

Doppler in Obstetrics: book by K Nicolaidis, G Rizzo, K Hecher

Chapter on safety of diagnostic ultrasound in fetal scanning by Colin Deane

INTRODUCTION

Diagnostic ultrasound is generally perceived by users and patients as a safe technique with no adverse effects. Since ultrasound is so widely used in pregnancy, it is essential for all practitioners to ensure that its use remains safe. Ultrasound causes thermal and mechanical effects in tissue which are increased as the output power is increased.

In the last 20 years there has been a general trend towards increased output with the introduction of color flow imaging, more use of pulsed 'spectral Doppler' and higher demands on B-mode imaging. In response to these increases, recommendations for the safe use of ultrasound have been issued by several bodies. In addition, regulations have changed the emphasis of responsibility so that more onus is now placed on the operator to ensure that ultrasound is used safely. This chapter summarizes the effects and the standards issued and outlines recommendations for safe use in obstetric practice.

EFFECTS

Ultrasound is a mechanical energy in which a pressure wave travels through tissue. Reflection and scattering back to the transducer are used to form the image. The physical effects of ultrasound are generally categorized as:

- Thermal effects - heating of tissue as ultrasound is absorbed by tissue. Heat is also produced at the transducer surface;
- Cavitation - the formation of gas bubbles at high negative pressure;
- Other mechanical effects - radiation forces leading to streaming in fluids and stress at tissue interfaces.

The implications of these effects have been determined by in vitro, animal and human epidemiological studies and are briefly summarized below.

Thermal effects

As the ultrasound waves are absorbed, their energy is converted into heat. The level of conversion is highest in tissue with a high absorption coefficient, particularly in bone, and is low where there is little absorption, such as amniotic fluid. The temperature rise is also dependent on the thermal

characteristics of the tissue (conduction of heat and perfusion), the ultrasound intensity and the length of time for which the tissue volume is scanned. The intensity is, in turn, dependent on the power output and the position of the tissue in the beam profile. The intensity at a particular point is altered by many of the operator controls, for example power output, mode (B-mode, color flow, spectral Doppler), scan depth, focus, zoom and area of color flow imaging. With so many variables, it has proved difficult to model temperature rises in tissue. In vitro studies have been used with a 'worst case' model of tissue to predict temperature rises. The transducer face itself can become heated during an examination. Heat is localized to the tissue in contact with the transducer.

Cavitation

Cavitation is the formation of transient or stable bubbles, described as inertial or non-inertial cavitation. Inertial cavitation has the most potential to damage tissue and occurs when a gas-filled cavity grows, during pressure rarefaction of the ultrasound pulse, and contracts, during the compression phase. Collapse of the bubble can generate local high temperatures and pressures. It has been hypothesized that ultrasonically induced cavitation is the cause of hemorrhage in the lungs and intestines in animal studies. In these studies, effects have been seen at tissue interfaces with gas. The absence of gas in fetuses means that the threshold for cavitation is high and does not occur at current levels of diagnostic ultrasound. The introduction of contrast agents leads to the formation of microbubbles that potentially provide gas nuclei for cavitation. The use of contrast agents lowers the threshold at which cavitation occurs, but this is not current practice in obstetrics.

Other mechanical effects

The passage of ultrasound through tissue causes a low-level radiation force on the tissue. This force produces a pressure in the direction of the beam and away from the transducer and should not be confused with the oscillatory pressure of the ultrasound itself. The pressure that results and the pressure gradient across the beam are very low, even for intensities at the higher end of the diagnostic range. The effect of the force is manifest in volumes of fluid where streaming can occur with motion within the fluid. The fluid velocities which result are low and are unlikely to cause damage.

Effects on fetuses

The primary concern in fetal imaging is temperature rise. It is known that hyperthermia is teratogenic. The efforts of investigators have concentrated on defining the temperature increases and exposure times which may give rise to biological effects and on determining the ultrasound levels which might, in turn, lead to those temperature rises. With this information, criteria have been identified for the safe use of diagnostic ultrasound.

Temperature rises of 2.5°C have been demonstrated in excised non-perfused guinea pig brain tissue after 2 minutes' exposure to ultrasound at the high end of pulsed wave Doppler ultrasound intensity levels. At the bone surface, temperature increases of up to 5°C were found. In a study on sheep using different intensity criteria, the temperature rise in utero was found to be 40% lower than that in the equivalent non-perfused test. While the observed temperature increases occurred in high-intensity modes (typical of pulsed wave Doppler used at maximum power), these levels of intensity are achievable with some current scanner / transducer combinations. The issue of sensitivity of fetal tissue to temperature rise is complex and is not completely understood. Acute and

chronic temperature rises have been investigated in animals, but study designs and results are varied.

The uncertainty over chronic changes is reflected in the WFUMB guidelines.¹ These state that ultrasound that produces temperature rises of less than 1.5°C may be used without reservation. They also state that ultrasound exposure causing temperature rises of greater than 4°C for over 5 min should be considered potentially hazardous. This leaves a wide range of temperature increases which are within the capability of diagnostic ultrasound equipment to produce and for which no time limits are recommended.

Epidemiology

Several studies have examined the development of fetuses receiving different levels of ultrasound investigation. In trials comparing ultrasound screened and non-screened groups, there has generally been no difference in birth weights between groups. There have been no unequivocal data to suggest that there is impaired development of hearing, vision, behavior or neurological function due to ultrasound screening. In a large, randomized trial of over 3200 pregnant women in which half were offered routine ultrasonography at 19 and 32 weeks, there was no evidence of impaired growth or neurological development up to follow-up at 8-9 years. There was a possible association of left-handedness amongst boys undergoing ultrasonography.² Scanning of this group was performed with B-mode only. There have been concerns that epidemiological studies to date do not reflect the higher output capabilities of modern scanners.

OUTPUT REGULATIONS, STANDARDS AND GUIDELINES - WHO DOES WHAT?

Regulations governing the output of diagnostic ultrasound have been set by the USA's Food and Drug Administration (FDA), the International Electrotechnical Commission (IEC), the Federation of Societies of Ultrasound in Medicine and Biology (EFSUMB) and the World Federation (WFUMB).

Past regulations

The initial FDA regulations on ultrasound output were produced in 1976. These imposed application-specific limits, based on existing output levels which had demonstrated no adverse effects. For spatial peak time-averaged intensity (I-SPTA) (the measure most associated with temperature rise), the maximum levels were:

- 17 mW / cm² for ophthalmic applications;
- 94 mW / cm² for fetal and other (including abdominal, pediatric, small parts);
- 430 mW / cm² for cardiac
- 720 mW / cm² for peripheral vessels

Scanners typically had a key / button which limited output for obstetric applications. Although power and intensity limits could be exceeded in some scanners, especially when using pulsed wave Doppler or color Doppler, this required a deliberate effort on the behalf of the users.

Current regulations

In revising its regulations in 1993, the FDA altered its approach to ultrasound safety. The new regulations combine an overall limit of I-SPTA of 720 mW / cm^2 for all equipment with a system of output displays to allow users to employ effective and judicious levels of ultrasound appropriate to the examination undertaken. The new regulations allow an eight-fold increase in ultrasound intensity to be used in fetal examinations. They place considerably more responsibility on the user to understand the output measurements and to use them in their scanning. The output display is based on two indices, the mechanical index and the thermal index.

Mechanical index

The mechanical index is an estimate of the maximum amplitude of the pressure pulse in tissue. It gives an indication as to the relative risk of mechanical effects (streaming and cavitation). The FDA regulations allow a mechanical index of up to 1.9 to be used for all applications except ophthalmic (maximum 0.23).

Thermal index

The thermal index is the ratio of the power used to that required to cause a maximum temperature increase of 1°C . A thermal index of 1 indicates a power causing a temperature increase of 1°C . A thermal index of 2 would be twice that power but would not necessarily indicate a peak temperature rise of 2°C . Because temperature rise is dependent on tissue type and is particularly dependent on the presence of bone, the thermal index is subdivided into three indices:

- Thermal index for soft tissue;
- Thermal index with bone at/near the focus;
- Thermal index with bone at the surface (e.g. cranial examination).

For fetal scanning, the highest temperature increase would be expected to occur at bone and TIB would give the 'worst case' conditions. The mechanical index and thermal index must be displayed if the ultrasound system is capable of exceeding an index of 1. The displayed indices are based on the manufacturer's experimental and modeled data. These measurements are not infallible; an independent study has demonstrated significant discrepancies over declared I-SPTA output of up to 400%.⁵

Guidelines

Ultrasound organizations (WFUMB and AIUM) have produced statements on the safe use of ultrasound. These are not regulatory statements but are intended to educate and advise. The European Committee for Ultrasound Radiation Safety has published statements on the use of pulsed Doppler measurement in fetuses, stating that its use in routine examinations during the period of organogenesis is considered inadvisable at present.

A PRACTICAL APPROACH TO SAFE FETAL SCANNING

No injurious effects have been identified from ultrasound scanning of the fetus. However, changes in power output, increased use of Doppler ultrasound and a change in regulations governing outputs means that every measure should be taken by users to maintain safe practices.

Scanning practice

The ALARA ("As Low As Reasonably Achievable") principle should be maintained. Power outputs used should be adequate to conduct the examination. If in doubt, use a low power and increase it as necessary. Application keys for obstetrics should bring in each mode at its lowest output so that the operator is required to increase power if the examination demands it.

B-mode generally has the lowest power output and intensity. M-mode, color flow and spectral Doppler have higher outputs which can cause more heating at the site of examination. The examination should begin with B-mode and use color and spectral Doppler only when necessary.

The intensity (and temperature rise) is highly dependent on scanner settings. For example, the intensity changes in response to changes in:

- Power Output,
- Depth of examination,
- Mode used (color flow, spectral Doppler),
- Transmitted frequency used,
- Color pulse repetition frequency (scale),
- Region of color flow interest,
- Focus.

If the display for the scanner/transducer combination shows thermal and mechanical indices, the indices should be readily visible. Of the thermal indices, TIB is most relevant to heating in the second and third trimesters. The operator should be aware of changes to the indices in response to changes in control settings.

Special care should be taken in febrile patients, since ultrasound heating will cause additional heating to the fetus.

The WFUMB recommends that ultrasound causing a temperature rise of no more than 1.5°C may be used without reservation on thermal grounds.

Thermal indices exceeding 1.5 should not be used routinely and, if required for specific diagnostic information, should be used for the minimum time necessary. The influence of higher intensity levels can be moderated by moving the transducer so that specific areas of tissue are not subjected to long periods of higher intensity investigation.

Do not scan for longer than is necessary to obtain the diagnostic information.

SELECTED WFUMB STATEMENTS ON THE SAFETY OF DIAGNOSTIC ULTRASOUND

B-mode imaging: Known diagnostic ultrasound equipment as used today for simple B-mode imaging operates at acoustic outputs that are not capable of producing harmful temperature rises. Its use in medicine is therefore not contraindicated on thermal grounds. This includes endoscopic, transvaginal and transcutaneous applications.

Doppler: It has been demonstrated in experiments with unperfused tissue that some Doppler diagnostic equipment has the potential to produce biologically significant temperature rises, specifically at bone/soft tissue interfaces. The effects of elevated temperatures may be minimized by keeping the time during which the beam passes through any one point in tissue as short as possible. Where output power can be controlled, the lowest available power level consistent with obtaining the desired diagnostic information should be used. Although the data on humans are sparse, it is clear from animal studies that exposures resulting in temperatures less than 38.5°C can be used without reservation on thermal grounds. This includes obstetric applications.

Transducer heating: A substantial source of heating may be the transducer itself. Tissue heating from this source is localized to the volume in contact with the transducer.

Recommendations on thermal effects: A diagnostic exposure that produces a maximum temperature rise of no more than 1.5°C above normal physiological levels (37°C) may be used without reservation on thermal grounds. A diagnostic exposure that elevates embryonic and fetal in situ temperature to 4°C (4°C above normal temperature) for 5 min or more should be considered potentially hazardous.

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