Intrarenal pressures during percutaneous nephrolithotomy: a porcine kidney model

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Short title :

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Lee Chien Yap[1] **Donnacha Hogan**[1] **Kenneth Patterson**[1] **Gerard McGuinness**[1] **Charles O'Connor**[1] **Ashraf Sharfi** [1] **Derek Barry Hennessey** AQ1[1]

[1]Department of Urology, Mercy University Hospital, Cork, Ireland

CONTACT Donnacha Hogan donnacha.hogan@umail.ucc.ie Department of Urology, Mercy University Hospital, Cork, Ireland

Abstract

Background

Increased intrarenal pressure during endoscopic lithotripsy is associated with increased adverse outcomes. The objective of this study was to evaluate the effect of various devices on IRP during percutaneous intrarenal surgery in *ex vivo* porcine kidney models.

Methods

Whole intact porcine urinary tracts were harvested. Intrarenal pressure was measured using cystometrometry software. Intrarenal pressure during PCNL was recorded using variations of percutaneous access sheath size, irrigation height of 100 cm and 60 cm, use of a ureteric catheter and use of suction. The primary outcome was absolute IRP measurements. Secondary outcomes were comparisons of IRP between techniques.

Results

Using a 30 Fr vs 26 Fr access sheath and 26 Fr nephroscope the mean pressure at an irrigation height of 60 cm was significantly lower than 100 cm ($p = 0.0013$ vs $p < 0.0001$, respectively). Pressure's during mini-PCNL were significantly higher than conventional PCNL in all variations. Using the 16.5 Fr access sheath and 12 Fr nephroscope produced a significantly lower pressure at a 60 cm irrigation height than 100 cm (*p*

= 0.0010). IRP was significantly lower with a ureteric catheter in place vs no ureteric catheter at 100 cm (p = 0.0015) and at 60 cm (p = 0.0040).

Conclusions

Using standard PCNL tract sizes intrarenal pressure varied significantly depending on the height of the irrigation fluid. Mini-PCNL is at higher risk of pathological pressure, however, the use of a ureteric catheter significantly decreased pressure. To maintain safe IRP during PCNL urologists should be aware of these significant variations.

Keywords: PCNL; intrarenal pressure; access sheath

Introduction

The lifetime risk of developing renal calculi is approximately 12% for men and 6% for women, with a rising incidence rate globally across the different sexes, ages, and races [1,2]. Increasing incidence has led to a corresponding increase in the demand for stone treatment [3]. As per current European Association of Urology (EAU) Guidelines, the optimal treatment of large (>2 cm) and complex renal stones is percutaneous nephrolithotomy (PCNL) [4]. PCNL is also considered a first-line option for stones 10–20 mm, and a second-line option for stones <10 mm [4]. Although PCNL is recommended as above, it is associated with significant complications including a post-operative urosepsis rate of 0.3–9.3% and a blood transfusion rate of 2–17.1% [5,6].

There has been an increase in the use of mini-PCNL as an alternative to PCNL for large and complex renal stones with satisfactory outcomes, particularly in centres with access to high powered laser devices [7, 8]. The use of continuous or intermittent saline irrigation fluid is an essential part of endourological surgery ensuring dilation of the collecting system for adequate vision, clearance of debris and temperature control. Intrarenal pressure (IRP) is an often-overlooked intraoperative metric in PCNL and mini-PCNL. Excessive IRP can lead to pyelorenal backflow, bacterial translocation, sepsis and renal damage [9,10]. Physiological IRP ranges from 0–15 cm H_2O. IRP in the range of 30–40 cm H_2O is associated with pyelotubular backflow, although it has been suggested that 40 cm H_2O is a safe upper limit [11,12]. At 80–90 cm H_2O, forniceal rupture can occur, resulting in pyelo-sineous as well as pyelo-lymphatic backflow [13]. A recent systematic review by Tokas et al. [14] has further highlighted the importance of awareness of raised IRP, especially during mini-PCNL, and advocates using novel intraoperative IRP measurement devices. They identified five human in-vivo studies with IRPs ranging from 2.4–53.44 cm H_2O [15–19].

The variables in PCNL which potentially affect IRP are tract/sheath diameter, the presence of ureteric catheter and the use of a suction lithotripter [20]. The importance of low IRP is a relatively new concept, and there is a lack of data on IRP during PCNL~~ and FURS~~. This study aims to evaluate IRPs in an *ex vivo* porcine kidney model using various combinations of percutaneous access sheath size, a ureteric catheter and irrigation fluid height to determine the safest combination.

Methods

Porcine kidney preparation

Whole intact urinary tracts were harvested from Landrace pigs that had been slaughtered for the food chain by a licenced veterinarian. The organs were harvested within 4 h of the animal's death and within 6 h of experimentation. Any unwanted residual tissue including Gerotas fascia was excised from the specimen.

Intrarenal pressure monitoring

The bladder was bivalved to expose the trigone and the ureter cannulated with a 0.035" guidewire (Boston Scientific, USA) that was advanced to the renal pelvis ensuring patency of the ureter. A 5 Fr cystometry abdominal pressure line connected to an external strain gauge was placed into the renal pelvis and sutured in place with a purse-string suture. The IRP was then calibrated to zero, representing atmospheric pressure. Pressure readings were recorded using calibrated cystometrometry software.

PCNL puncture

Lower calyx punctures were made with an 18-gauge coaxial needle. A bolus of irrigation fluid was pushed through the needle. Irrigation fluid identified at the ureteric orifice confirmed correct positioning in the collecting system prior to performing sequential tract dilatation to the required dimension.

Experiment protocol – intrarenal pressure in conventional PCNL

The pig kidney was punctured and dilated to 30 Fr or 26 Fr. A 26 Fr nephroscope was then placed into the kidney. A 3 L bag of saline was hung at 100 cm and 60 cm measured from the bottom of the bag to the level of the kidney with the irrigation fluid channel fully open on the scope. Five measurements of IRP were recorded at each step of the procedure.

Experiment protocol – intrarenal pressure in mini-PCNL

The pig kidney was punctured and dilated to 16.5 Fr and the 12 Fr mini-nephroscope was passed into the kidney similar to above. A 3 L bag of saline was hung at 100 cm and 60 cm measured from the bottom of the bag to the level of the kidney with the irrigation fluid channel fully open on the scope. IRP was measured ($n = 5$) with a ureteric catheter present and not present.

Statistical analysis

Data analysis was performed using *Stata Statistical Software: Release 17* (STATACorp, LLC, TX). Data were tested for normality using the Shapiro Wilks test. All data were normally distributed and therefore given as mean ± standard deviation. Independent *t*-test was used to compare mean values for normally distributed data. One-way ANOVA was used when three or more independent variable were compared. A *p*-value of <0.05 was considered statistically significant.

Results

Intrarenal pressure in conventional PCNL

Using a 30 Fr access sheath and 26 Fr nephroscope the mean IRP at 60 cm vs 100 cm irrigation height was 7.8 cm H_2O ± 2.6 vs 15 cm H_2O ± 2.6 (p = 0.0013). When a 26 Fr access sheath and 26 Fr nephroscope were used, the mean IRP at 60 cm vs 100 cm was 12.4 cm H_2O ± 1.7 vs 17.9 cm H_2O ± 1.6 ($p < 0.0001$). Increasing the height of the irrigation resulted in statistically significant increases in pressure for both variations of sheath and scope. However, the overall IRP~~R~~ was low (<40 cm H_2O) and did not risk pyelorenal backflow. The IRP was significantly higher when using the 26 Fr sheath compared with the 30 Fr sheath with an irrigation height at 100 cm and at 60 cm (p = 0.0239 and p = 0.0014, respectively). Results are summarised in Table 1.

Table 1. Intrarenal pressures during percutaneous nephrolithotomy in *ex-vivo* porcine kidney modules.

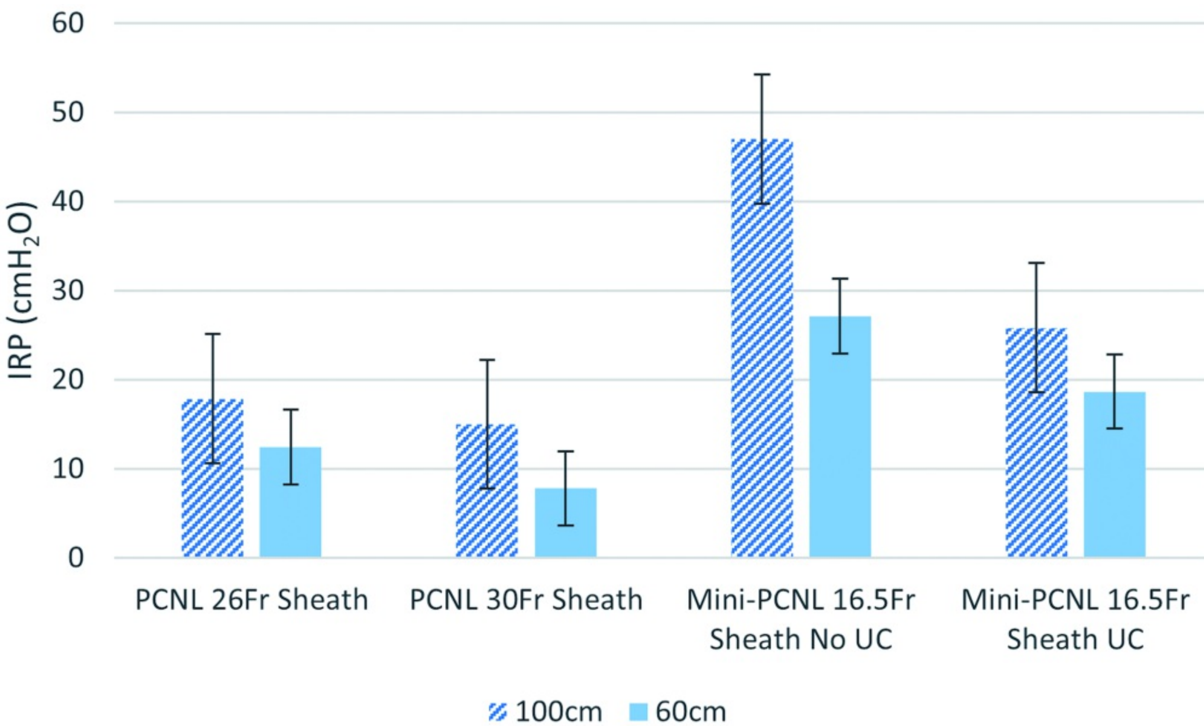
Type of renal access	IRP (cm H_2O)		*p*-value
	Irrigation height 100 cm	Irrigation height 60 cm	
PCNL 26 Fr sheath	17.9 ± 1.6	12.4 ± 1.7	<0.0001
PCNL 30 Fr sheath	15.0 ± 2.6	7.8 ± 2.6	0.0013
Mini-PCNL 16.5 Fr sheath			
No ureteric catheter	47.0 ± 12.7	27.1 ± 5.7	0.0010
Ureteric catheter in place	25.8 ± 1.7	18.7 ± 1.2	<0.0001

Data are displayed as mean ± standard deviation. IRP, Intra-renal pressure.

Intrarenal pressure in mini-PCNL

The IRP recorded during mini-PCNL was significantly higher than conventional PCNL in all variations. Using the 16.5 Fr access sheath and 12 Fr n~~N~~ephroscope there was a significantly lower mean IRP at 60 cm irrigation height compared with 100 cm (27.1 cm H_2O ± 5.7 vs 47.0 cm H_2O ± 12.7, $p < 0.0010$). With a 6 Fr ureteric catheter inserted into the renal pelvis the mean IRP at 60 cm (n = 5) remained lower than at 100 cm (18.7 cm H_2O ± 1.2 vs 25.8 cm H_2O ± 1.7, $p < 0.0001$). IRP was also lower with a ureteric catheter in place vs no ureteric catheter at 100 cm (p = 0.0015) and at 60 cm (p = 0.0040). Results are summarised in Table 1. A comparison of IRP is illustrated in Figure 1.

Figure 1. Comparison of intrarenal pressure’s during percutaneous nephrolithotomy, mini-percutaneous nephrolithotomy in *ex-vivo* porcine kidney models. IRP, Intra-renal pressure; PCNL, percutaneous nephrolithotomy; Fr, French; UC, ureteric catheter.



Discussion

In this study, the IRP recorded with conventional PCNL was low and below the threshold for pyelorenal backflow. The smaller sheath size during mini-PCNL caused a significant increase in IRP above the previously mentioned 40 cm H_2O, increasing the risks of complications. The use of a ureteric catheter reduced this IRP significantly. This data suggest that care must be taken when performing mini-PCNL.

Patients with struvite and infection-related calculi are at the most significant risk of post-operative sepsis [21]. In this group of patients, the surgeon should aim to have the lowest possible IRP. As such, the authors suggest a conventional PCNL should be the primary treatment option. In the setting of infection stones, mini-PCNL should be avoided due to its association with high IRP, increasing the risk of post-operative sepsis. Standard flexible ureteroscopy can also be associated with pressures of 80–135 cm H_2O and special consideration should be given to its use in infection stones [22]. In patients with non-infection related stones, all options could be considered.

Due to the smaller tract required and the subsequent decrease in bleeding risk, mini-PCNL has become a preferable option in some cases [23]. However, they are associated with increased IRP and have been shown to negatively impact patients post-operative pain and length of stay [9]. There also appears to be a direct relationship between the duration of raised IRP and the risk of developing complications, especially if raised for >10 min, but can occur in as little as 1 min [10,24]. In this study the highest baseline IRP was recorded during mini-PCNL, although it was reduced to safe levels with a ureteric catheter *in-situ*. Research is being performed in the area of biomechanical monitoring devices that may be used in real-time to monitor IRP, especially in mini-PCNL where IRP tends to be higher [25]. The present study suggests that mini-PCNL pressures remain in a safe range if the irrigation fluid is no higher than 60 cm above the kidney and with a ureteric catheter in place.

The importance of maintaining a low IRP cannot be overstated for stone surgery regardless of whether it is via PCNL or mini-PCNL. A previous study on porcine models identified focal scarring in the tested kidneys at 4–6 weeks after the experiment in the high-pressure specimens, which was not present in the normal pressure specimens [12]. Novel irrigation devices are available on the market, allowing for close control of IRP during endourological procedures [26]. There is a tendency among most urologists when vision deteriorates due to bleeding or stone fragments to increase the pressure and improve vision. However, this should be performed in a more controlled manner than manual pressure on the irrigation fluid [27]. The inferences of this study are that IRPs during conventional PCNL are safe and do not risk pyelorenal backflow.

There are several limitations to this study. First, this is an ex-vivo porcine model, therefore calculations made on IRP may be lower than *in-vivo* experiments due to lack of muscle contractions. However, this study identified differences in IRP based on multiple factors and this information will facilitate further *in-vivo* studies to measure IRP during PCNL and subsequent patient outcomes are required. Second, amplatz sheaths of 30 Fr and 26 Fr with a 26 Fr nephroscope were used along with a mini-PCNL sheath of 16.5 Fr. Numerous other combinations of sheath and nephroscope size are possible. However, we feel these combinations are representative.

Conclusion

Our study shows that IRP using standard PCNL tract sizes varied significantly depending on the height of the irrigation fluid. Mini-PCNL is at a higher risk of pathological IRP. However, the use of a ureteric catheter significantly decreased IRP. To maintain safe IRP during PCNL urologists should be aware of these significant variations. There remains a lack of research in adequately designed human studies to assess IRP and subsequent clinical sequalae.

Geolocation information

Mercy University Hospital, Grenville Place, Cork, Ireland, T12 WE28 (51°53'57.4"N, 8°28'57.7"W).

Disclosure statement

All authors confirm they have no conflicts of interest to disclose. There is no grant or funding to declare for this paper.

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