ORIGINAL RESEARCH

A Randomized Trial Using Ultrasound to Identify the High-Risk Fetus in a Low-Risk Population

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OBJECTIVE: To evaluate the effect of introducing two biophysical ultrasound examinations in a low-risk antenatal population.

METHODS: Scans were performed at 30–32 weeks' gestation and 36–37 weeks' gestation. Scans assessed placental maturity, amniotic fluid volume, and estimated fetal weight. One thousand nine hundred ninety-eight low-risk patients were randomized at 30 weeks' gestation to a control group receiving standard antenatal care, or to the study group who also received an ultrasound scan. Outcome measures were frequency of small for dates (less than 10th percentile at birth), intervention rates, and admissions to neonatal intensive care.

RESULTS: The proportion of infants assessed as small for dates at birth in the study group was 6.9% (69 of 994) compared with 10.4% (104 of 999) in the control group ($P = .008$). The rates of intervention in the study and control groups were 31.3% (313 of 999) and 16.9% (169 of 999), respectively ($P < .001$). Twenty-eight (2.8%) neonates in the study group were admitted to the neonatal unit compared with 34 (3.4%) in the control group ($P = .532$).

CONCLUSION: Introduction of an ultrasound scan at 30–32 weeks' and 36–37 weeks' gestation may reduce the risk of a growth-restricted infant and increases antenatal interventions. Rates of admission to a neonatal unit are not significantly affected. (Obstet Gynecol 2003;101:626–32. © 2003 by The American College of Obstetricians and Gynecologists.)

Eighty percent of pregnancies are considered antenatally to be "low risk." Mothers undergo routine antenatal care with fetal growth and fetal environment assessed by a clinical examination of the maternal abdomen. Clinical assessment of fetal weight and amniotic fluid volume has sensitivities of less than 50% in the hands of most providers, leading to a high degree of false-negative identification of the fetus at risk.[1] However, once a pregnancy is identified as "high risk," its outcome is maximized by sophisticated surveillance techniques and unexpected intrauterine death after viable gestation is reached in such pregnancies is nowadays an uncommon event. Paradoxically, we have become so expert in looking after our "high-risk" patients that large studies in Dublin[2] and Belfast[3] have demonstrated that the perinatal mortality rate is now higher in the apparent "low-risk" pregnancy than in the "high-risk" pregnancy.

Ultrasound observation of normal amniotic fluid volume and appropriate fetal weight is associated with a lower perinatal mortality rate in a "high-risk" population.[3] Both features are easily observed by ultrasound examination and require moderate skill. It has also been shown that 15% of placentae show grade 3 maturity (Grannum classification) at 35 weeks' gestation. This group is at an increased risk of morbidity and mortality.[4] Even more importantly, this study showed that by informing the carers of their abnormal biophysical findings, interventions resulted in the perinatal mortality rate being the same in both the "low-risk" and "high-risk" pregnancies.[4] The ultrasound assessment of the combination of the three parameters, placental maturity, amniotic fluid volume, and estimated fetal weight, have not, to date, been assessed as a predictor of fetal risk in a randomized controlled trial in a low-risk population. We designed a randomized controlled trial to study the effect of the introduction of a real-time ultrasound examination at 30–32 weeks' gestation and at 36–37 weeks' gestation to assess placental maturity, amniotic fluid volume, and estimated fetal weight in a previously identified low-risk pregnancy.

MATERIALS AND METHODS

The local Ethics Committee approved the study. Subjects were recruited, over a 21-month period, from the antenatal clinics by one of two research midwives at the Royal Maternity Hospital, Belfast, United Kingdom. It is

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Recruitment, patient consent, and ultrasound scans were performed by two research midwives, Briege Lagan and Catherine Lynch.

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the tertiary referral center for Northern Ireland. One thousand nine hundred ninety-eight pregnant women were assessed as "low risk" at 30 weeks' gestation and randomized either to the control group (999 subjects) or to the study (ultrasound scan) group (999 subjects).

The inclusion criteria to the trial were singleton pregnancies with gestational age confirmed by early ultrasound examination and/or 18–20 week anomaly scan.

The exclusion criteria were known maternal medical problems or previous obstetric complications identified at booking (eg, diabetes, essential hypertension, or previous severe pregnancy-induced hypertension); the identification of risk factors including pregnancy-induced hypertension, rhesus isoimmunization, and intrauterine growth restriction before 30 weeks' gestation in present pregnancy; multiple pregnancy; uncertain gestational age; late booking (after 20 weeks' gestation); or known fetal abnormality.

Assessments for both groups coincided with routine antenatal visits at 30–32 and 36–37 weeks' gestation. If randomized to the control group, the maternal abdomen was palpated by one of the two research midwives to determine uterine and fetal size, fetal presentation and position, and amniotic fluid volume. If randomized to the scan group, in addition to the above clinical assessment, each patient at 30–32 and 36–37 weeks' gestation had an ultrasound examination performed by the same research midwife to assess placental maturity (Grannum classification),[5] liquor volume, and estimated fetal weight. All of these scans were performed using the 3.5-MHz curvilinear probe of an ATL Ultramark 4 scanner (Advanced Technology Laboratories Inc., Bothell, WA). For the purpose of the study, we combined Grannum's original grade 0 and 1 into a single category named grade 1.

A placenta with a homogeneous appearance, with no echogenicity, and a smooth well-defined chorionic plate was classified as grade 1. A placenta demonstrating echo-free areas, compartmentalization resembling cotyledons, and irregular edges was classified as grade 3. A placenta that was neither grade 1 nor 3 was classified as grade 2. The amniotic fluid volume was calculated using the maximum vertical pool method.[6] This was performed by identifying the largest vertical pocket of amniotic fluid (free of limbs or loops of cord) anywhere in the uterine cavity and measuring it at right angles to the uterine contours. The value was categorized into one of five groups: less than 2 cm (oligohydramnios), 2–2.9 cm, 3–8 cm (normal), 8.1–10 cm, and more than 10 cm (polyhydramnios).

Estimated fetal weight (EFW) was calculated from the biparietal diameter (BPD) and abdominal circumference (AC) measurements employing the formula EFW (log 10) = $-1.749 + 0.166$ (BPD) $+ 0.046$ (AC) $- 0.002646$ (AC multipled by BPD), which was built into the Ultramark 4 machine used in the trial. The BPD was measured from the outer to inner margins of the fetal skull table perpendicular to the falx cerebri and in the plane incorporating the septum cavum pellucidum.[7] The abdominal circumference was measured around a "circular" view of the fetal abdomen incorporating the portoumbilical vein complex and fetal stomach and excluding the kidneys and thorax.[8] The EFW was recorded and allocated as one of the following: less than 10th percentile for gestational age, between 10th and 20th percentile, between 20th and 80th percentile, between 80th and 90th percentile, and more than 90th percentile. At the conclusion of each antenatal visit, the clinician made a management decision on the basis of the clinical findings and if randomized to the study group, the ultrasound scan result. The options for antenatal intervention were: 1) reviewing the patient earlier at the antenatal clinic, 2) referral to the Day Obstetric Unit for full biophysical fetal assessment including umbilical artery Doppler ultrasound, 3) admission to the antenatal ward, and 4) induction of labor.

The criteria for intervention in the control group were decreased fetal movement, impression by midwife of intrauterine growth restriction, impression of macrosomia, impression of oligohydramnios, and impression of polyhydramnios.

The absolute criteria for intervention in the study (ultrasound scan) group were grade 3 placental maturity, amniotic fluid volume less than 2 cm or more than 10 cm, or EFW less than 10th percentile or more than 90th percentile.

In the study (ultrasound scan) group, there were relative criteria for intervention, and patients meeting two or more of these criteria had an intervention. These relative criteria for intervention in the study (ultrasound scan) group were grade 2 placental maturity, amniotic fluid volume of 2–2.9 cm or 8–10 cm, or EFW 10–20th percentile or 80–90th percentile. Recruitment, consent, ultrasound scans, and data collection were performed by two research midwives. Both midwives had 3 months of intensive training in obstetric ultrasound before the commencement of the trial.

The primary outcome measures were the incidence of small for gestational age at birth (less than 10th percentile at birth), antenatal interventions, and admissions to the neonatal intensive care unit.

Secondary outcome measures were overall induction of labor rates, induction of labor for suspected fetal compromise, gestational age at delivery, mode of delivery, nonreassuring fetal status in labor, Apgar scores at 1 and 5 minutes, resuscitation of neonate, and fetal abnormalities.

Table 1. Baseline Characteristics

	Study (n = 999) (PAW PAW)	Control (n = 999) (routine)
Age (y)	27.7	27.3
Smoking at booking, n (%)	358 (35.8)	398 (39.8)
Booking weight (kg)	62.2	61.0
Alcohol, n (%)	150 (15.0)	147 (14.7)
Parity, n (%)		
0	413 (41.3)	388 (38.7)
1–2	465 (46.5)	457 (45.7)
3–4	97 (9.7)	134 (13.4)
≥5	24 (2.4)	22 (2.2)

PAW PAW = placental maturity (P), amniotic fluid volume (A), and estimated fetal weight (W).

A recruitment target of 2000 patients enabled the study to have 80% power to detect as statistically significant ($P < .05$) a 35% reduction in small for gestational age infants among the ultrasound scan group, relative to a 10% rate of small for dates in the control group. The recruitment target enabled the study to have 80% power to detect as statistically significant ($P < .05$) a 25% reduction in intervention rates among the ultrasound scan group relative to a figure of 20% intervention rate in the control group and a greater than 50% reduction in admissions to the neonatal unit among the ultrasound scan group, relative to a 5% neonatal admission rate in the control group.

Data management and analysis were performed by Epi-Info 6 (Centers for Disease Control and Prevention, Atlanta, GA) and SPSS (SPSS Inc., Chicago, IL). Primary outcome measures were compared between groups using χ^2 test with Yates' correction, and relative risks with 95% confidence limits were also calculated. The Mantel-Haenszel stratified relative risk was used to adjust for the potential confounding effect of maternal smoking.

Patient allocation was computer generated before commencement of the trial by a statistician from the Department of Medical Statistics at the Queens University, Belfast. Randomization was restricted to achieve balance. At the 30-week antenatal visit, patient eligibility to the trial was assessed. After written consent to the trial was obtained, each patient was randomized by a sealed numbered envelope by one of two research midwives. Patients were randomized to the study group (ultrasound scan) or to the control group (standard antenatal care). A data collection booklet was used for recording of clinical findings and ultrasound scan findings.

RESULTS

During the study, 2689 patients were booked in our antenatal clinic (Figure 1). Of these, 580 were deemed to be at "high risk" and therefore excluded from the study. Of the 2109 "low-risk" patients who booked during the study period, 111 were excluded from trial entry. Among these, 70 patients were late in booking at the antenatal clinic, and 16 patients had already had a scan between their 20-week anomaly scan and trial entry. Thirteen patients insisted on having antenatal scans, and five patients refused to have antenatal scans. Four patients were deemed to be poor attendees, and three patients spoke poor English.

With regard to demographics, there were no statistical differences between the two groups (Table 1).

Significantly fewer mothers randomized to the ultrasound scan group gave birth to small for gestational age infants[9] (ie, less than the 10th percentile) (Table 2). For the analysis, we used an Excel spreadsheet distributed by the Child Growth Foundation, and this program is recommended by the Royal College of Paediatrics and Child Health. There were significantly more antenatal interventions in the ultrasound scan group (31.3% versus 16.9%). After receiving an intervention, significantly more mothers subsequently had their labors induced for suspected fetal compromise in the ultrasound scan group (Table 3). In the study (ultrasound scan) group, 69 patients had their labors induced because of abnormal findings at the ultrasound scan or because further inves-

Table 2. Primary Outcomes

	PAW PAW n (%)	Control n (%)	RR (95% CL)	P
Small for dates (<10th percentile)	69/994 (6.9)	104/999 (10.4)	0.67 (0.50, 0.89)	.008
			0.70* (0.53, 0.93)*	.018*
All antenatal interventions	313/999 (31.3)	169/999 (16.9)	1.85 (1.57, 2.18)	<.001
Early antenatal review	194/999 (19.4)	87/999 (8.7)	2.23 (1.76, 2.83)	<.001
Biophysical fetal assessment	90/999 (9.0)	64/999 (6.4)	1.41 (1.03, 1.91)	.036
Admission to antenatal ward	7/999 (0.70)	7/999 (0.70)	1.00 (0.35, 2.84)	.788
Induction of labor	22/999 (2.2)	11/999 (1.1)	2.00 (0.98, 4.10)	.079
Admissions to neonatal unit	28/994 (2.8)	34/999 (3.4)	0.83 (0.51 ,1.35)	.532

PAW PAW = placental maturity (P), amniotic fluid volume (A), and estimated fetal weight (W); RR = relative risk; CL = confidence limit.
* Stratified for smoking.

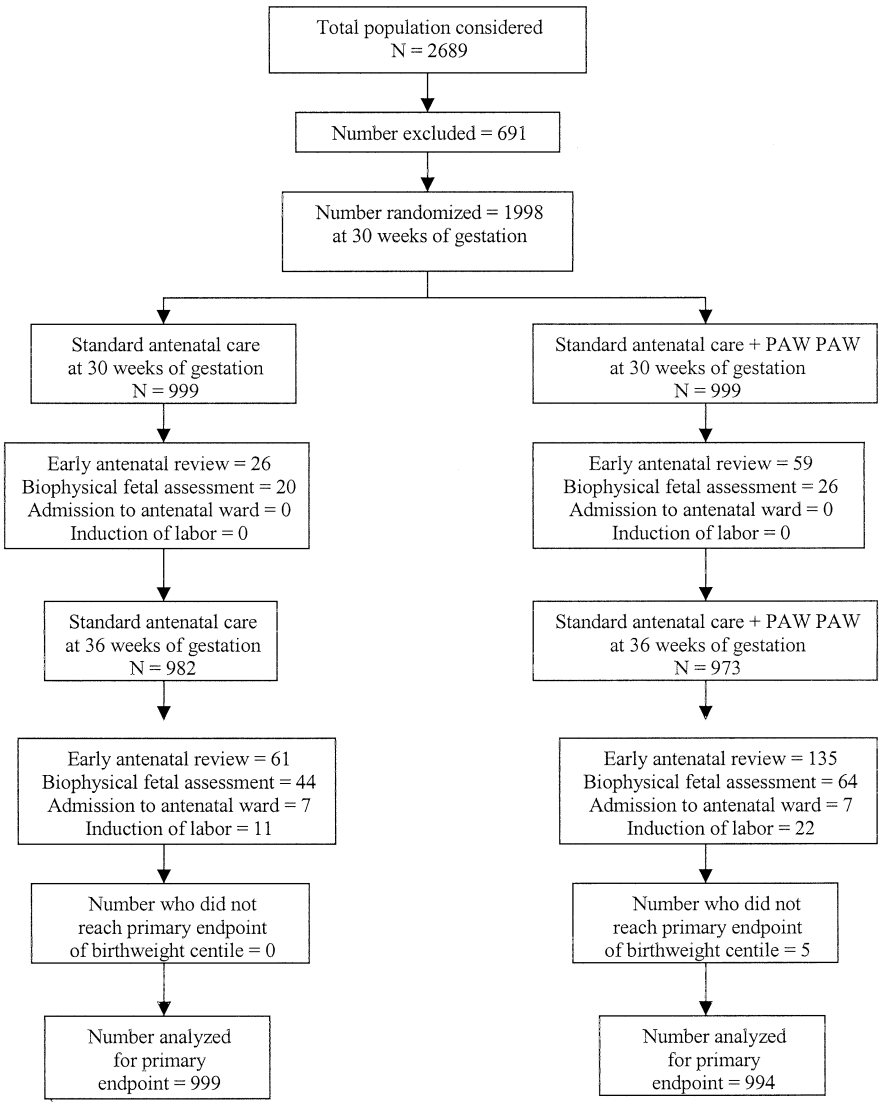

Figure 1. Trial profile. PAW PAW = placental maturity (P), amniotic fluid volume (A), and estimated fetal weight (W); scans were performed at 30–32 weeks' gestation and 36–37 weeks' gestation.

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tigations suggested induction of labor for suspected fetal compromise. Of this group, 37 patients had their labors induced before 38 weeks' gestation. All but two of these patients had their labors induced between 36 and $37^{6}/_{7}$ weeks' gestation. Of the 18 patients in the control group induced for suspected fetal compromise, six were suspected to be small for gestational age on clinical examination, but reduced amniotic fluid volume was not suspected in any. Of the 47 patients in the ultrasound scan group subsequently induced for suspected fetal compromise, nine were suspected to be small for gestational age on clinical examination. Again, in none of these pregnancies was an abnormality of amniotic fluid volume suspected on clinical examination. Among those randomized to the routine group, 34 (3.4%) delivered neonates who required admission to the neonatal intensive care unit. This contrasts with 28 patients (2.8%) in the study group. Twelve neonates in each group were admitted with prematurity. In total, 209 neonatal intensive care days were required to care for infants whose mothers had been randomized to the ultrasound scan group, and 201 days were required to care for infants whose mothers had been randomized to the control group.

In our study population of almost 2000 patients, three pregnancies ended in stillbirth after randomization to the study at 30 weeks' gestation. One stillbirth, caused by intrauterine death after a road traffic accident at 32 weeks' gestation, occurred in the control group. Two stillbirths occurred in the study group. In one case, both ultrasound scans, at 30 and 36 weeks' gestation, were normal. The mother presented at $40^{5}/_{7}$ weeks' gestation complaining of no fetal movements, and intrauterine death was discovered. Birth weight was 3050 g. In the second case, the ultrasound scan at 37 weeks'

Table 3. Secondary Outcomes

	PAW PAW *n* (%)	Control *n* (%)	RR (95% CL)	*P*
Overall induction of labor	388 (39.1)	350 (35.2)	1.11 (0.99, 1.25)	.08
Induction for suspected fetal compromise	47 (4.7)	18 (1.8)	2.62 (1.53, 4.48)	<.001
Gestational age (wk)				
39–42	800 (80.5)	821 (82.2)	1	
35–38	184 (18.5)	168 (16.8)	1.10 (0.91, 1.33)	.61
< 35	10 (1.0)	10 (1.0)	1.03 (0.43, 2.45)	
Delivery mode				
Normal vaginal delivery	671 (67.5)	711 (71.2)	1	
Assisted breech	7 (0.7)	5 (0.5)	1.48 (0.47, 4.64)	
Instrumental	133 (13.4)	131 (13.3)	1.06 (0.85, 1.33)	.36
Elective cesarean	91 (9.2)	75 (7.5)	1.25 (0.94, 1.67)	
Emergency cesarean	92 (9.2)	77 (7.7)	1.23 (0.93, 1.64)	
Nonreassuring fetal status in labor				
No	853 (85.8)	840 (84.3)	1	
Yes	141 (14.2)	157 (15.7)	0.90 (0.73, 1.11)	.36
Apgars at 1 min				
>7	902 (91.0)	899 (90.3)	1	
5–6	65 (6.6)	81 (8.1)	0.81 (0.59, 1.11)	.19
<4	24 (2.4)	16 (1.6)	1.48 (0.79, 2.77)	
Apgars at 5 min				
>7	987 (99.8)	981 (99.5)	1	
<7	2 (0.2)	5 (0.5)	0.4 (0.08, 2.05)	.29
Resuscitation of neonate required				
No	923 (93)	928 (92.9)	1	
Yes	70 (7.0)	71 (7.1)	0.99 (0.72, 1.36)	.97
Fetal abnormality				
No	979 (98.5)	987 (99.0)	1	
Yes	15 (1.5)	10 (1.0)	1.50 (0.68, 3.33)	.42

Abbreviations as in Table 2.

gestation was normal apart from the amniotic fluid pool measuring 8–10 cm. This mother also presented, at $38^{5}/_{7}$ weeks' gestation, complaining of no fetal movement, and intrauterine death was discovered. Birth weight was 3370 g. In both cases, autopsy showed evidence of intrauterine asphyxia, with no indication of the underlying cause.

DISCUSSION

In the developed world, vast sums of money pay for antenatal care, but current practice has been assessed in only a few randomized controlled trials. Furthermore, stillbirth and perinatal mortality rates have been static in the last few years, begging the questions, "Are we satisfied with our assessment of the fetus and its environment? How could we improve our practice?" The fourth Annual Report of the Confidential Enquiry Into Stillbirths and Deaths in Infancy found that the largest area for improvements in perinatal mortality was that of unexplained antepartum stillbirths.[10] The majority of these stillbirths occur in the low-risk obstetric population, and the only assessment of the fetal environment and growth is the clinical examination of the maternal abdomen. Analysis of over 23,000 fetal deaths in California on population-based percentile curves showed a strong link between low fetal weight for gestational age and fetal demise.[11] The Euronatal audit study suggests that stillbirths might be reduced by an improvement in the detection of severe growth restriction and the management of the growth-restricted fetus.[12] However, only 16% of small for gestational age infants will be detected using current routine growth screening strategies in a low-risk population.[13]

Eight biophysical features are commonly observed in the "high-risk" pregnancy—the five Manning profile features plus EFW, placental maturity, and umbilical artery Doppler waveform analysis. Four of these reflect the acute well-being of the fetus—fetal movement, fetal tone, fetal breathing movements, and cardiotocography. Four reflect the chronic state of the fetus—umbilical artery Doppler measurements, placental architecture, amniotic fluid volume, and EFW. Antenatal assessment of the maternal abdomen is actually endeavoring to assess placental function, amniotic fluid volume, and fetal weight estimation.

If perinatal mortality was to have been our end point, 30,000 patients would have been required to enable the study to have sufficient power to detect a 30% reduction in perinatal mortality rates between the two groups. Our surrogate end point was low birth weight for gestational age because 30% of low-birth weight infants suffer from intrauterine growth restriction, and their perinatal mortality is four to ten times higher than that of normally grown infants.[14]

If randomized to the scan group, a mother's risk of delivering an infant with a birth weight less than the 10th percentile was reduced by a third. There were significantly more interventions in the ultrasound scan group. However, there was a wide range of options available to the midwife if the patient was to have an intervention. These ranged from simply reviewing the patient earlier at the antenatal clinic to making the decision for induction of labor. This decision was based solely on the findings at the antenatal clinic. Few patients, 22 in the ultrasound scan group and 11 in the routine group, had this most invasive of interventions. However, significantly more patients in the ultrasound scan group were reviewed earlier at the antenatal clinic or were referred for a biophysical fetal assessment–interventions usually reserved for previously identified high-risk pregnancies. Increased surveillance, as the result of an ultrasound scan, has helped to identify the high-risk fetus in a low-risk antenatal population.

Once a pregnancy is identified as high risk, there is only one intervention that we can offer mothers with a compromised fetus–delivery of the infant. In the ultrasound scan group, significantly more patients had their labors induced for suspected fetal compromise after further assessment of the intrauterine environment and fetal growth. Intrauterine fetal growth occurs almost linearly in normal pregnancy.[15,16] If a fetus was failing to reach its growth potential, or if fetal growth had stopped, early induction of labor ensured its weight did not fall through the percentiles with advancing gestation. This reduced the risk of delivering an infant with birth weight less than the 10th percentile. The logic is that if infants can be delivered before they becomes small for gestational age, then the complications of that condition can be avoided. These include stillbirth, birth hypoxia, neonatal complications in the perinatal period, impaired neurodevelopment and cerebral palsy in childhood, and noninsulin-dependent diabetes and hypertension in adult life.[17] At present, the majority of these small infants are not diagnosed until delivery[18] when their blueprint for adult life has already been drawn.

In the study (ultrasound scan) group, there were fewer infants than one would have expected, 31, born with birth weights less than the 10th percentile. These patients were identified by an ultrasound scan and induced and delivered before the fetal weight fell through the percentile lines with advancing gestation. Sixty-nine patients in the study (ultrasound scan) group had their labors induced because of concerns for fetal well-being. Thirty-seven of them were delivered before 38 weeks' gestation. If these pregnancies had continued, we suggest that they were at risk of developing growth restriction, with the associated risks. This policy did not result in iatrogenic neonatal morbidity. In fact, fewer infants in the study group were admitted to the neonatal intensive care unit, although this was not statistically significant. With regard to maternal morbidity, there were no differences in instrumental delivery or cesarean delivery rates between the two groups.

Scans were performed by midwives with limited ultrasound training. Unfortunately, assessment of their scan findings was not conducted on a sample of trial participants to determine intraobserver and interobserver error in ultrasound measurements. However, in light of the significance of the results, it is our view that they represent an underestimate of the benefit of an ultrasound scan. A more skilled ultrasonographer, using better equipment, may have identified a larger number of compromised pregnancies.

We conclude that an ultrasound scan may be an appropriate screening tool to be used in the low-risk obstetric population, to verify the low-risk and identify the high-risk fetus. It can be performed in a matter of minutes but gives infinitely more information about fetal well-being than clinical examination alone. A multicenter trial to assess its worth in lowering perinatal mortality as well as reducing morbidity would be worthwhile.

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