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Ultrasound is safe. . . right?: Resident and maternal-fetal medicine fellow knowledge regarding obstetric ultrasound safety

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Ultrasound Is Safe . . . Right?

Resident and Maternal-Fetal Medicine Fellow Knowledge Regarding Obstetric Ultrasound Safety

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Includes CME test

Objectives—This study was created to assess the knowledge levels of postgraduate year 4 obstetrics and gynecology residents and maternal-fetal medicine fellows in the United States regarding the safety of obstetric ultrasound and the use of the output display standard.

Methods—An electronic survey was submitted to each Accreditation Council for Graduate Medical Education–accredited obstetrics and gynecology residency and each maternal-fetal medicine fellowship program in the United States over 2 academic years from 2008 to 2010.

Results—A total of 165 surveys were completed (67 by postgraduate year 4 obstetrics and gynecology residents and 92 by maternal-fetal medicine fellows). In total, 13.4% of residents and 20.9% of maternal-fetal medicine fellows knew how to find or use the output display standard, and 10.9% of residents and 22.7% of fellows reported use of the output display standard during their ultrasound examinations. Overall, 37% to 46% of residents and fellows reported no limitations to the use of obstetric ultrasound and 22% to 39% reported no limitations to the use of Doppler ultrasound in the first, second, and third trimesters. Maternal-fetal medicine fellow knowledge of ultrasound safety generally improved with each year of training; however, only 34.8% of third-year fellows reported use of the output display standard.

Conclusions—Currently, obstetrics and gynecology resident knowledge of obstetric ultrasound safety is low. Maternal-fetal medicine fellow knowledge is stronger overall; however, few are using the output display standard routinely in their last year of fellowship training. This study provides evidence of the need for improved education on the subject of obstetric ultrasound safety.

Key Words—mechanical index; obstetric ultrasound safety; output display standard; thermal index

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Abbreviations

MI, mechanical index; TI, thermal index

Ultrasound has become a routine part of obstetric care, with a good safety profile. Although most studies have not shown adverse clinical outcomes from ultrasound exposure, thermal and mechanical mechanisms are recognized as potential sources of biological effects. The output display standard was developed to approximate the thermal and mechanical risk during an examination, which could be displayed on the ultrasound screen and interpreted by the user.[1] Recent surveys, however, have shown poor overall knowledge of the output display standard in the obstetric community, questioning whether safety is consistently being ensured.[2,3] It is unclear whether the output display standard is being included as part of routine obstetric education today.

Thermal bioeffects refer to heat generated within or around cells exposed to ultrasound.[4] Nonthermal, or mechanical, effects refer to the potential impact on tissue from physical forces generated by ultrasound waves, such as radiation, streaming, free radicals, and cavitation. Cavitation refers to the potential for ultrasound to mechanically disturb gas bubbles; if present, those bubbles may then expand or collapse, affecting nearby tissue.[5] The output display standard created to approximate the risk of thermal injury is the thermal index (TI), and the standard for mechanical mechanisms is the mechanical index (MI). A low risk of thermal or mechanical bioeffects is seen with a TI or MI value of less than 1, and if an ultrasound machine is capable of producing output levels of greater than 1, then either the TI or MI must be displayed on the screen.

One may ask why this merits discussion in obstetrics today. The current issue is that modern machines have substantially higher output potential than machines used when most studies were performed. In 1992, the US Food and Drug Administration increased the upper limit for permissible output of ultrasound machines almost 8-fold (from 94 to 720 mW/cm^2 in obstetric ultrasound). In conjunction with this, the output display standard was created by the American Institute of Ultrasound in Medicine and the National Electrical Manufacturers Association so that a measure of safety would be available at the time of an examination with more powerful machines. In doing this, the responsibility of ensuring safety for the obstetric patient during an ultrasound examination was placed on the user.[1] Two studies, however, have shown that end users of obstetric ultrasound are largely unaware of the output display standard and are not routinely using it in practice. In 2005, Marsal[2] presented the results of a survey submitted to ultrasound end users from 9 European countries. In total, 22% and 11% of participants could explain the TI and MI, respectively, and 28% could identify where they were found on the ultrasound machine.[2] Similarly, in 2007, Sheiner et al[3] published a survey given to American end users with similar results seen. Overall, 32% and 22% were familiar with the TI and MI, and approximately 16% of physicians knew where to find them during an examination.[3]

Despite its purpose of ensuring safety, it seems that the output display standard is not currently a routine part of obstetric practice. It is unclear, however, whether ultrasound safety is being included in obstetric education. This study was designed to assess the knowledge level of obstetric and gynecology residents finishing their fourth and last year of residency and maternal-fetal medicine fellows in the United States as a means of determining to what extent the output display standard and ultrasound safety are currently being included in training.

Materials and Methods

With approval from the Human Research Protection Office of Washington University School of Medicine, an electronic survey was created and submitted to each Accreditation Council for Graduate Medical Education–accredited obstetric and gynecology residency program and each maternal-fetal medicine fellowship nationally. The survey was submitted initially to each residency and fellowship program director for review and if approved was sent to all postgraduate year 4 obstetrics and gynecology residents and all maternal-fetal medicine fellows in their respective programs. Surveys were submitted over 2 academic years from 2008 to 2010 in the second half of each academic year.

The survey included a total of 12 questions regarding ultrasound safety, with 6 additional questions assessing demographic information and prior ultrasound training (Table 1). Participants were asked to what degree ultrasound and Doppler ultrasound are considered safe in each trimester and to identify which mechanisms are considered potentially harmful. Their knowledge and use of the output display standard were assessed as well as whether they had received teaching specifically in ultrasound safety. They were also asked whether keepsake imaging is considered an appropriate indication for ultrasound and whether they felt comfortable educating patients on ultrasound safety. Questions regarding demographics, sex, state of the program, and year of training were included, as well as the anticipated career if a resident. The Fisher exact test was used for the comparison of categorical variables. Specifically, we examined whether knowledge and use differed by training status (resident or fellow), by receipt of formal training in ultrasound (yes or no), and among the fellows by year of training (first, second, or third). All analyses were conducted using SAS version 9.2 software (SAS Institute Inc, Cary, NC).

Results

A total of 165 surveys were returned over the 2-year period; 67 surveys were completed by postgraduate year 4 obstetrics and gynecology residents and 92 by maternal-fetal medicine fellows in all 3 years of training (6 participants did not identify their year of training). Thirty-three (21.2%) of the participants were male, with most of the respondents being female. Thirty-one states were represented among the participants. Approximately 60% of resident participants were anticipating general practice, with the remainder anticipating subspecialty training (18% for maternal-fetal medicine fellowship and <10% in the remaining subspecialties).

Table 2 shows the results of the survey based on training status. No statistical differences were noted between resident and fellow responses to questions regarding the safety of either standard 2-dimensional ultrasound or Doppler ultrasound throughout each trimester. Notably, however, 38.8% of residents and 38.0% of fellows reported no limitations to the use of ultrasound in the first trimester, and 26.9% of residents and 21.7% of fellows reported no limitations to the use of Doppler ultrasound in the first trimester. Similarly, 30% to 46% of residents and fellows reported no limitations to the use of standard or Doppler ultrasound in the second and third trimesters.

Table 1. Survey Regarding Obstetric Ultrasound Safety

For questions 1–6:
- a. Perfectly safe, no limitations
- b. Safe, but should be used mainly when medically indicated
- c. Should be used only for medical reasons

1. Ultrasound is safe during the 1st trimester.
2. Ultrasound is safe during the 2nd trimester.
3. Ultrasound is safe during the 3rd trimester.
4. Doppler ultrasound is safe during the 1st trimester.
5. Doppler ultrasound is safe during the 2nd trimester.
6. Doppler ultrasound is safe during the 3rd trimester.
7. Which mechanisms, if any, may potentially be harmful to a fetus from ultrasound exposure? (check all that apply)
   - a. Thermal
   - b. Mechanical
   - c. Pressure
8. Do you use the TI or MI for your ultrasound examination?
   - a. Yes
   - b. No
9. Do you know how to find or use the TI or MI?
   - a. Yes
   - b. No
10. Keepsake imaging is considered an appropriate ultrasound indication.
    - a. Yes
    - b. No
11. Have you received teaching in ultrasound safety?
    - a. Yes
    - b. No
12. Do you feel comfortable educating patients regarding ultrasound safety?
    - a. Yes
    - b. No

Demographic information:
1. Sex
2. Year of training (resident or fellow, year) and state of program
3. Number of residents or fellows per year
4. Prior formal ultrasound training or career
5. Formal ultrasound rotation in residency
6. Anticipated career if a resident

MI indicates mechanical index; and TI, thermal index. Questions 1 through 6 reprinted with permission from Sheiner et al.[3]

Regarding the output display standard, knowledge was generally low for both residents and fellows. Just 13.4% of residents reported that they could find or use the TI or MI, and 10.9% stated that they use the TI or MI during their ultrasound examinations. Numbers were similar (20.9% and 22.7%) for maternal-fetal medicine fellows. Thermal mechanisms were correctly identified by 73.1% of residents and 72.8% of fellows as potential sources of harm from ultrasound exposure, whereas mechanical mechanisms were recognized by a smaller percentage (34.6%) overall.

Maternal-fetal medicine fellows rarely reported that keepsake imaging is an appropriate ultrasound indication (3.3%), less often than residents (11.9%; $P = .05$). Approximately 50% of residents and fellows were comfortable educating patients regarding ultrasound safety.

There were no significant differences in answers from residents and fellows with a prior formal ultrasound rotation in residency (Table 3). Although there was a trend toward fewer participants with a prior ultrasound rotation reporting no limitations to ultrasound, there were no statistical differences seen.

Maternal-fetal medicine fellow knowledge improved overall with each subsequent year of training (Table 4). Although not statistically significant, there was a trend toward fewer senior fellows reporting no limitations to ultrasound in each trimester as well as Doppler ultrasound in the first trimester (only 13% of fellows in the third year reported that first-trimester Doppler ultrasound has no limitations). A significant increase in knowledge of mechanical mechanisms was noted with each year of training (from 21% in the first year up to approximately 61% in the third year; $P = .008$). Senior fellows were more likely to know how to use and to actually use the output display standard than junior fellows ($P = .001$ and .013, respectively). No graduating maternal-fetal medicine fellows reported that keepsake imaging is appropriate. Significantly more second- and third-year fellows reported having received teaching in ultrasound safety compared with first-year fellows (47.2% and 47.8% compared with 12%; $P = .002$).

Discussion

Ultrasound safety is currently the responsibility of the user. The output display standard was developed so that ultrasound users can assess the risk of thermal and mechanical bioeffects at the time of an ultrasound examination, and it is supported by the US Food and Drug Administration, American Congress of Obstetricians and Gynecologists, and American Institute of Ultrasound in Medicine.[1,6,7]

However, 2 studies have shown that end users in the obstetric community are not using the output display standard.[2,3] What has been less clear is whether ultrasound safety is currently included as part of obstetrics and gynecology resident and subspecialty maternal-fetal medicine fellow education. This study provides evidence that it is not routinely being included in resident education; it appears to be more represented in maternal-fetal medicine fellow education, although not thoroughly.

Most residents and maternal-fetal medicine fellows correctly recognized that keepsake imaging is not considered an appropriate indication for obstetric ultrasound. National recommendations from the American Congress of Obstetricians and Gynecologists and American Institute of Ultrasound in Medicine are clear regarding the use of obstetric ultrasound strictly for medical indications.[8]

It is important for obstetricians to respect modern machines. Many clinical studies in the past have been reassuring regarding short- and long-term clinical outcomes after ultrasound exposure, such as birth weight and school performance, and have not found a causal relationship between those outcomes and ultrasound.[9] However, those studies were done using older ultrasound machines, and well-designed clinical trials using modern machines are not currently available.

It is also prudent to be aware of the higher output potential with Doppler ultrasound, given that the ultrasound beam is focused on a specific area of tissue with that set-

Table 2. Answers to the Survey Based on Training Status

Question	All (n = 165)	Residents (n = 67)	Fellows (n = 92)	*P*
Ultrasound				
1st trimester				
No limitations	62 (37.6)	26 (38.8)	35 (38.0)	.87
Safe, medically indicated	85 (51.5)	35 (52.2)	46 (50.0)	
Only medical reasons	18 (10.8)	6 (9.0)	11 (12.0)	
2nd trimester				
No limitations	69 (41.8)	31 (46.3)	37 (40.2)	.68
Safe, medically indicated	83 (50.3)	32 (47.8)	47 (51.1)	
Only medical reasons	13 (7.9)	4 (6.0)	8 (8.7)	
3rd trimester				
No limitations	65 (39.9)	31 (46.3)	33 (36.7)	.44
Safe, medically indicated	85 (52.2)	32 (47.8)	49 (54.4)	
Only medical reasons	13 (8.0)	4 (6.0)	8 (8.9)	
Doppler ultrasound				
1st trimester				
No limitations	39 (23.6)	18 (26.9)	20 (21.7)	.66
Safe, medically indicated	66 (40.0)	25 (37.3)	40 (43.5)	
Only medical reasons	60 (36.4)	24 (35.8)	32 (34.8)	
2nd trimester				
No limitations	54 (32.7)	25 (37.3)	28 (30.4)	.66
Safe, medically indicated	80 (48.5)	31 (46.3)	47 (51.1)	
Only medical reasons	31 (18.8)	11 (16.4)	17 (18.5)	
3rd trimester				
No limitations	57 (34.6)	26 (38.8)	30 (32.6)	.75
Safe, medically indicated	79 (47.9)	31 (46.3)	46 (50.0)	
Only medical reasons	29 (17.6)	10 (14.9)	16 (17.4)	
Harmful mechanisms				
Thermal	121 (73.3)	49 (73.1)	67 (72.8)	.99
Mechanical	57 (34.6)	21 (31.3)	32 (34.8)	.73
Pressure	22 (13.3)	11 (16.4)	11 (12.0)	.49
Use TI or MI	31 (19.6)	7 (10.9)	20 (22.7)	.08
Find or use TI or MI	33 (20.2)	9 (13.4)	19 (20.9)	.29
Keepsake imaging appropriate	13 (7.9)	8 (11.9)	3 (3.3)	.05
Teaching in ultrasound safety	53 (32.5)	16 (24.6)	32 (34.8)	.22
Comfortable educating patients	82 (49.7)	31 (46.3)	46 (50.0)	.75
Prior formal training or career	14 (8.8)	3 (4.6)	11 (12.1)	.16
Formal ultrasound rotation	112 (69.1)	45 (67.2)	65 (70.7)	.73

Values are number (percent). MI indicates mechanical index; and TI, thermal index.

ting. The use of Doppler ultrasound in obstetrics represents the delicate risk to benefit ratio medicine uses every day. Often, when Doppler ultrasound is used, there is a valid medical reason: ie, middle cerebral artery Doppler ultrasound for fetal anemia or umbilical artery Doppler ultrasound for intrauterine growth restriction. Studies have shown that a TI value of greater than 1 can be achieved with the clinical use of Doppler ultrasound.[10] Also, middle cerebral artery Doppler ultrasound use is particularly worthy of discussion because of its proximity to bone, which has a higher absorption potential than other tissue. Although it is important to obtain the necessary clinical information, it is also our responsibility to perform the examination as safely as possible.

Limitations of this study included its small sample size, particularly for the resident response. Each year, there are approximately 1200 postgraduate year 4 obstetrics and gynecology residents in Accreditation Council for Graduate Medical Education–accredited programs and 265 maternal-fetal medicine fellows nationally. The survey was resubmitted in the second year to improve the response rate, which was approximately 3% for residents and 26% for fellows over 2 years. However, the responses were comparable with those of the 2 previously published studies on ultrasound safety,[2,3] supporting the validity of the results presented here. Also, this was a survey taken at will by participants; thus, there was the potential for self-selection bias. Some individuals are more willing to par-

Table 3. Answers to the Survey Based on Formal Ultrasound Rotation

Question	All (n = 162)	Yes (n = 112)	No (n = 50)	*P*
Ultrasound				
1st trimester				
No limitations	62 (37.6)	39 (34.8)	23 (46.0)	.08
Safe, medically indicated	85 (51.5)	63 (56.3)	19 (38.0)	
Only medical reasons	18 (10.8)	10 (8.9)	8 (16.0)	
2nd trimester				
No limitations	69 (41.8)	43 (38.4)	26 (52.0)	.14
Safe, medically indicated	83 (50.3)	61 (54.5)	19 (38.0)	
Only medical reasons	13 (7.9)	8 (7.1)	5 (10.0)	
3rd trimester				
No limitations	65 (39.9)	39 (35.5)	26 (52.0)	.07
Safe, medically indicated	85 (52.2)	63 (57.3)	19 (38.0)	
Only medical reasons	13 (8.0)	8 (7.3)	5 (10.0)	
Doppler ultrasound				
1st trimester				
No limitations	39 (23.6)	23 (20.5)	16 (32.0)	.22
Safe, medically indicated	66 (40.0)	45 (40.2)	20 (40.0)	
Only medical reasons	60 (36.4)	44 (39.3)	14 (28.0)	
2nd trimester				
No limitations	54 (32.7)	31 (27.7)	23 (46.0)	.06
Safe, medically indicated	80 (48.5)	60 (53.6)	18 (36.0)	
Only medical reasons	31 (18.8)	21 (18.8)	9 (18.0)	
3rd trimester				
No limitations	57 (34.6)	33 (29.5)	24 (48.0)	.07
Safe, medically indicated	79 (47.9)	59 (52.7)	18 (36.0)	
Only medical reasons	29 (17.6)	20 (17.9)	8 (16.0)	
Harmful mechanisms				
Thermal	121 (73.3)	85 (75.9)	33 (66.0)	.25
Mechanical	57 (34.6)	34 (30.4)	21 (42.0)	.16
Pressure	22 (13.3)	14 (12.5)	8 (16.0)	.62
Use TI or MI	31 (19.6)	19 (17.3)	9 (20.0)	.82
Find or use TI or MI	33 (20.2)	22 (19.8)	8 (16.0)	.66
Keepsake imaging appropriate	13 (7.9)	7 (6.3)	6 (12.0)	.22
Teaching in ultrasound safety	53 (32.5)	30 (36.4)	11 (22.0)	.10
Comfortable educating patients	82 (49.7)	57 (50.9)	22 (44.0)	.50

Values are number (percent). MI indicates mechanical index; and TI, thermal index.

ticipate in research or take a survey than others. Perhaps those who participated felt more comfortable with their knowledge base in this area or were encouraged to take the survey by their program directors, who felt this subject deserved attention.

This study was developed to bring awareness of obstetric ultrasound safety and ultimately to maximize safety for our patients in a time when we are using ultrasound machines with much greater output potential than previously used. Currently, obstetrics and gynecology postgraduate year 4 resident knowledge and use of the output display standard are low in the last year of residency training. Maternal-fetal medicine fellow knowledge appears stronger, although less than 50% are using it at the end of their last year of subspecialty training. This study provides evidence of the current need to bring ultrasound safety more consistently into obstetrics and gynecology and maternal-fetal medicine fellow education.

Table 4. Maternal-Fetal Medicine Fellow Answers to the Survey Based on Year of Training

Question	1st y (n = 33)	2nd y (n = 36)	3rd y (n = 23)	*P*
Ultrasound				
1st trimester				
No limitations	16 (48.5)	12 (33.3)	7 (30.4)	.66
Safe, medically indicated	14 (42.4)	19 (52.8)	13 (56.5)	
Only medical reasons	3 (9.1)	5 (13.9)	3 (13.0)	
2nd trimester				
No limitations	19 (57.6)	11 (30.6)	7 (30.4)	.16
Safe, medically indicated	12 (36.4)	21 (58.3)	14 (60.9)	
Only medical reasons	2 (6.1)	4 (11.1)	2 (8.7)	
3rd trimester				
No limitations	16 (50.0)	11 (30.6)	6 (27.3)	.42
Safe, medically indicated	14 (43.8)	21 (58.3)	14 (63.6)	
Only medical reasons	2 (6.3)	4 (11.1)	2 (9.1)	
Doppler ultrasound				
1st trimester				
No limitations	10 (30.3)	7 (19.4)	3 (13.0)	.59
Safe, medically indicated	14 (42.4)	15 (41.7)	11 (47.8)	
Only medical reasons	9 (27.3)	14 (38.9)	9 (39.1)	
2nd trimester				
No limitations	15 (45.5)	7 (19.4)	6 (26.1)	.18
Safe, medically indicated	12 (36.4)	22 (61.1)	13 (56.5)	
Only medical reasons	6 (18.2)	7 (19.4)	4 (17.4)	
3rd trimester				
No limitations	16 (48.5)	8 (22.2)	6 (26.1)	.20
Safe, medically indicated	12 (36.4)	21 (58.3)	13 (56.5)	
Only medical reasons	5 (15.2)	7 (19.4)	4 (17.4)	
Harmful mechanisms				
Thermal	20 (60.6)	28 (77.8)	19 (82.6)	.16
Mechanical	7 (21.2)	11 (30.6)	14 (60.9)	.01
Pressure	2 (6.1)	6 (16.7)	3 (13.0)	.40
Use TI or MI	2 (6.3)	10 (30.3)	8 (34.8)	.013
Find or use TI or MI	1 (3.0)	9 (25)	9 (40.9)	.001
Keepsake imaging appropriate	1 (3.0)	2 (5.6)	0 (0.0)	.78
Teaching in ultrasound safety	4 (12.1)	17 (47.2)	11 (47.8)	.002
Prior formal training	3 (9.1)	4 (11.1)	4 (18.2)	.60
Formal ultrasound rotation	23 (69.7)	26 (72.2)	16 (69.6)	>.99
Comfortable educating patients	13 (39.4)	21 (58.3)	12 (52.2)	0.31

Values are number (percent). MI indicates mechanical index; and TI, thermal index.

References

1. Barnett SB, Ter Haar GR, Ziskin MC, Rott HD, Duck FA, Maeda K. International recommendations and guidelines for the safe use of diagnostic ultrasound in medicine. *Ultrasound Med Biol* 2000; 26:355–366.
2. Marsal K. The output display standard: has it missed its target? *Ultrasound Obstet Gynecol* 2005; 25:211–214.
3. Sheiner E, Shoham-Vardi I, Abramowicz JS. What do clinical users know regarding safety of ultrasound during pregnancy? *J Ultrasound Med* 2007; 26:319–325.
4. Abramowicz JS, Barnett SB, Duck FA, Edmonds PD, Hynynen KH, Ziskin MC. Fetal thermal effects of diagnostic ultrasound. *J Ultrasound Med* 2008; 27:541–559.
5. Stratmeyer ME, Greenleaf JF, Dalecki D, Salvesen KA. Fetal ultrasound: mechanical effects. *J Ultrasound Med* 2008; 27:597–605.
6. American College of Obstetricians and Gynecologists Committee on Obstetric Practice. ACOG committee opinion: new ultrasound output display standard. Number 180, November 1996. *Int J Gynaecol Obstet* 1997; 57:227–228.
7. Fowlkes JB; Bioeffects Committee of the American Institute of Ultrasound in Medicine. American Institute of Ultrasound in Medicine consensus report on potential bioeffects of diagnostic ultrasound: executive summary. *J Ultrasound Med* 2008; 27:503–515.
8. American College of Obstetricians and Gynecologists Committee on Ethics. ACOG committee opinion: nonmedical use of obstetric ultrasonography. Number 297, August 2004. *Obstet Gynecol* 2004; 104:423–424.
9. Torloni MR, Vedmedovska N, Merialdi M, et al. Safety of ultrasonography in pregnancy: WHO systematic review of the literature and meta-analysis. *Ultrasound Obstet Gynecol* 2009; 33:599–608.
10. Sheiner E, Shoham-Vardi I, Pombar X, Hussey MJ, Strassner HT, Abramowicz JS. An increased thermal index can be achieved when performing Doppler studies in obstetric sonography. *J Ultrasound Med* 2007; 26:71–76.