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RESEARCH ARTICLE

"PERCUTANEOUS NEPHROLITHOTOMY VERSUS OPEN SURGERY FOR RENAL CALCULUS DISEASE- A COMPARATIVE STUDY".

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Abstract

Introduction: Renal stone disease is one of the most common disorders affecting mankind. Those who are treated for one stone event have a 50% risk of recurrence in next 5 years. PCNL is one of the more challenging Endo-urologic procedures. Although excellent stone free rates are universally reported in the literature, complication rates vary widely, especially related to the blood transfusion.

Aim and objective: To compare the results of PCNL with open surgery for renal calculus disease.

Material and methods: - This prospective study was conducted in Govt. Medical College Srinagar, Department of Surgery from June 2010 to July 2013. 120 patients with renal stones were included in the study, 60 patients had PCNL and 60 patients had open surgery.

Results: Intra-operative complications occurred in 10 patients (16.67%) during PCNL and 16 patients (26.67%) during open surgery (p=0.347). The common intra-operative complication for both groups was bleeding that required blood transfusion. Postoperative complications occurred in 16 patients (26.66%) following PCNL and 40 patients (66.66) following open surgery (P=0.002).PCNL was associated with lower VAS Score and required less analgesic than open surgery. PCNL was associated with shorter operative time (89.917 ± 30.288 VS 116.833 ± 27.64 minutes (P= 0.001), shorter hospital stay (3.377 ± 1.198 VS 7.850 ± 2.406days (p< 0.001). The stone free rate was 90% after PCNL and 86.66 % after open surgery (P= 0.688). The cosmesis was better in PCNL than open surgery (p<0.0001)

Conclusion: PCNL is a safe and effective procedure in the management of renal calculi, with less complications and stone free rates higher than that of open surgery. Moreover, it has lower morbidity, shorter operative time, shorter hospital stay, and better Cosmesis. Therefore, the results of the present study concur with prior literature stating that PCNL should be considered the first stage in the treatment for most patients with renal stones.

INTRODUCTION

Renal stone disease is one of the most common disorders affecting mankind. Those who are treated for one stone event have a 50% risk of recurrence in next 5 years. Partial or complete stag-horn calculi that are present in the renal

pelvis are not necessarily obstructive. If untreated, these "silent" stag-horn calculi can often lead to significant morbidity, including renal deterioration, infection complications, or both[10]. Complete removal of the stone is an important goal in order to eradicate any caustic organisms, relieve obstruction, prevent further stone growth and any associated infection, and preserve kidney function[8,12]. Open surgical removal of stag-horn calculi was at one time considered the gold standard to which all other forms of stone removal were compared[12]. Current 1st line options for managing renal stones include-SWL, PCNL, combined SWL and PCNL, RIRS, and laparoscopic procedures including laparoscopic pyelolithotomy, laparoscopic nephrolithotomy. Out of these options PCNL is especially used for managing large renal stones including stag horn calculi. PCNL is one of the more challenging Endo-Urologic procedures. In 2005, the American Urology Association Nephrolithesis Clinical Guidelines Panel recommended percutaneous stone removal as the first line treatment for the management of stag-horn calculi[2]. Although excellent stone free rates are universally reported in the literature, complication rates vary widely, especially related to the blood transfusion. New Endo-Urological techniques have led to treating renal calculi with more effective and less invasive methods.

The first description of percutaneous stone removal was that of Rupel and Brown (1941) of Indianapolis, who removed a stone through a previously established surgical nephrostomy track. In 1955, Goodwin described the first placement of a percutaneous nephrostomy tube to drain a grossly hydronephrotic kidney. In 1976, Fernstorm and Johnson first reported the establishment of percutaneous access with the specific intention of removing a renal stone.Reports have established that PCNL is a routinely used technique to treat patients with large or otherwise complex calculi (Alken et al, 1981; Wickham and Kellett, 1981; Segura et al, 1982; Clayman et al, 1984), with obvious advantages. With this background the present study has been undertaken in an attempt to compare the traditional open surgical procedures with minimally invasive percutaneous nephrolithotomy for the management of renal stone disease and to evaluate the merits and demerits of each technique.

MATERIAL AND METHODS

This prospective, randomized study entitled "Percutaneous nephrolithotomy (PCNL) versus open surgery for renal calculus disease-A comparative study" was conducted in the Post- Graduate Department of Surgery, Govt. Medical College Srinagar. All the patients with renal stones treated at our institute either by open surgery or by PCNL from July 2010 to July 2013 were included in the study sample. The study comprised of 120 patients, divided into two groups, 60 patients were subjected to PCNL and 60 patients to open surgery. Randomization was done using closed envelope method.

Following patients were excluded from this study

- Patients with renal Insufficiency
- Immuno-compromised patients
- Uncorrected coagulopathy
- Patients with previous renal surgery

Pre-operative assessment included, Physical Examination, routine laboratory investigations including **,**Complete urine analysis**,** Blood examination**,** Haemoglobin **,**TLC **,**DLC**,** Platelet count**,** BT/CT/PT/INR **,**Blood sugar **,**Blood urea **,**Serum creatinine **,**Serum Electrolytes, Na^+ , K^+ .All these investigations were within normal limit. Radiological evaluation included a plain X-Ray (KUB), Ultra-sonography (USG), intra- venous urography (IVU)**,** CT/CECT (optional)**,** ^{99}Tc DTPA (optional) was performed. In all patients informed and written consent was obtained before performance of each procedure. All patients receive prophylactic antibiotics.

PCNL was performed by one expert urological surgeon who has done more than 100 PCNL and open surgery was done by another expert surgeon who had done more than 80 open renal surgeries.

Data analysis:

The results of the observations made were tabulated and subjected to appropriate statistical analysis to calculate the p value using independent sample "t" test, chi-square test or fisher's exact test, Mann whitney test (as and when needed). A p value of less than 0.05 was taken as significant.

RESULTS: **A total of 120 patients were included in this prospective study and were randomly distributed into two groups.60 patients in each group. There demographic data were comparable in both groups (Table-I).**

Table-I Demographic data

Characteristic		**PCNL Group**	**Open Group**	**Total**	**P value**
Age (years) Mean ± SD (Min, Max.)		 38 ± 12.3 (20 , 65)	 38.9 ± 13.2 (9 , 68)	 38.5 ± 12.6 (9 , 68)	 0.785 NS
Sex	Male	30	40	70	0.190

	Female	30	20	50	NS
	M/F ratio	1:1	2:1	1.4:1	

The group difference was statistically insignificant. Pre-operative characteristic of both groups are shown in (Table-II.)

Table-II Pre-operative characteristic on the basis of USG and IVP

Characteristic	**PCNL Group**		**Open Group**			
Stone size (mm)						
Max size	23.8		22			
Min size	10		10.8			
Average size	15.8		16.72			
Site of stone	N	%age	N	%age	Total	%age
Superior calyx	8	13.3	10	16.7	18	15.0
Middle calyx	6	10.0	4	6.7	10	8.3
Inferior calyx	14	23.4	16	26.7	30	25.0
Renal pelvis	18	30.0	26	43.3	44	36.7
Proximal ureter	8	13.3	2	3.3	10	8.3
Stag horn	6	10.0	2	3.3	8	6.7
Grade of hydronephrosis	N	%age	N	%age	Total	%age
No hydronephrosis	24	40	28	46.7	52	43.4
Grade I	22	36.7	6	10.0	28	23.3
Grade II	8	13.3	20	33.3	28	23.3
Grade III	6	10.0	6	10.0	12	10

OPERATIVE TIME:

The mean operative time in open group was 116.833±27.64 minutes and in PCNL group was 89.917±30.288 minutes, (p=0.001) as shown in Table-IV and its graphic representation in FigI.

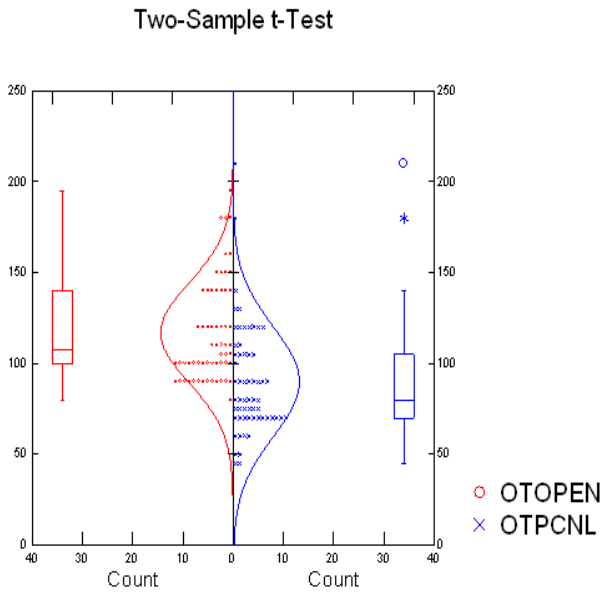


Fig. I Mean operative time in open surgery and PCN

The intra-operative complications in open group were 26.67% and in PCNL group were 16.67%.The major intra-operative complication in both the groups was bleeding that required transfusion, (p=0.347) as shown in Table-III

The post-operative complications in open group occured in 20(66.7%) patients and in PCNL (26.7%) of patients, (p=0.002) as shown in (Table-III)

Table-III Intra-operative and post-operative complication in study groups

Variable	**PCNL Group**		**Open Group**		**P value**
Intra-operative complication	**N**	**%age**	**N**	**%age**	**Chi-Square :0.884** **df : 1** **P=0.347 (NS**
Present	10	16.67	16	26.67	
vascular injury	0	0	0	0	-
visceral injury	0	0	0	0	-
pleural injury	2	3.3	4	6.7	1
ureteral injury	0	0	0	0	-
Transfusion needed	6	10.0	12	20	0.472
conversion to open	2	3.3	0	0	1
Post –operative complications	16	26.7	40	66.7	Chi-Square :9.643 df : 1 P=0.002 (Sig.)
1. Wound related					
a) haematoma	0	0	0	0	-
b) seroma	0	0	0	0	-
c) wound infection	0	0	6	10	0.237(NS)
d) wound dehiscence	0	0	0	0	-
2.Bleeding					
a)Retroperitoneal drains	0	0	12	20	0.0237(NS)
b) Haematuria	12	20	10	16.16	0.63(NS)
3.Fever/sepsis	2	3.3	4	6.6	1(NS)
4. persistent urinary leak	2	3.3	8	13.3	0.353(NS)

The VAS scores were lower in PCNL group as compared to open group, and was statistically significant at Day 2 and Day 3 as shown in (Table-IV)

Table -IV comparison of operative time, VAS score, Analgesic requirement, Hospital Stay, Stone clearance and Cosmesis between two groups

Variable	PCNL Group		Open Group		P value
OperativeTime (Mean ± SD) mint	(89.917± 30.288)		(116.833 ± 27.64)		0.001 (sig.)
VAS Score					
Day 1 (mean±SD)	62±10.63		62.66±12.01		0.7225(NS)
Day 2 (mean±SD)	32.33±13.047		42.33±11.65		0.0046 (sig.) <0.0001
Day 3 (mean±SD)	2.66±2.006		22±12.42		(sig.)
Analgesic (diclofenac sodium mgs)					
Day 1 (mean±SD)	175±45.48		190±47.16		0.3372 (NS)
Day 2 (mean±SD)	97.5±84		117.5±46.95		0.1924 (NS)
Day 3 (mean±SD)	12.5±28.429		42.83±46.67		0.0032 (sig
Hospital Stay (Mean ± SD days	(3.767 ± 1.198)		(7.850 ± 2.406)		< 0.001
	N	%age	N	%age	

Stone clearance	54	90	52	86.7	Chi-Square: 0.162 df : 1 P=0.688 (NS
Cosmesis (scar) Bad scar Good scar	 0 60	 0% 60%	 54 6	 90% 10%	 P <0.0001

PCNL patients were more comfortable in the postoperative period and required less analgesic than open surgery, and difference was significant at day 3 as shown in Table-IV.

The hospital stay was comparatively shorter in PCNL group (3.767±1.198 days) as compared to open group (7.850±2.406 days), (p<0.001) as shown in Table-IV and its graphic representation in fig II.

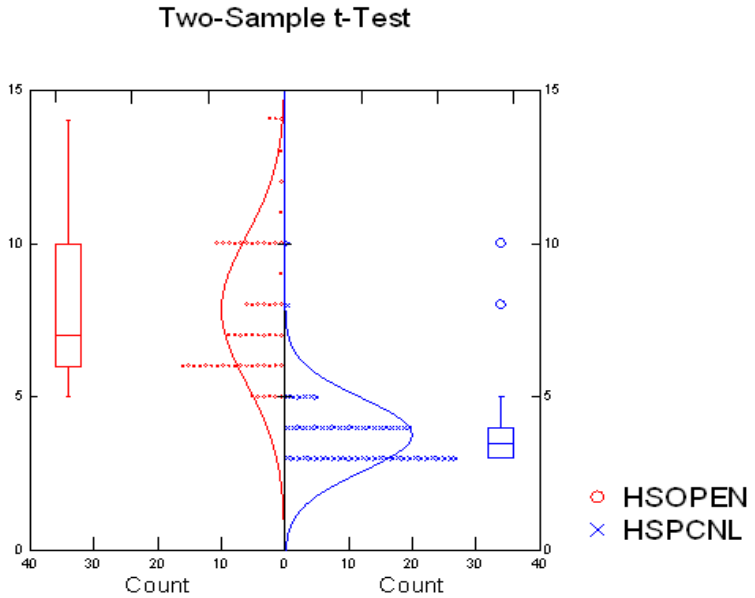
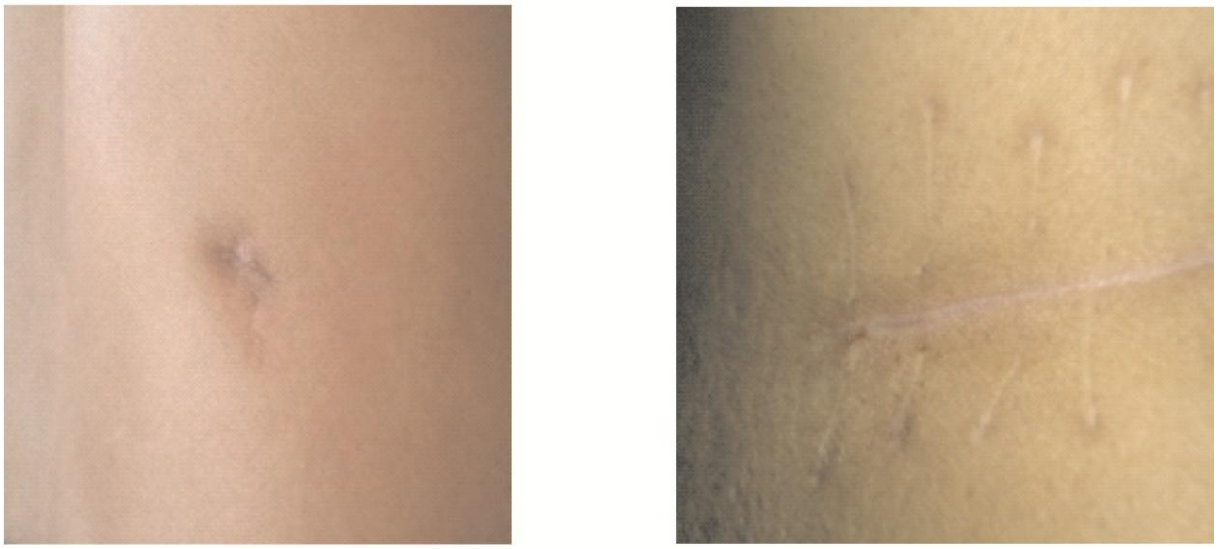


Fig. II Graphic distribution of hospital stays in open surgery and PCNL in days.

In this study, the stone free rate at follow up were 90% (58 patients) in PCNL group and 86.7 % (56 patients) in open surgery, (p<0.688), as shown in Table-IV.

PCNL has better cosmesis than open surgery p< 0.0001.Post operatively the scar mark is hardly visible in case of PCNL as compared to open surgery, as shown in fig 3.

Figure-III



Scar after 1 year (PCNL) Scar after 1 year (open)

Table -IV comparison of operative time, VAS score, Analgesic requirement, Hospital Stay, Stone clearance and Cosmesis between two groups

DISCUSSION

PCNL is currently the preferred first line treatment for renal stones not amenable to extracorporeal shock wave lithotripsy (SWL). The morbidity of PCNL with a single tract is less than that of open surgery, with better stone clearance rates. With increasing stone size and complexity, an inherent fear exists of greater bleeding and complication rates[18].

In the present study which consists of 120 patients (60 patients in PCNL group and 60 patients in open group) mean age was 38.9±13.2 (9-68) in open surgery group as compared to 38.0±12.3 (20-65) in PCNL group (P= 0.785) and male female ratio in open group2:1 and 1:1 in PCNL group (P= 0.190). The study conducted by Tugcu V et al[19] the mean age in open group was 42.6±10 years and in PCNL group mean age was 45.5 ±9.6 year and D.G. Assimos et al[6] in their series of 36 patients, reported mean age patient of 51.9 years in PCNL group against a mean a mean patient age of 46.7 years in anatrophic nephrolithotomy group.

The operative time was recorded from the skin incision to the closure of skin incision in open surgery and in PCNL from puncture to the placement of nephrostomy drain. The mean operative time in the PCNL group was shorter (91.167±32.66 minutes, which includes conversion time of 2 patients in open surgery, otherwise mean operative time in PCNL was 87.068 minutes) as compared to open group (113.33±26.042 minutes) and was statistically significant P=0.005.Sivash Falahatkar et al[17]shows similar results with mean operative time was 101±35.13 minutes in PCNL and in 120±20.15 minutes in open surgery. Another study of AL-Kohlany KM et al[3] showed similar results with mean operative time (127±30 VS 204±31 minutes for PCNL and open surgery respectively).

Intra-operative complications were found in 16 (26.67%) patients in open surgery group and in 10 (16.67%) patients in PCNL group, the difference was statistically insignificant P=0.347, and included: (i) Bleeding that required transfusion in 12 (20%) patients belonging to open group as compared to 6 (10%) patients in PCNL group, (ii) pleural injury occurred in 4 (6.7%) patients in open group and in 2(3.3%) patient in PCNL group, (iii) Conversion to open surgery from PCNL group in 2 patients, in one patient there was excessive bleeding during the procedure and in 2nd patient the tract was lost. The most common intra-operative complication for both groups was

bleeding that required blood transfusion. Siavash Falahtkar et al[17]reported similar results with intra-operative complication occurred in 9 patients (18.8%) during open surgery and 10 patients (13.9%) during PCNL (p=0.611).

The most intra-operative complication for both groups was bleeding that required blood transfusion. K.M. AL-Kohlany et al[3]in their study noticed that there were significantly more intra-operative complications in the open surgery group (38%) compared to the PCNL group (16%), p<0.05. The most significant complication in both groups was bleeding requiring blood transfusion(33% for open and 14% for PCNL, p=0.05). They also reported pleural injury (8.9% for open versus o% for PCNL), renal pelvis injury occurring only in 4.7% of PCNL group and ureteric injury in only 2.2% of open group patients.

R.Munver et al reported that supracostal approach was more suitable for reaching most of the stone bulk with an acceptable rate of chest complications (pleural injury) for the improvement in the results of PCNL. Other authors believed that the lower caliceal approach was the most appropriate and that supracostal puncture was valuable when stone branched in upper calyx. The site of puncture was selected according to the location of stone (inferior caliceal approach for pelvic stones and supracostal approach for superior caliceal stones).

The post-operative complications were lower in PCNL group 26.7 % (16 patients) as compared to open group 66.7% (40 patients) and were statistically significant (p=0.002.Such complications included : (i) Bleeding through (a) Haematuria 6(37%) patients for PCNL and 10(25%) patients for open surgery group (b) through nephrostomy drain, noticed in 6 (37%) patients of PCNL group, bleeding through retroperitoneal drain, noticed in 12 (30%) patients of open surgery group (ii) sepsis/ fever 2 (12%) patient for PCNL and 4 (10%) patients for open surgery[7] (iii) urinary leakage 2 (12%) patient for PCNL and 8 (20%) for open surgery group (iv) wound infection noticed only among 6 (15%) patients of open surgery group). Sialvash Falahthkar et al[17]repoted in their study that major post operative complications including obstructive uropathy, massive hematuria,nwound infection, and urinary leakage were observed in 2 patients (4.2%) following PCNL and 9 patients (12.5%) following open surgery , but the group difference was not statistically significant P=0.05).

K.M. Al-Kohlany et al[3]in their study noticed that there were significantly more post-operative complications in the open surgery group 14 (31%) patients compared to the PCNL group 8 (18.6%) patients. The results were comparable to our study.

J.A. Snyder and A.D. Smith et al[7] while studying a total of 100 patients (75 in PCNL and 25 in open group), also reported a higher percentage of sepsis in open surgery group (28%) than PCNL group (26%).

The VAS scores were calculated at Day 1, Day 2 and Day3 postoperatively. The pain was significantly lower in the PCNL as compared to open surgery at 1,2and 3 day. The significant difference was at day 2 and day 3. The mean visual analogue score for pain at day 1 was 62±10.63 and62.66±12.01 for PCNL and open surgery respectively (p=0.7225). The mean VAS was 32.33±13.047 and 42.33±11.65 at day2 for PCNL and open surgery respectively (p=0.0040). The mean VAS was 2.66±2.006 and 22±12.429 at day 3 for PCNL and open surgery respectively (p<0.0001). Syed Mohmmad Kazem Aghamir et al[16] in their study of 30 patients reported, that patients who underwent open surgery had more severe pain than PCNL group (P=0.001).

The pain was quantified by number of doses of analgesic required in the post operative period and VAS Score. 75 mgs of injection of Diclofenac sodium was set as one analgesic dose. The mean analgesia requirement was less in PCNL as compared to open surgery and there was significant difference at day 3. The mean analgesia required at day 1 was175±45.48mg and190±47.16mg for PCNL and open surgery respectively (p=0.3372), and at day 2 was 97.5±48.84mg and117.5±46.95 mg (p= 0.1924) and at day 3 was 12.5±28.429mg and 42.83±46.67mg for PCNL and open surgery respectively (p=0.0032). Rodrigues Netto N Jr et al[15]also reported that PCNL required less analgesic as compared to open surgery, in their study mean analgesics was 1.6 versus 4.7 doses per patient for PCNL and open surgery respectively. Rittenberg MH et al[14] in their study noticed that patients treated percutaneously stayed in the hospital for 8.9 days and required 6.5 doses of narcotics and patients treated by open surgical lithotomy remained in the hospital for 11.0 days and required 21 doses of narcotics.

After surgery our stone free rates at follow up were 90 % (54) patients) in PCNL group as compared to 86.7% (52 patients) in open surgery group (p=0.688), which is in contrast to the published literature where reported stone free rate is higher in open surgery as compared to PCNL procedure[1,3,17].Probably can be explained on the basis of experience of the operating surgeon. We found that PCNL was superior in establishing a stone free status compared to open surgery. Siavash Falahtkar et al[17]showed in their study that stone free rate was 81.9% after PCNL and 91.6% after open surgery, a difference was not statistically significant (p=0.84). Achleshwar Dayal et al[1] reported in their study that complete stone free rate was seen in 95% of patients following PCNL.

K.M. Al-Kohlany et al[3] while studying a total of 79 patients reported stone free rates at follow up equal to 74% in PCNL group as compared to 82% in open surgery group (p=0.284).

Based on AUA guidelines the overall estimated stone free rate is 78% following PCNL and 71% following open surgery[2]. The duration of days of hospital stay was shorter in PCNL group ranging from 3 to10 (4.434±1.478) days

as compared to 5 to 18 (8.433± 3.370) and (p<0.001). Siavash Falahatkar et al[17]reported in their study that PCNL has significantly shorter hospital stay as compared to open surgery, in their study PCNL had mean hospital stay of 3.93 days and open surgery had 5.08 days (P=0.003).N.N. Rodrigues et al[15] (1988) revealed an overall shorter hospitalization period in PCNL as compared to open surgery (5 versus 7 days respectively).

PCNL has better cosmesis than open surgery (p< 0.0001).The cosmesis comparison was done on the basis of, size of scar and no of scars. In case of open surgery there were two scars, one incision scar which was about 12-15cm size and other retroperitoneal drain scar about0.8 cm size while in case of percutaneous surgery there is only one nephrostomy drain scar about 0.9cm in size. Post operatively the scar mark was hardly visible in case of PCNL as compared to open surgery. We conclude that PCNL has better cosmesis than open surgery.

Conclusion:

The history of surgery is a replete with comparisons of one operative procedure or technique with another. There are different methods to manage renal stones. PCNL is less invasive than open surgery and represents a reasonable and most remarkable alternative to open surgical procedures for reasons of lesser operative time, lesser operative complications (intra, post), less pain and lesser analgesia required, higher stone free rate, shorter hospital stay and better cosmesis. We recognize that further endo urological advancements will eventually yield better results in future.

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Units of Measurement
S.I system is used

Abbreviations and Symbols
PCNL-Percutaneous Nephrolithotomy
ESWL-Extracorporeal shockwave Lithotripsy
RIRS –Retrograde intrarenal surgery
IVU-Intravenous Urogram
VAS –Visual analogue score
TLC- Total leucocyte count
DLC- Differential leucocyte count
BT- Bleeding Time
CT-Clotting Time
INR-International normal Ratio
CECT-Contrast enhanced Computed tomography
CT-computed tomography