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Is RIRS better than Mini PCNL in Renal Calculus of size 1-2cms? A Prospective Randomised Comparative Study in a Tertiary Care Teaching Hospital

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Abstract

Introduction: Incidence of urolithiasis has been increasing due to change in life style and dietary habits [1-3]. This has necessitated safe, efficacious, and affordable treatment. The treatment paradigm for urolithiasis has evolved rapidly over the past 30 years. various minimally invasive procedures have come in to fore to reduce the morbidity and the duration of the procedures. Standard PNL is known to have higher clearance rates for stones 1-2 cm. However, it is not promoted because of its associated morbidity, especially bleeding [4,5]. Minitiarization of the PNL has spawned a new interest in this modality for treating small bulk urolithiasis [6]. AUA/Endourology Society Guidelines advocate SWL or URS for non-lower pole renal stone burden ≤ 20 mm and total renal stone burden >20 mm, PCNL is advised as first-line therapy. However, there is no clear guideline as far as renal calculus between 1-2 cms [7]. There, are no studies comparing RIRS with PCNL for Calculi of size 1-2 cms [8].

Patients and Methods: As there is NO consensus regarding the management of Renal Calculus of size 1-2 cms this study which is a Prospective Randomised Comparative study is done to compare RIRS and PCNL in Renal stone of 1-2 cms size.

Results: Out of 100 patients in our study, 50 of them were from the PCNL group and 50 from RIRS group. We observed that the PCNL group had comparatively higher number of Clavien-Dindo grade 1 complications compared to the RIRS group which was statistically significant (p value 0.019208). PCNL group also showed CD grade 2-4 complications which were not seen in the RIRS group. The stone free rates were much better in the PCNL group, both in stones of size 1-1.5cm (p value 0.07) and 1.6 - 2cm (p value 0.449) which were found to be statistically significant.

Conclusion: Both RIRS and PCNL are safe and effective treatment options for renal stones of 1-2cms. PCNL has higher stone free rates compared to RIRS requiring less additional procedures, but slightly higher incidence of complications. Treatment modality should be decided with the patient by discussing both advantages and disadvantages of the both the procedure.

Keywords: PCNL; Renal Calculus; RIRS

Introduction

Incidence of Urolithiasis has been increasing due to change in life style and dietary habits [1-3]. The treatment paradigm for urolithiasis has evolved rapidly over the past 30 yr. Non-invasive SWL had become the predominant treatment modality with URS utilized only for lower ureteral stones and PCNL used more sparingly. However, regression in the efficacy of SWL combined with advances in endoscopic technology such as the introduction of holmium: YAG lasers has shifted these trends. The three most common procedures performed to remove upper urinary tract stones are Shockwave Lithotripsy (SWL), Ureteroscopy (URS), and Percutaneous Nephrolithotomy (PCNL). The increasing

stone burden combined with the advent of novel technology has contributed substantially to high global health care costs for the treatment of urolithiasis. Stone disease is now the second most expensive urological disease globally. Each treatment modality has unique associated costs that can be stratified into the direct cost of treatment, indirect costs, and the cost of retreatments. In the recent years, Retrograde Intra Renal Surgery (RIRS) has emerged as an alternative therapy to treat renal calculi. Advancement in ureteroscopy has now enabled unrestricted access to calculi at virtually all locations in the urinary tract [9-12]. EAU/Endourology Society Guidelines recommends PCNL for stones size > 2cms where, as for renal stones <1cm minimally invasive procedure like ESWL preferred [13]. There are many studies comparing ESWL, PCNL and RIRS for Renal calculi of stones larger than 3cms [14-18]. There, are many studies comparing the safety and efficacy of PCNL and RIRS in solitary kidney [17-19] and in associated co-morbities also [20]. Many studies have been done to prognosticate complications like bleeding by preoperative scoring systems [21-23]. The treatment of choice for renal calculus of size 1-2 cm is unclear [3]. Hence this study is done to assess the efficacy of RIRS and PCNL in Renal calculus of size 1-2cm.

Patients and Methods

This prospective randomized comparative study was done to compare the PCNL and RIRS methods for treatment of renal calculus of size 1-2 cms irrespective of the location of stone within the kidney. Subjects with pregnancy, bleeding diathesis, renal insufficiency, anatomic abnormalities of the kidney and BMI of more than 30 have been excluded from the study. The selected subjects were randomized into either PCNL [Mean tract size was 18.2 ± 2 F [15-20]] or RIRS groups and the outcomes were analysed.

Statistical Methods and Analysis

Sample size was calculated according to previous 2 yrs data. The 100 patients were randomised by Computer generated numbers in to two groups. The data was collected from the patients who underwent PCNL and RIRS in renal calculus of size between 1 and 2 cm in Mahatma Gandhi Medical College and Research Institute. The data was first entered into an excel file and was then exported into SPSS 21.0 version. Thus, using SPSS software, the present study results were analysed. Missing data, outliers and logical checks were performed at first level. To compare the procedures of PCNL and RIRS, the outcomes Were collected using Post op sepsis, post op VAS, procedural time, hospital stay, total amount of irrigation and residual calculus. Of these, VAS is ordinal type of variable so to compare two procedures, the appropriate test was Mann-Whitney U test with Median and Inter quartile range as summary measures. Further, post op sepsis is a count data and the comparison were made using proportions, and the Z -test for two proportions. For the variables, procedure time, hospital stay and total irrigation, the comparison was carried out using independent samples t-test with mean and standard deviation as summary measures. All the comparisons were made using 5% level of significance. The summary statistics are presented graphically such as Bar chart, line-whisker plots.

Data

Age In years.	PCNL Group.		RIRS Group	
<40	22	44%	11	22%
41-60	28	56%	39	78%
Total	50	100%	50	100%

Table 1: Age distribution.

The age varied between 18 and 60 years of age with a mean of 43.72 in PCNL group and 45.44 in RIRS group.

Gender	**PCNL Group**		**RIRS Group**	
Female	19	38%	10	20%
Male	31	62%	40	80%
Total	50	100%	50	100%

Table 2: Gender distribution.

There is male preponderance over female, 62% and 38% in PCNL group, whereas 80% and 20% in RIRS group.

Side	PCNL Group		RIRS Group	
Left	21	42%	22	44%
Right	29	58%	28	56%

Table 3: Side involved.

	PCNL Group		RIRS Group	
1.0-1.5	34	68%	25	50%
1.6-2.0	16	32%	25	50%

Table 4: Pre-operative calculus size (X-ray/USG correlation).

68% of patients of PCNL group and 50% of RIRS group had calculus measuring between 1-1.5cm, whereas, 32% of patients in PCNL group and 50% in RIRS group had calculus measuring more than 1.5cm.

Location	PCNL Group		RIRS Group	
UP	8	16%	9	18%
MP	6	12%	10	20%
LP	20	40%	20	40%
Pelvis	16	32%	11	22%

Table 5: Location of calculus based on USG/CT.

Majority of the calculi were present in the lower pole in both PCNL and RIRS groups. (Immediately after procedure 48 hours for PCNL & 5 days for RIRS).

Group	PCNL		RIRS	
Calculus Absent	48	96%	40	80%
Calculus Present	2	4%	10	20%

Table 6: Post-operative assessment by X-ray and USG.

Post-operatively, 4% of patients in PCNL group showed residual calculi whereas 20% of patients in RIRS group showed residual calculi.

Complications	PCNL		RIRS	
Grade	CD I	CD II	CDIII	CDIV
PCNL YES-18 NO-32	14	3	0	1
RIRS YES -7 NO-43	7	0	0	0

Table 7: Distribution of complications.

- In PCNL group, 18(36%) of patients had complications (CD grade I – 14(28%) & CD grade II -3(6%)and grade IV –1(2%).
- In RIRS group, only 7(14%) of patients had Clavien-Dindo Grade I and no patient had CD 2-4 complications.
- In PCNL group, 14 patients and in RIRS 7 patients had pain, fever and minimal bleeding which was treated by additional dose of analgesics, antipyretics and inj. Tranexamic acid.
- 3 patients were treated with blood transfusions in PCNL group.
- 1 patient in the PCNL group required ICU care for sepsis and AKI and was treated with dialysis, higher antibiotics with inotropes (CD grade IV).
- The PCNL group had comparatively higher number of CD grade I complications. The PCNL group also had CD grade II-IV complications which were not seen in the RIRS group, this difference was found to be statistically significant (p value 0.019208).

Duration	PCNL		RIRS	
<1.30 Hrs	4	8%	36	72%
>1.3Hrs	46	92%	14	28%

Table 8: Duration of the Procedure.

The mean time duration for PCNL was 125.6 +/- 22.03 min and 98.90 +/- 17.2 min for RIRS. The difference between time duration of surgery between the two groups was statistically significant- P value 0.0001.

Volume(Ltrs)	PCNL	RIRS
Mean Volume	9.16 +/- 2.37	4.32 +/- 1.17

Table 9: Amount of Irrigation fluid required.

The mean volume of irrigation fluid used during PCNL was 9.16 +/- 2.37 Litres while in RIRS it was 4.32 +/- 1/17 Litres and the difference between the two was found to be statistically significant with p value 0.001.

Groups	PCNL	RIRS
Calculus absent	34	22
Calculus present	0	3
Total	34	25
"P" Value - 0.07 (not significant)		

Table 10: Calculus (1.0 -1.5 cm) Stone Free Rates.

With regards to stone free rates in calculus less than 1.5cm, 3 out of 25 patients in RIRS group had residual calculus whereas in PCNL group no patients had residual calculus with P value of 0.07.

Groups	Stone free	Residual Calculus	Total
RIRS	18	7	25
PCNL	14	2	16
"P" Value not significant at P 0.4409			

Table 11: Calculus (1.6 - 2.0 cm) Stone Free Rates.

With regards to stone free rates in calculus more than 1.5cm, 7 out of 25 patients in RIRS group had residual calculus whereas in PCNL group 2 out 16 patients had residual calculus with a "P" value of 0.4409 which is was not significant.

Post-op Blood transfusion	Yes	No	Total
RIRS Group	0	50	50
PCNL Group	3	47	50

Table 12: Post-op Blood Transfusion.

In the PCNL group 3 patients had significant bleeding requiring Blood Transfusion while none of those in RIRS group required Blood Transfusion and the difference was not statistically significant - P value 0.2424.

VAS score	PCNL	RIRS
<5	**32 - 64%**	**44 - 88%**
>5	**1 -36%**	**6 - 12%**

Table 13: Post-op VAS SCORE.

The mean VAS score in PCNL group is 5.6 +/- 1.9 and 3.76 +/- 1.39 in RIRS group as shown in table **which** was significant between the RIRS and PCNL groups at P value 0.0001.

Secondary Interventions	PCNL	RIRS
No Intervention	48	40
YES	2	10
Type of Interventions		

ESWL	1	7
PCNL	1	2
RIRS	0	1

Table 14: Secondary interventions.

In PCNL group, 2 patients required secondary intervention whereas in the RIRS group, 10 patients required secondary intervention.

Type	PCNL	RIRS
Nil	6	0
DJ stent	36	37
Ureteric Catheter	8	13
Nephrostomy Tube	26	0
DJ Stent and Nephrostomy Tube	26	0

Table 15: Requirement of Post-op Drainage.

In PCNL group, 36 patients required DJ stent, 8 required ureteric catheter, 26 required Nephrostomy tubes and 26 required both Nephrostomy tube and DJ stent whereas in the RIRS group, 37 patients required DJ stent and 13 patients required ureteric catheter.

Group	< 4 Days	>4 days
RIRS	36	14
PCNL	25	25

Table 16: Hospital Stay.

In RIRS group, 36 patients got discharged in less than 4 days whereas in PCNL group only 25 patients got discharged within 4 days which was significant at p0.039.

Statistical Analysis

To compare the procedures of PCNL and RIRS, the outcomes Were collected using Post op sepsis, post op VAS, procedural time, hospital stay, total amount of irrigation and residual calculus. Of these, VAS is ordinal type of variable so to compare two procedures, the appropriate test was Mann-Whitney U test with Median and Inter quartile range as summary measures. Further, post op sepsis is a count data and the comparison were made using proportions, and the Z -test for two proportions. For the variables, procedure time, hospital stay and total irrigation, the comparison was carried out using independent samples t-test with mean and standard deviation as summary measures. All the comparisons were made using 5% level of significance. The summary statistics are presented graphically such as Bar chart, line-whisker plots.

The (Table I) is about the comparison of PCNL and RIRS procedures with respect to post op sepsis. The p-value is observed to be not significant, this means that proportionally there is no much difference in the subjects in having sepsis with these two procedures. In this study it is observed that the proportion of subject who had sepsis is almost similar in two procedures.

		Procedure	
		PCNL	RIRS
		Count	Count
Post Op Sepsis	No	45	42
	Yes	5	8
p-value>0.05; There is no significant difference between two procedures			

Table I: Comparison of two groups- Post Op Sepsis.

The (Table II) depicts the summary statistics such as Median and Inter quartile range. Upon comparison, the p-value is observed to be statistically significant at 0.05 level. This means that the mean VAS score observed in RIRS is comparatively better than the subjects who had PCNL procedure. The reduction of one value in RIRS responds better relief in subjects who had this.

Procedure	Statistic	Post Op VAS Score	Z-value (p-value)
PCNL	Median	5.00	2.493 (0.013*)
	Inter quartile Range	2	
RIRS	Median	4.00	
	Inter quartile Range	2	

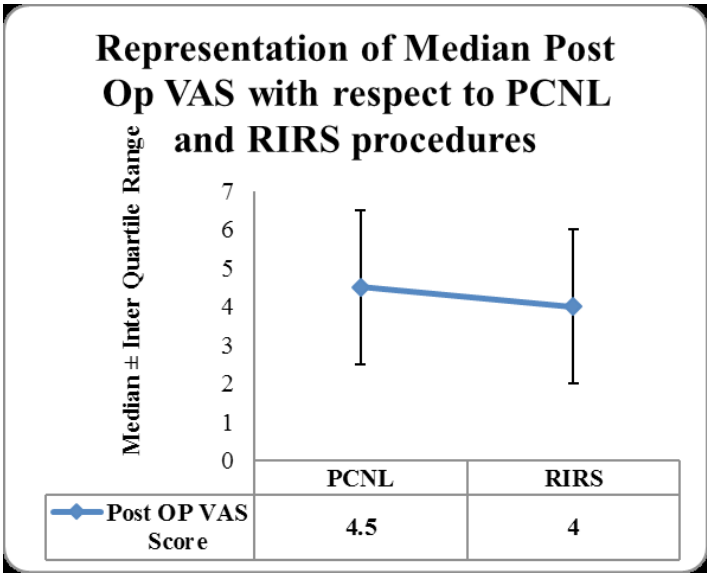
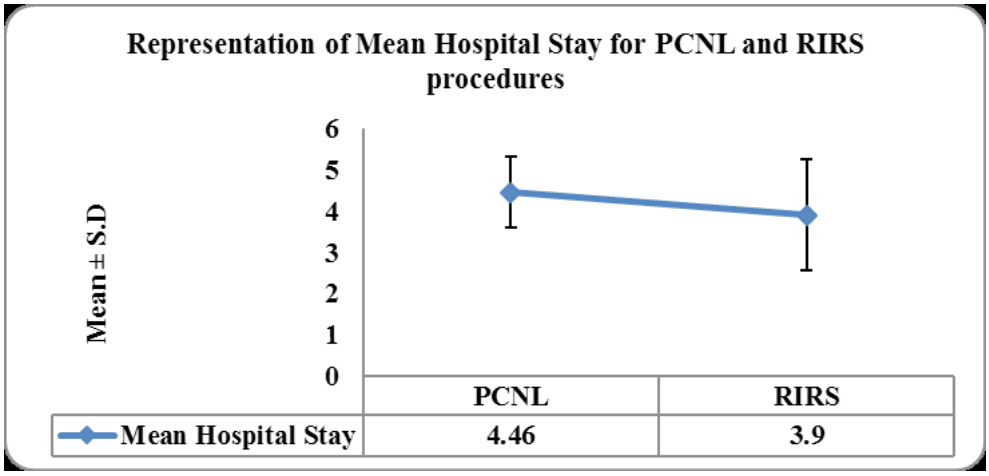


Table II: Post Op VAS Score.

In the following (Table III), the comparison is presented between PCNL and RIRS with respect to procedure time, hospital stay and total irrigation. In all the variables, the result is observed to be statistically significant (p-value<0.05). with respect to Procedure

time, on an average it was high in PCNL than that of RIRS. It is observed that on an average PCNL takes two hours' time where as RIRS lasts for around one and half hours. In respect of hospital stay, the subjects who had PCNL procedure has to stay on average of five days, whereas, the subjects who underwent RIRS needs to stay around four days. The difference a day between these two procedures is observed as significant. In terms of total irrigations used, on an average RIRS procedure requires more than that of PCNL procedures. All these summary statistics are depicted using line whisker plots below

Variable	Procedure	N	Mean	Std. Deviation	t-test (p-value)
Procedure time	PCNL	50	125.60	22.031	6.646 (0.000*)
	RIRS	50	98.90	17.937	
Hospital Days	PCNL	50	4.46	0.862	2.480 (0.015*)
	RIRS	50	3.90	1.344	
Total Irrigation	PCNL	50	3.18	0.983	7.071 (0.000*)
	RIRS	50	4.68	1.133	



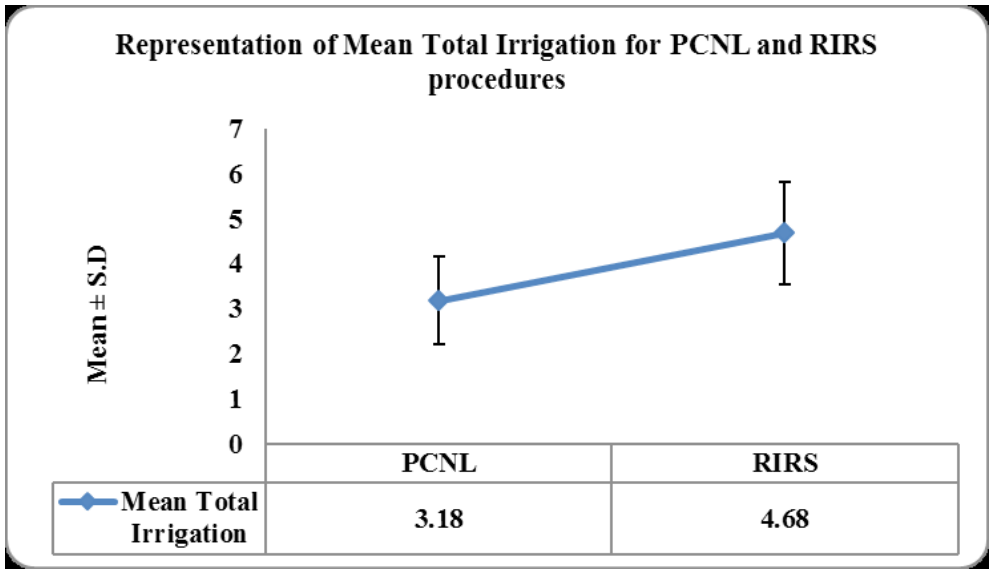


Table III: Comparison of Duration of procedure, Amount of irrigation Fluid used and Hospital Stay.

The following (Table IV) presents a cross tabulation between the PCNL and RIRS procedures and type of stent used. It is noticed that in almost equal proportion, the DJ stent has been used in both procedures whereas the ureteric catheter is proportionately used at higher number in RIRS than that of PCNL procedure.

Procedure * DJ Stent URETER Cross tabulation			DJ Stent /Ureteric Catheter			Total
			No tubes	DJ Stent	Ureteric Catheter	
Procedure	PCNL	Count	6	36	8	50
		% within Procedure	12.0%	72.0%	16.0%	100.0%
		% within DJ Stent URETER	100.0%	49.3%	38.1%	50.0%
	RIRS	Count	0	37	13	50
		% within Procedure	0.0%	74.0%	26.0%	100.0%
		% within DJ Stent URETER	0.0%	50.7%	61.9%	50.0%
Total		Count	6	73	21	100
		% within Procedure	6.0%	73.0%	21.0%	100.0%
		% within DJ Stent URETER	100.0%	100.0%	100.0%	100.0%

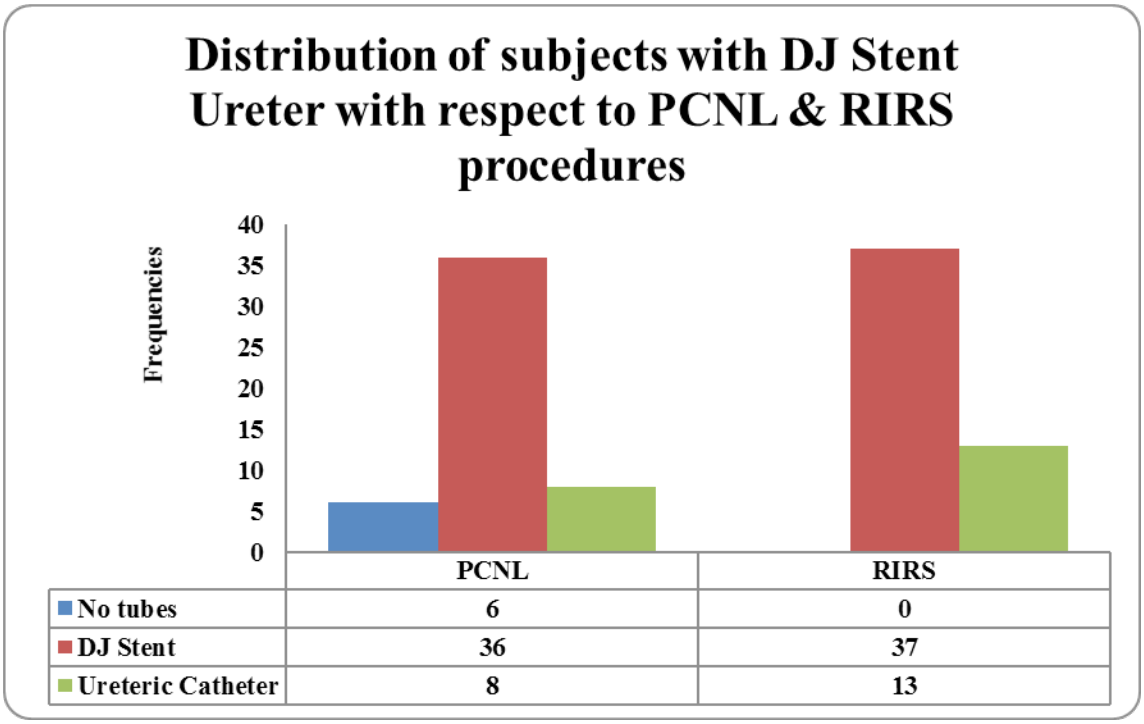


Table IV: Cross Tabulation of Post Op Drainage Procedures Used.

Discussion

In the era of minimally invasive surgery, RIRS and PCNL are the two leading surgical techniques for managing renal stones. PCNL was considered to be the recommended therapy for large stones > 2.0 cm by both AUA and EAU guidelines. Urologists were initially hesitant to do PCNL for stones less than 2 cm because of its morbidity. But with the emergence of Mini PCNL and inadequate results with ESWL, PCNL has emerged as a contender for stones between 1-2 cm. At the same time, RIRS has emerged as an alternative therapy to treat renal calculi. Advancement in ureteroscopy has now enabled unrestricted access to calculi at virtually all locations in the urinary tract. Initially RIRS was restricted to small renal stones. But with the improvement in optics and ancillary gadgets, RIRS is extended to stones more than 1 cm. Recent reports suggested that RIRS is a safer approach that could be done with less complications and Hb drop than normal tract PCNL in non-lower pole calculus as well as lower pole calculus.

At present, for stones of size 1-2 cm, the treatment option is not clear [5,6]. This study is about comparison of outcome of patients undergoing PCNL and RIRS for renal stones of size 1-2 cm.

This study showed a male predominance over female and majority of the calculus were seen on the right side. The preoperative assessment of calculus was done by USG KUB/ NCCT. Majority of the calculi were present in the lower pole in both PCNL and RIRS groups. In this study, Stone Free Rates (SFR) were assessed 24 hours after the procedure in both the groups. SFR is the most important parameter for estimating the efficacy of two approaches. With regards to stone free rates in calculus less than 1.5cm, 3 out of 25 patients in RIRS group had residual calculi, whereas in PCNL group no patient had residual calculus (P value of 0.07). With regards to stone free rates in calculus more than 1.5cm, 7 out of 25 patients in RIRS group had residual calculi whereas in PCNL group 2 out 16 patients had residual calculus with a "P" value of 0.4409 which is was not significant. Complications were assessed based on Clavien-Dindo Grading system in the present study. This grading system for complication was universally accepted because it is simple, objective and reproducible approach for comprehensive surgical outcome assessment. In our study 36% of patients had complications (CD grade I - 28% & CD grade II - 6% and grade IV - 2%) in PCNL group. In RIRS group only 14% of patients had complications. The PCNL group had comparatively higher number of CD grade I complications. The PCNL group also had CD grade II-IV complications which were not seen in the RIRS group and this difference was found to be statistically significant (p value 0.019208).

The mean time duration for PCNL was 125.6 +/- 22.03 min and 98.90 +/- 17.2 min for RIRS. The difference between time in duration of surgery between the two groups was statistically significant (P value 0-0001). Postoperative pain is important, and it may affect the hospital stay and comfort of the patient. The mean VAS score in PCNL group was 5.6 +/- 1.9 and 3.76 +/- 1.39 in RIRS group, which was significant between the RIRS and PCNL groups at P value 0.0001. The mean volume of irrigation fluid used during PCNL was 9.16 +/- 2.37 Litres while in RIRS it was 4.32 +/- 1.17 Litres and the difference between the two was found to be statistically significant with p value 0.001. In the PCNL group 3 patients had significant bleeding requiring Blood transfusion while none of those in RIRS group required Blood transfusion and the difference was not statistically significant at P value 0.242. In PCNL group, only 25 patients got discharged in less than 4 days whereas in RIRS group 36 patients got discharged within 4 days which was significant at p0.0397. In the present study, in PCNL group, 4% required secondary intervention (ESWL-2 %, REDO PCNL-2 %) whereas in the RIRS group, 20 % required secondary intervention. (ESWL-14 %, PCNL-4 %, REDO RIRS-2%).Our results are similar albeit slightly higher than the study conducted by Albala, et al. in which 16% of patients in RIRS group and 9% in PCNL group required secondary interventions and they have concluded that stone clearance following RIRS was poor in renal calculus of more than 1.5 cms which should be dealt with ESWL/ redo RIRS due to its high degree of efficacy.

Results

Out of the total 100 patients in our study, 50 of them were from the PCNL group and 50 from RIRS group. We observed that the PCNL group had comparatively higher number of Clavien-Dindo grade 1 complications compared to the RIRS group which statistically significant (p value 0.019208). PCNL also showed CD grade 2-4 complications which were not seen in the RIRS group. The stone free rates were much better in the PCNL group, both in stones of size 1-1.5cm (p value 0.07) and 1.6 - 2cm (p value 0.449) which were found to be statistically significant.

Conclusion

- Both RIRS and PCNL are safe and effective treatment options for renal stones of 1-2cms.
- PCNL has higher stone free rates compared to RIRS requiring less additional procedures.
- RIRS has less number of complications compared to PCNL. Sepsis was higher in PCNL group compared to RIRS group.
- Duration of surgery is longer in PCNL compared to RIRS.
- Amount of irrigation fluid used is more in PCNL Compared to RIRS.
- Duration of Hospital stay is more in PCNL than in RIRS.
- The statistical results which are significant show that RIRS is better than PCNL in calculi of 1-2 cms.
- Treatment modality should be decided with the patient by discussing both advantages and disadvantages of the both the procedure.

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