

ALARA - PRINCIPLE AND SAFETY PROBLEMS OF DIAGNOSTIC ULTRASOUND

HLINOMAZOVÁ Z.¹, HRAZDIRA I.²

¹Department of Ophthalmology, University Hospital Brno-Bohunice,
Faculty of Medicine, Masaryk University, Brno

²Department of Imaging Methods St. Anna University Hospital
Faculty of Medicine, Masaryk University, Brno

Received after revision November 2005

Abstract

The question of the safety of diagnostic ultrasound has been continually discussed as the manufacturers are producing technically sophisticated devices that provide more diagnostic information, often at the cost of higher acoustic output. Currently, an output display standard has been introduced, comprising two indices: thermal and mechanical. These indices indicate the potential of thermal and non-thermal bioeffects. Practicing the ALARA principle ensures that the total ultrasound energy is maintained below a level at which bioeffects are generated while diagnostic information is preserved. This is mainly valuable for applications of ultrasound methods in ophthalmologic diagnostics regarding the high sensitivity of eye tissues to ultrasound. However, not all examinations can be performed at such an extremely low level of acoustic energy because of low quality images or an insufficient Doppler signal. Implementation of ALARA enables obtaining the information needed while keeping the potential for bioeffects as low as reasonably achievable.

Key words

Diagnostic ultrasound, Bioeffects, Alara, Safety indices

INTRODUCTION

“Ultrasound is the safest of the main medical imaging modalities” declared *Francis A. Duck*, president of the European Committee for Medical Ultrasound Safety, in his EUROSON lecture, given at the EUROSON Congress 2002 in Warsaw.

Taking into account this declaration the question arises, why is it necessary to discuss the problem of safety? There are at least two reasons to do that.

1) All diagnostic methods based on interactions of physical energy with biological tissues are associated with potential risks for patients.

2) There is a continuous trend in the growth of output parameters of ultrasound diagnostic machines, especially in the last 20 years. Technical development, aimed at improving image quality and Doppler performance, has been responsible for this growth, which is especially dramatic in the spectral Doppler (*Fig. 1*).

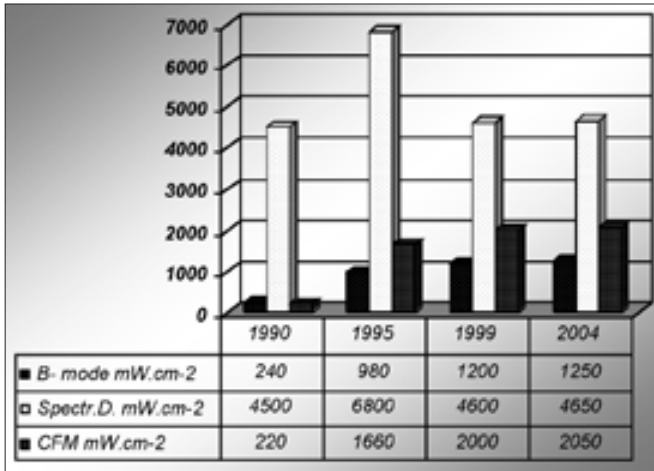


Fig. 1.

Max. values of I_{spta} (mW/cm^2) in B- mode, spectral Doppler, and CFM over the last 25 years (6,9)

In ultrasonography it is usual to distinguish two risk categories:

- Biological risks - based on biological effects of ultrasound.
- Non-biological risks - based on incorrect interpretation of ultrasound images.

The present paper aims at contributing to better understanding of the basic bioeffect mechanisms and practical application of safety indices.

Biological risks

When the ultrasonic wave propagates through human tissue, there is a potential risk for tissue damage. Two main mechanisms are known to alter biological systems: thermal and non-thermal. The **thermal mechanism** refers to heating of tissues due to absorption of acoustic energy in tissues and its transformation into heat. In contrast to the non-thermal effects of ultrasound heat is considered as a potential teratogenic factor (1,5,8).

Risk levels due to heating of tissues are represented in *Table 1*.

Table 1

Thermal threshold	Temperature (°C)
Physiological level	37.0
	<i>safe region</i>
Embryonic tissues	39.5
	<i>risks for obstetrics and paediatrics</i>
Adult tissues	41.0
	<i>general risks</i>

Factors that improve heating: higher ultrasound intensity, longer exposure time, higher frequency, higher absorption, higher thermal conductivity, lower perfusion.

The **non-thermal mechanism** involves the mechanical phenomena of ultrasonic action, mainly cavitation, i.e. production, oscillation, and collapse of gas-filled bubbles. This mechanism is responsible for the possible mechanical damage to biological structures (1,10).

Factors that improve cavitation: higher negative amplitude of acoustic pressure, lower frequency, longer duration of acoustic impulses, higher repetition frequency, lower viscosity.

In general, biological risks depend on:

- Physical characteristics of the ultrasound wave (mode, intensity, frequency)
- Sensitivity of the tissue examined to ultrasonic action (size, structure, attenuation).

For the assessment of possible biological risks there exist three main approaches (5).

- **Theoretical approach** is based on production of simplified models of biological systems and calculation of physical parameters responsible for biological effects

- **Experimental approach** comprises investigation of the experimental influence of biomedical ultrasound on different levels of biological organisation (biomolecules, cells and tissues, whole organisms).

- **Epidemiological approach** comprises retrospective and prospective studies of ultrasound diagnostic exposures on human population, especially during pregnancy. This approach has major importance for safety assessment.

Safety indices

In 1976, the FDA in the U.S.A. established limits to the average acoustic intensity level (I_{sata}) for diagnostic ultrasound equipment (Track 1) - *Table 2*.

Table 2

Application	I_{sata} (mW/cm ²)
eyes	17
foetal	94
cardio	430
other	720

Later, in 1993, the FDA established new regulations for assessment of possible risks due to heating and cavitation in machines with an acoustic intensity of 720mW/cm² (Track 3). In these machines two indices have to be displayed on the screen:

- thermal index
- mechanical index

Thermal index (TI) represents the ratio of total acoustic power to the acoustic power required raising the tissue temperature by 1 °C under the worst conditions of heat transfer.

Critical values:

For applications in ophthalmology $TI > 0.2$

For all other applications $TI > 4$

Thermal indices correspond to the different mechanism of heat production (combination of soft tissue and bone in the area of interest)

- TIS - soft tissue thermal index
- TIB - foetal bone thermal index
- TIC - cranial bone thermal index

Mechanical index (MI) estimates the potential for mechanical effects, like cavitation. It may be calculated using the spatial peak value of the rarefactional pressure P_{-3} , derated by 0.3 dB/cm/MHz at each point along the beam axis, divided by the square root of the centre frequency f_c :

$$M = \frac{P_{-3}}{\sqrt{f_c}}$$

Critical values:

Ophthalmology $MI > 0.23$

All other applications $MI > 1.9$

The value of the mechanical index determines the prudent use of ultrasound contrast agents. These agents in conjunction with specific imaging techniques are increasingly accepted in clinical ultrasonography. Users should balance the potential benefit from the use of ultrasound contrast agents against the theoretical possibility of associated adverse effects (3).

Implementation of ALARA

ALARA (As low as reasonably achievable) represents a general principle of prudent use of all diagnostic methods based on interaction of physical energy with biological tissues.

The prudent use of ultrasound diagnostics is influenced by many factors. To achieve ALARA, a thorough knowledge of the imaging mode, transducer capabilities, system set-up, and operator scanning techniques is needed (4, 7).

In a soft tissue examination (TIS) the maximum heating is usually close to the surface region examined.

Modifying factors:

- Capillary perfusion (high perfusion reduces thermal effects)
- Body size (increasing body size reduces thermal effects)

TIB is the relevant index for scanning the bone near the focus (obstetrics, 2nd and 3rd trimesters).

Maximum heating will occur at the location of the bone.

Modifying factors:

- Type of overlying tissue (soft tissue, fluid)
- Exposure time

TIC is the appropriate index for transcranial examination. An important factor is the presence of the bone near the surface.

- To reduce the TIC reading, consider scanning through a thinner part of the skull, so that a lower output setting can be used.

The risks of mechanical impairment (MI) can be reduced by correct selection of:

- Appropriate transducer type
- Ultrasonic frequency
- Focal zone
- Receiver gain

How to minimise the potential risks?

- Select transducer of appropriate type and frequency.
- Adjust the output power at the lowest possible setting to produce an image.
- Adjust the focus to the area of interest.
- Increase the receiver gain to produce a uniform representation of the tissue.
- Only after making these adjustments should the output level be increased.

Influence of system mode.

- The choice of B-mode, M-mode, or Doppler greatly affects the energy absorbed by the tissue.

- If the beam is moving, then each targeted tissue volume experiences the beam only for a fraction of the time in comparison with the stationary beam, typical of Doppler measurement. By examining eyes using an ultrasound machine for general use, both thermal and mechanical indices must be set at lowest values to avoid possible spurious effects.

Safety aspects of Doppler methods

Safety indices monitor only the acoustic output necessary for production of grey-scale images. For the prudent use of Doppler measurements it is necessary to respect the following steps:

- Set the Doppler output at the lowest level to produce a clear signal.
- Adjust the velocity scale.
- Increase the receiver gain to get a good diagnostic signal.

Due to a high intensity level in the sample volume, caution must be taken in applying the spectral Doppler in obstetrics during the 2nd and 3rd trimesters (2). Application of echo enhancing agents in obstetrics and in ophthalmology is not recommended.

CONCLUSIONS

The introduction of safety indices tends to relax limits on the acoustic output and transfers the responsibility for a safe examination from the manufacturer to the examiner. The examiner should be familiar with the possible risk factors and their efficiency. The examiner has to adjust the acoustic output personally to obtain a good image, taking into account the clinical state of the patient.

Hlinomazová Z., Hrazdira I.

PRINCIP ALARA A BEZPEČNOSTNÍ PROBLÉMY DIAGNOSTICKÉHO ULTRAZVUKU

S o u h r n

Otázka bezpečnosti diagnostického ultrazvuku je trvale diskutována, protože průmysl přináší na trh stále sofistikovanější přístroje, poskytující sice více diagnostických informací, často však za cenu vyššího akustického výkonu. V současnosti je zaváděn standard zobrazení výkonu, který zahrnuje dva bezpečnostní indexy – tepelný a mechanický. Tyto indexy jsou indikátorem tepelných a netepelných biologických účinků. Použití principu opatrnosti ALARA zajišťuje, že celková energie aplikovaného ultrazvuku je udržována pod hladinou vzniku biologických účinků, zatím co diagnostická informace zůstává zachována. Platí to především pro použití ultrazvukových metod v oftalmologické diagnostice vzhledem k citlivosti očních tkání k účinkům ultrazvuku. Extrémně nízká hladina akustické energie však může mít za následek špatnou kvalitu obrazu nebo nedostatečnou úroveň dopplerovského signálu. Uplatnění principu ALARA tak umožňuje získat požadovanou informaci a při tom udržovat možnost vzniku biologických účinků na co nejnižší úrovni.

REFERENCES

1. *Barnett SB, Rott H-D, ter Haar GR, Ziskin MC, Maeda K.* The sensitivity of biological tissue to ultrasound. *Ultrasound Med Biol* 1997; 23: 805–812.
2. *Doležal L.* Stručný přehled fyzikální a technické problematiky sonografie [Brief survey of physical and technical problems of sonography]. In: *Doležal L, ed. Základy sonografie v porodnictví a gynekologii.* Univerzita Palackého Olomouc 1998, pp. 13–44.
3. EFSUMB Study Group: Guidelines for the use of contrast agents in ultrasound. *Ultraschall in Med* 2004; 25: 249–256.
4. Guidelines for the safe use of diagnostic ultrasound equipment. *British Medical Ultrasound Society Bulletin*, August 2000, pp. 29–33.
5. *Hrazdira I.* Expoziční parametry a možná rizika moderních ultrazvukových diagnostických metod [Exposure parameters and possible risks of modern ultrasound diagnostic methods]. *Lékař a technika* 1993; 24: 5–7.
6. *Hrazdira I.* Stručné repetitorium ultrasonografie [Brief compendium of ultrasonography]. Audioscan, Praha, 2003.
7. *Medical ultrasound safety.* AIUM Publication, Laurel, MD, USA 1994.
8. *O'Brien WD.* Evaluation of the unscanned soft-tissue thermal index. *IEEE Trans Ultrason Ferroelect Freq Contr* 1999; 46: 1459–1476.
9. *Whittingham TA.* Acoustic outputs of diagnostic machines. In: *G ter Haar, FA. Duck (eds).* Safety of Medical Diagnostic Ultrasound. *British Institute of Radiology*, 2000: 16–31.
10. *Ziskin MC, Barnett SB.* Ultrasound and the developing central nervous system. *Ultrasound Med Biol* 2001; 27: 875–876.