Guidance document on ultrasound safety issues when scanning a neonate

Prepared by the Physics and Safety Committee of the British Medical Ultrasound Society

Recommendations

- Neonatal ultrasound training courses should include awareness of safety considerations.
- Neonatal departments should ensure that ultrasound scanning protocols follow safety guidelines and recommendations.
    - When setting up neonatal scanner pre-sets, advice from Medical Physics departments or Application Specialists should be sought.

Scope

This guidance document has been written by the Physics and Safety Committee of the British Medical Ultrasound Society (BMUS). It has been prepared in conjunction with the Royal College of Paediatrics and Child Health.

The note is intended for any clinician who performs diagnostic ultrasound imaging of the neonate. It should be read in conjunction with the detailed guidelines published by BMUS "Guidelines for the safe use of diagnostic ultrasound equipment." https://www.bmus.org/static/uploads/resources/BMUS-Safety-Guidelines-2009-revision-FINAL-Nov-2009.pdf

Review of literature of neonatal ultrasound safety.

Ultrasound imaging is an important primary diagnostic, imaging modality used when investigating the neonate. Its use has grown over many decades, starting with imaging of the neonatal head[1] from the 1970's, to neonatal cardiac imaging[2] in the 1990's, and most recently, imaging of the neonatal lung[3].

Ultrasound imaging uses non-ionising radiation and as such is rightly regarded as one of the safest imaging modalities[4]. To date there have been no validated reported adverse biological effects from the use of diagnostic ultrasound in humans. There is however a long and established body of literature[5] that covers the investigation of the potential for adverse biological effects as a result of the interaction of ultrasound with biological media. All these studies have been based on in-vitro or pre-clinical models because of the ethical difficulty in conducting human trials.

Ultrasound bio-effects seen in biological systems are due to thermal and/or non-thermal interactions. Miller and Ziskin's[6] review of the literature on ultrasound induced hyperthermia and its associated biological effects in pre-clinical studies from 1963 to 1986, established a logarithmic relationship between temperature elevation and exposure time for adverse bio-effects in pre-clinical fetuses. It should be noted that this review of the hyperthermia literature pre-dates the relaxation in acoustic output powers from diagnostic ultrasound scanners, by the FDA , which took place in 1991[7]. Surveys[8,9] of output power from diagnostic ultrasound scanners have shown a seven fold increase in output power for B-mode imaging, and a 3 fold increase in output power for pulsed Doppler modes, since this relaxation. Although the hyperthermia review was based on fetal pre-clinical models, various international and national bodies[10,11] have identified the fact that neonatal trans-cranial and spinal tissue is also vulnerable to potential thermal bio-effects due to a still rapidly developing central nervous system. Non-thermal interactions of ultrasound with biological media include cavitation and radiation force effects. Reviews of non-thermal mechanisms have suggested that gas containing organs, such as the lungs and intestines can be vulnerable to capillary bleeding[12,13].

The likelihood of thermal or non-thermal bio-effects occurring depends on many factors. These factors can be separated into those that depend on the biological system and those that depend on the properties of the ultrasound exposure. The relevant exposure properties are the frequency, peak pressures, output power, pulsing regime, and probably the most significant, exposure time. The likelihood[14] of bio-effects occurring from thermal mechanisms increases with increases in frequency, output power, pulse lengths and exposure time. The likelihood of bio-effects occurring from non-thermal cavitation mechanisms increases with increasing peak negative pressure, exposure time and a decrease in frequency.

Literature[15,16,17,18,19,20] on the safety of neonatal cranial ultrasound scanning suggests that temperature rises can occur (between 2^{o} C and 6^{o} C have been seen in pre-clinical models), but the magnitude of the temperature rise is dependent on the pre-clinical model, ultrasound imaging mode and experimental method. An important difference between these pre-clinical model studies and scanning of the neonate is that neonatal cranial scanning is performed through one of the neonatal fontanelles. It should be noted that the ossification of the neonatal fontanelles is significantly different from that in the pre-clinical model, and that this will have an influence on any subsequent temperature rise. Indeed measurements made in neonatal cranium head phantoms[21] suggest that the largest temperature rise is likely to be at the surface of the fontanelle.

The literature on the incidence of bio-effects relevant to neonatal cardiac scanning is sparse, however it has been reported[5,22] that clinical neonatal cardiac pre-sets may be at high default output power values, well above those recommended by national bodies[11]. Indeed it has been demonstrated that high output power values may not be required to obtain appropriate diagnostic clinical information[23] for neonatal colour flow examinations.

Neonatal pulmonary ultrasound is an emerging technique[24] that can provide valuable information on lung pathology without the need for ionising radiation. However, here again pre-clinical studies have demonstrated that ultrasound scanners operating at diagnostic output power levels have the potential to cause adverse bio-effects. In particular pre-clinical models demonstrate that a breach of the alveolar-capillary interface is possible[13,25]. This is known as ultrasound induced pulmonary capillary haemorrhage[26,27].

It is clear that ultrasound scanning of the neonate provides the clinician with a valuable diagnostic tool, and the recent publication of a number of clinical reviews[24,28,29,30,31,32] on this subject bear this out. It should be noted that only one of these reviews[32], mentions ALARA (As Low As Reasonably Achievable) or ultrasound safety in their clinicians' scanning protocols. Several surveys of clinical practice[33,34,35] have highlighted the lack of knowledge and training in aspects of ultrasound safety among clinicians who use ultrasound. Lalzad at al[36] surveyed neonatologists undertaking cranial scanning and found that only 13% of those that responded had received dedicated training in ultrasound safety issues, with 63% of respondents unaware that reducing overall scanning time was the most effective method of reducing total ultrasound exposure.

General safety considerations

- Although diagnostic ultrasound is one of the safest diagnostic imaging modalities and does not use ionising radiation, it has been shown to have the potential to produce bio-effects in pre-clinical models, and so caution should be exercised, especially in vulnerable subjects such as extremely premature infants.
- It is important to note that the responsibility for safe use of ultrasound lies with the user of the ultrasound equipment.
- The two main potential biophysical mechanisms associated with the interaction of a diagnostic ultrasound beam with neonatal tissue are
    - Energy absorption which results in tissue heating
    - Bubble oscillation and / or tissue displacement arising from mechanical effects.

The probability of these biophysical mechanisms occurring is related to the ultrasound scanning mode being used. Use of Colour Flow Doppler and Pulsed Wave Doppler is common. Both these modes emit higher power than B-mode. Increase in output power increases the likelihood of both thermal and non-thermal bio-effects. Pulsed Wave Doppler uses the highest power of all the imaging modes.

- Ultrasound equipment can display two safety indices, the Thermal index (TI) and the Mechanical Index (MI). These indices indicate the likelihood of thermal and non-thermal effects occurring respectively.
- These indices are there for guidance and are based on simple models of tissue heating and inertial cavitation thresholds in tissue. They allow the user to ascertain the risk relative to benefit between not scanning (and therefore missing a clinical finding) and the potential harm arising because of scanning.
- TI can be displayed in three different ways, depending on the clinical application; TIS (Thermal Index soft tissue), TIB (Thermal Index Bone) and TIC (Thermal Index Cranial). For neonatal scanning the ultrasound equipment should display TIC when a trans-cranial or spinal scan is performed, while for general and cardiac scanning TIB should be displayed.
- For all neonatal scanning the MI should be displayed when MI > 0.4.
- For all neonatal scanning the TI should be displayed when TI > 0.4.
- The BMUS guidelines provide tabulated guidance for the use of the safety indices. Since tissue heating increases with the length of time of scanning, these guidelines provide advice on safe scanning time associated with the TIC and TIB values displayed on the scanner. The thermal indices have upper limits beyond which scanning is not recommended.
    - Trans-cranial and spinal scanning settings which lead to a value for TIC > 3 are not recommended.
    - A value for TIB of > 6 is not recommended for cardiac scanning.
    - In the case of non-thermal mechanisms, when the MI is > 0.3, minor lung damage has been seen in pre-clinical models. Reducing the scanning time minimises risk.

- **Specific safety considerations for different applications**
    - **Neonatal cranial scanning:-**
        - High frequency probes are used (10 MHz to 15 MHz).
            - As ultrasound frequency increases, the probability of tissue heating also increases.
        - Scans are performed over the fontanelle which has cranial bone on either side.
            - Bone absorbs a large fraction of ultrasound energy and this can increase potential heating effects.

- Scans are performed using an ultrasound beam with a narrow focus and there is little transducer movement.
    - Narrow focussed beams confine the ultrasound energy into a small volume.
    - An almost stationary transducer increases the possible localised temperature rise.

- **Cardiac scanning:-**
  - Aerated lungs are in the beam path, when imaging the heart. These maybe a potential site for cavitation. They may also be a potential site for increased heating due to reflection at the air/tissue interfaces. This is important because these scans predominantly use Doppler modes which are known to have the highest output powers.

- **Pulmonary Scanning**:-.
  - Pulmonary Capillary Haemorrhage (PCH) has been seen in pre-clinical models using equipment and ultrasound output parameters that are commonly used during neonatal diagnostic scanning. However little is known about PCH and its importance, and the mechanisms of action are still under investigation
  - In pre-clinical models the longer the exposure the more probable the occurrence of PCH
  - The threshold for PCH does not appear to be frequency dependent, and so there is no concern about using the most appropriate probe for the desired application.

Guidance

THE PRINCIPLES OF ALARA (AS LOW AS REASONABLY ACHIEVABLE) SHOULD BE OBSERVED WHEN PERFORMING ALL SCANS.

Operators should always observe the displayed safety indices while scanning, and aim to keep the Mechanical Index (MI) and Thermal Index (TI) values as low as practicable while ensuring that diagnostic imaging quality is not compromised.

To reduce the potential for temperature rise, cavitation or PCH:-

- **Reduce scanning time without compromising clinical decision making.**
- **Reduce output power, to lower the thermal index and the mechanical index without compromising diagnostic image quality.**
- **The use of pulsed Doppler leads to higher MI & TI values, and so it is recommended that pulsed Doppler is only used once the target has been located using colour flow.**
- **Increase the receiver gain but ensure noise in the image does not result in poorer image quality.**
- **In cases where a reduction in output power or an increase in receiver gain reduces images quality, the ultrasound frequency can be decreased to reduce the thermal index. In such cases the user should ensure that any corresponding reduction in image resolution does not compromise image quality. The user should also monitor any increases in the mechanical index that may occur due to a reduction in ultrasound frequency.**
- **If the user wishes to reduce the mechanical index, without altering output power, then the ultrasound frequency can be increased. In such cases the user should be aware that the depth of penetration in the image may be reduced. The user should also monitor any increases in the thermal index that may occur due to an increase in ultrasound frequency.**

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