Prospective comparative study of Miniperc and standard PNL for treatment of 1 to 2 cm size renal stone

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What's known on the subject? and What does the study add?

Standard PNL is known to have higher clearance rates for stones 1–2 cm. However, it is not promoted because of its associated morbidity, especially bleeding. Minitiarization of the PNL has spawned a new interest in this modality for treating small bulk urolithiasis.

The study adds to a growing body of evidence in a prospective manner that smaller tract PNL "miniperc" is associated with a similiar efficacy of achieving stone-clearance rates while decreasing the invasiveness of the procedure and associated morbidity.

OBJECTIVE

- To evaluate the results of miniperc vis-à-vis standard PNL in the treatment of stones of 1–2 cm in size. Miniperc may represent a reasonable procedure in patients with nonbulky urolithiasis offering a similar outcome as standard percutaneous nephrolithotomy (PNL) with advantage of reduced morbidity.

PATIENTS AND METHODS

- 55 procedures including 27 miniperc and 28 standard PNL were performed for renal stones 1–2 cm in size. Pediatric patient, active urinary tract infection, renal malformation, uncorrected coagulopathy and morbid obesity patients were excluded from the study.
- The parameters studied were demography, operative time, postoperative analgesic requirement, hemoglobin drop, complications and stone clearance.

RESULTS

- Mean tract size was 18.2 ± 2 F (15–20) and 26.8 ± 2 F (24–30), *P* value <0.0001 in the miniperc and standard PNL, respectively. Holmium LASER and pneumatic lithotripter were the main energy sources used in miniperc and standard PNL, respectively.
- Miniperc operative time was longer than that of standard PNL (45.2 ± 12.6 vs 31 ± 16.6 min, $P = 0.0008$ respectively).
- Conversely, there was an advantage of miniperc over standard PNL in terms of a significantly reduced hemoglobin drop (0.8 ± 0.9 vs 1.3 ± 0.4 gram%, $P = 0.01$), analgesic requirement (55.4 ± 50 vs 70.2 ± 52 mg tramadol, $P = 0.29$) and hospital stay (3.2 ± 0.8 vs 4.8 ± 0.6 days, $P \leq 0.001$), respectively.
- Intra- operative conversion of the procedure into a tubeless PNL was significantly more in the miniperc group ($P \leq 0.001$). The miniperc and standard PNL group had clearance rates of 96% and 100%, respectively at 1 month follow up.

CONCLUSIONS

- This study demonstrated significant advantages of the miniperc procedure in terms of reduced bleeding leading to a tubeless procedure and reduced hospital stay.
- The stone free rates and the complications were similar in either group.

KEYWORDS

Percutaneous nephrolithotomy, Miniperc, comparative, tubeless

INTRODUCTION

Since its introduction in 1976 [1], percutaneous nephrolithotomy (PNL) has played an important role in urologists' treatment strategies. Shock wave lithotripsy (SWL) provides a low stone-free rate and has a high retreatment rate in stones more than 1.5 cm in size[2,3]. These issues have led to a renewed interest in PNL for stones measuring 1–2 cm in patients who have failed to respond to SWL or ureteroscopy and for all stones <2 cm located in the lower pole. Although PNL is minimally invasive, it is still a surgical procedure and thus it is necessary to carefully consider the patient's anatomy in order to avoid complications [3]. To reduce the disadvantages of conventional PNL, a 'mini-perc' technique was first developed for children and reported by Helal *et al.* [4]. Additionally, Jackman *et al.* [5,6] defined the 'mini-perc' as a percutaneous nephrolithotomy achieved through a sheath too small to accommodate a standard rigid nephroscope.

Although standard nephroscopes have shaft calibers of 24–30 F, so-called 'mini-perc' instruments have smaller dimensions ranging 12–20 F. We prospectively compared miniperc with standard PNL in the treatment of stone sizes 1 to 2 cm.

TABLE 1 Demography

	Miniperc	Standard PNL	*P* value
Total cases	26	26	
Renal units	27	28	
Sex distribution (Male : Female)	18 : 8	18 : 8	
Age (Years) (Mean ± SD)	42.2 ± 19.8	48.2 ± 16.8	0.24
BMI (Kg/m2) (Mean ± SD)	23.8 ± 2.6	22.6 ± 2.7	0.11
Mean size of stone (cm^2) (Mean ± SD)	1.47 ± 0.3	1.49 ± 0.6	0.88
Laterality (Left: Right)	19 : 8 (One bilateral)	18 : 10 (2 bilateral)	
Access			
Upper calyceal	2	3	
Middle calyceal	10	18	
Lower calyceal	15	7	
Site of stone			
Pelvis	9	13	
Upper calyx	2	3	
Middle calyx	1	2	
Lower calyx	15	10	

PATIENTS AND METHODS

This is a prospective quasi-experimental case control designed study aiming to compare miniperc and standard PNL. A total of 55 percutaneous procedures were performed in 52 patients for renal stones 1–2 cm in size between July 2009 and Jan 2010. The stone size was defined as the maximum length of the stone on a preoperative plain abdominal radiograph. In the case of multiple stones, the same was achieved by adding maximum length of the individual stones.

The institutional review board approved the study. An inclusion criterion for the study was 1–2 cm size stone in patients consenting for percutaneous renal stone removal. Pediatric patient, active urinary tract infection, renal malformation, uncorrected coagulopathy and morbid obese patients were excluded from the study. Patients were informed about the consent required for the study to be done. They were also informed regarding the investigational nature of the procedure in evolution and the limitations thereof miniperc in published studies so far (increased operative time, chances of clinically insignificant residual fragments due to laser fragmentation). Decision was left to the patient and attendants to be taken. If they wished to be a part of the study, they were placed in the miniperc group, else placed in the standard PCNL group, alternatively. A total of 26 and 40 patients underwent miniperc and standard PNL, respectively during the study duration. As a part of case control study, 26 cases of the standard PNL group were included for the analysis to keep the group numbers same and comparable. One patient in the miniperc and two in the standard PNL group underwent bilateral procedures under same anesthesia.

All the procedures were performed by a single surgeon (RBS). After general anesthesia, a 5 F ureteric catheter was placed transurethrally. Under ultrasound control, selective calyceal puncture, usually at the posterior lower pole calyx, was carried out with a 22 gauge Skinny Needle (Cook Medical, Bloomington, IN, USA). A flexible 0.035-inch Zebra guidewire (Boston Scientific Corporation, Miami, FL) was then inserted into the renal collecting system preferably in the ureter or else in the upper pole calyx. The access needle was removed and the skin and fascia incised. For miniperc, the tract was dilated upto 14F-18F by fascial dilators (Cook, Inc) in a stepwise manner, and a matched peel-away sheath (Cook, Inc) was then inserted. Nephroscopy was done by 12/14 F miniature nephroscope (Lahme, Richard Wolf, Knittlingen, Germany). Renal stone was fragmented by a Holmium: YAG laser using 200- or 365-μm fibre (Sphinx 30, LISA Laser, USA) or alternatively by a 1.9 mm ultrasonic lithotripter or a 1.6 mm pneumatic lithotripter probe (Swiss lithoclast). Occasionally, 2 mm stone grasping basket was also used to remove the fragments. For standard PNL, the nephrostomy tract was dilated with telescoping Alken's metal dilators (Karl Storz, Tuttlington, Germany) and a 24–28 F Amplatz sheath (Cook, Inc) positioned into the renal collecting system. Energy used was pneumatic lithotripsy (Swiss Lithoclast) or rarely by the previously mentioned techniques. At the end of both the procedures, a 6 F double-J stent was placed antegradely. Decision of the postoperative placement of nephrostomy was left to the discretion of the operating surgeon. Planning of a tubeless PNL (double J stenting but no nephrostomy) was done if the following criteria were met i.e. single percutaneous tract, no perforation of collecting system and no bleeding, complete stone clearance as assessed by intraoperative nephroscopy and fluoroscopy at the end of the procedure. For a tubeless procedure, the flank was compressed for 5 min. Patient was monitored for postoperative complications. Foley catheter was removed on post-operative day (POD) 1. In case a tubeless procedure was not planned, a 20 F nephrostomy was kept till POD 1. The tube was removed on POD 2. Catheter was removed on subsequent day and patient discharged. X-ray KUB assessed stone free rates in all patients at 1month follow-up. Clearance was defined as no stone visible on X-ray KUB and all fragments less than 4 mm were considered as clinically insignificant residual fragments.

Data was reported as number and percentage or mean and standard deviation, as appropriate. Categorical data between the groups was analyzed by Fisher's exact test from a 2X2 contingency table. Continuous data between the groups was analyzed by t test to compare two means. *P* values <0.05 were considered significant.

RESULTS

Patients' demographic data and the stones' characteristics are tabulated in Table 1. Both groups were comparable in terms of gender, mean age, mean body mass index, side of stone and mean stone burden. Mean tract size was 18.2 ± 2 F (15–20) and 26.8 ± 2 F (24–30), *P* value < 0.0001 in the miniperc and standard PNL, respectively. Single tract access was used in all cases. Holmium LASER and pneumatic lithotripter were the main energy sources used in miniperc and standard PNL, respectively.

Radiographic follow-up data at 1-month postoperative visit were available for all patients. The miniperc and standard PNL group had clearance rates of 96% and 100%, respectively. One patient in the miniperc group had residual fragment of size 6 mm in the lower calyx. Intraoperative parameters are as shown in Table 2. Intra- operative decision of a tubeless PNL was significantly more in the miniperc group (*P* < 0.001). Specifically, miniperc group required significantly longer nephroscopy time. Holmium laser was the predominant intracorporeal lithotripsy utilized for the miniperc group. In no case was it deemed necessary to convert from a miniperc to a standard PNL. The intraoperative complications were similar between the two groups. However, bleeding was significantly less in the miniperc group. The more number of tubeless procedures and significantly less hemoglobin drop in the miniperc group reflected this observation. No miniperc patient required blood transfusion, whereas one did so in the standard PNL group. The analgesic requirement was similar in both the groups. Hospital stay was less in the miniperc group.

TABLE 2 Results

	Miniperc	Standard PNL	*P* value
Mean tract size F (mean ± SD)	18.2 ± 2	26.8 ± 2	<0.0001*
(Range)	15–20	24–30	
Nephroscope size F (Range)	12–14	20–24	
Energy source			
Holmium Laser	19	1	<0.001*
Lithovac	6	0	0.01*
Ultrasonic lithotripter	2	2	1.00
Pneumatic Lithotripter	0	22	<0.001*
None (Intact removal)	0	3	0.23
Mean operative time minutes (mean ± SD)	45.2 ± 12.6	31 ± 16.6	0.0008*
Tubeless	21	4	<0.001*
Intra operative complication			
Pelvic perforation	1	2	1.0
Bleeding	0	4	0.11
Fever	2	4	0.66
Complete stone clearance (Skiagram at 1 month)	96%	100%	0.49
Mean Hemoglobin drop gm%	0.8 ± 0.9	1.3 ± 0.4	0.0098*
Analgesic requirement (mg tramadol prn)	55.4 ± 50	70.2 ± 52	0.28
Hospital stay (days)	3.2 ± 0.8	4.8 ± 0.6	<0.0001*

DISCUSSION

SWL, PNL and flexible ureteroscopy are the three main modalities for treating non-bulky renal urolithiasis. Cochrane data review comparing these modalities showed that the success rate at three months for lower pole kidney stones was statistically higher for PNL [7]. The disadvantages of SWL are overcome by PNL, which has a higher stone-free rate, shorter treatment time, and a reduced risk of febrile urinary tract infection [8–11]. The drawbacks of PNL are increased hospital stay, duration of treatment and complications [7]. The main risk of PNL is hemorrhage that requires a blood transfusion 11–14% of the time, and an increased risk of kidney loss [11,12]. Traditionally, PNL requires a 30-F nephrostomy sheath for renal access. The recent development of smaller sheaths suggested that percutaneous nephrostomy tract formation could be performed with minimal damage to the involved renal parenchyma, thereby reducing the procedure-related morbidity without diminishing its therapeutic efficacy [5,6]. Jackman *et al.* [5] defined the 'mini-perc' as a percutaneous nephrolithotomy achieved through a sheath too small to accommodate a standard rigid nephroscope. The same group of authors [6] adapted the 'mini-perc' to adult patients utilizing a 13-F ureteroscopy sheath for percutaneous access in seven patients. Monga *et al.* [13] reported similar results using a 20-F nephrostomy sheath in 21 patients. Lahme *et al.* [14] also described this technique using a 15-F Amplatz sheath in 19 patients.

For the PNL to be an appealing alternative to SWL, it must be fully effective in one step with acceptable morbidity. In our opinion, only a stone-free rate that approximates 100% would outweigh the drawbacks of a surgical procedure requiring general anesthesia. Many series with miniperc or mini PNL reported a stone free rates that were in range of 60 to 90% [5,6,15,16]. Interestingly, the stone free rates were immediate post-operatively. It is apparent, that stone fragments are known to be present after laser lithotripsy. It is worthwhile to see if they are clinically significant at 1 month. For this reason, we assessed clearance at one month, which was similar in both the groups. Only one patient had stone fragment of 6 mm, the rest of the patients were completely stone free. Miniperc is therefore effective in achieving acceptable clearance rates as with standard PNL.

The next criterion for acceptance of the procedure is technical feasibility. The most important drawback of miniperc is lengthy operative time [15,16]. Reasons for the observed difference is diminished intraoperative field visibility, the need for fragmentation by laser into very small stones suitable for ureteroscopic graspers and/or baskets, and the small sheath. In our experience, visibility was not a major issue for increased operative time. Rather on a contrary note, reduced diameter of tract dilation during miniperc reduces the potential for damage to the renal vasculature and infundibular calyceal tear [17]. In author's experience, visibility is hardly an issue if the access is perfect. On the contrary, it was better owing to insignificant bleeding. The increased operative time is contributed by the prolonged intracorporeal lithotripsy time required by the Holmium laser. In the later cases, we used Lithovac™ (Swiss Lithovac, EMS) that has a 1.6 mm probe and can be passed through the miniature scopes (18 F). The variable suction energy counteracts the propulsive energy of the lithoclast. Fragments as large as 3.5 mm could be evacuated with the Lithovac™ after removing the Lithoclast probe. Using the suction, clear vision could be achieved.

The primary aim of devising the miniperc technique was reduction of pain related to the procedure. Our results, however, demonstrated marginal difference in pain (as measured by analgesic requirements) between the miniperc and standard PNL groups. These findings support the general understanding that postoperative pain depends more on the presence of nephrostomy rather than on the tract's size, as initially thought [18–20]. Theoretically, miniperc by facilitating tubeless procedure should contribute to lesser analgesia. This however, was not proven in our study.

The limitation of the study includes a non-randomized controlled nature of the study. The planning of the study was a prospective quasi-experimental case control designed study. However, there may be unavoidable internal validity bias. One of the examples of this bias may be a statistically more numbers of tubeless procedures in the miniperc group. The decision to do a tubeless procedure was left to the discretion of the operating surgeon thereby inviting an internal validity threat. Further studies of a randomized controlled nature may actually give us a valid conclusion in this respect. The numbers of participants was also less, which limits any meaningful statistical power.

CONCLUSIONS

Miniperc is associated with similar clearance rate as standard PNL for stone sizes 1 to 2 cm. It is limited by longer operative time but ends more frequently in tubeless procedure as a result of significantly less bleeding. It has similar safety profile as of standard PNL and results in shorter hospital stay. Further, level I evidence is required to vigorously test the miniperc and establish its status in the current armamentarium for treating non-bulky urolithiasis.

CONFLICT OF INTEREST

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EDITORIAL COMMENT

PROSPECTIVE COMPARATIVE STUDY OF MINIPERC AND STANDARD PNL FOR TREATMENT OF 1 TO 2 CM SIZE RENAL STONE

Although it was first described more than a decade ago, the place for mini-PCNL within the range of stone interventions has yet to become firmly established.

This single surgeon, prospective case-control series from a high-volume centre has