Periodic health examination, 1992 update: 2. Routine prenatal ultrasound screening

Canadian Task Force on the Periodic Health Examination

The Canadian Task Force on the Periodic Health Examination was founded in 1976 by the deputy ministers of health to examine the scientific evidence of the effectiveness of preventive interventions in order to develop recommendations for the practice of periodic health assessments of Canadians.

The task force reviews the studies in which preventive interventions have been evaluated. The evidence is classified as good, fair or poor depending on the quality of the study design and analysis. Additional factors considered are the diagnostic accuracy or efficacy of the intervention, the safety and acceptability of the procedure to patients and physicians, the physical and psychologic risk:benefit ratio, the cost of implementing a recommendation and the ethical issues. The information is synthesized into graded recommendations regarding the inclusion of the clinical manoeuvre in or its exclusion from the periodic health examination of people in a targeted population.

The task force usually examines screening procedures for specific disorders.[1-18] Ultrasound examination has been suggested as a prenatal screening tool for various purposes, including the estimation of gestational age, the detection of multiple pregnancies and fetal anomalies, and the identification of intrauterine growth retardation (IUGR). The goal of prenatal ultrasound screening is to reduce the rates of perinatal illness and death from several causes, some of which (e.g., IUGR) are etiologically nonspecific. Therefore, the task force has reviewed the evidence on the impact of prenatal ultrasound screening on measures of perinatal illness and death rather than on its ability to detect specific abnormalities.

Although the use of prenatal ultrasonography was discussed in the working documents of the task force the original report did not make a specific recommendation.[1,2] In Canada the Federal Task Force on High Risk Pregnancies and Prenatal Record Systems[19] stated that "there seems to be very

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good evidence that ultrasound is a useful adjunct to clinical identification and assessment of intrauterine growth retardation" but that "the use of routine ultrasound without specific indications in pregnancy should be discouraged." In 1981 a subcommittee of the Perinatal Medicine Committee of the Society of Obstetricians and Gynaecologists of Canada[20] stated that the "routine use of ultrasound cannot be recommended." In 1984 the US National Institutes of Health held a Consensus Conference on the use of diagnostic ultrasonography during pregnancy. The panel[21] concluded that "the data on the clinical efficacy and safety do not allow a recommendation for routine screening at this time." More recently a consensus panel[22] in Norway concluded that "the medical utility of ultrasound screening, as opposed to examinations of pregnant women referred on the basis of clinical indications, has not been demonstrated." It went on to recommend routine ultrasound screening at 17 weeks' gestation because it felt that this would improve the quality of care and reduce the use of such screening in areas where 94% of the women were exposed to prenatal ultrasonography and 2.45 ultrasound examinations per pregnancy were done on average.

Prenatal ultrasonography is common in Canada as well. In Ontario and British Columbia 164 766 such procedures were billed to the provincial health insurance plans during 1981–82; the corresponding number of deliveries in the same period was 162 611, for a rate of 1.01 ultrasound examinations per delivery.[23] During 1989–90 the numbers increased to 393 666 and 189 196 respectively, for a rate of 2.08 examinations per delivery.[23] The cost to the two provincial health care plans was almost $29 million in 1989–90.[23] This rapid increase in the use and cost of ultrasonography underlines the need for careful assessment of the evidence on the benefits of this procedure.

Routine prenatal ultrasound screening (Table 1)

Practitioners are faced with the difficult task of deciding whether to use prenatal ultrasonography routinely when there is no clinical suspicion of a potential problem. If routine screening in normal pregnancies can detect problems or conditions that would not have been identified otherwise and if effective treatment of those problems is available, then the procedure could improve fetal outcome. On the other hand, if routine screening in normal pregnancies cannot provide better or more useful diagnostic information, then it may be a waste of resources and might present a risk to the fetus, given concerns over the effects of intrauterine exposure to high-frequency sound waves.[24,25]

Manoeuvre

A single ultrasound examination in the second trimester is used to estimate gestational age and to detect multiple pregnancies and malformations. Two examinations (one in the second trimester and one in the third) are used to screen for IUGR and to detect multiple pregnancies and malformations.

Ultrasound technology has improved over time, and current techniques and equipment may provide more useful results than those of previous clinical trials. Nevertheless, the potential benefits of such technical improvements can be fairly assessed only

Table 1: Summary of manoeuvre, effectiveness, level of evidence and recommendations for routine prenatal ultrasound screening

Manoeuvre	Effectiveness	Level of evidence*	Recommendation*
A single ultrasound examination in the second trimester in women without clinical indications	One trial[28] showed increased birth weight in the screened group. Another,[29] in a nonselected population, showed a decreased perinatal death rate in the screened group, largely because of increased detection and abortion of fetuses with malformations	Randomized controlled trials[28,29] (I)	Fair evidence to include in periodic health examination in normal pregnancies (B)
Serial ultrasound screening in the second and third trimesters in women without clinical indications	Trials[31–33] are not powerful enough to detect meaningful differences in perinatal outcomes	Expert opinion[19–22] (III)	Poor evidence to include in or exclude from periodic health examination in normal pregnancies (C)

*For descriptions of the other levels of evidence and classification of recommendations see Appendix 1 in part 1 of the 1992 update (*Can Med Assoc J* 1992; 147: 443).

through rigorous evaluation of their impact on health outcomes and cost-effectiveness.

Effectiveness of preventive intervention

To identify studies of the effectiveness of routine prenatal ultrasound screening we searched MEDLINE for pertinent articles as well as the references of those articles. Two criteria were used: (a) the study had to have randomly allocated subjects to undergo or not to undergo routine screening and (b) the outcomes had to have included measures of perinatal illness and death. Seven trials met these criteria.

The trials were separated into two groups. The first comprised four trials that examined the impact of a single ultrasound examination performed in the second trimester.[26-30] The single examination was used to estimate the gestational age and to detect multiple pregnancies and malformations. The second group included three studies of the impact of two examinations, one in the second trimester and one in the third.[31-33] The two examinations were used to screen for IUGR, to determine the final placental site and to detect multiple pregnancies and malformations.

Single ultrasound scan

The results from the first trial in this group were published in 1982[26] and updated in 1985.[27] A total of 1621 patients underwent an ultrasound examination, including a measurement of the biparietal diameter (BPD), at about 16 weeks' gestation. Of the women 836 were randomly allocated to an experimental group whose ultrasound results were released to the attending physician. The remaining 785 patients were allocated to a control group whose ultrasound results were not released to the attending physician. However, during the trial 30% of the control subjects had their ultrasound results released in response to specific requests from their physician because of clinical concerns. There were eight perinatal deaths in the experimental group and seven in the control group; this difference was not statistically significant. The Apgar score at 1 minute was 7 or less among 172 singleton infants in the experimental group and among 142 singleton infants in the control group; again, this difference was not statistically significant.

The second trial, the results of which were published in 1988, involved 4997 women with no clinical indication for an ultrasound examination.[28] A total of 2482 women were randomly assigned to undergo one ultrasound examination and BPD measurement at 15 weeks' gestation (experimental group). The remaining 2515 women did not have an examination before 19 weeks' gestation (control group). Both groups then received the same antenatal care, including ultrasound examinations later in pregnancy. In the experimental group 32 (1.3%) of the women did not undergo the examination; in the control group 103 (4.1%) had the examination before the 19th week.

The experimental group had 3068 ultrasound scans, as compared with 1279 in the control group. Of the women in the control group 68% never underwent ultrasonography. The numbers of prenatal hospital days and hospital admissions were the same in each group. Labour was induced in 41 women in the experimental group and 88 in the control group ($p = 0.0001$).

There were 12 perinatal deaths in each group. In the experimental group eight were in singleton infants and four in twins. In the control group singleton infants accounted for all of the deaths. After the perinatal period but before discharge from hospital there were two additional deaths in each group.

Analysis of the 4776 singleton births showed no significant difference between the two groups in the proportion of infants with Apgar scores of 7 or less at 1 or at 5 minutes. In each group mechanical ventilation was required at delivery in seven cases and neonatal seizures occurred in four. There was a tendency for fewer babies in the experimental group than in the control group (231 v. 275) to be admitted to the neonatal ward; however, this difference was not significant.

All 24 sets of twins in the experimental group were identified during the ultrasound examination. All 20 sets of twins in the control group were detected before delivery. There were no significant differences between the two groups in the proportion of twin babies who were premature, had a low Apgar score or had a prolonged hospital stay.

Singleton infants in the experimental group were 42 g heavier on average than those in the control group ($p = 0.008$). The average birth weight of infants of nonsmoking women did not differ significantly between the two groups. Infants of smoking women in the experimental group were 75 g heavier on average than those of smoking women in the control group ($p = 0.013$).

The third trial, the results of which were published in 1990, involved 9310 women from Finland.[29] The authors estimated that this sample included about 95% of the pregnant women in the catchment area of the Helsinki University Central Hospital from April 1986 to November 1987. A total of 648 women were not followed through to delivery: 569 had a miscarriage, 58 underwent an induced abortion, 17 were found not to be pregnant, and 4 were lost to follow-up.

There were 4353 deliveries (4317 of singletons and 72 of twins) in the experimental group. In this

group ultrasound screening was done between 16 and 20 weeks' gestation. The BPD was measured, the placenta located and the number of fetuses registered. Most of the 318 women who did not undergo the examination at the study hospital did so elsewhere. In the experimental group 1.6% of the women did not undergo the examination.

In the control group there were 4309 deliveries (4271 of singletons and 76 of twins). Although the women were not assigned to undergo an ultrasound examination 77% did so.

The overall perinatal death rate among the infants who were delivered was 4.6 per 1000 in the experimental group and 9.0 per 1000 in the control group ($p = 0.013$). In the experimental group 18 singleton babies died (11 were stillborn and 7 died within 1 week after delivery). In the control group 34 singleton babies died (22 were stillborn and 12 died within 1 week after birth). Of the babies that died, only 2 (11%) in the experimental group had major anomalies, as compared with 10 (29%) in the control group. Eleven induced abortions were performed because of the ultrasound findings in the experimental group; there were no such abortions in the control group. There were two deaths in twins in the experimental group and five in the control group.

Among the singleton infants there was no significant difference between the two groups in (a) mean birth weight, (b) proportion of infants with a birth weight of less than 2500 g, (c) mean Apgar score at 1 minute, (d) proportion with an Apgar score of less than 7 at 1 minute, (e) rate of admission to special care unit and (f) proportion with hospital stay of more than 5 days. The mean birth weight of the twins and the proportion of twins with a birth weight of less than 2500 g did not differ significantly between the two groups; however, all of the twins in the experimental group were detected by 21 weeks' gestation, as compared with 76% of those in the control group ($p = 0.005$).

The difference in the perinatal death rates between the two groups lost its significance when the induced abortions resulting from the ultrasound findings were included as deaths in the analysis. Also, 10 of the malformations detected at the ultrasound examination had disappeared by the time of the follow-up examination.

The final study, the results of which were published in 1990, took place in the United States.[30] The trial involved 915 women at low risk who were randomly allocated to routine prenatal ultrasound screening at 10 to 12 weeks' gestation or routine care. The two groups did not differ significantly in total adverse perinatal outcomes, as measured by the number of perinatal deaths, intensive care admissions and babies with an Apgar score of less than 6 at 5 minutes. The authors recognized the limited power of their study given the small sample.

Serial ultrasonography

The main features of the three trials in this group are summarized in Table 2. Two of the trials involved random allocation of patients selected from the general population.[31,32] The third involved random allocation of patients who had no clinical indications of IUGR.[33] The first two took place in Norway and used very similar serial screening techniques. The third trial was in Britain and used a different technique. The three studies used similar measures of fetal outcome and maternal hospital admission. The results of the trials are summarized in Table 3.

In the first study[31] three of the infants in the experimental group and eight in the control group died. Of the deaths in the experimental group one was intrauterine and of unexplained cause, and two were due to severe pre-eclampsia. In the control group four deaths were intrauterine and associated with IUGR, one was due to a severe malformation, and one was of unknown cause; the two postnatal deaths involved a premature twin and an infant with

Table 2: Features of trials of routine serial prenatal ultrasound screening*

Variable	Eik-Nes et al, 1984[31]	Bakketeig et al, 1984[32]	Neilson et al, 1984[33]
Type of population	General	General	Low risk
Sample size			
Experimental group	819	510	433
Control group	809	499	444
Interventions			
Experimental group	Measurement of BPD at 16 weeks and of BPD and AD at 32 weeks	Measurement of BPD at 19 weeks and of BPD and AD at 32 weeks	Measurement of CRL and TA at 24 and 35 weeks
Control group	Routine care	Routine care	Done, but results not reported to doctor

*BPD = biparietal diameter, AD = abdominal diameter, CRL = crown–rump length, TA = trunk area.

hydrops fetalis. There were no late neonatal deaths in the experimental group and three in the control group. The number of days of pediatric care for malformations due to "overdue pregnancy" ($p < 0.01$) and for hyperbilirubinemia ($p < 0.05$) was significantly lower in the experimental group than in the control group. The significantly fewer hospital admissions in the experimental group ($p < 0.01$) did not result in a difference in the number of days of prenatal care (828 days in the experimental group and 829 in the control group).

There was little description of the causes of perinatal death in the second study.[32] Two of the deaths in the control group involved twins identified through ultrasonography at 24 weeks' gestation. They were delivered 2 weeks later; one was stillborn, and the other died 2 hours postnatally. The distribution of birth weights did not differ significantly between the two groups. Forty-nine of the women in the control group were referred for ultrasonography as part of their routine care. The estimated cost of the screening program was $250 (US) per pregnancy. Two-thirds of the cost was from the increased use of inpatient services by the experimental group.

The only perinatal death in the third study[33] involved a child born with open spina bifida and microcephaly. The mean birth weight was the same in the two groups (3.42 kg). The number of inductions and the delivery methods did not differ significantly between the two groups.

Discussion

Because perinatal anomalies and death are rare outcomes, large samples are required to detect clinically significant effects. For example, to detect a reduction in the rate of perinatal death from 10 per 1000 to 5 per 1000 with a power of 90% at a 5% level of significance a sample of 6250 women in each group is required.[27]

Two of the trials of a single ultrasound examination had sample sizes that lacked the power to detect clinically important differences in perinatal outcomes, and their failure to show an impact of screening could be the result of a type II error.[27,30] However, the two other trials in this group had larger samples and did yield some positive results.

The Swedish trial[28] involved 4997 women with no clinical indication for prenatal ultrasonography chosen from a population of 7354. The reasons for exclusion from the study sample included difficulties identifying the date of the last menstruation, amniocentesis, poor outcome from previous pregnancy and medical complications. This trial revealed a significant effect on birth weight in the experimental group but no effect on the perinatal death rate or the Apgar scores.

The Finnish trial[29] had a sample of 9310 women and did not involve any exclusion criteria. The trial revealed a significant effect on the perinatal death rate but no such effect on the mean birth weight or the Apgar scores. The difference in the perinatal death rate was largely due to the greater number of induced abortions resulting from the ultrasound findings in the experimental group. Also, the results of the trial indicated that almost one-third of the malformations detected in the ultrasound examination had disappeared by the time of follow-up.

The results of these two trials, although promising, do not provide definitive evidence of a positive

Table 3: Results of trials of routine serial prenatal ultrasound screening*

Variable	Eik-Nes et al[31]	Bakketeig et al[32] †	Neilson et al[33]
No. (and %) of hospital admissions			
Experimental group	184 (22.5)	79 (15.5)	43 (9.9)
Control group	269 (33.2)§	46 (9.5)§	46 (10.3)
No. (and %) of infants with low Apgar score‡			
At 1 minute			
Experimental group	NM	34 (6.9)	37 (9.9)
Control group	NM	23 (4.9)	40 (9.0)
At 5 minutes			
Experimental group	NM	15 (3.1)	8 (1.9)
Control group	NM	9 (1.9)	5 (1.0)
No. (and %) of perinatal deaths			
Experimental group	3 (0.36)	5 (0.98)	0
Control group	8 (0.98)	5 (1.00)	1 (0.02)

*NM = not measured.
†Results are given for singleton births only.
‡Seven or less in study by Bakketeig et al and less than 7 in study by Neilson et al.
§ $p = 0.05$

effect of routine prenatal ultrasound screening on perinatal death rates in populations with no clinical indication for ultrasound examination.

The largest study of serial ultrasound screening conducted to date had a sample of only 1628. The failure of any of the three studies of serial ultrasound screening to show a significant impact of such screening could be the result of insufficient sample size. One way to get around the problem is to combine the results of individual trials in a meta-analysis.

Thacker,[27] in a meta-analysis of the results of the three serial trials, found that although the relative risk for perinatal death in the screened group was 0.63, indicating a 37% decrease in the number of deaths, the difference was not statistically significant (95% confidence interval [CI] 0.27 to 1.47). The relative risk of an Apgar score of 7 or less at 1 minute was 1.16 in the experimental group (95% CI 0.91 to 1.41).

Recently the Oxford Database of Perinatal Trials produced a series of meta-analyses that combined the results of trials of single and serial prenatal ultrasound screening.[34] The results of these meta-analyses are summarized in Table 4. The only outcomes that reached conventional levels of significance were decreased rates of admission to special care units for singleton babies and a decreased incidence of low birth weight in the screened group.

Prenatal ultrasound examination may not only provide the clinician with information on perinatal anomalies and intrauterine problems but also reassure the expectant mother and provide her with useful information. On the other hand, false-positive results can have an adverse psychologic effect on the expectant mother. Thus, the impact on the mother may be positive or negative regardless of the effects observed in trials of fetal outcome.[35] The finding that ultrasound screening of women who smoked resulted in an increased birth weight[28] suggests that screening can alter the behaviour of pregnant women.

Recommendations

Although results from randomized controlled trials indicate that a single ultrasound examination in the second trimester can lead to increased birth weight and can reduce the perinatal death rate (largely through early detection of major anomalies resulting in induced abortion) the effectiveness of a single examination in increasing fetal survival through early detection of treatable prenatal problems has yet to be clearly demonstrated, and the positive and negative psychologic effects of screening on parents have not been adequately assessed. Therefore, there is fair evidence to support the inclusion of a routine single ultrasound examination in the management of women with no clinical indication for prenatal ultrasonography.

There is no evidence from randomized controlled trials indicating that serial prenatal ultrasonography leads to improved perinatal outcomes. However, the trials performed were not large enough to detect clinically significant outcomes of this intervention. Therefore, there is poor evidence to support the inclusion of routine serial ultrasound screening in or its exclusion from the management of women with no clinical indication for prenatal ultrasonography.

Research priorities

1. Analysing further the benefits and disadvantages of a single ultrasound examination. Such an analysis should focus on the impact of the manoeuvre on fetal survival and perinatal illness rates and include bidirectional measurement of the psychologic effects of screening on the parents.

2. Assessing the impact of serial prenatal ultra-

Table 4: Summary of meta-analysis of single and serial prenatal ultrasound screening[34]

References included in meta-analysis	Outcomes compared	Odds ratio* (and 95% confidence interval)
28, 30, 32	No. of antenatal hospital admissions	1.11 (0.97–1.28)
	Apgar score of 7 or less	
	At 1 minute	1.11 (0.94–1.31)
	At 5 minutes	1.04 (0.75–1.44)
	No. of admissions to special care unit	0.83 (0.70–0.98)
26, 28–30, 32	Perinatal death rate	
	Overall	0.70 (0.48–1.02)
	Excluding infants with fatal malformations	0.61 (0.47–0.79)

*Screened:unscreened.

sound screening in a randomized trial with adequate power to detect clinically significant outcomes.

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