Clinical End Users Worldwide Show Poor Knowledge Regarding Safety Issues of Ultrasound During Pregnancy

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The use of diagnostic ultrasound (DUS) has become widespread, in labor rooms, private offices, emergency departments, and even the shopping mall, and is widely perceived as safe. Indeed, there has been no independently long-established report that DUS is harmful. However, as a form of energy, DUS has the potential to have effects on living tissues, that is, bioeffects. The two most likely mechanisms for bioeffects are heating and cavitation. The following section of this issue is dedicated to reporting results of the American Institute of Ultrasound in Medicine–sponsored Keystone conference, which dealt directly with these bioeffects. Many scientists took part in the conference to generate state-of-the-art information on the subject. It is imperative to try and assess clinical end users’ familiarity with these issues.

Recently, two studies evaluated ultrasound end users’ knowledge of safety issues. Marsal distributed a questionnaire to professionals using ultrasound for fetal examinations in Europe. The questionnaires were answered by participants and faculty members of staff meetings and postgraduate courses in obstetric ultrasound, Doppler ultrasound, and fetal echocardiography in Sweden, Norway, and Austria. One hundred ninety-
nine anonymous questionnaires were answered by physicians, sonographers, and midwives, all using DUS on a daily or weekly basis. Only 22% could explain what the thermal index (TI) was, and only 11% could give a correct explanation for the mechanical index (MI). Only 28% of the responders correctly indicated where, on their own machines, they could find the information about the acoustic indices. Although acknowledging the limitation that the questionnaire was distributed only among European ultrasound users, Marsal concluded that the output display standard (ODS) failed to provide a practical, useful platform during obstetric examinations.

Our group performed a similar survey distributed among ultrasound end users (obstetrician-gynecologists, sonographers, and nurses/nurse practitioners) attending two review courses in Chicago, Illinois, and Rochester, New York, and two hospital obstetrics and gynecology grand rounds from April through June 2006, both in the United States. Only questionnaires from participants who actually perform ultrasound scans were analyzed. Because the courses included a lecture on safety issues (ultrasound bioeffects), the participants were asked to complete the questionnaires before these lectures, and accordingly, no questionnaires were collected after the safety lectures.

One hundred thirty end users completed the questionnaires (63% response rate). Although 32.2% of the participants gave responses indicating that they were familiar with the term TI, only 17.7% actually gave the correct answer to the question on the nature of the TI. About 22% were familiar with the term MI, but only 3.8% described it properly. Almost 80% of end users did not know where to find the acoustic indices. Only 20.8% were aware that they are displayed on the ultrasound monitor during examinations. No significant differences were noted between physicians and other end users regarding knowledge of safety issues.

Although there were many differences between these studies, several questions on safety concerns were similar. Using the $\chi^2$ test or Fisher exact test, we compared knowledge of American and European ultrasound end users on safety subjects (Table 1). As shown in the table, end users worldwide were poorly informed regarding safety issues. End users in the United States were less likely to be familiar with the term MI (odds ratio, 0.5; 95% confidence interval, 0.3–0.9; $P = .016$) and were less likely to correctly define MI (odds ratio, 0.3; 95% confidence interval, 0.1–0.98; $P = .045$).

The purpose of the ODS is to provide the capability for end users of DUS to operate their machines at higher levels to presumably increase diagnostic capabilities. As expected, the acoustic indices tend to vary depending on the ultrasound modality, and particularly, TI values of 1.5 and higher have been noted during Doppler studies. One should remember that although manufacturers are obliged to provide information on safety indices, with implementation of the ODS, the responsibility for ultrasound output energy and patient safety lies on the clinical end users; therefore, education is vital: “To maintain an equivalent level of safety, the FDA requires manufacturers to educate users about the new capabilities of these devices, as well as the meaning of the ODS and the attendant responsibilities.” Furthermore, the ALARA (as low as reasonably achievable) principle was strongly recommended. For the acoustic indices to be meaningful, the diagnostician must be familiar

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>American End Users (n = 130)*</th>
<th>European End Users (n = 199)†</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Familiar with the term TI, n (%)</td>
<td>42 (32.2)</td>
<td>64 (32.2)</td>
<td>.978</td>
</tr>
<tr>
<td>Familiar with the term MI, n (%)</td>
<td>29 (22.3)</td>
<td>69 (34.7)</td>
<td>.016</td>
</tr>
<tr>
<td>Correctly defined TI, n (%)</td>
<td>23 (17.7)</td>
<td>43 (21.6)</td>
<td>.385</td>
</tr>
<tr>
<td>Correctly defined MI, n (%)</td>
<td>5 (3.8)</td>
<td>21 (10.6)</td>
<td>.045</td>
</tr>
<tr>
<td>Knew where to find information on TI/MI during ultrasound examination, n (%)</td>
<td>27 (20.8)</td>
<td>56 (28.1)</td>
<td>.132</td>
</tr>
</tbody>
</table>

*Adapted with permission from Sheiner et al.
†Adapted with permission from Marsal.
with safety issues and implications. On the basis of the two above-mentioned studies, this does not appear to be the case. The education goal explicitly included in the implementation of the ODS has failed.

In conclusion, ultrasound end users worldwide are poorly informed regarding the acoustic output of the ultrasound machines they use and the bioeffects and safety of ultrasound in general. Data regarding these should be an integral part of professional training of physicians, sonographers, and other ultrasound end users. We also hope that professional organizations will attempt to raise the knowledge of their constituents by including some educational material on bioeffects and safety at meetings, postgraduate courses, and other continuing medical education activities. The following articles and their associated continuing medical education tests form an excellent basis for this educational goal.

References


