

Acoustic Output as Measured by Thermal and Mechanical Indices and its Bio-effect During Ultrasound Scanning in Obstetrics

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Abstract

While ultrasound (US) is supposed to be totally safe, it is a form of energy. Diagnostic ultrasound (DUS) has the prospect to have effects on living tissues it crosses, such as bio-effects. The two most important mechanisms for effects are thermal and non-thermal, also called mechanical. These two main mechanisms are indicated on screen by two indices: the thermal index (TI) and the mechanical index (MI), to express the potential for rise in temperature at the ultrasound's focal point and the probability of harm from the mechanical effects such as cavitation. It is important to understand bio-effects of acoustic output during ultrasound scanning in obstetrics. This paper identifies the need for users of ultrasound to understand thermal and mechanical indices appearing on ultra-sound screens. Some users do not use the indices and others do not know or are unaware of their importance.

Keywords: ultrasound, acoustic output, bio-effects, thermal index, mechanical index, safety, fetus, diagnostic ultrasound.

1. Introduction

Physicians have used ultrasound (US) to make images of the inside of the human body for nearly half a century (*NCRP, 2002*). Ultrasound imaging has been used for more than 4 decades for fetal imaging (*NCRP, 1983*). It has become the most commonly used diagnostic imaging modality in obstetrics and gynecology (*Jacques S.A, 2008*). It has become available in every academic department, private offices, emergency departments, and even, recently, the shopping malls (*Jacques S.A, 2008*) (*Abramowicz, 2002*). Most pregnant women have at least 1 ultrasound scan during pregnancy, and almost 40% of all ultrasound scans performed are for obstetric use (*Hershkovitz et al., 2002; Duck, 1999*). To date, there is no confirmation that diagnostic ultrasound (DUS) causes harm in human tissues or the developing fetus when used correctly (*Thomas et al., 2009*).

2. Significance of the study:

The majority of physicians depend on ultrasound diagnoses in their clinics. Although, there are no studies concerning of safety of ultrasound, long-term epidemiological studies have failed to show harmful effects of ultrasound on human (*Lyons et al., 1988*) as a form of energy it might cause bioeffects.

This paper will be reviewed the former studies to evaluate the acoustic outputs (AOP) of ultrasound devices as measured by TI and MI, those appear on the screen. However, most of sonographers are not aware of the significance of those indices, which might affect harmfully on the patient. The study can also explain if the acoustic outputs are low or high.

3. Objective of the study:

This paper aimed at reviewing and presenting data for end-user on the safety of obstetric ultrasound scanning and acoustic output as measured by (TI) and (MI).

4. Background

Ultrasound is widely used in most medical clinics, especially obstetrical clinics, and it is 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 was established. But there are many disadvantages of 2DUS imaging. Several researchers have published information on the significance of patients showing the ultrasound screen during the examination, especially during three and four-dimensional (3D/4D) scanning.

4.1 Acoustic output and bio-effects

Diagnostic ultrasound (DUS) is an imaging modality that is useful in a wide range of clinical applications, and in particular, prenatal diagnosis (*BMUS, 2010*). It is considered very safe for a fetus (*Abramowicz, 2002; Hershkovitz et al., 2002*). However, data regarding effects on living tissues, e.g. bio-effects, are still inconclusive (*Hagi & Khafaji, 2013; Vavicchi & O'Brien, 1984; Child et al, 1990*). As a form of energy, ultrasound has the probability to have bio effects that cause damage on living tissues if used incorrectly. The two most probable mechanisms for these are heating and cavitation (*NCRP, 2002; AIUM, 2009*).

The cavitation mechanism includes the existence of gaseous bubbles in an air-water interface (*Hershkovitz et al., 2002*). The vibration of bubbles is caused by ultrasound waves through alternation of positive and negative pressures. However, it has not been documented in mammalian fetuses, since there is not air-water interface, which is needed for the cavitation mechanism (*Nyborg, 1965*).

The normal temperature of human body is commonly considered to be 37°C Celcius ($\pm 0.5 - 1^\circ\text{C}$). Temperature in the human fetus is higher than body temperature of the mother by 0.3 to 0.5 °C during the complete pregnancy but in the third trimester temperature of the fetus is higher by 0.5 °C than its mother (*O'Brien, 1992*). 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) (*Jacques, 2008*). The output display standard (ODS) consists of two indicators MI and TI (*Thomas et al, 2009*).

4.1.1 Thermal Index (TI)

TI indicates probability of a rise in temperature along the beam of ultrasound (*Sheiner et al, 2007*). 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*). It is assumed that with modern ultrasonic devices, there is no rise in temperature. Usually a small rise occurs which does not exceed 1°C (*Abramowicz et al, 2000*). Manufacturers were asked to display MI and TI on the screen (*WFUMB, 1992; AIUM, 2000*).

There are three shapes of TI which may be displayed on the screen (*BMUS, 2010. 110-118*). These are the thermal index for soft tissue, the thermal index for bone and the thermal index for cranial bone. The thermal index for soft tissue (TIS) is used when ultrasound penetrates soft tissue only. The thermal index for bone (TIB) is used when the ultrasound beam crosses or is near its focal area. The thermal index for cranial bone (TIC) is used when ultrasound transducer is very close to the bone (*BMUS, 2010. 52-59*).

The thermal index (TI) can be calculated “as a ratio of current acoustic power output from the transducer (W) to the power required to cause a maximum tissue temperature rise of 1°C (W_{deg}).

The following is the formula (*BMUS, 2010. 110-118; BMUS, 2010. 52-59*):

$$TI = \frac{W}{W_{deg}}$$

4.1.2 Mechanical Index (MI)

MI expresses the probability of harm from the mechanical effects such as cavitation. It is therefore displayed in B-mode imaging (*Holland et al, 1996*). It also expresses the possibility of ultrasound in inducing tissue cavitation (*O'Brien & Siddiqi, 2001*).

Its value is permanently updated by the operator, according to the control settings, using the formula:

$$MI = \frac{P - 0.3}{\sqrt{f}}$$

Where (f) is the pulse Centre frequency and ($P-0.3$) is the maximum value of peak negative pressure anywhere in the ultrasound field (*BMUS, 2010. 110-118; BMUS, 2010. 52-59*).

4.2 Acoustic safety and exposure control

Before 1976, there were no specific extents for acoustic output for diagnostic equipment ultrasound (*Thomas*

et al., 2009). In 1976, the US Food and Drug Administration (FDA) began regulating medical devices, including ultrasound to be no more than (94 mW/cm^2) (*Sheiner et al., 2007, 1665-1670*). Finally, it has established four (4) application-specific exposure limits (peripheral vascular, 720 mW/cm^2 ; cardiac, 430 mW/cm^2 ; fetal and others, 94 mW/cm^2 ; and ophthalmic, 17 mW/cm^2) (*AIUM, 2004*). These levels of output were selected in accordance with medical devices used in the market, and the clear safety of ultrasound at the time (*Thomas, 2009*).

From 1992, manufacturers were presented with two paths for approval (*BMUS, 2010, 110-118*). Track 1 (Table 1) was equivalent to control levels of the value of each application. It is worth mentioning, that some of the mechanical effects have been described in animals with exposure more than the upper limit ($\text{MI}=1.9$) imposed by the FDA (*Dalecki, 2004*).

Table 1. FDA Track 1 maximum permitted values of intensity and MI

Application	ISPTA (mW/cm ²)	MI
Peripheral vascular	720	1.9
Cardiac	430	1.9
Fetal and other	94	1.9
Ophthalmic	17	0.23

Spatial peak temporal average intensity (I_{SPTA}) is the time averaged value of Intensity, measured at the point in the ultrasound field where it is at its maximum [*BMUS, 2010, 110-118*].

Almost 1991, There were noticeable changes in the regulations concerning allowable upper limits of the acoustic output levels (AOL) of diagnostic ultrasound to be 720 mW/cm^2 for all applications (including obstetrical, i.e. an increase of a factor of almost 8) except Ophthalmic, which was set at (50 mW/cm^2) (*AIUM/NEMA, 1992; Donald, 1974*). Track 2 (Table 2) allowed manufacturers to use the highest output levels, In return for providing an on-screen display of thermal (TI) and mechanical (MI) safety indices (there is no Track2) (*BMUS, 2010, 110-118*).

Table 2. FDA Track 3 maximum permitted values of intensity, MI and TI

Application	I_{SPTA} (mW/cm ²)	MI	TI
All applications except Ophthalmic	720	1.9	6.0
Ophthalmic	50	0.23	1.0

FDA, Food and Drug Administration; MI, mechanical index; TI, thermal index; I_{SPTA} , Spatial peak temporal average intensity [*BMUS, 2010, 110-118*].

Since 1992, US devices have the ability to work with acoustic outputs of up to 720 mW/cm^2 with a specific acoustic output under full control and direct of the operator and with the expectations that techniques that are As Low As Reasonably Achievable (ALARA) will be used. Implementation of the output display standard (ODS) places the responsibility for the safety of the patient fully on users of ultrasound with compliance to the principle of ALARA (*Thomas et al., 2009*).

5. Literature review

5.1 First, second and third-trimester

In 2005, Sheiner et al. quantified acoustic output as measured by mechanical and thermal indices during routine obstetric ultrasound examinations. They collected data regarding duration of the examination and specific duration spent at each MI and TI. Thirty-seven (37) patients were recruited to participate in the study. The number of examinations evaluated was 11 in the first trimester, 14 in the second trimester, and 12 in the third trimester. First-trimester patients were randomly selected from those scheduled for viability ($n = 11$). Second-trimester patients (14-28 weeks) were randomly selected from those scheduled for anatomy examinations ($n = 14$). Third-trimester patients were randomly selected from those scheduled for follow-up examinations ($n = 12$) as shown in (table 3) (*Shiener et al., 2005*).

Table 3. Acoustic output during each Trimester of pregnancy

Trimester	TI	MI	P
FIRST	0.34	0.73	<.001
SECOND	0.28	1.04	
THIRD	0.34	1.06	

Sheiner E, et al. Acoustic Output as Measured by MI and TI During Routine Obstetric Ultrasound Examinations [Sheiner et al., 2005].

5.2 Two, three and four dimensional ultrasound (2D, 3D & 4D)

In 2007, Sheiner et al. compared acoustic output indices in 2D and 3D/4D ultrasound in obstetrics. They used three different commercially available machines. Forty ultrasound examinations were evaluated. Average thermal index (TI) during the three examinations (3D) and four-dimensional (4D), were similar with the thermal index during B-mode scanning or two-dimensional (2D). The mechanical index (MI) when using 3D was significantly lower than in the 2D B-mode ultrasound, and significantly lower than in the 4D ultrasound exam, but there are no large differences of TI or MI between the three devices, as shown in (Table3)(Sheiner et al., 2007, 326-328).

Table 4. Acoustic output during 2D & 3D/4D ultrasound:

characteristic	B-mode	Three-D	four-D	P
TI [mean ± SD]	0.28 ± 0.1	0.27 ± 0.1	0.24 ± 0.1	0.343
MI [mean ± SD]	1.12 ± 0.1	0.89 ± 0.2	1.11 ± 0.2	0.018*

Sheiner E, et al. Comparison between AOI in 2D & 3D/4D ultrasound in obstetrics [Sheiner et al., 2007, 326-328].

5.3 Color Doppler and pulsed wave

In 2007, the American Institute of Ultrasound in Medicine (AIUM) published a study on the evaluation of acoustic output during clinical ultrasound examinations, as expressed by the thermal and mechanical index, during the second half of pregnancy and comparing acoustic outputs between B-mode and Doppler examinations. The study was conducted by Sheiner et al (2007).

In that study, Patients with suspected fetal growth problems who were undergoing Doppler studies of the fetal circulation in addition to B-mode sonography were selected. Examinations were took place between 21 and 40 weeks' gestation, and data was collected by an obstetrician. A total of 63 examinations including Doppler studies in 63 patients were evaluated. Acoustic output, as indicated by the output indicators, during the ultrasound examinations are shown in Table 5 (Sheiner et al., 2007, 71-76).

Table 5. Acoustic output During B-mode & Doppler Ultrasound studies

characteristic	B-mode (n=190)	color Doppler (n=31)	pulsed wave (n=118)	P
TI mean ± SD	0.3±0.1	0.8±0.1	1.5±0.5	<.01
MI mean ± SD	1.1±0.1	1.0±0.1	0.9±0.2	<.01

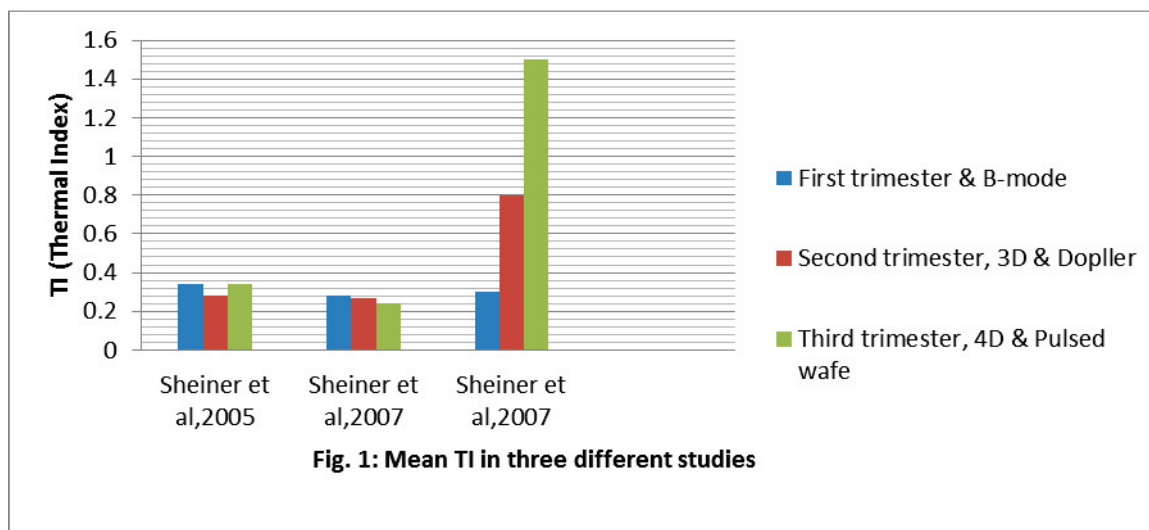
Sheiner E, et al. An increase TI can be achieved when performing Doppler studies in obstetrics ultrasound [Sheiner et al., 2007, 71-76].

6. Data analysis

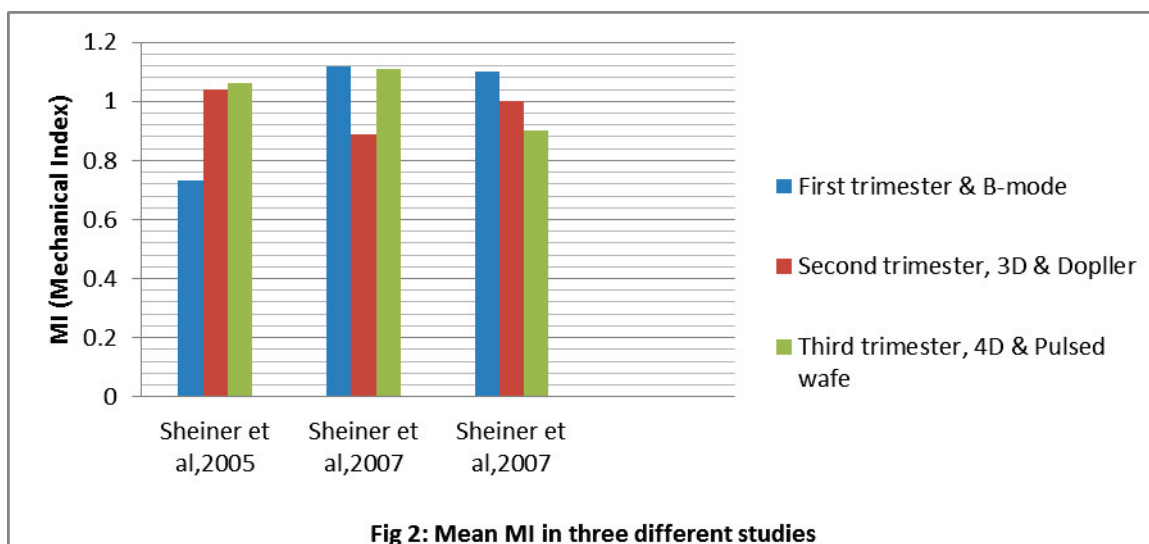
When the previous values that were obtained from different examinations were compared to each other,

acoustic output as measured by TI and MI during routine obstetrics ultrasound examinations were very close and comparable with each, as shown in fig 1. With the importance of knowing that, the calculated values of the indicators might vary from manufacturer to another and fluctuate with changes in the settings of equipment.

Except the pulse wave Doppler (PWD) which recorded values slightly more relatively with other values. Thermal (TI) can be recorded higher than 1.5 during (PWD). That indicates that exposure to Doppler ultrasound can heat biological tissue by a large proportion due to relatively high intensities used, and the need to keep a transducer motionless during the examination for a period of time (*Barnett & Maulik, 2001*).



Mechanical index (MI) values were also almost convergent together in various examinations. There is no record height in these tests as shown in fig. 2. Mean MI during all of last three examinations was approximately 0.94. This is low particularly in routine obstetrics ultrasound scanning when compared to the standard level set by the Ultrasound Food and Drug Administration (FDA) which is a maximum of 1.9 (*Sheiner et al., 2007, 1665-1670*).



7. Discussion

Ultrasound has been considered as a form of energy that may have the potential to cause bio-effects. However, epidemiological studies have failed to confirm harmful effects of ultrasound in humans (*Lyons et al., 1988*). As a result, ultrasound imaging has been considered to be generally safe if used correctly and monitoring of values of acoustic outputs that display on screen by two indices called TI and MI as described previously is performed.

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) describing the intensity of each pulse. But these are not useful during achievement of a clinical study (*Sheiner et al., 2007, 1665-1670*). For this reason and other and different other reasons, the Output Display Standard (ODS) was conducted in 1992 (*AIUM/NEMA, 1992*).

After that, the ODS has become an important factor to display on-screen by manufacturers. The objective of the output display standard was to provide the end-users of Diagnostic Ultrasound (DUS) the ability to operate their devices at higher levels, with a view to increase diagnostic abilities. The ODS did not allocate any upper limits. The manufacturers were forced to provide all information on-screen by safety indices (i.e. the TI/MI values). Nevertheless, the full responsibility for ultrasound output energy is on the end-users. Hence ultrasound end-users must be aware of the output energy, how to control it and how to use the machine in a safe way. In case, the end-users are not aware of acoustic indices or where to find them, they won't be able to control them (*Weiss, 2008*).

8. Conclusion

In general, acoustic output level during routine obstetric ultrasound examination, as measured by the TI and MI, are low in any kind of ultrasound examination. However, higher output levels, especially TI levels might achieve greater than 1.5 in Doppler pulsed wave examinations. Therefore, Doppler procedures should be performed with caution and be as short as possible during obstetric sonography. Literature suggests that these levels during 3D/4D ultrasound examination are almost similar with 2D B-mode ultrasound. The end-users should increase their awareness of safety issues to commitment to the principle of ALARA (As Low as Reasonably Achievable).

9. Future research

Further research should be conducted to quantify acoustic output of clinical ultrasound instruments during routine obstetric examinations. It should also focus on educational and practical interventions on users of ultrasound to promote obstetric outcomes. This can include awareness of evidence based guidelines on the use of ultrasound such as the ALARA principle and best practice training.

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