

Our views on the direction that research on nonconventional therapies should take are clear: first, objective evaluations should be developed using scientific methods; second, studies on physicians' knowledge and attitudes toward such subjects as the special American traditions of osteopathy and chiropractic should be extended in the light of local conditions.

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Routine Antenatal Diagnostic Imaging With Ultrasound (RADIUS) Study

Acheson and Mitchell,¹ in their acceptance of the conclusions of Ewigman et al² and LeFevre et al³ in the Routine Antenatal Diagnostic Imaging With Ultrasound (RADIUS) study, may be confusing the pristine and well-regarded design of the study with the highly controversial and uncertain conclusions they have drawn. Perhaps this editorial was written prior to the National Institutes of Health-sponsored meeting held on December 3, 1993, that had been called to discuss the less than responsible conclusions drawn by the authors of the RADIUS study. While no conclusions were formally reached at the meeting, and probably few minds were changed, it was obvious that there is strong disagreement by many competent scientists and physicians regarding the polemic conclusions of the study.

To state that "[T]he evidence from the RADIUS trial shows that routine prenatal screening by ultrasound examinations, compared with the use of [indicated] ultrasonography, had no effect on perinatal morbidity or mortality for either mothers or infants"¹ ignores some trends in the data that were overlooked or minimized by the RADIUS authors.

Some of the concerns voiced by critics of the study include the following: (1) the study population was not representative of the general population (the study population being 93% white); (2) 70% of the patients graduated from college or high school; (3) because 13% of the group were smokers does not generalize to the whole population and thus might give erroneously low results for adverse outcomes in both the study and control groups; (4) there were twice as many anomalies detected antenatally in the study group as in the control group (and the tertiary care centers were twice as likely to pick up anomalies as the other centers in the study); (5) there was not enough statistical power to show a difference in outcomes in twin gestations; the trend is strong, show-

ing a 50% higher adverse outcome in the control group; (6) there was not enough power to show a statistically significant difference in the numbers of women who delivered at or after 42 weeks; again, the trend seems quite strong (42% higher in the control group); (7) the rate of adverse outcomes among postdate pregnancies was 50% higher for the control group although this did not reach statistical significance because of lack of power, but, again, it shows a trend. All of these trends were ignored by the authors of the study and, apparently, by Acheson and Mitchell.¹

Perhaps the problem is that we as physicians have allowed the use of the term "screening" to gain acceptance. Ethics and the law have dictated that the fetus is our patient. I would accept no other patient without the opportunity to examine that patient. There does not appear to be any other noninvasive means of examining the fetus except by ultrasonography. This is a screening examination only in the same sense that an annual physical examination or a new patient examination is also a screening. Should we also avoid doing a complete physical examination on a pregnant woman because of a low yield of improved outcome?

I am certain that the controversy over the use of ultrasonography in pregnancy has not been resolved by the RADIUS trial. For Acheson and Mitchell to spout the party line without commenting on the valid criticisms, to bring in the unrelated and irrelevant controversy regarding electronic fetal monitoring, and then to attribute this to a "backlash against women's ability to control their own reproduction" strikes me as inappropriate paranoia. My concern is that the authors of the RADIUS study have made patients suspicious of the motivation of those of us who believe there is real value to the routine examination of the fetus with the use of ultrasonography.

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1. Acheson L, Mitchell L. The Routine Antenatal Diagnostic Imaging With Ultrasound study: the challenge to practice evidence-based obstetrics. *Arch Fam Med.* 1993;2:1229-1230.
2. Ewigman BG, Crane JP, Frigoletto FD, et al. Effect of prenatal ultrasound screening on perinatal outcome. *N Engl J Med.* 1993;329:821-827.
3. LeFevre ML, Bain RP, Ewigman BG, et al. A randomized trial of prenatal ultrasonographic screening: impact on maternal management and outcome. *Am J Obstet Gynecol.* 1993;169:483-499.

In reply

Far from resolving it, the RADIUS study has added substance to the controversy over the uses of ultrasound examination in pregnancy. Dr Smith objects to the term "screening" and raises concerns that the group of pregnant women studied were healthier, more ethnically homogeneous, and better educated than the general population. It is precisely in this group of healthy pregnant women without any ap-