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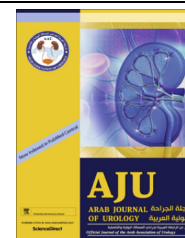
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Percutaneous nephrolithotomy vs. extracorporeal shockwave lithotripsy for treating a 20–30 mm single renal pelvic stone



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Single renal stone;
Cost

ABBREVIATIONS

PNL, Percutaneous nephrolithotomy;
BMI, Body mass index;
RIRS, Retrograde intrarenal surgery;
SFR, Stone-free rate

Abstract Objective: To compare the efficacy, safety and cost of extracorporeal shockwave lithotripsy (ESWL) and percutaneous nephrolithotomy (PNL) for treating a 20–30 mm single renal pelvic stone.

Patients and methods: The computerised records of patients who underwent PNL or ESWL for a 20–30 mm single renal pelvic stone between January 2006 and December 2012 were reviewed retrospectively. Patients aged < 18 years who had a branched stone, advanced hydronephrosis, a solitary kidney, anatomical renal abnormality, or had a surgical intervention within the past 6 months were excluded. The study included 337 patients with a mean (SD, range) age of 49.3 (12.2, 20–81) years. The patients' criteria (age, sex, body mass index) and the stone characteristics (side, stone length, surface area, attenuation value and skin-to-stone distance) were compared between the groups. The re-treatment rate, the need for secondary procedures, success rate, complications and the total costs were calculated and compared.

Results: In all, 167 patients were treated by ESWL and 170 by PNL. The re-treatment rate (75% vs. 5%), the need for secondary procedures (25% vs. 4.7%) and total number of procedures (three vs. one) were significantly higher in

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the ESWL group ($P < 0.001$). The success rate was significantly higher in the PNL group (95% vs. 75%, $P < 0.001$), as was the complication rate (13% vs. 6.6%, $P = 0.050$). The total costs of primary and secondary procedures were significantly higher for PNL (US\$ 1120 vs. 490; $P < 0.001$).

Conclusions: PNL was more effective than ESWL for treating a single renal pelvic stone of 20–30 mm. However, ESWL was associated with fewer complications and a lower cost.

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Introduction

Currently, minimally invasive treatments such as ESWL, percutaneous nephrolithotomy (PNL) and retrograde intrarenal surgery (RIRS) are the preferred treatments for renal stones. The choice of treatment depends on many patient, renal and stone factors. Stone size is the most important of these, because it strongly influences the stone-free rate (SFR), the need for secondary procedures, and the complication rate [1].

The European Association of Urology Guideline on Urolithiasis (updated April 2014) recommended PNL as the primary treatment for renal stones of > 20 mm, whilst ESWL was preferred as a second line of treatment, because ESWL often requires multiple treatments, and has the risk of ureteric obstruction, with the need for auxiliary procedures [2]. However, ESWL was considered by some authors as a reasonably successful treatment for renal stones of intermediate size [3] and for renal stones of 20–30 mm [4] in patients who prefer ESWL, provided that they accept potentially more treatments. For RIRS, the high SFR and low morbidity reported in high-volume centres with clinicians experienced in treating renal stones of > 20 mm, might not be sufficient to change routine practice [5]. Therefore, RIRS is not recommended as first-line treatment for stones of > 20 mm.

In the present study we compared the efficacy, safety and cost of ESWL and PNL for treating a single renal pelvic stone with a largest diameter of 20–30 mm.

Patients and methods

The computer-archived records and images of patients who were treated by PNL or ESWL for a 20–30 mm single renal pelvic stone between January 2006 and December 2012 were reviewed retrospectively. Patients aged < 18 years, or who had a branched stone, advanced hydronephrosis, solitary kidney, anatomical renal abnormality (such as a horseshoe, polycystic or ectopic kidney), or those who had undergone surgery for this stone within the past 6 months, were excluded. The preoperative evaluation for all patients included routine laboratory tests, i.e., urine analysis, serum

creatinine, liver function tests, a complete blood count and coagulation profile. Urine culture was requested for patients with pyuria and those with ureteric stents. Radiological investigations included a plain X-ray of the abdomen and pelvis, and unenhanced CT. The study included 337 patients, with a mean (SD, range) age of 49.3 (12.2, 20–81) years.

Procedures

In patients treated by PNL, a renal puncture was made with the patient prone, using multidirectional C-arm fluoroscopic guidance (BV Pulsera, Philips Medical Systems, Eindhoven, Netherlands). The tract was dilated using Alken's coaxial dilators (Karl Storz Endoskope, Tuttlingen, Germany) to 30 F. A 26 F rigid nephroscope (Karl Storz Endoskope) was used through an Amplatz sheath (Boston Scientific Corp., Natick, MA, USA). The stone was disintegrated with ultrasonic or pneumatic lithotripters, and fragments were removed using forceps. A 22 F nephrostomy tube was placed at the end of the procedure and left for 24–48 h.

In the ESWL group, the electromagnetic Dornier lithotripter S (Dornier MedTech GmbH, Germering, Germany) was used. Shockwaves were delivered at a rate of 80 shocks/min to a maximum of 3000 shocks per session. Stone disintegration was evaluated with a plain film and ultrasonography at 1 week after each session.

Evaluation

The patients' criteria (age, sex, body mass index, BMI) and the stone characteristics (side, length and width of the stone, stone surface area, stone radio-opacity, attenuation value and skin-to-stone distance) were compared between the treatment groups. The re-treatment rate, the need for secondary procedures and the costs of primary, auxiliary and secondary procedures were also calculated and compared.

Complications were defined and graded according to the modified Dindo-Clavien classification [6]. The stone-free status was evaluated at 3 months after PNL or the last ESWL session by non-contrast CT. 'Success' included patients who became stone-free or had insignificant residual (≤ 4 mm) fragments. Secondary procedures

were interventions used to treat significant residual fragments or failure of the primary treatment. Auxiliary procedures were interventions used to treat complications, e.g., ureteroscopy or JJ ureteric stents.

Cost calculation

The cost of PNL for each patient was US\$ 1,143 and for ESWL was US\$ 357 for the first session and \$70 for subsequent sessions. The cost of ureteroscopy was US\$ 570 and of JJ ureteric stenting was US\$ 285. If the patient required secondary or auxiliary procedures, the costs of these were added to the cost of the primary procedure to calculate the total cost per patient.

Continuous variables were compared using an independent sample *t*-test or Mann–Whitney test, and the chi-squared test was used for categorical variables. In all test, $P \leq 0.05$ was considered to indicate statistical significance.

Results

In all, 167 patients were treated by ESWL and 170 by PNL; **Table 1** summarises the comparison of patient demographics and stone characteristics in the treatment groups. Male patients were more frequently treated by ESWL ($P = 0.002$) whilst stone length and surface area were significantly larger in the PNL group ($P < 0.001$).

Table 1 also shows the efficacy, safety and the total costs in both groups. The re-treatment rate, need for secondary procedures and total number of procedures were significantly higher in the ESWL group ($P < 0.001$). The success rate was significantly higher in the PNL group ($P < 0.001$). There were significant residual fragments in eight patients (4.7%) after PNL, and these were treated with ESWL. In the ESWL group, 42 patients (25%) required secondary procedures in the form of PNL in 35 (21%) and flexible ureteroscopy in seven (4%). The total number of procedures was significantly higher in ESWL group (three vs. one, $P < 0.001$).

The incidence of complications was significantly higher in the PNL group ($P = 0.050$). There were complications after ESWL in 11 patients, in the form of steinstrasse that were treated with semi-rigid ureteroscopy in seven patients, and medical treatment (analgesics and α -blockers) in four. Complications in the PNL group included intraoperative bleeding, leading to termination of the procedure due to poor visibility by the surgeon, or the development of hypotension in six patients (3.5%), and postoperative haematuria in five (2.9%). They were managed with clamping of the nephrostomy tube and conservative measures. A blood transfusion was required in six patients (3.5%) but no patient needed renal angiography or embolisation. A second PNL under spinal anaesthesia was used for patients who developed intraoperative bleeding after

Table 1 The baseline comparison of patients and stone characteristics, and of efficacy, safety and costs, between the treatment groups.

Mean (SD) or <i>n</i> (%) variable	ESWL	PNL	<i>P</i>
N patients	167	170	
Age (years)	47.7 (11.7)	50.9 (12.4)	0.018
BMI (kg/m ²)	31.6 (4.6)	31.9 (7.4)	0.589
Gender			
Male	107 (64)	80 (47)	0.002
Female	60 (36)	90 (53)	
Stone characteristics			
Right	77 (46)	84 (49.4)	0.449
Left	90 (54)	86 (50.6)	
Largest diameter (mm)	23.5 (2.7)	25.1 (3.0)	<0.001
Stone surface area (mm ²)	295 (100)	383 (136)	<0.001
Opacity			
Radio-opaque	135 (80.8)	142 (83.5)	0.518
Radiolucent	32 (19.2)	28 (16.5)	
SSD (cm)	9.9 (1.9)	10.6 (2.5)	0.011
Attenuation value (HU)	826 (353)	740 (359)	0.122
Efficacy			
Success rate	115 (75)	162 (95.3)	<0.001
Re-treatment rate	126 (75.4)	9 (5.3)	<0.001
Secondary procedure	42 (25)	8 (4.7)	<0.001
Safety			
Complications			
Overall	11 (6.6)	22 (12.9)	0.050
Clavien grade			
I	0	7 (4.1)	<0.001
II	4 (2.4)	6 (3.5)	
IIIa	7 (4.2)	9 (5.3)	
Total cost (US\$)			
Median	490	1120	<0.001
Range	(350–1820)	(1118–1750)	

HU, Hounsfield units.
SSD, skin-to-stone distance.

stabilisation of their condition. There was urinary leakage through the nephrostomy tract in 11 patients (6.5%) and this was managed with a JJ ureteric stent in nine (Grade III). Grade I complications in the PNL group included five patients who developed bleeding that did not require a blood transfusion, and two who developed a temporary urinary leakage after removal of the nephrostomy tube, but that did not require ureteric stenting.

The mean (SD) hospital stay for PNL was 4.6 (1.7) days. The mean total cost was significantly higher for PNL ($P < 0.001$; **Table 1**).

Discussion

The optimum treatment for a patient with a 20–30 mm single renal stone should provide the maximum SFR with the fewest procedures and the lowest incidence of complications. In the present study, PNL provided a

better SFR than ESWL (95% vs. 75%) with less need for re-treatment (5% vs. 75%) and fewer procedures (one vs. three). These are the main reasons for recommending that PNL is the first line for treating such patients [2]. The SFR after ESWL is affected by many factors, including stone size, attenuation value and BMI [7]. However, the SFR after PNL is not affected by these factors, as the intracorporeal lithotripsy devices can disintegrate any type of renal stone of any size, and regardless of the patient's BMI [8,9]. This was obvious in the present study, as the mean stone surface area in the PNL group was significantly larger than in the ESWL group, but the SFR was higher in the PNL group. Other prognostic factors for the SFR after ESWL, such as stone location, multiplicity and renal anomalies, were not assessed in the present study.

Nonetheless, ESWL is still preferred by many authors as a viable treatment option for renal pelvic stones of intermediate size, because it is a noninvasive outpatient procedure that is easily performed with no anaesthesia [3,4]. Turney et al. [10] reported that use of ESWL for renal stones has increased by 69% in the last decade. In the present study, ESWL was safer than PNL, with a complication rate of 6.6% vs. 12.9%, which is why many patients prefer ESWL for treating their renal stones.

The other advantage of ESWL in the present study was the lower cost than for PNL. This is very important for healthcare authorities, because of the increasing number of patients with renal calculi and its effect on the total healthcare budget. The costs of PNL were higher than for ESWL because of inpatient hospitalisation and the higher costs of disposables for PNL. However, the need for multiple sessions to render patients stone-free in those treated by ESWL might make PNL equally cost-effective [11,12]. In the present study and despite the greater need for re-treatment and secondary procedures, ESWL was still more cost-effective than PNL. This might be attributed to differences in treatment costs among different countries. The lower costs in our patients than in the USA and Europe were related to the economic status of the country, because of the lower cost of instruments, consumables and personnel salaries. We calculated the cost in Egyptian pounds, and then converted the total number to US\$, because this is a standard currency that can be related to different currencies world-wide.

Research in ESWL is focused on improving the SFR. The first approach is to select patients who are more likely to become stone-free with ESWL. This can be done using multivariate analysis models [4] or clinical nomograms [13]. The second approach is by applying treatment strategies during the ESWL session that improve stone disintegration and reduce the complication rate, e.g., a slow shock-wave rate (60/min) [14] and power ramping [15,16].

However, research in PNL is concerned with decreasing the complication rate and shortening the hospital stay. This can be done by using smaller percutaneous tracts, such as minimally invasive PNL [17] and micro-PNL [18], and avoiding placing a nephrostomy tube after PNL (tubeless PNL) [19]. Another development in the treatment of renal stones of >20 mm is to use flexible uretero-rensoscopy and intracorporeal disintegration with a holmium laser [5]. This is a promising minimally invasive technique that requires more research before confirming its superior efficacy over ESWL and a lower complication rate than PNL. In the present study the hospital stay was prolonged for >2 days in patients who developed complications after PNL, such as haematuria and urinary leakage.

This study was limited by its retrospective design. Therefore, some variables were not comparable between treatment groups, e.g., the stone surface area and skin-to-stone distance were greater in the PNL group (Table 1). However, we attempted to make a fair comparison by excluding patients with multiple and calyceal stones, and those with congenital renal anomalies, because of their negative effect on the SFR after ESWL.

In conclusion, for treating a single renal pelvic stone of 20–30 mm, PNL was more effective than ESWL, but ESWL was associated with fewer complications and a lower cost.

Conflict of interest

None.

Source of funding

None.

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