

ULTRASOUND - THE MYTHOLOGY OF A SAFE AND PAINLESS TECHNOLOGY

A Paper presented by Beverley A Lawrence Beech to the Royal Society of Medicine on the 3rd October, 1995.

I would like to begin this presentation by acknowledging the work of Jean Robinson. Jean and I have been working together on ultrasound issues since the middle of the 1980s. We produced a report **Ultrasound - Unsound?** which identified our anxieties about this popular technology and this paper presents our views on these and subsequent developments.

Since its introduction in the 1960s ultrasound has developed and grown until there are now very few women who have not had ultrasound exposure during their pregnancy or labour. While the early researchers were aware of the potential harm that ultrasound could cause, and urged that "*the possibility of hazard should be kept under constant review*", the enthusiasm for finding out more and more about the baby hidden inside the mother's womb overcame any anxiety about potentially harmful effects.

Consumer awareness of potentially damaging effects of ultrasound was triggered by Doreen Liebeskind who published a paper on the effects of ultrasound on rat cells in vitro. Her research was dismissed on the grounds that the levels of ultrasound used were far higher than those commonly used antenatal clinics, and that no-one had managed to reproduce her findings. In a later paper, in 1982, Liebeskind pointed out that the researchers had studied continuous wave ultrasound instead of the pulsed ultrasound she used. In this later paper she stated

"The persistence of abnormal behaviour and motility in cells exposed to a single dose of diagnostic level ultrasound 10 generations after insonation suggests permanent hereditary effects."....."One can speculate that if fetal cells were to be subtly damaged,the effects might not become apparent until the next generation."

This information appeared to have little effect on the medical profession, although, in 1982, the American Food and Drug Administration issued the following statement:

"Increasing concern has arisen regarding the fetal safety of widely used diagnostic ultrasound in obstetrics. Animal studies have been reported to reveal delayed neuromuscular development, altered emotional behaviour, EEG changes,

anomalies and decreased survival. Genetic alterations have also been demonstrated in in-vitro systems."

The FDA warned that ultrasound should not be used routinely and should be reserved for cases where essential diagnostic information cannot be gained by other means. AIMS wrote to the then Minister of Health expressing concern and asking why a similar warning had not been issued in the UK. The Minister, Dr Gerard Vaughan, replied that in the four years since the Medical Research Council's Cell Biology and Disorders Board considered the possibility of conducting a controlled trial to evaluate the potential effects of ultrasound "*the use of ultrasonic techniques have become so widespread that a controlled trial along the lines originally proposed would no longer be ethically possible.*"

The ethics of condoning the continued use of a technology which had not been properly evaluated was clearly of lesser importance to the medical advisors.

While the medical profession persists in failing to address the safety issue they continue to tell women that ultrasound is safe. Even if they use the criteria that anything short of dead can be considered safe, ultrasound fails the test.

Two studies were published in 1990, one in Michigan (Lorenz et al, 1990) where obstetricians, looking at women at risk of giving birth prematurely, found that pre-term labour was more than doubled in the ultrasound group who were given weekly ultrasound examinations, than in the control group which had pelvic examinations instead. In the same year, researchers from Helsinki (Saari-Kemppainen et al, 1990) randomly divided women into two groups which did or did not have routine early ultrasound scans, there were 20 miscarriages after 16-20 weeks in the screened group and none in the controls. The authors made no comment about this in their paper.

In 1992, a report of a randomised controlled trial of doppler ultrasound of 2600 women at Queen Charlotte's Hospital (Davies et al, 1992) revealed that there were four times as many perinatal deaths (4:16) in the doppler group and almost three times as many stillbirths (4:11) compared with the group which did not have doppler ultrasound. The study was looking at blood flow in the arteries.

It is not only pregnant women who may be at risk. Physiotherapists use ultrasound to treat a number of conditions. A study done in Helsinki and published in 1990 (Taskinen et al, 1990) found that if the physiotherapist was pregnant and handling ultrasound equipment for at least 20 hours a week there was a significant increase in the risk of spontaneous abortion. The risk of spontaneous abortions occurring after the tenth week was significantly increased for deep heat therapies given for more than 5 hours a week, and ultrasound for more than 10 hours a week.

While most women roll up for their ultrasound scan thrilled with the idea that they will be able to "see" their baby, few of them realise that the main purpose of the scan is to identify babies with abnormalities and abort them (Marteau TM, 1991). I

am not against abortion, in my view it is a decision that should be made by the mother and she alone, after all she is the one who will bring up the child. Few women think through the implications of having a scan which detects an abnormality and many of them are unwilling to have an abortion. While women are encouraged to have screening tests few of them understand the slippery slope they are going to step on, and how one screening test leads to another, yet further interventions and, very often, even more ultrasound exposures.

Women think that extra scans mean that babies would be saved or sick babies would be healthier. This is not so, certainly there are the rare cases where something can be done, but in the vast majority of cases there is absolutely nothing that can be done to improve the condition of the baby. More information does not mean improved outcomes.

When any technology is used routinely new risks emerge. In early pregnancy the placenta is very low and may look as if the woman has placenta praevia. As the womb grows the placenta is drawn up and out of the way. If it remains low, and very few do, the mother will need a caesarean section to deliver the baby.

Research in Finland (Saari-Kemppainen, 1990) revealed that out of 4,000 women scanned at 16-20 weeks, 250 were diagnosed as having placenta praevia. When it came to delivery only 4 actually had placenta praevias - and one of those had not been diagnosed before. In the group of 4,000 women who did not have ultrasound 4 were found to have placenta praevia when they went into labour. They all had caesarean sections and all of the babies were fine.

So the ultrasound diagnosis made no difference at all to the outcomes for the babies, but 246 women who were told they had placenta praevia, but did not, presumably spent the rest of their pregnancies worrying about an operation they thought they would have to have.

In the 1980s, one of the most common complaints received by the Association for Improvements in the Maternity Services was from women who had been told, early in their pregnancy, that they had placenta praevia. They didn't have it by the time they got to the birth.

While ultrasound is promoted as offering the chance to detect abnormality there is little that can be done early in pregnancy about that abnormality, other than abort the baby or increase the anxiety of the mother. When I was presenting, for *The Pulse*, a Channel 4 TV programme on ultrasound, we filmed a group of pregnant women taking a keep fit course. In the discussions with those women afterwards, one of them told me that she had seven scans in her previous pregnancy because her baby had a "kidney problem." When I asked her what happened, she said gaily, *"Oh they scanned my baby at 40 weeks and told me that the kidney problem was now OK."* What they had not told her was that there was nothing they could do about the kidney problem until the baby was born. She had undergone a whole series of totally unnecessary ultrasound examinations. The irony is that with her

current pregnancy she rushed off to her doctor at 10 weeks and has already had five scans "*just to check that this baby is OK, and, so far, it is.*" No-one had told her about the possible risks of ultrasound or what the implications may be for her baby.

Liebeskind worried that the subtle effects of ultrasound may not emerge until the next generation. No-one mentions to women that when they are scanned their baby is already carrying the next generation's eggs, so when she becomes pregnant those eggs have already had x numbers of ultrasound scans. Her baby may already be ten scans down the road before her mother presents for her "first" scan.

Finding out more and more about the contents of the womb is more interesting to doctors than finding out whether their enthusiasms could have any long-term adverse effects.

HM Meire (1987) commented, "*The casual observer might be forgiven for wondering why the medical profession is now involved in the wholesale examination of pregnant patients with machines emanating vastly different powers of an energy which is not proven to be harmless to obtain information which is not proven to be of any clinical value by operators who are not certified as competent to perform examinations.*"

Instead of restricting ultrasound to those special cases that need it, doctors have extended its use so that everyone gets at least one examination, and many have considerably more. Not only is ultrasound used to "see" the baby in the womb, but the majority of women have it during their labour when they are strapped to a fetal heart monitor. The strap across the woman's stomach holds the transducer in place, held in one position for considerable periods of time. The development of the hand held doppler monitor, a sonicaid or doptone, has been enthusiastically taken up by midwives to the extent that in some hospitals it is almost impossible to find a Pinard stethoscope.

Ultrasound technology is developing so fast it is difficult to keep up with the developments. Power outputs of machines have risen steadily over the past 15 years. The output at the transducer face of some modern equipment in imaging mode is some hundred times greater than transducers in common use 20 years ago. As power outputs increase there is a proportionate increase in risk. As Jan Blauciak in his MA Thesis "Is the use of ultrasound ethical" has said "*It is reasonable to assume that modern equipment potentially poses significantly greater hazards than machines in routine use 5-10 years ago. Much of the literature which gave reassurance to many is now no longer applicable. It is clear that it is no longer justified to talk about the safety of diagnostic ultrasound on a basis of historic perspective. The rapid evolution of ultrasound devices, the power outputs of machines, the development of new techniques such as transvaginal scanning mitigates against successful evaluation of ultrasound safety.*"

Transvaginal ultrasound causes us considerable concern. It uses doppler ultrasound, a much more powerful form of ultrasound. It focuses on a very narrow area, it is very close to the baby's brain and the baby gets a much higher dose. It's

introduction has not been preceded by carefully controlled randomised trials with long-term follow-up to enable an evaluation of long-term safety.

The physicists tell us that the head of an ultrasound transducer produces heat. If that heat is focused on a specific area for a short period of time it can produce cavitation and heating effects. No-one understands the implications of these effects, but it can change cell structure. Obstetricians, midwives and now GPs who have their nice new shiny ultrasound machine may be only too keen to show the women particularly interesting areas on the screen, while they are doing so the transducer dwells over one particular area and may well be producing heating and cavitation effects in the baby.

The possibility of producing these effects is even more worrying when doctors use the ultrasound probe, because that probe is inside the woman's vagina and has very little scope for movement. It is very close to the baby's brain and what effect does that have?

Footnote.

A Transducer is the part of the ultrasound unit that comes into contact with the patient. It converts electrical energy into ultrasound waves, which pass through the patient's tissues; it also receives the reflected waves and changes them again into electrical energy.

Cavitation is the effect produced by ultrasound on the blood and cells. It causes bubbles to be formed and no-one knows what effects this could have in the future.

Safe in experienced hands

While some enthusiasts now claim that ultrasound is safe, providing it is in experienced hands, the evidence shows otherwise. The accuracy and interpretation of scans varies enormously from centre to centre, and also with the experience and training of the operators. Something women in Cardiff found out to their cost. In 1994 South Glamorgan Health Authority, to its considerable credit, set up a public enquiry to look into complaints from women who had early ultrasound scans and had been wrongly told that their babies were dead.

The enquiry revealed the numerous ways in which this technology can go wrong. Out of date machines, used by inadequately trained and unsupervised people, in departments which had no clear policy. Although two of the four women involved were in the hands of experts using the best, most up to date, equipment, they still got a false result!

What has not been pointed out to anyone is that all these women would have been better off without any scans at all. If a baby has died, or is threatening to miscarry early in pregnancy, there is nothing that can be done about it. What the mother needs is support, sympathy and understanding. Unfortunately, none of the Cardiff mothers got that. Instead, they got more ultrasound scans and an enquiry which recommended that mothers should now receive two vaginal scans.

The effects of Doppler ultrasound

In 1993 a landmark paper was published from researchers in Australia (Newnham et al, 1991) looked at the safety of repeated prenatal ultrasound imaging. 2843 pregnant women were randomised, half receiving ultrasound imaging and continuous doppler flow studies, while the other half received once imaging scan at 18 weeks. The only difference between the two groups was significantly higher (one third) inter uterine growth retardation in the intensively monitored group. The researchers concluded that *"It would seem prudent to limit ultrasound examinations of the fetus to those cases in which the information is likely to be of clinical importance."* Over the years there have been numerous studies on rats, mice and monkeys which have found reduced fetal weight in babies which had ultrasound in the womb compared with controls. What Newnham and his colleagues do not mention, is that in the monkey studies, the ultrasound babies sat or lay around the bottom of the cage, whereas the little control monkeys were climbing up the bars and were up to the usual monkey tricks.

In those two studies the baby monkeys had been exposed in the womb to many ultrasound scans - far more than women have, but each scan was no longer than many carried out in this country, and they were ordinary real-time scans with no greater intensity of exposure. How many exposures are too many? What is the mechanism by which growth is affected? How many exposures are necessary to affect behaviour? What happens when the monkeys grow up - do they reproduce as successfully as the controls? These questions and many others are still unanswered. And, of course, as Jean Robinson has pointed out, monkeys do not learn to read, write, multiply, sing opera, or play the violin.

In 1993 researchers in Norway (Salvesen K et al, 1993) reported on children aged 8-9 who were randomly allocated to have routine scanning or not in the womb. They found an increase in children who were not right handed. For this effect to take place it means that there is a possible alteration in the brain structure, but no-one knows how. The scanners used very low doses of ultrasound, real time, not doppler.

Delayed speech development

In Canada an ear, nose and throat specialist became concerned at the numbers of children he was seeing with delayed speech development (Campbell JD et al, 1993). He carried out a research project in which he examined the records of 72 of these children and compared them with twice as many matched controls. Campbell and his colleagues found that the children with speech problems were twice as likely as the controls to have been exposed to ultrasound in the womb.

This study, of course, does not prove that ultrasound causes speech delay, but it certainly suggests it might. When this study is put together with the Denver

study by Stark, which suggested an increase in dyslexia, and the Norwegian study by Salvesen, which showed an increase in left handedness, and animal studies, which suggest neurological damage, there is growing evidence that ultrasound exposure before birth may affect the development of the brain.

AIMS has been contacted by dozens of women who feel that the ultrasound exposure during pregnancy has caused speech and other problems in their children. Some of those women have had huge amounts of ultrasound, but we cannot do anymore than comment that their suspicions might well be correct. Unfortunately, the research into the potential adverse effects of ultrasound has been inadequate and, in some cases, non existent.

Over the years women have been bombarded with propaganda assuring them that ultrasound is safe:

"It is completely painlessIt can be very exciting to see a picture of your own baby before birth.." Health Education Council Pregnancy Book, 1984.

This statement is interesting. It originally stated that ultrasound was safe and completely painless. AIMS wrote to the Health Education Council and said that if they did not remove the claims of safety we would take legal action. The safety statement was removed. However, all users should learn that one has to be vigilant at all times. By 1993 the Health Education Council's New Pregnancy Book carried this statement:

"The scan is safe and completely painless...." Health Education Council Pregnancy Book, 1993

"There are 50 million people walking around today who were scanned in the womb, and there is not even laboratory evidence to indicate that it is hazard." Professor Stuart Campbell, Mother and Baby, May 1990.

In 1984 Professor Campbell was claiming that some 100 million people throughout the world had been scanned to no ill effect, somewhere in the intervening period he has managed to lose 50 million people! One can only speculate on what happened to them.

"Yet ultrasound had not thrown up a single problem in 25 years and had saved countless lives. Professor Campbell declared ultrasound entirely safe." Patrician Mowbray, She, November 1991.

"Ultrasound scans are safe for babies because they don't involve X-rays at all." Dr Stephanie Straw, Living, Dec 1992.

Interesting that the analogy with X-rays is only in terms of their lack of safety and nothing about the enthusiasm with which they were used before their dangers were realised.

"There is no evidence that anyone - either the baby, mother or operator - has suffered any harm as a result of using it." Dr Margaret McNay, Bella, April 1992.

"Ultrasound is entirely safe. You really do not need to have any fears on that score." Dr Pat Last FRCS, FRCOG, Woman's Realm, 19th October 1993.

"..an ultrasound scan, which - unlike amniocentesis - doesn't carry any known risks." Mother and Baby, 1993

"A scan at around 20 weeks can pick up abnormalities. There's no evidence of it causing major problems." Professor Richard Beard, Woman, 22 Nov 1993.

An interesting qualification, few women would appreciate the subtlety of using the word "major."

Despite the evidence that has been emerging over the last decade it is depressing that the medical profession persists in claiming safety for ultrasound. This week's edition of General Practitioner carries an article which claims that "ultrasound is safe."

When women are faced with constant claims of safety by doctors and Professors of obstetrics and challenges from informed lay people, who will the average woman believe?

It is a disgrace that for the last 35 years women have been taking part in the largest unevaluated medical experiment of all time. They are being used as guinea pigs in the medical profession's enthusiasm to find out as much as possible about the workings of the uterus and the developing fetus. Despite years of consumer pressure little is being done to inform women properly and address growing informed lay concerns.

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OCCASIONAL PAPER
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