Assessment of Safety and Exposure Conditions during Obstetric Ultrasound at King Abulaziz University Hospital

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Abstract: Purpose: The objective of this study was to measure and evaluate machine output indices during obstetric scans at a local public hospital. **Methods:** A cross-sectional descriptive study was conducted at the Radiology Department of King Abdulaziz University Hospital (KAUH), Jeddah, between September and October 2011. The machine settings, including the thermal index (TI) and mechanical index (MI) as well as scan times were recorded during obstetric ultrasound examinations. Data were analyzed using the Statistical Package for the Social Sciences. Independent t-test and one-way ANOVA were used to compare continuous variables. **Results:** A total of 347 scans were studied. Most of them were performed in pulsed Doppler mode (n=176 ; 50.7%). Examination scan times varied between 1 to 27 minutes. The highest recorded TI value was 2.1, with mean ± SD of 0.81 ± 0.53 for examinations that lasted less than 15 minutes. The highest TI and MI values were observed during pulse Doppler. **Conclusion:** Thermal index values are within recommended safety guidelines. However, MI values sometimes exceed 1 and exposure times should be monitored to restrict the occurrence of any biologic effects due to ultrasound waves.

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1. Introduction

The general perception in the medical practice is that ultrasound is considered a very safe imaging modality that allows noninvasive imaging of the interior of the human body by only exposing a patient to high frequency sound waves and is used routinely during pregnancy. At the same time, therapeutic uses of these sound waves have proven that their physical properties can be aggressive enough to smash kidney stones and burn cancerous tissue from a distance [1].

The energy from any ultrasound transducer passes through the tissue and interacts with it. It can be absorbed by the tissue, scattered, or reflected back to the transducer head. Scattered energy to the bone, brain, and spinal cord of a developing fetus is of concern specifically in the third trimester. Also, the energy deposited in tissue causes a temperature rise. Laboratory studies have shown that this rise could be significant and reaches 4°C for five minutes or more [2].

To date, there is no evidence that diagnostic ultrasound produces harm if used within clinical requirements; however, new technologies have higher acoustic output levels than earlier equipment. To ensure safety of patients, it is vital to continuously train sonographers and inform them of the potential bioeffects that can result with misuse.

Thermal heating and mechanical (cavitations) are two effects that have indicators displayed on the machines (thermal index [TI] and mechanical index [MI]). The acoustic output can be controlled to limit these effects.

Governing bodies like the British Medical Ultrasound Society (BMUS) and the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) recommend the use of the ALARA (as low as reasonably achievable) principle to ensure that the lowest acoustic output is used for the shortest duration to achieve optimal diagnostic information.

Concerns about ultrasound safety has led to the evaluation of acoustic output indices (AOI) and the proper training of technologists to understand how these outputs could result in bioeffects when not controlled. Since both thermal and mechanical effects in tissue increase proportionally with the machine's output power, guidelines and limitations have been set to avoid misuse. The guidelines for the safe use of prenatal scans are [3]:

1. TI values less than 0.5 should be used unless otherwise required, particularly in the first trimester.
2. TI values less than 0.5 can be used without time restriction.
3. Thermal index values greater than 0.5 and up to 1 should be limited to scanning times less than 30 minutes.
4. TI values greater than 2.5 should be limited to scanning times less than 1 minute.

5. MI values less than 0.4 should be used if gas bodies are present.
6. If no gas bodies are present, MI values can be increased as needed "but should remain low because mechanisms for bioeffects not related to gas bodies may be possible in the developing fetus."[3]

It is the responsibility of the sonographer to use their judgment and insight to adjust the intensity output of equipment to get the most information at the lowest output during the shortest time [4].

Different scan modes result in more temperature rise than others. Doppler ultrasound, although very useful, uses higher output level therefore can result in a significant temperature rise when compared to B-mode scans. Studies conducted on animals using exposure conditions similar to those of Doppler applications have shown that an increase in embryonic temperature of 2°C can result in development abnormalities. Temperature increase near bone or soft tissue interfaces was measured [3].

The literature showed that sonographers are not always familiar with acoustic output indices nor are they aware that these indices are displayed on the machine [5,6]. The FDA recommends educational programs [7] for sonographers to raise their awareness level of real time display of thermal and mechanical acoustic output indices. Safety indices should be routinely monitored to make sure that sonographers are working within the set guidelines. Therefore, the objective of this study was to measure and assess the acoustic output indices of clinical ultrasound during routine obstetric scans at King Abdulaziz University Hospital (KAUH).

2.Materials and Methods

A cross sectional descriptive study was conducted at the Radiology Department at (KAUH), Jeddah- Saudi Arabia. All obstetric scans performed between September and October 2011 were considered for this study. The scans were performed using Philips ultrasound machine models iU22 and HD11. Ethical approval was obtained from the Biomedical Ethics Research Committee at KAUH.

Sonographers were unaware of the objective of the study; therefore, conducted all scans as they do routinely without noticing the displayed parameters . Data was collected by means of a previously published structured questionnaire to record information about each scan [8]. Permission to use this questionnaire at KAUH was obtained from the authors before conducting the study. Scan parameters, scan duration, MI, TI, and machine settings for each patient was recorded.

Statistical analysis: Data were analyzed using the Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA). Kolmogrov smirov test was done to determine if the data was parametric or non parametric. Independent t-test and one-way ANOVA were used to compare continuous variables after log transformation for non-parametric data. *P*-value less than 0.05 was considered statistically significant.

3. Results

A total of 401 scans were performed during a period of two months. Complete information was available only for 347 (87%) scans, which were considered for this study. Table 1 represents the general characteristics of data analyzed.

Table 1. General Characteristics of Data Analyzed

	TI	MI	Scan Time (min)
Mean ± SD	0.81± 0.53	1.17± 0.12	6.08 ± 4.29
Maximum	2.1	1.7	27
Minimum	0.1	0.3	1

Abbreviations: TI, thermal index; MI, mechanical index; SD, standard deviation.

Thirty-six (10.4%) examinations were described as B-mode, 135 (38.9%) as Doppler color flow and 176 (50.7%) used pulsed Doppler. The acoustic output during these scans as categorized by scan type is shown in Table 2.

Table 2. Acoustic Outputs Based on Scan Type

Characteristic	B-Mode	Color Doppler	Pulsed Doppler
TI			
Mean ± SD	0.67± 0.44	0.79 ± 0.49	0.84 ± 0.56
Range(Min.-Max.)	(0.3 - 1.8)	(0.3 - 2.1)	(0.3 - 2.1)
95% CI of the mean	0.50– 0.84	0.70 – 0.87	0.76 – 0.93
MI			
Mean ± SD	1.14± 0.15	1.15 ± 0.11	1.18 ± 0.12
Range(Min.-Max.)	(0.6 - 1.5)	(0.7 - 1.4)	(0.8 – 1.7)
95% CI of the mean	1.1 – 1.2	1.13 – 1.17	1.16 – 1.2

Abbreviations: CI, confidence interval; MI, mechanical index; SD, standard deviation; TI, thermal index. One way annova was used. *P* value more than 0.05 insignificant.

Examination times ranged from 1 to 27 minutes for the 347 scans. For those lasting less than 15 minutes, the highest TI value was 2.1 with mean value of 0.81 ± 0.53. The highest MI value was 1.7 with a mean of 1.17 ± 0.12. For examinations that lasted more than 15 minutes, the highest TI noted was 1.8 with a mean value of 1.02 ± 0.55. The highest MI for these examinations was 1.4 with a mean value of 1.13 ± 0.16. The highest TI and MI values were recorded during pulsed Doppler examination.

No significant variations of TI or MI were noted between sonographers or machine models.

4. Discussion

Most studies evaluating the safety of obstetric ultrasound examinations have been conducted in countries such as the United Kingdom and the United States,[4, 5, 8-11] and to the best of our knowledge, this study is the first one to evaluate obstetric scans in Saudi Arabia.

Data from this study provide an insight into ultrasound machine settings used during obstetric ultrasound examinations in a busy public hospital like KAUH. Most scans were performed using Doppler color (38.9%) and pulsed Doppler modes (50.7%); only 10.4% were performed in B-mode. The mean ± SD TI value observed was 0.81± 0.53 for scans less than 15 minutes, which is within the safety guidelines of the BMUS. Based on these guidelines, a scanning time of less than 15 minutes is recommended for 1.5≤ TI ≤2.0 for obstetric scans [8]. For safety reasons, they have recommended that MI values for obstetric ultrasound should not exceed 0.7 when contrast agents are used.

Scanning times tend to be longer for obstetric scans than for other ultrasound examinations, and it has been shown that TI values usually increase during obstetric ultrasound [9].While the TI does not necessarily indicate a rise of the temperature, it is numerically equivalent to the estimated temperature rise due to exposure to ultrasound waves. However, sonographers should be aware that the TI values displayed on monitors vary from one manufacturer to the other and change when equipment settings are modified [9].Only two machine models were used in the current study, and fluctuations in the indices did not seem to be affected by the machine type or operator.

In this study, MI values of up to 1.7 were observed, with the highest values recorded during Doppler scans. However, these scans were done without the use of contrast agents and because the likelihood of having gas bodies is minimal, these high MI values are within safety guidelines. More so, the technologists at our department should be informed and trained to limit scan times when the MI reaches 1.5.

Contrary to thermal effects that are of main concern in first trimester scans, mechanical effects are less important because of the absence of gas bodies or the use of contrast agents. However, mechanical radiation effects have been demonstrated in the fetus with the use of obstetric Doppler,[10] and the sonographer should bear in mind that Doppler scans produce higher intensities and thermal indices than B-modes with similar mechanical indices.[11] In fact, because the fetal brain is known to be fragile, Doppler scans should be avoided early in pregnancy.

Conclusion

Although the TI values used were within recommended safety guidelines, they have reached high limits where scan time should be minimized to avoid possible bioeffects. In addition, the results have shown that the MI values can exceed 1 which signifies that continuous monitoring of obstetric ultrasound practice is essential. This is to ensure that the restrictions set internationally on exposure times are followed by ultrasound users in order to limit biological effects on the fetus.

Recommendation

Given the large number of obstetric ultrasound examinations that are performed every year at our department, a lot of emphasis has to be put on the proper use of these machines. More so, the staff at our department keep changing as most of them are expatriates who work on contract bases; hence, a valid reason to frequently organize workshops and seminars to update sonographers on current safety guidelines.

Limitation of the study or area for further research

The study had some limitations. First, it would have been interesting to record TI values for different tissue types (i.e. TIS: thermal index of soft tissue , TIB: thermal index of bone, TIC: cranial thermal index) as well as the associated scanning times. Second, the gestation age was not taken into consideration in the analysis of our data. Finally, since obstetric ultrasound scans are performed routinely in our hospital and could be done when patient requests in the private practices, awareness among practitioners and ultrasound users should be raised about these output indices to minimize potential harm.

Because of the potential risk associated with the use of obstetric Doppler,[11] I recommend that further studies be conducted at our department to specifically assess the acoustic output indices and duration of scan times with respect to the gestational age.

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