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Ultrasound - More powerful, more dangerous, more unethical

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When Professor Stuart Campbell says he is worried about the way ultrasound is being used on unborn children we should listen. Hitherto he has been the great apologist and defender - oft quoted in the press as saying it has been used on millions of babies and there is no evidence of harm (a claim which AIMS has strongly disputed, of course.)

However, recently he and Dr Platt his co-editor of a specialist journal on ultrasound were faced with a dilemma. [1] Two studies were submitted on early human embryos, and the most powerful forms of ultrasound - pulsed and colour Doppler - had been used.[2,3] These create intensities many times higher than normal scans. And, as we already know, when the probe is inserted into the vagina, as in this case, the ultrasound does not have to go through the wall of abdomen, which absorbs some of the energy. The journal had previously published studies where pulsed Doppler was used at 11-14 weeks gestation, but when it came down to 10 weeks it seems the editors became concerned.

The editors admit there is "a serious lack of experimental data on the effects on the fetus of colour and pulsed Doppler ultrasound when performed transvaginally in the first trimester." (In fact there is no adequate information on long term effects on the human embryo or fetus of ultrasound exposure via the mother's vagina or of exposure to colour and pulsed Doppler at any stage of pregnancy). And these were being used before 10 weeks gestation when the organs were not even formed. Please note that this was non-therapeutic research - there was no way it was going to benefit the mothers or babies concerned.

Was it ethical for the journal to publish the studies? They consulted their large international editorial board. Two members thought that such research should only be done if the woman was going to have an abortion. A third agreed, but said Doppler could be used if it was of proven clinical value.

But in that case, said the editors, how would doctors be able to find out if early studies could predict later problems in pregnancy? (Not that there is any early treatment for such problems, of course, even if they can be predicted, and the track record for benefits of later ultrasound is poor, as our readers will know.)

The editors have therefore evolved an "ethical policy" for future publication. It includes "informed patient consent" - and the patient information sheet is to be submitted to the journal. May we suggest they actually publish the information so we can all see it? Since there is, at the moment no information on

what happens to children exposed as tiny embryos to the most powerful forms of diagnostic ultrasound, it will be intriguing to see what women are to be told. It is far from reassuring to see a piece in the same issue by Chervenak (one of the editorial board) and McCullough, both ultrasound experts, simply saying "Pregnant women should be assured that only appropriate power levels will be used in fetal Doppler ultrasound studies. They should also be informed that there are no documented risks to the fetus at such power levels, that the research may benefit her fetus or her."[4] Appropriate for what and for whom? As a veteran member of three research ethics committees I don't know whether to be surprised at their ignorance or amazed at their effrontery.

The research must be also approved by an ethics committee, say the editors. But that is standard procedure in any reputable medical journal anyway. The two studies they published were approved by local ethics committees in Finland and Philadelphia, whose members now have egg on their faces. In future the information provided to the ethics committee on safety must also be submitted to the journal So how come they did not ask for all this information before publishing the two studies? We suggest they publish that information too, especially since the consumer interpretation of risk often differs from Professor Campbell's. [5]

Their future policy also includes insisting that the equipment must display the safety limits for the thermal index (TI) - how much the tissue may be heated - and the mechanical index (MI) - which refers to the force which can cause gas bubbles to be formed, stream and possibly damage tissue - and might show effects of radiation pressure. The embryo is submitted to a forward force every time a pulse passes through it. As medical physicist Dr Frances Duck points out, diagnostic Doppler ultrasound causes higher exposure than normal scans, and can heat soft tissue. [4] (From many human and animal studies we know that raised temperatures can cause abnormalities.)

In fact the TI is already known to be inadequate, because it does not estimate what happens to the tissues near the transducer. When ultrasound equipment is used in the oesophogaus, the transducers have a cut-out mechanism if they become too warm. Vaginal probes do not.

Frances Duck had already warned that the revised standards allowed since by the FDA since the early 1990s do not prevent the sale of excessively powerful machines[6] And now we don't even know how powerful they are. The ultrasound power is measured by the waves it creates in water. After a certain point the water becomes saturated so higher power is simply not measurable by this method.

The future ethical code of the journal also insists that exposure times must be based on the ALARA principle (As Low as Reasonably Achievable) and that exposure times must be given. We do not find this reassuring. A radiographer would use the least and shortest exposure to X-ray a fetus - but we don't X-ray the fetus at all unless it is absolutely necessary. Please note there was no unexposed control group in either study, and no plans are mentioned for follow up of the children.

What we find surprising is that neither study tells us how many of the babies were born alive, and in what condition.

48 women were studied in America; 60% of them had had ovulation induced. They had ultrasounds at 4-5 weeks, and then every two weeks until 13-14 weeks. Ten pregnancies miscarried before 13 weeks, having been involved in 27 studies, and the remaining 38 women had 145 examinations. We are told the surviving 38 pregnancies "progressed to term without any significant fetal complication or anomaly detected". For all we know the babies could be dead, but "normal". How odd that the editors did not require more detailed final data from such a meticulous study of the earliest fetal heartbeats. The authors show that the babies which miscarried were less likely to show early heart valve activity. Were these pregnancies destined to end, or were they the babies more vulnerable to ultrasound?

In the study from Ouolu, Finland, researchers looked at the development of the yolk sac in 16 women who had examinations at 5, 7, 8 and 10 weeks. They started with 20 but four were excluded because two pregnancies were outside the uterus, one was anembryonic and one was aneuploid. (We are not told at what stage the missing embryo or chromosome abnormality were detected.) The only information we get on outcome in the rest is "The course and the outcome of all pregnancies were uncomplicated." So - did they go to term, what were their Apgar scores, did they spend time in intensive care, were they born alive, are they still alive? After providing us with copious information about blood flow in yolk sacs, surely the authors could spare a sentence to tell us what happened to the babies, and it is surprising the journal did not require it.

There is no doubt that these studies can come up with interesting scientific information. The question is, what price will some mothers and babies be paying to provide it - and how shall we ever know, when it's only the powerless consumers who want to find out?

It is significant that one of the studies was done on women who had had fertility treatment. It is on this group that transvaginal probes and ultrasonic study of embryos began - these women were only too willing to agree to investigations they thought might help and give them early indication of pregnancy. Is it coincidence that outcome of such pregnancies - the most closely monitored of all - is so poor, with a high rate of both abnormalities and deaths?

References

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