Original Article

A Randomized Study Comparing Mini PCNL and RIRS for Renal Stones between 8 mm and 15 mm – A Single Institutional Experience

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Abstract

Background: Renal stone disease presents a persistent challenge in urology, necessitating advancements in minimally invasive techniques for enhanced patient outcomes. Retrograde intrarenal surgery (RIRS) and mini percutaneous nephrolithotomy (mPCNL) have emerged as contemporary modalities to address intermediate-sized renal stones (8–15 mm) with precision and reduced invasiveness. **Aims:** To provide a comparative analysis of RIRS and mini PCNL in managing intermediate sized renal stones. To evaluate stone clearance rates, operative metrics, complications, and patient reported outcomes was integral to identifying optimal treatment strategies. **Methods:** Participants randomized to RIRS or mPCNL groups, with stone clearance rate as the primary outcome. Secondary measures included operative time, complication profiles, pain management, and the need for additional procedures. **Results:** The demographic data were comparable in our study. The stone size was 11.282 ± 1.7996 mm in mPCNL group and 11.248 ± 2.0340 mm in RIRS group. The fluoroscopy time was 49.40 ± 2.515 s in the RIRS group and 77.28 ± 2.466 s in the mPCNL group. There was a statistically significant variance in the operative time. After a month, the stone-free rates were 96% and 90% in the mPCNL and RIRS groups, respectively. **Conclusion:** Our study emphasizes the importance of tailored treatment approaches based on patient characteristics. The overall operative time is higher in RIRS group, while the fluoroscopy time, complications, hemoglobin fall, and mean duration of hospital stay are higher in PCNL group. However, the stone clearance rates in both procedures have been remarkable. It is prudent to leave it to the discretion of the operating surgeon to choose the appropriate procedure for a given patient considering the variables.

Keywords: *Holmium laser lithotripsy, mini percutaneous nephrolithotomy, renal stone management, retrograde intrarenal surgery, urology*

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Introduction

The lifetime prevalence of renal stone disease is about 10% and is characterized by the formation of solid concretions in the renal collecting system.[1] The development of chronic kidney disease secondary to nephrolithiasis necessitates the treatment of renal stones.[2] Large and intermediate-sized stones should be treated because they can result in severe colicky pain, infection, urinary tract obstruction, and eventually renal damage.

The management protocols for renal stones have changed substantially over the years with advances in technology, finer instruments, and energy sources. Extracorporeal shockwave lithotripsy (ESWL) is

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of historical importance now in many centers and has been replaced by the newer minimally invasive methods, which provide better stone-free rates, quicker recovery time, and lesser morbidity. Mini percutaneous nephrolithotomy (mPCNL) and retrograde intrarenal surgery (RIRS) have become more popular than extracorporeal shock wave lithotripsy (ESWL) for the treatment of renal stones.[3-5]

Percutaneous nephrolithotomy (PCNL) is one of the minimally invasive techniques for clearing large kidney stones, and it has been proven to be better than conventional approaches such as open pyelolithotomy.[6] Although efficacious, PCNL carries potential risks of puncture site postoperative pain, bleeding, and infection.[7]

Alternatives to the conventional PCNL have come up over the past few years, such as RIRS and mPCNL, which have similar/more accuracy in stone clearance with less invasiveness.[8] Helal *et al*.[9] first performed and published the peel-away sheath nephrolithotomy for a pediatric patient as an mPCNL. In 1964, Marshall[10] designed the first flexible ureteroscope. Takagi *et al*.[11] reported the clinical application of a fiberoptic pyeloureteroscope in the 1970s as an original author.

RIRS employs a flexible, deflectable scope to see the stone within the renal collecting system.[12] It has the advantage of no incision and better clearance rates in the pelvic and upper pole stones. However, as it is done in a closed system, the risk of urosepsis is higher, and sometimes, tackling a lower pole calculus may be difficult.

Mini PCNL is a modification of the traditional PCNL aimed at reducing the procedure's invasiveness. With mPCNL, a smaller-diameter nephroscope is used to access the collecting system, typically less than 20 Fr in size. This approach offers the advantages of PCNL in terms of better stone clearance while reducing the risk of complications associated with larger incisions.[13]

Holmium laser lithotripsy is the preferred modality for intracorporeal lithotripsy due to its precision, low retropulsion rate, and safety profile.[14] Although RIRS and mPCNL have been widely used in clinical practice, there is still disagreement over the best way to treat renal stones that are considered intermediate-sized, typically defined as having a diameter of 8 to 15 mm. While both RIRS and mPCNL have demonstrated efficacy in this setting, comparative studies are needed to evaluate their respective outcomes in terms of stone clearance rates, complication rates, and early return to work.

Materials and Methods

Study design

This is a prospective, randomized study done at Sri Ramachandra Medical College, Chennai, India. The study was conducted from May 2023 to May 2024. Before enrolment, written informed consent was obtained from all participants.

Participants

Participants included individuals with renal stones ranging from 8 mm to 15 mm in size, as confirmed by noncontrast computed tomography of the kidney, ureter, and bladder (NCCT).

Exclusion criteria included anatomical anomalies, contraindications to either RIRS or mPCNL, history of ipsilateral renal surgery, need for prior stenting, pregnancy, or significant comorbidities posing as an increased surgical risk.

Randomization and blinding

Eligible participants were randomized in a 1:1 ratio to either the RIRS group or the mPCNL group using a chit-based sequence. Due to the nature of the interventions, blinding of participants and surgeons was not feasible. However, outcome assessors and data analysts were blinded to group assignments to minimize bias.

Interventions

Participants randomized to the mPCNL group underwent mPCNL under general anaesthesia utilizing an 12 Fr Karl storz nephroscope [Figure 1], 16.5/17.5 Fr amplatz sheath, and Holmium laser lithotripsy. A percutaneous tract made under fluoroscopic guidance provided access to the renal collecting system. Stone fragmentation and extraction were performed utilizing the nephroscope and triprong (or biprong) grasper. A 6 Fr 26 cm double J stent was kept post procedure for 4 weeks.

Participants randomized to the RIRS group underwent retrograde intrarenal surgery under general anesthesia utilizing a flexible ureteroscope (7.5 Fr Karl Storz flex × 2s) [Figure 2] and Holmium laser lithotripsy. Access to the renal collecting system was achieved, and stones were fragmented under direct visualization using laser energy. Stone fragments were subsequently extracted using graspers or baskets. A 6 Fr 26 cm double J stent was kept post procedure for 4 weeks.

Outcome measures

The primary outcome measure was stone clearance rate, defined as the absence of residual stones greater than 4 mm[15] on postoperative imaging (NCCT KUB) at 1 month. The secondary outcome measures included were operative time, complications (based on Clavien

Dindo classification[16] class 1–5), postoperative pain scores (numerical pain rating scale), length of hospital stay, and secondary procedures required.

Statistical analysis

Based on the distribution of the data, appropriate parametric or nonparametric tests were used to conduct statistical analysis. Categorical variables were shown as frequencies and percentages, and continuous variables were represented as mean ± standard deviations. Fisher's exact tests, Chi-square tests, or independent t-tests were used as needed to conduct comparative analyses between the RIRS and mPCNL groups. *P* values less than 0.05 were deemed statistically significant. To find treatment outcome predictors, multivariate regression models and subgroup analyses were used. IBM SPSS 29.0 was used as the statistical program for data analysis.

Ethical considerations

Institutional ethical committee clearance was obtained. Patient confidentiality was strictly maintained, and all study-related information was securely stored.

Table 1: Patient demographics

Variables	Mini PCNL	RIRS	*P*
Renal units	50	50	-
Age (years)	44.66±7.889	44.16±9.342	0.773
Sex			
Male	30 (60%)	28 (56%)	0.685
Female	20 (40%)	22 (44%)	
BMI (kg/m^2)	25.80±1.841	24.62±3.197	0.057
Laterality			
Right	26 (52%)	24 (48%)	0.689
Left	24 (48%)	26 (52%)	
Stone size (mm)	11.282±1.7996	11.248±2.0340	0.930
Stone distribution			
Upper calyx	20 (40%)	14 (28%)	0.586
Middle calyx	5 (10%)	8 (16%)	
Lower calyx	20 (40%)	22 (44%)	
Pelvis	5 (10%)	6 (12%)	

Results

The tables present a detailed comparative analysis of patient demographics and clinical outcomes between mPCNL and RIRS.

In terms of patient demographics [Table 1], both the mPCNL and RIRS groups consisted of 50 renal units each. The mean age of patients was similar, with mPCNL patients averaging 44.66 years (±7.889) and RIRS patients averaging 44.16 years (±9.342). Gender distribution was also comparable between the two groups, with 60% of the mPCNL group being male and 40% female, while the RIRS group comprised 56% males and 44% females, yielding a *P* value of 0.685. Regarding BMI, the mPCNL group had a mean BMI of 25.80 (±1.841) compared to 24.62 (±3.197) for the RIRS group, with a *P* value of 0.057, suggesting a marginal difference which was not statistically significant. Laterality of stones was evenly distributed, with 52% of mPCNL procedures and 48% of RIRS procedures performed on the right side and the remainder on the left, showing no significant difference (*P* value 0.689). Stone size was nearly identical between the groups, with mPCNL at 11.282 mm (±1.7996) and RIRS at 11.248 mm (±2.0340). Stone distribution across different parts of the kidney (upper calyx, middle calyx, lower calyx, and pelvis) showed no significant differences between the two groups, with a *P* value of 0.586.

The subgroup analysis [Table 2] based on stone location showed that on postoperative day 1, the clearance rates varied. For upper pole (UP) stones, mPCNL had a 95% clearance rate compared to 100% for RIRS, with a *P* value of 0.627. For intermediate pole (IP) stones, clearance was 80% for mPCNL and 87.5% for RIRS, with a *P* value of 0.385. Lower pole (LP) stones had a significantly higher clearance rate with mPCNL (95%) compared to

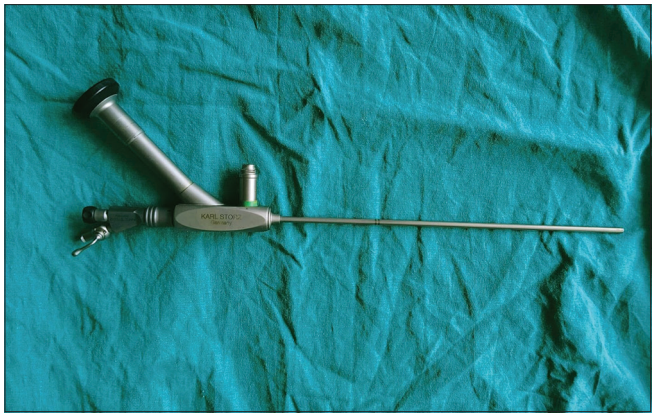

Figure 1: 12 Fr Nephroscope used for Mini PCNL

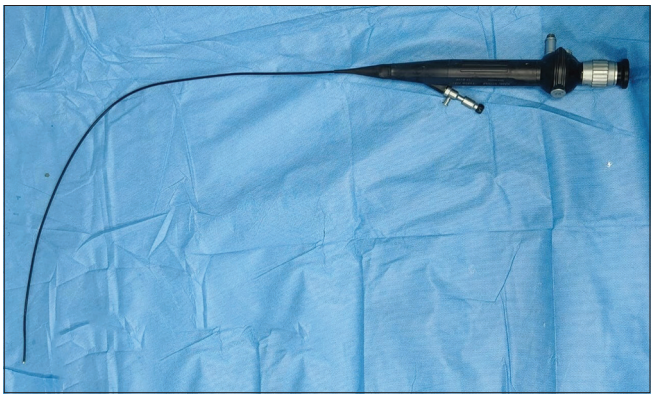

Figure 2: 7.5 Fr Flexible ureterorenoscope used for RIRS

Table 2: Subgroup analysis as per the location of stone on POD 1

Location	Stone-free rate on postoperative day 1 with respect to the location of stones		
	Mini perc	RIRS	*P*
UP	19 (95%)	14 (100%)	0.627
IP	4 (80%)	7 (87.5%)	0.385
LP	19 (95%)	17 (77.27%)	0.013
Pelvic	5 (100%)	6 (100%)	-
Total	47 (94%)	44 (88%)	0.249

Table 3: Comparison of intraoperative and perioperative variables

Variables	Mini PCNL	RIRS	*P*
Operative time (min)	45.64±2.481	58.32±3.814	<0.001
Fluoroscopy time (s)	77.28±2.466	49.40±2.515	<0.001
Lasing time (min)	10.74±1.337	18.80±1.829	<0.001
Hospital stay (hours)	62.58±5.771	47.36±5.631	<0.001
Pain score post op (Numerical pain rating scale)	4.5	2.2	<0.001

Table 4: Comparison of postoperative outcomes

Postoperative complications	Mini PCNL	RIRS	*P*
CD Grade 1 (Pain, Fever)	17 (34%)	5 (10%)	<0.001
CD Grade 2 (Urosepsis, Hematuria)	7 (14%)	2 (4%)	
CD Grade 3/4/5	-	-	
Stone-free rate (%)			
POD1	47 (94%)	44 (88%)	0.249
1 month	48 (96%)	45 (90%)	0.68
Second procedure			
Relook RIRS	2 (4%)	5 (10%)	0.68
Drop in Hb (gm/dl)	0.7890±0.0417	0.4710±0.0777	<0.001

RIRS (77.27%), with a *P* value of 0.013. Mini PCNL cleared stones in a higher percentage of patients with lower pole calculi; however, there was no statistically significant difference between the procedures in terms of stone-free rate. Both groups achieved 100% clearance for pelvic stones. Overall, mPCNL cleared stones in 47 cases (94%) and RIRS in 44 cases (88%) on postoperative day 1.

Intraoperative and perioperative variables [Table 3] revealed notable differences. The mean operative time for mPCNL was significantly shorter at 45.64 minutes (±2.481) compared to 58.32 minutes (±3.814) for RIRS, with a *P* value of <0.001. The fluoroscopy time was longer for mPCNL (77.28 seconds ± 2.466) than for RIRS (49.40 seconds ± 2.515), again with a significant *P* value of < 0.001. The lasing time was shorter for mPCNL at 10.74 minutes (±1.337) compared to 18.80 minutes (±1.829) for RIRS, with a *P* value of < 0.001. Hospital stay was longer for mPCNL patients, averaging 62.58 hours (±5.771), compared to 47.36 hours (±5.631) for RIRS patients, with a significant *P* value of < 0.001. The postoperative pain was at an average of 4.5 for the mPCNL group and 2.2 for the RIRS group; this difference was statistically significant.

Postoperative outcomes [Table 4] highlighted further differences. Mini PCNL had higher rates of Clavien-Dindo Grade 1 (34%) and Grade 2 (14%) complications compared to RIRS, which had 10% Grade 1 and 4% Grade 2 complications, with a significant *P* value of < 0.001. However, the higher rate of complications in the mPCNL was mostly due to postoperative site pain which was well managed by analgesics and gives a false picture of a higher rate of complications. Both groups had no Grade 3 or above

Table 5: Comparison with other studies

Variable	Sabnis *et al.* 2012[17]		Knoll *et al.* 2011[18]		Pan *et al.* 2013[19]		Jain *et al.* 2021[20]		Our study		*P*
	Mini PCNL	RIRS	Mini PCNL	RIRS	Mini PCNL	RIRS	Mini PCNL	RIRS	Mini PCNL	RIRS	
Renal units	32	32	25	21	59	56	40	40	50	50	-
Age	44.48	49.28	56	53	49.32	49.37	35.6	40.45	44.66	44.16	0.773
Sex	19:13	25:7	15:10	9:12	37:22	36:20	25:15	32:8	30:20	28:22	0.685
BMI	-	-	27	31	23.52	23.69	23	25.09	25.80	24.62	0.057
Stone size (mm)	15.2	14.2	18	19	22.37	22.28	12.35	12.9	11.282	11.248	0.689
OT time (min)	40.81	50.63	59	106	62.39	73.07	51.58	69.75	45.64	58.32	<0.001
Flouroscopy time (s)	-	-	-	-			-	-	77.28	49.40	<0.001
Complications	2	3	4	5	7	9	11	16	24	7	<0.001
Pain	2.74	2	-	-			4.45	3.20	80%	18%	<0.001
Hb drop	1.43	0.40	-	-	0.128	0.04	0.88	0.42	0.78	0.47	<0.001
Hospital stay	2.07	1.94	-	-	4.47	1.95	2.85	2.45	2.608	1.97	<0.001
Second surgery	0	1	-	-	-		3	5	3	6	0.249
SFR on POD 1	-	-	96	71.5	-	-	77.5	45	94	88	0.249
SFR at 1 month	100	96.88	100	85.8	96.6	71.4	90	85	96	90	0.68
SFR at 3 months	-	-	-	-	-	-	88.6	82.9	–	-	-

complications. The stone-free rate on postoperative day 1 was 94% for mPCNL and 88% for RIRS, with a *P* value of 0.249; on follow-up at 4 weeks for stent removal, the stone clearance rate was 96% in mPCNL and 90% in RIRS group. The second procedure (RIRS) was required in 4% of mPCNL cases and 10% of RIRS cases, with a *P* value of 0.68. The drop in hemoglobin levels was greater in the mPCNL group (0.7890 g/dL ± 0.0417) compared to the RIRS group (0.4710 g/dL ± 0.0777), with a significant *P* value of <0.001.

Discussion

This comparative analysis [Table 5] examines various parameters associated with both procedures by comparing our study with those of Sabnis *et al.*,[17] Knoll *et al.*,[18] Pan *et al.*,[19] and Jain *et al.*[20] The parameters include demographic data, clinical outcomes, and procedural specifics, providing a comprehensive view of the effectiveness and efficiency of the interventions.

Our study included 50 patients in each group, which is slightly more than the numbers reported by Sabnis *et al*.[17] (32 per group), Knoll *et al*.[18] (25 and 21 per group), and Jain *et al*.[20] (40 per group). The sample size in our study is comparable to that of Pan *et al*.[19] (59 and 56 in respective groups). This relatively larger sample size in our study provides a more robust dataset, potentially leading to more reliable and generalizable findings.

The mean age of patients in the mPCNL and RIRS groups was 44.66 ± 7.889 and 44.16 ± 9.342 years, respectively. This was similar to the age group reported by Sabnis *et al.*(44.48 and 49.28 years),[17] Knoll *et al.* (56 and 53 years),[18] Pan *et al.* (49.32 and 49.37 years),[19] and Jain *et al.* (35.6 and 40.45 years).[20] The *P* value of 0.773 indicates no significant age difference, suggesting age homogeneity. The sex ratio in our study also shows no significant difference compared to the other studies, which reported varying male-to-female ratios. The *P* value of 0.685 indicates a balanced gender distribution in our study.

BMI data were available for Knoll *et al.*,[18] Pan *et al.*, and Jain *et al.*[19,20] Our study reported similar BMI values (25.80 and 24.62) compared to Pan *et al.* (23.52 and 23.69) and Jain *et al.* (23 and 25.09).[19,20] Knoll *et al.*[18] had a slightly higher BMI distribution than our study (27 and 31). The *P* value of 0.057 in our study suggests that BMI differences might not substantially impact the outcomes.

The stone size in our study averaged 11.282 mm and 11.248 mm, respectively, in the mPCNL and RIRS groups, similar to the sizes reported by Sabnis *et al.*[17] (15.2 mm and 14.2 mm, respectively) and Knoll *et al.*[18] (18 mm and 19 mm, respectively). Pan *et al.*[19] reported larger stones (22.37 mm and 22.28 mm, respectively). Jain *et al.*[20] reported the stone size as similar to our study (12.35 mm nad 12.9 mm, respectively) Our study focused on the intermediate-sized group of stones (8–15 mm) to generate data on the most appropriate procedure considering all the variables.

The average operative time in our study was 45.64 minutes in the mPCNL group and 58.32 minutes in the RIRS group. Sabnis *et al.*[17] reported the shortest time of 40.81 minutes and 50.63 minutes, respectively. Knoll *et al.*,[18] Pan *et al.*,[19] and Jain *et al.*[20] reported longer operative times. The *P* value of <0.001 indicates a significant difference, emphasizing the significant difference in operative time between the two procedures. The fluoroscopy time is slightly higher in our study (77.28 s for MiniPCNL and 49.40 s for RIRS) than the times reported by Jain *et al.*[20] (56.78 and 40.20 s, respectively). The *P* value of <0.001 reflects less exposure to radiation in RIRS than in mPCNL.

Our study reported a higher number of complications (24 in mPCNL and 7 in RIRS group) compared to Sabnis *et al.*[17] (2 in mPCNL and 3 in RIRS), Knoll *et al.*[18] (4 and 5, respectively), Pan *et al.*[19] (7 and 9, respectively), and Jain *et al.*[20] (11 and 16, respectively). The *P* value of <0.001 indicates a significant difference, necessitating a closer examination of procedural factors contributing to these complications. The higher complication rate in our study largely included postoperative pain and fever in those patients who needed analgesics and antipyretics to treat them. Jain *et al.*[20] reported a higher number of complications in the RIRS group than in the mPCNL group.

Pain levels were reported in our study using a numerical pain rating scale with mPCNL group 4.5 and 2.2 in the RIRS group reporting mild pain. A significant *P* value of <0.001 suggests RIRS group patients had significantly less postoperative pain; however, it was well controlled with analgesics.

The hemoglobin drop in our study (0.78 and 0.47) was lower compared to Sabnis *et al.*[17] (1.43 and 0.40), with a *P* value of <0.001; however, there was no need of postoperative blood transfusion in any of the mPCNL group patients. Jain *et al.*[20] reported values similar to those of our study with a drop of 0.88 and 0.42 in mPCNL and RIRS groups, respectively.

The average hospital stay in our study (2.608 days for the mPCNL and 1.97 days for the RIRS group) was comparable to other studies, with *P* value <0.001, which suggested that RIRS patients had minimal need for hospitalization as compared to mPCNL group. Sabnis *et al.*[17] reported a hospital stay of 2.07 days for the

mPCNL group and 1.94 days for the RIRS group, and this was comparable to our study. Pan *et al.*[19] reported that mPCNL patients required an average hospital stay of 4.47 days, which was significantly higher. Jain *et al.*[20] reported a similar hospital stay of 2.70 days for mPCNL and 1.05 days for RIRS group.

The need for second surgeries did not significantly differ among studies, with our study reporting a similar rate to Sebaey *et al*.[21] The *P* value of 0.68 in our study suggested comparable initial procedure success rates. Even Sabnis *et al.* and Jain *et al.*[17,20] did not have a statistically significant need for relook RIRS procedure in their studies.

Stone-free rates (SFRs) at 1 month and 3 months were comparable across studies. Our study reported 96% SFR at 1 month in the mPCNL group and 90% at 1 month in the RIRS group. Higher SFRs were reported by Sabnis *et al.*[17] (100% and 96.88% in mPCNL and RIRS groups at 1 month) and Knoll *et al.*[18] (100% at 1 month and 85.8% in mPCNL and RIRS group, respectively). Jain *et al.*[20] reported 90% and 85% SFRs in respective groups at the end of 1 month. The *P* value of 0.68 indicates no significant difference in the SFR, affirming the effectiveness of both the procedures in achieving stone-free status.

Conclusion

Our study emphasizes the importance of tailored treatment approaches based on patient characteristics. Both RIRS and mPCNL have established their position in the management of stones less than 1.5 cm. Each procedure scores over the other in certain aspects. The overall operative time is higher in the RIRS, while the fluoroscopy time, complication rates, hemoglobin fall, and mean duration of hospital stay are higher with the PCNL group. However, the overall stone clearance rates in both procedures have been remarkable.

Recommendation

It is prudent to leave it to the discretion of the operating surgeon to choose the appropriate procedure for a given patient considering the variables.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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