1. Title Page

The feasibility and accuracy of ultrasound assessment in the labour room.

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Short Title: Transperineal ultrasound in the labour room.

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Key Words: Transperineal; Fetal position; Head perineum distance; Caput; Cervical Dilatation; Partogram

3. Abstract

Objective

Vaginal examination is widely used to assess the progress of labour; however, it is subjective and poorly reproducible. We aim to assess the feasibility and accuracy of transabdominal and transperineal ultrasound compared to vaginal examination in assessment of labour and its progress.

Methods

Women were recruited as they presented for assessment of labour to a tertiary inner city maternity service. Paired vaginal and ultrasound assessments were performed in 192 women at 24-42 weeks. Fetal head position was assessed by transabdominal ultrasound defined in relation to the occiput position transformed to a 12 hour clock face; fetal head station defined as head-perineum distance by transperineal ultrasound; cervical dilatation by anterior to posterior cervical rim measurement and caput succedaneum by skin-skull distance on transperineal ultrasound

Results

Fetal head position was recorded in 99.7% (298/299) of US and 51.5% (154/299) on vaginal examination ($p<0.0001$*). Bland-Altman analysis showed 95% limits of agreement, -5.31 to 4.84 clock hours.

Head station was recorded in 96.3% (308/320) on VE and 95.9% (307/320) on US ($p=0.79$*). Head station and head perineum distance were negatively correlated (Spearman's $r=-0.57$, $p<0.0001$).

54.4% (178/327) of cervical dilatation measurements were determined on US and 100% on VE/speculum ($p<0.0001$). Bland-Altman analysis showed 95% limits of agreement -2.51 to 2.16cm.

The presence of caput could be assessed in 98.4% (315/320) of US and was commented on in 95.3% (305/320) of VEs, with agreement for the presence of caput of 76% ($p<0.05$). Fetuses with caput greater than 10mm had significantly lower head station ($p<0.0001$).

Conclusion

We describe comprehensive ultrasound assessments in the labour room that could be translated to the assessment of women in labour. Fetal head position is unreliably determined by vaginal examination and agrees poorly with US. Head perineum distance has a moderate correlation with fetal head station in relation to the ischial spines based on vaginal examination. Cervical dilatation is not reliably assessed by ultrasound except at dilatations of less than 4cm. Caput is readily quantifiable by ultrasound and its presence is associated with lower fetal head station. Transabdominal and transperineal ultrasound is feasible in the labour room with an accuracy that is generally greater than vaginal examinations.

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4. Manuscript Body

Introduction

Vaginal examination (VE) is used globally to assess the progress of labour, commonly defined graphically by Friedman[1] and later adapted as partograms by Philpott[2] and Studd[3]. The use of the partogram has been questioned on the basis that its application in labour does not affect outcomes[4]. Most recently, revised labour curves have been developed from a large observational dataset[5,6].

All the studies on the progress of labour have been based on digital vaginal examinations. Vaginal examination as a method of assessing the progress of labour is inherently subjective[7,8]. Head position is inaccurate in at least a third of vaginal examinations prior to instrumental delivery[9-11]. Clinicians agree on cervical dilatation in only approximately 50% of cases[12] and similarly fetal head station is poorly reliable[7]. It can also be uncomfortably invasive, particularly for those women with vaginismus, a history of sexual abuse[13], and female genital mutilation, in whom vaginal examination may be uncomfortable or impossible[14]. Repeat vaginal assessments have been implicated in ascending infection of the fetus and chorioamnionitis[15,16].

Knowledge of the progress of labour is fundamental to the practice of obstetrics and midwifery. Prolonged labour is an important cause of maternal and fetal death and disability, with post-partum haemorrhage and maternal infection as well as fetal asphyxia being more common in a long labour[17]. Long-term complications of prolonged labour include urinary incontinence[18].

There is a clear rationale for the development of a less intrusive and more reproducible measure of the parameters that describe labour[19]. In this context, transperineal and transabdominal intrapartum ultrasound has recently emerged as a non-invasive alternative to VE as it allows reproducible and objective assessment, and is by and large well tolerated[20,21].

Previous studies have generally been small[22,23], and have not assessed multiple parameters comparing VE and ultrasound. In this study, we aim to build on previous work in a larger prospectively recruited cohort by assessing the feasibility and accuracy of intrapartum ultrasound compared to VE in measuring fetal head position, head station, cervical dilatation and the presence of caput. To achieve this, for each of the 4 parameters measured we sought to determine both whether it is possible to reliably record the parameter on ultrasound, and how the ultrasound value relates to the value determined by traditional vaginal examination.

Materials and Methods

We performed a prospective observational study of women recruited at a tertiary inner city unit maternity service, between April 2015 and February 2017. Nulliparous and parous women at 24-42 weeks' gestation (single or multiple pregnancy) aged between 18 and 44 years were invited to participate in the study as they presented to maternity assessment unit and the delivery suite. Assessments were performed where clinically indicated most commonly to determine the onset of labour and its progress; they were not performed in the second stage of labour. Repeat measurements were undertaken if indicated. This feasibility study formed part of a larger study, the SONO-VE study which received Regional Ethics Committee approval; REC 15/LO/0227.

Women could only be recruited when a research midwife or doctor was present. A midwife or doctor performed a digital vaginal examination where indicated as part of the patient's normal care. Cervical dilatation, fetal head descent and position, and the presence of caput succedaneum were assessed. Fetal head descent was recorded according to the WHO classification of fetal head station, with the ischial spines as reference point 0, -5cm at the pelvic inlet and +5cm at the pelvic outlet[24]. Caput was quantified on VE as either absent, +, ++ or +++ as per normal clinical practice.

Ultrasound examinations were performed by a research doctor (SU) or midwife (HB) independent of the participant's care team. The clinicians were blinded to research ultrasound findings, and these findings were also not disclosed to patients. The research midwife or doctor was also blinded to the clinical findings.

Women were examined in the supine position with hips and knees flexed and with an empty bladder. Vaginal examinations and ultrasound were performed in between contractions. Fetal position was assessed with a transabdominal scan and recorded

in clock hours with 12 hourly divisions (Figure 1); ≥10 o'clock and ≤2 o'clock were classified as Occiput Anterior (OA), >2 o'clock and <4 o'clock were recorded as the left occiput transverse position, >8 o'clock and <10 o'clock were recorded as right occiput transverse position (Figure 2A), ≥4 o'clock and ≤8 o'clock were defined as occiput posterior position. The transducer was then covered with a glove, and placed between the labia majora at the level of the posterior fourchette in a transverse position. Head-perineum distance (HPD) (Figure 2B) and cervical dilatation (Figure 2C) were measured. The transducer was rotated 90° and caput succedaneum was measured in a sagittal view (Figure 2D) and on ultrasound as present if the measurement was >10mm[25]. For a vaginal examination and ultrasound examination to be considered paired, they were undertaken within 30 minutes.

A Samsung PT60A or Samsung HM70 (Samsung Medison, Seoul, Republic of Korea) were used for the ultrasound assessments using standard 2D transabdominal probe.

Statistical Analysis

Analysis was performed using Microsoft Excel, Graphpad Prism 7 and MedCalc online calculators. Comparisons were made of the proportions of VE and US measures of each parameter that were unrecorded.

Power Calculation

A recent study by our group[26] has shown that 95% of transperineal ultrasound parameters can be obtained, compared to 82% for digital vaginal examination parameters. With an alpha of 0.05 and a power of 90%, the minimum sample size for this study was 250 assessments[27]. As most (70%) of measurements were paired, the risk of bias was low and we did not adjust for dependence based on repeated measurements.

Fetal head and spine position

Sub-analysis was performed to determine whether position or cervical dilatation affects the ability to assess position on VE. Paired measures were compared using Bland-Altman analysis to determine agreement.

Station

Paired measures were analysed using linear regression and correlation to determine agreement, and a one-way ANOVA performed to determine if mean HPD differed significantly between stations on VE. US measures of caput were assessed as a potential confounding factor in VE measurement of station.

Cervical dilatation

Sub-analysis was performed to determine whether the degree of cervical dilatation affects the ability to measure on US. Paired measures were analysed using linear regression, correlation, and Bland-Altman analysis to determine agreement.

Caput

Correlation analysis was performed on paired measurements to determine agreement. Caput size on US was compared to VE measures of caput. The relationship of caput to fetal head station and position on US was also assessed using one-way ANOVA.

Results

The median age of the 195 women recruited for the study was 31 (range 18-44) years, and body mass index (BMI) was 24.1 (range 15.7-42.4) kg/m^2. 93% of women were nulliparous (range 0-3). Of 1266 parameters measured, there was no significant difference in the total number of unrecorded values on US and VE (168 vs 170, p=0.91* respectively). The median gestational age at study inclusion was 40 (range 24-42) weeks. 3 women were excluded as complete assessments were not performed, leaving 192 women for analysis (Table 1). Repeat assessments were performed in 135 (70%) women in labour. The median time from vaginal examination to ultrasound was 0 minutes (range 0, 30)

185

186 ***Fetal head position***

187 Of 299 assessments, fetal position was recorded in 99.7% cases (298/299) on US
188 compared to 51.5% of positions recorded on VE (154/299, p<0.0001*). A further 30
189 assessments were excluded from analysis because the US and VE were performed
190 >30mins apart, leaving a total of 123 paired assessments (Figure 3).

191 The difference between VE and US measures was smaller for OP than for other
192 positions (p=0.03*), whilst ROA position was recorded more frequently on VE than
193 other fetal head positions (p=0.03*). Greater cervical dilatation was associated with
194 increased proportion of positions recorded on VE; 26% at 0-3cm dilatation, 62% at 4-
195 6cm, to 83% at 7-10cm (p<0.0001*) although this did not affect the accuracy of the
196 assessment of position on VE (One-way ANOVA, p=0.69).

197 Bland-Altman analysis showed low agreement between the position measured on US
198 and VE (bias of -0.232, 95% limits of agreement -5.31 to 4.84 clock hours) (Table 2,
199 Fig. 4).

200 ***Fetal Head Station***

201 Of 320 assessments, 96.3% (308/320) of stations were recorded on VE and 95.9%
202 (307/320) of HPD were determined on US (p=0.79*).

203 Of the 13 assessments unrecorded on US, the reasons for this were: 1 due to fetal
204 distress, 1 patient declined a transperineal scan, and 1 scan was of poor quality and
205 10 were due to the fetal head being too high to visualise at the extreme limit of probe
206 depth (typically around 7 cm). All patients where the fetal head was so high as to be

not measurable proceeded to emergency caesarean section; 1 case had cord prolapse and 1 shoulder presentation..

A further 76 assessments were excluded from analysis because the US and VE were performed >30mins apart, leaving a total of 219 paired assessments (Figure 5).

Station and HPD were negatively correlated (Spearman's r=-0.57, p<0.0001). 1- way ANOVA showed significant differences in mean HPD between stations of -2/-1 and -1/0 (p<0.01 and p<0.001 respectively) (Figure 6).

Cervical dilatation

A total of 327 assessments were undertaken, of those in 7 examinations, speculum was used as a preferred method to determine dilatation, this was determined by the clinician and was performed as per hospital policy in cases of early and preterm labour and pre-labour rupture of membranes. 54.4% (178/327, p<0.0001 (x^2)) of cervical dilatations were determined on US, compared to 100% on VE/speculum. A total of 135 paired assessments were analysed; 43 assessments were excluded because the US and VE were performed >30mins apart (Figure 7).

Dilatation on VE and US were positively correlated (linear regression, r^2 = 0.66, Spearman's r=0.85 (p<0.0001)). Measuring cervical dilatation on ultrasound became more difficult with increasing dilatation, with successful imaging at: 0-3cm (78%), 4-6cm (57%) and 7-10cm (11%). Bland-Altman analysis showed larger differences at wider dilatations, with a bias of -0.173 and 95% limits of agreement -2.51 to 2.16cm (Table 3, Figure 8). Including only dilatations ≤6cm on VE, the limits of agreement are reduced to -1.96 to 1.89cm (Figure 8).

Caput

Of 320 assessments, in 15 (4.7%) the presence or absence of caput was not determined on VE and 5 (1.6%) on US ($p<0.05$*). A further 81 assessments were excluded from analysis because the USS and VE were performed >30mins apart, leaving 219 paired assessments (Figure 9).

Taking HPD as the distance to fetal scalp rather than skull (accounting for caput), the relationship between HPD and station on VE became stronger (linear regression slope, -5.25 ± 0.481 to -8.36 ± 0.772, $p=0.0007$) where we would expect the perfect slope to be -7.5. The Spearman's R for Station in relation to HPD was -0.58 ($p<0.0001$), and accounting for caput -0.57 ($p<0.0001$). Of the 5 caput measurements unrecorded on ultrasound, 3 were due to technical issues, 1 scan was not performed due to fetal distress and 1 due to patient declining a transperineal scan.

US and VE measures were positively correlated (Spearman's $r=0.574$ ($p<0.0001$)), and agreed on the presence of caput 76% of the time (166/219). There was a significant difference in caput size on US where caput was detected on VE and where it was not detected (16.4mm vs. 6.6mm respectively, $p<0.00001$†). Where caput was detected on US, there was no significant difference in mean caput size on US (16mm vs. 14.5mm respectively, $p=0.20$†) based on whether or not caput was detected on VE.

Caput and HPD were negatively correlated (Pearson $r=-0.279$, $p<0.0001$). Lower head stations were found in those fetuses with caput (mean HPD of 44.9m, n=109) than those without (mean HPD 49.7mm, n=118), ($p<0.0001$†). Mean caput size was

254 significantly smaller at stations where HPD>50mm than if HPD was 35-50mm
255 ($p<0.01$†). There was no significant relationship between head position measured in
256 clock hours and caput size (One-way ANOVA, $p=0.49$).

257 * χ^2 test †Unpaired t-test

258

Discussion

Key Findings

In this study, data completeness overall was similar for VE and US, suggesting that neither technique has overall superiority over the other.VE is particularly poor at determining fetal head position, with low accuracy that is not improved on increasing cervical dilatation. Ultrasound is useful in assessing the cervix in early labour, although less effective in the active stage of labour (>4cm dilatation). For head station, VE is particularly subjective and is significantly affected by the presence of caput.

A previous proof-of-concept pilot study in 20 women on which the current study is based described the 'sonopartogram', an ultrasound based alternative to the traditional partogram , with 95% of sonopartogram assessments successful compared to 82% of conventional partogram assessments[26].

Ultrasound is more accurate than vaginal examination in determining fetal head position[28,29]. For fetal head station, several different ultrasound measurements have been proposed as a surrogate for clinical station, including head-perineum distance (HPD)[30], head-symphysis distance (HSD)[31] and angle of progression (AoP)[32]. The use of ultrasound to assess cervical dilatation[33] and caput succedaneum has been reported[25].

Fetal Head Position

A key finding was that almost half fetal head positions were not recorded on vaginal examination and of those assessed, the agreement was very poor confirming previous studies[34]. Head position is much more readily determined on transabdominal ultrasound. The 95% limits of agreement, based on clock-face hours, show that head position on ultrasound bears almost no relation to position determined by vaginal

examination. Since ultrasound has previously been established as more accurate than VE in determining position[9,35] we can conclude that VE is less reliable in determining head position..

An important observation is that a more dilated cervix appears to facilitate the assessment of fetal head position on VE though this does not result in a greater accuracy.

Previous findings are that the 'number needed to treat' for transabdominal ultrasound in diagnosing incorrect position on VE in the second stage of labour is 5[11]. This is not surprising as the objectivity of ultrasound combined with its greater feasibility in assessing fetal head position suggests that it should be regarded as the gold standard technique.

Station

There was no difference in the ability to assess fetal head station on ultrasound and vaginal examination. Head-perineum distance was chosen over other measures of head station due to the ease of measurement, and its validated potential in predicting outcomes[36].

There was a moderate negative correlation between US measured HPD and head station from VE. This could be interpreted as a limitation of transperineal ultrasound if clinical station is considered the gold standard, however the inter- and intra-observer variability of digital vaginal examination[7] means it may not reflect the true fetal head station. The advantage of ultrasound remains in its objectivity and ability to be recorded.

The imprecision of clinically determined head station is illustrated in our analysis of the effect of caput, which showed a stronger relationship between clinical station and

scalp-perineum distance than skull-perineum distance (in other words taking the ultrasound measured depth of caput into account). Thus, caput significantly affects the clinician's understanding of head station on vaginal examination. This relationship suggests the clinician tends to measure head station from the ischial spines to the fetal scalp, rather than to the skull, and so may not give an accurate representation of the true fetal descent. HPD measured on transperineal ultrasound offers an objective adjunct to vaginal examination in determining head station, if not an alternative.

An interesting and potentially clinically important finding was that in all patients where the fetal head station was too high to measure using transperineal ultrasound (10 cases >7cm), emergency caesarean sections were performed. It is tempting to speculate that if the head is too high to visualise on ultrasound, an earlier Caesarean section might avoid a prolonged labour and/or an acute emergency.

Cervical Dilatation

The cervix is more difficult to visualise on transperineal ultrasound than other parameters with almost half of assessments not recorded. The difficulty in visualising the cervix on ultrasound was particularly so at greater dilatations, being 7 times more likely to be recorded at <4cm than >7cm. An explanation for this may be that as the cervix effaces and the fetal head becomes more applied and it is more difficult to identify the different tissue planes using ultrasound. We chose to measure the Antero-Posterior (AP) diameter of the cervix as the transverse diameter may be more difficult to visualise[33].

The agreement between ultrasound and clinical measures of cervical dilatation was moderate, and 95% limits of agreement showing good concordance; however, a difference of >2cm between measures is significant enough to affect clinical decision

making. It is interesting to note that it has previously been determined that assessment of cervical dilatation on vaginal examination is also less accurate at greater dilatations [22].

Caput Succedaneum

Transperineal ultrasound offers an advantage in assessing caput as it can be measured directly, rather than relying on subjective assessment of a boggy swelling of the fetal scalp.

The agreement between ultrasound measures of caput and VE assessment of the presence of caput was moderate, with a positive correlation and an agreement rate of 3 in 4. The detection of caput on vaginal examination reflected the presence of caput on ultrasound variably and where caput existed on ultrasound, its detection on vaginal examination was not related its ize. Consequently, detection of caput on VE seems to be imprecise, and thus ultrasound represents an advantage over VE.

Interestingly, we observed that the finding of caput on VE or US is most frequently detected at lower head station, and on US measures significantly larger at lower head stations (35-50mm) than higher stations (>50mm). This shows that caput tends to develop in more advanced labour, which raises the possibility that it is a normal feature of advancing labour rather than a sign of obstruction. Though previous studies have shown that caput is associated with a malposition[37], we found no association between head position and caput.

Strengths and Limitations

We report the largest number of assessments of any study to date assessing intrapartum ultrasound. An important strength of this study is the blinding of the clinical team to the ultrasound findings and the research team to the vaginal examination

findings, thus the findings on vaginal examination and subsequent management did not influence the research findings or vice versa. The ultrasound examinations were performed by 2 operators, an obstetrician and a research midwife, which ensured consistency whilst also avoiding the possible bias of a single operator.

A limitation is that data was collected from a single unit and the majority of the women were nulliparous. However, the cohort is large and ethnically diverse, which improves the prospect of generalisability. Also, many assessments were excluded as the US scan and VE were performed >30 minutes apart; thus reflecting the nature of a study in an acute setting.

Conclusions

Ultrasound measurements of fetal head position, station and caput succedaneum have advantages over traditional vaginal examination in terms of both their non-intrusive nature and accuracy. Fetal head position, station and caput are most easily and reproducibly assessed with ultrasound but cervical dilatation less so. These findings underline the possible adjunctive nature of ultrasound assessment rather than arguing for the feasibility of replacing VE entirely.

More accurate and reproducible examinations could for the first time allow the development of a predictive model for labour outcome; our group has described a proof of principle study in predicting vaginal delivery for nulliparous women in the first stage of labour[39]. Such models are ubiquitous in for example screening for trisomy 21 and ovarian tumours[38]. Importantly however, ultrasound assessments can already allow obstetricians to reassure women in normal labour about their progress, without performing unnecessary and intrusive interventions.

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6. Tables

Table 1: Demographics Table (n=195)

Age (years)	Median 31 Range 18-44
BMI (kg/m^2)	Median 24.1 Range 15.7-42.4
Parity Nulliparous	 181/195 (93%)
Gestational Age (weeks)	 Median 40 Range 24-42
Ethnicity White Asian Black Other Mixed	n (%) 101 (52) 57 (29) 21 (11) 9 (5) 5 (3)
Mode of Delivery	n (%)
Emergency Caesarean Section Unassisted Vaginal Delivery Ventouse Forceps Elective Caesarean Section Breech Extraction	65 (33) 63 (32) 36 (18) 30 (15) 1 (0.5) 1 (0.5)

Table 2: Bland-Altman Fetal Position (clock hours)

Bias	-0.232
SD of bias	2.59
95% Limits of Agreement	
From	-5.31

To	4.84

Table 3: Bland-Altman Dilatation (cm)

Bias	-0.173
SD of bias	1.19
95% Limits of Agreement	
From	-2.51
To	2.16

7. Figure Legend(s)

Figure 1. Schematic illustrating the recording of fetal position in clock hours.

Abbreviations: OA – Occiput Anterior; LOA – Left Occiput Anterior; LOT – Left Occiput Transverse; LOP – Left Occiput Posterior; OP – Occiput Posterior; ROP – Right Occiput Posterior; ROT – Right Occiput Transverse; ROA – Right Occiput Anterior.

Figure 2. Transabdominal US was used to determine fetal head position (A), whilst transperineal US was used to determine HPD (B), cervical dilatation (C) and to measure caput succedaneum (D).

Figure 3. Flow chart of fetal head position assessments.

Figure 4. Bland-Altman plot showing the agreement between ultrasound and vaginal examination measures of position. The bias is -0.232 clock hours, and the dashed lines represent the 95% limits of agreement.

Figure 5. Flow chart of fetal head station assessments.

Figure 6. A boxplot showing the distribution of head-perineum distance (HPD) values as measured on transperineal ultrasound for each head station as measured on vaginal examination (VE).

Figure 7. Flow chart of cervical dilatation assessments.

Figure 8. Bland-Altman plot showing the agreement between ultrasound and vaginal examination measures of cervical dilatation. The bias is -0.173cm and the dashed lines represent the 95% limits of agreement.

Figure 9. Flow chart of caput succedaneum assessments.

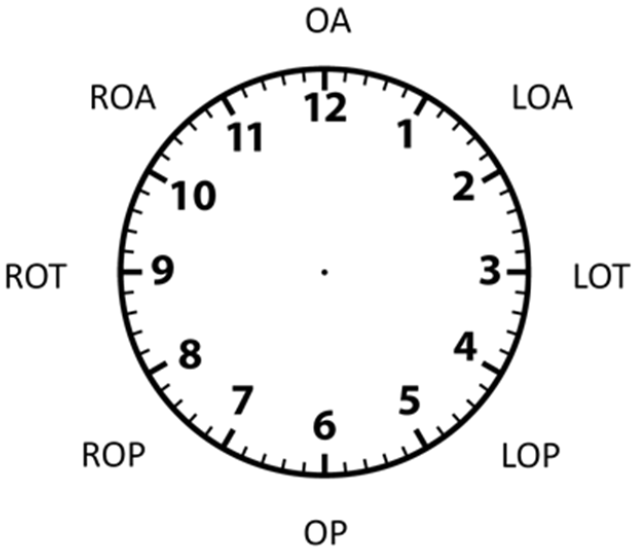

Figure 1: Schematic illustrating the recording of fetal position in clock hours with 12 hourly divisions; ≥10 o'clock and ≤2 o'clock were classified as occiput anterior, >2 o'clock and <4 o'clock were recorded as the left occiput transverse position, >8 o'clock and <10 o'clock were recorded as right occiput transverse position, ≥4 o'clock and ≤8 o'clock were defined as occiput posterior position.

Abbreviations: OA – Occiput Anterior; LOA – Left Occiput Anterior; LOT – Left Occiput Transverse; LOP – Left

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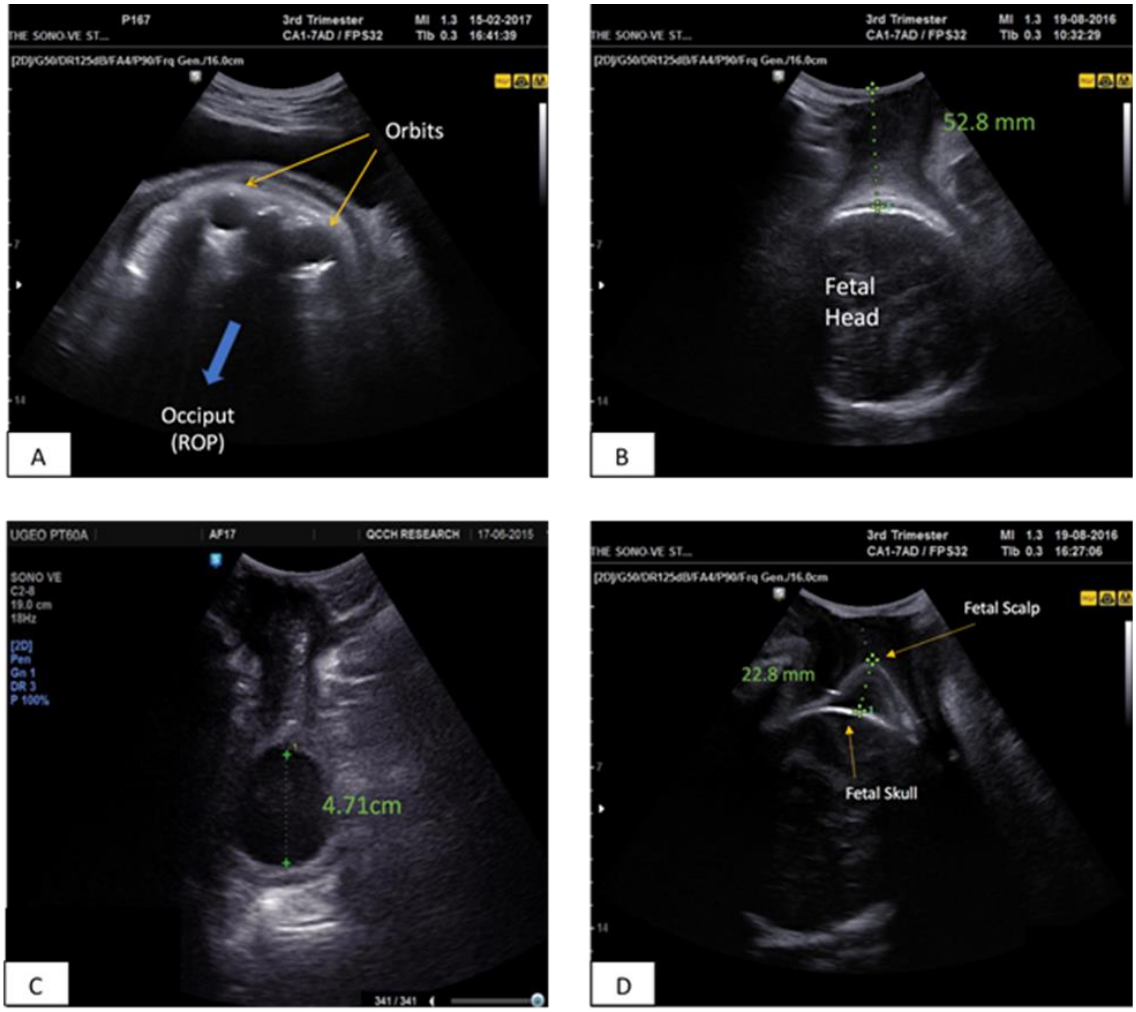

Figure 2: Transabdominal ultrasound was used to determine fetal head position (A), whilst transperineal ultrasound was used to determine Head Perineum Distance (HPD) (B), cervical dilatation (C) and to measure caput succedaneum (D).

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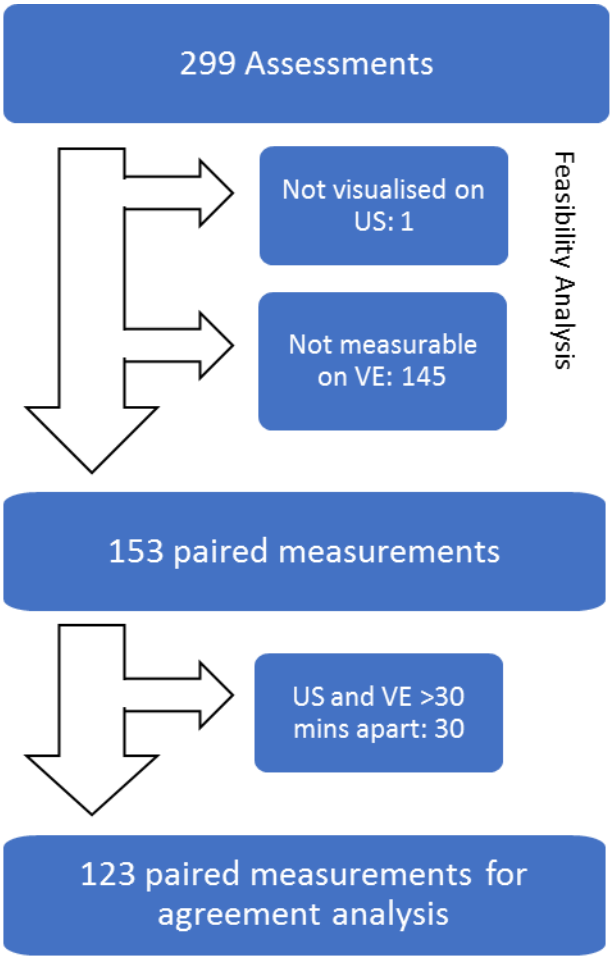

Figure 3. Flow chart of fetal head position assessments.

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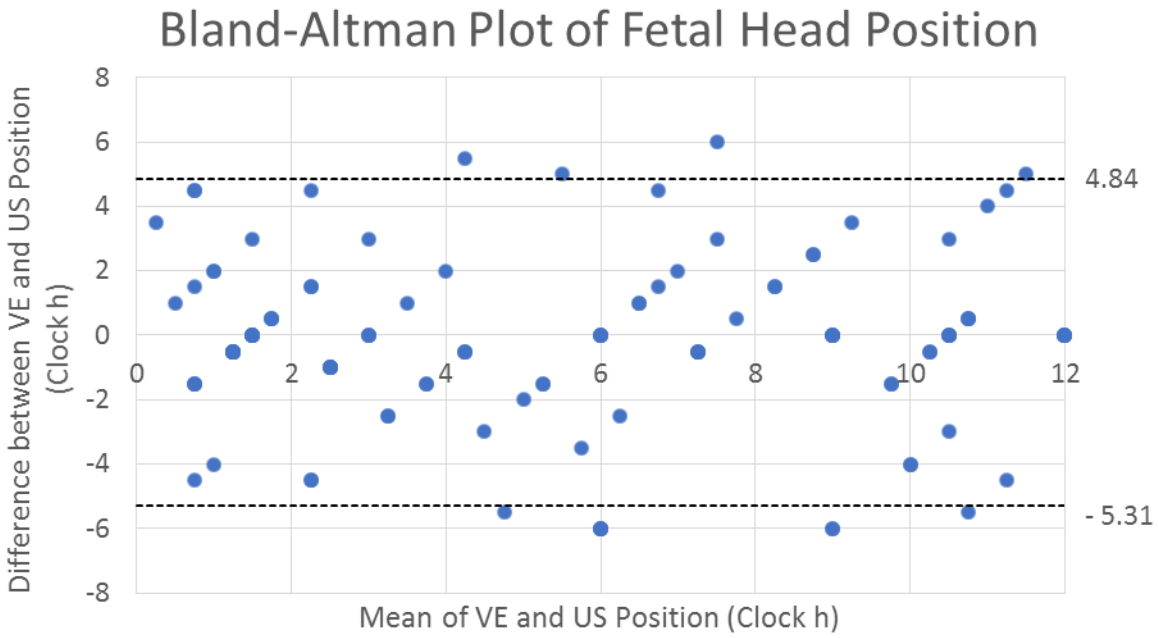

Figure 4. Bland-Altman plot showing the agreement between ultrasound and vaginal examination measures of position. The bias is -0.232 clock hours, and the dashed lines represent the 95% limits of agreement.

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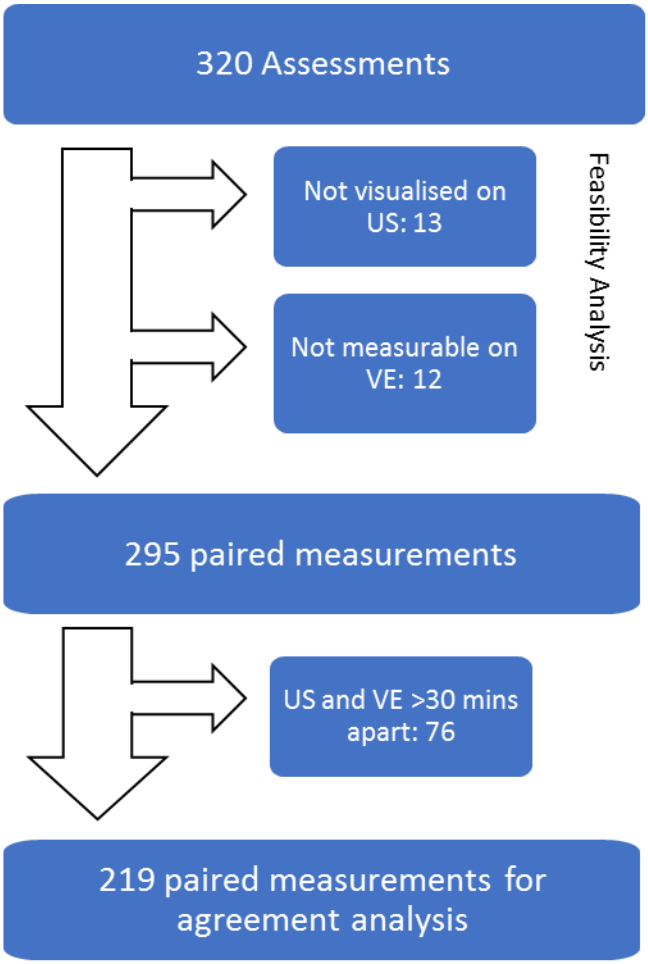

Figure 5. Flow chart of fetal head station assessments.

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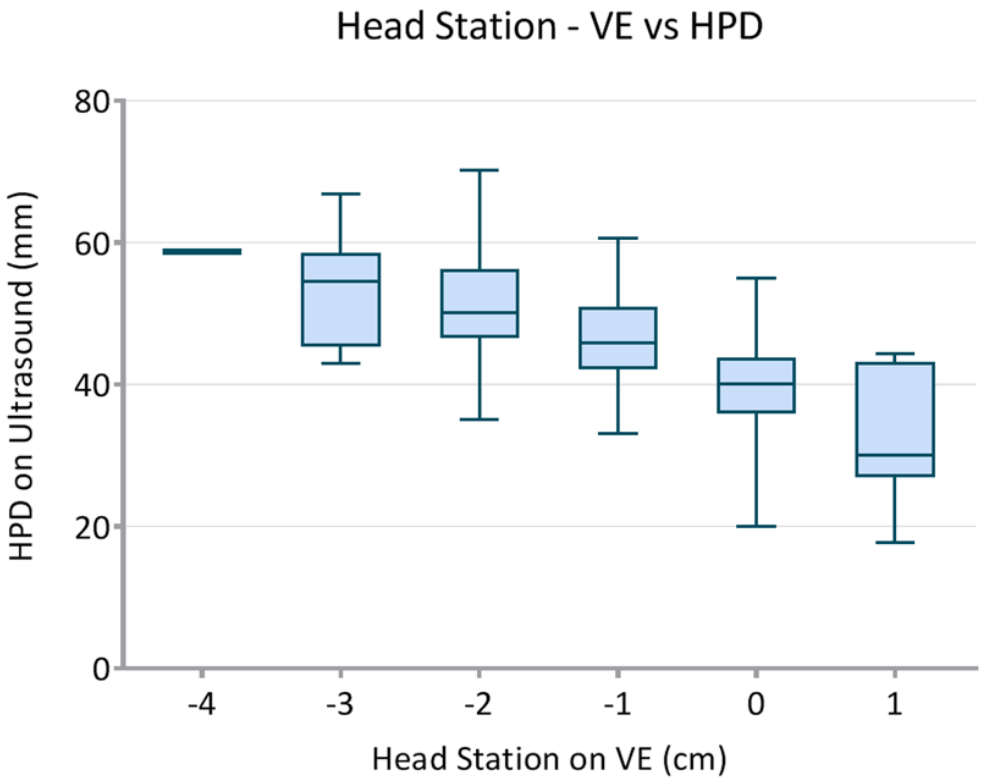

Figure 6. A boxplot showing the distribution of head-perineum distance (HPD) values as measured on transperineal ultrasound for each head station as measured on vaginal examination (VE).

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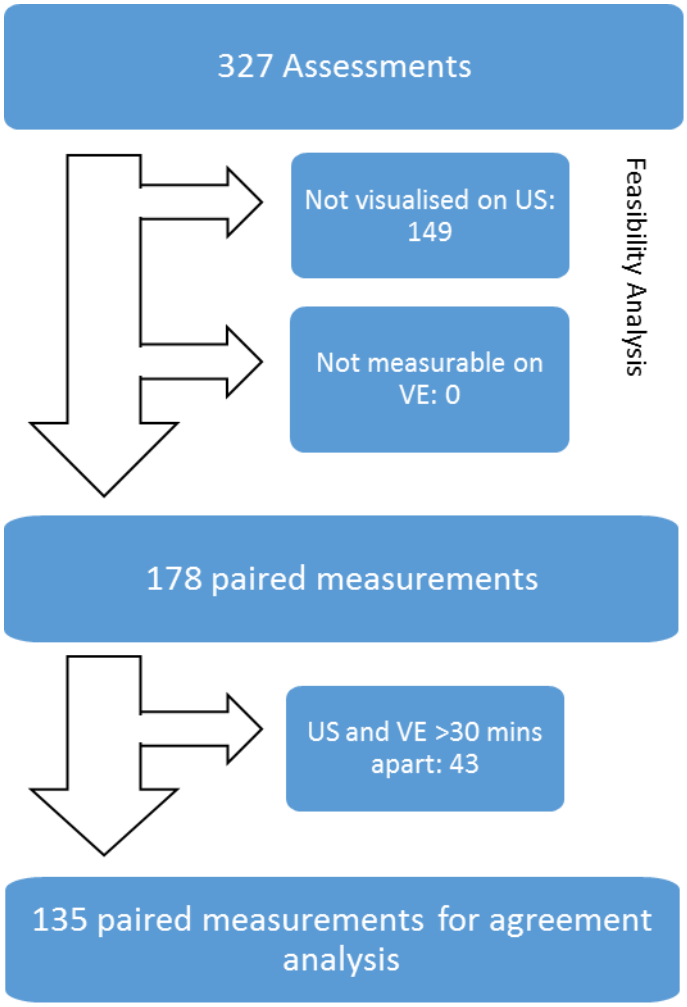

Figure 7. Flow chart of cervical dilatation assessments.

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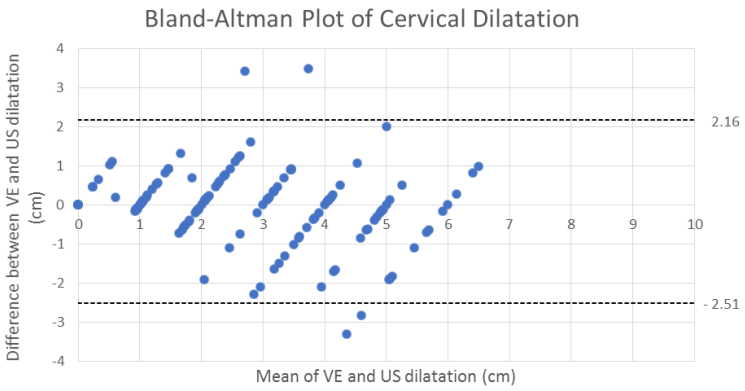

Figure 8. Bland-Altman plot showing the agreement between ultrasound and vaginal examination measures of cervical dilatation. The bias is -0.173cm and the dashed lines represent the 95% limits of agreement.

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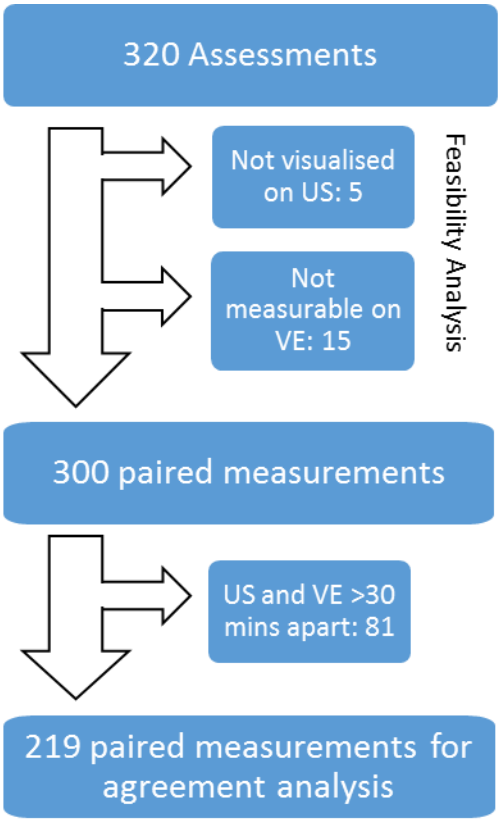

Figure 9. Flow chart of caput succedaneum assessments.

582