

Original Research Article

Study of the safety and efficacy of minimally invasive percutaneous nephrolithotomy in the management of large and complex renal stone

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ABSTRACT

Background: Nephrolithiasis is highly prevalent across all demographic groups in the india and beyond, and its incidence rates are rising. In addition to the morbidity of the acute event, stone disease often becomes a lifelong problem that requires preventative therapy to diminish ongoing morbidity. Objective of this study to evaluate the safety and efficacy of minimally invasive percutaneous nephrolithotomy (PCNL) in the management of large and complex renal stone.

Methods: This retrospective study includes 75 renal calculi patients with 100 renal units with large and complicated stone >20 mm. Stones were classified into simple (isolated renal pelvis or isolated calyceal stones) or complex (partial or complete stag horn stones, renal pelvis stones with accompanying calyceal stones). Then various parameter like decrease haemoglobin, surgical complication, creatinine level, duration of surgery etc were compared between simple and complex stones patients by calculation p value using online student t test calculator. P value less than 0.01 considered as a difference of significance.

Results: The mean stone size was 35.5±20.37 mm and mean operative duration was 60±35.3 min. In all, cases 60 (80%) were stone-free after the first procedure and another 10 needed an auxiliary procedure (5 second-look PCNL, 3 extracorporeal shockwave lithotripsy-ESWL, 2 ureterorenoscopy, and) to become stone-free, resulting in a 93.33% stone-free rate. Complications occurred in 9 procedures (12%).

Conclusions: From this study, it would be concluded that Minimally invasive PCNL provided significantly higher stone-free rate and efficiency quotient for management of urinary calculi. Overall complications are usually observed in patients having intraoperative hypotension and increased intra operative time.

Keywords: Complex ad large renal stone, Percutaneous nephrolithotomy, Safety and efficacy

INTRODUCTION

Nephrolithiasis is the most common chronic kidney condition, after hypertension, and an ancient one: treatments for patients with stones have been described since the earliest medical texts. Stones are a preventable cause of morbidity.¹ The reasons for the increasing prevalence are not clear, but one factor may be increased rates of obesity, as risk of stones increases along with body mass index and waist circumference, especially in

women. Both inherited and environmental factors play a role in stone formation.²

Percutaneous nephrolithotomy (PCNL), a minimally invasive method for removal of renal calculi, was initially started in the 1950s but gained popularity about two decades later and has now become standard practice for management.^{3,4} There has been an immense improvement in technique and various guidelines have been established for treatment of renal stones. However, it has its own

share of complications which can be attributed to surgical technique as well as anaesthesia related complications.

PCNL is the treatment of choice for large stone. PCNL attains stone free rates of up to 95%. AUA guidelines recommend PCNL as a treatment of choice for staghorn calculi. Larger stones in the lower pole are best managed by PCNL as the first treatment option.⁵ Given its decreased morbidity, lower cost, and shorter duration of hospitalization compared to open, PCNL has rendered open stone extraction obsolete.⁶ In an era when the demographics of the general populace are leading to the production of larger stones in unhealthier patients, PCNL is more relevant than ever.

So, authors have done this study to evaluate the safety and efficacy of minimally invasive PCNL in the management of large and complex renal stone.

METHODS

This retrospective study was conducted at Parul sevashram hospital, Parul institute of Medical science and research, Vadodara, Gujarat from June 2016- July 2018.

Inclusion criteria

Study includes total 75 patients of renal calculi who visited urosurgery OPD of Parul sevashram hospital, Vadodara, Gujarat, India.

Exclusion criteria

Patients with a single kidney or a congenital malformation and in whom more than one caliceal puncture was performed were excluded.

All patients underwent MIP prone using the modular miniature nephroscope system with automatic pressure control by Nagele (Karl Storz, Germany) as follows. After retrograde placement of a ureteric balloon occlusion catheter proximal to the PUJ in lithotomy position, patients were placed prone with an inflatable cushion placed just caudally to the xiphoid. Percutaneous access was obtained under ultrasonographic and fluoroscopic guidance. Single-step dilatation with a 16 F metal dilator was applied and then an 18 F metal Amplatz sheath was introduced. Using the 12 F nephroscope, stones were fragmented by pneumatic ballistic lithotripsy (Swiss Lithoclast-EMS, Switzerland) under vision and stone fragments were evacuated under continuous irrigation without additional pressure or suction using the hydrodynamic effects of the PCNL system. Only if fragments adhered to the parenchyma, a 2.4-F tipless nitinol basket (Zero Tip, Boston Scientific, USA) was used for stone retrieval.

At the end of the procedure, the balloon occlusion catheter was removed, and a JJ stent was placed antegradely. The Amplatz sheath was withdrawn and

usually the tract was closed using a gelatine matrix haemostatic sealant (GMHS; Baxter, Germany). The skin incisions were closed with adhesive skin closures.

Generally renal access was gained through the posterior lower calyx. If complete stone clearance via this access was not achievable, either flexible nephroscopy (Flex X2, Karl Storz, Germany) and laser lithotripsy through the 18F sheath was performed or, in case of a remaining large stone burden, a second access using a 15F Amplatz sheath was placed under ultrasonographic and fluoroscopic control in the middle or upper calyx. In cases of remaining large fragments at the end of the manoeuvre, the access tract was not closed but a 12 F nephrostomy tube was placed to allow for a second-look PCNL 2 - 3 days later.

Patients were examined with plain X-ray (of the kidneys, ureters and bladder) and abdominal ultrasonography on the first postoperative day. Haemoglobin level, serum creatinine and electrolytes were monitored pre- and postoperatively.

The clinical records were retrospectively reviewed for the following clinical parameters: stone complexity, operative duration (defined as the time from puncture to closure of the access tract), fluoroscopy time, decrease in haemoglobin level, hospital stay, stone-free rate and complications.

Stone complexity was recorded according to the scoring system described by Tefekli et al. in 2008.⁷ Stones were classified as simple (isolated renal pelvis or isolated calyceal stones) or complex (partial or complete staghorn stones, renal pelvis stones with accompanying calyceal stones) regardless of size. Patients were considered stone-free in the absence of any detectable stone fragment upon nephroscopy at the end of the procedure and on postoperative X-ray and ultrasonography. A complication was defined as any adverse event intraoperatively or ≤ 30 days after the procedure. The grade of complication was determined on the basis of the Clavien classification and its modification for percutaneous procedures.⁸

All collected data analysed statistically to see the significance of difference by calculating p value by using online student t test calculator and $p < 0.01$ was considered to indicate statistical significance.

RESULTS

Study included total 75 patients of renal calculi who visited urosurgery OPD of Parul Sevashram Hospital, Vadodara, Gujarat from 2016-2018.

The mean 35.5 ± 20.37 stone size mm. Among total 75 patients of renal calculi, 53 (70%) were classified as a complex stone and 22 (30%) were classified as a simple stone.

In 65 cases (87%), a single tract procedure was carried out. In 6 cases (9%), two tracts were used and in 4 cases (4%) three access sheaths were inserted simultaneously. All punctures of the lower and the middle calyx were subcostal; none of the punctures was above the 11th intercostal space.

The mean operative duration for all 75 renal units was 60±35.3 min and fluoroscopy time 213.5±40.5 second.

The p value for mean operative duration between simple and complex stone was not significant ($p > 0.001$).

The mean operative duration in complex stones and simple stone was 104±45 and 92±40 min ($p > 0.001$) (Table 1).

Table 1 : Univariate analysis of patients' characteristics and treatment results for simple and complex stones.

Variables	Simple stones	Complex stones	P value
Total number	22	53	-
Mean age (years)	47.30	48.50	>0.001 (NS)
Gender M:F	18:14	28:25	>0.001 (NS)
Mean decrease in haemoglobin (g/dl)	1.6	1.6	>0.001 (NS)
Mean fluoroscopy time (sec)	218±160.5	209±135.4	>0.001 (NS)
Stone free, N (%)			
Primary	21.80 (99)	39.75 (75)	<0.001 (NS)
With second-look MIP	-	5 (6.6)	
With any auxiliary procedure	22(100)	50(94.33)	>0.001 (NS)
Multiple access MIP	1	9	>0.001 (NS)
Complications, N (%)	3 (13.63)	6 (11.32)	>0.001 (NS)

Table 2: Intra and postoperative complications for simple and complex stones.

	Clavien grade	Simple stone	Complex	Total
Fever >38 °C	I	1	2	3
Gross hematuria	II	1	1	2
Urinoma requiring JJ stent	IIIb	0	1	1
Bladder haematoma requiring cystoscopic evacuation	IIIb	0	0	0
Transfusion	II	0	1	1
Perinephric haematoma	II	0	0	0
Extravasation treated conservatively	II	1	1	2
Angioembolisation	II	0	0	0
Total		3	6	9

The fluoroscopy time did not differ significantly between the two groups, at 209±135.4 and 218±160.5 sec for complex and simple stones, respectively ($p > 0.001$) (Table 1).

The mean decrease in haemoglobin level, stone free after surgery, complications etc. mentioned in Table 1 and 2.

DISCUSSION

In order to decrease morbidity associated with larger instruments like blood loss, postoperative pain and potential renal damage, a modification of the technique of standard PCNL has been developed. This is performed with a miniature endoscope via a small percutaneous tract (11-20 F) and was named as minimally invasive PCNL or mini-PCNL or mini Perc. Helal et al were the first to describe a technique for pediatric performed on a 2-year-

old premature female child with the use of instruments with smaller access diameters. The method involved sequential dilation to 16 F followed by use of a 15 F vascular peel-away sheath. A 10 F pediatric cystoscope and grasper were used to remove the stones. However, mini-PCNL technique was first developed and accomplished by Jackman et al in the pediatric population with the use of an 11 F access tract.⁸ Since then, the method has become a treatment option for adults as well.^{9,10} Usually, the term mini-PCNL is used for access sheaths below 20 F. However, the terminology has not been standardized yet, and the procedure lacks a clear definition.

Percutaneous access to the renal collecting system leads to a high stone-free rate and is therefore recommended as the treatment of choice for renal stones measuring >20 mm in diameter. PCNL generally is considered a

demanding procedure although safe and effective in experienced hands.

Conventional PCNL is usually carried out through a renal access with a diameter of 24-34 F and a semi-closed irrigating system. Reducing the diameter of the renal access sheath led to the implementation of the mini PCNL-technique. Meanwhile, it has been shown that mini PCNL can reduce blood loss and transfusion rate compared with conventional PCNL.¹¹ In an attempt to further reduce the morbidity of the procedure, the MIP has been established, characterized by a small-bore renal access (18 F), one-step dilatation technique, a continuous low-pressure irrigation allowing for rapid stone retrieval without the use of stone forceps or baskets and finally the direct closure of the renal access without the placement of a nephrostomy tube. The safety, feasibility and efficacy in the treatment of small renal and lower calyceal calculi has been shown earlier. Although the MIP concept leads to complete stone clearance in 92.9% of patients with renal stones of <20 mm, the application in patients with a larger stone burden has been questioned. It has been argued that the smaller access and putatively reduced irrigation flow leads to poorer visibility, difficulties in handling endoscopic graspers and therefore reduced stone clearance.¹² The goal of this retrospective analysis was to determine the safety and efficiency of the MIP concept in treating renal stones with a diameter >20 mm.

A comparative trial in 180 patients undergoing either conventional or mini PCNL found significantly longer OR-times for mini PCNL in simple (89.4 vs 77.0 min), staghorn (134.3 vs 118.9 min) as well as multiple stones (113.9 vs 101.2 min).¹³ In contrast, in a prospective comparative study between conventional and mini PCNL of 50 consecutive patients, Knoll et al noted no significant difference in OR-time between patients operated with an 18 F access sheath than with a 26 F sheath (mini PCNL 48 min vs PCNL 57 min).¹⁴

The primary stone-free rate for all MIP procedures in the present patient population was 80%, with a total stone-free rate of 93.3% with an auxiliary procedure. These results are similar to the stone-free rate in a large multi-institutional international prospective trial carried out by the Clinical Research Office of the Endourological Society (CROES). In 5803 patients undergoing conventional PCNL the stone-free rate was 75.7% with a re-intervention rate of 15.5%.¹³ However, the patient collective is very heterogeneous, including different surgical techniques, e.g. prone and supine PCNL, as well as small stones with a diameter of <20 mm and complete staghorn stones.

Considering that the mean stone size in the present analysis (35.5 mm) was higher than in the aforementioned studies, it can be assumed that stone clearance is not affected by the smaller diameter of the access tract. The stone retrieval using the vacuum cleaner

effect of continuous low-pressure irrigation without the need for endoscopic manipulation with stone graspers might in fact contribute to an effective stone clearance and accelerate the procedure.¹⁴

A comparative trial in 180 patients undergoing either conventional or mini PCNL found significantly longer times for mini PCNL in simple.¹⁵

However, the authors argue that this fact might be attributed to differences in stone burden between the two groups. The mean operating duration in the present study was 60 min.

One major concern in PCNL is significant blood loss and the need for blood transfusions. In the present investigation only 1 of the patients had to receive transfusions (transfusion rate 1.80%). This patient underwent multiple accesses MIP for a staghorn calculus. Contemporary studies state transfusion rates of ≈4.5% and 9% for non-staghorn and staghorn stones, respectively. A reason for the lower transfusion rate in MIP might be the smaller parenchymal trauma and the reduced risk of injuring larger segmental renal vessels with a small-bore dilator during establishment of the access tract. The reduced transfusion rate has also been reported previously.¹⁶

Most of the complications were modified Clavien grade I or II and could be managed conservatively. Grade I complications (mostly temperature >38.0 °C) were significantly more frequent in Complex stones. However, there was a tendency to higher grade complications in complex stones.

The present study investigated the feasibility of MIP for treating large renal stones. Although the data indicate that a minimally invasive approach results in a similar stone-free rate with an acceptable time and a low morbidity, the limitations of a retrospective study without a comparative control population must be considered.

CONCLUSION

From this study, it would be concluded that Minimally invasive percutaneous (PCNL) provided significantly higher stone-free rate and efficiency quotient for management of urinary calculi. Overall complications are usually observed in patients having intraoperative hypotension and increased intra operative time.

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