How safe is modern obstetric ultrasound? The use of modern technologies in routine examinations

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Introduction

A number of developments have a potential impact on the exposure of patients to ultrasound in obstetrics. The number of scanners has increased in response to increasing demands and expectations. Smaller and cheaper scanners are available and this has fuelled the increase in numbers as ad hoc scanning has become more feasible. Transducers have become more efficient with the development of composite materials and further development of matching layers and electronics. Scanners have more processing power with improvements in miniaturisation and processing speed of digital electronics. These advances have facilitated other developments such as harmonic imaging, more complex pulsing regimes and three- and four-dimensional (3D, 4D) ultrasound. Collective exposure has also increased as a result of the steady increase in the number of scans performed.

This article will outline safety considerations with respect to some modern technologies and reiterate recommendations for safe practice in obstetric ultrasound.

Safety

The two major physical effects of ultrasound with potential biological consequences are heating and cavitation. The ultrasound transducer introduces energy into the patient; a significant proportion is absorbed as heat and there can be a measurable temperature rise. Ultrasound passes into the patient as a pressure wave; pressure waves can be disruptive. Ultrasound waves are spatially small but pressures can be quite large; pressures of greater than 1 MPa (10 atmospheres, equivalent to 100 m of water) are common. The negative pressure component of the wave cycle can cause bubble expansion and collapse. When bubbles collapse, energy is released as heat and shock waves and free radicals can be produced.

Potential biological effects include cancer from heat or free radical production, cell death from heat or intracellular cavitation and haemorrhage from shock waves. Clearly there is a hazard and so we need to assess, and if necessary control, the risk. Historically risk has been controlled through limitation on outputs (by the Food & Drugs Administration in the USA, but this has had the effect of controlling outputs worldwide as the USA market is so large). Currently controls rely on the Output Display Standard (ODS), now a standard of the International Electrotechnical Commission (IEC); this requires the display of indices to reflect heating potential (Thermal Index – TI) and cavitation potential (Mechanical Index – MI).

The TI is the ratio of output power to the power required for a 1°C temperature rise, so can conveniently be read as the possible temperature rise. There are 3 TIs: TIS (soft tissue) is important when scanning the embryo or in gynaecology; TIB (bone) is important in the second and third trimesters of pregnancy; TIC (cranium) is important in neonatal head ultrasound. TI will increase when output increases or when intensity increases due, for example, to a change in focusing.

The MI does not have the intuitive appeal of TI, being the ratio of peak negative pressure to the square route of frequency. The definition does tell us that MI increases with increasing pressure or decreasing frequency.

In assessing risk in these circumstances it is important to know whether there are safe limits, ie is there an output level below which the risk is zero? Having reviewed the evidence the World Federation for Ultrasound in Medicine and Biology (WFUMB) stated that ultrasound giving temperature rises of up to 1.5°C may be used without reservation. At MI of up to 0.7 there is no risk. We therefore have safety thresholds, below which there is no known risk. Professor Francis Duck, at the British Medical Ultrasound (BMUS) Annual Scientific Meeting in 2010, discussed the existence of these thresholds in relation to the suggestion of the use of the ALARA (As low as reasonably achievable) principle proposed by BMUS in their safety guidelines. The ALARA principle is applied in the diagnostic use of ionising radiations where there is no risk threshold and reducing exposure reduces the risk no matter how low the exposure. In ultrasound, where we have risk thresholds, reducing exposure when already below the threshold has no impact on risk, which is already zero.

BMUS safety guidelines

The BMUS safety guidelines were recently re-issued in a more user-friendly format. The guidelines are divided into ‘basic’ and ‘detailed’. The basic guidelines require ultrasound to be used only for medical purposes, operators to be fully trained (to include bioeffects, safety and machine settings), a short examination time and ALARA. In the context of the earlier discussions on thresholds and ALARA, it might appear that ALARA and short scan times are unnecessary below the thresholds of risk. The detailed guidelines do expand on this by including the thresholds (TI reduced by a factor of two to allow for measurement uncertainty) and imposing time restrictions only above the modified TI threshold of 0.7. In addition, the detailed guidelines require a low default (preset) power (I would suggest that setting this just below the TI and MI risk thresholds is adequate) and not using a hot probe (due to self-heating).

The guidelines also recommend that Doppler modes are not used on sensitive tissues (embryo, head, brain, spine, eye); there are, however, justified clinical reasons for using Doppler in pregnancy, and even where the intended target is not one of these sensitive tissues it may be difficult to avoid exposing them. This is where knowledge of the risk thresholds may be particularly valuable, as working below the thresholds avoids the risk.

Technology and safety

The increasing number of scanners should not have an adverse effect on safety if operators are properly trained. Improved transducer efficiency is generally used to increase penetration without an increase in output (which is limited anyway by probe self-heating). Processing power is directed...
at improving image quality, which may lead to reduced outputs and shorter scan times.

More complex pulsing arrangements appear in a number of forms, e.g., image tiling to improve frame rate, coded pulses to improve sensitivity and, in some cases, the user is not (and need not be) aware of the pulsing regime. In many cases this will increase output. In image tiling, the image is not formed in the traditional sequence as a new pulse is fired from an area of the transducer remote from an area that is still receiving echoes; this increases the frame rate and thus TI may be higher and so should be carefully observed when adding focal zones. Coded pulses are longer and so deliver more energy. Pulsed Doppler, with a static beam, and colour Doppler, with multiple long pulses per line, also deliver more energy.

Spatial compound imaging works by making an image which is averaged over several different angles. This can be achieved by beam steering on transmission and reception or by forming only receive beams at different angles. For transmission compound imaging, although the frame rate may appear to be high, the images are averaged so any rapid movement may appear blurred; in obstetrics it may be useful for stationary anatomy but not for the fetal heart. In compound imaging on reception only there is no such effect as the angled beams are formed after echo reception. The advantages of compound imaging are reduced shadowing, speckle and clutter and improved border definition, so this may be useful when fetal anatomy is obscured by the ribs. In transmission compound imaging, probe movement must be slow to avoid blurring, leading to greater local energy deposition. Using TI below the threshold avoids the risk.

Harmonic imaging is possible as a result of improved transducer efficiency and relies on the distortion of the ultrasound wave by non-linear propagation through tissue. This distorted wave contains multiples of the transmitted (fundamental) frequency, called harmonics. Images are formed using the second harmonic (twice the fundamental frequency). As harmonics are formed only from the most intense part of the beam they are detected only from close to the centre of the beam and not at all from side lobes or grating lobes (figure 1). This improves lateral resolution and eliminates clutter from side/grating lobes.

The current method for harmonic extraction (pulse inversion) requires two pulses per line, so TI may be higher. Harmonic imaging also requires larger pulses as the intensity of the harmonic signal is very small compared with the fundamental echoes. Thus, TI and MI will generally be higher. TI should be observed when switching from fundamental to harmonic imaging.

3D and 4D imaging in obstetrics are currently achieved by sweeping a conventional array within a housing. Data are rapidly acquired and can be reformatted, viewed in 3D/4D to show surface anatomy and contribute to parental-fetal bonding. High contrast is required to define surfaces, which may tempt operators to use high outputs. There are two sides to the safety coin here; the scan plane is swept, stored images are observed, resulting in low exposure; there may be a lengthy search for the perfect image, using high output, which results in a high exposure.

Summary

Many technological advances can increase patient exposure but improved image quality and consequent reduced scan times may reduce exposure. The key to safe practice is therefore likely to be training and awareness. The ODS gives the user responsibility and information for the safe use of ultrasound, so the user must understand the scanner and its controls and be aware of sensitive tissues and ‘hot’ modes of operation.

Lead practitioners should ensure that default (preset) outputs are set below the modified threshold recommended by BMUS for obstetrics (TI<0.7). Ideally, through knowledge and experience of particular scanner performance, outputs should be optimised so that thresholds are exceeded only when diagnostically necessary. Operators should be aware of newer technologies that increase exposure and use them only when necessary to achieve a diagnosis. Advice on outputs and scanning modes should be included in protocols and practice should be audited.

Keep watching the TI.

References