Comparison of Mini Percutaneous Nephrolithotomy (Mini PCNL) and Retrograde Intrarenal Surgery (RIRS) for the Minimal Invasive Management of Lower Caliceal Stones

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Purpose: To evaluate the stone-free rates, quality of life, complications, use of fluoroscopy, analgesic requirements, and hospital stay following the management of lower calyceal with two different techniques (Mini Percutaneous Nephrolithotomy and Retrograde Intrarenal Surgery) in a prospective manner.

Material and Methods: 50 patients diagnosed with lower pole 1-2 cm stone were included in the study and randomized into two groups. (Mini PCNL n: 25) (RIRS n: 25). The safety and efficacy of both methods, along with some other certain related factors, were comparatively evaluated in both groups.

Results: There was no significant difference between preoperative stone size, stone-to-skin distance, hemogram, creatinine values, need for the analgesic drug, patients' replies to visual analog scale (VAS). The duration of both the hospital stay and the exposure to fluoroscopy, hematocrit decrease due to hemorrhage; complication rates were significantly higher in cases undergoing mini PCNL when compared to RIRS. Additionally, no significant difference was observed concerning the stone-free rates. Despite an increase in quality of life following both types of operations, there was no significant difference in the quality of life between the patients in both groups.

Conclusion: Our findings demonstrated that both surgical techniques are feasible alternatives in the minimally invasive treatment of lower pole stones. Although there was no meaningful difference in stone-free rates between the two groups, complications, use of fluoroscopy, bleeding, and duration of hospital stay were noted to be significantly higher in cases treated with mini PCNL.

Keywords: fluoroscopy; hospital stay; mini percutaneous nephrolithotomy(Mini PCNL); quality of life; retrograde intrarenal surgery(RIRS); visual analog scale (VAS)

INTRODUCTION

As a pathology affecting 1-5% of the industrial countries, urolithiasis is the third pathology influencing the urinary system after urinary tract infections and prostate pathologies. Although the prevalence of stone disease throughout life varies between 1-20%, this rate has been reported to be up to 37% in some countries reported during the last two decades.[1] 25 % of patients with kidney stones have a family history. Also, diseases transitioning by genetic such as renal tubular acidosis (RTA), cystinuria, xanthinuria, dent disease have been identified in a certain percent of stone forming cases.[2] Diagnostic evaluation requires a thorough physical examination, laboratory, and radiological imaging investigations to evaluate the stone and patient-related factors for a proper treatment plan. Despite the developed medical therapies alternatives regarding the treatment, definitive treatment of stones is performed with extracorporeal shock wave lithotripsy (ESWL) and minimally invasive surgery.

ESWL is the primary approach for stones smaller than 2 cm in the renal pelvis and calyx system.[3] Although ESWL has more excellent success rates in most of the stones mentioned above, in the event of a hard stone with a steep infundibulopelvic angle and narrow infundibular neck, the success rates of ESWL could be decreased.[4]

Furthermore, for larger stones (> 2 cm) requiring possible additional interventions, other minimally invasive surgical alternatives like PCNL or RIRS could be recommended as the first choice instead of ESWL treatment.[3] According to EAU guidelines, the surgical treatment of lower calyceal stones is the first choice for stones greater than 20 mm has been stated to be PCNL. For stones sizing between 10-20 mm, ESWL or endourological methods are recommended as equally effective, and for stones smaller than 10 mm, the first approach was defined as ESWL/RIRS, and as second-choice is PCNL.[3]

PCNL has replaced open surgery due to the short hospital stay, low cost, and morbidity. Although standard

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Table 1. Demographics and baseline characteristics of the patients.

	Mini PCNL	RIRS	*P* value
Number of Patients	25	25	
Age	44 ± 14	48 ± 13.9	0.4 ($p > 0.05$)
Gender	M:% 60 (15 patients)	M:%52 (13 patients)	0.569
	F: % 40 (10 patients)	F:%48 (12 patients)	($p > 0.05$)
Pre-operative Stone Size(mm)	15.7 ± 2.5	13.6 ± 2.2	0.09 ($p > 0.05$)
Stone-Skin Distance (mm)	95.6 ± 24.1	97.4 ± 15.2	0.294 ($p > 0.05$)
Preoperative Creatinine	0.9 ± 0.3	0.9 ± 0.4	0.586 ($p > 0.05$)
Preoperative Hematocrit	41 ± 5.6	40 ± 3.7	0.459 ($p > 0.05$)
Preoperative analgesic requirements.	Yes:% 44 (11 patients)	Yes:% 68 (17 patients)	0.87($p > 0.05$)
	No: %56 (14 patients)	No:% 32 (8 patients)	
*Preoperative VAS in pain	4 ± 0.4	4 ± 0.4	0.549 ($p > 0.05$)
Stones	Single:%44(11 patients)	Single:%36(9 patients)	0.564($p > 0.05$)
	Multiple: %56(14 patients)	Multiple: %64(16 patients)	

* VAS: Visual analog scale, M: Male, F: Female

PCNL has been used with 24-30 F nephroscope for an extended period, equipment sizes have started to be miniaturized subsequently due to the increased risk of complications due to the relatively higher invasiveness originating from large-sized access tracts. In 1998, Jackman et al. described the mini-PCNL technique in the pediatric patient group where a nephroscope sizing 11-18 F has been favored.[5]

Among surgical methods for the minimally invasive removal of lower calyceal stones, RIRS is one of the most frequently used methods due to its limited morbidity and the similar success rates obtained as an alternative to ESWL as well as PCNL. In an original study performed by Grasso et al., RIRS was applied for the management of different sized lower pole stones (less than 10 mm, between 10-20 mm, and greater than 20 mm, respectively), and the obtained success rates were 82%, 71%, 65%.[6]

In the light of this literature knowledges, we aimed to compare the RIRS and Mini PCNL in lower calyceal stones in all aspects.

PATIENTS AND METHODS

Between June 2016 and December 2016; patients referring to the urology department of Dr. Lutfi Kirdar Kartal City Hospital (aging between 18 and 65 years of age) with single or multiple stones (sizing 1-2 cm) localized in the lower calyx systems were included into the study program and evaluated prospectively. Following obtaining approval from the Ethics Committee of our hospital and informed consent forms filled by the patients. A total of 50 patients were included in the study in 2 groups of 25 people. Group 1 (n = 25) operated with mini PCNL and Group 2 (n = 25) treated with RIRS. Groups were divided into two groups by patient preference.

The exclusion criteria were assigned as the presence of bleeding diathesis, cognitive dysfunction, skeletal deformity preventing surgery, kidney collecting system anomaly, and the previous history of any renal surgery. To outline the stone-related factors (location, size, number) and kidney anatomy, a preoperative non-contrast spiral tomography was performed in all patients.

The patients were evaluated with direct genitourinary system radiography (DUSG) and/or urinary ultrasonography(USG) to outline the presence and size of residual stones during the postoperative first day, 1st week, 1st month, and 3 rd month. Non-contrast tomography was joined to those tests if necessary.

Preoperative and postoperative quality of life evaluation was performed on all patients. A visual analog scale (VAS) was used to outline the patients' pain both before the procedures and in postoperative follow-up. Wewers and Lowe had described VAS in 1990.[7] This form represents the severity of pain, whether ‘no pain’ with a score of ‘0’ or ‘the worst pain I could imagine with a score of ’10’. (**supplementary Figure1**)

In addition to the evaluation of pain, EuroQol 5D (EQ 5D) general health scale form was filled out for the quality of life questionnaire both before and 3 months after the procedures. The EQ5D common health scale was outlined in 1987 by the EuroQol bunch of the Western European Quality of Life examination Community. (**supplementary Figure 2,3**) It has been translated into more than 60 languages, and one of them is Turkish in 1990.[8]

At the first step of the mini PCNL to access to kidney collecting system, the combination of both ultrasound and fluoroscopy was used, after which the dilatation was performed with the amplatz dilation system (Microvasive-Boston Scientific, USA). For stone fragmentation, our choice was a pneumatic lithotripter (Elmed Vibrolith, PCK Electronic P 1500 Ankara-Turkey) along with an ultrasonic lithotriptor used with this aim. We do not have a specific protocol regarding the use of these two techniques. The success of stone fragmentation of the two methods was found to be similar in the literature. A nephrostomy tube was placed in all patients routinely.

In the RIRS technique, the following semirigid ureteroscopy evaluation, the ureteral access sheath was placed into the ureter over the stiff guidewire under fluoroscopic guidance. After getting access into the collecting system, a 5,5 F flexible ureterorenoscope (F-URS) (Karl Storz, Tuttlingen, Germany) was used for the flexible ureteroscopy procedure. Stones were fragmented with a holmium YAG laser (Sphinx 30 Watt holmium laser USA). A single experienced urologist performed all these procedures.

In addition to the demographic findings of the cases in both groups, surgical time, the extent of radiation in the course of operation, length of hospital stay(days), complications, blood transfusion rates, decrease in hematocrit levels, stone-free status, preoperative and postoperative analgesic requirements as well as the quality of life scores were compared in both groups. Regarding the size of residual fragments, fragments smaller than 3mm or large were accepted as clinically significant. Complications related to the procedures were classified

Table 2. Results of operations.

	Mini PCNL	RIRS	*P*
Operation Time (min)	71.7 ± 24.4	72.8 ± 24.2	0.696 ($p > 0.05$)
Floroscopy time using (sec)	18.9 ± 13.8	2.7 ± 2.8	0.001 ($p < 0.05$)
The Length of Hospital Stay(days)	4.6 ± 3,5	1.2 ± 0.59	0.000 ($p < 0.05$)
Analgesic requirement post-operative at 1 st week	Yes:12 (% 48) No:13 (% 52)	Yes:8 (% 32) No:17 (% 68)	0.248 ($p > 0.05$)
Blood Transfusion	Yes: 2 (% 8) No:23 (% 92)	Yes: 0 (% 0) No:25 (% 100)	0.490 ($p > 0.05$)
Hematocrit decrease (%)	4.8 ± 3.8	1.6 ± 2.6	0.000 ($p < 0.05$)
*(SFS) postoperative first day	16 (% 64)	12 (% 48)	0.254 ($p > 0.05$)
(SFS) postoperative 1 rd week	17 (% 68)	16 (% 64)	0.765($p > 0.05$)
(SF S) postoperative 1 rd day	17 (% 68)	17 (% 68)	1.000 ($p > 0.05$)
(SF S) postoperative 1 rd day	18 (% 72)	17 (% 68)	0.758($p > 0.05$)
VAS in pain postoperative 1 rd week	2 ± 0.2	2±0.38	0.346 ($p > 0.05$)
**Complications	Grade 1: 7 Patients Grade 2: 9 Patients Grade 3:6 Patients Grade 4:3 Patients Grade 5:none	Grade1: 22 Patients Grade2: 3 Patients	0.000 ($p < 0.05$)
DJ stent placement	Yes:4 (%16) No:21(% 84)	Yes:20 (% 80) No: 5 (% 20)	0.000 ($p < 0.05$)

*Stone-free status,
** Clavien classification: 1.Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions, 2.Requiring pharmacological treatment with drugs other than such allowed for grade I complications. 3. Requiring surgical, endoscopic or radiological intervention, 4.Life-threatening complications (including CNS complications) requiring IC/ICU-management, 5.Death of a patient.

by using a modified Clavien classification system.[9] In statistical analysis, SPSS for Windows 22 program was utilized. Numerical variables determined not to distribute in a normal manner were evaluated by using the Kolmogorov Smirnov test. , Mann Whitney U test and Chi-square tests. $P < 0.05$ was considered statistically significant.

RESULTS

Patients' demographic findings, preoperative values, and postoperative outcomes were recorded and evaluated comparatively in both groups. These findings are summarized in Table 1. The preoperative size of stones measured with non-contrast computed tomography(NCCT) in the mini PCNL and RIRS groups were 15,7 ± 2,5 mm, 13,6 ± 2,2 mm, respectively. Furthermore, values of the distance of stone from to skin based on preoperative non-contrast CT was detected as 95,6 (± 24,1) mm for mini PCNL and 97,4 (± 15,2) mm. for RIRS. These results pointed out no statistically significant difference between groups. ($p = 0.09$, $p = 0,294$) While 44 % of patients in the mini PCNL group and 36 % in the RIRS group demonstrated a single stone in the lower pole calyx, the remaining patients had multiple stones. There was no statistically significant difference in the preoperative routine biochemistry and serum hematocrit values (creatinine $p = 0.586$, hematocrit $p = 0,459$).

Regarding the comparison of VAS scale values in both groups and the requirement of an analgesic drug, there was no significant difference with respect to both parameters between two groups (Analgesia requirement $p = 0.87$, VAS in pain $p = 0.549$) Mean value of the pre-operative VAS score assessment in the event of pain was noted to be as "4" for both groups. Also, the highest pain value noted with VAS scoring was "8".

11 patients of the mini PCNL group (%44) and 17 patients of the RIRS group expressed use of oral analgesics due to severe pain. In the light of data obtained, the average operational duration for mini PCNL was 71.7 min(± 24.4) and RIRS 72.8 min (± 24.2); there was again no statistical difference among both groups. ($p = 0.696$)

Another notable point is the time of fluoroscopy exposure, which is measured by seconds. While this duration was18,9 sec (± 13,8) in the mini PCNL group, it was noted to be 2.7 sec (± 2.8) in the RIRS group, indicating that the need for fluoroscopy was less in RIRS group than the mini PCNL with a significant statistical difference among both groups. ($p < 0.05$) Similarly, bleeding and decrease in hematocrit values were less for the RIRS group. ($p < 0.05$) However, as noted during the follow-up period, only two patients operated with mini-PCNL required blood transfusion, and these findings have emphasized that the difference was not statistically significant between the two groups ($p = 0.490$).

Evaluation of the period in hospital demonstrated that the average value was 1,2 ±0.59 and 4,6 ± 3,5 days in RIRS and mini PCNL groups, respectively, with a statistically significant difference among the two groups. ($p < 0.05$) During the postoperative 1st week, the analgesic requirement was needed in 12 patients in mini

Table 3. The Questionnaire of pre-operative and post-operative quality of life (EQ5D index, EQ5D VAS scale)

	Mini PCNL	RIRS	*p*
Preoperative EQ-5DVAS (%)	% 61.4 ± 3.37	% 63.6 ± 2.2	0.239 ($p > 0.05$)
Preoperative EQ-5D indeks	0.271 ± 0.750	0.177 ± 0.631	0.865 ($p > 0.05$)
Postoperative 3rd Month EQ-5D VAS (%)	% 83.1± 2.4	% 81 ± 2.6	0.604 ($p > 0.05$)
Postoperative 3rd Month EQ-5D indeks	0.570 ± 0.914	0.740 ± 0.852	0.264 ($p > 0.05$)

PCNL and 8 patients in RIRS group, and the equivalent of this type of pain in the VAS score was found "2"(very little), which did not make any significant statistical difference. (analgesia requirement((2x1 75 mg diclofenac daily)) $p = 0.248$, VAS in pain $p = 0.346$)

To evaluate and compare complications associated with between groups, findings obtained according to modified Clavien Calcification were considered. Results with modified clavien classification of the complications showed that while grade 4 complications were observed in 3 patients, grade 3 in 6, and grade 2 in 9 patients in the mini PCNL, grade 2 complications were seen in 3 patients in the RIRS group. These results have clearly demonstrated that the complication rates were higher in cases undergoing mini PCNL. ($p < 0.05$)

While 20 of 25 patients in the RIRS group required the double J catheter placement, only 4 of 25 patients in mini PCNL had this stent after the procedure. ($p < 0.05$)

Postoperative stone-free rates of the patients in both groups are being summarized in Table 2. Despite evidently increased rates within three months noted in both groups, there was no statistically significant difference between the two groups on this aspect. (**Table 2**)

The evaluation of the pre-operative and postoperative measurements of the EQ5D index and EQ5D VAS values are being summarized in **Table 3**. A significant improvement in the quality of life of the patients was noted in all cases without any statistically significant difference between the groups on this aspect.

DISCUSSION

As the success rates in terms of stone-free status for kidney stones have been increased as a result of the improvements in endourology, the hospitalization period has been shortened, surgical complications, as well as other morbidity conditions, have decreased significantly.

The reported overall success rates of PCNL vary between 76-91% in the literature, with a rate of complications ranging from 20,5-29%.[10,11] Although this approach has been performed for an extended period with great acceptance, RIRS has started to play an important role in the surgical treatment of kidney stones with advancing laser technology.[12] During the RIRS procedure, stones in almost all anatomical locations within the kidney can be easily reached without any risk of damage to the renal parenchyma. Therefore, RIRS increased its popularity with low complications as well as comparable success rates. RIRS is also accepted as the most effective technique with minimal morbidity in patients with bleeding diathesis and the cases using anticoagulants.[13]

Concerning the stone location, PCNL and RIRS are effective methods for the surgical treatment of lower calyceal stones. The comparative valuation of these surgical methods from different aspects has often been subjected to various studies. Related to this issue, Albala et al. reported in 2001 that stone-free rates after PCNL were 100%, 93%, and 86%, respectively, in lower calyceal stones sizing less than 1 between 1-2 cm and above 2 cm.[11] In another study published by Preminger et al., the efficacy of ESWL and PCNL were compared in lower calyceal stones, and while 100% and 92% stone-free rates have been obtained after PCNL in stones between 1 cm and 1-2 cm, these rates were noted to be 67% and 21% after ESWL respectively.[14] Other studies in the literature have also reported high stone-free rates after PCNL for lower calyceal stones.[15,16]

Mini PCNL technique with low complication rates compared to the standard PCNL approach has become the focus of interest in such studies. Nagele et al. have used 12 F nephroscope during mini PNL procedure for lower calyceal stones (sizing between 0,8-1,5 cm) and have reported a stone-free rate of 96,5% without any need for blood transfusion. (17) Mishra et al. have compared standard PCNL with 12 f mini-PCNL in the treatment of kidney stones between 1 and 2 cm, a similar stone-free rate has been obtained in both methods, and bleeding was found to be significantly lower in mini-PCNL.[18] Also, ElSheemy et al. compared mini-PCNL with standard PCNL in 2019, and although the stone-free rate was lower in mini-PCNL, it was found to be advantageous in terms of complications and hospital stay.[19]

Reported data in the literature evaluating the success of RIRS, which is a convenient method for the minimally invasive surgical treatment of lower calyx stones, have demonstrated high stone-free rates with low complication after this modality when compared with PCNL. For instance, a study carried about by Grasso and Ficazzola revealed stone-free rates of 82%, 71%, and 65%, respectively, when the lower pole stones were smaller than 1cm, 1-2 cm, and greater than 2 cm were treated with RIRS.[20] Other studies in the literature have clearly reported that the stone-free rate for RIRS has gradually increased.[21,22,23]

While high stone-free and low-complication rates were obtained with both RIRS and mini PCNL approaches, the advantages and disadvantages of these techniques have been discussed in detail in a number of studies published in the literature. Pan et al. have compared the results of RIRS and mini PCNL in 2-3 cm kidney stones, and while the results showed higher stone-free rates for mini PCNL, complication rates were lower for RIRS.[24] Lee et al. have compared mini PCNL and RIRS methods for kidney stones larger than 1 cm and have emphasized that both methods were comparable. Although not statistically significant, cases in the RIRS group had a higher stone-free rate than mini-PCNL, but there is a higher need for analgesics in RIRS cases. [5] In their original study, Kıraç et al. compared mini PCNL and RIRS techniques in lower pole stones less than 15 mm, and it has been stated that no major complications were observed in any patient where the final stone-free rates were similar in both groups of cases.[26] In the same study, however, length of hospital stay and fluoroscopy exposure time were found to be higher in mini PCNL group when compared to RIRS group.

Although there are enough studies in the literature comparing PCNL and RIRS techniques for lower pole calculi, a limited number of randomized prospective studies comparing the efficacy of both techniques in the management of lower calyceal stones have been reported far in the literature. The basal criteria in many studies investigating the surgical treatment of lower pole stones include stone-free status, complication rates, length of hospitalization, fluoroscopy time, along with bleeding and transfusion rates. In the majority of such studies, while the stone-free rates following PCNL method were found to be higher, this approach was found to be relatively disadvantageous in the light of the other criteria evaluated. As shown in the review article focusing on the comparison of the results obtained with PCNL,

RIRS, and ESWL in lower pole stones; all complication rates, bleeding, transfusion need, and length of hospitalization were found to be significantly higher in cases undergoing PCNL[27]

In the light of the data obtained in our study, we were able to show that the duration of radiation exposure, length of hospitalization, the decrease rate in the percentage of hematocrit due to hemorrhage, and the rate of complications (evaluated by clavien classification) were all higher in cases undergoing mini PCNL procedure for lower pole stones. These findings were found to be parallel with the data reported in the literature. Considering the stone-free rates, we did not find any significant difference between the two groups during postoperative day 1, week 1, month 1, and month 3 evaluations. Although reported higher stone-free rates in favor of PCNL and mini PCNL compared to RIRS obtained in the literature.[24,28] However, the Stone-free success of both techniques was found similar in our study. Similarly, Di Mario et al. had reported stone-free for two similar operations in their study.[29] In this respect, our study showed that RIRS is an effective treatment alternative for lower calyceal stones, considering the fact that stone-free success is similar to mini PCNL associated with lower complication rates, shorter length of stay, and shorter duration of fluoroscopy exposure time. Nevertheless, in 20 out of 25 patients undergoing RIRS, double-j catheter-related lower urinary tract symptoms, as well as additional pathologies such as catheter migration, catheter fall, or encrustation (calcification), have been observed as the disadvantages of this method. In addition, re-hospitalization of these patients for catheter withdrawal may cause the further quality of life changes in these patients.

As an important parameter to be focused on, in addition to the limited number of studies comparing mini-PCNL and RIRS techniques in lower calyceal stones, none of these studies have aimed to evaluate the quality of life changes in these cases after both interventions. In our study, by using the EQ5D general health scale form filled by the cases during both the pre-operative and postoperative 3-month evaluation phases, changes in the quality of life (QoL) were well assessed, and our data did not show any significant difference in QoL of the cases between the two groups during both pre-operative and postoperative evaluations regarding the possible changes in patients' quality of life.

Regarding the limitations of our present study, the lower number of patients from a single center, the lack of data on the anatomy of the lower pole involved (length, width, and angle of the infundibulum) are important parameters to be taken into account in such studies. Also, criticism may be that there is no specific protocol regarding using these two stone-breaking techniques. But when review to literature, the success of stone fragmentation of the two methods was similar.[30]

Last but not least, the lack of statistical data regarding the possible unfavorable effects of double j catheter placement on lower urinary tract functions may constitute another limitation. However, due to the limited number of studies focusing on the success and complications of these two methods (especially when evaluated with patients' quality of life findings), we believe that our present findings will contribute sufficiently to the current literature data.

CONCLUSIONS

There is an ongoing controversy regarding the optimal minimal invasive management of lower calyceal stones. Our findings clearly indicate that RIRS could be applied as a more favorable procedure with respect to the rate of complications, risk of bleeding, length of hospital stay, and the duration of radiation exposure when compared to mini-PCNL approach. However, in addition to the stone as well as anatomy-related factors, the patient's preference, surgeon's experience, technical possibilities need to be considered as a whole in selecting the most appropriate surgical technique for such stones. All patients should be informed in detail about the complications and possible success rates of these methods. We believe that further multicenter studies, including large patient series, are certainly needed to improve the scientific quality of the data obtained in our current trial.

APPENDIX

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