Editorial

Risky business: applying risk/benefit analysis consistently in entertainment ultrasound

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Introduction

Fetal non-medical entertainment ultrasound (NEU) using three-dimensional (3D) and 4D fetal images is widely available. Couples are offered real-time scans, souvenir images, DVDs and sex determination. This is sometimes referred to as entertainment, boutique, shopping-mall, elective or fetal-keepsake imaging. It appears to be most prevalent in the USA where, in one study, 9% of pregnant women admitted having had non-medical scans1.

There is controversy regarding the use of fetal ultrasound for entertainment; professional bodies strongly oppose it. The principal reason cited is the risk of harmful bioeffects. For example, when actor Tom Cruise purchased an ultrasound system with plans to personally scan his fiancée Katie Holmes, doctors warned that: ‘if it is not medically necessary, the use of ultrasound raises unnecessary physical risk to the fetus’2.

The possibility that ultrasound could cause bioeffects in the fetus should be of immense concern to people in all countries. Virtually everyone under 25 years of age in western nations was exposed to ultrasound in utero, commonly during multiple scans. The impact of any bioeffects could be devastating.

In this paper we argue that professional organizations’ concerns about bioeffects in NEU are hypocritical. We advocate a relook at our approach; the important factors to consider are gestational age and the power of ultrasound, not the indication for the scan nor where it is performed. Current arguments using the risk/benefit balance to oppose NEU fail.

Entertainment ultrasound and bioeffects

Entertainment ultrasound comes in two forms. NEU is performed outside medical settings, with no therapeutic or diagnostic aim. Alternatively, non-medically indicated scans may be performed by sonographers in medical clinics within the context of a professional relationship – for example, as a supplement to a diagnostic scan. We will refer to this as medical entertainment ultrasound (MEU). Virtually all medically indicated scans include demonstration of fetal images to the couple and there is no sharp dividing line to clearly differentiate this from diagnostic segments of the scan.

There is no support for NEU among professional bodies. Exposing the fetus to ultrasound with no anticipation of medical benefit is said to be unjustifiable3. Other professional organizations also oppose NEU4–7. The underlying principle is ALARA (as low as reasonably achievable) acoustic output and dwell time8. Concern is so great that the American Food and Drug Administration can seize machines used for entertainment purposes without a prescription and it encourages states to take action against technicians who perform non-medical ultrasound examinations9. Others have argued, however, that there is little cause for ethical objection to boutique fetal imaging on the basis of bioeffects if the time and intensity of the ultrasound examination are reasonable10.

There is also concern about MEU. It is claimed that the use of two-dimensional (2D) or 3D ultrasound only to view the fetus, obtain a picture of the fetus or determine the fetal sex without a medical indication is inappropriate and contrary to responsible medical practice11. This implies that we are dealing with a dangerous technique. However, statements are contradictory; the British Medical Ultrasound Society states that research and ‘bonding’ scans endorsed by a clinician or midwife are acceptable8, yet it opposes NEU. It is unclear how non-diagnostic scans can carry differing risks depending on who requests them.

Is entertainment ultrasound higher risk than diagnostic ultrasound?

It is claimed that NEU is particularly risky since untrained commercial operators have no concerns that there might be some hidden danger of ultrasound12. However, trained medical operators may be guilty of the same failing. Since
1992 it has been the responsibility of the operator of the machine to monitor the output displays to ensure the safe use of ultrasound. Yet in one report, only 28% of regular ultrasound users knew where to find the safety indices on the screen of their own machine\textsuperscript{13}. Only 22\% knew how to adjust the energy output. Machine power displays have ‘failed to provide a basis for safe scanning’\textsuperscript{14}. Furthermore, there are no recommended limits on the number of, or indications for, ‘diagnostic’ ultrasound examinations. Doctors often perform numerous scans during each pregnancy; some obstetricians scan low-risk women at every antenatal visit. Guidelines do not discourage this practice.

The suggestion that NEU is riskier than diagnostic ultrasound is flawed because, given appropriate power levels, there is little likelihood that it is quantitatively or qualitatively more dangerous than diagnostic ultrasound. Imagine that in 40 years an individual is found to have suffered harm from ultrasound performed while he was a fetus. His mother had diagnostic ultrasound scans, including Doppler, at 8, 12 and 19 weeks, a scan researching aortic flow at 13 weeks and then an NEU at 26 weeks. It is not relevant to him that one of the scans was for entertainment. None of them was likely to offer him medical benefit; they were unlikely to show problems that would allow him health-enhancing treatments. Importantly, ultrasound bioeffects would almost certainly be due to the diagnostic scans because these were at earlier gestational ages and the power levels probably higher compared with the NEU scan. Similar thoughts apply to MEU. Focusing on the scan’s indication or where it is performed is a distraction.

Nevertheless, many professional statements are cautionary regarding the risks of NEU, and sometimes also MEU, but reassuring about the risks of diagnostic or teaching scans\textsuperscript{8,15}.

How much risk is too much?

It is not known if diagnostic ultrasound causes bioeffects, particularly using post-1992 power levels\textsuperscript{16}. We need to know. However, there is a separate question that also needs to be addressed, regarding how we should respond to small or theoretical risks. The approach that is sometimes taken is to draw on the principle of non-maleficence\textsuperscript{17} or the precautionary principle\textsuperscript{18,19} to justify avoiding such risks. However, the problem is that possible risks apply to almost any new treatment or medical intervention (e.g. gene therapies), and these principles might prevent the development of major medical advances. A more rational approach is to attempt to balance possible risks with potential benefits.

Professional bodies have shown a willingness to balance the potential risks and benefits of ultrasound. Many professional statements imply that the risks of ultrasound to the fetus are sufficiently high, or sufficiently uncertain, that scans should only be performed when they convey significant benefits to the woman. They claim that diagnostic ultrasound conveys such benefits, whereas NEU does not.

This line of argument faces two problems. First, it seems quite possible that many women receive benefits from NEU that are comparable to those that they receive from diagnostic ultrasound. Consider the case of women who undergo mid trimester medical ultrasound examination even though they would not consider abortion in the presence of an abnormality. Since it is primarily a test for fetal abnormality, the benefits that such women derive from the scans are likely to be small, little greater than those gained from NEU. In fact, some diagnostic scans, such as those intended to detect threatened miscarriages, are likely to have few, if any, medical benefits. The benefits may take the form of psychological reassurance – not dissimilar to the benefits of entertainment ultrasound.

Second, and most important, it is not at all clear that the ‘significant benefits to the woman’ test is an appropriate one. Is it ethical to impose risks on a fetus so that the woman can derive some significant (but not enormous) benefit? For example, we might find it unethical for a woman to drink alcohol or take recreational drugs if this may harm the fetus, even though the woman may consider that the benefits to her are significant. One of us has argued elsewhere that a pregnant woman has strong moral reasons to refrain from behavior that potentially causes a child to be born in a harmed state and that has little prospect of benefiting it\textsuperscript{20}. This reasoning does not presuppose that the fetus is a person, but is grounded on principles of respect for the interests of sentient beings and prevention of harm to future individuals\textsuperscript{20}. Debate needs to focus on when, if ever, it is reasonable to perform a test that is in the interests of the woman but has a risk, however low, of causing significant morbidity to the future child.

Perhaps a more defensible position for professional organizations would be one holding that the risks of ultrasound to the fetus are sufficiently high, or sufficiently uncertain, that ultrasound scans should only be performed when they convey significant benefits to the fetus. Again, it might be argued that diagnostic ultrasound would typically pass this test, whereas entertainment ultrasound would not. The first problem is that while some diagnostic ultrasound scans potentially benefit the fetus, such as those to identify third-trimester fetal compromise, the majority convey no such benefits. Scans commonly pose a net risk to the fetus, quite apart from any bioeffects. Many are performed to provide information that could result in termination of a fetus – hardly in the fetus’s interests! Nuchal translucency scans, for example, are performed primarily for risk assessment of chromosomal abnormality; the fetus faces a significant risk of abortion if a problem is found. They primarily offer women choice if an anomaly is detected. Teaching and research scans typically convey no benefit to the fetus, and expose the fetus to the risks of any bioeffects.

The second problem is that NEU may in a few circumstances pass the ‘significant benefit to the fetus’ test. These scans may increase bonding, and may therefore
reduce a fetus’s risk of therapeutic abortion. Indeed, several states in the USA require that women have a compulsory pre-abortion ultrasound examination to try to discourage abortion, NEU may be more in the fetus’s interests than are medical scans, which often increase the risk of abortion.

Conclusion

Professional bodies currently discourage NEU but not widespread use of diagnostic ultrasound. This is inconsistent. Because of its timing and likely power levels, NEU is low-risk compared to many diagnostic scans.

NEU may often be unethical because the risk of bioeffects is larger than any potential health benefit to the fetus, and because there is no sufficiently great benefit to the woman to outweigh the net risk imposed on the fetus. Yet the same is also true of many diagnostic, teaching and research ultrasound scans.

Criticism of NEU by professional organizations reflects their concern about potential bioeffects. There have been other objections but these too are not persuasive. Either such criticism should cease, or clear guidelines must be introduced to discourage training and research scans, frequently repeated scans in low-risk women and scans using higher power Doppler.

Since fetal ultrasound is believed to have non-negligible risks, a position that balances maternal and fetal interests in medical settings should be developed. Consistent policies should then follow, indicating when it is reasonable to perform or prolong scans for entertainment. Clear bioeffect statements, however, are predicated on having improved research into the potential adverse effects of current ultrasound equipment.

Statements by professional bodies seem to imply that the purpose of a scan can impact on the risk of bioeffects, but whether a scan is medically necessary cannot be relevant to its physical risk to the fetus. The risk of bioeffects varies with gestational age and ultrasound power, not the indication. Professional organizations misuse the risk/benefit concept and are hypocritical in its application.

If ultrasound produces adverse bioeffects, it is not a single late B-mode entertainment ultrasound that will result in most harm. It is diagnostic ultrasound. It is the multiple medical scans, often including Doppler, often in the first trimester and often for small clinical benefit. Doctors would be called to account, not businessmen. Our focus must be on reducing all fetal exposure, especially in the embryonic period. We should first face the major issue of documenting and reducing fetal diagnostic ultrasound exposure before confronting the more minor issue of entertainment ultrasound.

Given current clinical practice, there are no good reasons on the basis of bioeffects for opposing entertainment ultrasound.

REFERENCES


