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The need for standards in Medical Ultrasonics

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Ultrasound in the frequency range 0.75 - 10 MHz now has a wide variety of uses in both diagnostic and therapeutic medicine. Pulse-echo techniques are used for example for investigations in obstetrics, cardiology, ophthalmology, and studies of the breast, abdomen and vasculature. Therapeutic ultrasound is used increasingly in physiotherapy departments, and is the subject of investigation for its potential use in cancer treatment. High intensity ultrasound is sometimes used for surgical and dental applications.

As a result of this growth in the clinical uses of ultrasound many more people are being exposed to its irradiation. In order to ensure safe usage, it is therefore important to know the intensities to which patients are subjected, and to understand the interaction between the ultrasonic beam and human tissue.

The way in which ultrasound interacts with tissues to produce biological changes is not fully understood. Until there is better knowledge of this interaction, it is essential that ultrasound exposures are kept to the minimum needed to obtain the required information or effect. It is likely that, as biological assays become more sensitive, ultrasonic exposure levels required to produce detectable biological changes will decrease. It is important, however, to keep these observations in perspective - not all biological changes constitute a hazard to the patient, and the benefit derived from any form of ultrasonic treatment should outweigh any risk presented by it.

The biology and biophysics of the interaction of ultrasound with tissue have been reviewed many times. (See, for example, refs 1-3). It is conventional to divide the biological effects produced into two categories, namely thermal effects and non-

thermal effects.

As an ultrasonic beam travels through tissue, the energy is attenuated. Some energy is scattered out of the main beam by structures within the tissue, and some energy is absorbed. The absorption of energy causes a temperature rise in tissue. It can be calculated that the rate of temperature rise in soft tissue such as liver, due to the passage of continuous wave ultrasound of frequency f MHz and intensity I Wcm^{-2} is given approximately by the expression .1If ^{o}C/sec. Thus, for a 1 MHz, 1 Wcm^{-2} continuous wave therapy beam, a temperature rise of 2.88^{o}C/min would be expected. This calculation ignores the effects of blood flow and heat conduction out of the heated area, and is thus an over-estimate. Higher temperatures may be achieved, however, if soft tissue overlying bone is irradiated.

In a diagnostic pulse echo machine, the spatial peak pulse average intensity may be as high as 160 Wcm^{-2}, taken over the 1 us duration of the pulse (See Table I). These values give a temperature rise of $1.9.10^{-6o}C$ at 1 MHz and $1.9.10^{-5o}C$ at 10 MHz. These temperatures are too low to produce significant biological changes.

Many of the non-thermal biological effects seen in "in vitro" biological experimental systems are due to cavitation. Acoustic cavitation is the term used to describe the growth and activity of highly compressible gas or vapour bodies in a medium. These bodies (bubbles) oscillate in response to the applied ultrasonic field. This bubble activity may result in stable or collapse (transient) cavitation. Bubbles of resonant size grow rapidly, undergo unstable oscillations and collapse violently over one or two acoustic cycles. High temperatures and pressures are found in the vicinity of the collapse, and highly localized damage is sometimes seen. Other bubbles in the field will undergo stable oscillations about an equilibrium diameter. Eddying motions are set up in the fluid surrounding the bubble. This acoustic microstreaming can be seen for example when gas spaces in plant tissue are irradiated. High velocity gradients, and therefore shear stresses, are created. This can lead to tissue damage. Acoustic streaming can also be seen in the absence of gas bubbles, where there is a significant acoustic mismatch at a liquid/solid boundary.

The question of whether or not cavitation can occur in tissues "in vivo" has been the subject of some debate. Recently bubble formation as the result of treatment with an ultrasonic therapy transducer has been demonstrated in experimental animals (4). The damaging potential of such bubbles is not known.

Other non-thermal effects of ultrasound are discussed in references (1-3).

As long as the biophysics, and particularly the basis for extrapolating from laboratory systems to man, remain poorly understood, it is impossible to make reliable predictions as to the ultrasonic intensities that will cause hazardous biological changes in tissue. It is therefore necessary to base recommendations and standards for treatment levels on observations in biological systems.

Ultrasonic exposure levels are usually characterized by the intensity of the beam (usually given in Watts cm^{-2}). Since a variety of intensities may be quoted, it is essential that the type of intensity being used is specified. It may be a peak value or an intensity averaged in space and/or time. The difference in magnitude between these values is illustrated in Table 1. Intensity determination is discussed elsewhere in this Symposium (6).

It is by no means obvious that the exposure parameter that is most important in determining the possibility of production of biological effect is intensity. It is the commonly chosen characteristic as it has been easily measurable. It may be that some other parameter, such as acoustic pressure or displacement amplitude may be more relevant. This requires some investigation.

Table 1

Maximum acoustic intensities quoted in the literature for different current diagnostic ultrasound systems (taken from ref. 5).

Type of Equipment	Spatial average temporal average intensity at radiating surface SATA	Spatial peak temporal average intensity SPTA	Spatial peak pulse average intensity SPPA
Static pulse-echo & M-mode equipment	20 $mWcm^{-2}$	200 $mWcm^{-2}$	160 Wcm^{-2}
Automatic sector scanners -phased arrays & wobblers	60 $mWcm^{-2}$	200 $mWcm^{-2}$	75 Wcm^{-2}
Sequenced linear arrays	10 $mWcm^{-2}$	12 $mWcm^{-2}$	69 Wcm^{-2}
Pulsed Doppler (cardiac)	32 $mWcm^{-2}$	290 $mWcm^{-2}$	14 Wcm^{-2}
Obstetric Doppler	25 $mWcm^{-2}$	Spatial peak (SPD) 75 $mWcm^{-2}$	
C.W. Doppler	400 $mWcm^{-2}$	800 $mWcm^{-2}$	

Many attempts have been made to make statements as to ultrasonic intensity levels that may be regarded as completely without "hazard" to the patient. This is an impossible task at present due to the lack of data on biological effects produced by ultrasonic irradiation of humans "in vivo". It is true, however, that to date, there has been no indication that the extensive diagnostic and therapeutic use of medical ultrasound has led to any harmful side effects. It is important, however, that ultrasonic exposures are kept to the minimum level that still allows the clinician to use ultrasound to its best advantage.

The bodies involved in producing recommendations and standards for medical ultrasonic equipment at present are the International Electrotechnical Commission (IEC), the American Institute of Ultrasound in Medicine (AIUM), the National Electrical Manufacturers Association (NEMA) and the Food and Drug Administration of the United States (FDA).

The IEC interest in medical ultrasonics is covered by two committees: Committee 62 (Safety of electrical equipment) and Committee 29 (Electro-acoustics). The ultrasonics sub-committee (29D) has a working group (29D-4) concerned specifically with ultrasonic medical equipment. This group has drafted two documents so far which may shortly be published. These are:

i. Methods of measuring the Performance of ultrasonic pulse echo diagnostic equipment (ref.7).

ii. The characteristics and calibration of hydrophones for operation in the range 0.5 MHz to 15 MHz (in draft).

It was recently agreed that new working groups should be set up to look at:

i. Radiation force calibration methods.

ii. Performance of Doppler diagnostic systems.

iii. Focussed transducer systems.

iv. Surgical and dental ultrasound.

The IEC Recommendation Publication 150 (1963) "Testing and Calibration of ultrasonic therapy equipment" will also be revised.

Apart from these standards developed by the IEC, AIUM and NEMA have together produced a draft document "AIUM-NEMA safety standard for diagnostic ultrasound equipment". (Dec. 1979, draft IV). Also, the FDA is putting together a performance standard for diagnostic machines. This is in response to a Notice of Intent that it "may develop recommendations or mandatory performance standards related to diagnostic ultrasound equipment or may require manufacturers to supply purchasers with performance data or other information related to safety". (Feb. 1979).

In order to encourage manufacturers to supply technical data about their equipment, the AIUM has a Commendation scheme such that Certificates of Commendation are issued to manufacturers who supply quantitative information concerning electrical and acoustical characteristics of their diagnostic equipment. Unfortunately, the way in which these characteristics should be measured is incompletely specified. In the first year of the scheme, only one manufacturer qualified for the certificate.

Two groups, the AIUM Bio-effects Committee, and the European Committee for Ultrasound Radiation Safety, have been formed. These

groups are concerned with providing informed comment on reports of ultrasonically induced hazard. Groups such as these should provide the information necessary to draw up realistic guidelines and recommendations for safety standards. Thus, although the process of drawing up standards is still in its infancy, there is an increasing awareness for the need to control the performance of both diagnostic and therapeutic ultrasound equipment. Although there is at present no plan to produce legislation on this topic in Europe, the United States is discussing whether this will be necessary.

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