

# Miniaturized percutaneous nephrolithotomy versus retrograde intrarenal surgery in the treatment of renal stones with a diameter < 15 mm: A 3-year open-label prospective study

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## Abstract

**Aim:** The aim of this study is to compare the outcomes of miniaturized percutaneous nephrolithotomy (mini-perc) and retrograde intrarenal surgery (RIRS) in management of renal stones with a diameter < 15 mm.

**Materials and Methods:** This was an open-label prospective study that included a total of 80 cases underwent mini-perc ( $n = 40$ ) and RIRS ( $n = 40$ ) between July 2014 and August 2017. The primary outcome objective was stone-free rate, retreatment rate, complications, hospital stay, operative time, and reduction in hemoglobin level. Data were analyzed using SPSS version 16.0 Software.

**Results:** Overall, 80 patients were enrolled in this study. The mean age was 40.12 and 38.20 years, and the mean stone size was 1.15 and 1.30 cm in mini-perc and RIRS group, respectively. Majority of the study participants were males. Overall, mini-perc and RIRS had stone clearance rates of 100% and 95.4%, respectively. Two patients required retreatment in RIRS group. The duration of hospital stay and the rate of complication was similar in both the groups. Operative duration was more in RIRS group. Decrease in hemoglobin level was more in mini-perc group.

**Conclusions:** Results demonstrated that both modalities were associated with high stone clearance rates with minimal complications. RIRS was associated with less reduction in hemoglobin and could be used as standard treatment modality for small renal calculi.

**Keywords:** Mini-perc, retrograde intrarenal surgery, small renal calculi

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## INTRODUCTION

The treatment of calyceal stones presents a dilemma for the urologist.<sup>[1]</sup> With improvements in fiber optic designs, downsizing of instrumentations, better irrigation system and the availability of small instruments, both powered and

mechanical to allow complex manoeuvres within the confines of the upper urinary tract.<sup>[2]</sup> Owing to this role of miniaturized percutaneous nephrolithotomy (PCNL) (mini-perc) and flexible ureteroscopy in the urologist's armamentarium has undergone a dramatic evolution.<sup>[2]</sup>

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The treatment options for small renal calculi (<1.5 cm) include extracorporeal shock wave lithotripsy (ESWL), PCNL, and retrograde intrarenal surgery (RIRS).<sup>[3-5]</sup> However, the limitation of ESWL includes relatively lower stone clearance rates and the need for repeated sessions, especially in lower polar and harder stones.<sup>[6]</sup> While RIRS is a standard treatment option for small renal calculi, but the actual cost of each procedure is about six times greater than for ESWL.<sup>[5,7]</sup> RIRS has a better safety profile, but its stone clearance rates are lower than that of PCNL.<sup>[8]</sup> PCNL has good stone clearance rates but is associated with a significant risk of morbidity.<sup>[9]</sup> Since most of the morbidities associated with PCNL are related to the size of tract, a reduction in tract size can lower the number of complications associated with it.<sup>[10,11]</sup> Mini-perc is a recently described technique in which tract dilation is between 12 and 14F, thus minimizing the complications associated with standard PCNL still achieving a good stone clearance rates.

In the past few years, there has been a significant advancement in endoscopic instrumentation and laser technology, facilitating quick and minimally invasive stone extraction. Owing to patients' growing reluctance for repeated treatments and hospitalizations, along with the low stone-free rate of ESWL for stones of 1–2 cm,<sup>[12,13]</sup> questions have been raised about the use of this conservative noninvasive approach. As a result, there is renewed interest in minimally invasive approaches, such as mini-perc and RIRS. In this paper, we report our observations comparing mini-perc and RIRS in the management of renal stones with a diameter <15 mm.

## MATERIALS AND METHODS

### Study design

This was a prospective, open-label, randomized study conducted between July 2014 and August 2017. Eligible study participants were randomly (1:1) grouped into two groups (mini-perc [ $n = 40$ ] and RIRS [ $n = 40$ ]). Preoperative complete blood count, serum creatinine, platelet count, bleeding and coagulation profile, and urine culture were obtained from all patients. Radiological evaluation included ultrasonography (USG), intravenous urography, and in addition computed tomography (CT), if needed in few patients having radiolucent calculi. The stone burden was measured as the sum of the largest linear dimensions on kidney, ureter, and bladder (KUB)/CT films. Patients with hemoglobin level <10 g/dl were given blood transfusion before the surgery. Both mini-perc and RIRS were performed by same team of operating urologists.

The study protocol was reviewed approved by the Institutional Ethics Committee. All study procedures were

performed in accordance with the approved protocol and ethical principles that have their origin in the Declaration of Helsinki 1964, as revised in 2013. Written informed consent and/or assent were obtained from each participant or guardian (where applicable) for participation in the study.

### Study population

Patients of either sex aged above 15 years and having stone size <1.5 cm in calyx were included in this study. Patients with anatomical abnormalities, having stone in >1 calyx, had undergone previous renal surgery, pregnancy, children, morbid obesity, uncorrected coagulopathy, concomitant stones at other sites (e.g., bladder, ureter) were excluded from the study.

### Mini-perc and retrograde intrarenal surgery

Mini-perc was carried out under spinal or general anesthesia. A 6 Fr ureteral catheter was introduced through cystoscopy. Under fluoroscopic guidance, selective calyceal puncture was taken, and tract dilatation was performed using 16 F sheath. Miniature nephroscope 12 Fr Karl Storz was used in all the cases, stone fragmentation was done by a holmium: YAG laser using 550  $\mu\text{m}$  fiber, 0.5 Joules  $\times$  15 Hz frequency rate for dusting, and 1 Joules  $\times$  10 Hz frequency rate for fragmentation. The collecting system was examined by direct nephroscopy and fluoroscopy to confirm complete stone clearance. In all the cases, 6F 24 cm DJ stent was placed, and nephrostomy tube was placed for 24 h. If the urine was clear, nephrostomy was opened on postoperative day 1 and removed on postoperative day 2, and if remained uneventful, the patient was discharged on postoperative day 2 with oral antibiotics.

Patients undergoing RIRS were pretested 2 weeks prior, and the procedure was performed under general anesthesia. Cystoscopy was done, and 0.035-inch terumo guidewire was placed in the pelvicalyceal system. Ureteric access sheath 14 Fr (Cook Medical) was placed. A 7.5-Fr Flex X-2 flexible ureteroscope Karl Storz was used. The stone were fragmented using Holmium: YAG laser using 200 or 365  $\mu\text{m}$  fiber until they were deemed clinically insignificant fragments. The lower calyceal calculus was mobilized to the upper or middle calyx before fragmentation. DJ stent 6F 24 cm was placed in all the cases. If the postoperative period remained uneventful, the patient was discharged on postoperative day 2 with oral antibiotics.

Each patient had X-ray KUB and hemoglobin on postoperative day 1. Each patient received broad-spectrum antibiotics (Inj. Ceftriaxone 1 g [twice daily] and Inj. Amikacin 750 mg [once daily] for 2 days). Stent removed after 21 days.

Follow-up visits were scheduled at 1 month after the procedure and then at 3 months interval. In each visit, a thorough clinical examination, urine analysis, in case of pyuria (urine culture and sensitivity), USG, and X-ray KUB were performed.

**Assessment parameters**

Assessment parameters included overall operative time, reduction in hemoglobin, complete clearance of stones, hospital stay, complications (pelvicalyceal tear, fever, bleeding, injury to surrounding viscera, and need for blood transfusion), and need for any ancillary procedure. The complete clearance of stone was defined as no residual or insignificant residual stone material <4 mm on USG or CT. Difference in hemoglobin levels in pre- and immediate postoperative period was considered as indicator of intraoperative blood loss, and blood transfusion was given to the patient having postoperative hemoglobin below 9 g/dL.

**Statistical analysis**

All statistical analyses were conducted using SPSS version 16.0 Software. For comparison of mean, *t*-test was used, for comparison of nominal scale data used Chi-square test. *P* < 0.05 was considered as statistically significant.

**RESULTS**

Overall, 80 patients were enrolled, and all 80 patients completed the study. Patients’ demographics and clinical characteristics were comparable between two groups [Table 1]. The mean age was 40.12 and 38.20 years, and the mean stone size was 1.15 and 1.30 cm in mini-perc and RIRS group, respectively. Majority of the study participants were males. The overall location of stone among the majority of patients was middle calyx (40.0%) followed by lower calyx (35.0%).

Operative parameters are summarized in Table 2. The mean operative duration among patients who had mini-perc was 38.32 min and among patients who had RIRS was 48.45 min. The mean reduction in hemoglobin in mini-perc and RIRS group was 0.55% and 0.42%, respectively. Overall, the duration of the hospital stay for mini-perc group was 2.30 days and for RIRS group 2.15 days. Only two patients from RIRS group required the ancillary procedure.

The mini-perc group had complete clearance in all the cases. The success rate in mini-perc group was 100% as compared to RIRS group which had success rate of 95%, summarized in Table 3.

Overall, both the procedures were well tolerated in this study population. There were no serious adverse events (AEs), no discontinuations due to AEs, and no deaths during the study. Overall, 8 patients reported AE– 4 from mini-perc group (fever, *n* = 2; intraoperative bleeding, *n* = 2) and 4 from RIRS group (fever, *n* = 4). All these AEs were resolved before end of the last study visit. None of the patients reported pelvicalyceal tear and injury to surrounding viscera. None of the patients required blood transfusion after the procedure. Complications are summarized in Table 4.

**DISCUSSION**

The management of urinary stones is evolving rapidly. There has been a growing interest in techniques such as

**Table 1: Patient demographics and clinical characteristics**

Characteristics	Mini-perc (n=40)	RIRS (n=40)	P
Age (years)	40.12 (8.15)	38.20 (12.13)	0.760
Male, n (%)	22 (55.0)	26 (65.0)	-
Stone size (cm)	1.15 (0.19)	1.30 (0.18)	0.737
Stone location, n (%)			
Upper calyx	10 (25.0)	10 (25.0)	-
Middle calyx	14 (35.0)	18 (45.0)	
Lower calyx	16 (40.0)	12 (30.0)	

Data presented as mean (SD), unless otherwise specified.

Mini-perc: Miniaturized percutaneous nephrolithotomy,

RIRS: Retrograde intrarenal surgery, SD: Standard deviation

**Table 2: Summary of operative parameters**

Characteristics	Mini-perc (n=40)	RIRS (n=40)	P
Operative time (min)	38.32 (5.30)	48.45 (3.54)	0.000
Hospital stay (days)	2.30 (0.82)	2.15 (0.78)	0.063
Reduction in hemoglobin (%)	0.55 (0.27)	0.42 (0.31)	0.000
Ancillary procedure required, n (%)	0	2 (5.0)	-

Data presented as mean (SD), unless otherwise specified.

Mini-perc: Miniaturized percutaneous nephrolithotomy,

RIRS: Retrograde intrarenal surgery, SD: Standard deviation

**Table 3: Surgical outcomes**

Outcome	Mini-perc (n=40), n (%)	RIRS (n=40), n (%)	P
Success	40 (100)	38 (95)	0.006
Failure	0	2 (5)	
Total	40 (100)	40 (100)	

Mini-perc: Miniaturized percutaneous nephrolithotomy,

RIRS: Retrograde intrarenal surgery

**Table 4: Complications**

Characteristics	Mini-perc	RIRS	P
Pelvicalyceal tear	0	0	0.005
Fever	2	4	
Bleeding	2	0	
Injury to surrounding viscera	0	0	
Blood transfusion required	0	0	

Mini-perc: Miniaturized percutaneous nephrolithotomy,

RIRS: Retrograde intrarenal surgery

mini perc and RIRS, which might represent a reasonable middle ground, offering similar outcomes with reduced morbidity. In the present study, 80 patients were enrolled having calyceal stone of <1.5 cm.

Overall, the operative time was significantly lower for mini-perc (38.32 min) and RIRS (48.45 min). For acceptability of a procedure, its technical feasibility is most important, which is a limitation with RIRS that is the lengthy operative time. This can be attributed to the placement of the ureteral access sheath before procedure and the time-consuming maneuvering required in RIRS for stone fragmentation, i.e., placement of stones in a favorable calyx to avoid strain on the deflection mechanism and risk of laser fiber damaging the scope. Operating time can be reduced using the popcorn method. All the fragments are placed in a single calyx and the laser fiber fired at the middle of the fragments without focusing on a particular fragment, this saves a lot of time and breaks the stones into size <4 mm, which is sufficient to be passed out in the urine.<sup>[14]</sup> Giusti *et al.*<sup>[15]</sup> in their study noted that mini-perc took longer to finish (mean operative time of 155.5 min, vs. standard PCNL: 106.6 min) citing the diminished operative field visibility, need for fragmentation into very small stones suitable for ureteroscopic graspers and/or baskets and the small sheath size as contributing factors, though we did not face any major problems as far as visibility or fragmentation were concerned. Our operative times were also similar to those reported by Mishra *et al.* in their study comparing mini-perc with standard PCNL (45.2 min vs. 31 min, respectively).<sup>[11]</sup>

In our study, the average reduction in hemoglobin was significantly ( $P < 0.000$ ) greater in mini-perc (0.55%) than RIRS (0.42%). Giusti *et al.* also showed that blood transfusion rates were lower for mini-perc (0%) as compared to the standard and tubeless PCNL (2.9% and 3.7% respectively).<sup>[15]</sup> Although one needs to realize that none of the patients in the study, including those in the mini-perc group required a blood transfusion. This fact highlights the advantage in the form of the absence of major bleeding requiring blood transfusion due to the use of a smaller bore tract to perform a PCNL. One of the objectives of this study was to evaluate the safety and efficacy of both the procedures. Both the techniques were equally safe as there was no significant difference in complication rates between both the groups. Out of four patients in mini-perc group, two patients had fever and other two patients had intraoperative bleeding (which was not significant enough requiring blood transfusion). All the 4 patients in RIRS group had fever which was managed with intravenous antibiotics (no urosepsis). There were no major complications in the previous studies on mini-perc, but they had comparatively fewer cases.<sup>[16-20]</sup>

Monga and Oglevie in their study of 21 patients undergoing mini-PCNL did not report major complications, but there was one episode of prolonged fever secondary to atelectasis.<sup>[16]</sup> RIRS can be considered a safe procedure with no major complications. Major perforation is extremely rare and is reported in approximately 1% of the cases.<sup>[21]</sup> The risk of postoperative stricture of the ureter is <1%, since the diameter of the used instruments has decreased as well as stone fragmentation devices have improved.<sup>[22]</sup> Urinoma, urosepsis, or ureteral avulsion have not been reported in recent larger series including almost 1500 procedures.<sup>[21,23,24]</sup> Reported complications are minor. Postoperative colic rates are reported in 3.5%–9% of the patients.<sup>[25,26]</sup> Postoperative pyelonephritis and gross hematuria occur in <3% of the cases.<sup>[19]</sup>

Hospital stay was similar in both the group of patients (mini-perc: 2.30 days, RIRS: 2.15 days,  $P < 0.063$ ). Monga and Oglevie estimated 1.1 days of mean hospital stay in their series of patients undergoing miniperc.<sup>[16]</sup> Prabhakar discharged all of their patients after 24 h of performing RIRS.<sup>[14]</sup>

For mini-perc or RIRS to be taken as an alternative to ESWL, they must be fully effective in one step with acceptable morbidity. In our opinion, only a stone-free rate that approximates 100% would outweigh the limitations of a surgical procedure requiring general anesthesia. The stone-free rate at 1 month was 100% (40/40) for the mini-perc group and 95% (38/40) for the RIRS group, and they were not statistically different from each other. Two patients in the RIRS group required retreatment in the form of conversion to mini-perc, as the stone was in lower calyx, which was not accessible by flexible ureteroscope due the acute angle.

Many studies with mini-perc or mini-PCNL have reported stone-free rates in the range of 70-90%.<sup>[15,17,18,27]</sup> Previously reported stone-free rates for mini-perc have been 85% in children and 89% in adults by Jackman *et al.*,<sup>[17,18]</sup> 90% by Monga and Oglevie<sup>[16]</sup> and 100% by Lahme *et al.*<sup>[19]</sup> Sofer *et al.* conducted a retrospective analysis of 598 patients with upper tract calculi with mean size of 13.5 mm and achieved an overall stone-free rate of 84% for renal calculi.<sup>[21]</sup> In another retrospective study by Ferroud *et al.*, the 1 month stone clearance rate was 88% in the RIRS group, whereas it was 93% in the mini-perc group.<sup>[27]</sup>

## CONCLUSION

Results showed that the success rate was more in mini-perc group associated with prolonged hospital stay. Operative

time was more in RIRS group as compared to mini-perc group. Both the procedures were found to be safe with no major complications. This study demonstrated that both modalities give high stone clearance rates with minimal complications, in selected group of patients having only calyceal stone of <1.5 cm. RIRS is associated with less hemoglobin drop and can be used as standard treatment modality for small renal calculi, only limitation is its cost.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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