Original Article

Development of an innovative intrarenal pressure regulation system for mini-PCNL: A preliminary study

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ABSTRACT

Introduction: Miniaturized percutaneous nephrolithotomy (mini-PCNL) requires saline irrigation at high-pressures to maintain visual clarity. However, this may raise the intrarenal pelvic pressures (IRPs) beyond a safe range and may result in a higher complication rate. The aim of this study was to make and validate an automated pressure saline irrigation system to regulate IRPs during mini-PCNL.

Materials and Methods: A ureteric catheter was connected to an urodynamic machine and the minimum, maximum, and average IRPs reached during a standard 15 Fr mini-PCNL were measured in ten cases. Next, an intrarenal pressure regulation system (IPRS) was conceptualized, designed, patented, and constructed. IPRS was then tested on a mannequin model using the routine instruments. Lastly, the IPRS was evaluated on – five cases of 15 Fr mini-PCNL. The mean maximum IRP as recorded in the baseline data was set as the maximum permissible pressure on IPRS. The efficacy of IPRS was assessed by measuring the IRP, recorded in parallel, on both the IPRS and the urodynamic machine at various stages of the procedure.

Results: The mean maximum IRP reached during baseline evaluation was 25 cm of water which was set as the maximum permissible limit of the IPRS. Evaluation of the IRPS on mannequin models and validation clinical cases showed that IPRS measured the IRP accurately and prevented the pressure surge above the set limits Overall, higher IRPs were recorded during stone pulverization as compared to the other surgical steps.

Conclusions: The current IPRS is the first of its kind open platform, portable, automated pressure saline irrigation system. It precisely monitors and controls the IRP and has the potential to reduce the irrigation pressure-related complications.

INTRODUCTION

Percutaneous renal stone surgery is witnessing a shift toward miniaturization. This has mandated the use of high-pressure irrigation systems to maintain adequate visual clarity, which have the potential to raise the intrapelvic pressures beyond a safe range during endoscopy. Most of the pressure pumps deliver a fixed flow rate and lack pressure regulation/control unit, and may predispose the patients to complications related to high intrarenal pressures (IRPs), namely fornicial tears, septicemia, and hemorrhage etc., Wu *et al.* measured the IRPs during standard (24 Fr) and mini-PCNL (18 Fr) and found that pressures >30cm of H2O were a risk factor for postoperative fever.[1] Tokas *et al.* found that during mini-PCNL the IRPs ranged from 10 to 45 cm of water.[2] Alsmadi *et al.* found the renal pelvic pressure to be 19.51 ± 5.83 mmHg during 14 Fr supermini-PCNL using a suction irrigation sheath.[3]

We aimed to develop an open platform, portable, automated pressure saline irrigation system which would allow the surgeon to control intrarenal pelvic pressures during

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mini-percutaneous nephrolithotomy (mini-PCNL). We planned to design, prototype, and validate our portable intra-renal pressure (IRP) monitoring and regulation system which would prevent irrigation pressure related complications of mini-PCNL.

MATERIALS AND METHODS

The whole project was planned in four phases and ethics committee approval was taken prior to commencement of the study (IOU/EC/05/2017/2).

Phase 1: Prospective pilot study to assess the IRP during 15 Fr (internal diameter) mini-PCNL

The intrarenal pressure measurement module of the IPRS was developed first and used for measurement of the intrarenal pressures. Ten otherwise standard cases between 25 and 35 years of age, undergoing 15 Fr mini-PCNL for stone disease in prone position, with gravity-assisted irrigation were included in the study. A 6Fr open-ended ureteric catheter was inserted into the renal pelvis above the pelviureteric junction. After puncture and successful sheath placement, irrigation was started with fluid bottles placed 60 cm above the renal pelvis. An urodynamic machine and the intrarenal pressure regulation system (IPRS) were connected in parallel with the open-ended ureteric catheter to continuously monitor the minimum, maximum and average IRP throughout the procedure. These pressures were considered as the usual IRPs for the given size (15 Fr) of the mini-PCNL. For safety purposes, this mean of maximum pressures in each case was used as the maximum permissible pressure level during initial clinical evaluation of IPRS in Phase 4. If pressurized irrigation was required to maintain visual clarity for any reason or there was hemorrhage, that particular case was excluded from the analysis.

Phase 2: Prototyping of the IPRS

Once testing of the sensing system of the IPRS was successfully possible, we went on to design the module which converted the commercially available pump into a slave pump. The module then would control the speed of the pump. Both the modules were then finally incorporated and used in phases 3 and 4. The IPRS prototype [Figure 1] comprises of different subunits organized into a single cabinet.

Pressure transducer

A fluid pressure-measuring device which is connected to the open-ended catheter. The transducer converts hydrostatic pressure into interpretable electrical signals which are recognized by 'Board A'.

Board A

A pressure recording board. It collects pressure data from the pressure transducer and thus gets the pressure data from the renal pelvis. The renal pelvic pressure is displayed real time onto the front panel of the IPRS. A parallel feed of the data is amplified and fed into 'Board B'.

Board B

An intermediate board which interprets data received from 'Board A' and converts it into feeds which are interpretable by 'Board C'.

Board C

This receives data from Board B. It has an integrated circuit-based circuitry which titrates the power supply of the pressure pump and controls it, thus converting the commercial pressure pump into a slave unit.

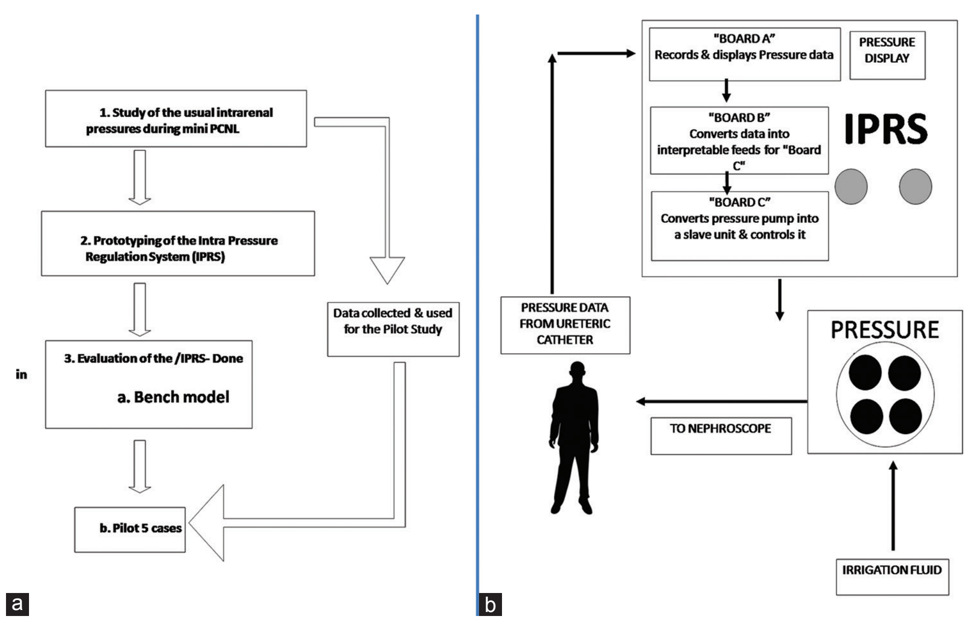

Figure 1: Intrarenal pressure regulation system study plan and prototype. (a) IPRS Study Plan, (b) Schematic representation of IPRS Prototype

Phase 3: Evaluation of the IPRS on the bench model:

The IPRS was tested on a stone manipulation simulator. The simulator has a silicon kidney with a ureter mounted into a mannequin and allows the surgeon to carry out nephroscopy and stone manipulation in a bench environment. Setting up the IPRS: the mannequin was placed prone. A 6 Fr open-ended catheter was placed up the ureter into the renal pelvis above the pelviureteric junction. The pressure sensor was flushed with saline to remove any air bubbles. The open-ended ureteric catheter was flushed with saline to remove any air bubbles and was connected to the pressure sensor. This facility allowed the pressure sensor to record the IRPs. The pressure lines were connected such that the pressures can be simultaneously measured by the IPRS and the urodynamic machine. The irrigation fluid from the slave pressure pump outlet was connected to the inlet of the nephroscope. This was followed by pump calibration; the pump speed was set to minimum. The required pressure limit (10–50 cm of water) was set. The IPRS and the pressure pump were switched "ON" and the IPRS displays a pressure reading. "Tare" button is pressed and zero calibration ("00:00" displayed on the screen) is observed. The Auto Zero button is pressed twice and the pump speed is increased as desired. The pump auto adjusts its speed and pressure during the PCNL as indicated by the red light emitting diode and the continuous pressure reading display on the IPRS. With the nephroscopy in progress, continuous intrapelvic pressure monitoring was performed using the IPRS. The space between the PCNL sheath and the nephroscope was blocked for 5 s to block the outflow which results in an increase in the intrapelvic pressure. The intrapelvic pressure changes and the ability of the IPRS to compensate for the same were studied. Continuous intrapelvic pressure readings were recorded from the urodynamic machine and the IPRS along with the IPRS response to sheath occlusion. The pressure limits of the IPRS were then set to 10, 20, 30, 40, and 50 cm of water and the study was repeated and successful functioning of the IPRS was confirmed before proceeding to Phase 4.

Phase 4: Testing

Five standard patients aged between 25 and 35 years, undergoing 15 Fr mini-PCNL in prone position, were included in the study. Open-ended ureteric catheter was placed into the renal pelvis for retrograde pyelography. The desired calyx was punctured, dilated and a 15Fr sheath was placed. The IPRS trolley [Figure 2] was then wheeled in and the setup was completed as described above. The maximum pressure limit was set to 25 cm of water (mean maximum pressure recorded during Phase 1 of the study). The PCNL was then completed using the IPRS. All the parameters described in the previous phase were recorded. The data was evaluated separately for the following three parts of the mini-PCNL procedure: (a) after successful sheath and endoscope placement but before pulverization, (b) during pulverization (assistant occluding sheath) and (c) postpulverization, and during antegrade stenting. During each part of the PCNL step, the space between the nephroscope and the sheath was occluded for 5 s, to block the outlet and increase the intrapelvic pressure till maximum set value to demonstrate the efficiency of pump regulation i.e. stoppage of irrigation within few seconds as soon as the maximum set pressures are reached. Any case with intraoperative hemorrhage, infection, or those which required higher intraoperative irrigation pressures to maintain visual clarity were later excluded from the study

RESULTS

The results for Phase 1, 3, and 4 were analyzed with respect to efficacy of the IPRS to monitor the intrapelvic pressures, to shut off the pressure pump when the IRP exceeds the set pressures, and to maintain the maximum set intrapelvic flow when the pressures were below the maximum set pressures.

Phase 1: The minimum and maximum IRPs as measured by the IPRS and the urodynamic machine were comparable (with no statistically significant difference) and shows the accuracy of IPRS to monitor the IRPs [Table 1]. The mean of maximum pressures recorded during the cases was 25 cm of water.

Phase 3: Table 2 shows the set maximum pressures and the minimum and maximum reading displayed on the IPRS. The maximum set pressures and the actual maximum IRPs recorded correlated on the bench model and the IRPs did not increase above the set limit of 10, 20, 30, 40, and 50 cm

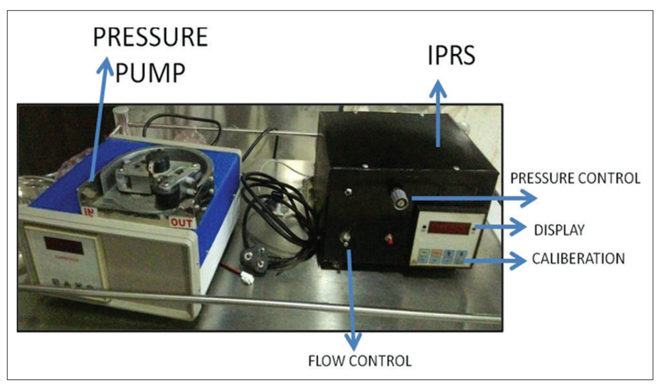

Figure 2: Intrarenal pressure regulation system – assembly

Table 1: Step 1. Pilot study to assess the intrarenal pressure during 15 Fr mini-percutaneous nephrolithotomy

Patient Number	IRPs (min-max) (cm of water)	Urodynamics (min-max) (cm of water)
Case 1	11–27	12–26
Case 2	13–25	12–27
Case 3	14–24	12–24
Case 4	12–26	12–26
Case 5	11–23	13–23
Average	12.2–25	12.2–25.2

IRPs: Increased intrarenal pressure; min – minimum; max – maximum; cm - centimeters of water respectively. The IPRS response to sheath occlusion is depicted in Figure 3.

Phase 4: during all three stages of the surgery, the maximum recorded pressures never exceeded the set limit of 25 cm of water [Table 3]. The minimum recorded pressures remained a little higher during the stone pulverization part of mini-PCNL.

No patient developed complications of the high pressure irrigation such as fever, signs of fluid intravasation, etc.

DISCUSSION

Mini-PCNL is rapidly becoming popular because of its smaller tract size, minimal trauma to the patient, and reduced bleeding.[4] However, it is associated with a higher IRP as compared to the standard PCNL.[2] Raised IRP during percutaneous endoscopic surgeries can result in complications such as pyelorenal backflow, intraoperative bacteremia, sepsis, and renal damage. The extent of injury is directly related to the IRPs reached, duration of the raised IRPs, and concomitant obstruction.[5-8] Alsyouf *et al.* in 2018 demonstrated that decreased IRPs are associated with less postoperative pain and shorter hospital stay. This mandates monitoring and limiting of IRPs especially when a a high flow irrigation system is used.[9] Wu *et al.* studied the renal pelvic pressures and the incidence of postoperative fever in the patients undergoing standard PCNL and mini-PCNL (tract size 18 Fr) and concluded that smaller the tract size higher are intrapelvic pressure and the chances of postoperative fever. Duration (>60 s) of raised renal pelvic pressure >30 mmHg also predicts the chances of postoperative fever, irrespective of the tract size.[1] Guo *et al.* in 2008 reported that higher intrapelvic pressures >30 mmHg for >10 min is associated with higher incidence of complications during mini-PCNL.[10]

The present study was conducted to validate our pressure regulation system which addresses the issues related to miniaturization of the tract in PCNL. The IPRS monitors and displays the IRPs and regulates the irrigation pressures during the procedure. The feed obtained from ureteric catheter placed in the pelvis is used to control the pressure pump. Thus, it employs source-to-source principle (STS principle), i.e., it directly records pressures from source (renal pelvis) and intelligently controls the source of the pressure, i.e., the pressure pump, restricting a surge in intrapelvic pressure in real time.

The infusion flow rate and the desired intrapelvic pressures can be fed into the device preoperatively. The IPRS then controls the flow of the irrigation fluid being pumped into the nephroscope allowing IRP to be maintained within the preset safety range, thus avoiding complications related to high pressure.

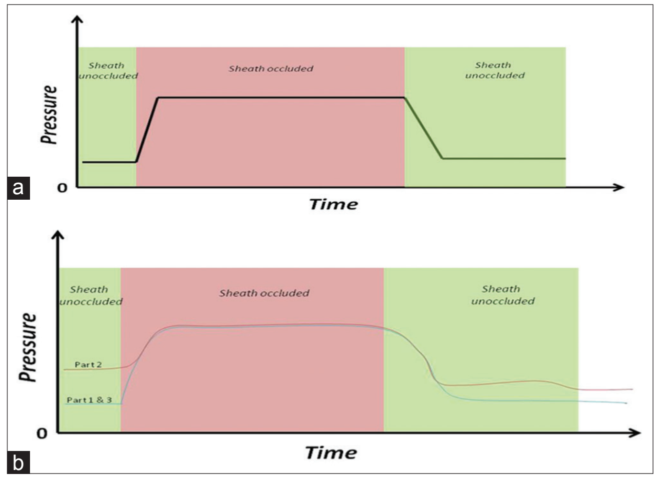

Figure 3: Intrarenal pressure regulation systems response to sheath occlusion. (a) During phase 3 testing - on bench model (b) During phase 4 testing - during Mini-PCNL

Table 2: Step 3. Evaluation of the Intra-renal Pressure Regulating System in the bench model

Set pressure (cm water)	10	20	30	40	50
Average recorded pressures (minimum-maximum)	8–11	12–20	15–30	15–40	15–50

Table 3: Phase 4. Initial clinical evaluation of the intrarenal pressure regulation system

Pressure recorded during parts of mini-PCNL	Patient number				
	1	2	3	4	5
Part 1 (cm of water) (min-max)-	15–25	16–25	18–25	15–25	17–25
Part 2 (cm of water) (min-max)	17–25	18–25	21–25	15–25	19–25
Part 3 (cm of water) (min-max)	14–25	15–25	19–25	14–25	17–25

The study was conducted in four phases. In the initial phase, the basic data of IRP during mini-PCNL was collected. The maximum value was used as a guide to set the maximum permissible pressures during the clinical evaluation phase of the study. The pressures recorded by the IPRS were also simultaneously compared with the pressures recorded by the urodynamic system. The values monitored by both the equipment were found to be comparable and consistent.

The efficacy of IPRS was then evaluated in a bench model before using it on actual patients. During the bench procedure, the IRP was increased by manually occluding the sheath outlet. It was observed that the pressure pump continued to operate at the same flow till the intrapelvic pressure reached within 5 cm of the upper set pressure limit. As the pressure rose within 5 cm of the set limit, the pump slowed down or pumped intermittently till the maximum set pressure was reached, when the pump stopped , thus decreasing the time for which the pressures remained high. When the occlusion was released and the IRP dropped, the pump would gradually restart the irrigation. This showed the efficacy of the IPRS in preventing a pressure surge during mini-PCNL.

During the initial clinical evaluation, the sheath was transiently occluded. It was observed that the pump responded similarly as discussed earlier [Table 3]. The IPRS successfully controlled the pump speed as the IRP gradually rose and stopped the irrigation. The findings during bench evaluation were confirmed in this step, and the surgeon could carry on the nephroscopy without the fear of exceeding the IRP limits.

In the present study, a PCNL system with a sheath of 15 Fr internal diameter was used. Further studies with different sheath sizes and larger number of patients may be required to better define the efficacy and safety of IPRS.

In our experience the IPRS can accurately monitor the IRP and effectively control the irrigation pump speed to maintain the IRP within a predefined upper limit.

CONCLUSIONS

Our IPRS is the first of its kind open platform, portable unit employing the "STS principle." It can be added on to the commercially available pressure pumps. This makes it affordable and universally adaptable and applicable. It precisely monitors and controls the IRP. It has the potential to reduce the complications related to high irrigation pressures associated with mini-PCNL. The idea could be extrapolated in the near future to flexible ureteroscopes also.

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