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Instrumental delivery and ultrasound : a multicentre randomised controlled trial of ultrasound assessment of the fetal head position versus standard care as an approach to prevent morbidity at instrumental delivery

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Objective To determine whether the use of ultrasound can reduce the incidence of incorrect diagnosis of the fetal head position at instrumental delivery and subsequent morbidity.

Design Two-arm, parallel, randomised trial, conducted from June 2011 to December 2012.

Setting Two maternity hospitals in the Republic of Ireland.

Sample A cohort of 514 nulliparous women at term (≥37 weeks of gestation) with singleton cephalic pregnancies, aiming to deliver vaginally, were recruited prior to an induction of labour or in early labour.

Methods If instrumental delivery was required, women who had provided written consent were randomised to receive clinical assessment (standard care) or ultrasound scan and clinical assessment (ultrasound). [Correction added on 17 April 2014, after first online publication: Sentence was amended.]

Main outcome measure Incorrect diagnosis of the fetal head position.

Results The incidence of incorrect diagnosis was significantly lower in the ultrasound group than the standard care group (4/257, 1.6%, versus 52/257, 20.2%; odds ratio 0.06; 95% confidence interval 0.02–0.19; $P < 0.001$). The decision to delivery interval was similar in both groups (ultrasound mean 13.8 minutes, SD 8.7 minutes, versus standard care mean 14.6 minutes, SD 10.1 minutes, $P = 0.35$). The incidence of maternal and neonatal complications, failed instrumental delivery, and caesarean section was not significantly different between the two groups.

Conclusions An ultrasound assessment prior to instrumental delivery reduced the incidence of incorrect diagnosis of the fetal head position without delaying delivery, but did not prevent morbidity. A more integrated clinical skills-based approach is likely to be required to prevent adverse outcomes at instrumental delivery.

Keywords Fetal head position, intrapartum ultrasound, randomised controlled trial, second stage of labour.

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Introduction

Most first-time mothers are aiming for an uncomplicated vaginal birth, but many experience complications in labour, resulting in instrumental delivery or caesarean section. In these circumstances, the obstetrician is aiming to assist by the safest means possible, cognisant that the mode of delivery and related morbidities will have implications for future deliveries.[1,2] Operative delivery rates vary greatly between operators, institutions, and countries, particularly for first-time mothers. In the USA, the overall caesarean section rate was 32.8% in 2010, and the instrumental

delivery rate was 3.6%.[3] In the UK and Ireland, caesarean section rates vary between 20 and 30%, with instrumental delivery rates varying between 12 and 17%.[4,5] Rates of instrumental delivery are highest among first-time mothers, accounting for up to 30% of births. The caesarean section rate continues to rise globally. It has been suggested that greater skill in instrumental delivery could reduce caesarean section rates, particularly for complex caesareans performed in the second stage of labour.[6,7]

Instrumental delivery is associated with an increased risk of maternal and neonatal morbidity, but with skilled care the risks are low.[2,8–10] Correct diagnosis of the fetal head position is a prerequisite for safe instrumental delivery.[11,12] Diagnosis of a fetal malposition will influence the level of skill required of the operator, the choice of instrument, the place of delivery, and the mode of delivery. Serious maternal and neonatal trauma is associated with excessive pulls, the sequential use of instruments, and caesarean section after a failed attempt at instrumental delivery.[2] Failure to identify a malposition (especially an occipito-posterior position) is one of the factors that increases the likelihood of failed instrumental delivery and neonatal trauma.[13–19]

The fetal head position is diagnosed on vaginal examination by delineating the suture lines of the fetal skull and fontanelles; however, accurate clinical diagnosis can be unreliable, varying between 20 and 75%.[20–29] The use of abdominal ultrasound to enhance the diagnosis of the fetal head position has been described in a number of small studies, but only two have evaluated the role of ultrasound at instrumental delivery.[21,26,27,29–31]

We aimed to compare ultrasound assessment of the fetal head position prior to instrumental delivery with standard care to determine whether the use of ultrasound can reduce the incidence of incorrect diagnosis of the fetal head position. We postulated that a routine ultrasound scan in addition to clinical examination would reduce the incidence of incorrect diagnosis of the fetal head position, and delivery-related maternal and neonatal morbidity.

Methods

The instrumental delivery and ultrasound (IDUS) trial was a two-arm, parallel, randomised controlled trial.

Population

We recruited women from two university teaching hospitals in Ireland, with a combined annual birth rate of 13 500 deliveries (40% nulliparous; overall instrumental delivery rate 18%; 33% for nulliparous women). In these units, instrumental deliveries are carried out by obstetricians of varying experience, with a consultant supervising the labour ward onsite during the day and offsite during the night. Nulliparous women at term (at least 37 completed weeks of gestation) with singleton cephalic pregnancies, aiming to deliver vaginally, were eligible to participate. We excluded women under 18 years of age, with limited understanding of English, or with a contraindication to instrumental delivery. Eligible women provided written consent prior to induction of labour or in early labour. Obstetricians could exclude women at their discretion where there was immediate urgency as a result of fetal compromise.

Intervention and comparison

We compared clinical and ultrasound assessment of the fetal head position with standard care (clinical examination alone).

Outcome measures

Primary outcome

The primary outcome measure was incorrect diagnosis of the fetal head position. We debated whether to use maternal and/or neonatal morbidity as the primary outcome, but chose incorrect diagnosis of the fetal head position as this relates directly to the trial intervention, rather than morbidity, which may result from many factors on the clinical pathway, from decision for instrumental delivery to completed delivery. The primary outcome was established in two ways. If the position of the fetal head before delivery was classified as occiput anterior (OA) and was then delivered occiput posterior (OP), the diagnosis was considered incorrect. Furthermore, the midwife or neonatologist who attended the delivery examined the neonate and recorded the markings of the instrument on a drawing of the head and face (Appendix S2). The recorded markings were used to indicate misplacement of the instrument at a distance from the flexion point (vacuum) or over the face (forceps), with the diagnosis being considered incorrect if the markings were more than 45° from the documented fetal head position. For example, if the recorded position prior to instrumental delivery was OA and the instrument placement suggested an occiput transverse (OT) or OP position, the diagnosis was considered incorrect. The primary outcome was validated independently by a single investigator (DJM) who was not involved in scanning, and who was blinded to trial allocation.

Secondary outcomes

Maternal morbidity outcomes included extensive perineal tearing involving the anal sphincter (third- or fourth-degree tears), postpartum haemorrhage (estimated blood loss >500 ml), shoulder dystocia, and length of postnatal hospital stay (prolonged if more than 3 days in duration). Neonatal morbidity outcomes included trauma, fetal acidosis (defined as arterial pH below 7.10 and base excess

greater than −12.0 mmol/l), and admission to the neonatal intensive care unit (NICU). Neonatal trauma included cephalhaematoma, intracranial haemorrhage, retinal haemorrhage, facial nerve palsy, brachial plexus injury, and fractures. Mothers and neonates were followed up for complications until hospital discharge.

Procedural outcomes were recorded in terms of the decision to delivery interval (i.e. the time from making the decision to intervene until the delivery of the infant), place of delivery, need for senior obstetric support, transfer to theatre, use of sequential instruments (more than one instrument), failure of instrumental delivery followed by caesarean section, or immediate caesarean section.

Trial procedures

After the decision to perform an instrumental delivery had been made, eligible women who had provided written informed consent were randomly assigned to either clinical examination and an ultrasound scan or clinical examination alone (standard care). Women allocated to standard care were assessed by abdominal and vaginal examination according to the guidelines of the Royal College of Obstetricians and Gynaecologists (RCOG).[32] Following clinical examination, the fetal head position was recorded by way of a cross on a data sheet depicting a circle, like a clock, divided into eight sections, each of 45° (Appendix S1). The position was classified as: OA for direct occipito-anterior, and ROA and LOA for right and left occipito-anterior, respectively; OP for direct occipito-posterior, and ROP and LOP for right and left occipito-posterior, respectively; and ROT and LOT for right and left occipito- transverse, respectively. The obstetrician then proceeded to instrumental delivery as usual.

Women in the ultrasound group were managed in the same way. In addition, the researcher performed an ultrasound scan to assess the position of the fetal head and spine. The obstetrician was provided with the ultrasound findings and used this information together with the clinical findings to define the position prior to instrumental delivery. Where there was discordance between the clinical and scan findings, the researcher recorded whether or not the ultrasound finding was accepted.

Two researchers (MR and PVO) were trained in ultrasound assessment by a subspecialist in fetal and maternal medicine before the start of the trial.[29] Image-directed pulsed Doppler equipment (Sonosite Titan) with a multifrequency sector array transabdominal transducer, and a 3.5–MHz sector ultrasound probe, was used for all ultrasound scans. The ultrasound probe was placed transversely over the maternal abdomen to identify the fetal spine, and then moved towards the pubic region to obtain a view of the fetal head. The landmarks of the fetal head used to identify and classify the position were as follows: midline cerebral echo, falx cerebri, thalamus, the orbits, and the nuchal region (Figure 1).

Randomisation

Women were assigned to the study groups in a 1:1 ratio using a secure web-based central randomisation service, ensuring concealment of allocation. The allocation sequence was computer generated, stratified by centre, and used random permuted blocks of 4, 8, and 12 women.

Study oversight

An independent trial steering committee (TSC) was set up to provide oversight of the study. We received institutional ethics approval and written informed consent from each woman. The study was conducted in accordance with the protocol.[32] The TSC advised us that a separate data-monitoring committee was not required as serious adverse events in this trial were likely to be inherent complications of the procedure (instrumental delivery), and were unlikely to be related to the intervention (ultrasound).

Statistical analysis

The incidence of incorrect diagnosis of fetal head position for the standard care group was estimated as 20% based on the published literature, and we sought to detect an absolute between-group difference of 10%, which we regarded as sufficient to change practice.[21–30] With 80% power and 5% two-sided alpha, a total sample size of 450 for analysis was required. We inflated the target sample to 500 to allow

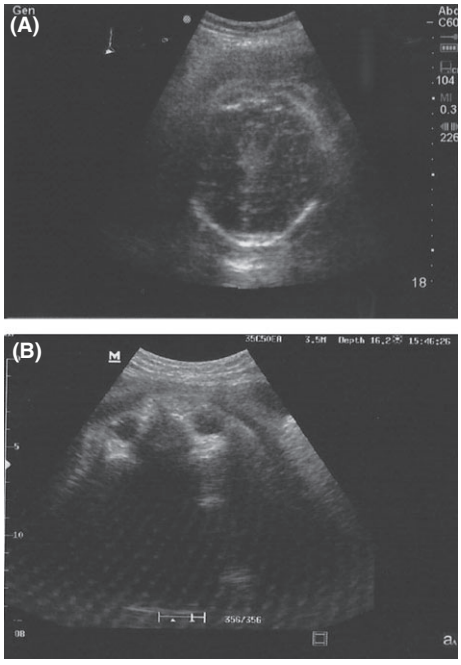

Figure 1. Fetal head positions: (A) direct occipito-anterior; (B) direct occipito-posterior.

for up to 10% non-collection of primary outcome data, for example in spontaneous vaginal deliveries after randomisation but before diagnosis.

We used descriptive statistics to assess the comparability of the trial groups at baseline. All between-group comparisons were conducted on an intention-to-treat basis without imputation: that is, all participants were analysed according to their randomised groups, and complete data collection for all outcomes meant that no imputation of missing data occurred. We used appropriate, that is logistic or linear, multivariable regression models to estimate between-group differences in the primary and secondary outcomes, adjusted for centre as a stratification variable. In sensitivity analyses of the primary outcome we investigated the effect of further adjustment for any variables that were imbalanced at baseline, and of clustering by operator, by using mixed-effects regression; however, the latter analysis had to be restricted to participants for whom the operator was known, as this was recorded in only one of the two study centres. In pre-planned subgroup analyses we investigated whether any effect of ultrasound on the primary outcome differed according to study centre or operator experience by including appropriate interaction terms in the regression models. All statistical analyses were conducted using SPSS 18 (SPSS Inc., Chicago, IL, USA) and STATA 12 (StataCorp, College Station, TX, USA).

Results

Study population

Between June 2011 and December 2012, we enrolled and randomised a total of 514 women: 257 to ultrasound and 257 to standard care. Figure 2 shows the participant flow.

Descriptive statistics

Baseline characteristics were similar between the two groups, with small differences in pathological cardiotocograph (CTG) and senior obstetrician (Table 1). There were 11 spontaneous vaginal deliveries in the ultrasound group and ten in the standard care group, after randomisation had occurred.

Primary outcome

The incidence of incorrect diagnosis of the fetal head position was significantly lower in the ultrasound group compared with the standard care group (ultrasound 4/257, 1.6%; standard care 52/257, 20.2%; adjusted odds ratio, aOR 0.06; 95% confidence interval, 95% CI 0.02–0.19; $P < 0.001$; Table 2). The results did not change when the following variables were taken into account: centre, pathological CTG, and senior obstetrician (aOR 0.06; 95% CI 0.02–0.16; $P < 0.001$). Further analyses that investigated whether the effect of the intervention differed according to individual operator clustering were not significant.

Subgroup analyses

There was a significant interaction seen between ultrasound and study centre. The benefit of ultrasound to reduce the incorrect diagnosis was greater in the first centre (OR 0.03 in first centre versus OR 0.41 in second centre; interaction co-efficient 13; 95% CI 1.5–120). This finding is probably linked to the overall lower rates of incorrect diagnoses in the Limerick centre, where more senior obstetricians performed the delivery and where vacuum deliveries were predominantly performed in some cases, making incorrect diagnosis more difficult to establish.

Secondary outcomes

The incidence of maternal and neonatal complications was not significantly different between the two groups (Table 3). There were three neonates who required neurological follow-up at discharge in both groups. There was one neonatal death in the ultrasound group from congenital cardiac anomalies. The mean time taken to perform the ultrasound scan was 30 seconds (range 5–120 seconds, SD 22 seconds; Table 4). The decision to delivery interval was no longer in the ultrasound group (ultrasound mean 13.8 minutes, SD 8.7 minutes, versus standard care mean 14.6 minutes, SD 10.1 minutes; difference in means −0.78 minutes; 95% CI −0.85 to 2.42 minutes; $P = 0.35$). The choice of primary instrument used for delivery was similar in the ultrasound and standard care groups. There was no significant difference in the number of sequential instruments used or number of caesarean sections after failed instrumental delivery (Table 4). There was weak evidence of an association in the ultrasound group with less immediate caesarean sections (2/257, 0.8%, versus 8/257, 3.1%; OR 0.24; 95% CI 0.05–1.16; $P = 0.07$). Overall, the ultrasound scan diagnosis was accepted in 242/257 (94.2%) cases and not accepted in 9/257 (2.5%) cases (unrecorded in six cases). There was significant maternal and neonatal morbidity in one case, where the ultrasound diagnosis of a fetal malposition was not accepted.

Discussion

Main findings

The results of this multicentre randomised trial show that an ultrasound assessment prior to instrumental delivery reduces the incidence of incorrect diagnosis of the fetal head position without delaying the delivery; however, enhanced diagnosis of the fetal head position did not reduce the incidence of maternal or neonatal complications, nor were there significant differences in instrument choice or mode of delivery between the two groups.

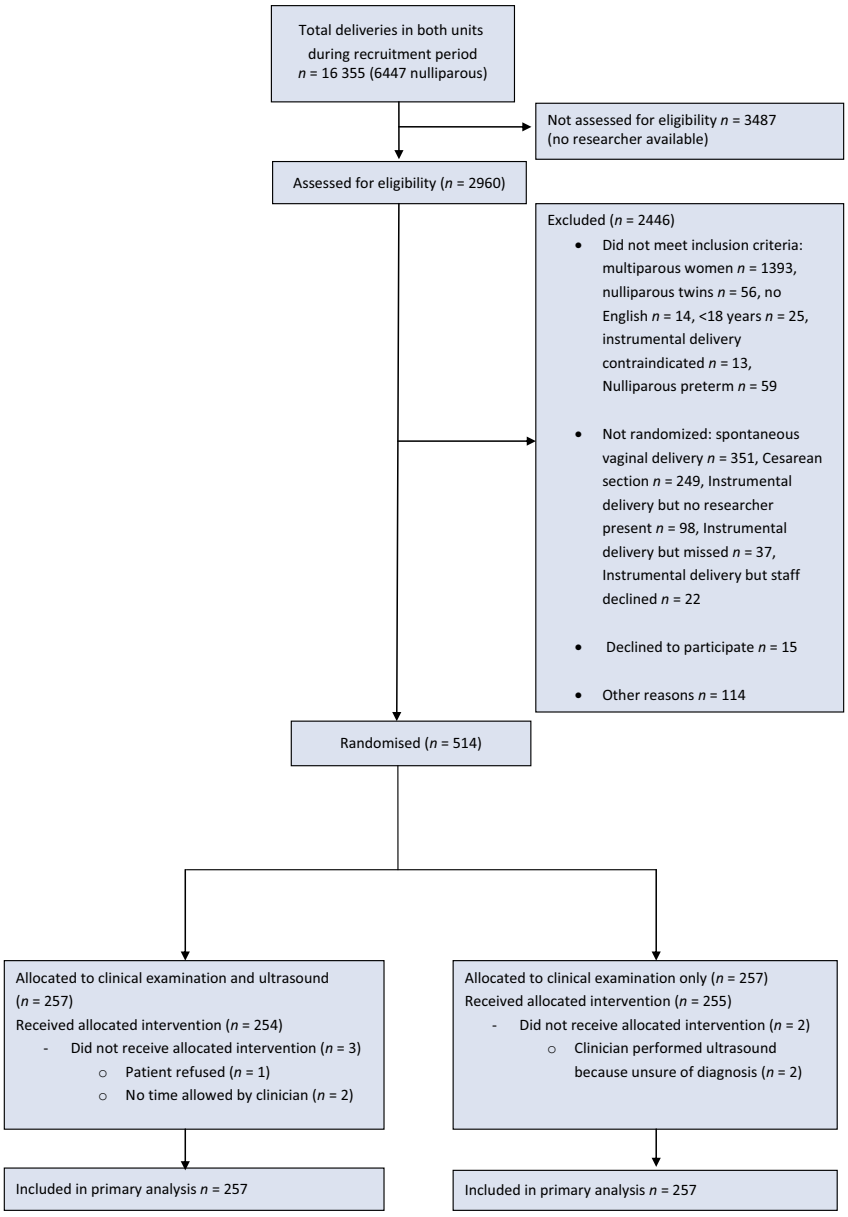

Figure 2. Enrolment and randomisation of study patients.

Strengths and limitations

The strengths of our trial include its large size, multicentre design, and the high compliance with group allocation after randomisation. The study population included a range of nulliparous women with varying body mass index, different types of anaesthesia, and the full range of indications for instrumental delivery, including fetal distress. Operators at all levels of experience were included. The results are generalisable to other centres where instrumental deliveries are performed.

The limitations of this trial should be considered. Although the researchers attempted to capture a variety of deliveries throughout the day and night, the majority of women were recruited during 'regular' working hours. We may have missed deliveries at night-time, when less experienced obstetricians managed complex cases with indirect supervision. Furthermore, it was challenging in some cases to differentiate between the incorrect diagnosis of the fetal head position and suboptimal instrument placement, particularly in cases of vacuum delivery. It is possible that the rate of incorrect diagnosis was even higher in the standard care group. We had considered an alternative study design in which we would perform an ultrasound scan on every woman and randomise to reveal or conceal the findings for

Table 1. Maternal, neonatal, and labour baseline characteristics

	Ultrasound (n = 257)	Standard care (n = 257)
Maternal		
Maternal age >35 years	20 (7.8)	19 (7.4)
Body mass index (BMI) ≥30.0 kg/m^2*	28 (11.0)	28 (11.4)
Smoker	28 (10.1)	21 (8.2)
Pre-eclampsia	5 (2.0)	4 (1.6)
Diabetes (type I or II, or gestational)	10 (1.2)	6 (0.8)
Neonatal		
Gender male	135 (52.5)	125 (48.6)
Head circumference >37.0 cm	33 (12.8)	29 (11.3)
Birthweight ≥4.0 kg	38 (14.8)	41 (16.0)
Birthweight <2.5 kg	3 (1.2)	2 (0.8)
Labour		
Induction of labour	129 (50.2)	129 (50.2)
Second stage of labour >2 hours**	125 (48.6)	142 (55.3)
Meconium-stained liquor	54 (21.0)	56 (21.8)
Senior obstetrician***	78 (30.4)	87 (33.9)
Pathological CTG in second stage of labour****	167 (65.0)	155 (60.3)
Primary indication for delivery—suspected fetal compromise	180 (70.0)	175 (68.1)
Regional analgesia	228 (88.7)	228 (88.7)
Local analgesia	18 (7.0)	14 (5.4)
Fetal head malposition: occipito posterior*****	48 (18.7)	39 (15.2)
Fetal head malposition: occipito transverse*****	66 (25.7)	70 (27.2)
Time of day: 08:00–17:00	149 (58.0)	159 (61.9)

Figures are represented as number (%).
*Body mass index measured as booking weight divided by the square of height (kg/m^2) (n = 255 in ultrasound group; n = 246 in standard care group).
**Included the passive and active phases of the second stage of labour.
***Senior obstetrician as primary operator: ≥3 years of specialist training (including consultants).
****Cardiotocograph (CTG) showing persistent late decelerations, tachycardia (>160 beats per minute) with decelerations, bradycardia (<100 beats per minute) for >10 minutes in second stage.
*****Fetal head position on clinical examination prior to delivery.

fetal head position. This was deemed unethical, as concealing a fetal malposition from an inexperienced operator could result in significant morbidity, and is flawed in terms of equipoise, as ultrasound would have been assumed to be more accurate than clinical examination. Although the study protocol was adhered to in both centres, we provided no direction on choice of instrument and there was a greater preference for vacuum delivery in the second centre. In cases of uncertainty we gave the operator the benefit of the doubt and classified the position as 'correct'. This is likely to account for the difference in the incidence of incorrect fetal head position between the two centres.

Interpretation

The incidence of incorrect diagnosis of the fetal head position by clinical examination alone was 20%, which is at the lower end of the published literature.[20–29] Most studies have compared ultrasound assessment and clinical examination earlier in labour rather than immediately before instrumental delivery. There may be less care taken with clinical examination earlier in labour, given that an accurate diagnosis is less critical to safety, unlike the case with instrumental delivery. Two small-scale studies had findings similar to ours.[21,31] A cohort study of 64 women reported an incorrect diagnosis rate of 27% for vaginal examination compared with ultrasound, with errors more likely with OP positions.[21] A randomised trial of 50 women undergoing vacuum extraction for prolonged second stage reported that cup placement was closer to the flexion point, and therefore more optimal, in the group assigned to ultrasound compared with vaginal examination only.[31]

The decision to delivery interval is an important consideration for instrumental delivery.[33] It was reassuring that the addition of an ultrasound scan as part of the assessment did not introduce a delay in delivery. Clinical guidelines highlight the greater risk of failed instrumental delivery with a fetal malposition, and recommend that recourse to caesarean section is available by transferring the patient to an operating theatre.[11] We were surprised that the enhanced diagnosis of fetal malpositions in the ultrasound group did not appear to influence management decisions, and equally that the higher rate of incorrect diagnoses in the standard care group did

Table 2. Primary outcome: intention to treat and sensitivity analyses

	Ultrasound n (%)	Standard care n (%)	aOR* (95% CI)	P	aOR** (95% CI)	P	Number needed to treat (95% CI)
Incorrect diagnosis of fetal head position	4/257 (1.6)	52/257 (20.2)	0.06 (0.02–0.19)	<0.001	0.06 (0.02–0.16)	<0.001	5 (5–6)

*Adjusted for study centre as a stratification variable.
**Adjusted for pathological CTG and senior obstetrician, in addition to study centre.

Table 3. Maternal and neonatal secondary outcomes

	Ultrasound (*n* = 257)	Standard care (*n* = 257)	OR (95% CI)	*P*
Maternal				
Postpartum haemorrhage (blood loss >500 ml)	49 (19.1)	43 (16.7)	1.16 (0.73–1.83)	0.53
Third- or fourth-degree perineal tear	10 (3.9)	7 (2.7)	1.42 (0.53–3.80)	0.49
Shoulder dystocia	9 (3.5)	13 (5.1)	0.67 (0.28–1.60)	0.37
Prolonged length of stay (>3 days)	52 (20.2)	42 (16.3)	1.29 (0.82–2.02)	0.27
Neonatal				
Neonatal trauma*	20 (7.8)	17 (6.6)	1.13 (0.57–2.22)	0.72
Apgar score <7 at 5 minute	0 (0.0)	2 (0.8)	NA	NA
Arterial pH <7.10/*n*	8/203 (3.9)	9/191 (4.7)	0.81 (0.31–2.16)	0.68
Admission to neonatal intensive care unit	31 (12.1)	30 (11.7)	1.05 (0.61–1.79)	0.87

Figures are represented as number (%).
*Excluding bruising and skin abrasions, and including facial nerve palsy, Erb's palsy, fractures, retinal haemorrhage, encephalopathy, and cephalhaematoma.

Table 4. Procedure-related secondary outcomes

	Ultrasound (*n* = 257)	Standard care (*n* = 257)	OR (95% CI)	*P*
Vacuum deliveries*	168 (65.4)	162 (63.0)	1.11 (0.77–1.59)	0.58
Forceps deliveries	76 (29.6)	77 (30.0)	0.98 (0.67–1.43)	0.92
Fetal head malposition: OP or OT**	114 (44.4)	109 (42.4)	1.04 (0.73–1.48)	0.83
Mean DDI in minutes (SD)***	13.8 (8.7)	14.6 (10.1)	−0.78 (−2.42 to 0.86)****	0.35
Transfer to theatre	19 (7.3)	29 (11.3)	0.64 (0.34–1.15)	0.15
Any caesarean section	12 (4.7)	18 (7.0)	0.65 (0.31–1.38)	0.26
Caesarean section after failed instrumental delivery	10 (3.9)	10 (3.9)	1.00 (0.41–2.45)	1.00
Caesarean section immediately	2 (0.8)	8 (3.1)	0.24 (0.51–1.16)	0.07
Sequential use of instruments	24 (9.3)	21 (8.2)	1.16 (0.63–2.14)	0.64
More than three pulls with instrument	34 (13.2)	23 (8.9)	1.54 (0.88–2.70)	0.13
Second operator involved in instrumental delivery	44 (17.1)	45 (17.5)	0.96 (0.60–1.52)	0.85

Figures are represented as number (%).
*Includes 'kiwi™' disposable device, and metal and silastic cups.
**Fetal head position on clinical examination prior to delivery: occipito-posterior (OP) or occipito-transverse (OT).
***Decision to delivery interval (DDI): the time between the decision to intervene and the delivery of the infant.
****Difference in means.

not affect the rate of sequential instruments or failed instrumental deliveries. These findings reflect the complexity of instrumental delivery. There are other factors such as engagement, station of the presenting part, fetal size, and maternal pelvic dimensions that may contribute to procedural decisions.[13] One potential explanation is that ultrasound enhanced the diagnosis of fetal malpositions but not the operators ability to deal with it. Given that enhanced diagnosis of the fetal head position had little impact on the management decisions made by operators, it is perhaps unsurprising that morbidity rates were similar in both groups. Of note, serious maternal and neonatal complications in this study were low, and were comparable with previous published data.[2,13] Future trials should incorporate the wider dimensions of clinical assessment and decision-making, as ultrasound-guided assessment of the fetal head position, although necessary, is insufficient in itself to prevent morbidity at instrumental delivery.

Clinical implications

The use of ultrasound on the labour ward is increasing with ready access to portable ultrasound equipment.[34] Our previous work demonstrated that abdominal ultrasound is acceptable to women in labour and to clinicians looking after them.[29] Furthermore, obstetric trainees can acquire the skills to perform an accurate ultrasound diagnosis of the fetal head position in labour within a short timeframe.[29,30] Given that knowledge of the fetal head position is a prerequisite for safe instrumental delivery, our findings suggest that ultrasound has an important role to play in getting this element of assessment right. The next stage is to establish how to translate enhanced assessment into better clinical decision-making. Among the secondary outcomes, the lower rate of transfers to theatre and immediate caesarean sections in the ultrasound group warrants further evaluation in a large, appropriately powered trial, but the potential benefits would need to be balanced with a higher risk of excessive pulls (more than three) at instrumental delivery.

Conclusion

Our findings support the use of ultrasound prior to instrumental delivery to identify the fetal head position, but also demonstrate that an imaging approach in isolation will not reduce morbidity. A more integrated clinical skills-based approach is likely to be required to enhance the safety of instrumental delivery, particularly when a fetal malposition has been identified.

Disclosure of interests

All authors have no financial connections with companies that may have an interest in the submitted work, and no non-financial interests that may be relevant to the article.

Contribution to authorship

DJM and GB had the original idea for the study. DJM, GB, MK, AM, and MR designed the trial. MR and PVO recruited women to the trial. MK and SATS provided ultrasound expertise during the trial design. MR and AM performed the analyses. MR and DJM drafted the article, which was revised by all of the authors. DJM is the guarantor.

Details of ethics approval

We received ethical approval from the Ethics Research Committee in the Coombe Women & Infants University Hospital on 5 October 2010, and from the Ethics Research Committee in the Mid-Western Regional Maternity Hospital, Limerick, on 9 August 2011. International Standard Randomised Controlled Trial Number (ISRCTN): 72230496.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Data recording sheet of clinical findings.

Appendix S2. Data recording sheet of instrument markings. ■

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