A PROSPECTIVE STUDY COMPARING TUBELESS MINI-PERCUTANEOUS NEPHROLITHOTOMY TO RETROGRADE INTRARENAL SURGERY FOR ≤2 CM RENAL STONES.

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Abstract

Objective :

The present study aims to assess the safety and efficacy of tubeless mini-PCNL and RIRS in the management of renal stones of ⩽2 cm size.

Patients and methods :

This was a prospective study in 80 patients with renal stones of ⩽2 cm and were divided into two equal groups of patients choice: Group 1 were managed by tubeless mini-PCNL and Group 2 by RIRS using flexible ureteroscopy and laser. Intraoperative events like duration of surgery, stone clearance and complications were noted. Postoperative parameters taken into account were pain score, parenteral analgesic requirements, bleeding, need for blood transfusion, fever, hospital stay, cost of the procedure and number of days taken to return to normal work.

Results :

Both groups were comparable for preoperative parameters. Mean duration of surgery in group 1 and group 2 was 68.88 ± 7.20 minutes and 92.25 ± 14.62 minutes respectively ($p<0.00001$). The mean haemoglobin fall in group 1 and group 2 was 0.47±0.24 g/dl and in group 2 was 0.28±0.18 g/dl respectively ($p=0.00013$). In group 2, residual stones were present in 4 patients (on follow-up at 3 weeks), while in group 1 there was no residual stones. The cost of the treatment was more in the RIRS group with statistically significant difference ($p<0.005$).

Conclusion :

In a urological setup where LASER and flexible ureteroscope are not available, tubeless mini PCNL is a safe, efficacious and cost-effective option for the management of smaller (⩽ 2 cm) stones compared to RIRS procedure.

Recommendations:

Mini PCNL and RIRS are safe and feasible surgical options to manage ⩽ 2 cm renal stones. We recommend tubeless mini PCNL in a setup where LASER and flexible ureteroscope are not available.

Keywords: RIRS, PCNL, miniPCNL, Renal stones, Submitted: 2023-02-16 Accepted: 2023-03-12

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1. Introduction

Urolithiasis is one of the most common urological problems with a high recurrence rate and significant socioeconomic implications.[1] The incidence of Urolithiasis is increasing globally probably due to the change in climate and environment. Reports suggest that the incidence of urinary tract calculi is up to 12%. The lifetime recurrence risk for renal calculi is reported to be as high as 50%.[2] The stone movement causes renal colic and the obstruction by calculi can lead to loss of renal function. Various non-invasive, minimally invasive and invasive treatment modalities are available for small renal stones including medical treatment, percutaneous nephrolithotomy (PCNL), retrograde intrarenal surgery (RIRS) and extracorporeal shockwave lithotripsy (ESWL).[3,4] The ideal treatment would be complete stone clearance in a single session without any severe trauma to the kidney and the patient. Even though we have not yet accomplished this, the therapeutic options are always being changed to increase effectiveness while reducing side effects.

PCNL, which was first described in 1976, has become the procedure of choice for large burden renal calculi and a management option for small renal calculi as well.[5,6] PCNL is a more effective treatment for stones <2 cm compared with the ESWL method.[7] PCNL is also used for calyceal diverticular calculi, upper calyceal calculi with infundibular stenosis, and a lower calyceal stone >10 mm, which cannot be completely removed by ESWL.[8,9] PCNL entails four steps: gaining access to the kidney, dilating the access site, performing a nephroscopy and fragmenting stones, and placing a nephrostomy tube. PCNL has good SFR but is associated with significant morbidity.[10] The main disadvantage of the traditional PCNL was the need to use a large size sheath (30-32Fr), with the resultant morbidities in the form of bleeding, injury to adjacent organs, postoperative pain and longer hospital stay. To decrease morbidity, a modification of this technique has been developed. This is being performed with a miniature endoscope via a small percutaneous tract (12-20 Fr) and is named as minimally invasive PCNL or mini-PCNL or 'mini Perc'. Helal et al. were the first to describe a technique for pediatric nephrolithotomy.[11] However, the mini-PCNL technique was first developed and accomplished by Jackman et al. in the pediatric population with the use of an 11 Fr access tract.[12] Since then, the method has become a treatment option for adults as well.[15] Usually, the term mini-PCNL is used for access sheaths below 20 F.

The standard PCNL procedure, which was used up until 1997, entailed the use of a nephrostomy tube for the drainage of the pelvicalyceal system and tamponading of the renal access tract. This procedure has a number of drawbacks, including a prolonged hospital stay, pain, and distress that are related to the size of the nephrostomy tube used. Total tubeless PCNL is now the trend to reduce discomfort, infection, and hospital stay.

Retrograde intrarenal surgery (RIRS) (also termed flexible ureterorenoscopy, F-URS), is another major minimally invasive treatment modality for managing the upper urinary tract calculi. RIRS has been considered as an effective alternative to the percutaneous approaches for the management of the small renal calculi, due to its characteristics of natural orifice introduction and access to the renal calculi, easy intrarenal manoeuvrability, LASER fragmentation or dusting of stones and faster recovery. RIRS is considered a safe procedure but has a higher cost of treatment due to LASER usage and costly flexible scopes with costly disposables and also there is lower SFR than PCNL.[15,16]

Two successful minimally invasive methods to remove the obstruction are mini-PCNL and RIRS. There aren't still enough greater data to provide a strong argument on whether one should replace the conventional tract PCNL. Several research have been done to assess the Efficacy and safety of controlling renal stones between mini-PCNL and RIRS. The few instances, various classifications of the goal stone size, and their definition of success were the key drawbacks of these earlier investigations. [17,18]

The present study aims to assess the safety and

efficacy of tubeless mini-PCNL and RIRS in the management of renal stones of $\leqslant$2 cm size and to determine the advantages and disadvantages of each procedure.

2. Materials and Methods

This was a Prospective study that was conducted in the department of urology at Batra Hospital, New Delhi, India, from July 2018 to December 2019. A total of 80 patients were included in the study, 40 patients in each group (tubeless mini PCNL group and RIRS group). All patients with renal calculus who were planned for tubeless mini-PCNL/ RIRS and satisfying inclusion/exclusion criteria were included in the study. The research ethics committee of the hospital reviewed and approved the study. Written informed consent was taken after explaining the details of the procedure, possible retreatment, and shift to another treatment, complications and investigative nature of the treatment protocol. Inclusion criteria were calculi in the upper, mid or lower pole and pelvis of the kidney, solitary calculus or multiple calculi with stone mass $\leqslant$2 cm. Exclusion criteria were patients with stone mass >2cm, renal stone in an anomalous kidney, bilateral Renal stone diseases, uncontrolled comorbidities [diabetes, hypertension, severe cardiac dysfunction], coagulopathy, renal insufficiency, pregnancy.

All patients were evaluated by a full clinical history, serum creatinine, blood urea nitrogen, bleeding profile, urine culture and radiological investigations in the form of USG followed by IVP/NCCT KUB, CT urogram.

For Tubeless mini PCNL, the patients received general or regional anaesthesia as per patient/anaesthetist choice. The instruments used were nephroscope 12F, Amplatz sheath (15F or 18F), and amplatz dilator (single step). The patients were placed in the lithotomy position. 17Fr cystoscope was used to insert a 5-Fr open-tip ureteric catheter. Patients were then placed in the prone position. Only one access puncture was performed in all patients. Access to the calyx was performed using a C-arm and 18-gauge needle after the injection of contrast media into the ureteric catheter to identify the pelvicalyceal system. Once the position of the needle was confirmed in the desired pelvicalyceal system a 0.9Fr (0.035cm) Terumo straight tip guidewire was inserted into the collecting system or down the ureter under image control and the needle was then retracted. With the aid of the guidewire, dilatation was performed with a single-step screw dilator, and an appropriate size Amplatz sheath (15Fr or 18Fr) was placed. Stone fragmentation was carried out with a pneumatic lithotripter (swiss lithoclast) in all cases. The fragments were removed using stone forceps or baskets. At the end of the procedure, the pelvicalyceal system was examined both endoscopically and radiographically for any residual fragments, bleeding or perforations. A Ureteric catheter was kept for drainage. No nephrostomy tube / JJ stent was kept and the tract site is closed with a deep 2/0 purse-string silk suture. Operative time was defined as the time passed from the insertion of the cystoscope to the skin suturing.

For RIRS, the patients received general or regional anaesthesia as per patient/anaesthetist choice. A safety guidewire was placed into the renal pelvis in the lithotomy position after visual assessment of the urethra, urinary bladder and ureteric orifice by Cysto-Pan-Endoscopy using a 17Fr cystoscope. Visual assessment of Ureter and ureteropelvic junction in all patients was performed with a 9.5 Fr semirigid ureteroscope, which was also used to dilate the ureter to facilitate placement of a ureteral access sheath of 9 Fr size. Ureteral balloon dilatation was performed where indicated. Accessible calyx was determined under fluoroscopic guidance using C-Arm. A 5 Fr fibre-optic (Storz FLEX-X2, Tuttlingen, Germany) flexible ureteroscope with a sheath size of 7.5 Fr and a 200 or 260 μm laser fibre was used for treatment. We used a holmium laser machine set at an energy of 0.8–1.5 J and a rate of 8–10 Hz. At the end of laser lithotripsy, stone fragments smaller than 2 mm were left for spontaneous passage, and basket retrieval was performed for fragments larger than 2 mm. A systematic inspection of the collecting system was performed at the end of the procedure to confirm the achievement of ad-

equate fragmentation and stone clearance. A 5 Fr JJ stent was routinely placed in every patient and was removed 3 weeks after the procedure. The operative time was defined as the time passed from the insertion of a cystoscope to the completion of stent placement.

Foley catheters were removed in both groups before discharge when urine was clear and no urinary leakage at PCN site either same day evening or the next day. All patients could be discharged within 24 hours. The patient needs to be fully conscious, tolerating orals, pain-free, no hematuria and stable vital signs after evaluation by the lead surgeon. A Check X-ray of the chest and kidney-ureter-bladder (KUB) region was done before discharge. Each patient was given verbal and written instructions about indications for returning to the hospital. Follow up was done at 1 and 3 weeks. Follow-up ultrasonography was performed on day 7 to confirm any collection formation or residual fragments.

Intraoperative events like duration of surgery, stone clearance and any complications were noted. Postoperative parameters, which were taken into account are the visual analogue scale (VAS; 1 to 10) for pain, parenteral analgesic requirements, bleeding(hematuria or fall in hematocrit), urinary soakage, and hemodynamic stability, need for blood transfusion, fever, hospital stay, readmission and retreatment rate. Postoperatively, patients were on injectable analgesics (Diclofenac sodium: 75 mg 12 hourly and Tramadol: 50 mg, SOS). At follow-up, parameters evaluated were pain score and analgesic requirements, any other complication and number of days taken to return to normal work.

2.1. ***Statistical analysis***

Data were collected, tabulated, and statistically analyzed by SPSS® software (Statistical Package for the Social Sciences software, version 15 for Windows). To compare qualitative data the chi-square test and fisher's exact test were used as appropriate. The t-test test was used to analyze quantitative data. P values were estimated; with a $P < 0.05$ indicated statistical significance.

3. Results

A total of 80 patients were included in the study and divided into two groups each having 40 patients. Group 1 is a tubeless mini-PCNL group and group 2 is the RIRS group.

Although there was a male preponderance in both the groups, the gender distribution between the two groups was similar. Number of males and females in group 1 was 23 (57.5%) and 17 (42.5%) respectively while in group 2 was 21(52.5%) and 19 (47.5%) respectively. p-value was 0.600, which showed that the difference was not statistically significant.

Patients were divided into four age groups of 20 years intervals. Although there was some difference in the number of patients in each interval the difference was not statistically significant (P-value=0.471), the groups were similar in terms of age distribution The mean age of patients of group 1 and group 2 were 37.6 ±13.94 and 39.78±12.92 years.

Although there was right-sided stones preponderance in both the groups, the side distribution between the two groups was similar. The number of patients with stones on the right and left side in group 1 was 25 and 15 respectively while in group 2 was 23 and 17 respectively. p-value was 0.648, which showed that the difference was not statistically significant.

Mean stone burden in group 1 and group 2 were 11.71±2.674 mm and 12.28±3.079 mm respectively. There was no statistically significant difference in stone burden between the two groups.

In group 1 most common location of stone was the pelvis (30.0%) followed by middle calyx (27.5%), Lower calyx (22.5%) and upper calyx (20.0%). In group 2 most common location was lower calyx (30.0%) followed by pelvis (27.5%), upper calyx (22.5%) and middle calyx (20.0%). There was no statistically significant difference in the location of stone between the two groups (Table 1).

The mean duration of surgery in group 1 was 68.88 ± 7.20 minutes and in group 2 was 92.25 ± 14.62 minutes respectively. Duration of surgery was more in group 2 as compared to group 1

Table 1: **Patients' preoperative characteristics**

Variable	Group 1(n=40) (Tubeless mini-PCNL)	Group 2(n=40) (RIRS)	p value
Gender			
Male	**23 (57.5%)**	**21 (52.5%)**	**0.600**
Female	**17 (42.5%)**	**19 (47.5%)**	
Age (years) Mean±SD	**37.6 ±13.94**	**39.78±12.92**	**0.471**
Stone size (mm) Mean±SD	**11.71±2.674**	**12.28±3.079**	**0.821**
Side of stones			
Right	**25 (62.5%)**	**23 (57.5%)**	**0.648**
Left	**15 (37.5%)**	**17 (42.5%)**	
Location of stones			
Upper Calyx	**8 (20.0%)**	**9 (22.5%)**	**0.787**
Lower Calyx	**9 (22.5%)**	**12 (30.0%)**	**0.447**
Middle Calyx	**11 (27.5%)**	**8 (20.0%)**	**0.429**
Pelvis	**12 (30.0%)**	**11 (27.5%)**	**0.802**

and there was a statistically significant difference ($p<0.00001$) (Table 2).

The mean HB fall in group 1 was 0.47±0.24 g/dl and in group 2 was 0.28±0.18 g/dl respectively. The difference between postoperative haemoglobin fall between the two groups was statistically significant ($p=0.00013$).

The mean postoperative pain score in group 1 was 4.1±1.14 (range 2-8) and in group 2 was 3.65±0.91 (range 2-6). The difference in postoperative pain score between the two groups was not statistically significant ($p=0.057$).

The mean postoperative analgesic requirement in group 1 was 131.25±68.63 mg and in group 2 was 116.25±52.90 mg. Although the requirement of dose of analgesic was more in group 1 as compared to group 2, the difference was statistically not significant ($p=0.283$).

In group 1, 2 (5.0%) patients developed fever, 8 (20.0%) patients developed hematuria while in group 2, 7 (17.5%) patients developed fever, 4 (10.0%) developed haematuria. The stone clearance rate was 100% in group 1 and 87.5 % in group 2 and the difference was statistically significant ($p=0.02$). No patient developed urinoma, perinephric hematoma in any group.

In our study group, 1 and group 2, the mean hospital stay was 28.5±9.09 hours and 27.8±6.23 hours respectively. The difference in hospital stay between the two groups was statistically not significant ($p= 0.693$).

Comparing of follow-up complications between the two groups, in group 1, 1 (2.5%) patient developed colic, 2 (5.0%) patients developed fever and 2 (5.0%) patients developed hematuria. While in group 2, 3(7.5%) patients developed colic, 1 (2.5%) patients developed fever and no patient developed haematuria. In group 2, residual stones were present in 4 patients (on follow up at 3 weeks), while in group1 there was no residual stone in any patient. The difference was statistically significant ($p=0.04$). (Table 3)

In group 1 and group 2, the meantime to return to normal activity was 4.42±2.19 days and 3.92±1.52 days respectively. The difference in days to return to normal activity between the two groups is statistically not significant ($p=0.245$).

The cost of the treatment was more in the RIRS group. The difference in cost of the treatment in the two groups was statistically significant ($p<0.005$). (Table 3)

Table 2: **Comparison of duration of surgery between two groups**

	Group 1(n=40) (Tubeless mini-PCNL)		Group 2(n=40) (RIRS)		p value
Duration of Surgery (minutes)	**Frequency**	**%**	**Frequency**	**%**	
<70	**20**	**50.0**	**0**	**0.0**	
70-80	**18**	**45.0**	**11**	**27.5**	
81-90	**2**	**5**	**13**	**32.5**	**<0.00001**
>90	**0**	**0.0**	**16**	**40.0**	
Mean±SD	**68.88 ± 7.20**		**92.25 ± 14.62**		

Table 3: **Patients' postoperative characteristics**

	Group 1(n=40) (Tubeless mini-PCNL)	Group 2(n=40) (RIRS)	p value
HB Fall in gm/dl Mean±SD	**0.47±0.24**	**0.28±0.18**	**0.00013**
Pain Score(VAS) Mean±SD	**4.18±1.28**	**3.85±0.85**	**0.191**
Analgesic requirement in mg Mean±SD	**131.25±68.63**	**116.25±52.90**	**0.283**
Hospital Stay (Hrs) Mean±SD	**28.5±9.09**	**27.8±6.23**	**0.693**
Post-op complications			
Fever	**2 (5%)**	**7 (17.5%)**	**0.077**
Haematuria	**8 (20%)**	**4 (10%)**	**0.211**
Residual calculi	**0 (0%)**	**5 (10%)**	**0.02**
Complications on followup			
Colic	**1 (2.5%)**	**3 (7.5%)**	**0.645**
Haematuria	**2 (5%)**	**0 (0%)**	**0.153**
Fever	**2 (5%)**	**1 (2.5%)**	**0.555**
Residual Stone	**0 (0%)**	**4 (10%)**	**0.04**
Readmission	**5 (12.5%)**	**4 (10%)**	**0.726**
Return to normal Activity (days) Mean±SD	**4.42±2.19**	**3.92±1.52**	**0.245**
Cost of the treatment(INR) Mean±SD	**86312.5±15702.18**	**122087.5±13988.78**	**<0.005**

INR- Indian rupee

4. Discussion

Conventionally, the placement of a nephrostomy tube after PCNL was considered a necessary safety option. However, the use of a nephrostomy tube has been associated with some co-morbidly (prolonged hospital stay and more postoperative pain).[19] In 1997, Bellman et al. first reported the procedure named "tubeless PCNL" using a double-J ureteral stent and Council catheter.[20] They demonstrated that length of hospital stay, the requirement of analgesia, time to return to normal activities, and cost were significantly less with this procedure. With the recent development of a high-density telescope, high-quality lithotripters, and radiological interventional techniques to embolize blood vessels, several investigators reported that tubeless PCNL in selected patients was safe and associated with a reduced hos-

pital length of stay and analgesic requirements. Some urologists used the approach of placing the smallest possible nephrostomy tube to minimize patient discomfort while maintaining access to the renal collecting system.[20]

To decrease morbidity associated with larger instruments a modification of the technique of standard PCNL called "mini perc" has been developed. With the development of smaller sheaths, it was found that mini-PCNL or "mini perc" could be performed with minimal damage to the renal parenchyma, thereby reducing the procedure-related morbidity without diminishing its therapeutic efficacy.[11]

RIRS has been considered as an alternative to the percutaneous approaches for the management of the lower calyceal small renal calculi, due to its characteristics of little trauma, quick recovery, easy operation, and little contraindication.[17] RIRS is a safe procedure but the main drawbacks of RIRS include the need for flexible scopes,reduced size of fragments removed, and the need for flexible lithotrites and baskets. Thus, the cost is a major deterrent to RIRS, particularly in developing countries. This study aimed to compare the safety, efficacy and cost-effectiveness of tubeless mini PCNL and RIRS procedures in patients with less than 2 cm renal stones.

In our study, there were no statistically significant differences between the tubeless mini PCNL (TmPCNL) and retrograde intrarenal surgery (RIRS) groups for the age and sex of the patients. The mean (± SD) age of patients was 37.6 ±13.94 years in the TmPCNL group and 39.78±12.92 years in the RIRS group. In TmPCNL group 23(57.5%) patients were male and 17 (42.5%) were female while in RIRS group 21(52.5%) were males and 19 (47.5%) were females. Also, there was no statistically significant difference between the two groups for stone size, side, and location within the kidney. The mean stone size was 11.71±2.674 mm in the TmPCNL group and 12.28±3.079 mm in the RIRS group. Our observations were similar to a study conducted by Amr S. Fayad et al, 2017[21] who reported that there was no significant difference between the two groups for patient demographics and stone characteristics. Pan J., et al. 2013[22] also reported that there was no significant difference between the two groups for patient demographics and stone characteristics.

The mean operative time was shorter in the TmPCNL group than in the RIRS group in our study. The mean (±SD) operative time in TmPCNL and RIRS was 68.88 ± 7.20 versus 92.25 ± 14.62 min, respectively and this difference was statistically significant ($p<0.00001$). Our observations were similar to a study conducted by Amr S. Fayad et al, 2017[21] who reported that the mean (±SD) operating time was statistically significantly longer in the RIRS group [109.66 (20.75) min] as compared to the TmPCNL group [71.66 (10.36) min]. In the study conducted by Pan J., et al. 2013[22] the operative time for RIRS was longer ($P = 0.000$). In a study by Knoll T., et al. 2010[23] total operative time was significantly longer for fURS (106 ± 51 vs. 59 ± 19 min., $P < 0.001$). But in the Lee J.W., et al. 2015[24] study, there was no statistically significant difference in operative time between the mPCNL and RIRS groups.

For the mean postoperative drop in haemoglobin, there was a significant difference between the two groups in the present study. The mean haemoglobin fall was 0.47±0.24 g/dl for TmPCNL versus 0.28±0.18 g/dl for RIRS. But no patient in any of the groups required blood transfusion. In some cases of TmPCNL which bleed immediately postoperatively, we used balloon tamponade for haemostasis (a foley catheter was introduced in the PCN tract, the balloon was filled with 2-3 ml of normal saline and little traction was applied for 15 minutes). Saline cross irrigation through the ureteric catheter was also used in these cases to avoid clot retention in the PCS. Lee J.W., et al. 2015[24] in their study concluded that there was no significant difference in haemoglobin decline ($P = 0.323$). In the study conducted by Guohua Zeng, et al. 2018[25] RIRS was found to be superior to the mini PCNL group in terms of lower haemoglobin drop. Blood transfusion was not required in either group.

The absence of a nephrostomy tube in TmPCNL resulted in less postoperative pain. A visual analogue scale was used for pain assessment

24 hours after surgery. The mean pain score in TmPCNL and RIRS groups was 4.18±1.28 (range 3-8), and 3.85±0.85 (3-8) respectively, with a statistically insignificant difference between the groups (P = 0.191). In a study by Guohua Zeng, et al. 2018[25] patients in the RIRS group experienced less postoperative pain. Surprisingly Lee J.W., et al. 2015[24] reported that pain visual analogue score at 1 hour postoperatively (P = 0.029) and analgesic requirement (P = 0.050) were higher in the RIRS group.

Postoperative pain management was done by nonsteroidal anti-inflammatory analgesic diclofenac. In our present study, the postoperative analgesics requirement (diclofenac sodium) in the RIRS group was less than that of the TmPCNL group mean of 116.25±52.90 mg versus 131.25±68.63 mg, respectively [p=0.283]. This is an advantageous feature of tubeless PCNL and has also been reported in other studies, such as that of Zhong et al.[26], as their overall results indicated that the tubeless PCNL group had a lesser analgesic requirement as compare to standard mini PCNL (Sm-PCNL). In the study of Khairy Salem et al.[27] in the TmPCNL group the mean (range), pain score was 4.6 (3–6), with no need for i.v. analgesia (only oral and per rectum); however, in the Sm-PCNL group the mean (range) pain score was 5.5 (5–8), and i.v. analgesia was needed but only in four patients. Less postoperative pain and analgesic requirement in the tubeless mini PCNL group in our study were mainly due to small tract size and lack of use of nephrostomy tube, which was the main cause of pain in standard PCNL. This advantage makes it comparable to RIRS in terms of postoperative analgesic requirement and also the duration of hospital stay.

In the present study, the immediate stone-free rate (SFR) in the TmPCNL group was 100 % while in the RIRS group was 87.5%. There was a statistically significant difference between the groups for the stone-free rate (p=0.02). After 4 weeks SFR was increased to 90% in the RIRS group (p =0.04). This result is also similar to other published studies such as that of Knoll T., et al. 2010[23] who reported immediate SFR 96% vs. 71.5%; P < 0.001). SFR after 4 weeks was 100% (mPNL) and 85.8% (fURS) (P < 0.01). Amr S. Fayad, et al, 2017[21] reported the stone-free rates were 92.72% in the TmPCNL group and 84.31%, in the RIRS group, which was not significantly different ($P = 0.060$). Lee J.W., et al. 2015[24] reported Mini-PCNL and RIRS had a stone-free rate of 85.7% and 97.0%, respectively (P = .199). SFR results of this study were different from our study as well as other studies.

There was no statistically significant difference between the two groups for postoperative urinary leakage. In our study, there was no evidence of postoperative fluid collection and perinephric hematoma on postoperative ultrasonography in both groups. There was no statistically significant difference between the groups for the postoperative complications other than residual stones.

Hospital stay plays an important role in the evaluation of a technique. In our present study hospital stay was shorter in the RIRS group as compared to the TmPCNL group. Mean hospital stay in group 1 and group 2 was 28.5±9.09 hours and 27. 8±6.23 hours respectively and this difference was statistically not significant [p=.693]. Our observations were similar to other published studies, such as in the study of Lee J.W., et al. 2015[24] (P = 0.728) and Amr S. Fayad, et al, 2017[21] ($P = 0.244$). In the study by Kirac M., et al. 2013[28] and by Pan J., et al. 2013[22], they reported that the mean hospital stay was longer in the TmPCNL group versus the RIRS group and the difference was statistically significant. In our study 15 (27.5%) patients in Group 1 and 14 (25%) patients in Group 2 were discharged from the hospital within 24 hours. These are the patients with a small burden of stone and staying close to the hospital.

There was no significant difference between the two groups in follow up complications after discharge from the hospital except for residual stones (p=0.04). In the RIRS group, 4 (10.0%) patients had residual stones as compared to zero patients in the Tm PCNL group on 4 weeks follow up, which was statistically significant (p=0.04).

In TmPCNL group, 1 (2.5%) patients developed colic, 2 (5.0%) developed fever and 2(5.0%)

developed mild hematuria while in RIRS group, 3(7.5%) patient developed colic, 1 (2.5%) patients developed fever, no patient developed hematuria. In group 1, 5 (12.5%) patients were readmitted and managed conservatively while in group 2, only 4(10%) patients were readmitted and managed conservatively.

In group 1, the stent was not placed, so there were no stent-related complications postoperatively while in group 2, 3(7.5%) patients developed stent-related dysuria, 1 (2.5%) patients developed urgency and 2 (5.0%) patients developed hematuria. The difference in the results for stent-related complications in both groups was not statistically significant. TmPCNL is a tubeless procedure with no nephrostomy or stent placement (only ureteric catheter is sufficient for drainage), while stenting is mandatory in all RIRS procedures, increasing morbidity.

Return to normal activity was described as the total number of days from the date of surgery to the day when the patient returns to normal life activity such as going to a job or school. In our study, there was no significant difference in days to return to normal activity. The mean days to return to normal activity was 4.42±2.19 and 3.92±1.52 in group 1 and group 2 respectively (p=0.245).

Overall, the results of this study again supported the findings that tubeless mini PCNL has better SFR, shorter duration of surgery and lesser cost of treatment as compared to RIRS procedure and can be done in the majority of patients with renal calculus ⩽2cm. Tubeless mini PCNL modification of PCNL help in reducing analgesic requirement, hospital stay, morbidity and duration to return to normal activity with no added complication.

5. Conclusion

In conclusion, both tubeless mini PCNL and RIRS are safe, effective and accepted procedures for the primary management of renal calculus. Tubeless mini PCNL has more SFR, less duration of surgery, less post-operative fever and less overall cost of treatment and no added complications as compared to the RIRS procedure, which makes this procedure safe, efficacious and therefore more cost-effective than the RIRS procedure. In a urological setup where LASER and flexible ureteroscope are not available, tubeless mini PCNL is a safe and cost-effective option for the management of smaller (⩽2 cm) stones. In the future tubeless mini PCNL can replace the standard PCNL as a gold standard treatment for renal calculi.

6. Conflicting interests

No conflict of interest

7. Funding: None

8. Ethical Approval:

Approved by the institutional ethical and research committee

Informed consent: Written informed consent was obtained from the patients for publication

9. Contributorship

Conception and design of study: DR Devendra Pal Singh Tomar

Acquisition of data: DR Devendra Pal Singh Tomar, DR Ershad Hussain

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