

ECMUS SAFETY COMMITTEE - 4 OCTOBER 1993

GUIDELINES FOR THE SAFE USE OF EXTRACORPOREAL SHOCK-WAVE LITHOTRIPSY (ESWL) DEVICES

EJU 3 (1994) 315-316

Introduction

Lithotripsy devices are becoming increasingly popular for the fragmentation of solid concretions, such as kidney stones or gall stones in vivo. The stones are subjected to numerous pulses of sufficiently high acoustic pressure amplitude to produce fragments small enough to traverse the ureter or common bile duct, thus obviating the need for traumatic surgical intervention.

As with any other therapeutic procedure, the use of lithotripters is associated with the possibility of risk resulting from damage to tissues other than the stone or stones that are to be fragmented. It is therefore a matter of clinical judgement as to whether or not the potential adverse effects that may result from this additional damage outweigh the potential benefits to be gained by employing the lithotripsy technique as against surgical intervention or some other form of therapy.

The purpose of this guideline is to direct the attention of clinical users of lithotripsy devices towards means for reducing the amount of unnecessary damage, and to encourage them and bioeffect researchers to perform the epidemiological and in vivo studies that are needed to improve both the clinical efficacy and risk/benefit ratio of their procedures. It has been drawn up by the Radiation Safety Committee of the European Federation of Societies for Ultrasound in Medicine and Biology, and has been endorsed by the Board.

Specific Recommendations

1. As a general precaution, the embryo or fetus should not be exposed to lithotripter shock waves.
2. Avoid the use of lithotripters in patients who have been given intravascular gas bubble ultrasound contrast agents,

because the destructive effects of cavitation activity in soft tissues are likely to be increased.

3. The simultaneous exposure of the patient to acoustic energy and x-rays should be minimised, because the ionizing radiation may generate additional cavitation nuclei (Messino et al.1963). Similarly, a time interval equivalent to at least 7 half lives should elapse between the administration of a gammaemitting radionuclide for nuclear medicine imaging, and the exposure of the patient to lithotripter pulses.

4. Endeavour to use the minimum number of acoustic pulses needed to achieve satisfactory fragmentation.

5. The interpulse interval should be as long as is practicably possible because animal studies have shown that giving the same number of pulses at a higher pulse repetition frequency has increased the amount of soft tissue damage (Delius et al. 1990).

6. Lung tissue is particularly sensitive to damage by shock waves (Hartman et al.1990), and so its exposure should be avoided during gall stone lithotripsy.

7. A bag containing a fluid absorber should be coupled to the side of the body opposite the shock wave source, if the body is not immersed in a large water bath. This would reduce the magnitude of the reflected wave and should also reduce the amount of soft tissue damage at the reflection site.

8. Patients being exposed in a large water bath should have a thin sheet of an acoustically transparent plastic film coupled to the skin at the site of entry of the acoustic pulse, to reduce the incidence of petechial haemorrhages, resulting from the occurrence of cavitation activity at the skin surface.

9. The presence of an artificial hydrophobic interface (such as a plastic catheter) within a blood vessel apparently increases the probability of obtaining cavitation activity (Williams et al. 1989), and so these exposures should be avoided if possible.

General Recommendations

Extensive follow-up studies are needed over several years to identify possible long-term complications in patients who have undergone lithotripsy therapy. In particular, it is necessary to:

(a) Establish the time interval between lithotripsy therapy and the regrowth of stones and to determine the optimal retreatment procedures and their efficacy.

(b) Perform appropriate in vivo animal studies to identify the types and severity of soft tissue damage produced by lithotripters, and to determine how this damage is affected by extraneous factors that modify cavitation activity, such as the choice of anaesthetic agent or the presence of gas within the alimentary tract.

(c) Correlate the effects of changing the various physical parameters of the acoustic pulses (e.g., their waveform, peak positive and peak negative pressure amplitudes, their repetition frequency and the total number of pulses delivered), with both their efficacy in disrupting stones in vivo and with the amount of additional soft tissue damage that they also produce.

(d) Optimise the techniques for quantifying the dimensions of the stone fragments so that the treatment procedure may be terminated as soon as the acoustic pulses cease to produce beneficial effects.

(e) Optimise the intervals between successive checking procedures to confirm or reposition the stone at the focus of the shock pulse, bearing in mind the disadvantages of prolonging the treatment time, and possibly increasing the patient's exposure to x-rays vs. the advantages of not administering shock waves that miss the stone and only damage soft tissue.

2. Training courses for clinical users of these devices should be established, with facilities for the rapid communication of relevant new information concerning efficacy and safety to all users.

References

Delius, M.; Jordan, K.; Liebich, H.-G.; Brendel, W. Biological effects of shock waves. Effects of shock waves on the liver and gallbladder wall of dogs-administration rate dependence. *Ultrasound Med. Biol.* 16:459-466;1990.

Hartman, C.; Child, S. W.; Mayer, R.; Schenk, E.; Carstensen, E. L. Lung damage from exposure to the fields of an electrohydraulic lithotripter. *Ultrasound Med. Biol.* 16:675-679;1990.

Messino, D.; Sette, D.; Wanderlingh, F. Statistical approach to ultrasonic cavitation. *J. Acoust. Soc. Am.* 35:1575-1963; 1963.

Williams, A. R.; Delius, M.; Miller, D. L.; Schwarze, E. Investigation of cavitation in flowing media by lithotripter shock waves both in vivo and in vitro. *Ultrasound Med. Biol.* 15:53-60; 1989.