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BIOPHYSICAL APPROACH TO THE PROBLEM OF SAFETY OF DIAGNOSTIC ULTRASOUND

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Every application of the ultrasonic technique in medical diagnostics involves the deposition of energy in tissues which can lead to some biological effects. The dependence of biological effects on physical characteristics of the ultrasonic field is often nonlinear. On the one hand, most of the mechanical factors of ultrasound are nonlinearly related to both the intensity and the frequency. On the other hand, the metabolic and regulatory processes of a given biological subject cause its nonlinear response to ultrasonic action. The nonlinearity increases with increasingly higher level of biological organisation. The biophysical approach to the problem of safety of diagnostic ultrasound consists in detailed assessment of relations between the acting ultrasonic impulse and the registered alteration of the biological system.

1. Introduction

Possible biological effects must be taken into account in each examining method when diagnostic information is conditioned by the emission of a certain amount of energy into a tissue studied. The situation is the same in all ultrasound diagnostic methods, extensive development of which needs the elaboration of obligatory recommendations that could either eliminate or reduce their risk to examined persons to a minimum.

The whole sphere of ultrasound examining methods belongs among the so-called passive interactions of ultrasound with living objects. They are called passive, because their aim is to provide information on the properties of a living environment by means of analysing ultrasound signal which came through this environment without provoking changes of the given medium by acoustic energy transferred by the signal. The essential constant characterizing the energy of ultrasound wave is its intensity (acoustic specific output).

To accomplish the condition of passive interaction, the intensity of ultrasound signal must be of sub-threshold value for the considered living system from the view of biological effectiveness. This condition mentioned above, however, makes the accurate establishment of biologically effective intensity very difficult. The causes are partly physical, partly biological.

2. Methods of expressing ultrasound intensity

Physical problems are connected with the expression of intensity and with methods of its accurate establishment. The expression of intensity depends on the character of ultrasound transducer and on the method of its exciting. Piezo-electrical transducers in the form of plates are used nearly exclusively in medical application. These transducers oscillate similarly to a piston, that is in an ideal case all points of their surface oscillate both with the same amplitude and the same phase. In fact, that is not the case and the emanating diagram of a piston-like oscillating transducer always shows, besides the central maximum, a few smaller side lobes and is not, in most cases, quite symmetrical rotarily. The consequence of this oscillation is then the disproportion between the central maximum intensity and the average spatial intensity of the whole transducer, which can vary from 1.5 to 3.6 in non-focused transducers. As the central maximum intensity of a transducer is decisive for the consideration of biological effectiveness, the average intensity, measured for example radiometrically, must be multiplied by this number.

To obtain diagnostic information, ultrasound is irradiated into tissues in the form of continuous harmonic waves (continuous Doppler systems) or in the form of short impulses (10^{-6}-10^{-5}s) with repetition frequency of 1.5-2.5 kHz. Intensity in continuous operations is given either as spatial average — SA or spatial peak — SP. Not only spatial but also time distribution of irradiated energy must be taken into account in pulsed reflection image-forming methods or in pulsed Doppler systems. Therefore, intensity can be expressed as spatial peak-temporal peak, SPTP, spatial peak-temporal average, SPTA, spatial average-temporal peak, SATP, and spatial average-temporal average, SATA. As the ultrasound pulses are not always of the exact rectangular form, another two terms have been used recently for the expression of intensity in pulsed mode: spatial average-pulse average, SAPA, which is the average intensity of pulse applied to the total cross-section of ultrasound beam. Spatial peak pulse average, SPPA, is the average intensity of pulse in the place of its maximum value.

Spatial average-temporal average, SATA, is most easily measurable and the most frequently given value. However, it is of limited importance for the appreciation of biological effectiveness. Here are of greater use the SPTA value determining the heat production by absorption in time dependence and the SPTP value which is the expression of the maximum mechanical energy in a given place of the field at a given time moment.

Frequency is another important constant for appreciating biological effects. The dependence of absorption phenomena on the basic frequency of ultrasound source is well known. In pulsed operations biological effectiveness is also influenced by the repetition frequency of ultrasound impulses.

3. Problems with determining the threshold of biological effectiveness

Biological problems connected with determining a biologically effective threshold must therefore be judged from a few aspects. First, we must take into account the fact that most living organisms, including man, have neither specific receptors for ultrasound energy nor specific regulatory mechanisms. Thus, from this point of view, the reaction of a living organism is non-specific and the threshold of biological effectiveness is conditioned by dissimilar sensitivity of tissue cells to ultrasound. Therefore, the relation between the biological effect and the physical properties of ultrasound field is often non-linear. The microstructure and macrostructure of the tissue through which ultrasound passes is another important factor. This causes various ultrasound suppression and qualifies the development of interference phenomena, thus deepening the process non-linearity.

Ultrasound interactions with biological objects were studied on various levels of biological arrangement under various experimental conditions. Fundamental mechanisms of the biological effect can be analysed more easily on isolated cells and cultures. On higher levels (in tissues and organs, in the whole organism) there gets into action a complex system of feedbacks and compensation mechanisms that superimpose and modify the primary effect.

4. Are the recommended safety criteria respected by manufacturers of ultrasound diagnostic devices?

In 1976 efforts to establish the safety criteria in ultrasound investigation methods led the American Institute for Ultrasound in Medicine (AIUM) to state its stance. It was, after small modifications, accepted by the working group of the World Health Organization in the same year. The value of 1 kWm^{-2} expressed as SPTA was recommended as the limit of biologically effective intensity in vivo and the value of $5 \cdot 10^5$ Jm^{-2} as the limit of biologically effective exposition within 1-500 s. Both of these limit values were formulated on the basis of appreciating all accessible data on biological effects of ultrasound within 0.5-10 MHz frequencies.

Comparison of average and peak intensity values emitted by various ultrasound diagnostic devices was performed from the angle of the recommended limits. This comparison is given in Table 1. The large intensity range found results, on the one hand, from a wide choice of diagnostic devices manufactured recently, on the other hand, it is conditioned by various measuring techniques used and their unequal accuracy.

Table 1. Ultrasound intensities emitted by diagnostic systems

Type of device	Emitted intensity [Wm^{-2}] SATA	Emitted intensity [Wm^{-2}] SPTA
Static $A-$ and $B-$mode scanners, $M-$mode instruments	4 – 200	100 – 2000
Dynamic $B-$mode scanners, sector	27 – 600	450 – 2000
Dynamic $B-$mode scanners, linear	0.6 – 100	1 – 120
Pulsed Doppler systems	30 – 320	300 – 2900
Continuous wave Doppler systems for obstetrics	30 – 250	90 – 750
Continuous wave Doppler systems for angiology	380 – 8400	1100 – 25000

The underlined values are higher than the recommended limit.

It follows from Table 1 that with the exception of fetal detectors and devices using linear probes for dynamic scanning, there exist in all the other groups devices whose SPTA intensity is higher than the recommended level of SPTA (1000 Wm^{-2}).

5. Relation of biological effectiveness and risk of ultrasound application

Intensive research of the biological effectiveness of very low ultrasound intensities performed recently has, however, shown the possibility of influencing sensitive biological objects at intensities lower than the recommended level of biological safety. This was the matter of changes in some morphological and functional properties proved in isolated cells and tissue cultures. Direct interpretation of these experimental findings is indisputably very difficult for clinical diagnostic application, first of all because the term of biological effectiveness is not a synonym for risk. On the other hand, up to now we have not had sufficient knowledge on the possible cummulative effect of small doses of ultrasound energy in biological systems generally and in man particularly.

Difficulties connected with the formulation of obligatory technical and physical standards for the operation of ultrasound diagnostic devices from the view of their biological effectiveness follow from the statement mentioned above. Ultrasound diagnosis is a complex of methods with dynamic development, where the optimum level of emitted intensity is a compromise between the effort for maximum differentiating abilities on the one hand and the maximum sensitivity of the device on the other hand.

Respecting the value of 1 kWm^{-2} as the recommended peak limit of emitted intensity for diagnostic systems, the manufacturers of these systems must aim at achieving the best quality picture of tissue examined at acoustic performance as low as possible. The examination itself must not exceed the time necessary for obtaining required diagnostic information.

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