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Original Article

Suctioning flexible ureteroscopy with automatic control of renal pelvic pressure: a porcine model

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Abstract: Objective: We designed a novel technique of suctioning flexible ureteroscopy with automatic control of renal pelvic pressure (RPP) by a patented system including a pressure-measuring ureteral access sheath (UAS) and an irrigation and suctioning platform. We sought to compare RPP values measured by the patented system and a nephrostomy catheter at different phases of flexible ureteroscopy. Materials and methods: Eight pigs with a total of 16 urinary tract systems were included. Via a subcostal incision a 6-F catheter was placed into the renal pelvis for RPP measurement by connecting to a pressure monitor. We then introduced the patented UAS retrogradely into the renal pelvis, through which the pressure was measured by the platform. RPP was measured at baseline period, irrigation and suctioning period, and therapeutic period. Results: Twelve renal pelves were successfully established models for pressure-measuring. Baseline RPP was 26.9±3.8 mmHg in the platform group and 26.3±5.2 mmHg in the nephrostomy group. There was no significant difference on RPP between the 2 methods either at irrigation and suctioning period (-5.21±2.11 vs. -3.59±1.45) or therapeutic period (-5.81±2.47 vs. -3.73±2.19). Conclusion: Renal pelvic pressure can be accurately and effectively monitored and controlled by our patented system.

Keywords: Intelligent control, pressure feedback control, irrigation and suctioning platform, suctioning sheath of flexible ureteroscope, renal pelvic pressure

Introduction

Since Marshall for the first time reported using flexible ureteroscopy (URS) to explore ureteral calculi, up to now the application of URS for stone management has a history of nearly 100 years [1]. In recent years, with the development of new type of ureteroscopy and related equipment, application of flexible URS technique in the treatment of upper urinary tract calculi is becoming more and more extensive [2]. Ideal intraoperative saline infusion is an important factor in determining stone breaking efficiency and clear visualization, and in preventing injury. However, high perfusion rate leads to RPP increase, resulting in absorption of liquid, bacteria, and endotoxin into blood [3], further leading to short-term complications such as systemic inflammatory response syndrome (SIRS, 8.1%) [4], sepsis (0-4.5%) [5], renal pelvic and ureteral tumor spread [6], and long-term complication of renal function impairment. Currently the commonly used ureteral access sheath (UAS) for flexible URS reduces the RPP to a certain extent, but still cannot monitor and control the RPP to reduce the incidence of complications [7, 8], which limits the clinical application of flexible URS.

To directly address the issue of high pressure within renal pelvis and to improve the efficiency of the flexible URS, we designed an irrigation and suctioning platform with function of pressure feedback and a suctioning UAS with func-

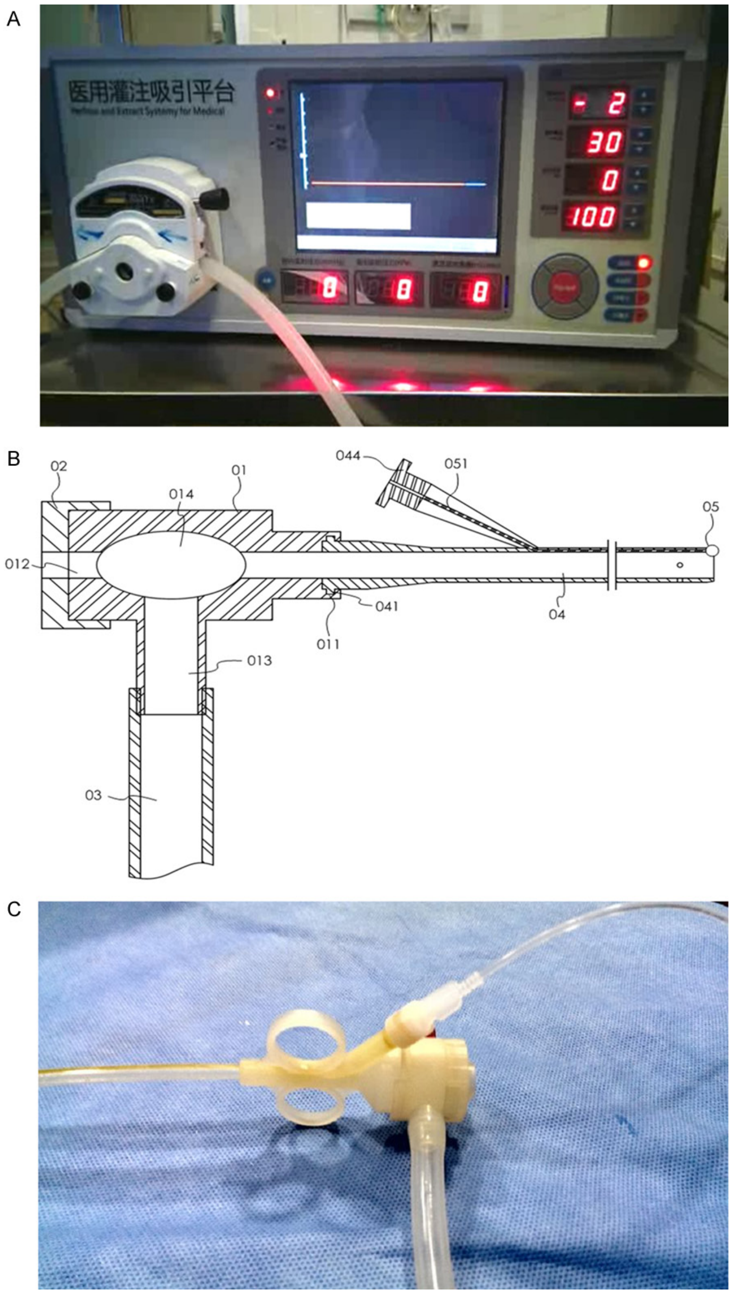

Figure 1. A. Irrigation and suctioning platform. B. Diagram of UAS (ureteral access sheath). C. Real picture of UAS.

tion of pressure-measuring to monitor and control intrarenal pressure intelligently. Through flexible URS on a porcine model using the intelligent pressure-controlling devices, we sought to compare intraluminal pressure profiles between platform group and nephrostomy group at different phases of ureteroscopy when flow rate was set at 100 mL/min, to explore the accuracy and reliability of the RPP measured by the platform. We now report our findings as below.

Materials and methods

Patented irrigation and suctioning platform and UAS

This patented system includes an irrigation and suctioning platform (Patent No. ZL201420055766.5, **Figure 1A**) and a UAS (Patent No. 201420055134.9, **Figure 1B**, **1C**). The irrigation and suctioning platform includes a main control unit, an infusion device, a suctioning device,and a pressure feedback unit. Perfusion flow, pressure control value (-5 mmHg), pressure warning value (20 mmHg), and pressure limit value (30 mmHg) can be set on the platform. Vacuum suctioning power was adjusted by the main control unit of the platform through pressure feedback. The platform has a total of 4 models including automatic (perfusion, suctioning, pressure monitoring, and pressure feedback control), semi-automatic (pressure monitoring, perfusion), pure perfusion, and pure suctioning, enabling real time display of monitored actual renal pelvic suctioning pressure and renal pelvic pressure. There are two connecting channels on the rear end of the UAS, which are connected to the vacuum suctioning device and pressure monitoring feedback device, respectively, wherein the suctioning channel can automatically suck out the stones, and the pressure monitoring feedback channel can monitor and automatically feedback to regulate the RPP.

The suctioning UAS with a pressure-sensitive tip is transparent with an outer body diameter at 15 F and working channel diameter at 11.55 F. The length of the UAS is 20-45 cm.

This patented system can precisely regulate the infusion flow and control the vacuum suc-

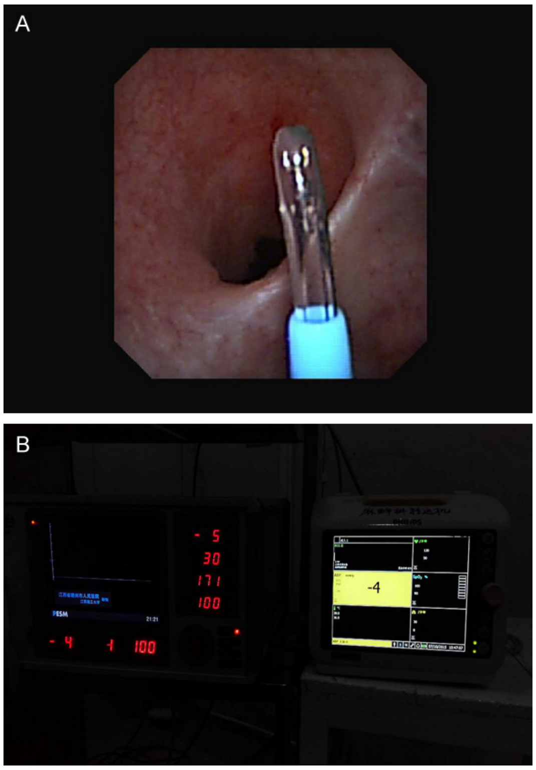

Figure 2. A. A 6F nephrostomy catheter was placed into renal pelvis for pressure measuring. B. Intrarenal pressure measured by 2 different methods (Left, platform connected to UAS; Right, pressure monitor connected to nephrostomy).

tioning by computerized real-time recording and monitoring of the RPP through pressure feedback, ensuring a stable RPP.

Animal model

Eight young female pigs (Meishan pig breeds Co., Ltd., Kunshan, China, weight 37.7-50.1 kg) were used for this study. All procedures were performed under general anesthesia with endotracheal intubation using intramuscularly injected ketamine (30 mg/kg), xylazine (2 mg/kg), and atropine (0.05 mg/kg), and intravenously injected propofol (2.5 mg/kg). The anesthetized pigs were placed on the dorsal lithotomy position [9].

Initially, a semi-rigid ureteroscopy was performed with an 8/9.8 F ureteroscope (Richard Wolf, Germany) and a 0.032-inch guidewire was inserted into the renal collecting system. Next, the semi-rigid ureteroscope was withdrawn and the patented UAS (9.5/11.5 F) with a pressure-sensitive tip was inserted into the proximal ureter along the guidewire without fluoroscopic guidance. A flexible ureteroscope (Storz, Germany) was then inserted into the sheath to do a comprehensive inspection of intrathecal delivery location of the transparent sheath, and mucosa of ureter and renal pelvis. We then retrogradely placed stone material (each approximately 5 mm in size) into each renal pelvis of the pig using the flexible ureteroscope and a nitinol basket. Lithotripsy was then performed using a 200-μm holmium: YAG laser fiber at 0.8 J/pulse with a frequency of 20 pulses/s (Lumenis).

Measurements

Via a small subcostal incision the kidney was identified retroperitoneally. Through a needle puncture into the renal pelvis, a guidewire was placed, serving as a guide for placing a 6 F nephrostomy catheter for RPP measurement (**Figure 2A**). A purse-string suture was used to close the site of the needle puncture. The subcostal incision was then approximated. The catheter was then connected to pressure transducers placed at the kidney level. Like the electrocardiogram electrodes they were connected to an amplifier and monitor (Mindray-PM9000) (**Figure 2B**). For RPP measured by the platform, pressure data were collected by the platform through the pressure sensor at the front end of the UAS (**Figure 2B**). Platform selection mode was set as fully automatic. Perfusion flow was set at 100 ml/min. RPP control value was set at -5 mmHg. RPP warning value was set at 20 mmHg, and the maximum (limit) value was set at 30 mmHg. Renal pelvic pressure by the nephrostomy catheter was measured every second yielding 60 measurements/min. Pressure by the platform was measured at 6 times per second.

Data collection

To make proper comparisons of data, three standardized study periods were defined during the procedures as below: Baseline period, two-minute period prior to ureteroscopic instrumentation was used for baseline RPP measurement; Irrigation and suctioning period, five-minute period of ureteroscopy without stone disintegration when the initiating perfusion flow was set at 100 mL/min, intraluminal pressure control value was set at -5 mmHg and intraluminal pressure warning value was set at 30 mmHg; Therapeutic period, five-minute period of stone disintegration and removal using Holmium laser and stone basket.

Table 1. Mean RPP observed during different phases of ureterorenoscopy

Group	Baseline (mmHg)	Irrigation and suction period (mmHg.)	Therapeutic period (mmHg)
Platform	26.9±3.8	-5.21±2.11	-5.81±2.47
Nephrostomy	26.3±5.2	-3.59±1.45	-3.73±2.19
P	0.86	0.42	0.39

Statistics

Statistical analysis was performed using SPSS 16.0 software. The results were analyzed using paired two tailed tests for paired comparisons, with statistical significance considered at $P < 0.05$. All measurement data with normal distribution were recorded as mean ± standard deviation (SD).

Results

The study comprised 16 macroscopically normal upper urinary tract systems; four renal pelves were excluded, three due to complicated bleeding while placing the nephrostomy catheter or the UAS, and one due to difficulty in placing the UAS through a stenosed ureter. Thus studies were completed in 12 renal pelves.

The mean RPP values through the two different methods of RPP measurement are presented in **Table 1** for baseline period, irrigation and suctioning period and therapeutic period, respectively. There was no statistically significant difference between the two groups at different periods.

Discussion

Renal pelvic pressure generally remains lower than the backflow level (30 mmHg) during minimally invasive percutaneous nephrolithotomy. However, the probability of intraoperative RPP increase is higher in flexible URS due to the fact that the channel being smaller and longer for the outflow. Any factors that brought about poor drainage would result in temporarily elevated RPP greater than 30 mmHg, and many such occurrences of high pressure would have an accumulating effect, which means enough backflow to cause bacteremia and postoperative fever [3, 10]. High RPP is the risk factor for SIRS [4]. Also, fluid absorption can occur through pyelovenous-lymphatic backflow, pyelotubular backflow, and forniceal rupture as a result of high RPP [11]. The absorption of perfusion fluid is a high risk factor for postoperative fever [12]. Serious operative complications such as urosepsis also occurred despite the rate are small, for 0-4.5%. However, once it happened, the mortality rate was as high as 20% [13], which required extended hospitalization, supplementary medication, or extended instrumentation. Therefore, control of RPP is critical in preventing serious complications. To directly address the issue of high pressure within renal pelvis and to improve the lithotripsy efficiency, we were able to design the irrigation and suctioning platform with function of pressure feedback and the suctioning UAS with function of pressure-measuring to monitor and control intrarenal pressure intelligently. On the platform, intraoperative required perfusion flow, intraluminal pressure control value, and intraluminal pressure warning value can be preset before the surgery. Intraluminal pressure was collected by the suctioning sheath and delivered to the platform. Vacuum suctioning power was then automatically adjusted by the platform through pressure feedback technology to regulate the intraluminal pressure. The principles of the intelligent pressure control include the followings: 1. When the intraluminal pressure is less than the control value, vacuum suctioning stops working; 2. When the intraluminal pressure is at a value between the control value and the warning value, suctioning power is adjusted according to the intraluminal pressure value to maintain the intraluminal value at a preset safety range; 3. When for a variety of reasons the intraluminal pressure is higher than the warning pressure, alarm will be activated and the system will automatically shut down for protection. The system cannot be restarted for operation until the intraluminal pressure goes back to the safety range.

The normal pelvic pressure in pigs was well characterized at 5-15 mmHg [14]. Renal backflow and thereby potential renal damage and septic complications had been shown to occur in pigs at pressure of 35-45 mmHg [15, 16]. We chose pigs as our experimental subjects in this study since the characteristics of their RPP are very similar to that of human. In this study, baseline RPP was found to be higher than 5-15 mmHg, which may be due to poor drainage of renal pelvic liquids after placing the UAS. The RPP values measured by the platform during irrigation and suctioning period and lithotripsy phase were smaller than those values measured by the nephrostomy catheter but no statistical difference. The contributing factors for this slight difference between the 2 groups may include quick clearance of liquids surrounding the pressure sensor at the front end of the UAS by vacuum suctioning and possible instant perfusion lash to the nephrostomy catheter when the flexible ureteroscope was very close to the catheter. Regardless, the lack of statistical differences between the 2 groups in three phases of the surgery implicates that the accuracy and reliability of the measured pressure values in different phases of the surgery by the platform. According to Helene Jung's report, there was significant difference in RPP values measured at two different phases of the surgery when the perfusion flow rate was at 8 mL/min. In her report, mean RPP values were 35 (±10) mmHg and 54 (±18) mmHg during simple ureterorenoscopy phase and stone management phase, respectively [17]. In our study, we found that RPP could be controlled within preset safety range in both irrigation and suctioning phase and lithotripsy phase at a high perfusion flow rate of 100 mL/min, which indicates that the RPP can be accurately and efficiently monitored and controlled by our technique. In addition, there are advantages of vacuum suctioning and perfusion flow presetting by using our devices. The lithotripsy efficacy is increased with the vacuum suctioning since the liquids and powderized gravels inside the renal pelvis can be sucked out more quickly. The hands-free irrigation and suctioning device has the advantages of simple operation and ability of meeting the need of continuous perfusion flow for continuous graveling of stone, to ensure clear operative field, improve stone crushing efficiency and shorten operative time.

Limitation of our study still exists. The diameters of the pigs' ureters in this study were generally larger than that of human, which made the pressure measuring point of the suctioning sheath at the renal pelvic outlet not easy to be blocked by gravel particles or other tissue. With each calyceal mouth relatively open, pressure feedback was able to control suctioning power timely, therefore intrarenal pressure was controlled within the preset range. In clinical setting, there are patients with relatively narrowed renal pelvic outlets which will make it difficult to advance the UAS and the pressure value collected from the front end of the sheath cannot reflect the intrarenal pressure value timely, resulting in high cumulative time of high intrarenal pressure and possible complications. If the sheath can smoothly be introduced into the renal pelvic outlet, the devices can timely and accurately control the pressure within the kidney, make the operation safer and more efficient. There are also patients with small renal calyx (calyces). In this group of patients, after inserting flexible ureteroscope to the narrowed renal calyx, the gap between the scope and calyceal mouth is small and liquid suctioning is not smooth, easy to cause increased calyceal pressure which cannot be found timely. The other drawback of this study is that we did not test whether the RPP can be controlled within preset safety range at different perfusion flow rates. We will do further research on this in our future study.

In summary, the results of this study indicate that the application of the intelligent control devices can keep the intrapelvic pressure constant at the preset safety range while meeting the perfusion flow rate required in operation. Creating a new intelligent pressure control device to monitor and control intrarenal pressure during operation can reduce the complications of intrarenal high pressure, and improve operative efficiency. The device is theoretically able to avoid potential gravel "snowstorm" effect during lithotripsy and prevent stone migration, with ability to suck gravel particles under negative pressure, which is worthy of further research.

Conclusion

Renal pelvic pressure could be accurately and effectively monitored and controlled using the medical irrigation and suctioning platform with function of pressure feedback and suctioning ureteral access sheath with function of pressure-measuring. We believe suctioning flexible URS with automatic control of RPP is feasible.

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Disclosure of conflict of interest

None.

Authors' contribution

Protocol/project development: Song, Deng, Xie, Huang, Zhu, Su, Ye. Data collection or management: Song, Deng, Huang, Zhu, Su, Liao, Zhang, Wang, Fan, Peng, Yang, Liu. Data analysis: Deng, Su, Xie. Manuscript writing/editing: Xie, Deng, Song.

Abbreviations

URS, ureteroscopy; RRP, renal pelvic pressure; UAS, ureteral access sheath.

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References

[1] Marshall VF. Fiber optics in urology. J Urol 1964; 91: 110-114.
[2] Donaldson JF, Lardas M, Scrimgeour D, Stewart F, MacLennan S, Lam TB, McClinton S. Systematic review and meta-analysis of the clinical effectiveness of shock wave lithotripsy, retrograde intrarenal surgery, and percutaneous nephrolithotomy for lower-pole renal stones. Eur Urol 2015; 67: 612-616.
[3] Zhong W, Zeng G, Wu K, Li X, Chen W, Yang H. Does a smaller tract in percutaneous nephrolithotomy contribute to high renal pelvic pressure and postoperative fever? J Endourol 2008; 22: 2147-5151.
[4] Zhong W, Leto G, Wang L, Zeng G. Systemic inflammatory response syndrome after flexible ureteroscopic lithotripsy: a study of risk factors. J Endourol 2015; 29: 25-58.
[5] De La Rosette J, Denstedt J, Geavlete P, Keeley F, Matsuda T, Pearle M, Preminger G, Traxer O. The clinical research office of the endourological society ureteroscopy global study: indications, complications, and outcomes in 11,885 patients. J Endourol 2014; 28: 131-139.
[6] Lim DJ, Shattuck MC, Cook WA. Pyelovenous lymphatic migration of transitional cell carcinoma following flexible ureterorenoscopy. J Urol 1993; 149: 109-111.
[7] Auge BK, Pietrow PK, Lallas CD, Raj GV, Santa-Cruz RW, Preminger GM. Ureteral access sheath provides protection against elevated renal pressures during routine flexible ureteroscopic stone manipulation. J Endourol 2004; 18: 33-36.
[8] Rehman J, Monga M, Landman J, Lee DI, Felfela T, Conradie MC, Srinivas R, Sundaram CP, Clayman RV. Characterization of intrapelvic pressure during ureteropyeloscopy with ureteral access sheaths. Urology 2003; 61: 713-718.
[9] Tunc L, Resorlu B, Unsal A, Oguz U, Diri A, Gozen AS, Bedir S, Ozgok Y. In vivo porcine model for practicing retrograde intrarenal surgery. Urol Int 2014; 92: 64-67.
[10] Guohua Z, Wen Z, Xun L, Wenzhong C, Yongzhong H, Zhaohui H, Ming L, Kaijun W. The influence of minimally invasive percutaneous nephrolithotomy on renal pelvic pressure in vivo. Surg Laparosc Endosc Percutan Tech 2007; 17: 307-310.
[11] Hinman F, Redewill FH. Pyelovenous back flow. Journal of the American Medical Association 1926; 87: 1287-1293.
[12] Kukreja RA, Desai MR, Sabnis RB, Patel SH. Fluid absorption during percutaneous nephrolithotomy: does it matter? J Endourol 2002; 16: 221-524.
[13] Levy MM, Artigas A, Phillips GS, Rhodes A, Beale R, Osborn T, Vincent JL, Townsend S, Lemeshow S, Dellinger RP. Outcomes of the Surviving Sepsis Campaign in intensive care units in the USA and Europe: a prospective cohort study. Lancet Infect Dis 2012; 12: 919-924.
[14] Mortensen J, Bisballe S, Jorgensen TM, Tagehoj-Jensen F, Djurhuus JC. The normal pressure-flow relationship of pyeloureter in the pig. Urol Int 1982; 37: 68-72.
[15] Schwalb DM, Eshghi M, Davidian M, Franco I. Morphological and physiological changes in the urinary tract associated with ureteral dilation and ureteropyeloscopy: an experimental study. J Urol 1993; 149: 1576-1585.
[16] Sonda LP, Fischer CP, Gross MD, Skinner RW. Pyelovenous backflow: implications for coagulum pyelolithotomy and nephroscopy. J Urol 1985; 133: 894-896.
[17] Jung H, Osther PJ. Intraluminal pressure profiles during flexible ureterorenoscopy. Springerplus 2015; 4: 373.