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ORIGINAL ARTICLE

Percutaneous nephrolithotomy versus extracorporeal shock wave lithotripsy for renal insufficiency

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Abstract
Objective To assess the effect and outcome of percutaneous nephrolithotomy (PNL) versus extracorporeal shock wave lithotripsy (SWL) in patients with renal insufficiency.
Patients and methods A prospective randomized clinical study of 104 renal insufficiency patients with renal stones (serum creatinine 2–4 mg/dl and eGFR < 60 ml/min/1.73 m^2 more than 3 months) randomized into two groups: Group A underwent PNL; Group B underwent shock wave lithotripsy (SWL). Treatment effects and outcomes compared between the two groups.
Results Between Group A of 50 patients and Group B of 54 cases, demographic data showed no statistically significant differences. The stone-free rate was 84% in Group A versus 26.6% in Group B after the first SWL session. After completion of all SWL sessions, the rate was 88.9% for Group B. Comparing pre and postoperative results of Group A, there is significant improvement of serum creatinine concentrations by 9.1% ($p = 0.001$), significant improvement of creatinine clearance ($p = 0.000$) and eGFR ($p = 0.003$). Although regarding Group B preoperatively and 3 months after SWL there is significant improvement by 8.7% ($p = 0.0001$), which is less than that of Group A, there is also, improvement of eGFR by 6.7% ($p = 0.001$), which is less than the eGFR improvement in Group A (12.3%). But there is no statistically significant difference is noted for creatinine clearance in Group B ($p = 0.09$).
Conclusion The outcomes for PNL and SWL in patients with renal insufficiency and renal stones are encouraging as minimally invasive procedures with no negative effects on kidney function.

Keywords Renal insufficiency · PNL · SWL

Introduction

Urolithiasis is thought to be an antecedent to renal impairment. Moreover, if urolithiasis is untreated or incorrectly treated, the obstruction and infection may lead to renal failure [1]. Considered to be a major health issue, the incidence of nephrolithiasis in patients with renal insufficiency estimated to be 17.5% [2, 3].

During surgical management of stones, patients are not only exposed to the risks of anesthesia, but also have a greater risk of postoperative complications [2].

For successful surgical intervention, in addition to retrieving the stone and achieving a good clearance rate, it is important for clinicians to be aware of the need to preserve maximum kidney function [4]. Management of renal stones in patients with renal insufficiency is considered to be a difficult challenge for urologists as well as nephrologists, and multiple modalities may be used, such as shock

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wave lithotripsy (SWL), percutaneous nephrolithotomy (PNL), retrograde intrarenal surgery (RIRS), laparoscopic and robotic approaches, and even open surgery [4, 5].

The effects of SWL and PNL on patients with normal functioning kidneys have been widely studied, whereas the outcomes of these procedures in populations with established renal insufficiency are still being investigated [2]. Chandhoke et al. compared the long-term effects of extracorporeal SWL and PNL monotherapy on renal function with chronic renal insufficiency that show change of 20% or greater in the glomerular filtration rate was considered a clinically significant deterioration of renal function [6].

Methods and patients

This prospective, randomized, clinical study evaluated adult renal insufficiency patients (serum creatinine 2–4 mg/dl and eGFR < 60 ml/min/1.73 m^2 for more than 3 months) with renal stones (1–3 cm) who presented to the authors' clinic from January 2017 to June 2019. Exclusion criteria were as follows: chronic renal dialysis, urologic congenital anomalies, uncorrected bleeding disorders, and unfitness for general anesthesia. Eligible patients were randomized at the clinic using the closed-envelope method into two groups: Group A underwent PNL (50 patients); Group B underwent SWL (54 patients). All patients underwent preoperative laboratory investigations as follows: complete blood count, serum creatinine, estimated glomerular filtration rate (eGFR), and creatinine clearance; imaging studies were abdominopelvic ultrasound; kidney, ureter, and bladder (KUB) assessment; and computed tomography without contrast. The study protocol was approved by the faculty ethical committee. Informed consent regarding the procedures and possible complications was obtained from all patients.

Statistical analysis

Categorical variables were recorded as frequencies, and continuous variables were recorded as the means with standard deviation. Differences between groups were assessed using the t test for continuous variables. The chi-square test was used to assess categorical variables, and $p \leq 0.05$ was considered statistically significant. All statistical analyses were performed using the statistical software SPSS, version 25 (IBM, Armonk, NY, USA). The number of study participants recruited was based on a type 1 statistical error < 5%, a type 2 statistical error < 20%, a possible drop-out rate of 10% and previous reports [7–9]. Figure 1 shows the flow of patient selection throughout the study.

Group A technique

Group A patients underwent PNL. After general anesthesia was initiated, a ureteric catheter (6 Fr) was placed with the patient in the lithotomy position on the ipsilateral side. Then the patient was repositioned into the prone position, and saline-diluted dye was injected into the ureteric catheter to opacify the pelvicalyceal system. The desired calyx was targeted and punctured with a needle under both fluoroscopic and ultrasonic guidance; then a J-tipped guide wire was inserted through it. Gradual dilatation was then performed using Alken dilators, then an Amplatz sheath was placed in position. Using a 24-Fr nephroscope, stone disintegration was achieved with an ultrasonic lithotriptor and the stone fragments extracted by a grasper. In some cases, with stones in the narrow neck of the calyx or far calyx, flexible cystoscopy was used to reach the stone and extract it with a no-tip dormie after laser disintegration if needed which enable us to using one track puncture for all cases.

At the end of procedure, the pelvicalyceal system inspected for residual stone fragments or clots. Saline-diluted dye was injected to assess any injury or extravasation of pelvicalyceal system. Some cases required JJ stent insertion at the end of procedure, which was inserted antegrade through an Amplatz sheath. Next, in all patients, a 20-Fr nephrostomy tube was inserted through the Amplatz sheath as tamponade. The nephrostomy tube was removed at 24 h postoperatively and both the ureteral and urethral catheters were removed at 5 days postoperatively.

Group B technique

Group B patients underwent SWL. Preoperatively, they received intravenous fluids with furosemide (10 mg) and nalbuphine hydrochloride (10–20 mg) as a potent analgesic. For the procedure, a fully integrated lithotripter with an electromagnetic shockwave source was used, the Dornier Gemini lithotripter with fluoroscopic and ultrasonic guidance. The stones were localized by ultrasound for radiolucent stones and fluoroscope for radiopaque stones.

The SWL session was started slowly to achieve the best result without exceeding the energy level of 100 J. The initial setting for SWL was E1, the lowest energy level at 16.0 mJ, which was then increased gradually until reaching energy level E7 at 55 mJ. The stepwise increase for the shocks typically began at energy level E1 for the first 250 shocks, and then increased to the next energy level for the next 250 shocks, and finally increased to reach energy level E7. The shock waves were delivered at rate of 70–80 shocks/minute. The number of shock waves

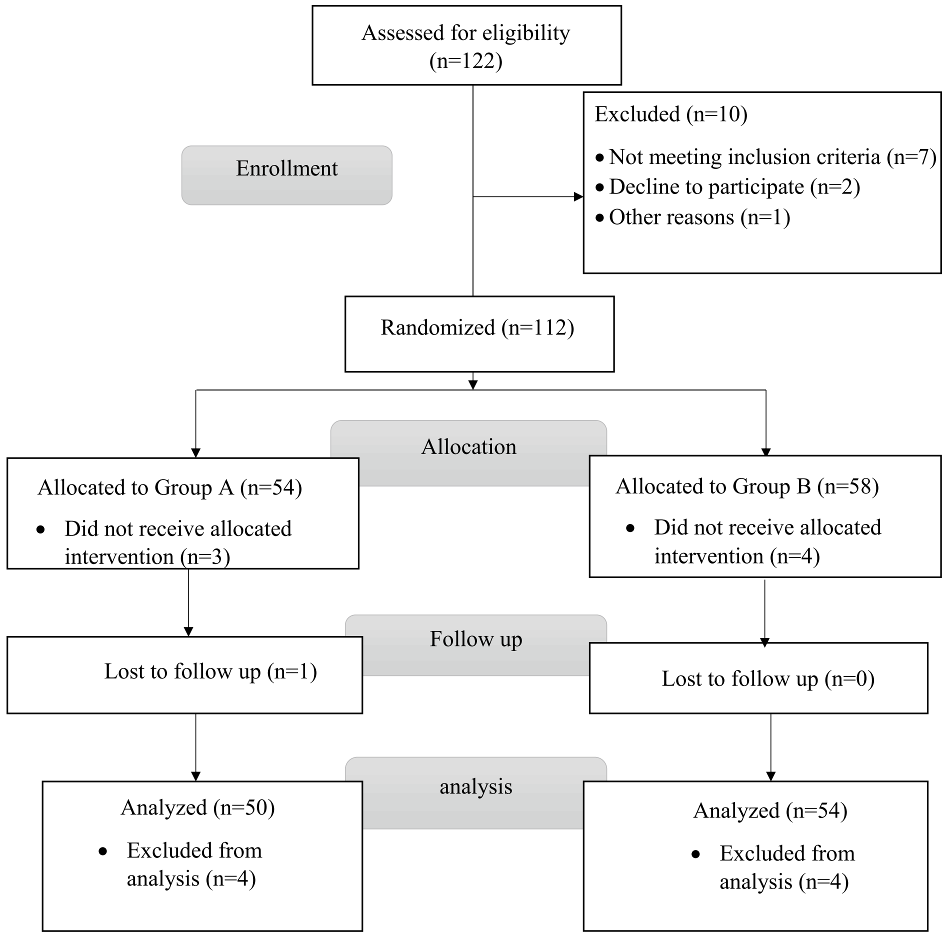


Fig. 1 Consort chart shows flow of patient throughout the study

Table 1 Patient's demographics

	Group A	Group B	*p* value
Number	50	54	
Age (years) mean/SD	53.96 (±6.6)	59.04 (±6.7)	0.08
Male:female	34:16	30:24	0.623
BMI (kg/m^2) mean/SD	27.8 (±5.31)	26.9 (±5.43)	0.089

was modified until adequate fragmentation was achieved, reaching either a maximum number of 3000 shocks per session or shock waves of 100-J energy. Postoperatively, all patients were followed for serum creatinine concentrations at 1 week, 2 weeks, 1 month, and 3 months. Creatinine clearance and eGFR were assessed at 1 month and 3 months postoperatively. Ultrasound and KUB assessment were performed at 2 weeks postoperatively. Computed tomography was performed after 3 months for assessment of the stone-free rate.

Results

The patient demographic characteristics are shown in Table 1. The mean age of both groups was comparable: 53.96 ± 6.6 years in Group A (PNL) and 59.04 ± 6.7 years in Group B (SWL. No statistically significant difference in sex distribution was noted between the two groups ($p = 0.623$). In addition, no statistically significant difference in body mass index was noted between the two groups ($p = 0.09$). Stone sizes and stone sites were comparable between the two groups, and Table 2 shows no statistically significant difference in stone size ($p = 0.4$).

Table 2 also compares the stone-free rate (SFR) for Group A (92%) and with the SFR after the first session in Group B (26.6%), considering a significant residual stone size > 3 mm, for which Group A cleared of most of the stones in a single session. Also compared were the SFR in Group A (92%) with the SFR in Group B after completion of all sessions (88.9%), which in some cases required two or even three sessions.

Table 3 shows the laboratory data for Group A preoperatively and 3 months after PNL. A statistically significant difference is noted for pre- and postoperative serum creatinine

Table 2 Stone characters and stone-free rate

	Group A	Group B		p value
Stone size (mm)	23.1 mm ± 5.8	22 mm ± 5.1		0.4
Stone site				
U. calyx	0 (0%)	2 (3.7%)		0.2
M. calyx	2 (4%)	6 (11.2%)		
L. calyx	26 (52%)	22 (40.7%)		
Pelvis	22 (44%)	24 (44.4%)		
Previous surgery				
Yes	14 (28%)	14 (25.9%)		
No	36 (72%)	40 (74.1%)		
Stone-free rate	46 (92%)	After one session	After all sessions	
		16 (26.6%)	48 (88.9%)	

Compares the stone-free rate (SFR) for Group A with the SFR in Group B after the first session and after completion of all sessions of SWL

Table 3 Laboratory data preoperative and 3 months postoperative

	Group A	p value	Group B	p value
Serum creatinine				
Pre	2.2 ± 0.3	0.001*	2.3 ± 0.3	0.000*
3 months post	2 ± 0.3		2.1 ± 0.3	
Creatinine clearance				
Pre	46.5 ± 11.6	0.000*	48.6 ± 13.8	0.09
3 months post	55 ± 11		47.7 ± 12.7	
eGFR				
Pre	47 ± 10.3	0.003*	41.8 ± 8.7	0.001*
3 months post	52.8 ± 14.6		44.6 ± 8.7	
HB				
Pre	12.6 ± 1.2	0.000*	12.1 ± 1	0.6
1 week	12 ± 1		12 ± 0.9	

*indicate that significant p value

Table 4 Means of renal function parameters improvement difference pre and 3 months postoperatively

	Group A	Group B	p value
S. creatinine	0.216	0.1437037	0.14
Creatinine clearance	8.94	0.66667	0.015
eGFR	5.996	2.679444444	0.1

concentrations ($p = 0.001$) with improvement by 9.1%. Also shown is a significant difference and improvement of creatinine clearance ($p = 0.000$) and eGFR ($p = 0.003$). Also shows the laboratory data for Group B preoperatively and 3 months after SWL. A statistically significant difference is noted for pre- and postoperative serum creatinine concentrations ($p = 0.0001$) with improvement by 8.7%, which is less than that of Group A. Also shown is a significant difference and improvement of eGFR ($p = 0.001$) of 6.7%, which is less than the eGFR improvement in Group A (12.3%). No statistically significant difference is noted for creatinine clearance in Group B ($p = 0.09$).

Table 4 shows that relative difference of renal function improvement pre and 3 months postoperatively between both groups in favor of group A regarding creatinine clearance ($p = 0.015$), but this improvement is not statistically significant between groups regarding eGFR and serum creatinine.

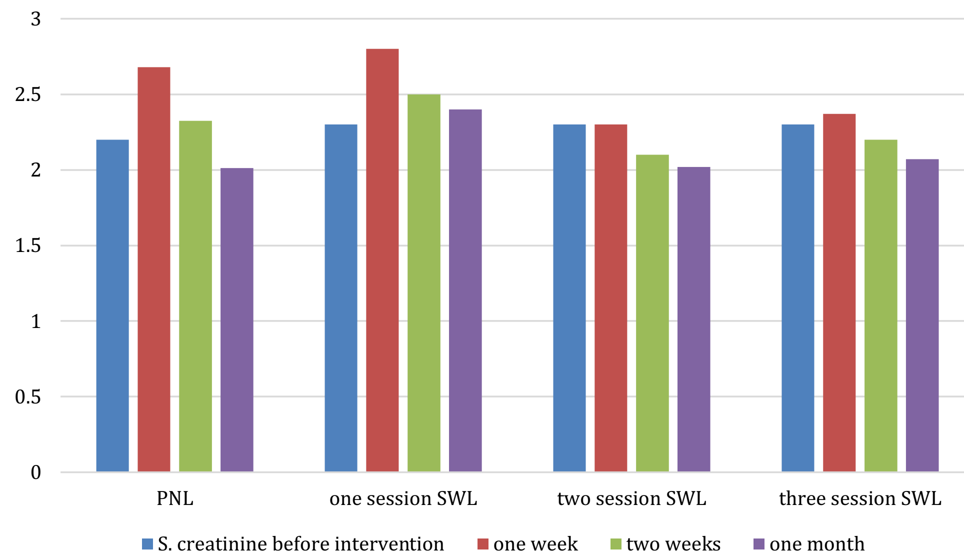
Figure 2 shows chart of serum creatinine changes at 1 week, 2 weeks and 1 month after PNL and SWL sessions, And the follow-up creatinine concentrations for both groups after either PNL (Group A) and after each session of SWL (Group B).

A statistically significant reduction in hemoglobin (HB) concentration was noted 1 week postoperatively in Group A ($p = 0.0001$) as shown in Table 3. The rate of postoperative complications was 12 cases in Group A and 13 cases in Group B. In each group, 2 cases had fever treated with an antipyretic (paracetamol 500 mg/8 h for 1 day), and an antibiotic (ceftriaxone, 1 g) (Clavien II). In Group A, bleeding from the PNL tract occurred in five patients; three patients were managed conservatively (Clavien I), and two patients received 1 unit of blood transfusion which was anesthetist recommendation as their preoperative Hb level was 9.7 and 9.5 gm/dl and postoperatively 8.8 gm/dl and 8.7 gm/dl, respectively (Clavien II).

In Group B, two patients had hematuria (Clavien I), which was successfully treated with intravenous fluids and a hemostatic agent.

Other complications were as follows. In Group A, one patient had leakage from tract site that stopped spontaneously with frequent dressing (Clavien I). In Group B, three patients had with obstruction after SWL, for which subsequent KUB revealed ureteric stones had passed with medical treatment (Tamsulosin 0.4 mg once daily) (Clavien I). Finally, residual stones were noted for four patients in Group A and six in Group B.

Fig. 2 Mean serum creatinine change after 1 week, 2 week and 1 month in all groups' cases



Discussion

Renal insufficiency is a progressive condition in which kidney function deteriorates and may lead to end-stage renal disease that ultimately requires dialysis [3]. The presence of stones increases the risk of deterioration of kidney function because of obstruction and infection of the renal parenchyma [10]. The duration of the stones and their effects, the manipulations and multiple procedures to remove the stones, and stone recurrence increase the negative influence on renal function [3]. Therefore, renal function of patients with renal insufficiency is improved by stone clearance and thereby worse effects on kidney function are avoided and postpone the need for dialysis [11].

Therefore, the use of less-invasive techniques such as PNL and SWL in the treatment of patients with renal stones, especially patients with renal insufficiency, has less effect on kidney function than more invasive procedures such as pyelolithotomy and nephrolithotomy [12]. Many centers studied the effects of PNL and SWL on kidney function using many tests as blood and urine markers [1, 13]. The effect of SWL is thought to be dependent on the type of lithotripter used, the total energy and the number of shock waves delivered, and the focal size of the shock waves. The outcomes of SWL also can be complicated by hematoma formation, hematuria, and residual stones [6].

The success of PNL depends on the number of punctures, the type of lithotripter, the site and size of stones. The PNL procedure can cause parenchymal damage with the hazards of radiation exposure with fluoroscopy, as well as the risk of bleeding, calyceal or infundibular tear, and persistent urine leak [2, 7]. In this study, 104 patients with renal insufficiency and renal stones presented to the clinic and randomized into two groups: Group A of 50 patients who underwent PNL and Group B of 54 patients who underwent SWL. The overall SFR with PNL for Group A was 92% versus 88.9% with SWL in Group B; however, but the SFR with PNL for Group A compared with SWL for Group B after the first session was about 26.6%; therefore, these results favor PNL as monotherapy for achieve a successful SFR with no need for retreatment.

On follow-up assessment for serum creatinine concentrations, creatinine clearance, and eGFR for at least 3 months, the results of PNL and SWL on serum creatinine concentrations and eGFR showed significant improvement, whereas creatinine clearance showed a slight deterioration with SWL, which may be due to the exposure to shocks that affect the renal parenchyma. In addition, poor drainage after SWL, no presence of a ureteric stent to help drainage, and the incidence of infection affect the results of SWL. Moreover, the relative improvement difference shows statistically significant difference between groups regard creatinine clearance which may be due to the slight deterioration of creatinine clearance with SWL and that the creatinine clearance exceeds eGFR due to tubular creatinine secretion. Chandhoke et al. supported the conclusion that SWL is as safe as PNL in the treatment of renal insufficiency for patients with renal stones [6].

The use of SWL is an appropriate and noninvasive intervention in patients with renal stones; its short-term effects on kidney function are known; and it is accepted that SWL is safe in the long-term for kidney function [5, 6]. Kulb et al. found no significant change in serum creatinine 3 months after SWL [14, 15]. Zanetti et al. reported no change in serum creatinine in long-term follow-up (24–56 months) after SWL [16].

The choice of PNL is appropriate as one of the most effective procedure in patients with renal stones and achieves a good SFR. Deem et al. randomized 32 patients to PNL and SWL and followed up at 3 months with KUB and non-contrast computerized tomography showing and SFR for PNL superior to SWL (85% vs. 33%, respectively [5, 17]. Ozden et al. reviewed 67 patients who underwent PNL showing improvement of eGFR from baseline (37.9 ± 14.05) to post-operative status (45.1 ± 16.8) the mean follow-up time was 45.7 ± 17.08 months [5, 18]. Complications recorded in this study were mild, ranging from fever, hematuria, leakage, and, in some cases, residual stones.

Limitations of study

Further studies are needed with a greater number of patients with renal insufficiency and renal stones to provide a better groundwork for the statistical results. Longer follow-up periods for renal function are also needed for an improved assessment of long-term outcomes.

Conclusions

Both PNL and SWL may be safely used in patients of renal insufficiency and renal stones as minimally invasive procedures with no negative effects on kidney function. The results of both procedures show a high SFR and minimal or even no effect on kidney function on follow-up.

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Author contributions MA: Project development, data collection, manuscript writing, and revision; AA: data collection and data analysis; MSAK: data collection; AMH: data analysis; AMHa: data collection; GA: data analysis and revision.

Declarations

Informed consent Informed consent was submitted for each patient. The procedures that followed were approved by the Institutional Ethical Committee Clearance of the Faculty of Medicine South Valley University No: P.R.R/03/00111. The study was registered on University Research Affairs as prospective randomized study and the registration number was SVU.MED0193111.

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