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Chapter 5

Extracorporeal Shock Wave Therapy: Non-Urological Indications and Recent Trends

Noha Maraie, Omar Mohammed Osman and Hosni Khairy Salem

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Abstract

Extracorporeal shockwave lithotripsy (ESWL) was introduced in 1980 as the preferred tool by the urologist for the treatment of renal stones and or upper ureteral stones. ESWL is minimally invasive procedures, exposes patients to fewer anesthesias, and has equivalent stone-free rates comparable to open surgery and endourology interventions for the treatment of renal stones. Urolithiasis is not the only application for extracorporeal shock waves but there are also other applications for it. Extracorporeal shock wave is used for the treatment of gall bladder stones, common bile duct stone clearance, pancreatic calculi, salivary stones, erectile dysfunction, and refractory angina pectoris chronic wound healing. This chapter gives full review about ESWL as minimally invasive procedures in the following items: (i) ESWL l in treatment of gall stones; (ii) ESWL for common bile duct (CBD) stones; (iii) ESWL for pancreatic stones associated with pancreatic pseudo cysts and chronic pancreatitis; (iv) ESWL in the treatment of salivary stones; (v) ESWL in the treatment of erectile dysfunction (ED); (vi) Cardiac shock wave therapy (ESWL) in treatment of refractory angina (RA); (vii) ESWL and chronic wound healing; (viii) Recent trends in extracorporeal shockwave lithotripsy (ESWL); (ix) Post ESWL complementary therapy; and (x) The future of ESWL in the year 2038.

Keywords: extracorporeal shock wave therapy (ESWT), extracorporeal shock wave lithotripsy (ESWL), gall stones, biliary stones, lithiasis, pancreatic stones, chronic pancreatitis, salivary stones, cardiac shock wave therapy (CSWT), erectile dysfunction, chronic wounds, healing, diabetic foot

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1. Introduction

Shock waves are single high amplitude sound waves produced by electrohydraulic, piezoelectric or electromagnetic methods that are transmitted into tissues with sudden rise from low pressure to its highest pressure at wave front followed by lower tensile amplitude [1]. The international society for medical shock wave treatment [2] defines shock waves as sonic pulse characterized by high peak pressure (500 bar), short life cycle (10 ms), fast pressure rise (<10 ns) and a wide frequency spectrum. The shock waves are condensed at a zone of highest energy concentration in the targeted area within the treated tissues. The most important effects of shock waves are reflection with pressure and tension powers at levels of different resistance and the production of cavitation bubbles in liquids. These bubbles collapse and produce local shear forces by high velocity liquid streams (so-called jet stream) [1, 3, 4]. The introduction of ESWL during the early 1980s markedly changed the management of urinary tract stones, and during the last two decades, the development of new techniques of ESWL has changed completely the way of treatment of patients with renal stones [5]. ESWL was first successfully used in children in 1986 [6], and now, it is the first-line treatment of pediatric renal stones [7, 8]. Urolithiasis is not the only application for extracorporeal shock waves, but there are also other applications for it. Extracorporeal shock wave is used for the treatment of gall bladder stones [9], common bile duct stone clearance [10], pancreatic calculi [11, 12], salivary stones [13, 14], erectile dysfunction [15, 16], refractory angina pectoris [17, 18], and chronic wound healing [19, 20].

2. ESWL in treatment of gallstones

When ESWL was first used for gall stone lithotripsy, it was combined with bile acid therapy, which was only effective against non-calcified cholesterol stones. That is the reason why ESWL was only used against these types of stones [9]. However, some recent studies have proven that ESWL combined with bile acid therapy showed no significant improvement in gall stone clearance in comparison to ESWL alone [21, 22].

2.1. Efficiency of ESWL in comparison with cholecystectomy (CC)

Being minimally invasive, ESWL was preferred by patients and doctors to be used for gall stone clearance in contrast to surgery. However, cholecystectomy has proven less recurrence rates for gall stone development than ESWL [9].

On the other hand, a randomized, prospective study by Nicholl et al. [23] stated that both ESWL and CC groups had similar results regarding the 1-year health status following treatment. Moreover, the ESWL group health status was improved within 2 weeks in contrast to that of CC group that was improved in 5 weeks.

2.2. Future of ESWL in gall stones treatment

The lack of sufficient studies for the optimal application of ESWL in patients with gall stones hindered the Food and Drug Administration (FDA) approval for its use for gall stone lithotripsy.

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However, this did not prevent several medical centers in Europe and Asia to use it for gall stone treatment on a constant rate [9].

3. ESWL for common bile duct (CBD) stones

Several studies reported the use of extracorporeal shockwave lithotripsy for common bile duct stones. As an instance, Tandan and Reddy [10] applied a certain protocol using ESWL for large CBD stones in their institute (Asian Institute of Gastroenterology, India). This protocol stated the start with endoscopic retrograde cholangiopancreatography (ERCP) as an initial procedure with placement of a nasobiliary tube to opacity the calculi to bath them in saline and to facilitate their targeting. This was followed by ESWL till the calculi were fragmented to a diameter less than 5 cm. Finally, ERCP is performed using a balloon or a basket to clear the CBD, and stenting was done only if indicated.

ESWL was indicated in all cases with large CBD stones with failure of their extraction by using the routine techniques; sphincterotomy followed by basket or balloon traw [10].

Tandan and Reddy reported some complications following the use of ESWL, including skin ecchymosis, pain at the site of administration, abdominal pain, occasional fever and hematobilia [10].

These complications can be reduced using a third-generation lithotripter with more accurate targeting and reduced patients' movements [24, 25].

4. ESWL for pancreatic stones associated with pancreatic pseudo cysts and chronic pancreatitis

A prospective study, by Li et al. [11], was performed on chronic pancreatitis patients with at least one stone in the main pancreatic duct of less than 5 mm in diameter. A total of 849 patients were divided into two groups: the case group was 59 patients with pancreatic stones and pancreatic pseudocysts (PPC) and the control group was 790 patients with pancreatic stones only. Following 116 ESWL sessions, 10.17% of patients in the PPC group showed complete stone clearance. Partial stone clearance occurred in 15.25% of patients. When ESWL was followed by ERCP, these percentages were raised to 67.24 and 20.69%, respectively. The authors concluded that ESWL—when followed by ERCP—was a successful strategy for lysis of pancreatic stones and regression of pancreatic pseudo cysts.

On the contrary, a retrospective study done by Vaysse et al. [12] has found that ESWL—as a sole treatment—was proven a safe and effective treatment for patients with obstructing stones in the main pancreatic duct. There was no need for adjuvant ERCP that showed no additional benefit. It was done on 146 patients with pancreatic duct stones resulting in chronic or recurrent acute pancreatitis. Only 132 patients continued to follow-up at 6-month period. About 69% of patients received adjuvant ERCP. At the end of 6 months, 76% of patients achieved successful treatment in the form of no need for analgesia, no acute

pancreatitis or no need for surgical treatment for chronic pancreatitis. There were no significant differences in success rates between patients who received ESWL alone and those who received adjuvant ERCP.

5. ESWL in the treatment of salivary stones

ESWL sources used for salivary stones lithotripsy are either the electromagnetic source or the piezoelectric source. The electromagnetic shock wave source is more commonly used for being minimally invasive without need for anesthesia, so it can be done as an outpatient practice [26, 27]. Capaccio et al. [13] have done a prospective study on 415 patients on two groups in two time periods. Both groups received ESWL via an electromagnetic device that was preceded by ultrasonography (US) for localizing the stones. Follow-up was done using ultrasonography at 1 week, then at 1, 3, 6 and 12 months after ESWL application. Complete stone clearance percentages were generally higher in patients with parotid duct stones (group A: 69.3% and group B:68.8%) than in those with submandibular duct stones (group A: 35.9% and group B: 48.8%). However, with US follow-up, some residual submandibular and parotid dust stones were observed. Post-ESWL procedures to remove the symptomatic residual stones included sialendoscopy or transoral removal of stones. This proved that ESWL achieves good results for salivary stones especially parotid duct stones with small diameters.

In another retrospective study by Schmitz et al. [14], 31% of patients reached total stone clearance, and in 55% of patients, the treatment was partially successful with asymptomatic residual stone identified using US. Failure of treatment occurred in 14% of cases.

In spite of being non-invasive efficient alternative to surgery in management of sialadenitis, ESWL is contraindicated in the following cases: acute sialadenitis, gingivitis, pregnancy, bleeding disorders and calculi that cannot be detected using US. Relative contraindications include patients with cardiovascular diseases or artificial pace makers [13, 14].

6. ESWT in the treatment of erectile dysfunction (ED)

Several trials studied the efficacy of ESWT in the treatment of ED. Clavijo et al published a systematic review and meta-analysis of seven randomized clinical trials with 602 patients with vascular ED [15]. The seven studies used low-intensity shockwave therapy (Li-ESWT) for ED and used the erectile function domain of the International Index of Erectile Function (IIEF-EF) to assess the response to treatment. The IIEF-EF is a validated questionnaire that includes six questions about erectile frequency, firmness, penetration ability, frequency of maintenance, ability to maintain erection and erectile confidence on a scale of zero to five [28]. The difference in IIEF-EF score pooled change was measured in patients with ED treated with Li-ESWT and compared to that measured in patients treated with sham therapy. The IIEF-EF score in ESWL group was 6.40 points compared to the sham group which was 1.65 [15].

Another systematic review and meta-analysis by Fojecki et al. [16] included four studies that also used IIEF questionnaire, in addition to erectile hardness scale (EHS) to assess the success of treatment. One study of the four also examined the penile hemodialysis as an indicator for erectile dysfunction [29]. All of them compared ESWT to sham therapy. Three out of the four studies showed positive effect of ESWT on EHS scale compared to sham group. Only one study reported negative effect of ESWT on both EHS scale and IIEF score [30]. Hence, the effect of ESWT on ED is still inconclusive, although according to EHS scale, it is proven to have some potential in the treatment of ED [16].

7. Cardiac shock wave therapy (CSWT) in treatment of refractory angina (RA)

Cardiac shock wave therapy (CSWT)—which is also known as extracorporeal shockwave myocardial revascularization (ESMR)—represents a recent option for the treatment of refractory angina [17, 18]. Alunni et al. [17] performed a prospective case-control study over 6 months. They studied the efficacy of ESMR on cardiac perfusion in 72 patients with refractory angina (RA), 43 patients in the ESMR group and 29 in the control group (did not receive ESMR). They were compared at baseline and 6 months following ESMR therapy as regarding angina class score (CCS class score), the need for nitroglycerin consumption and the rate of hospitalization. Significant improvement in the patients' conditions occurred. Angina class score (CCS) improved in the ESMR group with an average of 1.33 versus 1.92 in the control group. Nitroglycerin consumption was lowered (20% in ESMR group versus 44.8% in control group) as well as the significant reduction in the rates of hospitalization (13.9% in the ESMR group versus 37.9% in the control group).

Vainer et al. [18] also applied cardiac shockwave therapy on the ischemic myocardial areas of 33 patients with end-stage coronary artery disease, chronic angina and reversible ischemia on myocardial scintigraphy. Patients were followed up after 1 and 4 months from the last CSWT session and assessed using CCS class score, their need for nitrate consumption, cardiac magnetic resonance imaging and myocardial scintigraphy. Follow-up showed an improvement in CCS score to drop from class III to class II, reduction in sublingual nitrate consumption from 10 times to twice per week, and myocardial scintigraphy showed improved myocardial perfusion. In conclusion, CSWT has proven to be an efficient non-invasive therapeutic option for patients with refractory angina.

8. ESWT and chronic wound healing

A recent systematic review done by Omar et al. [19] included 11 studies about the role of ESWT in the treatment of chronic wounds of lower limbs. A total of 925 patients were enrolled. About 85% of them received ESWT, and 15% represented the control group. Chronic wounds included diabetic foot ulcers (39.6%), traumatic wounds (20.3%), venous leg ulcers (12%) and

others as pressure ulcers, acute burns, arterial leg ulcers, disturbed wound healing and surgical wounds. Several parameters were used to assess the rate and quality of wound healing. They include time to healing, reduction of wound surface area and tissue viability using laser Doppler perfusion imaging to measure the blood flow perfusion rate.

One of the included studies was done by the same author [20] as a single-blinded randomized controlled trial on the effect of ESWT in the treatment of chronic diabetic foot ulcers. They used almost the same parameters in measuring the rate of ulcers healing in addition to wound bed preparation. Standardized wound care was given, including wound debridement, blood-glucose control agents and special footwear to minimize the pressure. 20 weeks following the last ESWT session, 54% of ESWT group had completely healed ulcers versus 28.5% in the control group. There was significant reduction in the healing time with an average of 664.5 days in ESWT group versus 81.17 days in the control group.

The complications reported included pain, itching, infection, pigmentation and skin irritation. However, these complications were self-limiting and resolved in 5–7 days [19]. That is the reason why ESWT is recommended as an adjunctive therapy alongside with the standard wound care program [19, 20].

9. Recent trends in extracorporeal shockwave lithotripsy (ESWL)

The large number of patient treated by SWL in the past 25 years gives an important information about indications, contraindications, adverse effects of the procedures and the required development to improve the techniques of SWL for better treatment and less side effects [31]. Krambeck et al. [32] found that HTN incidence was significantly correlated with bilateral procedures done by using a Dornier HM3 lithotripter, while DM was correlated with shock wave number and frequency. The author postulate that occurrence of DM and HTN may be due to unobserved microtrauma on the pancreas and the kidney. Chew et al. [33] compared the incidence of DM and HTN in patient treated with an unmodified lithotripter HM3 (USWL) and second-generation modified HM3 lithotripter (MSWL); they found that there was no association between lithotripter and development of either DM or HTN in multivariate analysis and they suggest that the prevalence of DM and HTN in patient with renal stones is due to the presence of metabolic syndrome. Where there is increasing evidence, the patient with renal stones get HTN and DM and vice versa through this syndrome. Lee et al. [34] introduced that SWL treatment at frequency of 60 shocks/min gave better outcome compared with SWL at 120 shocks/min. On the other hand, pretreatment did not impact renal injury. Salem et al. compared slow and fast shock wave frequency, delivery rates in disintegrating pediatric renal stones smaller than 20 mm and the impact on stone clearance. Terms of comparison include treatment success, anesthesia time, secondary procedures, cost and efficiency quotient. They found that slow delivery rate of SWL has better stone clearance results than fast delivery rate [5]. Mazzucchi et al. [35] found no significant differences in the stone-free rate and complications development by reducing the total number of impulses from 4000 to 3000 and the frequency from

90 to 60 impulses/min. Vakalopoulos [36] developed a mathematical model to predict ESWL outcomes where predictive equations can be generated for different lithotripters. Wiesenthal et al. [37] developed a remarkable nomogram to predict the outcomes of renal and ureteral stone SWL treatment dependent on patient and stone factors. The risk of SWL failure is significantly related to increase radio density both in vivo and in vitro; cysteine, calcium oxalate, monohydrate and brushite stones are less liable to be treated by SWL [38, 39]. Salem et al. [40] conducted a prospective randomized trial over 200 patients comparing the SWL and semi rigid ureteroscopy for management of proximal ureteral calculi. He found that URS has higher free stone rate than SWL but more adverse effects so SWL should be the first-line treatment for proximal ureteral calculi of size < 1 cm. The introduction of second- and third-generation lithotripter not improves the stone-free rate or decreases the number of operations needed, but they have less anesthesia and minimal tissue injury [41, 42].

10. Post-ESWL complementary therapy

Micali and coworkers [43, 44] found the use of *Phyllanthus niruri* (a plant belonging to the euphorbiaceae family used in Brazilian folk medicine by patients with urolithiasis) with SWL lower calyx stone expulsion.

Also Micali [45] and Zheng et al. [46] found that the use of nifedipine and tamsulosin, both associated with ketoprofen after SWL of ureteral stones, increases stone-free rate for proximal and middle ureter (85.7% vs 51.7%) and distal ureter (82.1% vs 57.1%).

11. The future of ESWL in the year 2038

Understanding all effects of ESWL will lead to reliable production of <2 mm as sized reduction of the stones instead of fragmentation. This will result in a sawing back to non-touch shock wave lithotripter due to better shock wave generators with larger focal zones, respiratory regulated hit control based on color duplex ultrasound and computer-assisted shock wave navigation adapted to the individual anatomy. All will lead to increasing the quality of stone disintegration with almost complete pulverization of the stone, and these techniques can be applying without anesthesia producing no side effects [47].

Author details

Noha Maraie, Omar Mohammed Osman and Hosni Khairy Salem*

*Address all correspondence to: dr_hosni@yahoo.com

Faculty of Medicine, Cairo University, Cairo, Egypt

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