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REVIEW

Extracorporeal shock wave lithotripsy: What is new? ☆

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Technique;
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ABBREVIATIONS

PCNL, percutaneous nephrolithotomy;
EAU, European Association of Urology;
US, ultrasonography

Abstract ***Objectives:*** Thirty years after its introduction, extracorporeal shockwave lithotripsy (ESWL) is still first-line treatment for more than half of all urinary tract stones, but machines and treatment strategies have significantly developed over time. In this review, we summarise the latest knowledge about the clinically important aspects of ESWL.

Methods: We searched PubMed to identify relevant reports and the latest European Association of Urology guidelines, and standard urological textbooks were consulted.

Results: New technical developments include: Twin-head and tandem-pulse shock-wave generators; wide-focus, low-pressure systems; optimised coupling; and automated location and acoustic tracking systems. Indications have been refined, making possible the identification of patients in whom ESWL treatment is likely to fail. By lowering the shock-wave rate, improving coupling, applying abdominal compression, power 'ramping' and postoperative medical expulsion therapy, treatment protocols have been optimised.

Conclusions: Promising new technical developments are under development, with the potential to increase the stone-free rate after ESWL. For optimal results, the refined indications need to be respected and optimised treatment protocols should be applied.

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Introduction and historical background

The first lithotripter for the treatment of human kidney stones, the HM1 (Human Model 1, Dornier, Germany; now Dornier MedTech America, Inc., Kennesaw, GA, USA), was introduced in 1980 by Chaussy et al. [1]. This is a classical example of a 'spin-off' from a military development, as in this case observations from the Dornier Star Fighter programme were translated into the development of this innovative medical device [2].

The first serial lithotripter, the Dornier HM3, became so successful that ESWL quickly replaced open stone surgery and became the first-line option for most stones in the upper urinary tract [3], and until the present, despite all the advances in percutaneous nephrolithotomy (PCNL) and transurethral stone treatment (ureteroscopy) [4], still more than half of all stones worldwide are treated using ESWL [5].

The current third- and fourth-generation machines are versatile, user-friendly and safe. Usually in a day-case setting, procedures are conducted under analgesia or sedo-analgesia [6].

One drawback remains: Despite all technical advances, the stone-free rates of the reference machine, the Dornier HM3, have never been reached again [7].

Evidence acquisition

With no specific system, we searched the Medline (PubMed) database using the following keywords; 'shock wave lithotripsy', 'SWL', 'ESWL', 'lithotripter' and 'lithotripsy'. Only recent papers in English were included. In addition, the latest European Association of Urology (EAU) guidelines were consulted; expert opinions of experienced stone surgeons and ESWL technicians were incorporated.

Evidence synthesis

Physics of stone fragmentation

Various mechanisms responsible for stone disintegration have been described. The original concept of tear and shear forces leading to stone fragmentation [1] was later completed by the description of cavitation [8], spallation [9] and quasi-static [10] as well as dynamic squeezing [11].

The underlying concept is that repetitive stress finally leads to stone fragmentation. For the development of new lithotripters it would obviously be advantageous to know which individual variable calculated from the shock-wave model, e.g. acoustic energy, energy flux density and effective energy, can reliably predict stone disintegration or tissue damage, but despite all efforts this is not yet possible [12].

Lithotripter technique; change of focus

Unchanged in the latest generation of machines in comparison to the HM3, four components remain essential and thus can be found in all modern machines, regardless of the manufacturer. These are the shock-wave generator, a mechanism to focus the shock waves onto a target, a system for stone location, and a coupling medium [13].

For the shock-wave source there are several promising concepts under development and currently under evaluation. The Direx Duet (Direx Corp., Natick, MA, USA) is a dual-head lithotripter where two shock-wave heads are installed at 72° and deliver shock waves which meet at one focal point [14]. Firing is either synchronous, with both heads firing simultaneously, or asynchronous, where the firing alternates between the shock-wave sources. However, the latest publications on this technique are experimental *in vitro* studies and this device it is not in widespread clinical use.

Another system of delivering two shock waves is the tandem-pulse shock-wave generator, where a second shock wave is emitted along the same acoustic axis in rapid succession, to drive the forceful collapse of bubbles against the stone [15]. However, these machines have as yet shown no significant advantage in terms of the stone-free rate.

Classically, shock waves are generated electrohydraulically, electromagnetically or piezoelectrically. Recently, with the Sonolith® i-sys (EDAP TMS, Vaulx-en-Velin, France) an electroconductive system has been used, for which promising results are reported [16]. In this generator the spark electrodes are surrounded by a highly conductive solution, resulting in a shock wave generated at the same geometric point and at the same intensity from shot to shot, reducing the potentially efficacy-reducing 'jitter' effect known from conventional electrohydraulic shock-wave sources [12].

To date, the consensus is that focal width is critical in stone fragmentation [12]. Whilst the original Dornier HM3 had an intermediate-sized focus of ≈12 mm in diameter, and at ≈40 MPa a moderate peak pressure, later-generation machines tended to have smaller focal zones with higher peak pressures. Their wider area of shock-wave entry over the skin made treatment less painful but also less effective, as the small focus made it difficult to target the stone and changed the mechanism of energy delivery on the target. Recently, wide-focus, low-pressure lithotripters have become commercially available (XiXin Medical Instruments Co. Ltd., Suzhou, China). With a focal zone of 18 mm and a low acoustic peak pressure of < 20 MPa they show very encouraging results in terms of stone fragmentation, patient comfort and side-effects [17]. The first *in vivo* series of 297 patients had a stone-free rate of 86% at mean number of 1532 shock waves per session. However, drawbacks of this report are that the stone-free status was mainly determined by ultrasonography (US) and no follow-up data beyond 3 months were provided [18].

An interesting feature of some modern lithotripters is their ability to switch between different focal sizes. For example, in the Storz Modulith® SLX-F2 (Storz-Medical, Kreuzlingen, Switzerland) the focal size is changed electronically by modifying the shock-wave pulse duration. This allows an adjustment of the characteristic of the shock wave according to the target, with a wider focus for multiple, larger and rather soft stones, and a smaller focus for smaller and harder stones, e.g. an impacted ureteric calculus [12]. Another lithotripter allowing a change in the focal size is the PiezoLith 3000 (Richard Wolf, Knittlingen, Germany) which has a double-layer arrangement of piezoelectric elements that allows three different focal zones by modifying the synchronisation of both travelling waves [12]. Although a conclusive theoretical concept, higher stone-free rates remain to be reported [19].

For stone location modern lithotripters are equipped with both fluoroscopy and US to combine the advantages of both imaging methods. Fluoroscopy has the advantage that urologists are familiar with it and ureteric stones can be visualised [7,20]. US has the advantage of real-time imaging with no X-ray exposure, and can be used to identify radiolucent stones, but the operator needs special training, and ureteric calculi cannot be visualised.

Recent developments in imaging include optical or acoustic tracking systems, which facilitate stone targeting and reduce X-ray exposure [12]. To monitor stone disintegration in real time and prevent overtreatment, acoustic feedback systems are under development, and to overcome the poor stone clearance in lower-pole stones, focused ultrasound has been used to expel fragmented lower-pole calculi effectively and safely from their dependent position [21].

The original Dornier HM3 had excellent coupling properties with the least possible loss of shock-wave energy, as patients were lying in a water bath. To be more patient-and user-friendly, modern lithotripters became dry-head devices, where the shock-wave head is brought into contact with the patient but mediated by a layer of high-viscosity ultrasound-transparent jelly. The only exception to date is the Storz SLX lithotripter (Storz Medical, Tägerwilen, Switzerland), where a partial water bath is used for coupling [17].

Indications

In the early days of ESWL enthusiasm about the new ‘no-contact’ treatment was so great that nearly all stones, regardless of their size and position, were treated with ESWL. Realising that stone-free rates are strongly dependent on various factors the indications were refined over time.

For stones of >20 mm, stone free rates of $<50\%$ have been reported [22], and lower-pole stones show an equally low clearance rate after ESWL, as gravity prevents the fragments from leaving the dependant parts of the collecting system. Other anatomical factors related to a reduced clearance rate are a steep infundibulopelvic angle of $>70°$, an infundibular length of >3 cm, and a narrow infundibular neck with a diameter of <5 mm [23]. However, for single lower-pole stones of <10 mm, there was no statistically significant difference between ESWL and ureteroscopy [24], in contrast to calculi of >10 mm, where ureteroscopy or even PCNL are recommended by some authors [25,26]. The EAU guidelines recommend flexible ureteroscopy or PCNL for lower-pole stones of >15 mm [27].

These results have been incorporated into the EAU guidelines, where ESWL is recommended as the first-line treatment only for stones of <20 mm diameter, given that the kidney anatomy is favourable.

For upper ureteric stones of $\leqslant 10$ mm ESWL is considered the first choice, but for larger diameters ureteroscopy is equally strongly recommended. In distal ureteric stones of $\leqslant 10$ mm, ESWL and ureteroscopy are both indicated as first-line treatments, but for larger calculi ureteroscopy is considered as more favourable.

The only exception to these recommendations is in patients with a uric acid stone, where nearly always the first-line treatment consists of oral chemolitholysis and, if obstructive, ureteric stenting [27].

A further classical indication for ESWL is a residual stone burden after a primary stone de-bulking with PCNL, the so-called ‘sandwich’ therapy. However, this approach has been shown to have a lower stone-free rate and requires more interventions as the primary therapy is extensive PCNL, and it is therefore no longer recommended [28].

ESWL has also been used for the removal of encrustation on overdue ureteric stents and urethral catheters, in the treatment of Peyronie’s disease, for bile-duct and salivary-gland stones, and in a variety of musculoskeletal disorders. In addition, recently published data showed that shock-wave treatment stimulates angiogenesis and re-epithelialisation and improves ventricular function in patients with ischaemic heart disease [29–31].

Contraindications

The only absolute contraindication for ESWL remains pregnancy, as a potential disruptive effect on the foetus cannot be excluded. Nevertheless, there are reports of patients being treated with ESWL even in the first trimester of pregnancy, with no consequent side-effects on the healthy foetus [32]. ESWL is not contraindicated in young children and in the elderly [33,34].

Uncorrected bleeding diathesis and renal artery or aortic aneurysms are relative contraindications, as the shock wave could provoke renal haematomas or cause the aneurysm to rupture. However, there are reports of patients with aortic aneurysms being treated successfully [35], and it seems reasonable to proceed if the aneurysm is not directly in the shock-wave path [36]. If the preoperative correction of coagulation is not possible, ureteroscopy is the method of choice for stone removal rather than ESWL.

Acute UTI must be treated accordingly before using ESWL, as endotoxins and bacteria can be washed into the bloodstream with every shock wave, and bacteraemia, up to severe sepsis or perinephric abscess, can be provoked. Even if the urine is found to be sterile preoperatively, acute infectious complications can occur, as bacteria are sometimes harboured inside infectious stones [37]. Antibiotic prophylaxis is recommended especially for infection-related staghorn stones and struvite calculi, and should be continued for at least 4 days [2].

Complications of ESWL: The role of stenting, and clinically insignificant fragments

Even after successful treatment in terms of stone fragmentation, side-effects like renal colic and ureteric obstruction can occur. In rare cases a ‘steinstrasse’ can develop, defined as an accumulation of fragments behind a leading, obstructing fragment.

There is a current debate about preoperative ureteric stenting and its effects on complications and stone clearance. Recent data suggest that stone clearance for ureteric stones is reduced in patients with a JJ stent, and is most probably due to the loss of ureteric peristalsis [38,39]. Clearly, the incidence of infectious complications and especially bothersome LUTS is higher with such an indwelling foreign body [40]. However, for stones of >20 mm or for solitary kidneys, stenting is still recommended [27], and for faint radio-opaque ureteric stones, a JJ stent can facilitate localisation of the stone.

Another frequently discussed matter is the relevance of residual fragments after ESWL. In many reports fragments of <5 mm are sometimes called ‘clinically insignificant fragments’ (CIRFs), as they have a high chance of passing spontaneously. However, the reported stone re-growth rates are as high as 21–59% [36]. Furthermore, residual fragments of infectious stones can be a nidus for recurrent stone formation and UTIs, and therefore complete stone clearance should be the aim. Some authors actually propose that the term CIRF is a misnomer and should therefore be avoided [41].

The most common clinical sign for tissue damage after ESWL is macrohaematuria, usually resolving spontaneously after a few days [36]. Symptomatic kidney haematomas occur in $<1\%$, but if routine CT is used after treatment their true incidence seems with $\approx 4\%$ and thus much higher [42]. Haematomas can usually be treated conservatively [36].

Immediately after ESWL renal function is impaired and the GFR is reduced. This has shown to become normal shortly thereafter, and although the debate continues, there is no proof to date that ESWL can cause long-term kidney damage [36].

Apart from renal insufficiency, it has been hypothesised that hypertension and diabetes mellitus could be caused by repeated ESWL treatments. The evidence for this is inconclusive and to date no randomised controlled trial has been able to confirm this hypothesis [43,44].

Gastrointestinal side-effects after ESWL have been reported but overall they are rare, with an incidence of 1.8% for gastric ulcers, bowel, liver or spleen lesions, fistula formation and pancreatitis [45].

Cardiac arrhythmias can be triggered frequently by ESWL, but morbid cardiac events or myocardial damage are extremely rare, and even in patients with cardiac pacemakers the treatment can be applied safely, although close cooperation with a cardiologist is recommended [36].

Good clinical practice: improving the success rate

Preoperative imaging is an important factor for successful ESWL. Ideally, non-contrast CT (kidney and bladder) is used to assess the stone burden, position and anatomical features of the urinary tract. If there are any doubts about the position of the stone(s) in relation to the urinary collection system, then contrast-enhanced CT, preferably with three-dimensional reconstruction, or IVU, are recommended [27]. To correlate the position of the stone with the surrounding anatomical structures, and to reconfirm its presence, a plain abdominal film taken immediately before the treatment remains good clinical practice for ureteric stones, which can change their position rapidly [46].

Although the latest generation of lithotripters are optimised towards patient comfort, treatment can still be painful, and adequate pain management is important for successful treatment. Pain might prevent the maximum recommended shock-wave energy level to be reached, and the patient will involuntarily move away from the shock-wave source and thereby out of the target area. However, despite its crucial role, there are no standardised protocols for pain control [6].

Classically, the drugs used are NSAIDs (e.g. diclofenac 100 mg rectally), sometimes accompanied by fast-acting intravenous opioids like fentanyl and its derivatives (e.g. alfentanyl 5–30 μg/kg body weight, corresponding to 1–2 mg for an average 70 kg patient). An interesting development is the revived interest in inhalation anaesthesia with nitrous oxide, local anaesthesia with deep infiltration of the tissue, and dermal anaesthesia with EMLA or dimethyl sulphoxide, as the results in terms of pain control are good and the side-effect profile is favourable [6].

Tamsulosin is a well-known drug to the urologist and is effective for increasing the stone-free rate after ESWL and decreasing the use of opioid analgesics in patients with renal colic [47]. However, for pain relief during ESWL no significant benefit has been reported to date [48].

A diuretic, anti-inflammatory, analgesic and spasmolytic effect was reported recently for terpenes, as well as quicker stone expulsion and reduced symptoms after ESWL for renal calculi [49].

The shock-wave frequency is currently regarded as an important variable for treatment success. Lower frequencies minimise tissue damage and increase the fragmentation rate [12], and in this regard the EAU guidelines recommend a frequency of 60 shots/min.

Proper acoustic coupling is under the direct control of the operator and is critical for treatment success. In a recent study using a camera system, suboptimal conditions were shown in 67% of all treatments. Even the smallest air bubbles in the shock-wave path can reflect a considerable amount of the shock-wave energy and significantly decrease the disintegration capacity [50]. Therefore, a generous amount of air-free (no shaking), preferably warm, low-viscosity coupling gel should be applied directly from the stock container, and in-line US should be used to confirm proper acoustic coupling [17,51,52].

With every respiratory movement the stone moves potentially out of the shock-wave target area. To keep this movement as minimal as possible, an abdominal compression belt can be used. In addition such a belt can reduce the skin-to-stone distance in obese patients [53,54].

Starting a treatment with a low energy and increasing it in steps until the maximum recommended energy level is reached seems logical and is generally applied. Furthermore, it has been shown to induce vasoconstriction and thereby prepare the kidney for higher shock-wave levels [13], and interestingly better stone fragmentation and significantly increased stone free rates were reported with such a protocol [55].

The stone clearance is especially poor for lower-pole stones. In this regard mechanical percussion, diuresis and inversion therapy have been proposed to dislodge stones from their dependant position, and indeed, stone clearance rates were increased [56]. However, in clinical practice this concept was not adopted, as it requires a high degree of manpower, time and effort [57].

An interesting current concept is emergency ESWL; when ESWL was used in the first 6 h after the onset of renal colic (as long as ureteric peristalsis is not yet reduced due to obstruction) excellent stone-free rates were reported [58,59].

Re-treatments are often necessary. For kidney stones it is not advisable to repeat the treatment on consecutive days, whereas for ureteric stones such a schedule seems to be safe [27].

There is currently no consensus on the follow-up after ESWL, but silent ureteric obstruction has been reported, and apart from plain abdominal films, both CT or US should be used if there is any doubt [46].

ESWL in children

For urolithiasis in children ESWL shows excellent results and has therefore traditionally been the first-line treatment even for large stone burdens. This is because the paediatric ureter is shorter and more elastic, and therefore has a higher stone-transporting capacity, such that even staghorn calculi can be cleared after a few sessions, and in most cases stenting is unnecessary [60]. However, in the current EAU guidelines, PCNL is recommended for larger stones (>20 mm) and the same stratification criteria are applied as for adults [61].

Conclusion

Promising new technical developments are under development, with the potential to increase the stone-free rates of ESWL. For optimal results the refined indications need to be respected, and optimised treatment protocols should be applied.

Take home message

New developments in lithotripter design and technique are aiming to increase stone free rates and keep treatment safe and comfortable. The challenge for the urologist remains to respect the refined indications and apply the optimized treatment protocols.

Conflict of interest

None declared.

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