were taken for both the 10/12F and 12/14F, 35 cm Re-Trace[™] access sheaths, with the same flexible scope position. We looked at the effect of four different size Nitinol ureteric baskets (1.3F, 1.5F, 1.9F and 2.2F) and three 200 μ m laser fibers (Boston Scientific Flexiva[™] 200, Lumenis SlimLine[™] EZ200 and Optical Integrity ScopeSafe[™]). We also examined the effect that a simple hand-held arthroscopy pump device had on flow and pressure with no instrumentation. Maximum intrarenal pressures are reported for the hand-held pump device, as this is very transient and depends on pressure applied to the device. The pump testing was performed by the same surgeon (NJR) in an attempt to standardize the results. Measurements were repeated multiple timesand mean values were reported.

Irrigation height was kept constant at one meter above the kidney (from kidney to top of a three liter irrigation bag), and all instruments protruded 1 cm from the end of the flexible ureteroscope. Statistical analysis was performed using one-way ANOVA (non-parametric) with GraphPadTM Prism software (GraphPad Software Inc, California, USA). Statistical significance was defined by a p-value <0.01.

RESULTS

Table 1 demonstrates the flow and pressure characteristics of the 10/12F and 12/14F, 35 cm access sheath with the FlexX2 flexible ureteroscope, including various different instruments. In terms of irri-



Figure 1. In vitro fresh cadaveric porcine kidney model with access sheath and pressure transducer.

	10/12F Re-Trace	12/14F Re-Trace	ace p-Value iin)	10/12F Re-Trace	12/14F Re-Trace	p-Value
	Flow (mls/min)	Flow (mls/min)		Pressure (cmH ₂ O)	Pressure (cmH ₂ O)	
Control	17	33	p<0.0001	46	16	n <0.0001
Hand held pump	47	83	p<0.0001			p<0.0001
Basket (F)		•	•			
1.3	10	18	p<0.0001	30	15	p<0.0001
1.5	8	13	p<0.0001	30	14	p<0.0001
1.9	4	7	p<0.0001	24	14	p<0.0001
2.2	3	4	p<0.0001	21	14	p<0.0001
200 μm laser fibre						
Optical Integrity ScopeSafe™	11	18	p<0.0001	38	15	p<0.0001
Boston Scientific Flexiva™	10	15	p<0.0001	34	14	p<0.0001
Lumenis SlimLine™	10	16	p<0.0001	33	15	p<0.0001

Table 1. Table demonstrating differences in flow and pressure with different size ureteric access sheaths with scope instrumentation using in a Flex $X2^{\text{TM}}$ ureterorenoscope

gation flow, using the FlexX2 flexible ureteroscope, there was a marked variation between each access sheath. Without instrumentation, the mean irrigation flow was 17 mls/min for a 10/12F access sheath, compared to 33 mls/min for a 12/14F sheath. This difference was significant and corresponds to an increase in irrigation flow rate of 95%. With basket instrumentation, it is evident that increasing the size of the basket results in gradual decrease in the flow of both sized access sheaths. Any basket greater than 1.5F has a dramatic reduction in flow rate. Direct comparison (Table 1) demonstrates significantly improved irrigation flow rates (p < 0.0001)for the larger sized access sheath, with all basket sizes. Similar findings are demonstrated for the three different laser fibers used. Again, there were significantly improved flow rates with the larger sized access sheaths. The use of a surgeon dependent hand-held pump device had marked effect on irrigation rates in both sized sheaths. Interestingly the hand-held pump had a marked effect on flow, increasing standard irrigation flow, in both sized sheaths, by 151–176% compared to no pump.

The effects of the different access sheaths on intrarenal pressure are also shown in Table 1. Reassuringly, the intrarenal pressure studies demonstrate low overall pressure (<40 cm H_2O). With standard flexible ureteroscopy, with no instrumentation, the effects of access sheath size and intra-renal pressure were quite marked, with significantly reduced intrarenal pressure by approximately 65% when using the 12/14F sheath (p <0.0001). With all forms of scope instrumentation, there was a significant reduction in intrarenal pressure when using the larger 12/14F access sheath. Of note, with larger instrumentation size, the intrarenal pressure fell.

Interestingly, the effect on intra-renal pressure was marked with the use of the hand-held pump device. Using a 10/12F, 35 cm access sheath the pump device had a concerning high transient intrarenal pressure; rising up to 121 cm H_2O . With the hand-held pump device, the 12/14F access sheath produced significantly less maximum transient intrarenal pressure (29 cm H_2O).

DISCUSSION

This data demonstrates that ureteric access sheaths have a direct effect on the flow dynamics and intrarenal pressures during flexible ureteroscopy. The varying size sheaths offer both advantageous and detrimental effects. The reported size of the sheath corresponds to the internal and external diameter of the sheath. Despite sheaths being universally classified, there are differences in the acceptability of different flexible ureteroscope in the same sized sheaths (often made by multiple manufacturers). Indeed, with digital 'chip on the tip' scopes, it is vitally important to know what sheath will fit your scope. Such data has been previously reported and is a good reference for those embarking on flexible ureteroscopy or looking to move to using digital scopes [15]. Flow and pressure characteristics may also be different in newer ureteroscopes with separate instrument and irrigation channels rather than those with a single channel [16].

We looked specifically at the FlexX2 scope and the Re-Trace^M 10/12F and 12/14F sheaths only. The FlexX2 optical scope easily fitted both 10/12F and 12/14F sheaths. By using access sheaths from the same company (Coloplast, Denmark) we have alleviated the individual manufacturer's variation. Due to varying differences in alternative scopes and sheath design, there may be slightly different results than if other equipment had been used. Despite this, the overall trends would be similar with a larger sheath

offering significantly improved flow and reduced pressure, but the actual numbers may vary.

Vision in flexible ureteroscopy is paramount to having a successful procedure and good SFRs. With improved irrigation flow, vision is maximized and this effect is evident in the 12/14F sheath. Improved vision is particularly important when performing stone dusting. Although there is a significant improvement in flow, we cannot directly say this will lead to improved SFRs, but evidence suggests that this is in the case of clinical practice [17]. This measurement is beyond the remit of this study, but could be addressed with a well-designed randomized study into sheath size.

The effect on pressure is again marked between the two different sized sheaths, with the larger 12/14Fsheath offering reduced intrarenal pressure. This model used a fresh cadaveric pig's kidney as a surrogate for human tissue. It would be unethical to perform such studies on fresh human kidney; therefore, we feel the fresh porcine kidney is an adequate substitute for the purposes of this study. Indeed, porcine kidneys are thought to be more suitable for human transplantation than primate ones [18] and thus this is why we feel that they are a reliable model. What the porcine kidney does offer is real time tissue elasticity. Previous studies have demonstrated similar findings in a plastic kidney model, but this model does not reflect the true elasticity of living tissue; our porcine model has been designed to overcome this issue. Although we do appreciate it, there are still the limitations in exactly replicating pressures in living human tissue. The compliance of the tissues was confirmed by repeat analysis following the prolonged experimentation with the same specimen, which revealed the same pressures, internally validating our results.

Instrumentation has a direct effect on flow and pressure within the model kidney. The explanation for this is based around the internal channel of the flexible ureteroscope. Most scopes have a 3.6F working channel. Any instrumentation will affect flow, with an increasing instrument size having a proportionally larger effect on flow and pressure. With larger instrumentation, flow is reduced proportionally. Without sufficient flow pressure, there will usually be a fall in pressure in a relative closed system such as the kidney. The larger sized sheath allows fluid to flow backwards around the ureteroscope more easily than the smaller sheath, therefore making the system easier to fill (improved flow rate) and guicker to drain (less intrarenal pressure). Similar findings for flow have been demonstrated in laser fibers, with small sized laser fibers offering improved irrigation flow rate [19].

One may argue that the actual increase in size between these 2 sheaths is minimal, particularly with reference to the size of stone fragment that can be removed. Indeed, *via* a 10/12F sheath the maximum size of fragment removable is 3.2 mm. Compared to a 12/14F, the maximum size fragment is 3.8 mm. The difference of 0.6 mm is small and some may argue that it is insignificant when attempting removal of stone fragments. Therefore the use of the larger sized sheath cannot be argued on solely by the size of the fragment removed.

Larger sized sheaths may offer theoretical advantages, but the increase in size does come at a cost. It must be acknowledged though that using larger ureteric access sheaths does lead to a reduction in ureteric blood flow, in animals at least, with the potential to cause long-term ureteric problems such as stricture formation [20]. Although ureteric blood flow returns to normal following sheath removal with no histological evidence of ischemia at 72 hours, the long-term effects in humans are not known. The other issue with sheath size is their ease of insertion. Indeed, a pre-stented ureter is likely to accept both sized sheaths without major risks [21, 22]. Using a larger access sheath in a virgin ureter is different and the authors accept that pre-stenting is not routine practice in all centres. A 12/14F sheath might not be able to be placed where a 10/12F sheath can be placed. When using a ureteric access sheath, care must be taken to inspect the ureter post-procedure, as the reported incidence of some degree of ureteric injury has been as high as 47% [12]. The use of pre-procedure double J stenting has been demonstrated to significantly reduce the risk of such injury [12].

The choice of sheath size is both ureteric and surgeon specific, with the experienced endourologist being able to decide which sheath is more likely to be placed with least risk [23]. In this study we did not examine the direct effect the differing sheath sizes had on ureteric ischemia or ureteric injury from placement, but one must consider these factors when choosing the appropriate sized sheath.

The hand held pump device significantly improves flow [24], but caution must be taken in a 10/12F access sheath as the pressure can rise dramatically (121 cm H_2O). With rapidly rising intrarenal pressures the risk of extravasation is greater, with the potential to cause pyelosinus, pyelovenous, and/or pyelolymphatic backflow of irrigant. These documented rises in intrarenal pressure with the pump device are very transient, often for only a few seconds, and as such these high intrarenal pressures do not persist in the kidney. Therefore, the exact clinical effects of these acute, short term pressure rises are unknown at present and worthy of further research. It must be noted that user variation can play a significant factor in the pressure and flow generated with hand-held pump devices. In this study, an experienced endourology surgeon (NJR) performed all the pump manipulation. The pressure applied was that which would normally be used in clinical practice. Secondly, we are using a cadaveric, non-perfused renal model and we cannot directly say similar results would be found during standard flexible ureteroscopy in humans. We accept that with due care and attention, such transient increases in pressure can be reduced with this knowledge.

CONCLUSIONS

A 12/14F access sheath offers significantly improved irrigation whilst maintaining a lower intrarenal pressure, when compared to a 10/12F access sheath in a cadaveric porcine model. However, other surgical factors might need to be considered when choosing an access sheath. Scope instrumentation does affect irrigation flow and intrarenal pressure in both sized sheaths.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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