Variation of safety indices during in the learning curve for color Doppler assessment of the fetal heart at 11+0 to 13+6 weeks’ gestation.

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Abstract

Aims: The aim of our study was to analyze the variation of acoustic output, as expressed by the thermal (TI) and mechanical index (MI), during the learning curve for a fetal heart scan at 11-13 gestational weeks, with the introduction of a new ultrasound system. Material and methods: This was a prospective, observational study on 303 normal fetuses. The fetal heart was examined transabdominally using B-Mode and high definition (HD) color Doppler to obtain standard parameters: four-chamber, outflow tracts and three-vessel-trachea views. Data were analyzed in groups of 20 consecutive examinations and the percentage of successful examinations was calculated. TI and MI were retrieved from HD color Doppler examinations of the fetal heart and from pulsed-wave Doppler assessment of the tricuspid flow and ductus venosus. Results: MI values from the color Doppler examination of the fetal heart showed a continuous decrease (0.81 to 0.75, p<0.001), along the learning phase. TI and MI indices from pulsed-wave Doppler evaluation of the tricuspid flow increased at the beginning of the learning phase and stabilized afterwards (0.34 to 0.36, p<0.05 and 0.37 to 0.4, p<0.001, respectively). TI from color Doppler exam of the heart and indices from ductus venosus assessment were very constant and did not change along the studied periods. The length of Doppler examination of the heart increased after about 80 cases by 25%, to a mean of 4 minutes (p<0.05). Conclusions: Safety indices from Doppler evaluation of the fetal heart and tricuspid flow vary during the learning curve for fetal heart assessment. Also, the occurrence of constant values suggests the potential for their supplementary active reduction. For a better adaptation to a new ultrasound technology, the sonographer should scan the fetal heart longer in the first trimester and follow displayed safety indices along the first 80 cases.

Keywords: fetal echocardiography, first trimester, Doppler ultrasound, thermal index, learning curve

There is an increased interest in the evaluation of the fetal heart in the first trimester of pregnancy. Even if a detailed examination is not possible with current ultrasound technology, a basic assessment of the fetal heart at 11 to 14 weeks of gestation has been used mainly in high-risk patients [1,2] and some groups have investigated its routine incorporation into the first-trimester scan [3,4].

At this gestational age, color flow mapping has a dominant role, improving the visualization of heart chambers and great vessels as well as demonstrating flow direction. There are often associated with the tricuspid flow and ductus venosus (DV) pulsed Doppler evaluation as a part of aneuploidy screening [5], improving the early detection of cardiac defects [6].

As a form of energy, the ultrasound has the potential for causing bioeffects by heating and cavitation. Ultrasound machines have to display the thermal index (TI) and mechanical index (MI) on the screen during examination as an indication of the likelihood of ultrasound-induced bioeffects. These enable the application of the ALARA (as low as reasonably achievable) principle to limit the risks.

Safety indices are automatically computed and displayed by the ultrasound system. Besides probes’ power, these indices are continuously influenced by scanning parameters such as window size, probe frequency, depth, position, and number of the focus, velocity scale and sample volume (gate) size [7]. The current recommendation...
is that TI should not exceed 1.0; the exposure time should be kept as short as possible (usually no longer than 5-10 minutes) and should not exceed 60 minutes for the first-trimester color Doppler examinations [8,9]. In the case of the obstetric ultrasound (up to or after 10 weeks), in the absence of ultrasound contrast agents, for MI values less than 0.3, there is no known reason to restrict scanning times. However, there is a theoretical risk of cavitation, which increases when the MI values are above 0.7 [10].

The levels of TI and MI are generally low when in nuchal translucency measurement [11] and fetal echocardiography at 11-13 weeks’ gestation [12]. However, it has been found that ultrasound specialists could exceed the limits during Doppler recordings [13] and many of them have insufficient knowledge of TI and/or MI and do not observe or adjust the acoustic power level of their machines [14,15].

The color and pulsed Doppler modes have an increased potential for high-output ultrasound energy levels and because the probability of a successful echocardiography is directly dependent on the heart examination length [16,17], these might expose the fetus to high energy during its early development, when it is sensitive to external influences [18]. Also, the adaptation with a new ultrasound system could lead to an increased energy exposure. In this study, we tested the hypothesis that the safety indices have a significant variation during the learning curve for fetal echocardiography, at the time of the first-trimester scan, with the introduction of a new ultrasound system.

Material and methods

This was part of a prospective observational study on 303 women attending their first-trimester ultrasound screening at our care center, between March 2011 and May 2013. The study protocol was approved by the Ethics Committee. Patients were enrolled in a consecutive manner, after they signed an informed consent. Viable singleton pregnancies with a crown-rump length (CRL) 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.

The study started with the introduction of a new ultrasound system Voluson E8 (GE Healthcare, Zipf, Austria). All examinations were performed transabdominally (RAB4-8D probe) by a single trained operator, certified by the Fetal Medicine Foundation, with more than three years of experience in obstetrical scanning and performing 1000 fetal morphology scans per year. At the beginning of the study, the operator had performed 435 first trimester scans.

The image of the fetal thorax was magnified using the machine zoom (HD zoom) so that it occupied most of the image. Usually, after examination using the B-mode, the operator interrogated the tricuspid flow and then applied the color flow mapping on the same zoomed heart window. Systematically, we evaluated the 4-chamber view (4CV) – ventricular filling, right and left ventricular outflow tracts (RVOT, LVOT), crossover of the great arteries, 3-vessel and trachea view (3VTv) using high definition (HD) color Doppler as previously described.[19-21] HD color flow Doppler (HD-Flow™, GE Healthcare) is a bi-directional power Doppler mode that depicts the flow at a lower velocity than color or power Doppler [22]. The cine-loop facility of the ultrasound machine was used to identify studied fetal heart segments. The operator could choose to switch on a transvaginal approach, if the image quality was poor, but these cases were not included in the study. The tricuspid and DV flows were evaluated as previously described [23,24].

The images of fetal structures defined by the operator as optimally viewed were stored in the ultrasound equipment and subsequently exported. Visualized heart segments were recorded into a database at the end of the exam. We retrieved from the saved displays TI (for soft tissues) and MI values from color flow mapping and pulsed-wave Doppler examinations of the heart and from the DV assessment. The time from the beginning to the end of the Doppler heart exam was also measured. We did not consider the time for settings’ adjustment and the safety indices’ variation during an individual ultrasound exam.

We started with specific presets defined by the manufacturer for first-trimester evaluation of the heart and these were then adjusted and saved, usually at the end of the exam, as the study progressed. For the DV evaluation we used distinct settings. Depth, focus, overall gain (post-processing) and power were adjusted as necessary. The sonographer was unaware of the data followed by the study and fully complied with the guidelines on the safe use of ultrasound at this gestational age [8].

The feasibility of fetal echocardiography was assessed through the frequency of adequate cardiac examinations (visualization of 4CV together with LVOT, RVOT and 3VTv). The outflow tract crossover was not directly included in a complete heart scan, but its composing structures were assigned accordingly. Thus, the ‘b’ sign (the visualization straight line of the pulmonary artery surrounded by aortic arch) was counted to 3VTv and the ‘X’ sign (the crossing of the main pulmonary artery by the aorta) was counted for LVOT and RVOT. The data were analyzed in groups of 20 consecutive examinations and in each group we calculated the percentage of successful examinations. We used the univariate polynomial regression to produce a learning curve and to identify its learning phase and plateau.
Statistical analyses
Statistical analyses were performed using the SPSS program, version 21.0 (SPSS, Chicago, IL). Data were expressed as mean ± standard deviation for normally distributed data, and median with range otherwise. The differences between the periods of the learning curve were assessed using the Student’s t test and Mann–Whitney U-tests for quantitative data. The level of significance was set at p < 0.05.

Results
We studied a population of 303 pregnancies undergoing nuchal translucency screening. We excluded 5 fetuses with cardiac malformations, 6 cases with aneuploidies, 5 cases with major fetal anomalies and 9 cases that needed also a transvaginal approach.

Evaluating the relationship between the acoustic output expressed by TI and MI and the learning curve we found three distinct periods of variation, respectively first 80, next 60 and the last 163 cases. There were no significant differences between these groups for maternal age (30.4±4.5 years), CRL (60.9±0.9 mm), body mass index (22.9±3.7 kg/m²) and transducer-heart distance (6.3±1.2 cm) (mean ± standard deviation).

A complete cardiac exam was feasible in 76% of cases in the first period (first 80 cases), in 80% of cases in the second period (cases 81-140) and in 98% of cases from the third period (the last 163 cases). The length of the Doppler examination of the heart increased from 3.12±1.52 minutes during the first period to 3.67±1.77 minutes in the second and were stable afterwards, at 3.95±1.96 minutes (p<0.05 for the 1st vs 2nd period; t=-3.4, p<0.01 for the 1st vs. 3rd period and not statistically significant for the 2nd vs 3rd period). Our fitted equation for the first-trimester fetal echocardiography learning curve achieved the plateau from the beginning of the third period, after 140 cases (fig 1).

We found that MI values, from the color Doppler examination of the fetal heart, showed a continuous, significant decrease along the learning curve until this achieved the plateau. TI and MI values from the pulsed-wave Doppler assessment of the tricuspid flow presented an initially, significant increase but then stabilized, after the first period of the learning curve (first 80 cases). The maximum acoustic outputs are presented, for the three periods of the learning curve, in Table I.

TI values retrieved from color Doppler imaging of the heart, TI and MI values from the DV evaluations were very stable and did not change along the studied periods. Their median (range) values were respectively: 0.2 (0.2 – 0.2), 0.1 (0.1 – 0.1) and 0.4 (0.4 – 0.4).

Discussion
This study demonstrated that acoustic output expressed by thermal and mechanical indices varies while in the learning curve. We found a continuous, significant

![Fig 1. The mean value of safety indices, the percentage of successful examination of the heart (♦) and the learning curve for first-trimester fetal echocardiography (—) in relation to the number of cases examined in consecutive groups of 20 scans heart MI: MI for color Doppler examination of the heart; TR MI and TR TIs: MI and soft tissues TI for pulsed-wave Doppler evaluation of the tricuspid flow.](image)

Table I. Safety indices values, recorded at the first trimester evaluation of the fetal heart, during learning curve periods.

<table>
<thead>
<tr>
<th></th>
<th>1st Period (n=80)</th>
<th>2nd Period (n=60)</th>
<th>3rd Period (n=163)</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td><strong>Thermal Index</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>PD TR</td>
<td>0.3 (0.3 – 0.4)</td>
<td>0.4 (0.3 – 0.4)</td>
<td>0.4 (0.3 – 0.4)</td>
<td>0.04, 1 vs. 2, 0.001, 1 vs. 3, NS 2 vs 3.</td>
</tr>
<tr>
<td><strong>Mechanical Index</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Color Doppler</td>
<td>0.8 (0.5 – 1)</td>
<td>0.8 (0.5 – 0.9)</td>
<td>0.7 (0.5 – 1.1)</td>
<td>0.001, all combinations</td>
</tr>
<tr>
<td>PD TR</td>
<td>0.4 (0.2 – 0.4)</td>
<td>0.4 (0.2 – 0.4)</td>
<td>0.4 (0.3 – 0.4)</td>
<td>0.001, 1 vs. 2, 1 vs. 3, NS 2 vs 3.</td>
</tr>
</tbody>
</table>

Data are given as median (minimum – maximum). All comparisons were made using the Mann–Whitney U-test. PD TR, pulsed-wave Doppler tricuspid flow assessment.
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In the learning phase, the Doppler examination time increased by 25% at the beginning of the learning curve. This result appears mainly because the probability of a successful echocardiography is directly dependent on the length of the heart examination. Thus, our result may occur because of the use of the ultrasound machine cine-loop facility and by studying a smaller number of fetal heart parameters.

A limitation of our study was the fact that our data was based on the experience of a single operator. For that reason, it would be worthwhile to compare the results of several sonographers with different skill levels before a wide-scale application. We assessed the safety indices values at the time when the operator considered the optimum image and not their variation along an individual ultrasound examination. This aspect could also be viewed as a limitation of the study and requires the observation of the safety indices throughout the entire scan. Furthermore, it is not sure that these results can be generalized to all ultrasound systems.

The TI expresses the potential for a rise in temperature along the ultrasound beam. The MI indicates the probability for the ultrasound to induce inertial cavitation. These indices are not perfect. Thus, it has been shown that the TI can underestimate the actual temperature and in the worst-case, the temperature rise may be three times higher than the displayed value [25]. There is no way to measure actual in situ exposure in human fetuses, but the TI is the best estimate of relative risk for a thermally induced biologic effect, and the operator may gain some idea of acoustic output change if the on-screen indices are used.

The MI is valid under conditions for the onset of inertial cavitation: the presence of the bubble nuclei in the tissue. Therefore, it is highly improbable that cavitation can be generated at diagnostic levels within fetal soft tissues or fluids, in the absence of an air-water interface in the tissues such as the lung or intestine, or without presence of gas-based ultrasound contrast agents.

Our study showed low values for indexes of the acoustic energy during fetal echocardiography at the time of the first-trimester scan. However, these results should be considered with caution [27]. Users should regularly check both indices while scanning and should adjust the machine controls to keep them as low as reasonably possible.
achievable (ALARA principle) without compromising the diagnostic value of the examination. Where low values cannot be achieved, examination times should be kept as short as possible [28].

Conclusions

Our objective was to analyze the levels of TI and MI and their variation during the learning curve for fetal echocardiography at the time of first-trimester scan, once with the introduction of a new ultrasound system. We found that safety indices from the Doppler evaluation of the fetal heart and tricuspid flow have a significant variation, but this variation was small and below the actual recommended limits. For some types of Doppler heart exams, the occurrence of the safety indices with constant values suggests the potential for their supplementary activity reduction.

As the operator adapts with the scanning technology and first trimester protocols, by the machine settings’ optimization, the safety indices varies in terms of decreasing TI and increasing MI. Adaptation to a new ultrasound machine needs a longer heart scan in the first trimester and safety indices during the first 80 cases examined.

Conflict of interest: none

References