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MINI PERCUTANEOUS NEPHROLITHOTOMY VERSUS EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY IN TREATMENT OF NON LOWER POLAR HIGH DENSITY RENAL STONE 10-20 MM

(A PROSPECTIVE RANDOMIZED STUDY)

By

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ABSTRACT

Background: The optimal management of medium sized renal stones differs from one patient to another according to different factors. Stone attenuation value (SAV) is one of these factors which affect stone free rate (SFR) after extracorporeal shock wave lithotripsy (ESWL) with limited effect on mini-percutaneous nephrolithotomy (mini-PCNL).

Objective: To compare safety and SFR of mini-PCNL and ESWL in the treatment of non-lower pole renal stones with high density and size of 10-20 mm.

Patients and Methods: This prospective randomized study was carried out at Sayed Galal, Al Azhar University Hospital, Cairo, Egypt from November 2019 to October 2020 and included 70 patients with non-lower pole renal calculi 10 to 20 mm. Patients were randomly allocated in 2 equal groups: Group A was treated by mini-PCNL and group B was treated by ESWL. The primary end point was SFRs (no stone or residual 3>mm) in ESWL and mini-PCNL in this category of stone. The secondary end points were the complication rate, retreatment rate, and need for auxiliary procedures in each group.

Results: The overall operative time was significantly lower in mini-PCNL group (median: 50.00; IQR: 20.00) compared to ESWL group (median: 55.00; IQR: 28.00) (p= 0.001). The overall fluoroscopy time was significantly lower in mini-PCNL than ESWL (3.2 versus 3.6 minutes, p=0.040). In mini-PCNL group, 32 out of 34 (94.1%) patients were stone free. In ESWL group, 10 out of 33 (30.1%) were rendered stone free after the third ESWL session. The SFR was significantly higher in mini-PCNL group (p<0.001). In mini-PCNL group, none of cases needed a second look PCNL. The 2 failed cases had significant residual fragments that migrated into inaccessible calyx during pneumatic lithotripsy. In ESWL group, all cases had normal hemoglobin (Hb) level at each follow-up visit. In mini-PCNL group, when comparing pre- and post-operative Hb, a very highly significant differences were observed between pre- and post-operative Hb level (p<0.001).

Conclusions: Mini-PCNL is superior to ESWL in treatment of non-lower pole medium sized renal stones of high density with high SFR, and low complication rate as need for re-hospitalization or need for auxiliary procedure.

Keywords: Percutaneous Nephrolithotomy, Extracorporeal Shock Wave Lithotripsy, Stone attenuation value, Stone free rate, Non-lower pole, renal stones.

INTRODUCTION

The European Association of Urology (EAU) Guidelines of urolithiasis stated that the treatment options for renal stones 10-20 mm include either Extracorporeal shock wave lithotripsy (ESWL) or endourology (retrograde intrarenal surgery (RIRS) and percutaneous nephrolithotomy (PCNL) *(Turk et al., 2016)*.

However, the limitations of ESWL include relatively lower stone free rate (SFR) and the need for repeated sessions and auxiliary procedures especially in lower pole and harder stones. In a study divided the patients in to 3 groups according to stone attenuation value (SAV) : <500, 500-1000, and >1000 Hounsfield units (HU), SFR was 100%, 95.7%, and 44.6% respectively. Also, the number of sessions increases with increased SAV. SFR after the first session in these 3 groups was 100%, 49%, and 0% respectively *(Massoud et al., 2014)*.

In another study, SFR in patients with a stone diameter less than 10 mm was 79.3% and 45.7% in those with stone diameter above 10 mm. Regarding SAV, SFR was 93.8%, 62.7%, and 24.5% in the groups with SAV <500 HU, 500 to 1,000 HU, and >1,000 HU, respectively *(Waqas et al., 2018)*.

PCNL is now considered the 'gold standard' treatment for managing simple and complex renal stones, with a success rate of >90% *(Gonen and Basaran, 2014*; *Ferakis and Stavropoulos, 2015)*. It has good SFR but is associated with a significant risk of morbidity *(Zeng et al, 2013)*.

Most of the complications associated with PCNL are related to the tract size. So, reduction in tract size can lower the complications associated with it *(Yamaguchi et al., 2011*; *Mishra et al., 2011)*.

The term mini-PCNL is usually used for smaller diameter sheaths (12 to 18 F compared to 24–30 F in standard PCNL). It has lower morbidity due to less bleeding, and reduced pain *(Ferakis and Stavropoulos, 2015)*.

Mini-PCNL has comparable SFR to the standard method, even for large stones. In a study comparing mini-PCNL and standard PCNL, the clearance rates were 96% and 100%, respectively at 1 month follow up *(Mishra et al., 2011)*.

The European guidelines put ESWL and PCNL as an equal treatment options for non-lower pole renal stones from 10 to 20 mm size regardless SAV. But, there are several studies reporting markedly reduced SFR after ESWL with increased SAV. Several studies were comparing ESWL with PCNL or RIRS in lower calyceal stones, but no studies to compare these options in non-lower pole stones with high density.

The present work aimed to compare safety and SFR of mini-PCNL and ESWL in the treatment of non-lower pole renal stones with high density and size of 10-20 mm.

PATIENTS AND METHODS

This study was prospective randomized study comparing mini-PCNL versus ESWL in treating non-lower pole high dense renal stones of 10-20 mm size. The study was conducted at the Department of Urology, Sayed Galal University Hospital, Cairo, Egypt, The study was done

between November, 2019 and October, 2020. Inclusion criteria were single non-lower pole medium size (10-20 mm) and high dense (> 1000 HU) renal stones. Patients with BMI > 40 kg/m2, uncorrected bleeding disorders, solitary kidney, anatomical renal abnormalities, obstruction distal to the stone or those below 18 years were excluded.

Patients were evaluated preoperatively through history, physical examination, BMI, urine analysis with culture and sensitivity, CBC, Serum creatinine, Hb, plain urinary tract (PUT), computed tomography (CT), pelviabdominal ultrasonography (US). Intraoperative evaluation of fluoroscopy time, operative time and complications such as bleeding, perforation, hypotension and organ injury was done. Postoperative evaluation of Hb, creatinine, SFR and complications as fever, hematuria, leakage and urosepsis was done.

In group (A), the procedure was carried out under general anesthesia. In lithotomy position, a 6 Fr ureteral catheter was introduced through cystoscopy. Then patient was put in the prone position. Under fluoroscopic guidance and after opacification of the pelvicaliceal system with contrast, the desired calyx was punctured using 18-G puncture needle, followed by insertion of guide wire (0.035inch, J-tip). Another guide wire was inserted as a safety wire. Tract dilation was performed up to 16 F sheath using either Alkan or Amplatz dilators. Miniature nephroscope 12 Fr Karl Storz was used, stone fragmentation was done by pneumatic lithotripsy. The fragments were removed using stone forceps or Zero Tip baskets. The collecting system was examined by endoscopically and by fluoroscopy to confirm complete stone clearance. At the end of procedure, 14-F nephrostomy tube was inserted and nephrostogram was done to exclude any significant extravasation or perforation. Then nephrostomy tube was fixed to the skin and closed. Ureteric catheter was left in place. Nephrostomy tube was placed for 24 h then removed on postoperative day 1, the ureteric catheter was removed on postoperative day 2 then patient was discharged. **In group (B),** all patients were treated by Dornier lithotripter SII. All patients were treated in supine position with the water cushion adjusted below the flank. The localization was done by fluoroscopy. A maximum of 3000 shocks was given at each session or until complete fragmentation occurs at a rate of 80 shocks per minute and maximum power 3-4. Group A (mini-PCNL): Patients were considered to be stone free if there was no stone on US or PUT or stone < 3 mm. Group B (ESWL): Patients were considered to be stone free if there was no stone on US or PUT or stone < 3 mm after two weeks of last sitting. The primary end points were the SFRs in ESWL and mini-PCNL in this category of stone. The secondary end points were the complication rate, retreatment rate, and need for auxiliary procedures in each group.

Statistical analysis:

Statistical analysis was performed using SPSS 17.0 for Windows software (SPSS, Inc, Chicago, IL, USA) with the Student's t test for continuous variables and the chi-square and Fisher's exact tests for categorical variables. The continuous variables were compared between groups

using independent sample t-test or Mann-Witney U test. Pre-operative and post-operative Hb levels were compared using Wilcoxon signed-rank test. Differences resulting in a P value of <0.05 were considered statistically significant. The data was presented in the form of percentage, tables and numbers.

RESULTS

The overall operative time was significantly lower in mini-PCNL group (median: 50.00; IQR: 20.00) compared to ESWL group (median: 55.00; IQR: 28.00) (p= 0.001). The overall fluoroscopy time was significantly lower in mini-PCNL than ESWL (3.2 versus 3.6 minutes, p=0.040). In mini-PCNL group, 32 out of 34 (94.1%) patients were stone free. In ESWL group, 10 out of 33 (30.1%) were rendered stone free after the third ESWL session. The SFR was significantly higher in mini-PCNL group (p<0.001) **(Figure 1)**.

In mini-PCNL group, none of cases needed a second look PCNL. The 2 failed cases had significant residual fragments that migrated into inaccessible calyx during pneumatic lithotripsy. One of them refused further intervention and the second was referred for ESWL unit. No data available about the result of ESWL in this patient.

In ESWL group, none of cases became stone free after the first ESWL session. One case became stone free after the second session, and nine after the third session. Two of failed cases underwent ureteroscopy (URS) after the second ESWL session; one due to steinstrasse and one due to downward migration of unfragmented stone upper calyx into the lower ureter. Eight of failed cases were shifted for mini-PCNL during the study period and all osf them became stone free (data not included) **(Figure 2)**.

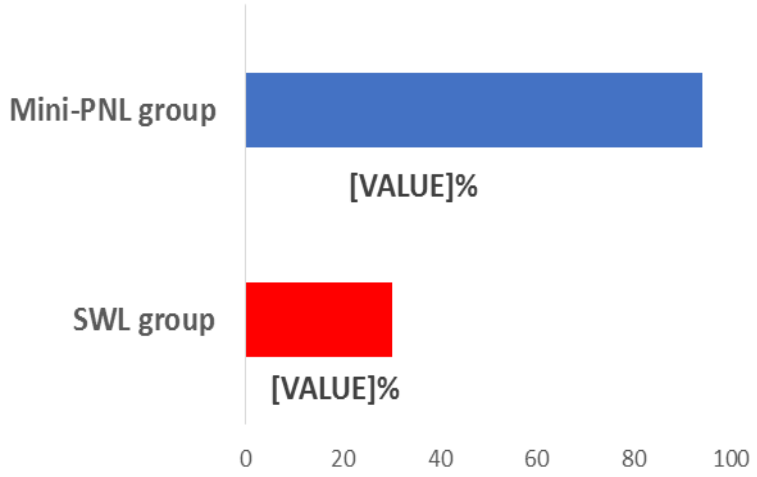

Figure (1): Bar chart demonstrating the stone free rate in both groups.

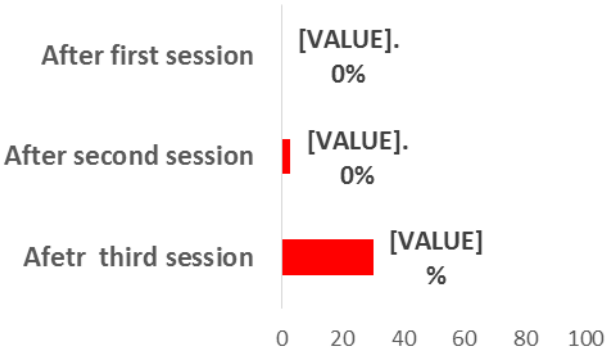

Figure (2): Bar chart demonstrating the cumulative stone free rate in ESWL group after each ESWL session

The median pre-operative Hb level was 13.70 gm/dl (IQR:0.90), there was no significant differences observed between mini-PCNL and ESWL groups regarding the preoperative Hb. In ESWL group, all cases had normal Hb level at each follow-up visit. In mini-PCNL group, significant differences were observed between pre and post-operative Hb ($p<0.001$). The median reduction of Hb was 1.00 gm/dL (IQR: 2.15). In mini-PCNL group, only one case required post-operative blood transfusion. The main indication of blood transfusion was reduction of post-operative Hb (<7 gm/dL). In ESWL group, all sessions were performed as a day-case procedure. In mini-PCNL group, the median hospitalization time was 4 days (IQR:0.00).

Regarding unscheduled re-hospitalization, 5 cases (all in ESWL group) were re-hospitalized; 3 of them due to persistent renal pain, one due to gross hematuria and one due to acute pyelonephritis. The unscheduled rehospitalization rate was significantly higher in ESWL group (15.2% vs. 0.0%; $p=0.018$).

In mini-PCNL group, 8 cases developed peri-operative complication. Perforation of renal pelvis with intra-operative bleeding was reported in one case. Post-operative complications were reported in 7 cases. The most common post-operative complication was fever (15.3%) followed by transient urine leakage after nephrostomy tube removal (10.6%). The intra- and post-operative complications, its modified clavien classification (MCC) grades and management were summarized in **Table (1)**.

Table (1): Intra- and post-operative complications in mini-PCNL group

	MCC Grade	Number (34)	%
Overall		**8**	**23.5**
Intra-operative:		**1**	**2.9**
● Bleeding requiring blood transfusion	2	1	2.9
Management: transfusion of one unit of whole blood + IV crystalloid infusion			
● Perforation of renal pelvis	3b	1	2.9
Management: double-J ureteral stenting (no long-term follow-up data)			
Post-operative:		**7**	**20.6**
● Post-operative fever	2	4	11.8
Management: IV broad-spectrum antibiotics			
● Transient bleeding	1	2	5.9
Management: clamping of NP tube + IV crystalloid infusion			
● Transient urine leakage after removal of NP tube	1	3	8.8
Management: watchful waiting			

IV, Intravenous; MCC, Modified Clavian classification; PCNL, Percutaneous nephrolithotomy; NP, Nephrostomy.

The total number of complications is more than the actual number of cases as some patients had more than one complication. In ESWL group ,no reported intra-procedural complications. Five cases developed post-procedural complications and all of them needed hospital admission. Two cases had persistent renal pain and imaging study revealed steinstrasse (after the 2nd ESWL session) in one and stone migration down from upper calyx into the lower ureter (after the 1st ESWL session) in the other. The first case underwent double-J ureteral stent fixation. The second case underwent URS with stone fragmentation and extraction (data not included). Post-operative complications, its MCC grades and management are summarized in **Table (2)**.

Table (2): Post-procedure complications in ESWL group

	MCC Grade	Number (33)	%
Overall		**5**	**15.2**
● Renal pain	1	1	3.0
Management: analgesics			
● Hematuria	1	1	3.0
Management: conservative			
● Steinstrasse	3b	1	3.0
Management: URS and double-J ureteral stent placement			
● Migration of stone into lower ureter	3b	1	3.0
Management: URS, and stone fragmentation and extraction			
● Pyelonephritis	2	1	3.0
Management: IV broad-spectrum antibiotic			

IV, Intravenous; MCC, Modified Clavian classification; ESWL, Shockwave lithotripsy; URS, ureteroscopy.

The total number of complications is more than the actual number of cases as some patients had more than one complication. On comparing the overall complication rates, no significant difference was observed between mini-PCNL and ESWL groups (23.5% vs. 15.2%; p=386). of lower calyceal stones, ESWL has high SFRs for renal stones 20mm or less *(Zheng et al. 2015)*. SFRs after single treatment for medium sized stones 10-30mm are 95.3% for PCNL vs 87.8% for RIRS and 60.4% for ESWL *(Wiesenthal et al., 2011)*. In a study done by Chung and Turney on the efficacy of ESWL on medium sized renal stones 10-20mm, the overall SFR was 66.4 %. The results were similar in different stone locations. But, SFRs were higher (70.4 %) with stone size <15mm compared to only 53.1% in stone size 15–20 mm *(Chung and Turney, 2016)*. In spite of achieving high SFRs with PCNL, it is also associated with increased risk of bleeding and blood transfusion *(Yamaguchi et al, 2011).*,

DISCUSSION

The ideal treatment for the stone 10-20mm, non-lower pole, with density above 1000 HU is that provide the highest SFRs with fewer sessions, and minimal complications. In this study, mini-PCNL provided higher SFRs (97.1%) than ESWL (30.3%). Also, in mini-PCNL, all patients in the success group were stone free after one procedure. While, in ESWL group, none of the patients became stone-free after the first session, and this SFR was achieved after 3 sessions. Our results showed high discrepancy between the SFRs in both groups.

In our series, Hb drop was highly significant in mini-PCNL group in comparison with ESWL. The mean Hb drop was 1.2 g /dL.

There were no reported intraoperative complications in ESWL group. While in mini-PCNL, intraoperative complications were recorded only in one patient. There was no significant difference regarding postoperative complications in both groups.

The mean operative time and fluoroscopy time were significantly lower in the mini-PCNL group compared with the ESWL group (51 versus 63 minutes, and 3.2 versus 3.6 minutes, respectively).

In several studies, the overall SFRs after ESWL for medium sized renal stones were 66.4% *(Chung and Turney, 2016)*, 75% *(Hassan et al, 2015)*, 79.2% *(Wiesenthal et al, 2011)*, and 83% *Massoud et al. 2014)*. With the exception of lower calyceal stones, ESWL has high SFRs for renal stones 20mm or less *(Zheng et al. 2015)*. SFRs after single treatment for medium sized stones 10-30mm are 95.3% for PCNL vs 87.8% for RIRS and 60.4% for ESWL *(Wiesenthal et al., 2011)*. In a study done by Chung and Turney on the efficacy of ESWL on medium sized renal stones 10-20mm, the overall SFR was 66.4 %. The results were similar in different stone locations. But, SFRs were higher (70.4 %) with stone size <15mm compared to only 53.1% in stone size 15–20 mm *(Chung and Turney, 2016)*. In spite of achieving high SFRs with PCNL, it is also associated with increased risk of bleeding and blood transfusion *(Yamaguchi et al, 2011).*,

As regard Hb drop, similar results were reported in a study comparing RIRS with mini-PCNL in multiple renal stones 10-30mm, the Hb drop was high in mini-PCNL group and was 1gm/dL *(Yanaral et al., 2019)*. But, this Hb drop is lower than that in standard PCNL. In a study comparing standard and mini-PCNL, the overall SFRs were high in both groups, 97.1% and 95.4%. The Hb drop was significantly lower in mini-PCNL group The mean Hb drop and the bleeding necessitating blood transfusion were 0.6 vs 1.9 gm and 1.2 vs 9.8 % in mini-PCNL and standard PCNL groups, respectively *(Sakr et al., 2017)*.

Also, in a study comparing mini-PCNL and standard PCNL, the mean operation time in mini-PCNL was 83minutes, and mean fluoroscopy time was 4.3 minutes *(Sakr et al, 2017)*. The postoperative hospitalization time was significantly higher in the mini-PCNL group But, unscheduled hospital readmission was reported only in ESWL group in about 15% Similarly, in a study comparing ESWL, RIRS, and PCNL in treatment of medium sized renal stones, postoperative hospitalization was significant in PCNL group *(Wiesenthal et al., 2011)*.

CONCLUSION

Mini-PCNL is superior to ESWL in treatment of non-lower pole medium sized renal stones of high density with high SFR, and low complication rate as need for re-hospitalization or need for auxiliary procedure.

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مقارنة إستخراج الحصوات بمنظار الكلى الصغير عن طريق الجلد وتفتيت الحصوات بالموجات الصدمية من خارج الجسم فى علاج حصوات الكلى فى غير الكأس السفلى وذات الكثافة العالية وحجم من 10 الى 20 مم
(دراسة مستقبلية عشوائية)

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خلفية البحث: يختلف علاج حصوات الكلى متوسطة الحجم من شخص إلي آخر طبقا لعوامل مختلفة. وتعتبر كثافة الحصوة من هذه العوامل التى تؤثر على معدل الخلو من الحصوات بعد تفتيت الحصوات بالموجات الصدمية خارج الجسم وذات تأثير بسيط علي إستخراج الحصوات بمنظار الكلى الصغير.

الهدف من البحث: مقارنة معدل خلو المرضى من الحصوات و الطريقة الآمنه لذلك بين إستخراج الحصوات بمنظار الكلى الصغير وتفتيت الحصوات بالموجات الصدمية وذلك فى الحصوات ذات الكثافة العالية ومتوسطة الحجم.

المرضى وطرق البحث: تمت هذه الدراسة المستقبليه العشوائيه بمستشفى سيد جلال (مستشفى جامعة الأزهر) حيث تم تجميع 70 مريض ممن يعانون حصوة بغير الكأس السفلى للكلى وتم تقسيمهم الى مجموعتين متساويتين بطريقه عشوائيه المجموعة (أ) تم علاجهم بمنظار الكلى الصغير والمجموعة (ب) تم علاجهم بتفتيت الحصوات بالموجات الصدمية.

نتائج البحث: كان وقت التدخل أقل بشكل ملحوظ في المجموعة (أ) (الوسيط: 50.00؛ معدل الذكاء: 20.00) مقارنة بمجموعة (ب) (الوسيط: 55.00؛ معدل الذكاء: 28.00). في مجموعة (أ)، تم شفاء 32 من أصل 34 (94.1٪) من المرضى أصبحوا خاليين من الحصوات. وفي مجموعة (ب)، تم شفاء 10 من 33 (30.1٪) وأصبحوا خاليين من الحصوات بعد جلسة التفتيت الثالثة. وكان معدل

الخلو من الحصوات أعلى وذات دلالة إحصائية كبيرة في مجموعة (أ)، كما لم تكن أي من الحالات بحاجة إلى تدخل مرة أخرى. وتحتوي الحالتان الفاشلتان على شظايا متبقية كبيرة هاجرت إلى كأس غير مستهدف أثناء تفتيت الحصوات بالهواء المضغوط. وفي مجموعة (أ)، كان لجميع الحالات مستوى هيموجلوبين طبيعي في كل زيارة متابعة وعند مقارنة الهيموجلوبين قبل وبعد الجراحة، لوحظ فروق ذات دلالة إحصائية كبيرة بين مستوى الهيموجلوبين قبل وبعد الجراحة.

الاستنتاج : إستخراج حصوات الكلى متوسطه الحجم وذات الكثافة العالية وموجودة فى غير الكأس السفلى للكلى بمنظار الكلى الصغير كان بمعدل خلو أعلى من الحصوات ومعدل مضاعفات أقل من إستخدام الموجات الصدمية خارج الجسم.

الكلمات الدالة: إستخراج حصوات الكلى بمنظار الكلى الصغير، تفتيت الحصوات بالموجات الصدمية خارج الجسم,كثافة الحصوه، معدل الخلو من الحصوات، غير الكأس السفلى، حصوات الكلى.