SOGC CLINICAL PRACTICE GUIDELINE

No. 359, May 2018 (Replaces No. 160, June 2005)

No. 359-Obstetric Ultrasound Biological Effects and Safety

This guideline was prepared by the main author and Diagnostic Imaging Committee.

Michiel C. Van den Hof, MD, Halifax, NS

Diagnostic Imaging Committee: Kimberly Butt (co-chair), MD, Fredericton, NB; Yvonne Cargill, MD, Ottawa, ON; Nanette Denis, MSc, Saskatoon, SK; Johanne Dube, MD, Mont-Royal, QC; Phyllis Glanc, MD, Toronto. ON; Ken Lim, MD, Vancouver, BC; Ori Nevo, (co-chair), MD, Toronto, ON; Mila Smithies, MD, Ottawa, ON.

Disclosure Statement: Disclosure statements have been received from the author.

Key Words: Safety, bio-effects, ultrasound, obstetric, thermal index, mechanical index

Abstract

Objective: To review the biological effects and safety of obstetric ultrasound.

Outcome: Outline the circumstances in which safety may be a concern with obstetric ultrasound.

Evidence: The 2005 version of this guideline was used as a basis and updated following a Medline search and review of relevant publications. Sources included guidelines and reports by Health Canada and the American Institute of Ultrasound in Medicine.

Values: Review by principal author and the Diagnostic Imaging Committee of the SOGC. The quality of evidence and classification of recommendations have been adapted from the Report of the Canadian Task Force on the Periodic Health Examination.

Benefits, Harms, and Costs: Obstetric ultrasound should only be done for medical reasons, and exposure should be kept as low as reasonably achievable because of the potential for tissue heating. Higher energy is of particular concern in the following scenarios: Doppler studies (pulsed, colour, and power), first trimester ultrasound with a long trans-vesical path (>5 cm), second or third trimester exams when bone is in the focal zone, when scanning tissue with minimal perfusion (embryonic), or in patients who are febrile. Operators can minimize risk by limiting dwell time and exposure to critical structures. It is also important to be aware of equipment-generated exposure information.

Recommendations:

1. All obstetric ultrasound operators should understand and utilize the output display standards (III-A).
2. Obstetric ultrasound should only be used when the potential medical benefit outweighs any theoretical or potential risk (II-2A).
3. Obstetric ultrasound should not be used for nonmedical reasons, such as sex determination, producing nonmedical photos or videos, or for commercial purposes (III-B).
4. Ultrasound exposure should be as low as reasonably achievable (ALARA) because of the potential for tissue heating when the thermal

J Obstet Gynaecol Can 2018;40(5):627–632

https://doi.org/10.1016/j.jogc.2017.11.023

index exceeds 1. Exposure can be reduced through the use of output control and/or by reducing the amount of time the beam is focused on one place (dwell time) (II-1A).
5. All diagnostic ultrasound devices should comply with the output display standards (mechanical index and thermal index) (III-B).
6. Spectral power and colour Doppler should be avoided while imaging the fetus in the first trimester, except in those circumstances where their use contributes to the investigation of pregnancies at high risk for trisomies or anomalies (III-B).
7. When ultrasound is done for research or teaching purposes, efforts should be made to keep the thermal index (TI) at ≤0.7 and the mechanical index (MI) at ≤1.0. If adequate imaging requires a TI greater than 0.7 or an MI greater than 1.0, learners should be directly guided by supervising sonographers or physicians (III-B).
8. At <14 weeks, learners should only undertake pulsed, colour or power Doppler while being directly guided by supervising sonographers or physicians (III-B).

Table 1. Key to evidence statements and grading of recommendations, using the ranking of the Canadian Task Force on Preventive Health Care

Quality of evidence assessment[a]	Classification of recommendations[b]
I: Evidence obtained from at least one properly randomized controlled trial	A. There is good evidence to recommend the clinical preventive action
II-1: Evidence from well-designed controlled trials without randomization	B. There is fair evidence to recommend the clinical preventive action
II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group	C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in the category	D. There is fair evidence to recommend against the clinical preventive action
III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees	E. There is good evidence to recommend against the clinical preventive action
	I. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

[a]The quality of evidence reported in these guidelines has been adapted from The Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

[b]Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in The Canadian Task Force on Preventive Health Care.

BACKGROUND

Obstetric ultrasound provides significant medical benefit to pregnant women and has helped to improve both maternal and perinatal outcomes. As obstetric ultrasound applications continue to expand, it is important that operators be aware of standards for its safe use. This Guideline reviews the biological effects and safety of obstetric ultrasound. For recommendations, quality of evidence and classification have been adapted from the Report of the Canadian Task Force on the Periodic Health Examination (Table 1).[1]

Although there have been no proven adverse biological effects associated with obstetric diagnostic ultrasound, one must be cognizant of the potential for an unidentified risk. Epidemiologic research on ultrasound safety is limited. Prospective randomized studies are difficult to undertake due to the prevalence of routine obstetric ultrasound in current practice.[2,3] In the past, adverse neonatal/pediatric effects of ultrasound exposure that have been studied include childhood malignancies, dyslexia, delayed speech, and low birth weight. No significant association was identified in any of these areas; however, most studies were done prior to 1993, when acoustic output was allowed to increase from 94 mW/cm^2 to 720 mW/cm^2.[4,5] An association between non-righthandedness and prenatal ultrasound exposure has been studied in 3 randomized trials and 2 cohort studies. A meta-analysis of the randomized trials showed a statistically significant increase in non-righthandedness among ultrasound-exposed children compared with controls, although this association was only identified in males and has not been related to neurological deficit.[6] Cohort studies have corroborated this finding and have shown that the effect is associated with first and/or second trimester exposures.[7,8] No studies have shown a cumulative adverse effect with repeat exposures. Although obstetric ultrasound has gained a reputation for safety, the possibility of subtle effects such as left- or non-righthandedness cannot be dismissed. The concern about bio-effects is particularly important, given that acoustic output from equipment intended for obstetric use has increased, and fetal imaging is being practiced at earlier gestations when the fetus is potentially more vulnerable.[9,10] For these reasons, obstetric ultrasound should only be undertaken for medical reasons. Exposure should be limited by using the lowest output setting that maintains image quality and by minimizing exposure time.[11,12] Experimental systems suggest that biological effects from ultrasound can result from both thermal and mechanical mechanisms.[5,13] Since 1993, ultrasound machines have been equipped with output displays, TI, and MI that reflect potential thermal and mechanical risks. These indices must be visible if medical ultrasound equipment, including hand-held or portable devices, has the capacity to have either index greater than 1.[11]

ABBREVIATIONS

AIUM	American Institute of Ultrasound in Medicine
ALARA	as low as reasonably achievable
GA	gestational age
MI	mechanical index
TI	thermal index
TIB	TI bone
TIC	TI cranial
TIS	TI soft tissue

Thermal Effects

The main potential for an adverse biological effect with obstetric ultrasound appears to involve tissue heating from energy absorption of the ultrasound beam (thermal effect).[13] There are many publications on the adverse sequelae of ultrasound heating in animal studies. Research on the teratogenic potential of temperature elevation in humans is based on maternal hyperthermia (infections, environment) rather than focal temperature changes by ultrasound. Embryonic and fetal animal studies have shown that, if in situ ultrasound heating produces a temperature rise of <1.5°C above physiological level, there appear to be no harmful sequelae. At higher temperature elevations, the potential for harm increases with both the exposure duration and the degree of elevation of in situ temperature for embryonic or fetal tissues. Additionally, there is an inverse relation between temperature rise and the exposure time needed to create a potential hazard on thermal grounds.[14] For example, a temperature increase of 4°C in a fetus for five or more minutes has the potential for severe developmental sequelae.[2,4,12]

Thermal Index

TI is an estimate of the maximum temperature rise that could occur in exposed tissue during an ultrasound examination.[12] This computed TI is unitless and is calculated using standard tissue heating models that have been derived from clinical situations and measurable properties of the ultrasound field as determined in water under standard conditions. The TI will be adjusted with changes in user-control settings and is calculated to be directly proportional to the potential for heating. This is important because it is impossible to monitor actual temperature rise in clinical examinations. There are 3 user-selectable TI categories: TIS, TIB, and TIC.[15] Most early obstetric examinations fall under TIS, in which the ultrasound path is predominantly through homogenous soft tissue or fluid. TIB applies to many second- and third-trimester scans, in which fetal bone is in the focal region. TIC would normally not apply to obstetric ultrasound because bone is seldom close to the transducer surface. Various studies have supported the use of these 3 types of thermal indices.[16–20]

At any GA, concerns also arise in scanning tissues if the patient is febrile or with trans-vaginal probes that may produce additional direct heat to adjacent tissue. The TI would not reflect these additional thermal inputs.[15]

For electronic fetal heart rate monitors, the maximum thermal effect is low enough that an output display standard is not required, and heating should not be a concern even with prolonged exposure.[21]

Mechanical Effects and Mechanical Index

Mechanical effects result from radiation force, streaming, and cavitation. Mechanical effects at diagnostic ultrasound levels have been seen in tissues with stable gas bodies (lung, intestine) or with the use of gas contrast agents.[5] The MI is an estimate of the risk for capillary hemorrhage in lung, taking into account operating conditions.[15] No harm has been identified if the MI is less than 1.9, but given the specific vulnerability of fetal tissues, the value should be maintained below 1 unless the expected benefits of a higher exposure have been judged to outweigh the potential hazards.[13] Mechanical effects are unlikely to occur in obstetric ultrasound because of the absence of gas bodies or the use of contrast media; thus the MI has less relevance than TI in this context. However, mechanical radiation pressure effects have been demonstrated in preliminary studies of physical models[22] and the fetus[23] using obstetric Doppler. Because Doppler yields higher intensities and TIs than B-mode with similar MIs, potential biological effects might be both mechanical and thermal.[21] It is reassuring that no adverse fetal effects have been directly linked to non-thermal mechanisms; however, most authorities recommend further research in this area.[2,24]

Dwell Time

With expanding ultrasound applications, it is important that all obstetric ultrasound operators understand the output display standard (MI and TI) and their responsibility to maintain prudent use of equipment and settings.[11] There are multiple factors that contribute to the actual biological exposure on tissue from ultrasound, and though the MI and TI take the majority into account, these indices do not consider exposure or dwell time. Dwell time is controlled by the operator. It is the time the ultrasound beam consistently remains in the same tissue proximity and usually is related to operator knowledge, experience, and skill. In obstetrics, it is particularly important to be cognizant of dwell time in keeping exposure as low as reasonably achievable (ALARA) to minimize any potential for tissue heating.

First Trimester Ultrasound and Doppler

Ultrasound in early pregnancy involves focused exposure to much of the fetus at a potentially more vulnerable time. Additional concerns arise in scanning tissue with limited perfusion (embryonic tissue) or through a long trans-vesical path (>5 cm). In this latter circumstance, the tissue temperature rise as displayed by the computed TI may be off by a factor of 2–3.[9,25,26] This exposure in the first trimester (<14 weeks) has become more relevant given recommendations for routine dating with early ultrasound,[27] the use of early ultrasound (11–14 weeks) to screen for fetal abnormalities, and the application of Doppler as part of these early

assessments.[28] Higher energy intensities are associated with pulsed, power, and colour flow Doppler studies. In this early gestational period, Doppler should not be used routinely. When Doppler is required for refining trisomy or anomaly risk, attention should be made to keep the TI ≤0.7.[29] If greater output reflected by a higher TI (0.7–1.5) is needed, exposure time should be limited (usually <10 minutes). Output with a TI >1.5 is not recommended. These concerns do not apply to uterine artery Doppler studies since the fetus is outside of the area of focused insonation.[29]

Documentation of fetal viability and measurement of the fetal heart rate can also be important parts of early pregnancy assessment. The AIUM suggests using M-mode over spectral Doppler, given the lower time averaged acoustic intensity.[30] Storing a short ultrasound clip of fetal heart activity can also achieve the goal of documenting potential viability without additional Doppler exposure.

Ultrasound for Research, Education, or Commercial Applications

The medical indications for obstetric ultrasound have expanded and even encompass value in providing reassurance and bonding for select pregnant women. However, the theoretical risk of an adverse biological effect, even from standard 2-D obstetric ultrasound, makes it hard to justify its use for non-medical reasons, such as sex determination, taking non-medical photos or videos, or for commercial purposes. With obstetric ultrasound at <14 weeks, AIUM recommends that with the use of Doppler, attempts should be made to maintain the TI ≤0.7. Similarly, for AIUM-sponsored educational activities, output targets should be a TI ≤0.7 and an MI <1.9.[29,31] Our recommendation is that whenever possible, simulation opportunities be maximized, but if an obstetric ultrasound (2-D or Doppler) is done for research or teaching purposes, or when such a scan is done independently by a learner, that efforts be made to keep the TI ≤0.7 and the MI <1. If adequate imaging requires a TI greater than 0.7 or an MI greater than 1.0 (up to MI of 1.9), learners should be directly guided by supervising sonographers or physicians. These recommendations are for any GA. Direct guidance by supervising sonographers or physicians should also be practiced if, at <14 weeks, learners undertake pulsed, colour, or power Doppler studies.

CONCLUSION

There are significant medical benefits with the various applications of obstetric ultrasound and reassuringly no proven adverse effects have been identified with its safe and prudent use. To maximize safety, it is essential that all obstetric ultrasound operators be familiar with the potential biological effects of ultrasound and be knowledgeable about the output display standard (TI and MI). Obstetric ultrasound should only be done for medical reasons, and exposure should be kept as low as reasonably achievable (ALARA) because of the potential for tissue heating. Higher energy is of particular concern for pulsed, colour, and power Doppler, for first trimester ultrasound with a long trans-vesical path (>5 cm), for second or third trimester exams when bone is in the focal zone, and when scanning tissue with minimal perfusion (embryonic) or in patients who are febrile. Operators can minimize risk by being cognizant of these additional factors, limiting dwell time, limiting exposure to critical structures, and following equipment generated exposure information.

Acknowledgements

The author and Diagnostic Imaging Committee wish to thank Dr. Stephen Bly for his input and contributions to the original version of the guideline.

REFERENCES

1. Woolf SH, Batrista RN, Angerson GM, et al. Canadian task force on the periodic health exam. Ottawa: Canadian Communication Group; 1994. p. xxxvii.
2. Fowlkes JB, Abramowicz JS, Church CC, et al. American Institute of Ultrasound in Medicine consensus report on potential bioeffects of diagnostic ultrasound: executive summary. J Ultrasound Med 2008;27:503–15.
3. Whitworth M, Bricker L, Neilson JP, et al. Ultrasound for fetal assessment in early pregnancy. Cochrane Database Syst Rev 2010;(4):CD007058.
4. Salveson KA, Eik-Nes SH. Is ultrasound unsound? A review of epidemiological studies of human exposure to ultrasound. Ultrasound Obstet Gynecol 1995;6:293–8.
5. National Council on Radiation Protection and Measurements Exposure Criteria for Medical Diagnostic Ultrasound: II Criteria Based on All Known Mechanisms [NCRP report No. 140]; 2002.
6. Salvesen K, Eik-Nes SH. Ultrasound during pregnancy and subsequent childhood non-right handedness - a meta-analysis. Ultrasound Obstet Gynccol 1999;13:241–6.
7. Kieler H, Cnattingius S, Haglund B, et al. Sinistrality-a side effect of prenatal sonography: a comparative study of young men. Epidemiology 2001;12:618–23.
8. Kieler H, Cnattingius S, Palmgren J, et al. First trimester ultrasound scans and left-handedness. Epidemiology 2002;13:370.
9. Shaw A, Martin K. The acoustic output of diagnostic machines. In: ter Haar GR, editor. Safe use of ultrasound in medical diagnosis [chapter 3]. London: British Institute of Radiology; 2012. p. 18–45.
10. Salvesen KA, Lees C, Abramowicz J, et al. Board of International Society of Ultrasound in Obstetrics and Gynecology (ISUOG). ISUOG statement on the safe use of Doppler in the 11 to 13+6 week fetal ultrasound examination. Ultrasound Obstet Gynecol 2011;37:628.

11. American Institute of Ultrasound in Medicine (AIUM). Medical ultrasound safety. Rockville (MO): AIUM Publications; 1994.

12. Guidelines for the safe use of diagnostic ultrasound. Health Canada 2001; Cat. No. 46-2/01-255E/F. Available at: www.hc-sc.gc.ca.

13. National Council on Radiation Protection and Measurements (NCRP). Exposure criteria for medical diagnostic ultrasound: 1. Criteria based on thermal mechanisms. Bethesda (MO): NCRP; 1992.

14. Church CC, Barnett SB. Ultrasound induced heating and its biological consequences. In: Ter Har GR, editor. Safe use of ultrasound in medical diagnosis (chapter 4). London: British Institute of Radiology; 2012. p. 46–64.

15. American Institute of Ultrasound in Medicine/National Electrical Manufacturers Association (AIUM/NEMA). Standards for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment. Rev 1. Laurel (MO): AIUM Publications; 1998.

16. Duggan PM, Liggins GC, Barnett SB. Ultrasonic heating of the brain of the fetal sheep in utero. Ultrasound Med Biol 1995;21:553–60.

17. Ramnarine KV, Nassiri OK, Pearc JM, et al. Estimation of in-situ ultrasound exposure during obstetric examinations. Ultrasound Med Biol 1993;19:319–29.

18. Siddiqi TA, O'Brien WD, Meyer RA, et al. In-situ human obstetrical ultrasound exposimetry: estimates of derating factors for each of three different tissue models. Ultrasound Med Biol 1995;21:379–91.

19. Bosward KL, Barentt SB, Wood AKW, et al. Heating of guinea-pig fetal brain during exposure to pulsed ultrasound. Ultrasound Med Biol 1993;19:415–24.

20. Horder MM, Barnett SB, Gilbert JV, et al. In vivo heating of the guinea-pig fetal brain by pulsed ultrasound and estimates of thermal index. Ultrasound Med Biol 1998;24:1467–74.

21. US Food and Drug Administration (FDA). Information for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers. Rockville (MD): FDA; 2008.

22. Bronshtein M, Zimmer EZ. In vitro demonstration of the radiation pressure effect caused by obstetric Doppler. Ultrasound Obstet Gynecol 1999;14:290–1.

23. Fatemi M, Ogburn PI, Greenleaf JF. Fetal stimulation by pulsed diagnostic ultrasound. J Ultrasound Med 2001;20:883–9.

24. Nightingale K, Church C, Harris G, et al. Conditionally increased acoustic pressures in nonfetal diagnostic ultrasound examinations without contrast agents: a preliminary assessment. J Ultrasound Med 2015;34:1–41.

25. Henderson J, Willson K, Jago JR, et al. A survey of the acoustic outputs of diagnostic ultrasound equipment in current clinical use. Ultrasound Med Biol 1995;21:699–705.

26. Whittingham TA. Estimated fetal cerebral ultrasound exposures from clinical examinations. Ultrasound Med Biol 2001;27:877–82.

27. Butt K, Lim K, Diagnostic Imaging Committee. Determination of gestational age by ultrasound. J Obstet Gynaecol Can 2014;36:171–81.

28. Maiz N, Valencia C, Kagan KO, et al. Ductusvenosus Doppler in screening for trisomies 21, 18 and 13 and Turner syndrome at 11–13 weeks of gestation. Ultrasound Obstet Gynecol 2009;33:512–7.

29. American Institute of Ultrasound in Medicine. Statement on the Safe Use of Doppler Ultrasound During 11–14 week scans (or earlier in pregnancy). AIUM Official Statements. October 30, 2016.

30. American Institute of Ultrasound in Medicine. Statement on Measurement of Fetal Heart Rate. AIUM Official Statements. October 30, 2016.

31. American Institute of Ultrasound in Medicine. Guidelines for Hands-on Scanning in Pregnant Subjects During AIUM-Sponsored Educational Activities. AIUM Official Statements. October 30, 2016.