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ORIGINAL ARTICLE

Initial Experience and Outcome of Extracorporeal Shockwave Lithotripsy (ESWL) by Dornier Gemini EMSE 220-F XXP-HP in Hospital Sultanah Aminah, Johor Bahru Malaysia

William Ong Lay Keat [1], Shamsuddin Omar [1]

Corresponding Author Email: william_olk@hotmail.com

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ABSTRACT

BACKGROUND & OBJECTIVES:

Extracorporeal Shockwave lithotripsy (ESWL) was developed in early 1980's and proven to have excellent safety profile while achieving acceptable stone clearance. This study aims to assess the efficacy and safety of ESWL with Dornier Meditech lithotripter (Dornier Gemini EMSE 220F XXP-HP) in managing the patients with urolithiasis.

METHODOLOGY:

A total of 224 patients have undergone outpatient ESWL for renal and ureteral calculi from November 2016 till June 2018 in Hospital Sultanah Aminah Johor Bahru. The patients' demographic data, stone characteristics & locations, energy and total number of shockwaves were investigated along the stone-free rate and periprocedural complications.

RESULTS:

We analysed 217 patients who have underwent ESWL, excluding 7 defaulted follow-up patients. 169 (77.8%) had renal stones and 48 (22.1%) had ureteric stones. The mean age of the patients was 52.55 ±12.29 years with male: female= 1.46:1. The mean ± SD stone size

[1] Department of Urology, Hospital Sultanah Aminah, Johor Bahru, Malaysia

was 1.39 ±0.55 cm. Treatment success (defined as complete clearance of ureteric stones, stone-free or clinically insignificant residual fragments of <0.4 cm for renal stones) was 59.7% for renal stones and 58.3% for ureteric stones. 79 patients required additional sessions to archive stone clearance. Complications occurred in 11.1% patients with majority of them (n=8) suffered from loin or suprapubic pain. Using simple Logistic Regression analysis, the only pre-treatment factor found to have significant effect on stone-free rate was the stone size ($p<0.001$).

CONCLUSION:

Extracorporeal shockwave lithotripsy using Dornier Gemini EMSE 220F XXP-HP is a safe, non- invasive and relatively effective modality for treating the renal and ureteric calculi.

INTRODUCTION

Extracorporeal Shockwave lithotripsy (ESWL) was initially developed in the early 1980's and proven to have an excellent safety profile while achieving acceptable stone clearance [1]. European Association of Urology (EAU) has recommended ESWL as the preferred first-line treatment for all the kidney stones smaller than 10mm [2].

Years of experience utilizing ESWL for stone treatment has helped many urologists optimize its use and minimize its complications. Deciding an optimal treatment for a given patient depends very much on variables, for example, stone-related factors, renal anatomical and clinical factors [3]. Improvements in technique along with a more stringent selection on patients and stones have helped ESWL remain a mainstay in the treatment of stone diseases. The newer lithotripters have better improved quality of stone localization imaging with either fluoroscopy or with ultrasound. Moreover, the manufacturers have improved the functionality of ESWL machine and the patients' comfort by using coupling bellows.

Thus, in our centre, Dornier Gemini inevitably becomes one of the paramount important treatment assets for urolithiasis patients. We would like to study the outcome in terms of stone fragmentation and clearance, in addition to the incurred complications, which subsequently require ancillary management and extra health cost.

This study aims to assess the efficacy and safety of ESWL with Dornier Meditech lithotripter (Dornier Gemini EMSE 220F XXP-HP) in the management of the patients with renal and ureteral calculi.

MATERIALS & METHODS

A total of 224 patients have undergone outpatient treatment with ESWL for their renal or ureteral calculi from November 2016 till June 2018 in Hospital Sultanah Aminah Johor Bahru.

The patients' demographic data, targeted stone characteristics & locations, energy amount and the total number of shockwaves were investigated along with the stone-free rate and periprocedural complications. All treated patients were reviewed with post-procedural imaging either by ultrasonography or by computed tomogram.

Complete case-notes and imaging were evaluated, and follow-up of these patients in our out-patient urology clinic. Full blood count, urea and creatinine, electrolytes, serum uric acid, coagulation profile, urinalysis, urine culture and electrocardiogram were the standard routine investigations before the ESWL. Stone size is determined by the widest diameter for renal and ureteric stones. Stones are categorized according to stone size into ≤10, 11-15 and 16-20 mm diameter. Pre-treatment plain abdominal X-ray films of the kidney, ureter, and bladder (KUB), as well as ultrasonography or non-contrasted CTU are used for the initial diagnosis.

The patients who were taking Aspirin or other antiplatelets were requested to discontinue for 7 days before ESWL. All subjects did not have pre-procedural fasting. All patients were administered with the oral analgesia- tablet paracetamol 1gram with single-dose Indomentacin.

The patients' vital signs heart rate, blood pressure (BP) and Oxygen saturation (pulse-oxymetry) were monitored during the procedure. At the end of treatment, they were discharged on oral medications including either Diclofenac 50 mg tds or T. tramadol 50mg tds, T. paracetamol 1g QID and Ural 1 sachet OD for 2 weeks.

The patients were treated in the supine position with stone localization using the fluoroscopy or ultrasound. ESWL settings used were as follows: For the Kidney, Number of shockwaves=3000-3500, Energy level (max)=5-6, Starting: 100 shock waves with Level 1 with frequency SW/min=80. Energy levels start with E1 and gradually increase to a maximum of E5-6. The average and maximum energy levels, as well as the total energy delivered, are automatically shown at the end of each session. For the Ureter: Number of shockwaves = 3500-4500 Energy level (max)=4 (upper ureter), 6 (lower ureter) with Frequency SW/min Upper and middle ureter=90, Lower ureter=120. All treatments were administered on the outpatient basis for a maximum of three sessions.

The stones will be reassessed initially after 2 weeks using KUB and ultrasound to assess fragmentation. Repeat treatment would be applied immediately after follow-up if there was no or inadequate fragmentation of the stone. The number of shock waves, shock waves

intensity, shock-wave energy, stone-free rate, auxiliary procedure rate, re-treatment rate and complication rate were assessed.

Treatment success was defined as complete clearance of ureteric stones, while being stone-free or the presence of clinically insignificant residual fragments of <4 mm was considered as a success for the renal stones. The success rate was correlated with the stone size and site. Those patients with failed therapy were offered an alternative treatment.
Chi-Square test was used for statistical evaluation, with the level of significance set as $p<0.05$. Univariate and Multivariate Binary Logistic Regression analysis were used to determine factors affecting complete stone clearance.

RESULTS

We analysed 217 patients who have underwent extracorporeal shock wave lithotripsy in our centre, excluding 7 patients from this study due to default follow up. 169 patients (77.8%) had renal stones and 48 patients (22.1%) had ureteric stones. The majority of the stones were located at the renal pelvis (33.6%), followed by proximal ureter (19.4%), lower pole kidney (17.1%) and upper pole kidney (11.5%). The mean age of the patients was 52.55 ±12.29 years. There are 129 male patients and 88 female patients (male: female ratio= 1.46:1). The mean ± SD stone size was 1.39 ±0.55 cm. Mean shockwaves given was 2902.86 ± 299.63 and mean energy was 99.29 ± 18.76 kJ. (Table 1) Treatment success (defined as complete clearance of ureteric stones, stone-free or clinically insignificant residual fragments of <0.4 cm for renal stones) was 59.7% for renal stones and 58.3% for ureteric stones. 79 (61.2%) patients required the additional sessions of extracorporeal shock wave lithotripsy to archive stone clearance. Most patients who failed ESWL underwent adjunctive treatment such as ureteroscopic lithotripsy, percutaneous nephrolithotripsy and chemolysis. Looking at the stone-free rate in relationship to stone location, the renal pelvis was the best location for stone clearance with 33.3% among all the stones (Figure 1). Complications occurred in 24 patients (11.1%) with a majority of them (n=8) suffered from loin or suprapubic pain (Table 2). None of the patients had severe renal colic mandating hospital admission. Steinstrasse, which is a complication of ESWL in which stone fragments obstruct the ureter to form a “street of stone”, occurred in 3 patients (1.3%). In this series, the urinary tract infection post-procedure occurred in 2 patients (0.9%). Fortunately, there was no patient developed urosepsis that warrant admission. There was only 1 patient developed subcapsular renal hematoma after ESWL and was treated conservatively without surgical intervention. None of these patients required blood transfusion. Using simple Logistic Regression analysis, the only pre- treatment factor found to have significant effect on stone-free rate was the stone size ($p<0.001$).

Patient Demographics and Stone Characteristics	Value
Mean Age, (years)	52.55(12.29)
Gender, n(%)	
Male	129(59.4)
Female	88(40.6)
Stone Side, n(%)	
Right	106(48.8)
Left	109(50.2)
Bilateral	2(0.9)
Stone location, n(%)	
Lower pole	37(17.1)
Middle pole	15(6.9)
Upper pole	25(11.5)
Renal pelvis	73(33.6)
Proximal Ureter	42(19.4)
Distal ureter	6(2.8)
PUJ	19(8.8)
Stone size range, n(%)	
<1.0cm	57(26.3)
1.0-2.0cm	139(64.1)
>2.0cm	21(9.7)
Mean energy, kJ (SD)	99.29(18.76)
Mean shock	2909.86(299.63)
Mean duration, min (SD)	56.30(11.80)

Table 1

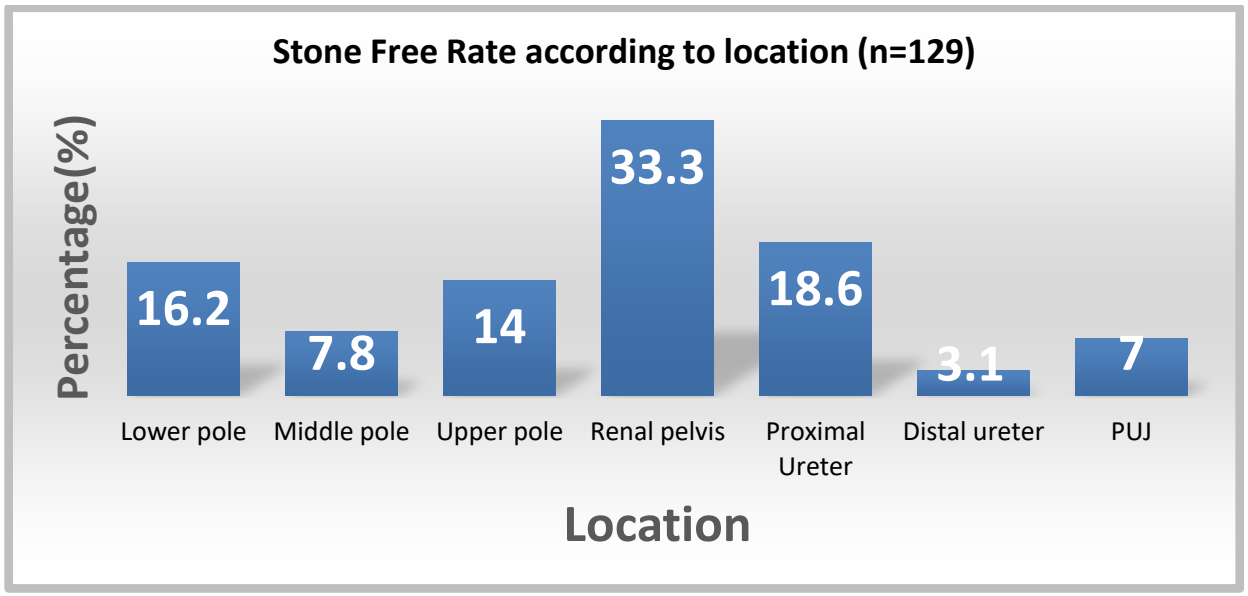

Figure 1

Complication	Total number of cases (%)
Hematoma	1(4.2)
Blood transfusion	0
Hematuria	5(20.8)
Sepsis requiring admission	0
Urinary tract infection	2(8.3)
Severe loin pain requiring admission	0
Loin or Suprapubic pain	8(33.3)
Steinstrasse	3(12.5)
Multiple complications	5(20.8)

Figure 2

DISCUSSION

Urolithiasis is a common urological disease in Malaysia because of the geographical location, hot climate, dehydration and dietary factors. In Malaysia, the incidence was lower than 40/100000 in the 1960s but it grew dramatically to 442.7/100,000 after 3 decades later [4]. Upper urinary tract stones are seen to be increasing trend, holding a major portion of urolithiasis [5]. The advent of extracorporeal shockwave lithotripsy in the 1980s propelled the treatment of urolithiasis from open surgery into the non-invasive procedure [1]. Its use has come under scrutiny with a shift in focus to cost-effectiveness and

healthcare outcomes. Advances in lithotripter technology have spawned several generations of devices that strive to improve stone-free rates and reduce complications. ESWL is non-invasive, it usually requires none or minimal anaesthesia and can be performed as day-care procedure [1, 2, 3], therefore it remains a good choice for treating small renal and ureteric stones among the Malaysian population.

Dornier Gemini is a premier, fully integrated workstation that provides an unparalleled platform for Lithotripsy [6]. It is integrated with shock-wave technology, tends to deliver consistent shock wave to boost the success of non-invasive kidney stone treatments with proper patient positioning. Dornier Gemini has the advantages of greater comfort to our patients during the procedures, providing an excellent quality image with the fluoroscopy and ultrasound to localize renal stones [6].

In our study, we have more male preponderance (M:F 1.46:1). Treatment success was 59.7% for renal stones and 58.3% for ureteric stones, regardless of the gender. This is comparable with the reported success rate of 41-90%, despite the discrepancy rate in the efficacy of ESWL [7]. The cross-sectional design raises the issue of potential selection bias which are likely to have influenced the ESWL treatment results. Apart from the upper calyx, intra-renal stone location was not associated with treatment efficacy, whereas an inverse relationship was found between stone size and treatment efficacy. In other words, the smaller calculi resulted in a higher stone clearance rate. Our patients could tolerate the ESWL therapy fairly with oral analgesia without any sedation.

The overall complications rate in our study was 11.1% (n=24) with the majority of them (n=8) suffered from loin or suprapubic pain. No major complication was reported in our study. None of our patients had severe renal colic mandating admission. Steinstrasse occurred in 3 patients (1.3%) and urinary tract infection post-procedure in 2 patients (0.9%). Those patients who experienced steinstrasse (streets of stones) were treated with ureteroscopic lithotripsy eventually and achieved stone-free status after that. On the other hand, the infection rate is very low in this study. The exact pathophysiology of sepsis and urinary tract infection secondary to ESWL is not understood completely. Cavitation bubble collapse created forces applied to the stones during the extracorporeal shockwave lithotripsy may cause damage to the small vessels that would result in the release of cell mediator and inflammatory response cells. Thus, the pathogens which present in the urine would pass and enter the bloodstream, resulting in acute infection or sepsis. There are controversies in the literature regarding the need for antibiotic prophylaxis in the patients undergoing extracorporeal shock wave lithotripsy. A meta-analysis study was performed to evaluate the efficacy of antibiotic prophylaxis in patients with proven sterile urine before they underwent ESWL and found that the incidence of urinary tract infections after ESWL is fairly low [8], as also shown by our present study, thus we suggest that the prophylaxis antibiotics is not necessary prior to ESWL. Previous literature reported the incidence of acute renal failure after ESWL. Very rarely, it was associated with serious complications such as bowel perforation and gastrointestinal injury. Long term risk of hypertension and chronic renal disease is not associated with ESWL [9].

The limitation of this paper is lacking data collection of the patients' body mass index, skin to stone distance, urinary tract anatomy & stone composition. These factors are particularly important to affect the overall outcome of ESWL treatment. We did not examine the treatment failure causes and most patients seen post-treatment were evaluated with inherent diagnosis limitation by X-ray KUB or ultrasonography. Though non-contrasted CT is the most sensitive radiological tool to assess urinary stones, we did not advocate its use post ESWL therapy due to long-waiting appointments and risk of radiation justifications. Further studies are warranted into the efficacy of mobile lithotripsy service, the learning curve for ESWL technicians and commercialised health care services in general.

CONCLUSION

Extracorporeal shockwave lithotripsy using Dornier Gemini EMSE 220F XXP-HP is a reasonably safe, highly tolerable, non-invasive and relatively effective modality for treating the renal and ureteric calculi.

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