Clinical audit of a new extracorporeal shockwave lithotripsy machine

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Objective: To evaluate the effectiveness and safety of the newly installed ESWL machine (Storz Modulith SLX-F2) in the treatment of urinary tract stones.

Methodology: All patients who had been treated with urinary tract stone (larger than 5 mm in size) by the newly installed ESWL machine in 2009 to 2010 were included. Patients’ demographic data, target stone characteristics, patients’ discomfort and treatment outcomes were prospectively collected. Treatment was considered a success if the patient was stone free or had asymptomatic, unobstructed stone fragments less than 4 mm.

Results: 329 patients were analysed. M : F = 2.6:1. Age ranged from 24 to 81. 135 patients had renal stone and 194 patients had ureteric stone. Their stone size ranged from 5–36 mm, mean 8.7 mm. 92.7% of the target stone were radio-opaque and 56.7% of the stones had obstructive effect. 76.3% of them had their procedures performed under sedoanalgesia. 95.4% of the target stones were localized by X-ray. The no. of shocks given per treatment ranged from 1000 to 4000 shocks. The overall single session success rate was 88.1% (Complete stone clearance: 64.4%; CIRF: 23.7%). The single session success rate / complete stone clearance rate for renal and ureteric stone was 84.4%/40% and 93.3%/81.4% respectively. Stone size was the only pre-treatment factor associated with the treatment outcome (p = 0.010). 79.9% and 2% of the patients complained minor symptoms on D1 and D14 respectively.

Conclusion: Storz Modulith SLX-F2 lithotripter is effective and safe in the treatment of urinary tract stones.

Key words: Extra-corporeal Shock Wave Lithotripsy (ESWL), Outcomes, Urinary tract stones

Introduction

Urinary tract stones have been a part of the human condition for millennia; in fact, bladder and kidney stones have even been found in Egyptian mummies. Their treatment had been described in some of the earliest medical literature. Prior to the introduction of extracorporeal shockwave lithotripsy (ESWL) in 1980, the only treatment available for stones that could not pass through the urinary tract system was open surgery. Since then, ESWL has become the preferred tool in urologists’ armamentaria for the treatment of urinary tract stones. Compared with open and endoscopic procedures, ESWL is minimally invasive, exposes patients to least anaesthesia and yields equivalent stone-free rates in appropriately-selected patients.

The first ESWL machine in Hong Kong was introduced in a private hospital by Dr George Koo, one of the pioneer urologists in 1985. Because of the escalating demand for the treatment of urinary tract stones, and in order to meet patient’ higher expectations, our hospital introduced the new ESWL machine (SLX-F2; Storz Medical, Swiss) in late 2008.

The device consists of a therapy unit, an ultrasonography (USG) imaging system and a X-ray fluoroscopy imaging system (Fig. 1). The core of the therapy unit is an electromagnetic cylindrical wave generator housed in a large diameter (30 cm) parabolic reflector (Fig. 2). The shockwaves produced are extremely short-pressure pulses with peak pressures between 10 and 150 MPa, which can be introduced into the body without significant soft tissue damage, but effectively disintegrate minimally-elastic structures, such as urinary tract stones. The electromagnetically-generated shockwaves provide excellent dosing capacity and can be triggered without significant fluctuations at low energy levels and high pressures. Moreover, the cylindrical source is designed for penetration depths of up to 165 mm, and thus effective fragmentation can be ensured, even in obese patients. Standard (6 x 28 mm) and extended focal zones
(9 × 50 mm) are available for different stone dimensions. The combination of X-ray and USG localization enables the urologist to choose the localization method best suited to a specific application or to use both localization systems simultaneously. The cylindrical design of the therapy head allows the USG transducer to be installed in the centre of the therapy head, and this in-line arrangement ensures obstacles, such as ribs or the iliac wing, are directly visible in the USG image. Fluoroscopic localization of the stone is performed by an X-ray system, which swivels in the lateral direction to provide a better image quality. The design of the machine also allows simultaneous endourological treatment to be performed at the same time as shockwave lithotripsy, aiming to provide treatment for different stones in the urinary system in one goal (Fig. 3).

The aim of the present study was to evaluate the effectiveness and safety of the newly-installed ESWL machine (SLX-F2; Storz Modulith, Swiss) in the treatment of urinary tract stones.

Methods

All patients who had been treated with urinary tract stones (larger than 5 mm in size) by the newly-

installed ESWL machine between 2009 and 2010 were included in this clinical audit. Patient demographic data and target stone characteristics were prospectively collected. Absolute contraindications for ESWL included pregnancy, active urinary tract infection, uncontrolled bleeding tendency, and uncorrected distal urinary tract obstruction. Relative contra-indications included: body weight > 135 kilograms, poor renal function with serum creatinine > 3 mg/dL (lower stone-free rate), severe orthopaedic deformities, complex intrarenal drainage (e.g. infundibular stenosis), and poorly-controlled hypertension (due to increased bleeding risk). Pre-existing pulmonary and cardiac problems are not contraindications, provided they are appropriately addressed both preoperatively and intraoperatively. In patients with a history of cardiac arrhythmias,
the shockwave can be linked to electrocardiography (ECG), thus firing only on the R wave in the cardiac cycle (i.e. gated lithotripsy). Cardiac pacemakers are also not contraindicated, although seeking assistance from a cardiologist for possible changes to pacemaker settings would be prudent. Oral anticoagulants [e.g. clopidogrel (Plavix) and warfarin (Coumadin)] should be discontinued to allow normalization of clotting parameters. Platelet function is normalized by discontinuing aspirin-containing products and nonsteroidal anti-inflammatory drugs 7 days before treatment.

Pre-ESWL work-up would include updated complete blood picture, renal function test, clotting profile (PT/APTT/INR) and urine analysis and culture. Plain X-ray Kidney-Ureter-Bladder (KUB), and preferably contrast imaging, including CT-urogram or intravenous urogram, should be available.

Patients were put in the supine position for renal stones, and in the prone position for both upper and lower ureteric stones (except when there was excessive bowel gas). Standard focal zones were used in all cases. Patient’s vital signs, including Blood pressure and pulse (BP/P), Oxygen saturation (SaO2) and Electrocardiogram (ECG) were continuously monitored during the procedure. Treatment was terminated when complete fragmentation of the target stones was identified on fluoroscopy/USG, or the maximum number of shocks for the renal and ureteric stones had been delivered. The maximum treatment shockwaves delivered during each treatment session, as recommended by Storz Medical, was 3000 shocks at an energy level up to 6.0 for renal stones and 4000 shocks at an energy level up to 8.0 for ureteric stones, respectively. The number of shocks given per treatment ranged from 1000 to 4000 shocks. The overall single session success rate was 88.1 per cent (complete stone clearance: 64.4 per cent; CIRF: 23.7 per cent). The single session success rate for ureteric stones was much higher than renal stones (93.3 per cent vs 84.4 per cent). Furthermore, 81.4 per cent of patients with ureteric stones were able to achieve complete stone clearance, while only 40 per cent of patients with renal stones could achieve the same outcome.

Stone size was the only pretreatment factor associated with the treatment outcome ($P = 0.010$), as with follow-up data with respect to stone clearance were analysed. Of these, 238 were male (72.3 per cent) and 91 were female (27.7 per cent). Age ranged from 24 to 81 years, with a mean of 48.3 years [standard deviation (SD): 10.09]. Body mass index (BMI) ranged from 17.2 to 39.2, with a mean BMI of 24.9 (SD: 3.86). The left-sided urinary tract was affected in 181 patients (55 per cent), and the right-sided urinary tract was affected in 148 patients (45 per cent). A total of 135 patients had renal stones, and 194 patients had ureteric stones (Fig. 4). The mean stone sizes for renal stones and ureteric stones were 10.47 mm (range: 5–36 mm) and 7.48 mm (range: 5–20 mm), respectively. A total of 92.7 per cent of the target stones were radio-opaque, and 56.7 per cent of the stones caused some degree of obstruction, as evidenced on contrast imaging. Most of the patients (76.3 per cent) had their procedures performed under sedoanalgesia. Others had managed anaesthetic care, general anaesthesia and intravenous sedation respectively. A total of 95.4 per cent of the target stones were localized by X-ray, with a mean radiation time of 164.0 s (SD: 108.5). The number of shocks given per treatment ranged from 1000 to 4000 shocks. The overall single session success rate was 88.1 per cent (complete stone clearance: 64.4 per cent; CIRF: 23.7 per cent). The single session success rate for ureteric stones was much higher than renal stones (93.3 per cent vs 84.4 per cent). Furthermore, 81.4 per cent of patients with ureteric stones were able to achieve complete stone clearance, while only 40 per cent of patients with renal stones could achieve the same outcome.

Stone size was the only pretreatment factor associated with the treatment outcome ($P = 0.010$), as
determined by univariate analysis. However, patient ages, BMI, radiation time, obstruction or lack of obstruction, modes of anaesthesia and frequency of shockwaves delivered (90 shocks/min vs 60 shocks/min) were all shown to have no correlation with the treatment outcome. However, there was also a trend (but not to the extent of statistical significance) towards younger age in successfully-treated patients.

A total of 79.9 per cent of patients complained of some degree of discomfort on one day after procedure (D1). Gross haematuria was almost the norm, and occurred in 61.4 per cent of the patients after ESWL treatment; 15.9 per cent complained of renal colic, and required pain-relieving medications; 8.8 per cent complained of dysuria; and 2.7 per cent complained of bruising over the treatment area. No major complication occurred for all patients, and only 2 per cent complained of renal stones, as most could achieve complete stone clearance.

Discussion

Since the introduction of the electrohydraulic energy-based Dornier HM-3 lithotripter in 1980,12 ESWL has quickly become the preferred non-invasive treatment for renal and ureteric stones. Early studies with the Dornier HM-3 reported success rates in excess of 90 per cent,3,4 and its effectiveness was considered the gold standard. Newer generation lithotripters, which use alternative electromagnetic or piezoelectric technology, are smaller, easier to use, more versatile, have a longer life and require no water bath; however, they have poorer outcomes.5–7 In order to reduce the pain associated with the procedure, and thus allow it to be carried out with sedoanalgesia instead of general anaesthesia, the size of the aperture of the latest lithotripters was increased. This in turn had the secondary effect of decreasing the size of the focus.8 At first sight, a smaller focal zone might seem advantageous, as it should allow for a greater fraction of the energy generated by the source to be incident on the stone, and thus minimize damage to the surrounding tissue, but this comes at a price.9 During respiratory excursion, the stone might move in and out of the focal zone; this could compromise fragmentation rates.10,11 One in vitro study compared the effect of stone motion on the fragmentation efficiency of the Storz Modulith SLX.12 An artificial kidney stone (a cylinder 6.5 mm in diameter and 7 mm long) was continuously translated laterally to the acoustic beam (as would occur for respiratory motion) in an oscillatory motion. The study showed that motion of 10-mm amplitude resulted in a 50 per cent reduction in stone fragmentation.

Studies using other lithotripters report a 44–88 per cent stone-free rate, 64–96 per cent clinical success rate and 4–62 per cent retreatment rates.13–21 In our study, the overall single session success rate was 88.1 per cent (complete stone clearance: 64.4 per cent; CIRF: 23.7 per cent), which compared favourably with other lithotripters. The clinical outcome for patients with ureteric stones was much better than those with renal stones.

In contrast to some other studies, the BMI of the patients was not shown to be correlated with the treatment outcome.27–30 This could be explained by the fact that our cylindrical shockwave source is designed for penetration depths of up to 165 mm, and thus effective fragmentation can be ensured, even in obese patients.

To improve the success rate of ESWL, efforts have been devoted to defining the parameters the urologist can control, such as patient selection, treatment protocols and what manipulations might improve the efficacy of the technology. One of the parameters that has been the subject of a number of studies is the rate at which shockwaves are delivered during ESWL. The in vitro piezoelectric model,31 the in vitro porcine model32 and multiple randomized, controlled trials35–38 confirmed that patients treated at a rate of 60 shocks per minute have a significantly better treatment outcome than patients treated with higher shock-rate frequency. The exact mechanisms by which a slower shockwave rate might enhance stone fragmentation are not well understood. They could be related to inhomogeneities in the fluid that surrounds a stone, such as small fragments fractured off of the stone surface, and could persist between shockwaves and serve as nuclei or promoters of cavitation. As subsequent shockwaves are delivered, the growth of cavitation bubbles seeded by these nuclei might draw energy from the negative pressure phase of the shockwave.39 The ultimate consequence of such an effect might reduce stone breakage. We were unable to demonstrate in the present study the effect of shockwave frequency on treatment outcomes. One of the possible reasons behind this was the inadequate sample size treated with 60 shocks per minute when compared to those treated with 90 shocks per minute in this retrospective review.
Further prospective, randomized trials are required to illustrate the difference. In conclusion, the Storz Modulith SLX-F2 lithotripter is effective and safe in the treatment of urinary tract stones.

References


