

Comparative Study of Stone Free Rate, Morbidity and Need for Retreatment Procedures between Various Surgical Modalities for 10-20 mm Upper Urinary Tract Calculi

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Abstract

Introduction: The constant technological refinement in the field of minimal invasive treatment modalities of endourology influences their efficacy and the associated morbidity. Added to this are the surgeons' ability to learn and adapt to the changing technology that in turn has a significant impact on the final outcome.

Materials and Methods: The study is a prospective observational comparative study conducted in a single institution over 1-year period from November 2013 to October 2014. A total of 287 cases of renal and upper ureteric calculi of 10-20 mm size were included in the study.

Results: A total of 287 patients were included in our study over 1-year. This included 161 cases of percutaneous nephrolithotomy (PCNL), 45 of retrograde intrarenal surgery (RIRS), and 81 of shockwave lithotripsy (SWL). The mean age was 43.69 years with a median of 42 years. There were 202 males and 85 females in our study, with a male:female ratio of 2.38:1. The mean stone size in PCNL, RIRS, and extracorporeal SWL groups were 14.73, 13.84, and 13.52 mm, respectively. The overall success rate with respect to stone clearance was 88.9% ($n = 255$) and the failure rate was 11.1% ($n = 32$). An average of 12.5% of patients had residual stones, with the maximum seen in SWL (17.3%). Nearly, one-fifth of the patients who had SWL done and needed retreatment.

Conclusions: PCNL and RIRS have comparable success and complication rate, whereas SWL has lower complication rate. When comparing the stone free rate PCNL and RIRS are better. Thus, tailoring the management with respect to the patient, stone and other technical factors with respect to better stone free rate is needed.

Key words: Lithotripsy, Nephrolithotomy, Percutaneous, Steinstrasse, Ureterorenoscopy, Urolithiasis

INTRODUCTION

The primary goal while treating renal calculi and upper ureteric calculi is to achieve maximum clearance of stone

with minimal morbidity. The various minimally invasive modalities described are extracorporeal shockwave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), and retrograde intrarenal surgery (RIRS).^{1,2} The other modalities in the management of these stones are open and laparoscopic nephrolithotomy or pyelolithotomy, which are more invasive. The preferred approach for stones <1 cm is SWL, whereas for stones >2 cm, it is PCNL, but the management of stones of 1-2 cm is still controversial.³ Addition of RIRS to the armamentarium in the last two decades has added to the dilemma. The constant technological refinement in the instruments of

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Month of Submission : 11-2016
Month of Peer Review : 12-2016
Month of Acceptance : 12-2016
Month of Publishing : 01-2017

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the minimal invasive treatment modalities influences their efficacy and the associated morbidity. Added to this are the surgeons ability to learn and adapt to the changing technology, impacts the outcome. Hence, there is a need to re-evaluate the relative roles and efficacies of these treatment modalities from time to time. This study is an attempt to compare the three modalities available for the treatment of upper urinary tract calculi.

Aim

To compare SWL, PCNL, and RIRS in the management of renal and upper ureteric calculi above L4 transverse process of 10-20 mm size in terms of stone-free rate, morbidity and need for retreatment procedures. The various parameters such as success rate, retreatment rate, need for an auxiliary procedure, complication rate, mean Procedure time, and mean hospital stay are taken into consideration during this study.

MATERIALS AND METHODS

The study is a prospective observational comparative study conducted in a single institution over 1-year period from November 2013 to October 2014. A total of 287 cases of renal and upper ureteric calculi of 10-20 mm size were included in the study. These patients underwent PCNL, RIRS or SWL. The study model was presented to the Ethical Committee of the institute and was approved.

Inclusion and Exclusion Criteria

The inclusion criteria were all patients presenting with calculi of 10-20 mm in otherwise normal renal pelvicalyceal system, pelvi-ureteric Junction or proximal ureter up to L4 transverse process. The exclusion criteria included all stones identified distal to L4 transverse process, multiple renal calculi with second calculi size >4 mm, abnormal upper urinary tract anatomy such as duplex system, horseshoe kidney, ectopic kidney, and pelvi-ureteric junction obstruction, any axial skeletal abnormality such as scoliosis and kyphosis, and associated bleeding diathesis.

An elaborate history and physical examination were done. The imaging modalities used for the diagnosis consists of one or more of the following and includes ultrasonography, X-ray KUB, and noncontrast computed tomography KUB with or without contrast. In addition, the patients also underwent the relevant blood and urinary investigations such as hemoglobin, renal function test, and coagulation profile.

Choice of Procedure

The choice of treatment modality for the management of the upper urinary tract calculi of 10-20 mm calculi is

largely determined by the individual surgeon taking into consideration the patients' anatomy, comorbid conditions, urinary tract anatomy, the stone density, and location as well as patients preference. PCNL and RIRS with flexible ureterorenoscope were done under general anesthesia. ESWL was done under intravenous sedation. Following the procedure, the patient undergoes ultrasonography and X-ray KUB in the 2nd post-operative day and at 2 weeks and 6 weeks with ultrasonography and X-ray KUB. Complications from each group were categorized as minor and major.

Statistical Methods

Descriptive statistical analysis was performed in this study. To describe the data frequency analysis, percentage analysis were used for categorical variables and for continuous variables the mean and standard deviation (SD) were used. For the multivariate analysis, the Kruskal–Wallis test and ANOVA were used and for trivariate and bivariate analysis Mann–Whitney test was used. To find the significance in categorical data, Chi-square test was used. The $P < 0.05$ is considered as significant level. The statistical software SPSS 16.0 version was used for the analysis of the data and Microsoft Word and Excel have been used to generate figures and tables.

RESULTS

A total of 287 patients were included in our study over 1-year. This included 161 cases of PCNL, 45 of RIRS, and 81 of SWL. The mean age was 43.69 years, with a median of 42 years and a standard deviation of 13.275. The minimum age was 18 years, with one male child, who was aged 10 years was also included in our study (Figure 1). There were 202 males and 85 females in our study, with a male:female ratio of 2.38:1. The right and left sides were almost equally affected by the stone disease, with the left kidney slightly more commonly affected than the right. Table 1 gives the demographic details of the number, mean

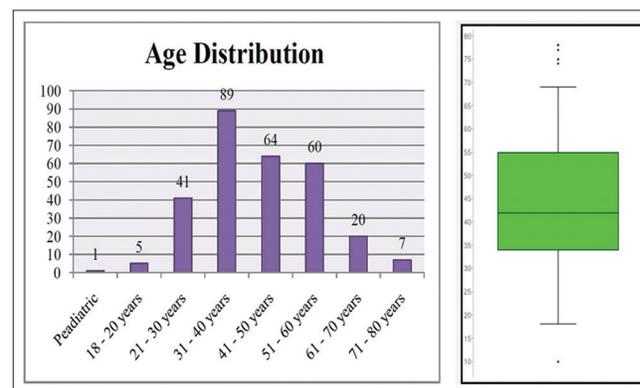


Figure 1: Graphical and box plot representing the age distribution

age distribution, sex ratio, and the laterality of renal stone disease in our study.

The mean stone size in PCNL, RIRS, and ESWL groups were 14.73, 13.84, and 13.52 mm, respectively. The overall mean stone size was 14.25 mm with an SD of 2.881. The mean stone size of RIRS group was comparable with that of PCNL group as well as SWL group. However, the mean stone size of PCNL group was statistically different which is bigger than ESWL group even though the actual mean difference was only 1.21 mm ($P = 0.009$) (Table 2). Whereas the average time taken for the procedure is fairly constant with SWL, for PCNL and RIRS it was 81 and 85 min, respectively. PCNL and RIRS took a statistically significantly longer time in comparison to SWL (Table 2). The average duration of hospital stay was significantly longer for PCNL and RIRS in comparison to SWL (Table 2). While most of the ESWL was done as a day care procedure, a few of them needed inpatient care in view of health-care insurance or co-existing comorbidities and hence the average duration of hospital stay in this subgroup was 1.21 days.

The overall success rate with respect to stone clearance was 88.9% ($n = 255$), and the failure rate was 11.1% ($n = 32$).

Table 1: Demographic details of cases in our study

Demographic details	PCNL	RIRS	SWL	Total	P-value
Total number of cases	161	45	81	287	-
Mean age (in years)	45	40.56	42.96	43.73	0.138
Sex					
Male	114	37	51	202	0.075
Female	47	8	30	85	
Laterality					
Right	82	23	31	136	0.152
Left	79	22	50	151	
Failure rate	16/161	6/45	14/81	36/287	0.796

PCNL: Percutaneous nephrolithotomy, RIRS: Retrograde intrarenal surgery, SWL: Shockwave lithotripsy

Table 2: Stone size, duration of procedure and mean stay period in hospital

Group	n	Mean±standard deviation	Chi-square test	P-value
Mean stone size (in mm, longest diameter)				
PCNL	161	14.73±3.066	9.338	0.009
RIRS	45	13.84±2.449		
SWL	81	13.52±2.545		
Total	287	14.25±2.881		
Procedural time (in min)				
PCNL	161	81.34±30.902	129.402	0.0005
RIRS	45	84.89±29.358		
SWL	81	45±0.000	Kruskal–Wallis test	
Mean duration of stay in hospital (in days)				
PCNL	161	4.61±1.189	183.315	0.0005
RIRS	45	3.49±1.424		
SWL	81	1.21±0.754	Kruskal–Wallis test	

PCNL: Percutaneous nephrolithotomy, RIRS: Retrograde intrarenal surgery, SWL: Shockwave lithotripsy

Table 1 gives the details of the failure rates with each of the procedures. However, there was no significant difference between the failure rates between the two sides. Table 3 gives details of the failure rate with respect to the stone location.

Table 4 and Figure 2 provide the details of the residual fragments after the three procedures. A residual fragment of more than 4 mm is considered to be a significant residual fragment. An average of 12.5% of patients had residual stones, with the maximum seen in SWL (17.3%), closely followed by RIRS in 13.3%. However, the numbers are not statistically significant.

Table 4 also provides details regarding the number of patients who needed retreatment. Nearly, one-fifth of patients who had SWL done and needed retreatment. One patient who had RIRS needed a relook ureteroscopy, as after the initial procedure there was bleeding. Relook RIRS was done 3 weeks after double J-stenting. Nine patients in the PCNL group and five from RIRS group needed SWL. However, none of the patients in the SWL group needed any other auxiliary procedure (Table 4).

Table 5 gives the details of the residual stones at 2 weeks and 6 weeks following the procedure. At 2 weeks, the residual calculi noted following the primary procedure was analyzed but are not statistically significant with all three groups. However, clinically SWL has the maximum number of patients (17.3%) with significant residual calculi at the end of 2 weeks needing auxiliary procedures. When reviewed at the end of 6 weeks following auxiliary procedures, all the patients are stone free in all 3 groups.

RIRS was associated with maximum percentage of complications. Table 6 illustrates the list of complication associated with each of these procedures. When comparing the various complications between groups, the values

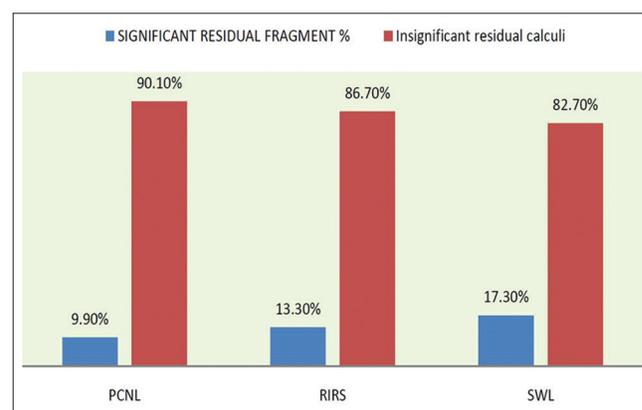


Figure 2: Comparison of significant and insignificant residual fragments

Table 3: Location of stones

Procedure	Upper calyx		Middle calyx		Lower calyx		Renal pelvis		Upper ureter	
	Number	Failure	Number	Failure	Number	Failure	Number	Failure	Number	Failure
PCNL	25	6	42	2	35	1	42	7	17	0
RIRS	9	0	2	0	5	1	5	0	24	5
SWL	33	4	2	2	0	0	22	2	5	2
<i>P</i> -value	0.0005		0.0005		0.0005		0.0005		0.0005	

PCNL: Percutaneous nephrolithotomy, RIRS: Retrograde intrarenal surgery, SWL: Shockwave lithotripsy

Table 4: Residual fragments, retreatment rate and auxiliary procedures in each group

Variables	Groups (%)			Total	Chi-square test	<i>P</i> -value
	PCNL	RIRS	SWL			
Residual fragments						
No fragments	145 (90.1)	39 (86.7)	67 (82.7)	251 (87.5)	2.681	0.262
Fragments present	16 (9.9)	6 (13.3)	14 (17.3)	36 (12.5)		
Retreatment						
No retreatment required	154 (95.7)	44 (97.8)	65 (80.2)	263 (91.6)	47.609	0.0005
SWL	0	0	16 (19.8)	16 (5.6)		
Flexible ureteroscope	0	1 (2.2)	0	1 (0.3)		
Redo PCNL	7 (4.3)	0	0	7 (2.4)		
Auxiliary procedure						
No auxiliary procedure	152 (94.4)	40 (88.9)	79 (97.5)	271 (94.4)	13.018	0.011
ESWL	9 (5.6)	5 (11.1)	0	14 (4.9)		
Ureteroscopy	0	0	2 (2.5)	2 (0.7)		

PCNL: Percutaneous nephrolithotomy, RIRS: Retrograde intrarenal surgery, SWL: Shockwave lithotripsy, ESWL: Extracorporeal shock wave lithotripsy

Table 5: Residual fragments at 2 weeks and 6 weeks after surgery

Residual fragments	Groups (%)			Total	Chi-square test	<i>P</i> -value
	PCNL	RIRS	SWL			
At the end of 2 weeks						
No residual fragments present	145 (90.1)	39 (86.7)	67 (82.7)	251 (87.5)	2.681	0.262
Significant residual fragments present	16 (9.9)	6 (13.3)	14 (17.3)	36 (12.5)		
At the end of 6 weeks						
No residual fragments present	161 (100)	45 (100)	81 (100)	287 (100)	0	

PCNL: Percutaneous nephrolithotomy, RIRS: Retrograde intrarenal surgery, SWL: Shockwave lithotripsy

Table 6: Complication rates in each group

Complications	Groups (%)			Total (%)	Chi-square test	<i>P</i> -value
	PCNL	RIRS	SWL			
No complication	149 (92.5)	40 (88.9)	75 (92.6)	264 (92)	19.641	0.033
Bleeding	11 (6.8)	3 (6.7)	2 (2.5)	16 (5.6)		
False passage	0	1 (2.2)	0	1 (0.3)		
Hematoma	0	0	2 (2.5)	2 (0.7)		
Perforation	1 (0.6)	1 (2.2)	0	2 (0.7)		
Steinstrasse	0	0	2 (2.5)	2 (0.7)		
Groups						
PCNL versus RIRS					0.677	
PCNL versus SWL					0.804	
RIRS versus SWL					0.751	

PCNL: Percutaneous nephrolithotomy, RIRS: Retrograde intrarenal surgery, SWL: Shockwave lithotripsy

are statistically significant ($P = 0.033$). When assessing individually the RIRS group has a maximal complication rate with 11.1% compared with PCNL and SWL groups which were 7.4% and 8.0%, respectively.

On assessing, the overall success rate of the three modalities, a residual fragment of ≤ 4 mm following the procedure is considered as the success of the primary procedure. On assessing the groups, PCNL has the maximum success rate

with 90.1% cases while RIRS has 86.7% and SWL has the least success rate of 82.7% (Figure 3).

DISCUSSION

The term endourology was defined as a closed controlled manipulation within the genitourinary tract.¹ The development of minimally invasive surgical techniques for treating renal stones has largely revolutionized due to various technologic advances in the fiber optics, better radiographic imaging, and various types of lithotripsy modalities (pneumatic, ultrasonic, electrohydraulic, and laser) available these days. All these developments redefined the modern techniques of stone removal, including ESWL, flexible ureteroscopy, and PCNL.

The factors determining which type of management suits a particular patient depends on various factors associated with the stone, anatomy of kidneys, and patient related issues. The stone factors include their number, size, and composition. Renal anatomic factors are the presence of obstruction, degree of hydronephrosis, location of the stone, and associated anomalies such as pelvi-ureteric junction obstruction, renal ectopia or fusion, calyceal diverticulum, and horseshoe kidney, as all these can hinder stone clearance after SWL. The patient related factors include age, obesity, body habitus and deformity, presence of infection, hypertension, renal failure, and associated coagulopathy.

Stone burden plays an important role in the treatment decision. For patients with nonstag horn stones of size lesser than 10 mm, SWL is the primary modality. For patients with size between 10 and 20 mm, SWL can still be considered even though successful outcome may be achieved with other modalities. Patients with stones of size larger than 20 mm should ideally be managed by PCNL unless specific indications for ureteroscopy are present like

obesity or bleeding diathesis.^{2,4} SWL results vary inversely with stone burden whereas PCNL stone free rates were largely independent of stone burden.⁵

Lingeman reported the influence of composition when adjusted for size of the stone. Cystine, brushite calculi, and calcium oxalate monohydrate appeared more resistant to SWL, followed in descending order of resistance by struvite, calcium oxalate dihydrate, and uric acid stones.⁶ Hence, SWL should be offered with great caution in such patients only when the stone size is <1.5 cm.^{7,8} Wang *et al.* confirmed that stone density higher than 900 HU is a predictor of a poor SWL outcome.⁹ El-Nahas *et al.* also found that a stone density more than 1000 HU predicted failure after SWL.¹⁰ Khalil studied 438 patients with stones of size 1 cm, 1.1-2 cm and more than 2 cm and concluded that stone burden rather than stone location is the most important predictor of SWL outcome.¹¹

Our study helps to compare SWL, PCNL, and RIRS in the management of renal and upper ureteric calculi above L4 transverse process of 10-20 mm size in terms of stone free rate, morbidity experienced by the patient on the completion of the treatment. In the PCNL group of the 161 patients who underwent the procedure, the laterality was more or less equal with 5.6% failure seen on left side when compared to right which is 4.3%. Even though the difference is small and insignificant, this predominant left sided failure may be due to the highly placed left kidney, which needs further validation. The average size of the stone was 13.84 mm with 13.3% having residual calculi following primary procedure thus needing a second procedure. When comparing the failure with location of the stone, upper ureteric calculi have the maximum failure 11.1% followed by lower calyceal calculi (2.2%). This can be explained because of difficulty in using a flexible ureterorenoscopy in a non-stented ureter following up migration of the stone proximally. However, the same authors had later on started doing pushback PCNL for such upper ureteric stones, claiming a much higher success rate.¹²

In our study, the mean stone size in each group was 14.73 mm for PCNL group and 13.84 mm and 13.52 mm in RIRS, and SWL group, respectively. Resorlu *et al.* revealed that the mean stone size for the PCNL group was a little higher with 17.3 mm and 15.6 mm for RIRS and 14.9 mm for SWL group.¹³ In both studies, the mean stone size was statistically significant. PCNL had a success rate of 90.1% in our study at 2 weeks from the procedure. Similarly with RIRS and SWL, the success rates were 86.7% and 82.7%, respectively. On the other hand, Resorlu *et al.* showed good result with PCNL of 91.4% success while SWL had only 66.5% success on review post procedure requiring auxiliary procedure for complete stone clearance. Akman

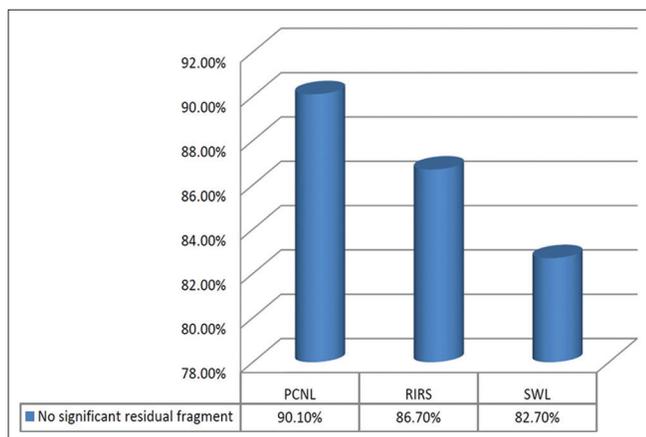


Figure 3: Overall success rate of study groups

et al., compared PCNL with RIRS, showing better success with PCNL (92.8%) compared with RIRS (82.1%).¹⁴ Cecen *et al.* compared RIRS with SWL showing better results with RIRS (92% vs. 87%).¹⁵ Nearly, 17.3% patients in SWL group needed retreatment with the same modality that required to undergo 2nd and 3rd sitting SWL for the residual calculi. Resorlu *et al.* group had a retreatment of 21.9% for SWL group, and in Cecen *et al.* study, the retreatment rate with SWL was 12.9% (Table 7).

Table 7 also compares the outcomes of various studies with regard to stone free rates, mean hospital stay, and complication rates. From our study, the mean hospital stay for PCNL was 4.61 days and least for SWL as it is mostly done as day care procedure. Resorlu *et al.* published his results where the mean stay in hospital was 2.6 days for PCNL and 1.3 days for RIRS. SWL was done as an outpatient procedure. Carlsson *et al.* observed that post PCNL patients stayed for 7.4 days when compared to SWL patients, where the mean hospital stay was 4.1 days.¹⁶ The need for such a prolonged stay in the hospital and an inpatient care in SWL group is debatable. Carlsson *et al.*, observed that one of the reasons for inpatient treatment was to standardize the management of patients in the ESWL unit. According to their observation, this routine practice also facilitates a high patient turnover, which reduces the cost per session. Akman *et al.* noted an average of 2.8 days in PCNL group and 1.2 days for RIRS patients.¹⁴ Table 7 also illustrates the comparison of overall complication rate between various studies. In our study, it was high in RIRS group with 11.1% while PCNL group had

7.4% and SWL group had 9.9%. All complications reported were minor. Resorlu *et al.* published his complication rate with 20% in PCNL group. The decision to offer SWL for moderately sized stones was also biased because of the higher percentage of complications. However, we observed that as learning curve improves, with time and in well-experienced hands, PCNL can achieve a maximal success outcome with minimal morbidity.

Limitations of Our Study

Our sample size is small and associated difficulty with performing statistical analysis. Moreover, there is a variable *n* value in the study groups. The study was unable to exclude many of the other confounding factors which may have influenced some of the outcomes analyzed which is beyond the scope and purview of this study. However, further studies with larger sample size and after elimination of confounding factors would have been ideal and are recommended.

CONCLUSION

PCNL and RIRS have comparable success and complication rate, whereas SWL has lower complication rate. When comparing the stone free rate, PCNL, and RIRS are better than SWL. More number of cases needed auxiliary procedures in SWL patients. Thus, tailoring the management with respect to the patient, stone parameters, and other technical factors is needed to achieve a good stone clearance with least morbidity. In the case of PCNL, the complications can be reduced using smaller nephroscope and smaller tract dilatation, but its invasiveness is always a cause for

Table 7: Comparison with various other similar studies

Group	Our study	Resorlu study	Cecen <i>et al.</i> study	Akman <i>et al.</i> study	Others
Stone free rate (%)					
PCNL	90.1	91.4	-	92.8	-
RIRS	86.7	87.0	92	82.1	-
SWL	82.7	66.5	87	-	-
Retreatment rate (%)					
PCNL	4.3	5.7	-	0	-
RIRS	2.2	8.7	0	17.9	-
SWL	17.3	21.9	12.9	-	-
Need for auxiliary procedures (%)					
PCNL	5.6	5.7	-	-	Albala <i>et al.</i> , 2001 1.72
RIRS	11.1	8.7	0	-	-
SWL	19.8	21.9	12.9	-	15.63
Duration of mean hospital stay (Days)					
PCNL	4.61	2.6	-	2.8	Carlsson <i>et al.</i> 7.4
RIRS	3.49	1.3	-	1.2	-
SWL	1.21	0	-	-	4.1
Complication rate (%)					
PCNL	7.4	20.1	-	10.7	-
RIRS	11.1	10.9	7.5	7.1	-
SWL	9.9	7.6	6.4	-	-

PCNL: Percutaneous nephrolithotomy, RIRS: Retrograde intrarenal surgery, SWL: Shockwave lithotripsy

great concern. In the case of RIRS, the stone can be managed endoscopically, but pre-stenting the patient before RIRS can improve the easy manoeuvrability of flexible ureterorenoscopy, thus reducing the failure rate and showing comparable success to PCNL. The reduced stone free rate of SWL can be pointed to the efficacy of the technician performing the procedure and also the quality of the hardware. RIRS will be a better modality for the treatment of upper urinary tract calculi of size 10 – 20 mm provided all patients were stented before RIRS when comparing the invasiveness of PCNL and higher retreatment and failure rate of SWL.

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How to cite this article: Muniasamy S, Palaniyandi V, Krishnamoorthy S, Kumaresan N, Ramanan V. Comparative Study of Stone Free Rate, Morbidity and Need for Retreatment Procedures between Various Surgical Modalities for 10-20 mm Upper Urinary Tract Calculi. *Int J Sci Stud* 2017;4(10):37-43.

Source of Support: Nil, **Conflict of Interest:** None declared.