SHOULD EVERY PREGNANT WOMAN UNDERGO ULTRASONOGRAPHY?

DIAGNOSTIC ultrasonography has unquestionably revolutionized the care of obstetrical patients. Before this procedure became available, the uterus of a pregnant woman was a closed space that effectively hid most of its secrets. Since the mid-1970s, however, remarkable improvements in ultrasonography have exposed that protected space to investigation throughout the course of pregnancy and have thereby provided sophisticated insight into life before birth.

Ultrasonography has proved to be of invaluable assistance in a variety of high-risk situations. Recognition of what could be learned in problem pregnancies led to the question of whether examining every pregnant woman with ultrasonography offered advantages over scanning only those with recognized indications for the test. In 1980 the Federal Republic of Germany initiated a two-stage ultrasonographic screening program as an integral part of antepartum care offered to every pregnant woman in the country. Similar policies have been either adopted or recommended in several other European nations.

In 1984 a consensus conference convened by the National Institutes of Health (NIH) addressed the issue of performing ultrasonography on all pregnant women.[1] The panel listed 28 clinical situations in which the use of ultrasonography was potentially beneficial, but it did not find evidence that routine ultrasonography decreased perinatal morbidity or mortality. The rate of detection of twin gestations and congenital malformations was increased with ultrasonography, and pregnancy could be dated more accurately, but outcome was not improved. The panel therefore recommended that ultrasonographic examinations should be performed during pregnancy only for specific medical indications and that "randomized, controlled clinical trials of routine ultrasound screening during pregnancy should be conducted in the United States."

In this issue of the *Journal*, Ewigman and members of the Routine Antenatal Diagnostic Imaging with Ultrasound (RADIUS) Study Group present the results of the type of study requested by the panel.[2] After women with a total of 19 known or suspected problems had been excluded, more than 15,000 low-risk pregnant women were assigned randomly to undergo either screening ultrasonography at 15 to 22 weeks and 31 to 35 weeks of gestation, or ultrasonography performed solely for medical indications according to the clinical judgment of their physicians. Although more major anomalies were detected antenatally in the screened group, there were no significant differences in the rate of adverse perinatal outcome (fetal or neonatal death or substantial neonatal morbidity). Furthermore, the rates of preterm birth in the two groups were almost identical, and the perinatal outcomes of post-date pregnancies, multiple gestations, and infants who were small for gestational age were similar.

The strengths of the RADIUS study include its rigorous design, the size of the population studied, the large number of participating sites (109 obstetrical and family practices in six states), and the clear difference in the number of scans performed in the screened and control groups (2.2 vs. 0.6 per patient). It should be noted, however, that the women studied were at extremely low risk for perinatal problems. Ninety-three percent were white, 70 percent had at least some college education, 90 percent were in the ideal prepregnancy weight range, only 13 percent were smokers, and the mean birth weight of their babies was about 3400 g. Furthermore, only 17 percent of fetal structural anomalies were detected before 24 weeks, as compared with an average of 52 percent in five European screening studies involving a total of 48,222 women (range, 21 to 84 percent).[3-7] In addition, although the adverse-outcome rate among women with post-date pregnancies may not have been different, only 245 women in the screened group delivered at 42 weeks or later, as compared with 347 women in the control group. This statistically significant reduction in the number of women at risk for the iatrogenic and biologic complications associated with post-date pregnancies presumably reflects more accurate gestational-age assessment in the screened group, which is one of the objectives of routine scanning.

A recent meta-analysis of four previously published studies encompassing 15,935 pregnancies appears to support some of the findings of the RADIUS study.[8] The rate of live births was identical in the screened and control groups, and that of perinatal morbidity as measured by Apgar scores below 7 at one minute was not substantially different. However, perinatal mortality was significantly lower in the screened group because the increased rate of induced abortion of structurally abnormal fetuses reduced the mortality by 49 percent in the largest of the four studies. Although no details are given about the rates of detection of anomalies, the authors state that "for many women routine ultrasound scanning may be of considerable benefit by offering the option of an early abortion of a malformed baby and by reducing the concern of giving birth to a malformed baby."

So, where does this leave us? The trend in recent years has been to adopt new forms of technology uncritically, without verifying their usefulness,[9] a trend that has increased the expenditure of scarce health care dollars without necessarily improving outcomes. Grimes has made a plea for critical appraisal[9] before we jump on the bandwagon of a new, unproved technique, even if common sense suggests it will be beneficial. This argument could certainly be applied to the question of universal ultrasound screening during pregnancy. None of the studies published to date demonstrate an effect on the outcome of pregnancy in most low-risk women. However, the meta-analysis by

Bucher and Schmidt[8] indicates that routine scanning does detect more structural anomalies than would be detected otherwise, and that their detection can result in reduced perinatal mortality. More anomalous fetuses were also detected in the screened group in the RADIUS study, even though there was no effect on any measured outcome variable. Nevertheless, despite the fact that the percentage of anomalous fetuses identified before 24 weeks was far lower than in other series, it was still more than three times higher than the rate in the control group (17 percent vs. 5 percent). Therefore, if a woman is motivated to undergo routine ultrasonography in order to detect an unsuspected anomaly at a time when she could elect to terminate her pregnancy, she is likely to interpret the existing data as supporting universal scanning. Moreover, detection of structural anomalies in utero should not be thought of only in terms of the termination of pregnancy. This knowledge can be helpful in situations in which prenatal therapy or early delivery may markedly improve perinatal outcome, or when the mother should be transferred to a tertiary care facility for delivery in a setting that increases the chances that her infant will survive.

The fact that the RADIUS study did not find a substantial effect of routine ultrasonography on perinatal outcome in low-risk pregnancies is undoubtedly important information for health policy planners, but these findings should be interpreted with caution. Women in the lowest socioeconomic groups, who are the most likely to have their health care funded from governmental sources, are the group of women at highest risk for perinatal complications in the United States. Disproportionately large numbers of these women will qualify for indicated scans. On the other hand, women in the highest socioeconomic groups, who are often truly at low risk, may be very concerned about the possibility of having a baby with a major anomaly and may choose to have elective ultrasonography even if it is not offered as a routine part of antenatal care. Furthermore, it must be stressed that the studies discussed here do not call into question the value of scanning performed for the long list of indications mentioned in the NIH consensus report. Therefore, if routine ultrasonography is not offered to all pregnant women, physicians will have to be extremely vigilant in searching for the many problems or conditions that are indications for obtaining a scan.

The principal benefit of routine ultrasonography performed in the middle of the second trimester is the detection of unsuspected fetal anomalies. The correction of inaccurate dating and early diagnosis of multiple gestation may be of benefit to individual women, but they have not been proved to affect outcome in large prospective studies. The advantages of routine scanning must be weighed against the possibility of false positive and false negative diagnoses, concern about currently unidentified subtle bioeffects of exposure to ultrasound in utero, and the substantial cost of providing this service to every pregnant woman in the United States. Some authors have argued that ultrasound screening for low-risk women should be an acceptable practice after informed consent is obtained, on the basis of the ethical principle of patient autonomy rather than on that of beneficence.[10] This would be an extremely defensible position if the control of health care expenditures were not an issue. Assuming, however, that epidemiologic evidence of a favorable cost:benefit ratio is required for any screening test, the rate of detection of anomalies in the RADIUS study does not appear to support a national policy of routine ultrasonography, despite the fact that it might be of psychological benefit to many women and have a favorable effect on the outcome of some pregnancies. This should be accepted as a challenge by those who provide ultrasound examinations to pregnant women in the United States. When the success achieved in other large screening programs has been duplicated in this country, the benefits of routine scanning should be reevaluated.

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