

THE KNOWLEDGE OF USERS REGARDING SAFETY OF ULTRASOUND DURING PREGNANCY

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ABSTRACT

Ultrasound (US) is widely used in most medical clinics, especially obstetrical clinics. It is a way of imaging methods that has important diagnostic value. Although useful in many different applications, diagnostic ultrasound is especially useful in antenatal (before delivery) diagnosis. The use of two-dimensional ultrasound (2DUS) in obstetrics has been established. However, there are many disadvantages of 2DUS imaging. Several researchers have published information on the significance of patients being shown the ultrasound screen during examination, especially during three- and four-dimensional (3D/4D) scanning. In addition, a form of ultrasound, called keepsake or entertainment ultrasound, has boomed, particularly in the United States. However, long-term epidemiological studies have failed to show the adverse effects of ultrasound in human tissues. Until now, there is no proof that diagnostic ultrasound causes harm in a human body or the developing foetus when used correctly. While ultrasound is supposed to be absolutely safe, it is a form of energy and, as such, has effects on tissues it traverses (bio-effects). The two most important mechanisms for effects are thermal and non-thermal. These two mechanisms are indicated on the screen of ultrasound devices by two indices: The thermal index (TI) and the mechanical index (MI).

Keywords: Acoustic output, foetus, thermal index, mechanical index, questionnaire survey.

INTRODUCTION

Ultrasound (US) has become an important diagnostic tool used for obtaining information about function or structure in human beings (Minister of Public Works and Government Services, Canada, 2001). It is widely used in healthcare institutions, especially obstetrical clinics. The World Health Organization manual of diagnostic ultrasound (WHO, 2013) states that during the last decades, the use of ultrasonography increased in health care practice globally, and the benefits have been widely reported. Although useful in many different applications, diagnostic ultrasound is especially useful in antenatal (before delivery) diagnosis. Malhotra, Shah, Kumar, Acharya, Panchal and Malhotra (2014) state that the use of two-dimensional ultrasound (2DUS) in obstetrics is well established. But there are many disadvantages of 2D-US imaging.

Several researchers have published information on the significance of patients being shown the ultrasound screen during examination, especially during three and four-dimensional (3D/4D) scanning. In addition, a form of ultrasound, called keepsake or entertainment ultrasound has boomed, particularly in the United States, even though long-term epidemiological studies have never succeeded in showing the adverse effects of ultrasound on human bodies (Hershkovitz et al., 2002; Newnham et al., 2004). Until now, there is no proof that diagnostic ultrasound causes harm in humans or the developing foetus when used correctly (Chan & Perlas, 2011). While ultrasound is supposed to be absolutely safe, it is a form of energy and, as such, has effects on tissues it traverses. From the early days of ultrasound, researchers have been aware of the potential bio-effects of ultrasound. After World War I, Chilowsky and Langevin took advantage of the enabling technology of

piezoelectricity for transducers and vacuum tube amplifiers to realise the practical echo range in water (Szabo, 2004). They used high-powered echo-ranging systems to detect submarines and, during transmissions, they observed schools of dead fish floating at the water surface (Szabo, 2004).

Acoustic outputs of ultrasound devices can be described by special indices. Intensity can be described in duration of its value in relation to time of the cycle. For example, the most commonly used spatial-peak temporal-average intensity (I_{SPTA}) (milliwatts per square centimetre) (mW/cm^2) or spatial-peak pulse-average intensity (I_{SPPA}) (mW/cm^2) describes the intensity of each pulse. But these are not useful during a clinical study (Sheiner et al., 2005, 1665-1670). For this reason and other different reasons, the Output Display Standard (ODS) was conducted in 1992 (AIUM/NEMA, 1992).

LITERATURE REVIEW

Ultrasonic imaging has been used for more than five decades and its use as a means of diagnosis is becoming more popular (Hangiandreou, 2003:1019-1033). Epidemiological studies have failed in the past to identify the adverse effects of ultrasound on human bodies (Lyons et al., 1988:687-690; Newnham et al., 2004:2038-2044), which is considered a form of energy that causes bio-effects. The two mechanisms of ultrasound are heating and cavitation (AIUM, 2000:69-72). The two most important mechanisms for effects are thermal and non-thermal. These two mechanisms are indicated on screens of ultrasound devices by two indices: the thermal index (TI) and the mechanical index (MI).

The thermal index (TI) shows the probability of temperature increase along the ultrasound beam (Sheiner et al., 2007; AIUM Technical Bulletin, 2004). It is the ratio of the total acoustic energy to the energy required to raise the temperature of the tissues by 1 °C (Sheiner et al., 2005: 1665-1670). It is assumed that with modern ultrasonic devices, there is no rise in temperature; usually only a small rise which does not exceed (Abramowicz et al., 2000:594-596). Manufacturers are required to display MI and TI on the screen (Jacques, 2008:17-21). The AIUM Technical Bulletin (2004), states that there are three specific thermal indices: the soft tissue thermal index (TIS), the bone thermal index (TIB) and the cranial bone thermal index (TIC). The TIS is used to provide data on increase in temperature in homogeneous soft tissue, the TIB provides data on increase in temperature in bones at or near the focus of the beam, and the TIC provides data on increase in temperature at or near the surface, such as during a cranial exam.

The mechanical index (MI) shows the probability of the ultrasound producing cavitation in tissues in the presence of gaseous bubbles in an air-water interface (O'Brien & Siddiqi, 2001; Abramowicz, Kossoff, Marsal & Ter-Haar, 2000). It is therefore displayed in B-mode imaging (Holland et al., 1996: 917-925). It also expresses the possibility of ultrasound inducing tissue cavitation (O'Brien & Siddiqi 2001:29-48).

According to Sheiner, Shoham-Vardi and Abramowicz (2007:319-325), cavitation can be either back-and-forth movements of bubbles (stable cavitation) or growth and implosive collapse of these bubbles (inertial or transient cavitation). According to the AIUM Technical Bulletin (2004), the MI can range up to 1.9 for all uses except ophthalmic, which has a maximum MI limit of 0.23. The index levels do not indicate that a biological effect is actually happening, but only informs users regarding the possibility of a biological effect. This is the reason it is vital to implement the ALARA principle, using the smallest possible TI and MI

values, while keeping the quality of the scan as high as possible (AIUM Technical Bulletin, 2004).

METHODOLOGY

This study uses a quantitative research methodology. Quantitative research is a means of testing objective theories by examining the relationship among variables. These theories can be measured using instruments so that numbered data can be analysed using statistical procedures. A descriptive cross-sectional study in the form of observation and a survey was employed. The study took place in September and October 2014. Descriptive studies are used to merely describe the phenomenon. The researcher does not manipulate any variables as in experimental designs and makes no effort to determine the relationship between variables.

Surveys are a type of descriptive study design which is quick to administer and is given at one point in time. Through a survey, a researcher can obtain information on the knowledge of end users on the safety of ultrasound. The study was conducted at public and private hospitals located in Cape Town – South Africa. These hospitals are Groote Schuur Hospital, New Somerset Hospital (Department of Obstetrics and Gynecology), Christian Bernard Hospital and the Fetal Assessment Centre, Kingsbury Hospital.

An adapted version of a questionnaire was used for data collection. The questionnaire had been used by Sheiner, Shoham-Vardi and Abramowicz (2007) on end user knowledge regarding the safety of ultrasound. The questionnaire consisted of 17 questions. The questions addressed general demographic information, familiarity with ultrasound bio-effects and knowledge regarding the safety of ultrasound, in closed ended questions.

Data from questionnaires were entered into an Excel spread sheet. The data are then analysed descriptively. The findings are presented in figures, tables and narratively. Statistical analyses are performed using the SPSS package (SPSS Inc., Chicago, IL).

RESULTS

A total of 30 users of ultrasound participated in this study. Eighteen of those completed the survey, for a response rate of 60%. Twelve (12) users did not respond, a non-response rate of 40%. The completed questionnaires were from five (5) different hospitals (including public and private) in Cape Town. Most of participants were sonographers, for a response rate of fifty per cent (50%) (n=9). The number of ultrasound examinations per day ranged between 4 and 42, with a mean of 18.

About sixty-one per cent (61%) (n=11) of the participants were from the private sector. Almost all the participants reported that ultrasound examinations were safe, for a response rate of 94% (n=17). Forty seven present (61%) (n=11) of the end users agreed that there should be limitations regarding the number of ultrasound examinations in low-risk pregnancies. About eighty-three per cent (83%) (n=15) of the participants did not agree with keepsake ultrasound examinations.

Approximately three-quarters (72%) of the participants agreed that they were familiar with the term thermal index (TI). These included a physician, a gynaecologist and a radiologist, but most of the participants did not answer the specific question regarding the TI correctly. Participants were also requested to respond whether they knew what MI was. Slightly less

than half of the participants knew what the mechanical index was, for a response rate of 39% (n=11).

The majority (n=12) did not know that the acoustic indices TI and MI are displayed on the monitor of the ultrasound machine during the examinations. About seventy-eight per cent (78%) (n=14) of the participants did not observe these indicators during the examinations.

DISCUSSION

There is always concern regarding ultrasound end users' knowledge of safety issues. During this study a questionnaire was distributed to professionals using ultrasound for fetal examinations in Cape Town. The study included 18 participants in different professions and from five different hospitals. Half of the participants (50%) were sonographers and nearly twenty-two per cent (22%) were physicians. Fourteen (78%) of the participants were females and the majority (61%) were working in private practice (see Table 1).

Table 1: Characteristics of the study group

Characteristics	Result
Six	
Male	4 (22%)
Female	14 (78%)
profession	
Admin Clerk (11.11%)	2
Gynecology (22.22%)	2 (11.11%)
Physician (22.22%)	4
Radiology	1 (5.56%)
Sonographer	9 (50%)
Place of work	
Hospital	7 (39%)
Private practice	11 (61%)
Average examinations/day	18 / day

Almost seventy-two per cent (72%) knew what the meaning of TI is, and just thirty-three per cent (33%) could give a perfect definition. Thirty-nine per cent (39%) knew what the meaning of MI is, but only twenty-two per cent (22%) could give a correct definition of MI. Only twenty per cent (20%) knew the location of the indices on their own machines (see Table 2).

Table 2: Knowledge of safety issues.

Characteristics	Result
Familiar with the term TI.	13 (72%)
Familiar with the term MI.	7 (39%)
Correct answer of TI definition.	6 (33%)
Correct answer of MI definition.	4 (22%)
Knowledge of location of TI/MI.	3 (20%)

Unfortunately, the study does not show a good background about acoustic output indices. The participants show poor knowledge of safety issues, at least from the gynecologist and the physician.

Most of the participants did not answer the TI question correctly, and even fewer answered the MI question correctly. The main purpose of the output display standard (ODS) was to provide the capability for end users of diagnostic ultrasound to operate their own devices at higher levels to increase diagnostic capabilities. The ODS did not specify any upper limits with a specific acoustic output under full control of the end users.

Table 3: Personal views of end users of diagnostic US Examinations and Practice

Characteristics	Result
Do you think that ultrasound examinations are safe? Yes No	17(100%) none
Do you think there should be limitations regarding number of examinations in low-risk pregnancy? Yes No	11 (61%) 6 (33%)
How many ultrasound examinations during low-risk pregnancy?	3 ± 1 (72%)
Are there any adverse effects to the foetus during ultrasound examinations? Yes No	3 (17%) 14 (78%)
Opinion about using ultrasound for entertainment (keepsake ultrasound). Agree Disagree	15(17%) 3(83%)

Manufacturers have been forced to supply information on safety indices (i.e. the TI and MI values), but the responsibility for the ultrasound output energy is, eventually, the end users'. End users of diagnostic ultrasound should be aware of the output energy, how to control it, and, accordingly, how to use the device safely. However, where the end users are not aware of the acoustic indices or where to find them, one can believe that they will not be able to control them. Almost 83% of the ultrasound professionals actually disapproved of keepsake ultrasound examinations without any clinical indication (see Table 3 above).

CONCLUSIONS

Ultrasonic imaging has been used for more than 5 decades and its use as a means of diagnosis is becoming more popular. It has become an important diagnostic tool used for obtaining information about function or structure in human beings. It is widely used in healthcare institutions, especially obstetrical clinics. Epidemiological studies have missed in the past to identify the adverse effects of ultrasound in human, which is considered a form of energy that cause bio-effects. The two mechanisms of ultrasound are heating and cavitation. These

mechanisms are referred to on the screen of the device by two of the indicators: the thermal index (TI) and the non-thermal index called also the mechanical index (MI).

It is necessary to know and observe those indicators during ultrasound examinations. So we determined end users knowledge regarding safety aspects of diagnostic ultrasound during pregnancy. A questionnaire was distributed to ultrasound end users working at different hospitals in Cape Town (five different hospitals), and we noted that the majority of participants do not have enough information about those indicators. The participants do not even know where those indicators despite they appear on screen in their machines. Most of the participants also do not familiar with the term TI and MI and what can cause the rise in the value of them.

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