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Benchmarking Acoustic Parameters During Diagnostic Ultrasound Scanning for Patient Safety

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Abstract: Background advancement in acoustic technology has led to an increase in ultrasound machine output which has the potential to increase thermal and mechanical effects in tissue. The safety committee of the British Medical Ultrasound Society (BMUS) has emphasised the importance of monitoring output levels during clinical ultrasound. The objective of this study is to assess Acoustic Output Indices (AOI) used at King Abdulaziz University Hospital (KAUH), Saudi Arabia and to benchmark the current practice with a survey conducted by BMUS. A questionnaire was used to collect data during every ultrasound scan performed between June 2nd and 23rd, 2011. The data collected consisted of type and duration of scan, ultrasound machine parameters and output indices (mechanical and thermal). About 408 scans were conducted using 10 different machines. Scan types were: abdominal, obstetrics, pelvic, transvaginal and small parts. Scan time ranged from 2-36 min. Maximum Thermal (TI) and Mechanical (MI) indices recorded were 1.3 and 1.5, respectively. Scans performed complied with the safety guidelines set by BMUS. However, the recommended scan time was exceeded during 2 (1.5%) obstetric scans. Further efforts in educating and training sonographers regarding the risks of thermal and mechanical hazards are needed.

Key words: Acoustic output indices, ultrasound, patient safety, thermal index, mechanical index, bioeffects

INTRODUCTION

Ultrasound imaging has been in use for over five decades and its use as a diagnostic tool has increased (Hangiandreou, 2003). Although, there have not been any reported harmful effects of ultrasound as a form of energy it has the ability to induce bioeffects in human tissues or organs. However, literature regarding bioeffects is still inconclusive (Sheiner *et al*., 2005; Ter Haar, 2010). Over the last few years, growing attention has been directed towards patient safety during radiological investigations (Donnelly *et al*., 2010). In 2000, the British Medical Ultrasound Society (BMUS) published guidelines for the safe use of diagnostic ultrasound and these were updated in 2009 after a national wide survey was conducted (BMUS, 2009; Ter Haar, 2011). They highlighted the importance of keeping the output levels As Low As Reasonably Achievable (ALARA).

Since, the two damage mechanisms of ultrasound waves are heating and cavitation, two safety indices have been developed to predict risk and possible biological effects. The Mechanical Index (MI) indicates the potential for harm caused by inducing cavitations in tissue. On the other hand, Thermal Index (TI) expresses the potential for temperature rise in the ultrasound beam and is defined as the ratio of the total acoustic power to the acoustic power required to raise the tissue temperature by 1°C (NCRPM, 2002). Three types of TI are defined: for soft tissues (TIS) for bone (TIB) and for cranial bone (TIC) (The Safety Group of the British Medical Ultrasound Society, 2010). It is important to understand that these indices increase with increasing machine output power. Safety guidelines are designed to help users apply diagnostic ultrasound in a safe manner.

Different modes are used for different examinations, (i.e., arterial/venous system, small parts, abdomen, pelvis, obstetric and joints). Power level, frequency and gain all determine the clarity of the image. These parameters are controlled by the sonographers as they alter with the settings of an ultrasound machine.

A world-wide concern about ultrasound safety has led to the evaluation of Acoustic Output Indices (AOI). These are indicative of patient acoustic exposure from ultrasound machines. The proper training of the technologist in the understanding of how these outputs may result in bioeffects when not properly controlled is vital.

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Due to the fact that KAUH is going through accreditation and evaluation of research flow by external international bodies, high impact was put on measuring the quality of healthcare service and implementing benchmark strategies to ensure good practice. The performance of the department of radiology at KAUH was evaluated to measure its effectiveness, improve work flow and indemnify patient's safety. Therefore, the survey conducted on the behalf of the BMUS and their published guidelines were used as a benchmark to assess the current ultrasound practice within our healthcare facility (Ter Haar, 2008).

The objective of this study is to assess the AOI used during general clinical ultrasound examinations for diagnostic purposes at the Department of Radiology, KAUH, Jeddah Saudi Arabia and to benchmark the current practice with the published safety guidelines. This is the first study that evaluates the acoustic output during general diagnostic ultrasound in Saudi Arabia.

King Abdulaziz University Hospital is one of the largest public hospitals in the Western region of Saudi Arabia with a total bed capacity of 878. After implementation of the accreditation process and evaluation of workflow, the hospital management has supported all initiatives that directly affect any improvement in quality of care and patient safety. In addition, ethical approval was obtained from the hospital's bioethics committee before commencing with this study.

MATERIALS AND METHODS

A cross sectional study was carried out at the Department of Radiology at KAUH from June 2nd till June 23rd 2011 as part of benchmarking the performance of the department for accreditation purposes. All sonographers within the department were asked to record ultrasound machine parameters, settings and output indices during all patient scans completed during that period. Guidelines established by BMUS (2009) were used to evaluate the current practice.

Permission to use the questionnaires ealier published by the BMUS for their national wide survey (Ter Haar, 2008) was obtained. Two questionnaires were used to collect data for this study. One questionnaire was completed for each ultrasound machine used in this study and a second was used for each patient scan conducted. This showed scan settings (mode and probe parameters), scan time and output indices. The results were compared to those from the BMUS-UK based survey to assess the current practice.

Equipment: Ten ultrasound machines were used throughout this study. They were all manufactured by Philips and were following models: IU22, HD11XE and KD1.

Data analysis: Data is reported in the form of means and standard deviations for comparison.

RESULTS AND DISCUSSION

Five sonographers participated and reported information on a total of 408 scans conducted during the chosen period. Scan types were: abdominal, obstetrics, pelvic, transvaginal, small parts and other, Fig. 1. Scan duration, Thermal Index (TI) and Mechanical Index (MI) for each scan type are reported in comparison to those from the survey conducted on the behalf of the BMUS in Table 1.

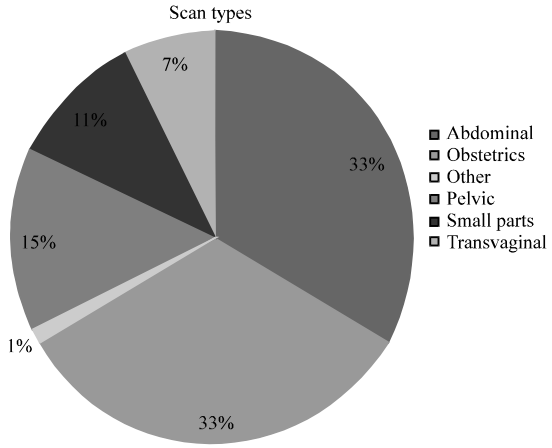

Fig. 1: Scan type

Table 1: Benchmarking current practice of general ultrasound scans

Scan type/parameter	Benchmark (ranges)	KAUH study (ranges)
Abdominal		
Scan duration (min)	2-25	2-32
TI	0-1.2	0.2-1.3
MI	0.4-1.6	0.2-1.3
Obstetric		
Scan duration (min)	2-34	2-35
TI	0.1-2.5	0.2-1.3
MI	0.2-1.6	0.3-1.5
Transvaginal		
Scan duration (min)	2-24	2-10
TI	0.1-0.4	0.2-0.8
MI	0.4-1.0	0.6-1.3
Small parts		
Scan duration (min)	4-24	2-36
TI	0-0.3	0.1-0.9
MI	0.4-0.9	0.1-1.3

KAUH: King Abdulaziz University Hospital; TI: Thermal Index; MI: Mechanical Index; Min. = minutes

Abdominal scans: A total of 136 abdominal scans were reported. Of these 83 (61%) used B-mode only, 24 (18%) used harmonic imaging and 53 (39%) combined B-mode and Doppler color flow. The examination time ranged from 2-32 min with a mean of 11.3±6.1 min. The longest scan time reported was 32 min for a Doppler color flow examination. For all Doppler scans reported, the average scan time was 10.98±6.3 min. The average was 11.4±5.2 min for B-mode. The TI values reported were described as 121 (89%) TIS and 15 (11%) TIB. The TIS and TIB values ranged from 0.4-1.3 and 0.2-1, respectively. The mean TI_{max} used for all abdominal scans was 0.78±0.14. The MI recorded ranged from 0.2-1.3. The MI_{max} recorded for any scan was 1.3 with a mean of 1.22±0.05.

Obstetric scans: The 136 obstetric scans were reported. Of these 59 (43%) used B-mode only, 57 (42%) used harmonic imaging, 53 (39%) combined B-mode and Doppler color flow and 15 (11%) used pulsed Doppler. The examination time for this type of scan ranged from 2-35 min with a mean of 5.42±3.87 min. The longest scan time reported was 35 min for a Doppler color flow. For all Doppler scans reported, the average scan time was 5.3±3.4 min. The average was 5.6±3.1 min for B-mode. The TI values reported were described as 31 (23%) TIS, 96 (71%) TIB and 9 (6%) TIS/TIB/TIC. The TIS and TIB values ranged from 0.2-1.0 and 0.3-1.3, respectively. The mean TI_{max} displayed during obstetric scans was 0.55±0.14. The MI recorded during obstetric scans ranged from 0.3-1.5 and the mean for MI_{max} recorded 1.13±0.19.

Pelvic scans: A total of 59 pelvic scans were reported. All of them used B-mode only except for one scan which used Doppler color flow. The 19 (32%) of those used harmonic imaging. The examination time for pelvic scans ranged from 2-35 min with a mean of 5.0±4.8 min. The longest scan time reported was 35 min for a B-mode. The number of examinations reported as displaying TIS and TIB were 29 and 30, respectively. The TI ranged from 0.2-1.2 and the mean for maximum TI displayed during pelvic scans was 0.82±0.76. The MI recorded for these scans ranged from 0.6-1.3 and the mean for MI_{max} recorded 1.12±0.17.

Small parts scans: Total 43 small parts scans were conducted. Only 4 (9%) used B-mode while 39 (91%) used Doppler color flow. Examination time ranged from 2-36 min with a mean of 10.5±6.7 min. The TI values reported were described as 36 (84%) TIS and only 7 (16%) TIB. They ranged from 0.1-0.9 and 0.1-0.2 for TIS and TIB, respectively. The mean TI_{max} displayed during this type of scan was 0.23±0.21. The MI recorded ranged from 0.1-1.3 and the mean MI_{max} was 0.74±0.16.

Transvaginal scans: A total of 30 transvaginal scans were reported. All of which used B-mode. Only 7 (23%) were described as using harmonic imaging. The scan time ranged from 2-10 min with a mean of 5.3±1.75. The TI values reported were described as 23 (77%) TIS and 7 (23%) TIS/TIB. The mean TI_{max} displayed during this type of scan was 0.51±0.19. The MI recorded ranged from 0.6-1.3 and the mean MI_{max} was 1.04±1.17.

The maximum TI and MI reached during each patient scan at KAUH were recorded and they were categorized by scan type. Their means were benchmarked with the UK study in Fig. 2 and 3.

Ultrasound waves have been used in diagnostic imaging for many years and have proven to be a very useful and safe form of imaging (Hangiandreou, 2003). Technology has advanced immensely over the years resulting in machines with improved imaging capabilities but also with an increase in their acoustic output. This resulted in a worldwide concern about the possible bio-effects and patients safety. It highlighted the need to educate physicians and sonographers about the established safety guidelines based on the ALARA (as low as reasonably achievable) principle and emphasized the importance of continuous monitoring of MI and TI values (NCRPM, 2002).

Accreditation and certification procedures have stimulated the department of radiology to audit and improve its performance. This study has identified the current practice at KAUH. Since, a national wide survey

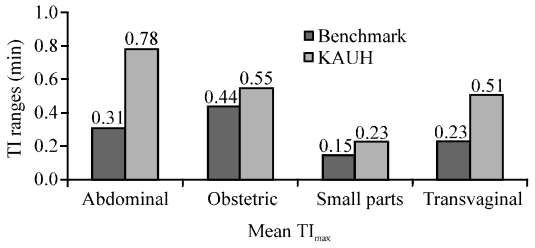

Fig. 2: Mean TI_{max} (maximum thermal index) used for all scan types

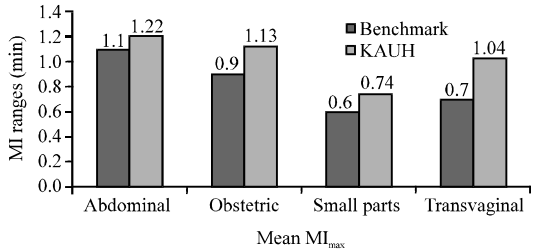

Fig. 3: Mean MI_{max} (maximum mechanical index) used for all scan types

was conducted in the UK by Ter Haar (2008) on behalf of the Safety Committee of BMUS to get a snapshot of the practice, researchers have used it as a benchmark. Their results show that only 1.75% of the scans performed did not comply with the BMUS guidelines. They also highlighted the need to make sure that those who perform these examinations have up to date knowledge of current safety guidelines.

The results recorded at KAUH show similar findings to those of BMUS, Table 1. The results confirmed that during routine scanning TI and MI levels could reach 1.3 although the mean remained within the limits of the guidelines. The scan time was exceeded in 2 scans. As scan times were exceeded in obstetric scans, an area of great concern for safety due to the possibility of cell damage which might lead to fetal anomalies, the need to educate sonographers regarding the risks of thermal and mechanical hazards is highlighted.

The sonographers performing the ultrasound scans carry qualifications from different educational programs but all stated that they were unaware of the TI and MI values displayed on the machine before this study. The literature shows that sonographers are not always familiar with acoustic output indices nor they are aware that these indices are displayed on the machine (Sheiner *et al*., 2007). Since, this was the case in the study as well, data was collected with no influence from the sonographers and reflects a true representation of the TI and MI levels acquired during routine scanning.

CONCLUSION

Since, KAUH is a teaching hospital, researchers have a greater responsibility to monitor and control the use of these machines in an effort to maintain their safe use. Users must be educated about the exposure capabilities of these new, higher-output devices. Since, there are no automatic safeguards for the output of ultrasound machines required, the user is expected to minimize patient's risk by keeping the thermal and mechanical indices low and by limiting scan time during all examinations (NCRPM, 2002; The Safety Group of the British Medical Ultrasound Society, 2010).

An initiative focused on patient safety during radiological investigations has been adapted hospital wide. Continuous education of technologists, introducing them to acoustic output indices can dramatically improve quality, safety and patient care.

Routine audit of these indices should be conducted on yearly basis to ensure best practice. In addition, further efforts during orientation of new staff (sonographers) can help increase their level of awareness of possible bioeffects of misuse of ultrasound machines. The current study used 10 ultrasound machines from the same manufacturer, same model. The use of different models by different manufacturers could have resulted in more variation is acoustic output. Also, this study has given us a preliminary indication of the current practice of clinical ultrasound at KAUH however more data regarding the effect of the scan modes, TI type (i.e., TIS, TIB, TIC) and repeated examinations is still needed.

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