

Undergo ultrasound studies of the fetus only for medical reasons

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Abstract. The Swedish Radiation Safety Authority (SSM) has reacted to the increase of non-medical ultrasound (US) examinations of the fetus with the purpose to achieve images or videos “just for fun”. Although US examinations are regarded as safe, there is a risk for harmful warming-up of the fetus, especially when non-professional personal is involved. There are also epidemiological studies showing neurological effects of US, an increased occurrence was found for left-hand boys who were irradiated prenatally with US.

With reference to the precaution principle SSM decided to start a campaign with the aim to prevent abuse of US. A letter was sent to all antenatal clinics in Sweden in which information was given about SSM:s concerns. The mid-wives were asked to pass this information to the pregnant women to whom they have early contact and thus to encourage them to restrain from souvenir images.

SSM is giving the following recommendations:

Diagnostic US shall only be used if the medical benefit is larger than the predictable harm. Only certified personnel with adequate training and education shall conduct US-examinations.

Diagnostic US shall not be used for taking images or videos of the fetus, neither for assessing the sex of the fetus on grounds others than medical.

KEYWORDS: (Ultrasound, fetus, medical)

RECOMMENDATIONS REGARDING ULTRASOUND STUDIES OF THE FETUS

The demand for ultrasound souvenir photos and videos increases

Since 1980s diagnostic ultrasound has been used in order to obtain information about the fetus. Ultrasound is widely considered as a safe diagnostic method. Due to this view, together with the development of 3D and 4D ultrasound, parents more often demand souvenir photos and videos on the fetus, often several times during a pregnancy.

Avoid unnecessary exposure of the fetus

Although the method is generally considered safe, ultrasound, when it is improperly used, may cause harmful heating of the fetus. In addition, epidemiological studies have shown that there is a risk of neurological impairment in fetuses exposed to ultrasound. In accordance with the precautionary principle, the Swedish Radiation Safety Authority (SSM) assess that the fetus shall be exposed to ultrasound only when there is a medical reason and the benefit of the examination outweigh the risk of harmful effects.

Medical benefits shall be greater than the foreseeable risks

A diagnostic ultrasound should always be performed by qualified personnel, properly trained in ultrasound diagnosis and with a good knowledge of parameters such as thermal and mechanical index. Risks should be minimized by the person performing the ultrasound examination by handling the ultrasound equipment according to guidelines for thermal and mechanical indexes and limit exposure time according to current guidelines.

Recommendations

The Swedish Radiation Safety Authority (SSM) recommends pregnant women to undergo ultrasound studies only for medical reasons. In order to reach pregnant women with the recommendations, a letter was sent to all Swedish antenatal clinics. The mid-wives were asked to pass the recommendations to pregnant women to encourage them to restrain from souvenir photos and videos, solely for non-medical reasons.

SSM gives the following recommendations:

Diagnostic ultrasound shall be performed only

- when the medical benefits outweigh the foreseeable risks
- by qualified staff, educated and trained in ultrasound diagnostics.

Even when ultrasound is used in teaching and research, the medical benefits shall outweigh the foreseeable risks.

Ultrasound shall not be used to

- take photos and videos of the fetus, for any reason other than medical
- determine fetal sex, for any reason other than medical.

There have only been positive reactions reported to the recommendations.

Basis for recommendations

SSM:s recommendations are based on medical experts in various international organizations and associations, on a systematic review and analysis of literature on the subject, conducted by the World Health Organization (WHO), and on recommendations issued by the responsible authorities in USA and Canada.

Health Canada

- The use of diagnostic ultrasound to obtain information about function or structure in human beings should be restricted to situations in which the medical benefit that may accrue from the diagnostic data outweighs any foreseeable risk.
- Situations of training, demonstration or research may also provide a medical benefit from diagnostic data that outweighs any foreseeable risk.
- Ultrasound should not be used for any of the following:
 - (i) to have a picture of the fetus, solely for non-medical reasons;
 - (ii) to learn the sex of the fetus solely for non-medical reasons;and
 - (iii) for commercial purposes, such as trade shows, or producing pictures or videos of the fetus.

(Guidelines for the Safe Use of Diagnostic Ultrasound, 01-HECS-255, Health Canada)

Food and Drug Administration (FDA)

The use of ultrasound imaging devices for producing fetal keepsake videos is viewed as an unapproved use by the Food and Drug Administration (FDA). Doppler ultrasound heartbeat monitors are not intended for over-the-counter (OTC) use. Both products are approved for use only with a prescription. Using ultrasound equipment only through a prescription ensures that pregnant

women will receive professional care that contributes to their health and to the health of their babies, and that ultrasound will be used when medically indicated.

(Fetal Keepsake Videos, March 24, 2008, Food and Drug Administration (FDA))

World Federation for Ultrasound in Medicine and Biology (WFUMB)

- The WFUMB disapproves of the use of ultrasound for the sole purpose of providing souvenir images of the fetus. Because the safety of an ultrasound examination cannot be assured, the use of ultrasound without medical benefit should be avoided. Furthermore, ultrasound should be employed only by health professionals who are well trained and updated in ultrasound clinical usage and bioeffects.
- The use of ultrasound to provide keepsake images or videos of the fetus may be acceptable if it is undertaken as part of the normal clinical diagnostic ultrasound examination, provided that it does not increase exposure to the fetus.
- Ultrasound imaging for non-medical reasons is not recommended unless carried out for education, training or demonstration purposes.

(Policy statement on non-medical use of ultrasound, June 2008, World Federation for Ultrasound in Medicine and Biology)

International Society of Ultrasound in Obstetrics and Gynecology (ISUOG)

ISUOG disapproves of the use of ultrasound for the sole purpose of providing souvenir images of the fetus. There have been no reported incidents of human fetal harm in over 40 years of extensive use of medically indicated and supervised diagnostic ultrasound. Nevertheless, ultrasound involves exposure to a form of energy, so there is the potential to initiate biological effects. Some of these effects might, under certain circumstances, be detrimental to the developing fetus. Therefore, the uncontrolled use of ultrasound without medical benefit should be avoided.

(ISUOG statement on the non-medical use of ultrasound, 2009, International Society of Ultrasound in Obstetrics and Gynecology (ISUOG))

European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) and European Committee of Medical Ultrasound Safety (ECMUS)

- Ultrasound scans should not be performed solely for producing souvenir images or recordings of a fetus or embryo.
- The production of souvenir images or recordings for the parents to keep is reasonable if they are produced during a diagnostic scan, provided that this does not require the ultrasound exposure to be greater in time or magnitude than that necessary to produce the required diagnostic information.
- Ultrasound examinations should be performed only by competent personnel who are trained and updated in ultrasound safety matters.

(Statement on the use of Diagnostic Ultrasound for Producing Souvenir Images or Recordings in Pregnancy, 2006, and Clinical Safety Statement for Diagnostic Ultrasound, 2008, European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) and European Committee of Medical Ultrasound Safety (ECMUS))

World Health Organization (WHO)

A systematic literature review and meta-analysis to evaluate the safety of human exposure to ultrasonography in pregnancy found out that ultrasonography was not associated with adverse maternal or perinatal outcome, impaired physical or neurological development, increased risk for malignancy in childhood, subnormal intellectual performance or mental diseases. According to the available clinical trials, there was a weak association between exposure to ultrasonography and non-right handedness in boys. Based on the available publications, diagnostic prenatal ultrasonography should continue to be considered relatively safe for both the mother and the exposed fetus. However the findings of this systematic review should be interpreted with caution. Safety implies absence of any deleterious effect, recognized or unrecognized, and it must be kept in mind that deleterious effects resulting from ultrasound may be subtle and appear many years after exposure. Moreover, the various studies included in this systematic review did not necessarily assess all possible harmful biological effects produced by prenatal ultrasound. Furthermore, owing to the lack of sufficient detail in the existing publications, it is impossible at this time to state exactly what combination of factors (gestational age, duration and number of exposures, acoustic output and fetal position) offer the least risk to the fetus. Therefore, as stated in the ALARA (As Low As Reasonably Achievable) principle proposed almost 20 years ago, based on the currently available evidence it is still prudent to expose patients to the least amount of ultrasound energy necessary to obtain diagnostic information.

(Safety of ultrasonography in pregnancy: WHO systematic review of the literature and meta-analysis, Ultrasound Obstet Gynecol 2009; 33:599-608)

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