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Safety and efficacy of mini-percutaneous nephrolithotomy as daycare procedure: a prospective observational study

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Abstract

Background: To evaluate the safety, feasibility of mini-percutaneous nephrolithotomy (mPCNL) being carried out as a daycare surgery and to study the re-admission, stone clearance rate and complication rates following mPCNL. We also sought to find out the rate of requirement of ancillary procedure, after mPCNL.

Methods: In this prospective observational study, easily accessible patients above 18 years of age with renal and/or upper ureteric calculi, who underwent mPCNL between September 2018 and February 2020, were included. Seventy patients were selected, as per statistical methods. Preoperative evaluation including history, blood and urine investigations and radiological images was collected. Intra-operative and post-operative events were analyzed. Written consent was obtained from the patients to participate in the study and to publish their data. Institutional Ethical and scientific committee clearance was obtained.

Results: Out of 70 patients who underwent mPCNL in the study, in the age group ranging from 24–68 years, most of the cases were partial staghorn with maximum size of stone up to about 3.5 cm. Inferior calyx was most frequently punctured. Six cases had multipuncture mPCNL, four patients had bilateral procedure, and two had supra-costal puncture. Eighteen patients had tubeless mPCNL, of which four were totally tubeless procedures. Four patients had hematuria, none requiring transfusion. Two patients had sepsis, managed with higher antibiotics. Limitation of the study was the sample size. To derive a sturdy conclusion, large scale studies are recommended.

Conclusions: We can conclude that mPCNL can be safely done as daycare or ambulatory surgery in properly selected patients. In centers with experienced urologists, bilateral and multipuncture mPCNL can be done as an ambulatory surgery. Thus, this addresses the stone disease as well as cost containment, without patient safety being compromised. Bed occupancy rate is reduced, helping effective utilization of hospital resources.

Keywords: Percutaneous access, Kidney calculi, Ureteral calculi, Daycare

1 Background

High prevalence, increasing incidence combined with a high recurrence rate of urolithiasis, makes the ideal treatment modality and goal to be elusive [1, 2]. Treatment aims at complete clearance of calculi without any residual fragments, along with pain management and complete

eradication of the causative micro-organisms [3]. Percutaneous nephrolithotomy (PCNL) is now being offered as a standard treatment option for patients with complex and fairly large renal stones. Further improvisation of instruments and techniques has resulted in “miniperc” and “ultraperc,” which were found to be safe and effective [4]. The aim of the present study is to evaluate the safety and feasibility of mPCNL, being carried out as an ambulatory surgery. The objectives are to identify the re-admission rate, stone clearance and the complication rate

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following daycare mPCNL, where the patient gets operated, recovers and returns home within a day or within 24hrs of the surgery [5].

2 Methods

This study is a prospective observational study which was conducted in our hospital, Department of Urology, between September 2018 and February 2020. The target population were the patients who underwent mPCNL as a daycare surgery. The sample size is 70 in our study.

Inclusion Criteria include that all patients above 18 years with renal and/or upper ureteric calculi and who underwent mPCNL.

Exclusion Criteria were patients who were found to have evidence of active infection in urine, altered renal anatomy such as pelvic kidney, co-morbidities that preclude the surgery (coagulation abnormalities or cardiac, respiratory and other co-morbidities) and complete stag-horn calculus.

All the patients who underwent mini-percutaneous nephrolithotomy (mPCNL) in the specified time period were included as per the inclusion & exclusion criteria, after explaining about the study and getting written, informed consent from the patient for participating in the study and publishing the data. Institutional scientific and ethical committee clearance was obtained for the study. The procedures adhered to the ethical guidelines of Declaration of Helsinki and its amendments.

Pre-operative Evaluation included detailed medical history, physical examination and hematological investigations. Patients with positive urine cultures were given intravenous antibiotics pre-operatively for 5 days. Intravenous Urogram (IVU) or computerized tomography (CT) to assess stone size, site, anatomy of the pelvicalyceal system was done to plan optimal access to the renal calculi. The size of the stone was measured by analyzing the stones' longest diameter or in cases of multiple calculi by measuring the sum of each stones' diameter. All the patients were operated under general anesthesia. In supine-mPCNL, patient was placed in Galdakao-modified Valdivia position. In prone-mPCNL patient was placed in prone position with supporting rolls below the shoulder and pelvis. Percutaneous access to the Pelvicalyceal system (PCS) was performed under fluoroscopic guidance. Mini-PCN sheath and a 12Fr nephroscope were used. Stone fragmentation was done using pneumatic lithoclast or Holmium laser. Irrigation, flushing or grasper were used to extract small stones. Stone clearance was confirmed by endoscopy and fluoroscopy. Double J(DJ stent) or ureteric catheter was placed post-surgery, based on surgeon preference. Nephrostomy was deployed in cases of renal pelvis injury, abnormal calyceal anatomy and calyceal diverticular calculi. Time

from starting of cystoscopy to withdrawal of Amplatz sheath was taken as operative time. None of the patients included in the study underwent endoscopic combined intra-renal surgery. The PCN tract was infiltrated with anesthetic agent (0.25% bupivacaine) once the procedure was completed. Intra-operative complications were recorded.

Post-operatively patients were observed for minimum of 6 h to look for complications such as hematuria, sepsis, pain based on Visual Analog Score(VAS), signs of other complications and vitals were monitored. Persistent hematuria, hypotension or other complications were a markers for re-admission and further observation and management. Patient was discharged only if they progressed well. Outpatient follow-up was done on post-operative day (POD) -1. The nephrostomy tube and Foley's catheter (the following day if no urine leak) were removed in cases where they were deployed. Foley's catheter and retrograde ureteric catheter (if deployed) were removed on POD-1, if there was no nephrostomy tube. On POD-5, patients were reviewed with serum creatinine, hemoglobin and X-ray of the KUB region (or CT of radiolucent calculi). In case of residual stone fragments, ancillary procedure was done. DJ stents, if deployed, were removed 6–8 weeks after surgery. Complications were graded as per modified Clavien–Dindo classification.

2.1 Statistical methods

Continuous and categorical variables were expressed as mean \pm standard deviation and percentages, respectively. Comparisons of categorical variables and continuous variables were done by Chi-square test and independent t-test, respectively. p-values less than 0.05 were considered statistically significant. Data analysis was achieved by using SPSS software version 16.0.

3 Results

The demographic data of the patients are discussed in Table 1.

The most common complaint is flank pain (65.7%), and 17% of patients had their stones incidentally

Table 1 Parameters of patients undergoing mPCNL

Parameters	N	Minimum	Maximum	Mean	SD
<i>Descriptive statistics</i>					
Age	70	24	68	45.06	10.671
BMI	70	18.1	33.2	24.820	4.0240
Pre-op hemoglobin	70	7.5	16.7	12.766	2.0716
Pre-op Creatinine	70	0.5	7.10	1.2546	1.26149
Size of stone in cm	70	2.0	3.5	2.480	0.4862

Table 2 Site of renal calculi in Patients

Site of stone	Frequency (n)	Percent (%)
Inferior calyx	10	13.6
Middle calyx	6	8.1
Upper calyx	4	5.4
Pelvis	22	29.7
Partial staghorn	24	32.4
Proximal ureter	4	5.4
Inferior calyx + middle calyx	2	2.7
Inferior calyx + upper calyx	2	2.7
Total renal units	74	100.0

Table 3 Intraoperative parameters of patients undergoing mPCNL

Parameters	Minimum	Maximum	Mean	SD
<i>Descriptive statistics</i>				
Duration of surgery in mins	50.00	120.00	80.0	19.70369
Hospital Stay in hours	7	60	17.25	11.23
Post-op Hb	7.10	15.90	12.4571	1.90484
Post-op serum creatinine	0.60	5.40	1.1057	0.86158

detected. Out of 70 patients, 14 patients (20%) were found to be diabetic and 28 patients (40%) were hypertensive. Right-sided calculi were seen in 42 (60.0%) patients and left side calculi in 24 patients (34.3%) and bilateral in about 4 (5.7%) patients. Table 2 shows the sites of stone lodging.

Two patients had stone in upper and lower calyx, and two others had in middle and lower calyx. The average stone size was 2.48 cm (range 2.0–3.5 cm). Table 3 shows intraoperative and postoperative parameters.

The change in Hb level was found to be statistically significant, but clinically it was not significant. The significant change in creatinine value was mainly due to fall of creatinine values in patients with azotemia, due to the relief of obstruction and hence resolving acute kidney injury (Table 4).

All 70 patients had radio-opaque calculi, 60 patients (85.7%) underwent prone mPCNL, and 10 (14.3%) of patients underwent supine mPCNL. The most common site of puncture was inferior calyx (70.3%), followed by middle (16.2%) and upper calyx (5.4%). In six renal units, dual punctures were done into the middle and lower calyx.

Only two patients had supracostal puncture (supra twelfth) into the upper calyx, and all other patients had infracostal puncture. Complete stone clearance was achieved in 91.4% of patients. In 88.6% of patients ($n=62$), DJ stenting was done and in 11.4% ($n=8$) RGC was left in situ. PCN was deployed following PCNL in 18 cases (25.7%) and not in the rest of the 52 patients. No intra-operative complications were seen in any of the patients. About 68.6% of patients had mild pain, Visual Analogue Score (VAS) [one, two], 17.1% of patients, experienced moderate pain VAS—[three, four], 14.3% experienced no pain and none of them had VAS more than 4.

Only six patients were admitted in the ward. The rest were discharged as daycare patients. Two patients (2.9%) had signs of sepsis (fever with rigors, tachycardia and hypotension) and were treated with fluids and higher antibiotic (Meropenem 1 g), and they responded well (Clavien–Dindo grade 2). Four patients had hematuria (Clavien–Dindo grade 1), responded well to intravenous fluid and diuretic (furosemide). No blood transfusion was required. There was no complication in 91.4% patients. In 5.7% patients, there was hematuria not warranting blood transfusion. In 8.6% of patients, ancillary procedure—Shockwave lithotripsy (SWL), was done and in the rest complete stone clearance was achieved.

4 Discussion

Renal calculi result from disturbance in the balance between precipitation and solubility of salts with most calculi containing calcium [6]. At least 10% of people are affected by Urolithiasis. Almost 70% of people who suffer kidney stone will have recurrence [7]. In Asia, between 1 and 19.1% suffer from urolithiasis. Recurrence rate of renal calculi varies in between 21 and 53% after 3–5 years. In a study by Kruck et al, the recurrence rates

Table 4 Hemoglobin and creatinine levels of patient before and after surgery

	Parameters	Mean	N	SD	Std. Error mean	P value
Pair 1	Pre-op Hb	12.766	35	2.0716	0.3502	0.0001
	Post-op Hb	12.4571	35	1.90484	0.32198	
Pair 2	Pre-op Creatinine	1.2546	35	1.26149	0.21323	0.060
	Post-op serum creatinine	1.1057	35	0.86158	0.14563	

were found to be much lesser when comparing mPCNL with retrograde intrarenal surgery [8].

The mean body mass index (BMI) of patients in our study was 24.82 ± 4.04 kg/m² (18.1–33.2) which was almost similar to the study by Walid Sharour et al. where the mean BMI of the patients was 25.9 kg/m² (22.9–31.7) [9]. BMI is important, mainly because of the skin–stone distance requiring longer sheaths and positioning of the patient. All patients were stable clinically with no requirement of blood transfusions. To prevent recurrence and to preserve renal function, it is crucial to correct any underlying metabolic or anatomical abnormalities [10, 11].

Surgical treatment has drifted from open surgeries to endoscopic surgeries [1]. Recent developments in PCNL and SWL have made management better [12]. PCNL is minimally invasive procedure for removal of renal stones that are more than two centimeters in size. In 1976, Fernstorm and Johanssen, for the first time, reported the removal of renal stones through a nephrostomy tract [13]. PCNL has been identified globally for its safety with considerable success rate and reduced complications suitable for all age groups including pediatric cases [14, 15]. It facilitates a direct approach to the calculus and subjects surrounding structures to less trauma. Many modifications have come up, including use of regional blocks, single-step dilatation, “Mini-Perc” technique and ultraperc (are associated with lesser frequency and severity of complications) [4], tubeless PCNL and sandwich therapy [12, 16]. mPCNL has been promoted as an alternative monotherapy for staghorn and multiple renal stones [17]. However, experience of the urologist also plays a crucial role. Most available reports are from developed countries, and there is shortage of data from developing and underdeveloped countries [18]. Most institutes in India still practice mPCNL as an in-patient procedure.

In our study, most of the stones were partial staghorn 32.4%. In two patients, stone was there in upper and lower calyx and in two others, stone was in middle and inferior calyx. In the study done by El-Tabey et al., most of the stones were located in the renal pelvis -50% (42), followed by inferior calyx-28.6% (24) and then partial staghorn-21.4% [19].

Walid Sharour et al.'s single-puncture PCNL study demonstrated a 70% inferior, 20% middle and 10% upper calyceal puncture which is similar to our study [9]. Desai et al. also advocate the use of mPCNL for a safer anterior calyx and supra-costal puncture [20]. In our study, 18 patients underwent mPCNL without PCN insertion, amongst whom, stenting was also not done in 4 patients (5.7%)—completely tubeless PCNL. In Ahmed Fahmy et al. study, 128 patients (79%) underwent tubeless PCNL

and 34 patients (21%) had PCN deployed, which is almost similar to our study [21].

The operative time was calculated from the beginning of cystoscopy to the withdrawal of sheath. The average operative time in our study was 80 ± 19.7 min (range of 50–120 min). The mean operative time was similar to the studies conducted by Fahmy et al. (94 min), Sharma et al. (72 min), Beiko et al. (86 min), Walid et al. (83.5 min) [9,21,22,23]. It was comparatively higher than the studies conducted by Iqbal Singh et al. (48.8 min) and El-Tabey et al. (46.6 ± 6.3 min) [19, 24]. This higher mean operative time could be secondary to lengthier operative time taken for 4 cases of bilateral PCNL and 6 units of multi-puncture PCNL.

The mean hospital stay in our study was 17.25 ± 11.23 h with the earliest discharge at 7 h and maximum being 60 h. The mean hospital stay in El-Tabey et al. and Iqbal Singh et al. studies was 33.4 ± 17.5 h (24–96 h) and 40 h which showed longer hospital stay than our study [19, 24]. In Sharma et al. (12.5 h, range 5.5–23.5) and Ahmed et al. (9 h), the average hospital stay was shorter as they excluded the duration of stay of the re-admitted patients and calculated the average from the patients discharged as day-care [21, 22].

In our study, 91.4% of patients were completely cleared off the stone, which was similar to studies by Ahmed Fahmy et al. (SFR- 90.7%) and El Taby et al. (SFR- 91.7%) [19, 21]. In studies by Iqbal Singh et al., and Sharma et al., 100% stone clearance was achieved [22, 24].

The readmission rate is 8.6% ($n = 6$), similar to the studies by Fahmy et al., (9.8%) [21] and Sharma et al. (15%) [22], and it is better than El-Tabey et al. study (28.6%) [19]. Two patients (2.9%) in our study had sepsis and were treated with higher antibiotic (intravenous Inj.Meropenem 1 g) and responded effectively. Six of 162 (3.7%) patients in Fahmy et al. study [21], one of 50 (2%) patients in Beiko et al. study [23], five of 84 patients (6%) of El-Tabey et al. study [19] and one of 10 patients (10%) of WalidSharour et al. study [9] had signs of sepsis requiring admission and higher antibiotics. The emergency department visit and readmission rates of ambulatory PCNL in a study done by Schoenfeld et al. was 11% [25]. Bechis et al., in their study, found that the urologist performing daycare mPCNL should be prepared to admit 10% of well selected daycare mPCNL patients and approximately 18% of non-selected patients after the procedure [26].

None of the patients in our study had colonic injury or hydrothorax. Six patients (8.6%) in our study had residual calculi and underwent SWL as an ancillary procedure before removing the stent, which was higher than the El-Tabey et al. study (4.8%). There is continuous miniaturization of the PCNL techniques, like micro-PCNL,

mini-micro-PCNL and super-mini-PCNL. The super-mini-PCNL technique has lesser complication rate when compared to mPCNL as well as better stone clearance rates in pediatric patients [27].

4.1 Limitation

Sample size was as per statistical calculation but to derive a sturdy conclusion large scale studies are recommended. However, this has been done as a pilot study and more cases of mPCNL as well as PCNL are being done as a daycare surgery and the data are being collected which could provide valuable changes in the near future.

5 Conclusion

Out of 70 patients, most of the cases were partial stag-horn with maximum stone size upto 3.5 cm, inferior calyx was the most frequently punctured with 6 multipuncture mPCNL. Four patients had bilateral procedure with 2 supracostal puncture. Eighteen patients had tubeless mPCNL, of which four were totally tubeless procedures. No major intraoperative or postoperative complications were noted. We can conclude that in tertiary care centers with experienced urologists and in properly selected patients, bilateral as well as multipuncture mPCNL can be safely done as a daycare surgery. Faster recovery, reduced bed occupancy and cost-effective care for patients can thus be obtained. Since experienced urologists performed all cases, those surgeons in the earlier part of learning curve of the procedure have to decide carefully before discharging the multipuncture, supracostal puncture or bilateral PCNL patients as day-care.

Abbreviations

mPCNL: Mini-percutaneous nephrolithotomy; IVU: Intravenous urogram; CT: Computerized tomography; PCS: Pelvicalyceal system; DJ: Double J; VAS: Visual analog score; POD: Post-operative day; RGC: Retrograde ureteric catheter; SWL: Shockwave lithotripsy; BMI: Body mass index; PCN: Percutaneous nephrostomy.

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Authors' contributions

AP, MT, DR, NJ and AKB done Concepts, Design, Definition of intellectual content, Literature search, Clinical studies, Experimental studies, Data acquisition, Data analysis, Statistical analysis, Manuscript preparation, Manuscript editing and Manuscript review. SPJ and SB done Design, Definition of intellectual content, Literature search, Clinical studies, Experimental studies, Data acquisition, Data analysis, Statistical analysis, Manuscript preparation, Manuscript editing and Manuscript review. CM done Concepts, Design, Definition of intellectual content, Literature search, Experimental studies, Data acquisition, Data analysis, Statistical analysis, Manuscript preparation, Manuscript editing and Manuscript review. RP and NS done Design, Definition of intellectual content, Literature search, Experimental studies, Data acquisition, Data analysis, Statistical analysis, Manuscript preparation, Manuscript editing and Manuscript

review. All the authors have contributed in few surgeries each and case management, concept and design of the study, data collection, analysis and validation, writing of the literature, manuscript editing and review. All authors have read and approved the manuscript and agreed for authorship criteria set, by the journal editorial committee. Guarantor for the above statement would be the corresponding author.

Availability of data and material

Available on reasonable request from the corresponding author.

Consent for publication

Written consent was obtained from participants of the study.

Ethics approval and consent to participate

Name of the committee which gave ethical clearance for study: Institutional Ethics Committee—Clinical studies, Apollo Hospitals, 1/16 & 1/17, 2nd Floor, Krishna Deep Chambers, Wallace Garden Street, Chennai—600 006. All the patients who underwent mini-percutaneous nephrolithotomy (mPCNL) in the specified time period were included as per the inclusion & exclusion criteria, after explaining about the study and getting written, informed consent from the patient for participating in the study and publishing the data.

Competing interests

The authors declare that they have no competing interests.

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