Ultrasound: Prematurity and Potential Risks

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Over 50 years ago, Ian Donald experimented with using ultrasound to investigate babies in the womb. In 1980 he warned, "Sonar is not a new medical religion…nor an end in itself. A tool exploited for its own sake is no better than a saw given to a small boy for cutting wood, who must presently look around the house for suitable objects of furniture inviting amputation … the possibility of hazard should be kept under constant review" (Donald 1980, 1).

Sadly, that has not happened. In 1982, AIMS (Association for Improvements in the Maternity Services) wrote to the Minister of Health, Gerard Vaughan, expressing our concern about the widespread use of ultrasound before it had been evaluated. To our astonishment we were told that the issue had been discussed by the Medical Research Council and they concluded, "The use of ultrasonic techniques have become so widespread that a controlled trial along the lines originally proposed would no longer be ethically possible" (Beech and Robinson 1994).

The ethics of exposing every fetus to an unevaluated technology was not considered important.

It took over 30 years to identify the risks of diethylstilbestrol and 65 years to recognise the dangers of X-rays; one can only speculate how long it is going to take before the risks of ultrasound are properly evaluated. In the meantime we no longer have an unexposed population with which to make comparisons. Ian Donald said he would not use antenatal ultrasound before three months gestation, but now all embryos are routinely scanned and there is no data on safety, including possible effects on miscarriage rates.

Ultrasound Screening

The vast majority of pregnant women attend their first antenatal appointment around 12 weeks expecting to have an ultrasound examination in the happy expectation that they will have a picture of their baby. Poggenpoel's study of the value of a universal booking scan revealed that it had no significant benefit, apart from a small reduction in presumed postterm pregnancies (2012), but women's expectations are such that they expect to have a scan, if only to confirm that they are pregnant and to have a picture of their baby. Their confidence in responding to the messages from their own bodies is undermined from the minute they become pregnant—they have to have it confirmed by ultrasound.

Women who experience early bleeding have scans to find out if they are still pregnant, a fact which would become obvious in time. Press reports and our help-line reveal cases where women who refused intervention when told the embryo had died go on to have a full-term successful pregnancy. No one knows how many living embryos have been destroyed in the past by erroneous scan results.

Accuracy of Screening

A key issue with identifying intrauterine growth restriction (IUGR) is establishing accurately the expected date of delivery (EDD).

Charts showing the rates at which the fetus is "supposed" to grow may not be applicable to all women and, more specifically, to all ethnic groups. A study by Dua and Schram (2006) at Blackburn Hospital, which has a mainly Indo-Pakistani population and uses standard growth charts based on Caucasian populations found that 58% of the cases induced for IUGR had babies within the normal range on the customised growth charts—had these customised charts been used, 53% of antenatal day unit appointments for fetal monitoring would have been unnecessary. They make no mention of the stress the mothers will have suffered worrying about a baby that was supposedly not growing properly.

The latest letter we have is from a woman of Western European origin married to an Indian. She pointed out that if she had followed the hospital's advice, the repercussions would have very nearly cost her a normal birth. She said, "My baby could have been induced early, which if this was the route we had gone down there was a strong chance she would have been born below the 2.5 kg "threshold" potentially leading to her being put [in the NICU] (she was born weighing 5 lb 11 oz at 40 wks + 4 days)" (Mrs. S 2012).

At a Royal Society of Medicine forum on ultrasound in obstetrics in 1985, a midwife in the audience suggested that claims made for ultrasound's ability to diagnose growth restriction overlooked the fact that babies grow at different rates and in spurts. She said a baby suspected of growing too slowly one week might have caught up by the next week and this would be observed if the woman was being seen regularly by the same professional. She also said that insufficient attention was given to eliciting diet and lifestyle from mothers whose babies did not appear to be growing at the expected rate, and attention given to these simple matters might prevent the need for technological intervention.

AIMS is frequently contacted by women who are disputing their EDD, and woe betide the woman who refuses the scan. It appears that many hospital midwives have lost the skill of dating the pregnancy and rely on an ultrasound examination instead. I received this e-mail a few weeks ago:

> They kept telling me how they need to do the dating scan for the midwives to know my dates, etc., and when I said I was happy to sign something not to have this done, they just told me to start the scan … and I was told that I was 12 + 1! This incidentally moves my EDD forward by four days, which potentially leads to additional hassle associated with going past 42 weeks. It is not possible as I really know exactly when this baby was conceived, and of course I asked them not to do this. (Regrettably, I did not say "I do not consent." I really assumed a request should be straightforward enough.)

It seems that people who work in maternity are not aware of the women's right to choose what they have done. I only had one booking visit (during which the midwife was pleading with me to do the blood draws to make her job easier) and this little scan, and I am already very disappointed (London, personal communication).

Amniotic Fluid Index

Part of the assessment of IUGR is measuring the amniotic fluid index (AFI). Unfortunately, it does not accurately predict whether or not the fetus is at risk. Khunpradit et al. (2010) found that the caesarean rate for fetal distress was double that of the controls with no improvement in outcomes when an AFI was done on admission compared with those who had no ultrasound on admission. The *Cochrane Review* found that "The use of the amniotic fluid index increases the rate of diagnosis of oligohydramnios, and the rate of induction of labour, without improvement in peripartum outcomes" (Nabhan and Abdelmoula 2008).

Biophysical Profiles

So, some women will have a biophysical profile (BPP). This includes ultrasound monitoring of fetal movements, fetal tone breathing and ultrasound assessment of liquor volume with or without assessment of the fetal heart rate. The BPP is performed in an effort to identify those babies that may be at risk of poor

pregnancy outcome so that additional assessments of well-being may be performed, labour may be induced or a caesarean section performed to expedite birth. Unfortunately, this system does not improve outcomes, but is associated with a significant increase in induction and caesareans. The researchers noted, "The impact of the BPP on other interventions, length of hospitalisation, serious short-term and long-term neonatal morbidity and parental satisfaction requires further evaluation" (Lalor 2008).

Despite this conclusion, if the fetus has a low score the mother is referred for a Doppler assessment of the blood flow in the umbilical cord and an assessment of the uterine arteries. A Cochrane review of Doppler ultrasound for low-risk pregnancy found no conclusive evidence that the use of routine umbilical artery Doppler ultrasound or a combination of umbilical and uterine artery Doppler ultrasound in low-risk or unselected populations benefits either the mother or the baby (Alfirevic et al. 2010). An earlier randomized study by Davies (1992) of 2475 women reported in *The Lancet* revealed a fourfold increase in perinatal deaths in babies exposed to routine Doppler ultrasound examination of umbilical and uterine arteries at 19–22 weeks and 32 weeks (16 vs. 4 perinatal deaths of normally formed infants). The authors dismissed the large difference in deaths by commenting that a meta-analysis of four randomised studies had shown Doppler scans to be associated with reduced perinatal mortality. At the time AIMS wrote to *The Lancet* pointing out our concerns: the fact that none of the studies used Doppler screening as early as 19–22 weeks; in two of the four studies there was no control group; the average gestational age in the third study was over 32 weeks (perinatal deaths were the same in both groups, but low Apgar scores were more common in the exposed group); and finally the meta analysis covered only high-risk pregnancies where the risk/benefit would be different. *The Lancet* refused to publish the letter.

Disadvantages to Detecting IUGR

In 1998, a German study compared babies whose growth-restriction was diagnosed by ultrasound in the womb, with those whose smaller growth was not detected until after birth (Jahn 1998). Out of 2378 pregnancies, only 58 of 183 growth-restricted babies were diagnosed before birth. Forty-five fetuses were wrongly diagnosed as being growth restricted when they were not. Only 28 of the 72 severely growth-restricted babies were detected before birth. The babies diagnosed as small were much more likely to be delivered by caesarean (44.3% compared with 17.4% for babies who were not small for dates). If a baby actually had IUGR, the cesarean rate varied hugely according to whether it was diagnosed before birth (74.1%) or not (30.4%). preterm delivery was five times more frequent in those whose IUGR was diagnosed before birth compared with those who were not. The average diagnosed pregnancy was two to three weeks shorter than the undiagnosed one. The admission rate to intensive care was three times higher for the diagnosed babies.

Hand-held Dopplers

Many women are not aware that the hand-held machine to listen to the baby's heartbeat, commonly used by midwives instead of a stethoscope or a fetoscope, uses Doppler ultrasound. Unfortunately, there have been no studies to determine the short- or long-term risks of using these machines. We know, however, that Doppler ultrasound is more powerful than the standard ultrasound that is used to check women's dates and for screening.

This important study from Heidelberg University shows a huge difference between percentage of IUGR babies detected in everyday care and real life, and the much higher percentage shown in published studies elsewhere. We think this is true for many aspects of medical care, where research studies show promising results which are not replicated outside centres of excellence (and maybe not even inside them). It also provides further evidence that the scans German women are guaranteed under their health care plan are not benefiting their babies.

Risk of Premature Labor

A randomised prospective trial, published in 1990, suggested the possibility of increased risk of premature labour when ultrasound scans were used. In Michigan, obstetricians were studying 57 women at risk of giving birth prematurely. Half of them were given a weekly ultrasound examination and the rest had pelvic examinations instead (Lorenz et al. 1990). Preterm labour was more than doubled in the ultrasound group (52% compared with 25% in the controls). Although the numbers were small, the difference was unlikely to have emerged by chance. We would have preferred a comparison to have been done with an untreated group, who were not exposed to the risks of infection from so many internal examinations, but where would one find such a population today?

Animal Studies

AIMS has been questioning the safety and possible long-term adverse effects of ultrasound since Liebeskind published her findings about the effects of diagnostic levels of pulsed ultrasound on the growth pattern of animal cells, which persisted for 10 generations. She warned, "If germ cells were…involved, the effects might not become apparent until the next generation" (Liebeskind et al. 1982, 176–86).
This year, two African researchers published a paper which reviewed the issue of ultrasound safety and referred to the numerous animal studies which offered robust evidence of damage (Bello and Ekele 2012). They observed the following:

> In human subjects, several studies have shown an association between in utero insonation of foetuses and delayed speech, dyslexia and non-right-handedness. These are suggestive of at least subtle neurological effects and are consistent with the results of animal studies. … A well-designed randomized controlled trial by Newman et al., revealed a strong association of low birth weight with in utero insonation, also suggesting that animal findings may indeed be extrapolated to humans. Furthermore, the effect on birth weight appears to be stronger after four or more exposures, suggesting sensitivity to cumulative dosing and dose dependency.

The Commercialisation of Ultrasound

As ultrasound developed from the fuzzy, grainy blobs that required skilled interpretation to 3D and 4D moving pictures, commercial opportunities became evident. It is now possible to arrange your own scans. Private companies charge high fees to undertake scans for social reasons. I e-mailed some of them and asked if they could tell me what the risks of scans are. This response from the London Ultrasound Centre is a common response: "I can advise you that all types of ultrasound scans, including trans-vaginal scans and 3D and 4D scanning, are all safe and completely harmless to the unborn baby."

It is not just private companies that make claims of safety. The NHS Choices website states: "Ultrasound scans use sound waves to build a picture of the baby in the womb. The scans are completely painless, have no known side effects on mother or babies and can be carried out at any stage of pregnancy. Talk to your midwife, GP or obstetrician about any concerns you have."

The University College Hospital in London has a free, walk-in scanning service. These scans can take up to 40 minutes and the public is encouraged to take away a video so that they can show Granny, the neighbours and their friends.

It is only now as a result of these private scanning services, operated in some areas by unskilled technicians, that the medical profession has been provoked into warning of the possible risks.

Ultrasound is defined as high frequency sound waves with frequencies above 20 kHz (kilohertz). There are some uncertainties regarding ultrasound imaging of the fetus which suggest the possibility of subtle effects on the developing brain cannot be ruled out.

The Health Protection Agency (HPA) considers that parents-to-be should be aware of uncertainties regarding ultrasound imaging of the fetus and take these into account when deciding whether to have ultrasound scans that do not have a defined diagnostic benefit and provide only keepsake images or "real time" scans. HPA advises that further research is done to address gaps in knowledge about the health effects of ultrasound and infrasound (HPA February 2010).

It is a disgrace that 30 years after AIMS expressed concern at the widespread and unevaluated use of ultrasound, we only have a statement from HPA calling for yet more research. Such research will be extremely difficult to do because over 90% of the pregnant population will have been exposed to ultrasound scanning during their pregnancies. In the UK alone, it is estimated that the NHS spends over £100,000,000 a year on a technology that still does not address the question of safety or effectiveness. In the meantime, parents are consenting to examinations with very little knowledge of the potential risks.

Informed Consent

In order for women to give informed consent, they need to be told of the risks as well as the possible benefits of ultrasound. Universally, women are told that ultrasound is safe and has no known adverse effects. Clearly, this does not conform to the principles of informed consent and, therefore, it can be argued that without adequate information, the woman has not consented. One of these days women are going to take legal action for assault as a result of being inadequately informed of the risks.

References:

- Alfirevic, Z, T Stampalija and GM Gyte. 2010. "Fetal and Umbilical Doppler Ultrasound in Normal Pregnancy." *Cochrane Database Syst Rev 4* (8): CD001450.
- Beech, BAL, and J Robinson. 1996. *Ultrasound Unsound?* Association for Improvements in the Maternity Services.
- Bello, SO, and BA Ekele. 2012. "On the Safety of Diagnostic Ultrasound in Pregnancy: Have We Handled the Available Date Correctly?" *Annals of African Medicine* 11:1.
- Cohain, JS. 2012. "Risks and Responsibilities Arising from Prenatal Ultrasound." *MIDIRS* 22 (1): 39–43.
- Davies, JA, S Gullivan and JAD Spencer. 1992. "Randomised Controlled Doppler Ultrasound Screening of Placental Perfusion during Pregnancy." *Lancet* 340 (8831): 1299–303.
- Donald, I. 1980. "Sonar: Its Present Status in Medicine." In Progress in Medical Ultrasound, Vol 1, edited by A Kurjak, 1–4. *Amsterdam: Elsevier Science*.
- Dua, A, and C Schram. 2006. "An Investigation into the Applicability of Customised Charts for Assessment of Fetal Growth in Antenatal Population at Blackburn, Lancashire, UK." *J Obstet Gynaecol* 26 (5): 411–13.
- Jahn, A, O Razum and P Berle. 1998. "Routine Screening for Intrauterine Growth Retardation in Germany: Low Sensitivity and Questionable Benefit for Diagnosed Cases." *Acta Ob Gyn Scand* 77 (6) 643–48.
- Khunpradit, S, P Lumbiganon and M Laopaiboon. 2011. "Admission Tests other than Cardiotocography for Fetal Assessment during Labour." *Cochrane Database Syst Rev* DOI:10.1002/14651858.CD008410.pub2.
- Lalor, JG, et al. 2008. "Biophysical Profile for Fetal Assessment in High Risk Pregnancies." *Cochrane Database Syst Rev*2000 (2):CD000038.
- Liebeskind, D, et al. 1982. "Diagnostic Ultrasound: Time-lapse and Transmission Electron Microscopic Studies of Cells Insonated In Vitro." *Br J Cancer* 45 (Suppl V): 176–86.

- London, M. May 23, 2012. Personal communication.
- Lorenz, RP, et al. 1990. “Randomised Prospective Trial Comparing Ultrasonography and Pelvic Examination for Preterm Labor Surveillance.” *Am J Obstet Gynecol* 162 (6): 1607–10.
- Mrs. S. 2012. November 7, 2012. Personal communication.
- Nabhan, AF, and YA Abdelmoula. 2008. “Amniotic Fluid Index versus Single Deepest Vertical Pocket As a Screening Test for Preventing Adverse Pregnancy Outcome.” *Cochrane Database Syst Rev* CD006593. doi: 10.1002/14651858.CD006593.pub2.
- Poggenpoel, EJ, L Geerts and GB Theron. 2012. “The Value of Adding a Universal Booking Scan to an Existing Protocol of Routine Mid-gestation Ultrasound Scan.” *Int J Gynecol Obstet* 116 (3): 201–05.