A comparative review of extracorporeal shock wave generation

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Summary

Shock waves are specific sound waves produced by shock-wave generators; the generators currently available have different physical properties and represent different technical solutions. The measurement of shock-wave pressure is necessary in laboratory settings to define the physical characteristics of a given shock-wave source. Under clinical conditions other variables, e.g. the stone-free rate or the percentage of complications, are used to describe the efficacy and safety of a lithotripter.

Introduction

Shock waves are sound waves and their behaviour in different media is described by the laws of acoustic physics. A shock wave consists of a initial sharp rise of positive pressure and an ensuing negative wave over the duration of their expansion (Fig. 1). In the medical context shock waves are generated extracorporeally and transmitted into the human body to disintegrate hard material, e.g. urinary or biliary tract calculi. Recently they have been used to specifically affect bone or neural tissue when orthopaedic disorders are treated, but initially they were used to treat urinary calculi [1]. Shock waves can be generated by different technical means and it is important that the clinician uses the shock waves which best serve the clinical need [2]. Different shock-wave generation systems can be compared using only physical data or by the clinical outcome after treatment of a representative and comparable cohort of patients with different lithotripters. However, published comparisons of lithotripters based on the outcome of treatment are relatively scarce, as most clinical institutions only have one lithotripter at any given time. The objective of this review is to assess recent publications for descriptions and comparisons of lithotripters.

Technical aspects

A lithotripter is constructed using various components, i.e. the shock-wave source, the shock-wave focusing element, the coupling device for shock waves and the calculus imaging unit [2]. All components are important in ensuring that stones are disintegrated successfully. This review concentrates on the shock wave source. Comparing technically different shock-wave sources from various companies has always been difficult. Recently there have been attempts to standardize the physical variables that are sufficient to describe shock-wave sources, independently of their technical mode of action [2].

Physical variables describing shock-wave sources

The International Electrical Conference devised a draft set of definitions to become the standard for shock-wave measurements. According to these standards the Technical Working Group of the German Society of Shock Wave Lithotripsy has generated a selection of useful variables to define a shock-wave source [3].

Peak positive pressure, $P^+$: During the time course of a single shock wave the pressure increases sharply at the beginning to reach its maximum, the pressure $P^+$ (Fig. 1). This value varies with the energy setting of the device and should be reported at the lowest, medium and highest energy level available. The maximum pressure point is called the focus, and is surrounded by a focal zone.

$6\,\text{dB zone}$: This is the zone around the focus, where half of the original $P^+$ is measured. The volume of this zone is defined by its extent along the $x$, $y$, and $z$ axes.

$5\,\text{MPa focal extent}$: In contrast to the above variables the $5\,\text{MPa}$ isobar, which was chosen arbitrarily and represents a low-pressure zone, which may or may not be a threshold for the medical effects of shock waves on living tissue.

$5\,\text{mm focal zone}$: For practical reasons related to location devices (X-ray or ultrasonography) the $5\,\text{mm}$ zone is defined as an additional zone of interest inside which the pressure is constant.

$\text{Shock-wave energy, } E$: The shock-wave energy (in millijoules) is defined as the time integral over the pressure-time function of a given shock wave. The shock-wave energy is required to be declared in a well defined area such as the focal areas mentioned above.

$\text{Energy flux density, } ED$: This is defined as a certain amount of energy passing through a defined area (given in $\text{mJ/mm}^2$; Fig. 2). This variable is used to describe the power of a given lithotripter or treatment arrangement, e.g. low-energy vs high-energy treatment strategies in orthopaedic shock-wave therapy.
Energy of the −6 dB focus, the 5 MPa focus, and the 5 mm focal area: From the definitions of the pressure zones given above, respective energy zones can be defined [3].

Measurement of shock-wave pressures

Beyond the technique of optical visualization of sound waves with high-speed cameras in two dimensions (Schlieren optical measurement), which is too slow, the most widely used instruments to measure shock-wave pressure are the so-called hydrophones. Essentially these are microphones that are used underwater to receive the sound waves of a given shock-wave source. To measure a pressure-field distribution, the hydrophone has to be moved around and repetitive measurements made. In particular the PVDF hydrophones are very sensitive and become worn during repeated measurements [4], but fibre-optic hydrophones are being used to measure shock-wave pressures. They measure the varying density of water during the time of passage of a shock-wave front [5]. As a surrogate, some researchers use human or artificial stones which are subjected to fragmentation by multiple shock waves in an in vitro system until they are completely disintegrated. The number of shock waves necessary for complete disintegration is then counted [6].

Principles of shock wave generation

Electrohydraulic source

This is the oldest principle used to generate shock waves, developed by the Dornier company (Germany) and built into the first lithotripter used clinically [1]. The discharge of an underwater spark-gap produces a gas bubble which expands with supersonic velocity, and the ensuing spherical shock wave is reflected by the wall of the surrounding metal semi-ellipsoid, thus concentrating the wave in the second elliptic focus. The focal zone is fairly large with high peak pressures. The spark gap becomes worn after a few thousand shock waves and needs to be replaced. The focal zone of a spark-gap lithotripter tends to migrate and is not very reproducible [2]. Coupling was ensured by the surrounding water in the original device, where the patient was submerged into a specially prepared water bath, whereas newer lithotripters have closed shock-wave applicators coupled locally to the patient’s body using an appropriate jelly.

Electromagnetic source

The first lithotripter with local coupling (the Siemens Lithostar) incorporated two new electromagnetic shock-wave systems on either side of the patient, who was placed supine on an ordinary X-ray table and locally coupled to the shock-wave source.

A metal membrane is layered on a spiral coil; as soon as high voltage is applied to the coil, the metal membrane is repelled, thus producing a shock wave advancing through the water in a parallel pattern. The energy is focused with an ‘acoustic lens’ system, which can be used for several hundred thousand shock waves with no need to replace the elements [7]. A variation used by another system is that the repelling membrane is formed as a cylinder and the sound waves are reflected by a surrounding parabolic reflector. This particular construction allows for an in-line ultrasonographic head for stone location [8]. In both systems the shock waves are very reproducible, with constant energy and focusing (Fig. 3).
Piezoceramic source

Several piezoceramic elements are mounted onto a spherical bowl, thus producing a self-focusing device. The elements send sound waves after being charged in parallel by a high-voltage current. The emitted energy of each element is fairly weak, reaching higher energies only at the focus, where all single waves are combined [9]. Piezoceramic shock-wave sources are also very reliable. The large aperture of the source allows for almost pain-free treatment because of the low pressures at the skin entry zone. The focal zone is fairly small and cigar-shaped.

Microexplosive source

The microexplosive source is mentioned only for historical interest: a small pellet of lead acid is exploded in the first focus of a semi-ellipsoid container, thus producing a shock wave. This in turn is then reflected by the surrounding wall to focus the waves towards the second focus of the ellipsoid [10]. However, this method has not gained acceptance and has been abandoned because of the risks of explosives.

In vitro comparison of different shock-wave sources

A variety of in vitro experiments have been conducted to compare different shock-wave sources. They include pressure measurements, destruction of plaster cubes and disintegration of artificial stones in a water bath. Different shock-wave sources create different holes in plaster cubes, with piezoceramic elements causing small and deep holes, electromagnetic shock-wave generators giving rectangular cone-shaped holes and electrohydraulic lithotripters wide and shallow craters. The volume loss of plaster cubes after exposure to an increasing number of shock waves was greatest with the electrohydraulic, medium with the electromagnetic and least with a piezoceramic generator [11]. In another simpler experiment, artificial stones are trapped in a net. Repeated shock waves produce small fragments which eventually fall through the mesh of the net; thereby, the total number of shock waves necessary to empty the net can be compared [6].

Clinical aspects

An obvious factor for clinical comparison is the stone-free rate after ESWL on different lithotripters, provided that comparable groups of patients have been treated and comparable treatment regimens imposed. There are few reports of clinical comparisons of lithotripters. Early publications compared the original Dornier HM3 lithotripter with other machines like the EDAP LT01 or Sonolith 2000 [12]. Rassweiler et al. [13] compared a modified HM3 lithotripter with a Piezolith 2200 device; while stone fragmentation was similar, the re-treatment rates were 12% with the HM3 and 54% with the piezoelectric device.

To better compare the clinical data an efficiency quotient was introduced, incorporating the stone-free rate, first treatment and re-treatment rates and the auxiliary measures required [14]. Based on this efficiency quotient, Bierkens et al. [15] compared the Siemens Lithostar, Dornier HM4, Wolf Piezolith 2300, Direx Tripter X-1 and Breakstone Lithotriptor in 1822 patients with 2206 treatments. The overall efficiency quotient was 31% for the Lithostar, 38% for the Dornier device, 28% for the Piezolith, 32% for Direx and 43% for the Breakstone lithotripter. In a different series the Siemens low-pressure and high-pressure (Siemens Lithostar system C) shock-wave sources were compared during the treatment of patients with ureteric calculi, assessing adjuvant procedures and stone clearance rate in relation to stone location. Interestingly there were no significant differences between the patient groups [16].
Variables used for clinical comparison

Provided that comparable groups of patients are examined, several clinical variables can be used for comparative studies. The ultimate variable is the true stone-free rate after a defined follow-up period; frequently 3 months is chosen as an adequate interval until final evaluation, as it is common clinical experience that clearance of fragments can be prolonged during that time. Somewhat more subjective is the patient with so-called ‘spontaneously passable fragments’ or ‘clinically insignificant residual fragments’; 10% of these patients are later found to have clinically significant fragments which require further active treatment [13]. The number of necessary retreatments is another factor used to describe the efficacy of a given lithotripter, and is incorporated into the efficiency quotient [14]. However, personal experience and patients’ requests may compromise the validity of this variable. Moreover, the number or percentage of auxiliary measures is the weakest variable, as it depends on pre-existing UTIs, their adequate antibiotic therapy, stone composition (e.g. struvite), the therapy given before ESWL (e.g. pigtail catheter), the subjective complaints of the patient, and the clinical assessment and activity level of the treating physician.

Altogether the clinical comparison of different lithotripters is a challenge to the physician. In the near future it may become more important to further define the optimal variables of shock-wave sources under which lithotripsy can be performed effectively and safely. Currently the initial evidence is only about how and why renal stones are disintegrated by extracorporeal shock waves [17,18].

Conclusions

A given lithotripter with a certain shock-wave source will have some inseparable advantages and disadvantages, e.g. anaesthesia-free treatment is linked with a limited capability for stone fragmentation. Intensive stone disintegration may be followed by greater temporary parenchymal changes. Given these factors further studies may allow better clinical management of lithotripters. When artificial stones are disintegrated at different rates of shock-wave delivery a frequency of 60 pulses/min seems to be the most effective, no matter what energy level is chosen. Higher rates (up to 120/min) are less effective [19]. Furthermore in vivo measurements have shown at least a 30% reduction of pressure inside the kidney compared with in vitro measurement of the same shock wave in water. The focus is also broader in the tissue than in vitro [20]. The increase in the energy level or discharge voltage of an unmodified Dornier HM3 shock-wave source leads to a substantial increase in acute laceration of functional parenchyma in animal experiments [21]. Therefore low-frequency application at 60 pulses/min with moderate energy should be used in the clinical setting. Financial aspects, the management of the clinic and the patients’ needs must also be considered when a lithotripter with a given shock-wave source is to be incorporated into the urological equipment for treating urolithiasis.

References

14 Clayman RV. Lithotripters new and old: which, why and how much? Abstract 538, 5th World Congress on ESWL and Endourology, Washington DC, 1990

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