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● *Original Contribution*

ACOUSTIC OUTPUT MEASURED BY THERMAL AND MECHANICAL INDICES DURING FETAL ECHOCARDIOGRAPHY AT THE TIME OF THE FIRST TRIMESTER SCAN

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Abstract—We measured acoustic output, expressed as the thermal index (TI) and mechanical index (MI), during fetal echocardiography at the time of the first trimester scan. TI and MI were retrieved from the saved displays during gray-mode, high-definition color flow Doppler and pulsed-wave Doppler (tricuspid flow) ultrasound examinations of the fetal heart and from the ductus venosus assessment. A total of 399 fetal cardiac examinations were evaluated. There was a significant increase in TI values from B-mode studies (0.07 ± 0.04 [mean ± SD]) to color flow mapping (0.2 ± 0.0) and pulsed-wave Doppler studies (0.36 ± 0.05). The TI from ductus venosus assessment (0.1 ± 0.01) was significantly lower than those from Doppler examinations of the heart. MI values from B-mode scans (0.65 ± 0.12) and color flow mapping (0.71 ± 0.11) were comparable, although different, and both values were higher than those from pulsed-wave Doppler tricuspid evaluation (0.39 ± 0.03). There were no differences in MI values from power Doppler assessment between the tricuspid flow and ductus venosus. Safety indices were remarkably stable and were largely constant, especially for color Doppler (TI), tricuspid flow (MI) and ductus venosus assessment (TI, MI). We acquired satisfactory Doppler images and/or signals at acoustic levels that were lower than the actual recommendations and never reached a TI of 0.5. (E-mail: dragos.nemescu@umfiasi.ro) © 2015 World Federation for Ultrasound in Medicine & Biology.

Key Words: **Fetal echocardiography, First trimester, Doppler ultrasonography, Output energy, Safety, Thermal index, Mechanical index.**

INTRODUCTION

In recent years, growing acceptance of the first-trimester nuchal translucency measurement has led to the early detection of fetuses at high risk for major congenital heart disease and, therefore, has increased the interest in early evaluation of the fetal heart (Sotiriadis et al. 2013). This has applied mainly on high-risk patients (Bellotti et al. 2010; Persico et al. 2011; Volpe et al. 2012; Weiner et al. 2008), but some groups have investigated its routine incorporation into the first trimester scan (Lombardi et al. 2007; Smrcek et al. 2006; Volpe et al. 2011; Votino et al. 2012).

In the first trimester, color flow mapping has a dominant role, improving the visualization of chambers and vessels, as well as revealing flow direction. It is often associated with pulsed Doppler evaluation of tricuspid flow, as a part of aneuploidy screening (Kagan et al. 2009), and with the assessment of ductus venosus (DV) flow as it is improving the early detection of cardiac defects (Papatheodorou et al. 2011).

As a form of energy, ultrasound has the potential to cause bio-effects through heating and cavitation. Ultrasound machines have to display the thermal index (TI) and mechanical index (MI) on the screen during examinations, to indicate the likelihood of ultrasound-induced bio-effects. The TI expresses the potential for rise in temperature along the ultrasound beam. The MI indicates the relative probability that the ultrasound will induce inertial cavitation. However, because of the absence of a gas–liquid interface *in utero*, this effect has not been observed in mammalian fetuses, and there is no direct evidence to date as to whether or not this effect can occur in humans (World Federation for Ultrasound in Medicine and Biology [WFUMB] 1998; Sheiner and Abramowicz 2009).

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Values of TI and MI are generally low during routine measurements of nuchal translucency (Sheiner and Abramowicz 2009), but the exposure remains unknown for Doppler examinations in the first trimester (ter Haar et al. 2013). Studies in the second half of pregnancy indicate that the TI values occasionally exceed 1.5 when pulsed-wave Doppler mode is applied (Sheiner et al. 2007b). Therefore, the fetus is considered to be at risk of exposure to high ultrasound levels during its early development, when it is sensitive to external influences (Salvesen et al. 2011b).

Current recommendations vary with the different societies. The TI value should be ≤1.0, and exposure time should kept as short as possible (usually no longer than 5–10 min) and should not exceed 60 min for first-trimester Doppler examinations (Salvesen et al. 2011a; World Federation for Ultrasound in Medicine and Biology/International Society of Ultrasound in Obstetrics and Gynecology [WFUMB/ISUOG] 2013). Others recommend that the TI values be <0.7 for an extended first trimester scan, and at TI values between 0.7 and 1, the length of the scan should be limited to 60 min (British Medical Ultrasound Society [BMUS] 2010). In the case of the obstetric ultrasound (up to or after 10 wk), in the absence of ultrasound contrast agents, for MI values <0.3, there is no known reason to restrict scanning times (BMUS 2010). However, there is a theoretical risk of cavitation, which increases with MI values >0.7 (BMUS 2010). For imaging with contrast agents containing gas microspheres, the recommended MI upper safe limit varies from 0.4 (American Institute of Ultrasound in Medicine [AIUM] 2008) to 0.7 (BMUS 2010). The evidence for the safety of ultrasound is insufficient, and caution has been advised (Salvesen et al. 2011b).

Our objective was to analyze TI and MI values and exposure time during fetal echocardiography at the time of the first trimester scan.

METHODS

This study was part of a prospective observational study in women undergoing first trimester ultrasound screening at our care center between March 2011 and December 2013. We searched the database and retrieved from the saved displays the TI (for soft tissues) and MI values from gray-mode, color flow mapping and pulsed-wave Doppler ultrasound examinations of the heart and from assessment of the ductus venosus. The study protocol was approved by the ethics committee. Patients were enrolled consecutively after they signed an informed consent form. Viable singleton pregnancies with a crown–rump length of 45 to 84 mm were included. We excluded major fetal anomalies, chromosomal anomalies and fetal heart defects diagnosed during pregnancy or the postnatal period.

All examinations were performed transabdominally using the Voluson E8 (RAB4-8D probe) ultrasound system (GE Healthcare, Zipf, Austria) by a single trained operator, certified by the Fetal Medicine Foundation, who had more than 5 y of experience in obstetric scanning and was performing 1000 fetal anomaly scans per year.

The image of the fetal thorax was magnified using machine zoom (high-definition zoom) so that it occupied most of the image. Usually, after examination using B-mode, the operator interrogated tricuspid flow and then applied color flow mapping to the same zoomed heart window. Systematically, we evaluated the four-chamber view, ventricular filling, right and left ventricular outflow tract views, crossover of the great arteries and three-vessel and trachea view using high-definition (HD) color Doppler, as previously described (Abuhamad and Chaoui 2010; Lombardi et al. 2007). HD color flow Doppler (HD-Flow, GE Healthcare) is a bidirectional power Doppler mode that depicts flow at a lower velocity than color or power Doppler (Yagel et al. 2007). The operator could choose to switch to a transvaginal approach if the image quality was poor, but these cases were not included in the study. Tricuspid flow and ductus venosus flow were evaluated as previously described (Faiola et al. 2005; Maiz et al. 2008).

We started with specific presets defined by the manufacturer for first-trimester evaluation of the heart and then adjusted and saved these as the study progressed. For the ductus venosus, we used distinct settings. Depth, focus, overall gain (post-processing) and power were adjusted as necessary. The sonographers were unaware of the data being sought and fully complied with the guidelines on the safe use of ultrasound at this gestational age (Salvesen et al. 2011a).

The images of the structures defined by the operator as visualized were stored in the ultrasound equipment and subsequently exported. We calculated the time from the beginning to the end of the Doppler heart exam. We did not consider the time for adjustment of settings. We also evaluated the distance between the transducer and the fetal heart.

Statistical analyses were performed using SPSS Version 21.0 (IBM, Armonk, NY, USA). Data were available for all four types of examinations, for each patient. The acoustic output differences between the four types of examinations were assessed using the Wilcoxon signed-rank test for two related samples. The level of significance was set at $p < 0.05$.

RESULTS

We evaluated 399 fetal cardiac examinations. The median age of participants was 30 y (range: 18–43),