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Obstetric Ultrasound Biological Effects and Safety

This guideline has been prepared and reviewed by the Diagnostic Imaging Committee and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

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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: Medline was searched, and a review of a document on this subject published by Health Canada and of bibliographies from identified articles was conducted.

Values: Review by principal authors and the Diagnostic Imaging Committee of the SOGC. The level of evidence was judged as outlined by 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 (ALARA) because of the potential for tissue heating. Higher energy is of particular concern for pulsed Doppler, colour flow, first trimester ultrasound with a long transvesical path (> 5 cm), second or third trimester exams when bone is in the focal zone, as well as when scanning tissue with minimal perfusion (embryonic) or in patients who are febrile. Operators can minimize risk by limiting dwell time, limiting exposure to critical structures, and following equipment generated exposure information.

Key Words: Safety, bioeffects, ultrasound, obstetric, fetal, thermal index

Recommendations

1. Obstetric ultrasound should only be used when the potential medical benefit outweighs any theoretical or potential risk (II-2A).
2. Obstetric ultrasound should not be used for nonmedical reasons, such as sex determination, producing nonmedical photos or videos, or for commercial purposes (III-B).
3. Ultrasound exposure should be as low as reasonably achievable (ALARA) because of the potential for tissue heating when the thermal 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).
4. All diagnostic ultrasound devices should comply with the output display standards (MI and TI) (III-B).
5. When ultrasound is done for research or teaching purposes, exposed individuals should be informed if either the MI or TI are greater than 1 and how this exposure compares to that found in normal diagnostic practice (III-B).
6. While imaging the fetus in the first trimester, Doppler and colour Doppler should be avoided (III-B).

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BACKGROUND

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 do because routine ultrasound is so prevalent, and even when performed for specific clinical indications, most fetuses in control groups will also have undergone exposure.[1] In the past, adverse neonatal/pediatric effects that have been studied included childhood malignancies, dyslexia, delayed speech, and low birth weight. No association was found with childhood malignancies. Also, literature reviews and subsequent studies[2,3] indicated design weaknesses and inconsistent findings in reports on the other endpoints. However, an association with non-right-handedness and prenatal ultrasound exposure has been reported from 2 randomized studies,[4] and more recently, an association with left-handedness has been shown in a cohort study.[5] This statistical association has only been

Table 1. Criteria for quality of evidence assessment and classification of recommendations

Level of evidence*	Classification of recommendations†
I: Evidence obtained from at least one properly designed randomized controlled trial.	A. There is good evidence to support the recommendation for use of a diagnostic test, treatment, or intervention.
II-1: Evidence from well-designed controlled trials without randomization.	B. There is fair evidence to support the recommendation for use of a diagnostic test, treatment, or intervention.
II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.	C. There is insufficient evidence to support the recommendation for use of a diagnostic test, treatment, or intervention.
II-3: Evidence from comparisons between times or places with or without the intervention. Dramatic results from uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.	D. There is fair evidence not to support the recommendation for a diagnostic test, treatment, or intervention.
III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.	E. There is good evidence not to support the recommendation for use of a diagnostic test, treatment, or intervention.

*The quality of evidence reported in these guidelines has been adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on the Periodic Health Exam.[22]

†Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on the Periodic Health Exam.[22]

found in males, has not been related to neurological deficit, and requires further investigation.

Obstetric ultrasound has gained a reputation for safety; however, the possibility of subtle effects such as left or non-right–handedness cannot be dismissed. Additionally, the bioeffects issue is particularly important as more imaging moves into an earlier gestational period when the fetus is more vulnerable and acoustic output from equipment intended for obstetric use appears to be rising.[6] For these reasons, obstetric ultrasound should only be undertaken for medical reasons. Exposure is limited by using the lowest output setting that maintains image quality and by minimizing exposure time.[7,8] Experimental systems suggest that biological effects from ultrasound can result from both thermal and mechanical mechanisms.[3,9]

The quality of evidence and classification of recommendations have been adapted from the Report of the Canadian Task Force on the Periodic Health Examination (Table 1).[22]

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).[9] There are many publications on the adverse sequelae of ultrasound heating in animal studies. Embryonic and fetal animal studies show the following[10]: (1) If in-situ ultrasound heating produces a temperature rise of < 1.5°C above physiological level, there appears to be no harmful sequelae (2); 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; and (3) there is an inverse relation between temperature rise and the exposure time needed to create a potential hazard on thermal grounds (Table 2).

THERMAL INDEX

Thermal index (TI) is an estimate of the maximum temperature rise that could occur in exposed tissue during an ultrasound examination.[8] The TI can be used with Table 2 and summary statements 2 to 10 (below) to assess potential thermal hazard to the fetus. 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 thermal index 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. Since 1993 ultrasound machines have been equipped with an output display for both thermal and mechanical risks, which should be visible if either index is greater than 1.

There are 3 user-selectable TI categories: soft tissue (TIS), bone (TIB), and cranial (TIC).[11]

Most obstetric examinations would fall under TIS, in which the ultrasound path is predominantly through homogenous soft tissue or fluid. TIB would apply to some second and third trimester scans, in which fetal bone is in the focal region. TIC would normally not apply to obstetric ultrasound, in which bone is extremely close to the transducer

surface. Various studies have supported the use of these 3 types of thermal indices.[12–16] 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.[17]

MECHANICAL EFFECTS

Mechanical effects result from radiation force, streaming, and cavitation.[3] 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.[3] The mechanical index is an estimate of the risk for capillary hemorrhage in lung, taking into account operating conditions.[11] Unless the expected benefits of a higher exposure have been judged to outweigh the foreseeable hazard, the value should be maintained below 1 when scanning tissue at risk.[9] Mechanical effects are unlikely to occur in obstetric ultrasound because of the absence of gas bodies or the use of contrast media; thus the mechanical index has less relevance. However, mechanical radiation pressure effects have been demonstrated in preliminary studies of physical models[18] and the fetus[19] using obstetric Doppler. Because this imaging tool yields higher intensities and thermal indices than B-mode with similar mechanical indices, potential biological effects might be both mechanical and thermal.[17] The early fetal brain is considered more susceptible, and thus Doppler should be avoided in early pregnancy.

CONCLUSION

Since the implementation of the output display standards, there has been a concern that more equipment is being developed with intensities which now approach the limits of safety.[20] Although thermal indices can sometimes exceed 1 in standard 2-D real-time B-mode ultrasound, higher intensities are of particular concern for pulsed Doppler, colour flow, and in first trimester ultrasound with a long transvesical path (> 5 cm).[6,9,20,21] Concerns also arise in scanning tissues with limited perfusion (embryonic tissue) or if the patient is febrile. As well, transvaginal probes may produce additional direct heat to adjacent tissue.[11] In these circumstances, operators need to pay special attention to limiting dwell time, limiting exposure to critical structures, and to carefully following the exposure information.

The theoretical risk of an adverse biological effect even from standard 2-D obstetric ultrasound makes it hard to justify its use for nonmedical reasons, such as sex determination, making nonmedical photos or videos, or for commercial purposes. When obstetric ultrasound is done for research or teaching purposes, exposed individuals should be informed if either the TI or MI are greater than 1 and of how this exposure compares with that found in normal diagnostic practice.[8]

Table 2. Exposure duration needed to create a potential thermal hazard when embryonic/fetal temperature rises above 37°C.

Degrees above normal (37°C)	Exposure duration, minutes
2	60
3	15
4	4
5	1
6	0.25

The values [8] are a compromise between conclusions of the National Council on Radiation Protection[3] and the World Federation for Ultrasound in Medicine and Biology.[10]

Summary Statements

1. Mechanical effects from ultrasound are less important in the absence of gas bodies as is the situation with obstetric ultrasound (monitored with the mechanical index [MI]).

2. Thermal effects are of particular concern in obstetric ultrasound with first trimester Doppler and colour flow (monitored with the thermal index).

3. Differing tissue conditions have led to 3 different thermal indices (soft tissue, or TIS; bone, or TIB; and cranial, or TIC). TIS and TIB can be relevant in obstetric ultrasound, and the appropriate index should be used to monitor the situation. TIB should be used if bone is within the focal zone.

4. Thermal effects may increase with ultrasound exposure of poorly perfused tissues or in febrile patients.

5. Diagnostic ultrasound that produces a maximum in-situ temperature rise of 1.5°C above normal can be considered to be safe from thermal damage. This would normally be reflected by a TI of less than 1.5.

6. In estimating the potential hazard of a thermal effect, there is an inverse relation between the degree of in-situ temperature elevation for fetal or embryonic tissue and the exposure duration.

7. Prolonging temperature elevation increases the risk of adverse effects when absolute temperature elevation is greater than 1.5°C. This would normally be reflected by a TI of greater than 1.5.

8. For first trimester transabdominal ultrasound through a transvesical path of > 5 cm, there is evidence that the maximum temperature elevation may be 2 to 3 times that displayed by the TIS, with a maximum normally of 2°C. In this

circumstance, it is particularly important not to prolong dwell time.

9. With transvaginal ultrasound, there may be additional heat to adjacent tissue that comes directly from the probe.

10. Fetal heart rate monitoring is done through intensities that are so low that there are no thermal concerns even for extended periods.

11. Ultrasound machines should display an MI or TI if either index is greater than 1.

Recommendations

1. Obstetric ultrasound should only be used when the potential medical benefit outweighs any theoretical or potential risk (II-2A).

2. Obstetric ultrasound should not be used for nonmedical reasons, such as sex determination, producing nonmedical photos or videos, or commercial purposes (III-B).

3. Ultrasound exposure should be as low as reasonably achievable (ALARA) because of the potential for tissue heating when the thermal 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).

4. All diagnostic ultrasound devices should comply with the output display standards (MI and TI) (III-B).

5. When ultrasound is done for research or teaching purposes, exposed individuals should be informed if either the MI or TI are greater than 1 and of how this exposure compares with that found in normal diagnostic practice (III-B).

6. While imaging the fetus in the first trimester, Doppler and colour Doppler should be avoided (III-B).

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