

THE VALUE OF ROUTINE MID-TRIMESTER ULTRASOUND IN LOW-RISK PREGNANCIES AT PRIMARY CARE LEVEL

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ABSTRACT

This study investigated the effect of routine second-trimester ultrasound scanning on obstetric management and pregnancy outcomes. This was an open cluster, randomised, controlled trial. Clusters of women with low-risk pregnancies presenting in the second trimester were randomised to receive an ultrasound scan followed by usual antenatal care, or to an unscanned control group undergoing conventional antenatal care only. Out of the 962 women randomised, follow-up was successful for 804 (83.6%), with 416 allocated to the ultrasound scan group and 388 controls. There were no significant differences between the ultrasound scan group and the control group in terms of prenatal hospitalisation, mode of delivery, miscarriage, perinatal mortality rate and low birthweight rate. Ultrasound dating was associated with a lower rate of induction of labour for post-term pregnancy (1.4% vs. 3.6%; $P=0.049$). However, ultrasound scanning in low-risk pregnancies was not associated with improvements in pregnancy outcome.

OPSOMMING

Hierdie studie het die effek van roetine mid-trimester ultraklankskandering op swangerskapsorg en -uitkomst ondersoek. Dit was 'n oop tros, lukrake, beheerde proef. Groepe vroue met laerisikoswangerskap in die mid-trimester is lukraak toegewys vir 'n ultraklankskandering, gevolg deur voorgeskrewe voorgeboortesorg, of vir 'n kontrolegroep wat voorgeboortesorg volgens nasionaal voorgeskrewe protokol sonder skandering ontvang het. Van die 962 vroue wat aan die steekproef deelgeneem het kon data vir 804 (83.6%) suksesvol opgevolg word, met 416 in die ultraklankgroep en 388 in die kontrolegroep. Geen beduidende verskille is tussen die twee groepe gevind ten opsigte van voorgeboortehospitalisasie, geboortemethode, miskraamstatistiek, perinatale komplikasies of laegeboortegewig nie. Ultraklankdatering van swangerskappe is met minder kraaminduksie (1.4% teen 3.6%; $P=0.049$) vir natrimesterswangerskap geassosieer. Roetine ultraklankskandering in laerisikoswangerskap het egter geen verbetering in swangerskapsuitkomst te weeg gebring nie.

INTRODUCTION

The development of clinical ultrasound has brought about irrevocable change in the management of the pregnant patient (Ewigman, LeFevre & Hesser, 1990:189-194). Prenatal ultrasound has developed into a science which has empowered antenatal care-givers to provide a superior service, especially to the high-risk obstetric patient. Increasingly, ultrasound scanning has come to be expected as part of routine antenatal care. This is not possible in all countries, however, and certainly not in the South African public health sector (Department of Health, 2002:9). The majority of pregnant patients in South Africa receive antenatal care in primary health care clinics and, owing to the structure of the South African public health care system, hospital patients do not have access to routine antenatal ultrasound screening (Department of Health, 2002:9). This may complicate antenatal management and lead to increased perinatal morbidity or mortality.

PURPOSE, RESEARCH QUESTION AND OBJECTIVES

It is tempting to assume that prenatal management may be facilitated and pregnancy outcomes improved by early knowledge of foetal normality, gestational age and number of foetuses. The question was posed whether routine ultrasound would prove beneficial in a developing country, such as South Africa, where high rates of perinatal morbidity and mortality prevail (Department of Health, 2002:9; Berkowitz, 1993:1-3) and where routine aneuploidy screening is not currently feasible. This study was done to investigate and compare the effect of routine second-trimester ultrasound scanning on obstetric management and pregnancy outcomes to the selective use of ultrasound during pregnancy.

LITERATURE REVIEW

The use of ultrasound in antenatal care originated in 1955 when the Scottish obstetrician, Dr Ian Donald, first recognised its potential for direct observation of the foetus (Wagner, 1994:1-7). Since the mid-1970s, improvements in ultrasound equipment and imaging techniques have allowed insight into the protected space of the uterus, revealing a wealth of information about the foetus and its environment (Persson &

Kullander, 1983:942-947). According to Berkowitz (1993:12), the availability of diagnostic ultrasound brought about a revolution in the care and management of pregnant patients.

Since the use of ultrasound in the management of high-risk obstetric patients was found to be of such great value, the question was raised if there is a place for ultrasound in routine antenatal care and, if so, whether it would bring about improvements in conventional obstetric management of the low-risk patient (Berkowitz, 1993:1-3).

Several studies have been conducted in different parts of the world to assess the value of routine prenatal ultrasound as a screening tool (Wagner, 1994:1-7; Geerts, Brand & Theron, 1996:501-507). National policies formulated on the basis of these studies still reflect differences of opinion. In the United States of America, there is a strong belief that there is insufficient evidence to support the use of routine ultrasound. This recommendation was predominantly based on the findings of the RADIUS study (Ewigman, Crane, Frigoletto, LeFevre, Bain & McNellis, 1993:821-827). Patients who were unsure of their last menstrual date and in whom a discrepancy existed between the palpated size of the uterus and dating based on the last menstrual period were all excluded from the study. The reason for this exclusion is not clearly stated, but could possibly be that "uncertain dates" are viewed as a valid indication for the selective use of ultrasound. Since the study population was restricted to women who were sure of dates, the results of the RADIUS trial cannot be applied to women with an unreliable menstrual history (Saari-Kemppainen, Karjalainen, Ylostalo & Heinonen, 1990:387-391).

Recently, however, the American College of Obstetricians and Gynecologists (2007:217-227) recommended routine aneuploidy screening for pregnant women, based on ultrasound with or without biochemical markers.

Canadian and European health policy-makers share the sentiment that the benefits of routine ultrasound outweigh the cost, and routine ultrasound screening is either national policy or a recommendation in those countries (Saari-Kemppainen *et al.*, 1990:501-507; Public Health Agency of Canada, 2006). The EuroFetus

study found that ultrasound screening in Europe was much more effective in the identification of high-risk pregnancies than was reported in the United States. In contrast to the RADIUS study, which was only able to detect 17% of congenital abnormalities in the ultrasound screening group, the European detection rate was 56%. These findings strengthened the case for ultrasound screening and raised questions about studies conducted in the United States (Levi & Montenegro, 1998).

In his review in the authoritative Cochrane Library, Neilson (1998) summarised the main objectives and results from nine trials that investigated the benefits of routine ultrasound assessment in early pregnancy and its effects on perinatal morbidity and mortality. He concluded that the assumption that routine ultrasound in early pregnancy resulted in better gestational age estimation, earlier detection of multiple pregnancies and earlier detection of foetal abnormalities had been scientifically justified through the results of these studies. Ultrasound assessment resulted in fewer post-term pregnancies and a reduced incidence of induction of labour for post-datism in the screened group. There was, however, no conclusive evidence that the benefits of routine ultrasound led to improvement in foetal outcome.

Only two studies focused on the early detection of foetal abnormalities. The Helsinki trial reported a good detection rate of foetal anomalies and fewer perinatal deaths owing to termination of foetuses with congenital abnormalities. The low detection rate in the RADIUS trial drew attention to the dependency of this diagnostic tool on the experience and expertise of the operator and stressed the need for adequate training in this modality.

The national guidelines for maternity care in South Africa follow the policy of selective use of ultrasound in antenatal care, probably largely based on the lack of resources, but at the same time acknowledge the value of ultrasound in routine obstetric management whenever the resources are available (Department of Health, 2002). The methods of pregnancy risk assessment are not clearly defined in the national policy document, but are presumably based on the patient's clinical history and a physical examination. One of the strengths of routine ultrasound lies in the ability of the procedure to detect high-risk obstetric problems early in order to

facilitate appropriate pregnancy management (Bakketeig, Eik-nes, Jacobsen, Ulstein, Brodtkorb, Balstad, Eriksen & Jorgenson, 1984:207-211).

In the only comparable randomised controlled trial conducted on urban South African women from primary health care clinics, Geerts *et al.* (1996:501-507) express doubt about the financial feasibility of an ultrasound screening programme in a developing world setting, but acknowledge that it provides a superior method of estimating gestational age with associated spin-offs.

STRUCTURE OF ANTENATAL CARE IN SOUTH AFRICA

Maternity care forms an integral part of primary health care and is focused on meeting the basic needs of the South African population. Different levels of care have been instituted for the efficient functioning of the national health care service. Since most medical conditions do not require treatment at a large hospital, this structure allows the patient load to be shared by different levels of care. In Gauteng low-risk patients attend a primary health care clinic during the course of their pregnancy and are referred to a Level 1 district hospital in the third trimester with a view to delivering at the Level 1 hospital. High-risk pregnancies are referred to Level 2 regional hospitals owing to the availability of a full-time specialist obstetrician. Level 3 hospitals are tertiary institutions that run specialist clinics for high-risk obstetric problems and make provision for advanced obstetric procedures such as chorionic villus sampling or cordocentesis. All Level 3 hospitals in Johannesburg offer a referral-based ultrasound service provided by skilled sonologists and sonographers. In Level 1 and 2 hospitals a limited ultrasound service is provided, mostly by self-taught medical officers, based on the selective use of ultrasound for obstetric problems.

METHODOLOGY

An open cluster, randomised, controlled trial was conducted in a district hospital (Dr Yusuf Dadoo Hospital) and a regional referral hospital (Leratong Hospital) in western Gauteng. These two hospitals serve a predominantly black working class population who depend on free state-funded maternity care facilities. These hospitals, in line with government maternity care

guidelines (Department of Health, 2002), do not offer routine ultrasound scanning to pregnant women. Ultrasound scans are done only for specific indications such as suspected multiple pregnancy. The trial was undertaken with the approval of the Faculty Research and Ethics Committee of the University of Johannesburg and permission was obtained from the chief executives at the two hospitals where the research was conducted. The trial was registered with the United States clinical trials database (<http://www.clinicaltrials.gov>) with protocol registration number NCT 00204139.

Women in the mid-trimester of pregnancy, who had no specific indication for ultrasound, were randomly selected to either have a single prenatal ultrasound followed by routine antenatal care, or receive conventional antenatal care only. The study population consisted of 962 women at 18 to 23 weeks' gestation by best clinical estimate, who had a low risk of developing complications during pregnancy, and planned to deliver at either of the two hospitals. High-risk pregnancies were excluded, as were pregnancies in which first- and second-trimester ultrasound scans had already been done. Women with uncertain menstrual dates were included because current South African guidelines suggest that their uncertainty can be resolved by clinical palpation or measurement of symphysis-fundal height (Department of Health, 2002). Similarly, those aged 35 years and above were included because the existing prenatal care policy provides for genetic counselling, and not necessarily for routine ultrasound scan. Routine aneuploidy screening based on ultrasound or biochemical markers is not available at South African public health institutions. Clinical gestational age was estimated by the attending midwives, based on the last normal menstrual period, or by measurement of the symphysis-fundal height and uterine palpation in women whose menstrual dates were unknown or uncertain.

Eligible women were identified by the attending midwives, and interviewed for participation in the trial. After giving written consent, a relevant obstetric history was obtained and entered onto the project data sheet. Participant women were randomised in clusters to an ultrasound screening (USS group) or to no ultrasound scans (control group). A cluster was defined as all women presenting for prenatal care on a single day, who met the inclusion criteria for the trial and who agreed to participate. This meant that all participants who

presented on a certain day would be randomised in one cluster to either the USS group or the control group. Randomisation was done by blinded selection of cards from a box. Half of the cards were marked A, and half were marked B. If an A was drawn, the cluster was assigned to the USS group, entitling all participants on that morning to an ultrasound scan. All ultrasound scans were done by the researcher, a licensed ultrasonographer with extensive experience in pregnancy ultrasound. Ultrasound scans entailed transabdominal determination of single or multiple pregnancy, placental site identification, estimation of gestational age based on a combination of biparietal diameter, head circumference and femur length measurements using Chitty's growth tables (Chitty, Altman, Henderson & Campbell, 1994a:35-43; Chitty, Altman, Henderson & Campbell, 1994b:132-135), and a thorough search for foetal abnormalities including soft markers for aneuploidies. All scans were performed on an Aloka SSD/1000 unit (Aloka, Tokyo, Japan) with a 3.5 MHz curvilinear transducer. The ultrasound findings were entered on the project data sheets, and on the participants' prenatal records, for use by the hospital midwives. If a B was drawn, the cluster was assigned to the control group and no participants received scans on that morning. No entries were made on the prenatal cards of the controls. Further pregnancy care for both the USS and control groups was left to the hospital midwives. This care could include referral for ultrasound scans by hospital ultrasonographers for clinical indications. The researcher played no further part in the management of these pregnancies.

The primary outcome measures in this study were induction of labour for post-term pregnancy and perinatal death. Number of prenatal visits, hospitalisation before onset of labour, detection of foetal abnormalities and neonatal admission rates were also determined. This data was obtained from the maternity units of Dr Yusuf Dadoo and Leratong Hospitals. Participant women were contacted by telephone if there was no evidence of giving birth at either of these institutions; the same information was accepted verbally if written records were unavailable.

A sample size calculation was done based on the assumption that routine second-trimester ultrasound reduces the requirement for post-term pregnancy induction. To show a statistically significant difference

($P < 0.05$) in reduction of post-term pregnancy rate from 10% to 5%, with a power of 80%, a minimum of 948 participants would be required, divided into equal USS and control groups. No adjustment was made for a design effect as there was no reason to expect clusters to differ systematically from each other in terms of clinical or demographic characteristics. Comparison of USS and control groups was performed using Epi-Info 6 statistical software. Comparison of frequencies was done using the chi-square test or, where applicable, Fisher's exact test. Comparison of continuous data was done using analysis of variance for normally distributed variables, and the Mann-Whitney test for non-parametric data.

RESULTS

A total of 962 women were enrolled in the study. Four hundred and ninety were allocated to receive ultrasound scans, and 472 were allocated to the control group. The USS group comprised 71 clusters with a median of 7 women per cluster and a range of 1 to 19. The

control group consisted of 79 clusters with a median of 5 women per cluster and a range of 1 to 31. Follow-up was successful for 804 women (83.6%). One hundred and fifty-one (15.7%) were lost to follow-up and 7 (0.7%) had to be excluded as they were found after enrolment to have pregnancy risk factors defined as exclusion criteria. This left 804 women for analysis, with 416 in the USS group and 388 controls.

Table 1 shows basic demographic and obstetric data at the time of enrolment in the study, comparing women allocated to receive routine mid-trimester ultrasound scans with control women who did not receive routine scans.

Comparison of women allocated to the USS and control groups showed no significant differences in age, race, parity, HIV status, gestation by dates at enrolment and uncertainty regarding the LMP (Table 1). There was uncertainty regarding the LMP (defined as inability by the participant to assign a date) in 134 women (32.2%) in the USS group and in 133 (34.3%) in the control

Table 1: Basic demographic and obstetric data

	Ultrasound scan group N=416	Control group N=388	P value
Mean age in years (SD)	25.3 (5.8)	25.6 (5.7)	0.45
Median parity (range)	1 (0-7)	1 (0-6)	0.49
Mean gestation by LMP in weeks (SD)	20.7 (2.8)	20.5 (2.9)	0.39
Number who were certain about LMP	282 (67.8%)	255 (65.7%)	0.53
Race:			
Black	364 (87.5%)	346 (89.2%)	0.29
White	38 (9.1%)	37 (9.5%)	
Mixed race	9 (2.2%)	3 (0.8%)	
Asian	5 (1.2%)	2 (0.5%)	
HIV status:			
Positive	91 (21.9%)	63 (16.2%)	0.12
Unknown	140 (33.7%)	143 (36.9%)	
Negative	185 (44.5%)	182 (46.9%)	

SD = standard deviation LMP = last menstrual period

Table 2: Maternal and pregnancy outcomes

	Ultrasound scan group N=416	Control group N=388	Relative risk (95% confidence interval)	P value
Women who had subsequent ultrasound scans	68 (16.3%)	85 (21.9%)	0.75 (0.56-0.99)	0.045
Mean number of prenatal care visits (SD)	5.8 (1.8)	5.9 (2.0)		0.35
Women hospitalised before labour	68 (16.3%)	51 (13.1%)	1.24 (0.89-1.74)	0.20
Induction of labour for all indications	18 (4.3%)	29 (7.5%)	0.58 (0.33-1.03)	0.06
Induction of labour for post-term pregnancy	6 (1.4%)	14 (3.6%)	0.40 (0.16-1.03)	0.049
Delivery by Caesarean section*	60 (15.1%)	59 (15.8%)	0.95 (0.69-1.33)	0.75

SD = standard deviation *Excludes nine women and six women from the USS and control groups, respectively, whose modes of delivery are unknown

Table 3: Comparison of foetal and neonatal outcomes

	Ultrasound scan group N=415	Control group N=389	Relative risk (95% confidence interval)	P value
Major foetal abnormality	7	3	2.16 (0.56-8.31)	0.34
Termination of pregnancy	1	0		1.0
Miscarriage <500 g	4	3	1.25 (0.28-5.55)	0.76
Stillbirth ≥500 g	14	10	1.31 (0.59-2.91)	0.51
Neonatal death ≥500 g	4	6	0.62 (0.18-2.19)	0.46
Perinatal mortality ≥500 g	18	16	1.05 (0.54-2.03)	0.88
Neonatal admission	30	25	1.12 (0.67-1.88)	0.65
Twin pregnancies	6	2	2.80 (0.57-13.8)	0.29
Birthweight <2.5 kg				
Mean birthweight in g (SD)	2 944 (618)	2 962 (631)		0.70

SD = standard deviation. The data excludes five women who were not pregnant at enrolment, and three whose foetal and neonatal outcomes are unknown.

group. Women who were successfully followed up did not differ significantly from those who were lost to follow-up in terms of age, parity, uncertainty about LMP and allocation to USS or control groups (data not shown).

Table 2 compares the maternal and pregnancy outcomes of women allocated to receive routine mid-trimester ultrasound scans with control women who did not receive routine scans.

Sixty-eight women (16.3%) in the USS group had subsequent ultrasound scans during their pregnancies, compared with 85 (21.9%) in the control group ($P=0.045$). There were no significant differences between the groups in terms of number of prenatal care visits, number of women hospitalised before the onset of labour and Caesarean section rate. There was a trend of fewer inductions of labour in the USS group (4.3% vs 7.5%; $P=0.06$), with a lower rate of induction of labour for post-term pregnancy in the USS group (1.4% vs 3.6%; $P=0.049$).

Table 3 shows a comparison of foetal and neonatal outcomes between the USS and control groups.

Miscarriage rates, and stillbirth, neonatal mortality and perinatal mortality rates for infants ≥ 500 g at birth, and $\geq 1\ 000$ g at birth, did not differ significantly between the groups. There were no significant differences in low birthweight rates, severe foetal abnormality or rates of neonatal admission. In both groups, the most frequent indication for neonatal admission was prematurity. However, when a search for foetal abnormalities was made in each woman in the USS group, the following findings were recorded: Two women with soft markers for aneuploidy accepted amniocentesis, one foetus presenting with a normal karyotype and a good outcome. The second foetus presented with trisomy 18 and demised spontaneously in utero. Another woman had genetic counselling for a foetus with hyperechogenic bowel and a short femur. She did not return for amniocentesis and karyotyping, but delivered a stillborn baby at 27 weeks' gestation. Two foetuses were found to have cystic renal abnormalities suggestive of unilateral multicystic renal dysplasia. On neonatal follow-up, this was confirmed in one of these infants, while the other had entirely normal kidneys. Neural tube defects were detected in four foetuses. One of these underwent therapeutic termination. The other three were born alive after the

mothers declined pregnancy termination. Two had open spina bifida, one of whom died in the neonatal period, while the other underwent successful surgery. One infant had a closed spina bifida with associated hydrocephalus and severe lower limb and neuromuscular pelvic abnormalities. No other major abnormalities were detected in the USS group at delivery. Three infants with major abnormalities were delivered in the control group, one liveborn with tetralogy of Fallot, one liveborn with a cleft lip, and one stillborn with severe amniotic band syndrome. None of these abnormalities were suspected or detected before delivery.

DISCUSSION

This study showed that routine second-trimester ultrasound scanning at district and regional level in a developing country is not associated with substantive improvements in maternal or foetal outcome. Routine scanning had no effect on indices of health service usage either, such as prenatal admission, prenatal visits, Caesarean delivery and neonatal admission. There was a small reduction in the need for a subsequent scan in the USS group. In this study, all seven foetuses with severe abnormalities were detected prenatally in the USS group, while all three in the control group were recognised only after delivery. The women with foetal abnormalities in the USS group were therefore able to make decisions about their pregnancies before their infants were born. An area of potential benefit was in gestational age estimation with routine ultrasound scanning resulting in fewer inductions of labour for post-term pregnancies. About one-third of women in the study were uncertain about their menstrual histories. In such women, this difficulty can easily be resolved by early pregnancy ultrasound. This has shown to be more reliable for gestational dating than clinical methods (Taipale & Hilesmaa, 2001:189-194; Campbell, Warsof, Little & Cooper, 1985:613-620).

The findings of this study are in general agreement with those of a Cochrane review on this subject (Neilson, 1998). Neilson concluded that routine ultrasound in early pregnancy results in better gestational age estimation, earlier detection of multiple pregnancies and earlier detection of foetal abnormalities. This results in fewer post-term pregnancies and a reduced incidence of induction of labour for post-datism in the ultrasound-screened groups. Neilson found that ultrasound does

not result in reduction of perinatal mortality or morbidity rates.

High priority therefore cannot be placed on the provision of routine second-trimester ultrasound scanning in developing or poorly resourced countries. Certainly, it is unlikely that such a service would save lives to any significant degree. Even prenatal detection of foetal abnormalities is rarely life-saving. A good argument can, however, be made for ultrasound scanning to be offered in the second trimester to women with uncertain menstrual histories. This may facilitate management of pregnancy and assist in deciding on the timing of inductions of labour or elective Caesarean sections where indicated.

This study has certain limitations. The sample size was not large enough to provide conclusive results on the beneficial effect of early prenatal ultrasound on important outcomes such as morbidity in twin pregnancies, perinatal death or congenital abnormalities. Small but statistically significant differences may have been missed. This study did not include addressing the issue of routine ultrasound screening for aneuploidies. The failure to achieve follow-up in almost 16% of enrolled women may be problematic. However, the women lost to follow-up did not differ significantly in baseline data from those followed up successfully. Drop-outs were expected in this study, as the community served has a large migrant component with many families having two homes, one in the study area and another in rural areas. A factor not investigated in this study was the possibility of maternal psychological benefit or harm related to second-trimester ultrasound screening.

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