

Ultrasound: More Harm than Good?

by Marsden Wagner

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The ultrasound story begins in July 1955 when an obstetrician in Scotland, Ian Donald, borrowed an industrial ultrasound machine used to detect flaws in metal and tried it out on some tumors, which he had removed previously, using a beefsteak as the control. He discovered that different tumors produced different echoes. Soon Donald was using ultrasound not only for abdominal tumors in women but also on pregnant women. Articles surfaced in the medical journals and its use quickly spread throughout the world.

The dissemination of ultrasound into clinical obstetrics is reflected in inappropriate statements made in the obstetrical literature regarding its appropriate use: "One of the lessons of history is, of course, that it repeats itself. The development of obstetric ultrasound thus mirrors the application to human pregnancy of diagnostic X-rays. Both, within a few years of discovery, were being used to diagnose pregnancy and to measure the growth and normality of the fetus. In 1935 it was said that "antenatal work without the routine use of X-rays is no more justifiable than would be the treatment of fractures" (Reece, 1935: 489). In 1978: "It can be stated without qualification that modern obstetrics and gynecology cannot be practiced without the use of diagnostic ultrasound" (Hassani, 1978). Two years later, it was said that "ultrasound is now no longer a diagnostic test applied to a few pregnancies regarded on clinical grounds as being at risk. It can now be used to screen all pregnancies and should be regarded as an integral part of antenatal care." (Campbell & Little, 1980). On neither of these dates did evidence qualify the speakers to make these assertions.

It is not only doctors who have tried to promote ultrasound with statements that go beyond the scientific data. Commercial interests also have been actively promoting ultrasound and not only to doctors and hospitals. As an example, an advertisement in a widely read Sunday newspaper (The Times, London) claimed: Toshiba decided to design a diagnostic piece of equipment that would be absolutely safe . . . the name: Ultrasound. A consumer organization in Britain complained to the Advertising Standards Authority that Toshiba was making an untrue claim and the complaint was upheld. In many countries, the commercial application of ultrasound scanning during pregnancy is widespread, offering "baby look" and "fun ultrasound" in order to "meet your baby" with photographs and home videos.

The extent to which medical practitioners nevertheless followed such scientifically unjustified advice and the degree to which this technology proliferated, can be illustrated by recent data from three countries. In France, in one year three million ultrasound examinations were done on 700,000 pregnant women-an average of more than four scans per pregnancy.

These examinations cost French taxpayers more than all other therapeutic and diagnostic procedures done on these pregnant women. In Australia, where the health service pays for four routine scans, in one recent year billing for obstetrical ultrasound was \$60 million in Australian dollars. A 1993 editorial in U.S.A Today makes the following statement: "Baby's first picture-a \$200 sonogram shot in the womb-is a nice addition to any family album. But are sonograms medically worth \$1 billion of the nation's scarce health-care dollars? That's the question raised by a United States study released this week. It found the sonograms that doctors routinely perform on healthy pregnant women don't make any difference to the health of their babies."

After a technology has spread widely in clinical practice, the next step is for health policymakers to accept it as standard care financed by the official health sector.

Several European countries now have official policy for one or more routine ultrasound scans during pregnancy. For example, in 1980 the Maternity Care Guidelines in West Germany stated the right of each

pregnant woman to be offered at least two ultrasound scans during pregnancy. Austria quickly followed suit, approving two routine scans. Do the scientific data justify such widespread use and great cost of ultrasound scanning?

When is Ultrasound Helpful?

In assessing the effectiveness of ultrasound in pregnancy, it is essential to make the distinction between its selective use for specific indications and its routine use as a screening procedure.

Essentially, ultrasound has proven valuable in a handful of specific situations in which the diagnosis "remains uncertain after clinical history has been ascertained and a physical examination has been performed." Yet, considering whether the benefits outweigh the costs of using ultrasound routinely, systematic medical research has not supported routine use.

One of the most common justifications given today for routine ultrasound scanning is to detect intrauterine growth retardation (IUGR). Many clinicians insist that ultrasound is the best method for the identification of this condition. In 1986, a professional review of 83 scientific articles on ultrasound showed that "for intrauterine growth retardation detection, ultrasound should be performed only in a high-risk population." In other words, the hands of an experienced midwife or doctor feeling a pregnant woman's abdomen are as accurate as the ultrasound machine for detecting IUGR. The same conclusion was reached by a study in Sweden comparing repeated measurement of the size of the uterus by a midwife with repeated ultrasonic measurements of the head size of the fetus in 581 pregnancies. The report concludes: "Measurements of uterus size are more effective than ultrasonic measurements for the antenatal diagnosis of intrauterine growth retardation."

If doctors continue to try to detect IUGR with ultrasound, the result will be high false-positive rates. Studies show that even under ideal conditions, such as do not exist in most settings, it is likely that over half of the time a positive IUGR screening test using ultrasound is returned, the test is false, and the pregnancy is in fact normal. The implications of this are great for producing anxiety in the woman and the likelihood of further unnecessary interventions.

There is another problem in screening for IUGR. One of the basic principles of screening is to screen only for conditions for which you can do something. At present, there is no treatment for IUGR, no way to slow up or stop the process of too-slow growth of the fetus and return it to normal. So it is hard to see how screening for IUGR could be expected to improve pregnancy outcome.

We are left with the conclusion that, with IUGR, we can only prevent a small amount of it using social interventions (nutrition and substance abuse programs), are very inaccurate at diagnosing it, and have no treatment for it. If this is the present state of the art, there is no justification for clinicians using routine ultrasound during pregnancy for the management of IUGR. Its use should be limited to research on IUGR.

Once again it is interesting to look at what happened with the issue of safety of X-rays during pregnancy. X-rays were used on pregnant women for almost fifty years and assumed to be safe. In 1937, a standard textbook on antenatal care stated: "It has been frequently asked whether there is any danger to the life of the child by the passage of X-rays through it; it can be said at once there is none if the examination is carried out by a competent radiologist or radiographer." A later edition of the same textbook stated: "It is now known that the unrestricted use of X-rays through the fetus caused childhood cancer." This story illustrates the danger of assuming safety. In this regard, a statement from a 1978 textbook is relevant: "One of the great virtues of diagnostic ultrasound has been its apparent safety. At present energy levels, diagnostic ultrasound appears to be without injurious effect . . . all the available evidence suggests that it is a very safe modality."

That ultrasound during pregnancy cannot be simply assumed to be harmless is suggested by good scientific work in Norway. By following up on children at age eight or nine born of mothers who had taken part in two controlled trials of routine ultrasound in pregnancy, they were able to show that routine ultrasonography was associated with a symptom of possible neurological problems.

With regard to the active scientific pursuit of safety, an editorial in *Lancet*, a British medical journal, says: "There have been no randomized controlled trials of adequate size to assess whether there are adverse effects on growth and development of children exposed in utero to ultrasound. Indeed, the necessary studies to ascertain safety may never be done, because of lack of interest in such research."

The safety issue is made more complicated by the problem of exposure conditions. Clearly, any bio-effects that might occur as a result of ultrasound would depend on the dose of ultrasound received by the fetus or woman. But there are no national or international standards for the output characteristics of ultrasound equipment. The result is the shocking situation described in a commentary in the *British Journal of Obstetrics and Gynaecology*, in which ultrasound machines in use on pregnant women range in output power from extremely high to extremely low, all with equal effect. The commentary reads, "If the machines with the lowest powers have been shown to be diagnostically adequate, how can one possibly justify exposing the patient to a dose 5,000 times greater?" It goes on to urge government guidelines on the output of ultrasound equipment and for legislation making it mandatory for equipment manufacturers to state the output characteristics. As far as is known, this has not yet been done in any country.

Safety is also clearly related to the skill of the ultrasound operator. At present, there is no known training or certification for medical users of ultrasound apparatus in any country. In other words, the birth machine has no license test for its drivers.

Looking Ahead: Ultrasound and the Future

Although ultrasound is expensive, routine scanning is of doubtful usefulness, and the procedure has not yet been proved to be safe, this technology is widely used, and its use is increasing rapidly without control. Nevertheless, health policy is slow to develop. No country is known to have developed policies with regard to standards for the machines, nor for the training and certification of the operators. A few industrialized countries have begun to respond to the data showing lack of effectiveness for routine scanning of all pregnant women. In the United States, for example, a consensus conference on diagnostic ultrasound imaging in pregnancy concluded that "the data on clinical effectiveness and safety do not allow recommendation for routine screening at this time; there is a need for multidisciplinary randomized controlled clinical trials for an adequate assessment."

Denmark, Sweden, and the United Kingdom have made similar statements against routine screening. The World Health Organisation (WHO), in an attempt to stimulate governments to develop policy on this issue, published the following statement:

"The World Health Organisation stresses that health technologies should be thoroughly evaluated prior to their widespread use. Ultrasound screening during pregnancy is now in widespread use without sufficient evaluation. Research has demonstrated its effectiveness for certain complications of pregnancy, but the published material does not justify the routine use of ultrasound in pregnant women. There is also insufficient information with regard to the safety of ultrasound use during pregnancy. There is as yet no comprehensive, multidisciplinary assessment of ultrasound use during pregnancy, including: clinical effectiveness, psychosocial effects, ethical considerations, legal implications, cost benefit, and safety.

"WHO strongly endorses the principle of informed choice with regard to technology use. The health-care providers have the moral responsibility: fully to inform the public about what is known and not known about ultrasound scanning during pregnancy; and fully to inform each woman prior to an ultrasound examination as to the clinical indication for ultrasound, its hoped-for benefit, its potential risk, and alternative available, if any."

This statement, sadly, is as relevant today. During the 1980s and early 1990s, a number of us were raising questions about both the effectiveness and safety of fetal scanning. Our voice of caution, however, was like a cry in the wilderness as the technology proliferated.

Then, during the course of one month in late 1993, two landmark scientific papers were published. The first paper, a largely randomized trial of the effectiveness of routine prenatal ultrasound screening, studied the outcome of more than 15,000 pregnant women who either received two routine scans at 15 to 22 weeks and 31 to 35 weeks, or were scanned only for medical indications.

Results showed that the mean number of sonograms in the ultrasound group was 2.2 and in the control group (for indication only) was 0.6. The rate of adverse outcome (fetal death, neonatal death, neonatal morbidity), as well as the rate of preterm delivery and distribution of birth weights, was the same for both groups. In addition, in the author's words: "The ultrasonic detection of congenital abnormalities has no effect on perinatal outcome." At last we have a randomized clinical trial of sufficient size to conclude that there is no value to routine scanning during pregnancy.

The second landmark paper, also a randomized controlled trial, looked at the safety of repeated prenatal ultrasound imaging. While the original purpose of the trial was hopefully to demonstrate the safety of repeated scanning, the results were the opposite. From 2,834 pregnant women, 1,415 received ultrasound imaging at 18, 24, 28, 34 and 38 weeks gestation (intensive group) while the other 1,419 received single ultrasound imaging at 18 weeks (regular group). The only difference between the two groups was significantly higher (one-third more) intrauterine growth retardation in the intensive group. This important and serious finding prompted the authors to state: "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." Ironically, it is now likely that ultrasound may lead to the very condition, IUGR, that it has for so long claimed to be effective in detecting.

Although we now have sufficient scientific data to be able to say that routine prenatal ultrasound scanning has no effectiveness and may very well carry risks, it would be naive to think that routine use will not continue.

Unfortunately, medical doctors are inadequately educated in the basics of scientific method. It will be a struggle to close the gap between this new scientific data and clinical practice.

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