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New Zealand sonographers do not outperform their European or American colleagues in the knowledge of ultrasound safety

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Introduction

Recent surveys of clinical users of ultrasound conducted in Europe and North America show that users of ultrasound worldwide are poorly informed about the safety issues of diagnostic ultrasound technology. For instance, only 32% of American and European users reported being familiar with the term Thermal Index (TI), and only 18% of Americans and 22% of Europeans could correctly define or describe what TI means[1,2]. Little is known about the level of knowledge that Australasian users have regarding ultrasound safety. In general, Australia and New Zealand enforce stricter educational and licensing requirements for sonographers than USA and Europe. Does this mean our sonographers are better informed about issues of ultrasound safety such as monitoring and regulating of thermal indices during obstetric examinations? A survey of sonographers was performed in Hamilton, New Zealand to answer this question.

Methods

A nine-point questionnaire (Table 1) was constructed based on previously published work by Marsal[1] and Sheiner, *et al*[2]. The survey was distributed to clinical users of ultrasound practicing sonography in Hamilton during July 2010, totalling 35 users consisting of sonographers, sonography trainees, one obstetric sonologist and one fetal medicine registrar. All users of ultrasound will be henceforth referred to as "sonographers". The sonographers surveyed practiced in a variety of clinical settings ranging from small private practice setting, large volume private practice and a regional tertiary university hospital. The author was excluded from this survey. Overall, 20 sonographers returned the questionnaire. The responses were analysed using simple descriptive statistics. Levels of statistical significance were not evaluated due to the small number of individuals studied. The user's response to Question 6 ("Define what the TI means"), was judged as correct if the user identified in some reasonable form that the TI is a ratio of current power output to the power output required to raise temperature by 1°C. The user did not need to differentiate between TIs, TIb and TIc for the purpose of this question, nor did they need to discuss a) the location of the transducer, b) focal zone position with respect to the tissue of interest or c) potential limitations of the TI computational models.

Please tick the box which best applies to you ☐ I am a sonographer with < 5 years of clinical experience ☐ I am a sonographer with 5–10 years of clinical experience ☐ I am a senior sonographer with > 10 years of clinical experience
Do you adhere to the ALARA principle during your examinations? Tick one: ' Always, ' Most of the time, ' Sometimes, ' Seldom, ' Never, ' I don't care because ultrasound is safe
Are you familiar with the term TI? ☐ YES ☐ NO
Which machines do you primarily use for Obstetric imaging? (List systems you use the most)
For each machine you work on, briefly describe where on the system you could find the TI.
Define what the Thermal Index means
Which of the following TI indices are most relevant during nuchal translucency scanning? Tick one: ☐ TIe, ☐ TIc, ☐ TIs, ☐ TIn, ☐ TIb, ☐ TIo
During your obstetric examinations (2nd and 3rd trimester) performed within the last month, what is the range of TI you have encountered?
If you wanted to reduce the potential for thermal bioeffects during your obstetric examinations, what steps could you take?

Table 1: Survey questions.

Results

Twenty sonographers returned the questionnaire which represents survey response of 61%. The level of clinical experience was equally split between junior sonographers of < 5 years' experience (30%), sonographers with 5-10 years' experience, (35%) and senior sonographers of >10 years' experience (35%). While 100% of the sonographers surveyed reported being familiar with the term TI and 90% claimed they adhered to the Action Learning Action Response Association (ALARA) principle all the time or most of the time, only 15% of sonographers correctly described or defined what the term TI means. Of the sonographers 80% knew where to find the TI during real-time examinations but only 35% knew which TI index to use for nuchal translucency (NT) scan and only 10% knew the expected range of TI encountered during routine obstetric examinations. Of the eight sonographers who reported adhering to ALARA all the time, the majority (64%) could not describe or define TI. In the same subgroup, the majority (64%) did not know which TI to monitor during a NT

Output Display Standard (ODS) Indices and Recommended Levels

ODS Index	Use	Applications
TIs	Examinations where no bony interface is present within the beam path	Prenatal: Conception to 8 weeks GA Postnatal: Soft tissue scanning
TIb	Examinations where bony interface is present within the beam path near focus	Prenatal: After 8 weeks GA Postnatal: Where bony interfaces are expected
TIc	Examinations where bone is present close to transducer surface	Neonatal brain scanning or Other applications where bone is superficial
MI	Examinations where gaseous bodies are expected within the beam path (lung, bowel, contrast agent)	Not normally applicable in obstetrics Abdominal and chest scanning, esp neonatal
Examinations	**ODS Index Level**	**Examination duration**
Prenatal	**TI < 0.5–1**	**This level should be used for all prenatal examinations unless otherwise required and can be used for extended periods of scanning**
	TI 0.5–1	< 30 minutes
	TI > 2.5	< 1 minute
Postnatal	**TI < 2**	**This level can be used for extended periods of scanning**
	TI 2–6	< 30 minutes
	TI > 6	< 1 minute
	MI < 0.4	If gaseous bodies present
	MI up to current limit (1.9)	If gaseous bodies not present

Thomas R Nelson, PhD J Brian Fowlkes, PhD Jacques S Abramowicz MD, Charles C Church PhD
Ultrasound biosafety considerations for the practicing sonographer and sonologist. *J Ultrasound Med* 2009; 28: 139–50.

Table 2: Recommended levels of TI and MI.

scan. Only three of 20 (15%) sonographers knew what the term TI means. Of these, two were junior sonographers with < 5 years' experience and one had 5–10 years' experience. Despite understanding the term TI, one of the three sonographers still selected the incorrect index to monitor during a NT scan. Not one of the seven senior sonographers with > 10 years of experience could define or describe the TI. In total, only 10% of sonographers knew what the TI means and which TI to monitor during NT scanning.

Discussion

European, American and New Zealand users of ultrasound demonstrate equally poor knowledge of basic ultrasound safety considerations. It should be noted that in the previous work of Marsal[1] and Sheiner, *et al*.[2], the clinical user group included sonographers, doctors, nurses and other health-allied staff; whereas this study only included practicing sonographers or sonologists. It would seem intuitive that sonographers and sonologists would be better informed about ultrasound safety than a heterogenous group of ultrasound users, but this did not prove to be the case. Compared to European and American colleagues, New Zealand sonographers claimed much higher familiarity with the term TI (100% compared to 32%), but only a small fraction could describe or define what the term TI means (15%). Only one in 10 sonographers not only knew what TI means but could also correctly identify the appropriate TI for a nuchal translucency scan. The majority of users who report they are adhering to the ALARA principle do not demonstrate sufficient knowledge to be able to apply ALARA in everyday clinical situations.

Even though the majority of sonographers did not know which TI index to use for NT scan, it is interesting to note that nobody picked a fictitious index (TIe, TIn or TIo) from the list of possible indices. This seems to imply that sonographers are generally aware of the existence of TIb, TIs and TIc, but do not know how to apply these indices. The findings of this study reaffirm the results to two previous international surveys both of which demonstrated that clinical users of ultrasound have very poor knowledge of basic safety considerations.

There are several limitations to this study. First, despite the fact that Hamilton is New Zealand's fourth largest urban area (125,000 inhabitants), the total population and the ultrasound user group are relatively small. Nonetheless, it is the experience and opinion of the author that the clinical-professional environment in which Hamilton sonographers work is similar to that of other New Zealand and Australian centres. Second, despite excellent percentage of surveys returned, not all users responded to the survey. The non-respondents' lack of participation may have had an impact on the data. This is a common limitation of most voluntary survey methods. Finally, the survey was performed on a specific group in one geographical area and the applicability of the findings to other groups in other geographical areas is debatable. This survey does, however, concur very closely with the findings of the previously mentioned works from heterogeneous user groups in Europe and North America which suggests that generalised lack of knowledge regarding safety considerations exists worldwide across all ultrasound user groups.

Safety considerations in diagnostic ultrasound have been broadly published in numerous science and review papers[3,4,5,6,7]. Professional organisations such as the ASUM[8,9,10,11,12,13,14], American Institute for Ultrasound in Medicine (AIUM)[15], British Medical Ultrasound Society (BMUS)[16,17]and others provide prolific references to the safe use of ultrasound, ALARA and in some cases, recommended

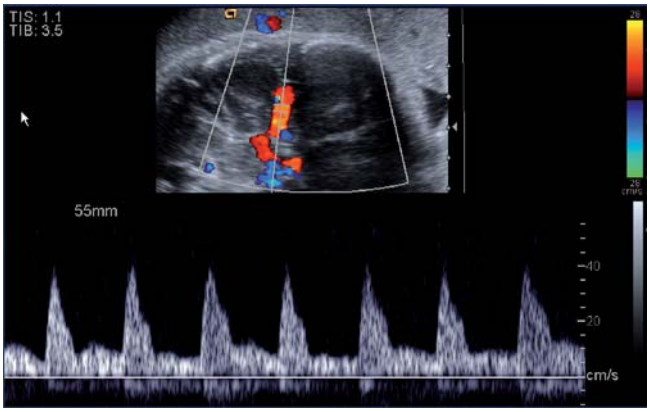

Fig. 1a: MCA PSV sampling in a mid-trimester fetus at risk for anaemia. The TIb is very high (3.5) at default settings without the reduction of power output. This level of TI is not only unnecessary, but it is in breech of the ALARA principle when reduction of output power is possible.

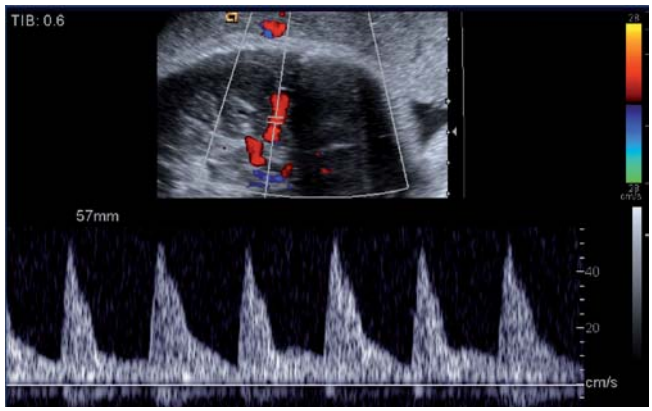

Fig. 1b: Reduction of power output in the same patient results in dramatic drop in TIb (now 0.6) without any loss of diagnostic information. From the biological safety standpoint and in accordance with ALARA, this is the correct way to perform Doppler imaging in obstetrics.

TI and MI values[17]. A recent paper by Nelson and colleagues titled *Ultrasound biosafety considerations for the practicing sonographer and sonologist*[7] provides a non-technical, detailed, clinician-focused overview of the topic as well as practical recommendations about TI and MI values in prenatal and post-natal examinations. A graphical summary of these recommendations can be found in Table 2. For prenatal examinations, the authors instruct the user to monitor the thermal index in soft tissue (TIs) in gestations under eight weeks and Thermal Index for Bone at Focus (TIb) in gestations of more than eight weeks. The recommended values of the respective thermal indices are TI < 0.5 unless otherwise necessary and TI in the 0.5–1 range for examinations of < 30 minutes duration. For post-natal examinations, the monitoring of TIb, TIs, and TIc is based on the presence and position of bone within the beam path. TIs can be used when no bone is present within the beam path, TIb should be used whenever bone is present near the focal point and TIc is appropriate when bone is near the transducer surface. The recommended levels are: TI < 2 for examinations of any duration, TI of 2–6 for examinations < 30 minutes and TI < 6 for examinations < 1 minute. The MI in postnatal examinations should be monitored when gaseous bodies are present within the beam path and the recommended MI value is < 0.4. It is nothing short of a lucky coincidence that during routine obstetric scans if the operator doesn't do anything at all to control acoustic output, they probably operate within the upper region of these safety guidelines as a default most of the time. However, this may not be the case during examinations where spectral Doppler is being used, such as 1) first trimester screening for aneuploidy with incorporation of tricuspid regurgitation and ductus venosus flow characteristics, 2) fetal echocardiography and 3) specialist examinations involving sampling of the fetal MCA and other vessels. The recommended MI levels can be easily breeched during paediatric abdominal and chest scanning.

Relatively high levels of TI are achievable during obstetric imaging unless the operator actively reduces power output during the examination. For instance, in Fig. 1a, the sonographer is performing assessment of MCA peak systolic velocity in a fetus at risk for anaemia. While the image is technically excellent, the sonographer failed to reduce the acoustic output level and obtained the sample at TIB = 3.5. This means the current acoustic output power is 3.5 times greater than the power which would be required to cause a temperature rise of 1°C at the surface of fetal bone near the focal point. To an experienced sonographer or sonologist, this level of TI should be highly concerning. Fig. 1b shows the same measurement being performed in the same fetus following the reduction of power output. Now the TIb is only 0.6 (nearly six times less) and the overall diagnostic quality of the image has not been adversely affected. Sonographers should always strive to control acoustic output especially in high energy modes such as spectral Doppler and to stay within the recommended guidelines. Default reduction of power output can be built into obstetric and other pre-sets by clinical super-users of the ultrasound equipment or by the manufacturer, but individual sonographers must still have sufficient knowledge to monitor the Output Display Standard (ODS) indices and to take corrective action if these indices are high.

The equipment manufacturers have not been particularly forthcoming when it comes to educating users of ultrasound about ALARA, power output and ODS. Many ultrasound systems start up at maximum power, not minimum power. This ensures improved system sensitivity at higher frequencies, best signal to noise ratio, and best performance of tissue harmonic mode which is particularly susceptible to attenuation problems. Unfortunately, the strategy of high acoustic output as a default then hands the responsibility for reducing the output power to sonographers or sonologists who are not well informed about how to do this. There is a long list of other grievances that an experienced sonographer may have about the design and default behaviour of some ultrasound machines. For instance some ultrasound machines feature a hidden power output control which is not readily available to the user during scanning unless the operator activates a secondary control screen. Other manufacturers only display one or two indices and require the user to select their preferred ODS index from a set of technical system menus. Some machines display the ODS indices during a real-time scan, but turn them off once the image is frozen which prevents any meaningful retrospective review of the ODS indices from frozen images. While the Food and Drug Administration (FDA) stipulates that ODS must be available

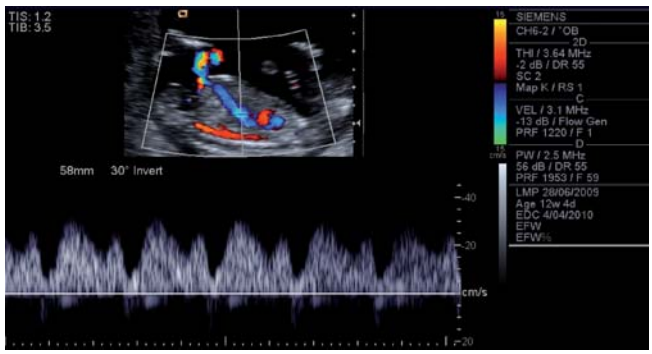

Fig. 2: Image of ductus venous sampling which meets the FMF technical criteria for competence[19], but which none-the-less demonstrates disregard for biological safety with a TIb at an alarming level (Tib = 3.5). The recommended level of TI during obstetric examinations when bone is present is Tib < 0.5 whenever possible or at least Tib < 1 for examinations under 30 minutes[7]. While TIb levels of > 2.5 may in extreme circumstances be permissible for a duration of unto one minute[7], it is not known how long the operator spent sampling and re-sampling in order to obtaining the perfect technical image.

for the operator in real time[18], the FDA does not stipulate where on the machine the ODS should be displayed. Some machines do not feature the ODS on the monitor but have a separate display elsewhere on the console which requires the operator to look away from the monitor in order to check the ODS. This is simply not practicable during real-time ultrasound scans. Such "external" displays also prevent retrospective review of TI in frozen images or cine loops.

The above discussion leads us to the next question: "whose responsibility is it to educate users of ultrasound?" Ultimately, it is the user's responsibility to practice safely, and to practice within the published guidelines provided by their respective professional society (ASUM, ASA), registration/accreditation body (MRTB, ASAR) and scientific literature. Even senior sonographers who are experts in ultrasound imaging and who may be teaching junior staff need to refresh their knowledge of safety, since in this study not one of the seven senior sonographers could describe or define the TI. The burden of educating users of ultrasound also falls on the equipment manufacturers who already have a mandate of responsibility to educate end-users under Track 3 (Subsection 6.2.2 and Section 6.3) of FDA's *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*[18]. Finally, universities and other ultrasound educational providers as well as individual clinical tutors of ultrasound should do more to educate students and their colleagues about ultrasound safety issues.

Safety considerations should be at the forefront of ultrasound education curricula, including theoretical and clinical teaching. Unfortunately, in the drive for ever increasing clinical performance of ultrasound and ever expanding ultrasound applications, safety considerations are often sidelined and forgotten. It is astonishing that even the Fetal Medicine Foundation (London, UK) which provides education and certification of competence in a range of ultrasound examinations (including first trimester pulsed wave Doppler of ductus venosus and tricuspid flow) does not include any provision for the observance of ODS, TI and ALARA on their otherwise highly specific protocols for these examinations[19,20]. As a result, an ultrasound user can be certified as 'competent' in the performance of pulsed wave Doppler examinations in the first trimester without demonstrating any theoretical knowledge or practical application of ultrasound safety principles (Fig. 2). Both Marsal[1] and Sheiner, *et al*.[2] lamented precisely this lack of educational support for the ODS. Regarding education, Sheiner and colleagues concluded: "The education goal explicitly included in the implementation of the ODS has failed". The author of this paper would argue that the safety of ultrasound and clinical applications of ALARA and ODS should be taught with greater emphasis and should be examined by educational providers on a "must-pass" basis. This approach would ensure that at least the newly qualified ultrasound operators enter clinical practice with adequate safety knowledge. Building safety recommendations into clinical protocols and performing simple audits of ODS parameters could assist practicing sonographers in gaining greater familiarity with ultrasound safety and taking appropriate action to control safety parameters.

Conclusion

The principles of ALARA are deeply entrenched in our professional standards and codes of practice. Regrettably, the concept of ALARA in ultrasound has been largely ignored. Critical application of ALARA requires: 1) knowledge of safety issues in ultrasound, 2) monitoring or the correct ODS index during scanning and 3) continuous, proactive and judicious control of power output and scan duration. Most of the time, it's a matter of turning one button (power output) and watching one number (TIs, TIb, TIc or MI). New Zealand sonographers did not outperform their European and American colleagues in the game of basic ultrasound safety trivia. While the overwhelming majority of sonographers reported that they are familiar with the term TI and that they adhere to ALARA, only 10% demonstrate sufficient knowledge to justify such claims. Our profession needs to do more to educate all users of ultrasound about biological safety issues, the ODS and thermal and mechanical indices.

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