Ultrasound Safety in Research

Bioeffects: Two types of ultrasound use in medicine are diagnostic ultrasound and therapeutic ultrasound. Ultrasound images are produced by inducing tissue vibrations at ultrasonic frequency. There is little evidence that those vibrations have any biologic consequences. This is not true for ultrasound energy that is converted to heat (main basis for therapeutic ultrasound). The tissue heating is related both to the intensity and focus of the ultrasound beam. This allowed the US Food and Drug Administration and the American Institute of Ultrasound in Medicine to establish intensity limits: 100 mWatts/cm^2 for unfocused and 1000 mWatts/cm^2 for focused ultrasound [1-3]. Most of the available epidemiological evidence on ultrasound safety is derived from B-mode scanners in use before the 1990s. There is little data on the use of color flow or pulsed wave Doppler, and today's scanners can produce 10–15 times higher output levels than did these earlier scanners[4]. We will not be using color flow or pulsed wave doppler for imaging during this study. A recent publication from engineering discipline shows the highest risks are associated with the use of gas-bubble contrast agents[5-8]. It is concluded that there is a medium risk associated with trans-cranial Doppler use, and that this use of ultrasound deserves more detailed safety review. The risks associated with the current practice of obstetric ultrasound are low. The severity of radiation pressure as a hazard is low, it is always present. Little is known about any associated cell responses and so the associated risk cannot be evaluated. This article also comments on the previously mentioned topics on tissue heating and cavitation. Two types of safety index can be displayed on the scanner screen, one concerned with potential heating (the thermal index, TI) and the other with mechanical (mainly cavitational) events (the mechanical index, MI). MI is of most concern when microbubble contrast agents are being used. The recommended exposure times are linked with upper limits of TI[9].

Aside from thermal effects on tissue, the other significant effect is called cavitation. Soft tissues contain microscopic areas of gas bubbles that can be heated by the ultrasound beam, resulting in their rapid expansion and bursting. The evidence for this cavitation injury in 'diagnostic' ultrasound is scant. This possibility prompted the AIUM in 1988 to issue a safety statement applicable to diagnostic ultrasound[1-2]:

1. No study should be performed without valid reason
2. No study should be prolonged without valid reason
3. The minimal output power should be used to produce optimal images if the ultrasound machine allows control of output power (As Low As Reasonably Achievable, or ALARA principle)

Institute of Medicine work titled "Crossing the Quality Chasm" applied six domains[10]: safety, effectiveness, equity, timeliness, and patient-centeredness. Safety – errors diagnosed as diagnostic errors, treatment errors, preventive errors, and 'other or unclassified errors. Ultrasound improves procedure performance by direct visualization, avoids delays in interpretation. Effectiveness – available EBM for ultrasound use already available in specific

disciplines like radiology, emergency medicine, surgery, trauma, ob/gyn. Efficiency – No lag time between decision and action; operator and decision maker same and no need for transport. Timeliness – ultrasound must be available at all times to be effective and equal to all patients. Equality – improves access for all ICU patients since available in ICU. Patient-centeredness – immediate access to specific interventions and next steps, alleviates need for patient transportation out of the ICU, expands breadth of diagnostic and procedural capabilities.

A few other organizations have put out safety guidelines in ultrasound use and have been listed in the references below [11-12].

References:

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