

ORIGINAL RESEARCH

Intrapartum ultrasound for cervical dilatation: Inter- and intra-observer agreement

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Abstract

Introduction: Digital vaginal examination (DVE) is considered the standard of care for assessing labor progress and cervical dilatation. However, it may be painful and is a subjective method that can increase the risk of chorioamnionitis. Known inter- and intra-observer variability exists in measurements of cervical dilatation obtained digitally. However, little is known about the inter- and intra-observer variability when using intrapartum transperineal ultrasound (TPUS). Our objectives were to investigate the relationship between cervical dilatation as assessed by TPUS and DVE. To assess inter- and intra-observer variability in both single and repeated ultrasound assessments of cervical dilatation during active labor.

Material and Methods: This single-center study was conducted at an inner-city maternity unit in London, UK. Nulliparous participants at term with a live, singleton fetus in cephalic presentation were recruited between May 2021 and November 2022. During active labor, TPUS was performed subsequent to DVE. Repeat ultrasound assessments were performed where feasible. Participants were in a supine position, with flexed hips and knees and with an empty bladder. The ultrasound transducer was placed transversely on the maternal perineum. The anteroposterior (AP) diameter of the cervix was measured, and two-dimensional (2D) cine-loop videos were analyzed to obtain accurate measurements. Data were excluded if the time difference between DVE and TPUS exceeded 60 min.

Results: Of the 206 participants who consented to the study, complete data were obtained from 110 participants, yielding 147 paired TPUS and DVE observations. Ninety-six participants were excluded. The absolute difference between TPUS and DVE assessments was 0 cm in 34% of the observations, 1 cm in 46.3%, and between 2 and 4 cm in 19.7%. The mean difference was -0.9 cm (intraclass correlation coefficient = 0.85; $p < 0.001$). Data from 30 participants, with 50 cervical dilatation measurements, were used to assess inter- and intra-observer variability. The mean

Abbreviations: 2D, Two-Dimensional; AP, Anteroposterior; CI, Confidence Interval; DVE, Digital Vaginal Examination; ICC, Intraclass Correlation Coefficient; LOA, Limit of Agreement; TPUS, Transperineal Ultrasound.

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difference for the first ultrasound assessment was 0.07 cm (95% limit of agreement = -0.96 to 1.10 , $p < 0.001$), for inter-observer variability, and 0.01 cm (95% limit of agreement = -0.29 to 0.30 ; $p < 0.001$) for intra-observer variability.

Conclusions: Assessment of the cervix with TPUS during active labor is feasible and shows a strong correlation with DVE measurements. The majority of ultrasound measurements yielded readings within 1 cm of the corresponding DVE values, demonstrating high intraclass correlation and good inter- and intra-observer agreement.

KEYWORDS

cervical dilatation, digital vaginal examination, transperineal ultrasound

1 | INTRODUCTION

Digital vaginal examination (DVE) is used worldwide to assess fetal head descent, cervical effacement and dilatation, and fetal head position before and during labor. However, it can be uncomfortable¹ and may cause more pain than a transperineal ultrasound (TPUS) examination, leading to poor tolerance, especially among women in labor.² Furthermore, DVE can be associated with ascending infections, including chorioamnionitis and endometritis, as well as a shortened time to delivery in cases of preterm labor.³ It may not be a reliable method for assessing fetal head position,⁴ cervical dilatation,⁵ or fetal head station.⁶ Moreover, DVE is a notoriously subjective technique with frequently reported poor inter- and intra-observer agreement.⁵⁻⁷ Despite these limitations, DVE remains the most commonly used method among midwives and obstetricians for routine examination in intrapartum care.

Cervical dilatation assessment is a widely used indicator of labor progress. Various techniques, including mechanical, electromagnetic, and electronic sensors, in addition to DVE, can be employed to measure cervical dilatation.⁸ However, these methods often lack the capacity to provide an objective assessment of cervical dilatation.

Transabdominal ultrasound is a long-established method for detecting fetal heartbeat, fetal presentation and lie, multiple gestations, and placental localization. Over the last two decades, advanced ultrasound techniques have increasingly been used on delivery suites. These techniques can objectively determine fetal head position,^{9,10} cervical dilatation,¹¹ fetal head station,¹² fetal head attitude, and flexion,¹³ and allow an estimate toward the prediction of delivery mode.¹⁴⁻¹⁶ TPUS reduces the need for invasive DVE and is associated with lower rates of intrapartum fever and chorioamnionitis.¹⁷

There is a scarcity of literature concerning ultrasound measurement of cervical dilatation during active labor. However, some studies have reported the reproducibility of ultrasound as an effective diagnostic tool, producing measurements that highly correlate with DVE.¹⁸⁻²³ Moreover, limited knowledge exists regarding the inter- and intra-observer variability associated with the use of intrapartum TPUS for cervical assessment.

The objectives of this study were to assess the correlation between ultrasound measurements of cervical dilatation during active labor and corresponding DVE values, with evaluating the validity of

Key message

Transperineal ultrasound enables visualization and objective measurement of the cervical rim during labor, across varying cervical dilatations and irrespective of membrane status. The measurements of cervical dilatation correlate highly with digital vaginal examinations showing minimal observer variation.

the two-dimensional (2D) cine-loop ultrasound technique for enhancing the visualization of cervical rims, thereby facilitating more accurate measurements of the cervix. Furthermore, we aimed to investigate both inter- and intra-observer variability in single and repeated ultrasound measurements of cervical dilatation during active labor.

2 | MATERIAL AND METHODS

A prospective longitudinal observational cohort study was conducted from May 2021 to November 2022 in the labor ward of an inner-center maternity unit in London, UK and included a TPUS assessment of cervical dilatation. Informed consent was individually obtained from each participant prior to study inclusion. Consent was obtained during the early stage of labor, ensuring ample time was provided for the participants to comprehend and make an informed decision regarding their involvement in the study. Inclusion criteria were nulliparity, active labor as defined by NICE²⁴ (progressive cervical dilatation from 4 cm and/or regular painful contractions), including both spontaneous and induced labor, age 18–44 years, gestational age 37–42 weeks, and a live singleton fetus in cephalic presentation. Exclusion criteria include life-threatening maternal or fetal complications necessitating immediate medical intervention or delivery, and those unable to provide fully informed consent for the study.

DVE was performed by the responsible healthcare professional (doctors and midwives) in the delivery suite in accordance with standard management of labor.²⁴

TPUS was conducted within 60min of the DVE by one of the two researchers (A.H. and M.K.). Data were excluded if the interval between the DVE and TPUS assessments exceeded 60min. The ultrasound operators were not involved in the clinical management of labor, and both the ultrasound operators and attending midwives were blinded to each other's assessments.

Ultrasound examinations were performed and recorded using portable ultrasound equipment (GE Voluson™ SWIFT) equipped with a curved real-time four-dimensional (4D) and a 2–5 MHz wide-band three-dimensional (3D) convex ultra-light volume probe. A 3D/4D probe was utilized with 2D acquisitions to achieve maximum image resolution. DVEs and TPUS assessments were performed both with and without epidural anesthesia, timed to occur between uterine contractions. The operating hand was gloved, and aseptic gel was applied to the transducer, which was then covered with a medical glove; subsequently, sterile gel was applied to the gloved transducer. The transducer was positioned between the labia majora at the posterior fourchette, serving as a barrier to prevent cross-infection. The ultrasound transducer was maintained under sanitary conditions and cleaned appropriately after each scan.

Participants were examined in a supine position with their knees and hips flexed and with an empty bladder. The ultrasound transducer was placed in the transverse plane at the maternal perineal area.

The method used to visualize the cervix involved positioning the probe along the midsagittal plane at the perineum. This approach resulted in the visualization of the fetal head outline on the ultrasound screen and often a portion of the symphysis pubis. The transducer was then rotated 90° counterclockwise, and the probe marker was directed toward the patient's right to obtain a transverse view of the region of interest. Subsequently, the fetal cranium became visible (Figure 1A,B). At this point, the transducer was gently tilted toward the rear to capture a view of the rectal region and then gradually readjusted forward until the rectum was no longer within the field of vision (Figure 2A–C). When the transducer is inclined toward the anterior direction, the cervix is observed following the rectum at the internal os level. Cervical dilatation is measured as the AP diameter with the clearest cervical rim on cine-loop (Figure 3A,B). However, excessive tilting toward both the front and the back was avoided

to prevent overlooking the critical region, the cervix, or acquiring images from an incorrect perspective. Once the cervix was identified, measurements of the AP diameter at different dilatations were obtained (Figure 4).

Inter-observer measurement variability was assessed through repeated observations by A.H. and M.K. (Figure 5). Intra-observer variability was evaluated by A.H. In both cases, the cervical dilatation measurement (AP diameter) was assessed offline using the 2D cine-loop videos that had been recorded and saved on the ultrasound device.

2.1 | Statistical analyses

The relationship between the TPUS and DVE measurements was evaluated using a bubble chart. The size of the bubbles increases with the number of paired DVE and TPUS values. The absolute difference between the two measurements was calculated, and the number of concordant and discordant pairs was reported. Agreement was graphically investigated using the Bland–Altman plot with a 95% limit of agreement (LOA), and the intraclass correlation coefficient (ICC) with a 95% confidence interval was reported. ICC values between 0.75 and 0.90 indicate good reliability, and values greater than 0.90 reflect excellent reliability. Statistical significance was set at an alpha value of 0.05.

Inter- and intra-observer variability between ultrasound measurements of the cervix was graphically investigated using the Bland–Altman plot with a 95% LOA. The difference between values was plotted against the average of the two measurements. The correlation was reported as an ICC with a 95% confidence interval.

3 | RESULTS

Demographic characteristics of the participants included nulliparous women aged 18–44 years (mean, 31 years), with a mean gestational age of 39 weeks and 6 days and mean body mass index (BMI) of 24.7 kg/m² (range, 18–47 kg/m²).

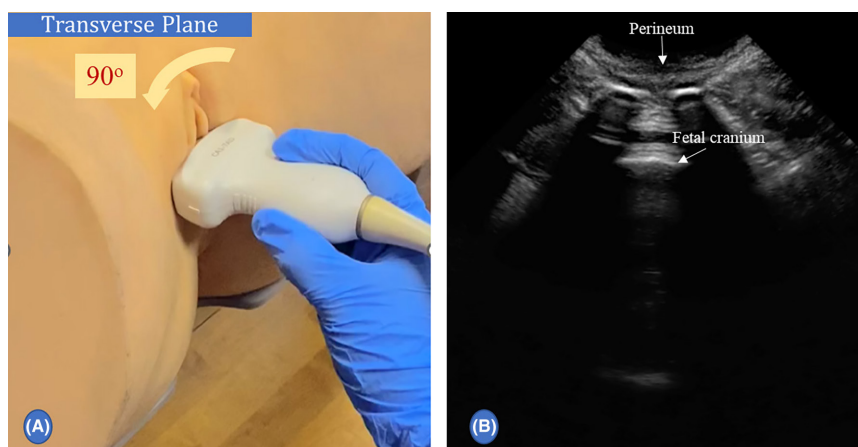


FIGURE 1 Transperineal ultrasound technique during labor: (A) Ultrasound transducer is rotated 90° counterclockwise to obtain the transverse plane orientation, (B) Ultrasound image demonstrating the fetal skull and the maternal perineal area.

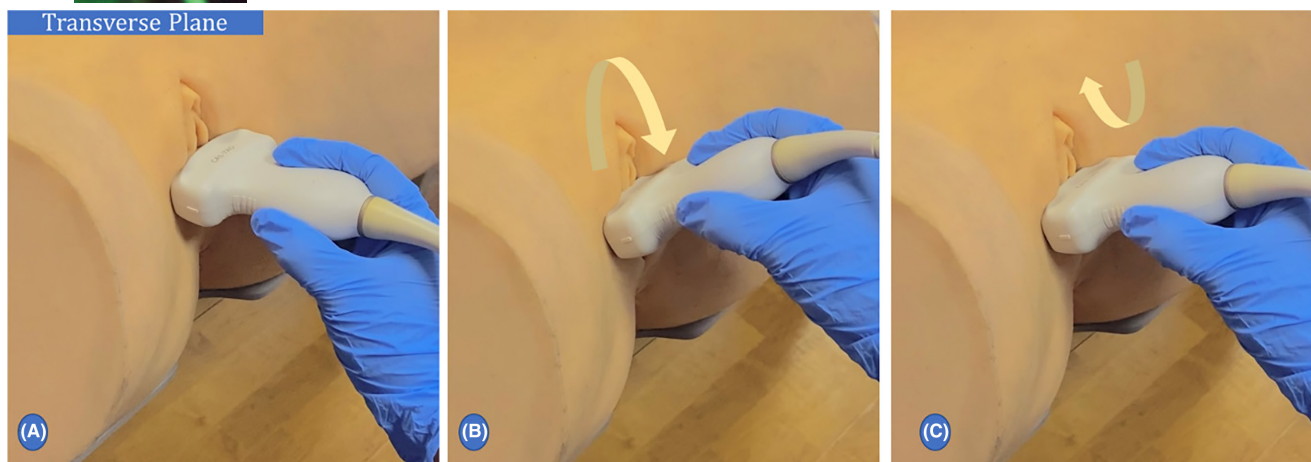


FIGURE 2 Transperineal ultrasound technique and ultrasound probe movements to measure cervical dilatation during active labor: (A) Ultrasound transducer is positioned in a true transverse plane. (B) Ultrasound transducer is tilted posteriorly to visualize the rectum. (C) Ultrasound transducer is gradually tilted back anteriorly until clearly visualize the region of interest, 'the cervix'.

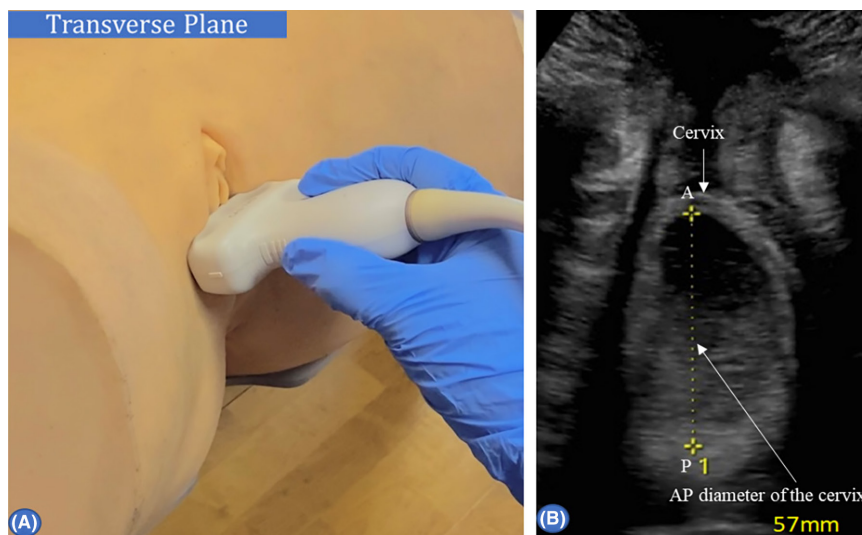


FIGURE 3 Transperineal ultrasound technique to measure cervical dilatation during active labor: (A) Ultrasound transducer is inclined toward the anterior direction, the well-observed area following the rectum at the internal os level is 'the cervix.' (B) Ultrasound image demonstrating the cervical dilatation is measured at 57 mm. Anterior (A) and posterior (P) rims of the cervix are clearly visible. The anterior lip is the closest to the ultrasound transducer.

3.1 | Association between DVE and TPUS measurements

Among the 206 participants who provided consent from May 2021 to November 2022, 96 participants (46.6%) were excluded due to the time interval exceeding 60 min between the DVE and TPUS scan. Consequently, the analysis included data from 110 participants, comprising 147 observations from repeated ultrasound assessments undertaken at a median of 27.2 min from the DVE (range, 4–50 min). Thirty-seven participants (33.6%) underwent repeated ultrasound assessments of the cervix during the active phase of labor. The TPUS assessment was conducted with a median completion time of 4.75 min (range, 2–7 min).

The cervix was visible in 147 observations of cervical dilatation, with 83% showing cervical dilatation <8 cm, 17% \geq 8 cm. In 56.5% of the observations, the membranes were ruptured (Figure 6). The association between DVE and TPUS measurements is depicted in a bubble chart (Figure 7A), revealing a significant correlation

between the two. The absolute difference between DVE and TPUS measurements was 0 cm in 50 observations (34%) and 1 cm in 68 observations (46.3%). This indicates that the value between DVE and TPUS was within 1 cm in 118 observations (80.3%). An absolute difference of 2–4 cm was demonstrated in 19.7% of the observations. The Bland–Altman plot (Figure 7B) revealed a mean difference of -0.925 cm (95% LOA = -0.777 to 2.628 cm) between DVE and TPUS. The ICC for the association between the two methods was 0.85 (95% confidence interval (CI) = 0.75 – 0.90 ; $p < 0.001$, $\alpha = 0.05$).

3.2 | Inter- and intra-observer variability for TPUS measurements of the cervix

Of the 110 participants, we randomly selected 30 participants with 50 observations to assess inter- and intra-observer variability. Of these 50 observations, 36 had ruptured membranes. Twenty

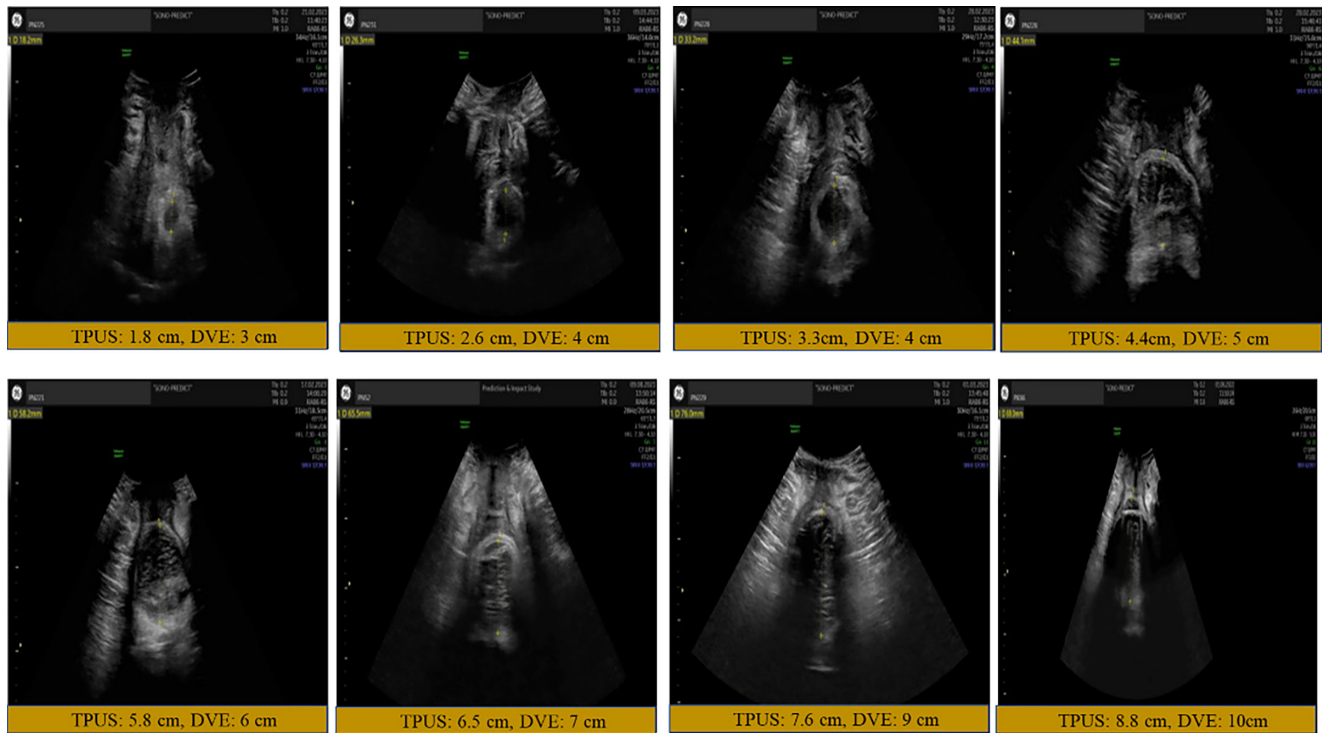


FIGURE 4 Ultrasound images demonstrating different cervical dilatation measurements assessed by transperineal ultrasound technique gathered from eight nulliparous women during active labor. Ultrasound images were captured at various depths and focal points. Digital vaginal examination, DVE; Transperineal ultrasound, TPUS.

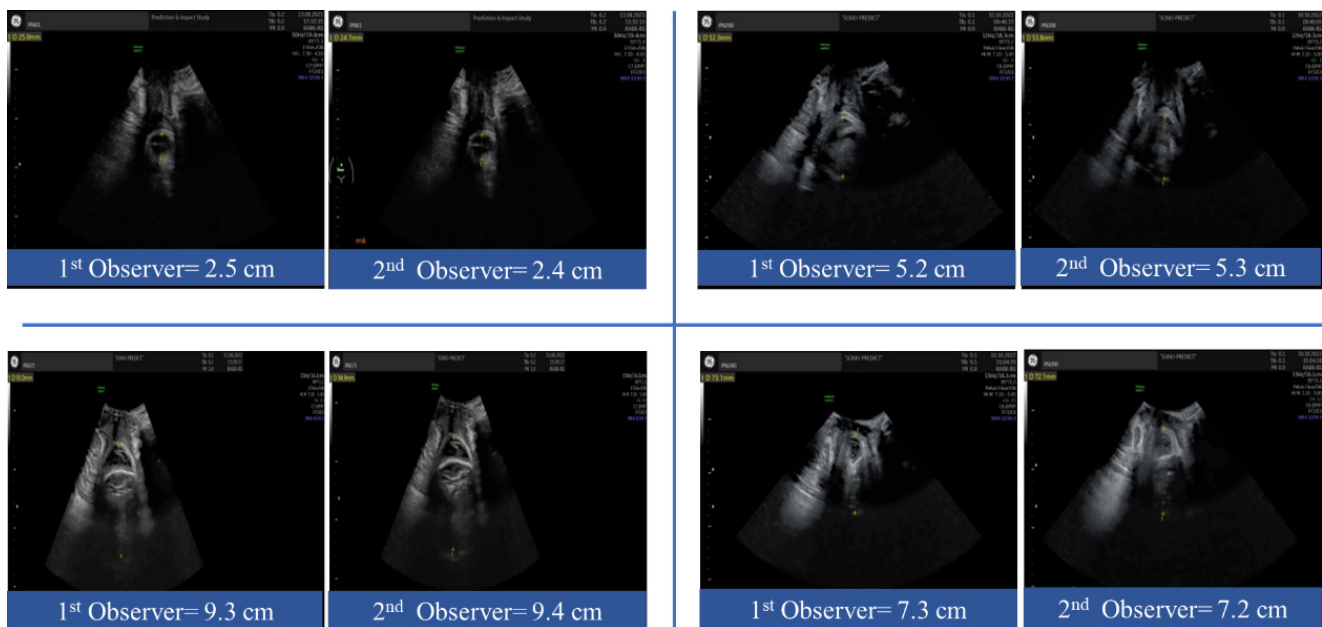


FIGURE 5 Four ultrasound image sets demonstrating inter-observer variability of cervical dilatation measurements assessed by two observers during active labor. Ultrasound images were captured at various depths and focal points.

participants (66.6%) underwent paired ultrasound assessments of the cervix during active labor (Figure 6).

Regarding inter-observer agreement, the mean difference for the first ultrasound scan was 0.07 cm (95% LOA = -0.96 to 1.10 cm), with an ICC of 0.939 (95% CI = 0.870–0.972; $p < 0.001$).

The mean difference for the second ultrasound scan was 0.09 cm (95% LOA = -0.67 to 0.85 cm), with an ICC of 0.969 (95% CI = 0.933–0.986; $p < 0.001$) (Figure 8).

For intra-observer agreement, the mean difference in the first ultrasound scan was 0.01 cm (95% LOA = -0.29 to 0.30 cm) with

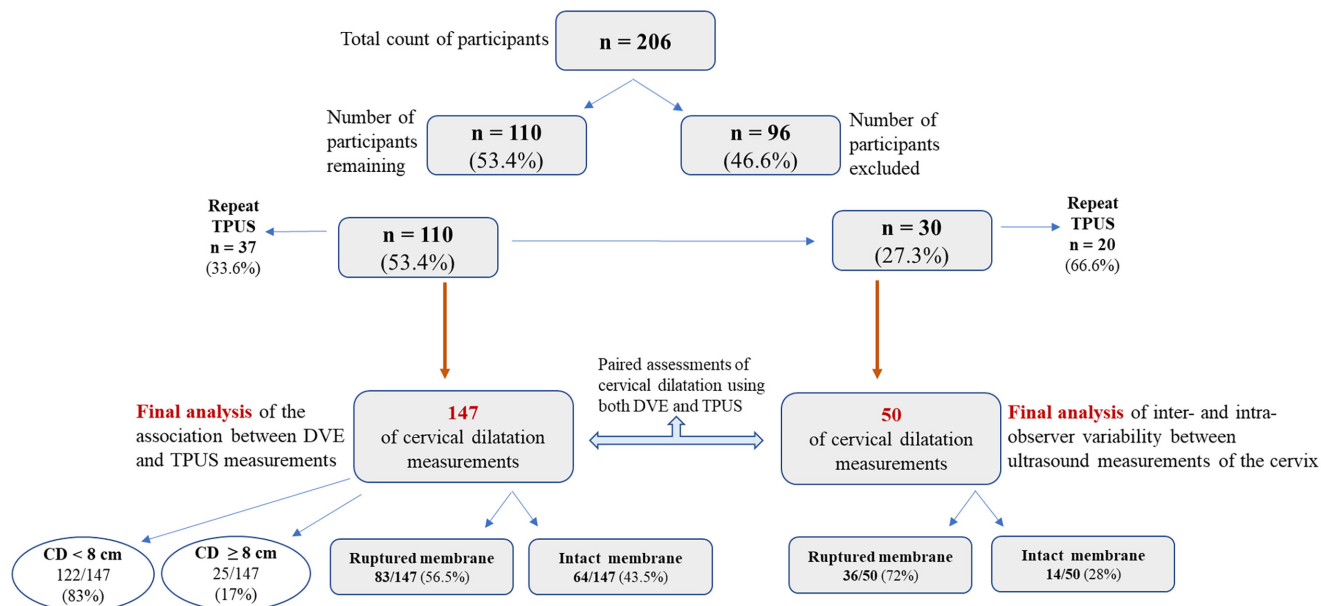


FIGURE 6 Flow-chart showing the study cohort. CD, Cervical dilatation; DVE, Digital vaginal examination; n, Number of patients; TPUS, Transperineal ultrasound.

an ICC of 0.995 (95% CI=0.989–0.998; $p < 0.001$). Similar results were obtained with the repeated ultrasound assessments. The mean difference in the second ultrasound scan was -0.02 cm (95% LOA= -0.31 to 0.28 cm) with an ICC of 0.996 (95% CI=0.990 to 0.998; $p < 0.001$) (Figure 9).

4 | DISCUSSION

The main findings of our study show that intrapartum 2D transperineal ultrasound (TPUS) is a feasible technique for evaluating cervical dilatation during active labor by measuring the anteroposterior diameter along the inner-to-inner cervical layer. This method is closely correlated with clinical examination of the cervix. TPUS effectively assessed the cervix across a broad range of cervical dilations, with ultrasound images enhanced by the addition of cine-loop videos. Importantly, there was a robust inter- and intra-observer consensus in both the initial and repeated TPUS assessments of the cervix. Ultrasound measurements closely aligned with clinical examinations, with the majority of readings (80%) falling within a 1 cm of the corresponding DVE values.

Agreement between DVE and TPUS has been documented in prior investigations. Hassan et al.¹¹ conducted the first 2D ultrasound-based cervical assessment study, including 21 participants, to quantify cervical dilatation. This study reported the anteroposterior diameter of the cervix; a metric that has been subsequently adopted in various cohort studies.^{21,25,26}

We also focused on the anteroposterior diameter of the cervix, chosen for its superior visibility and capacity for reliable measurement based on enhanced axial resolution. Notably, some studies have favored measuring the transverse diameter, which may suffer

from reduced resolution and visibility, particularly during advanced cervical effacement. These divergent measurement approaches may explain the lower concordance observed between DVE and TPUS in Togar's study.²⁷ In contrast, Connell et al.²² reported a strong correlation between ultrasound measurements in the transverse dimension and clinical readings. Cervical dilatation, encompassing both anteroposterior and transverse diameter measurements, has been studied.^{18,20,28} Importantly, Wiafe et al.²⁸ found no significant difference in measurements of cervical dilatation between the anteroposterior and transverse approach.

Zimerman et al.¹⁸ conducted a 1-week study with 52 participants, assessing a 3D TPUS system's ability to measure cervical dilatation. The study findings revealed a good correlation between the mean and maximal cervical diameters, as well as the inner cervical area measured by 3D transperineal ultrasonography, and the dimensions obtained through DVE. When assessing the cervix during labor, 3D TPUS may prove to be more effective than other methods. While we did not utilize it in this study, this technique may provide a clearer visualization of the cervix and offer high measurement accuracy, particularly when the cervix is in close proximity to the bony structure of the fetal head.

In a Swedish study by Benediktsdottir et al., two cervical dimensions were examined in 86 participants.²⁰ They compared DVE with TPUS while also assessing intra-observer consistency of ultrasound measurements. Their findings indicated that TPUS measurements showed cervical dilatation ~ 1 cm less than those obtained from clinical evaluations but displayed good intra-observer agreement. In our study, most of the ultrasound measurements closely matched DVE readings within a 1 cm margin ($n = 118/147$, 80%). This variance is likely attributed to factors including cervical stretching during clinical examinations and methodological differences in assessment using DVE, which is not standardized in respect of anteroposterior

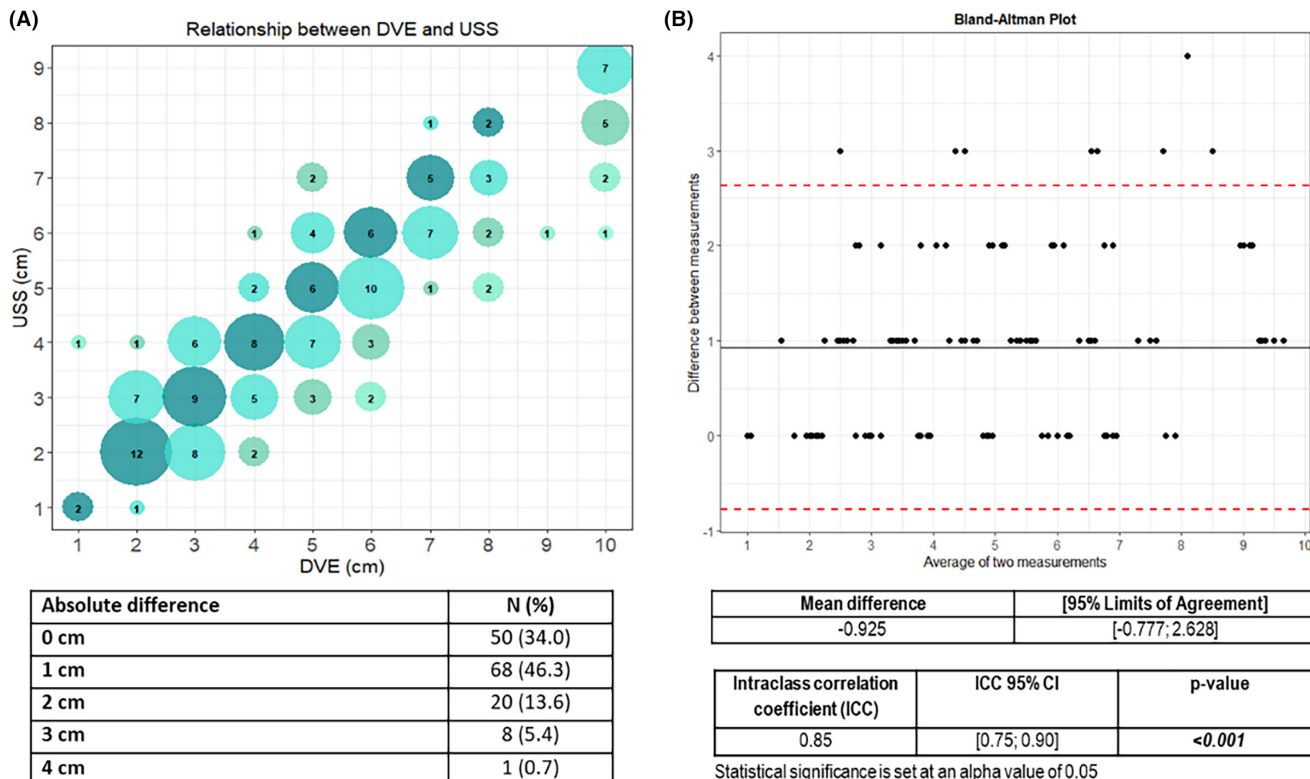


FIGURE 7 Correlation between digital vaginal examination and transperineal 2D ultrasonographic of the anteroposterior cervical diameter: (A) Bubble chart illustrating the association between the two methods with calculation of the absolute difference, (B) Bland-Altman plot with calculation of the mean difference of inter-method agreement between DVE and TPUS.

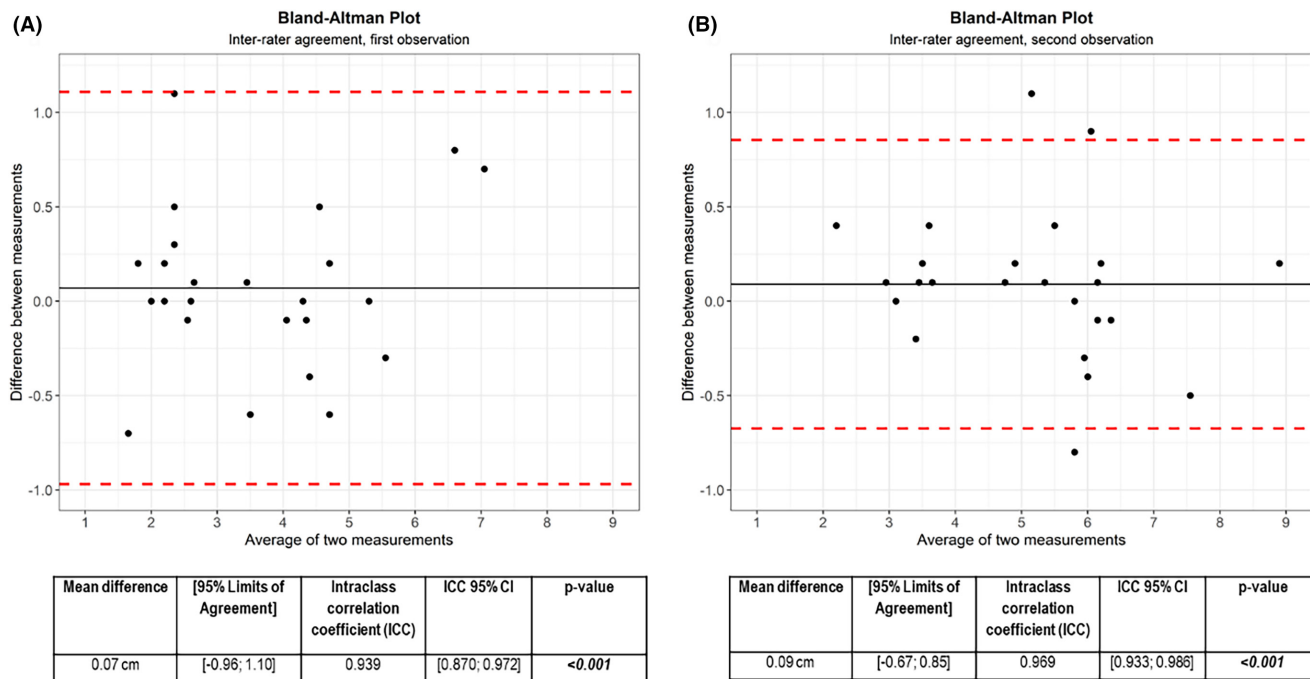


FIGURE 8 Inter-observer agreement: Bland-Altman plot of differences in 2D ultrasonographic measurements of cervical dilatation between two observers for the anteroposterior diameter. (A) Inter-observer agreement in the initial ultrasound assessments. (B) Inter-observer agreement in the repeated ultrasound assessments.

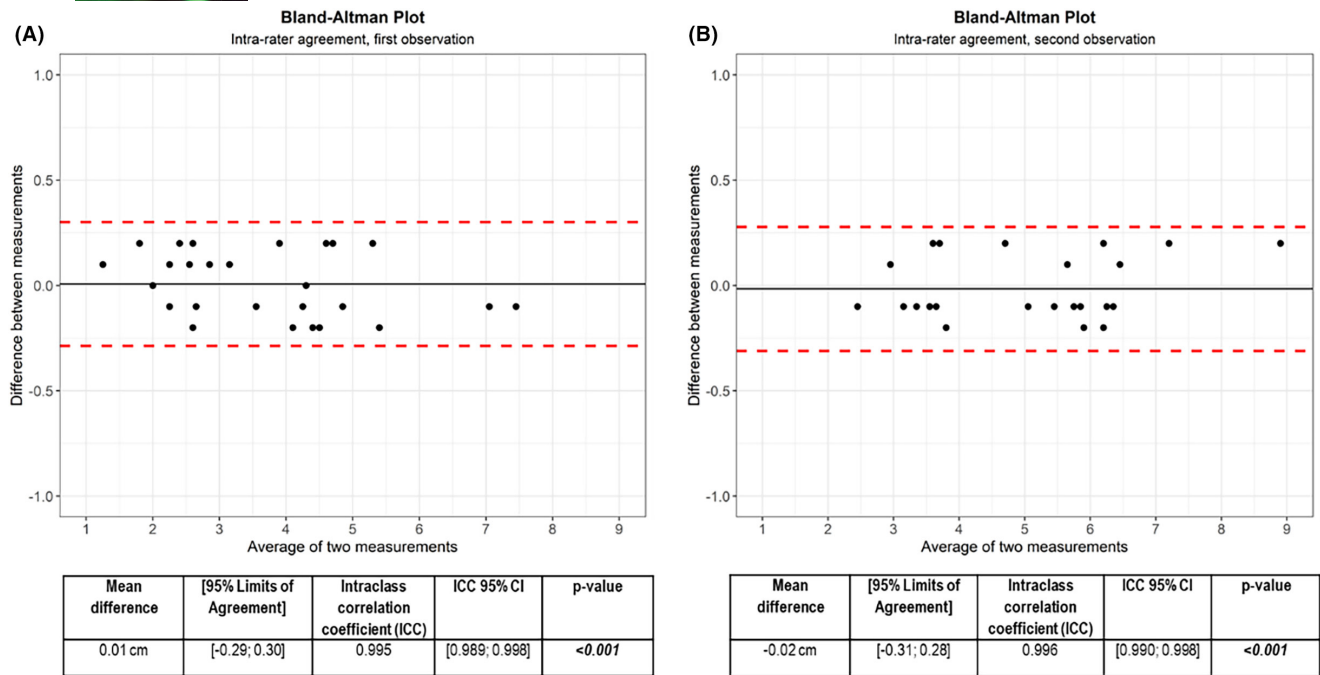


FIGURE 9 Intra-observer agreement: Bland–Altman plot of differences in 2D ultrasonographic measurements of cervical dilatation assessed by one observer for the anteroposterior diameter with a time interval of 10 days between each set of ultrasound measurements. (A) Intra-observer agreement in the initial ultrasound assessments. (B) Intra-observer agreement in the repeated ultrasound assessments.

or transverse measurements, and hence can vary among healthcare providers and clinical settings.

An imprecise evaluation of cervical dilatation can contribute to variability in clinical decisions within obstetrics. This may lead to delayed interventions, unwarranted actions, or suboptimally managed labors.⁸ TPUS, when used in conjunction with traditional clinical assessment, has demonstrated superior accuracy compared with DVE.³⁰ It not only enhances the precision of cervical measurements but also offers a noninvasive approach, which many women prefer over traditional examinations, making a strong argument for its incorporation into intrapartum care.^{29,31,32} Furthermore, using TPUS reduces the potential infection risks associated with DVE.¹⁷ Implementing ultrasound assessment may diminish the need for repetitive clinical examinations, particularly during the early stages of labor, consequently optimizing the efficiency of labor monitoring processes in an objective manner and holding significant implications for clinical practice.^{19,25}

A modest discrepancy in measurements between DVE and TPUS is evident. It is important to note that this does not imply inherent inaccuracy in TPUS measurements. Instead, this variability may be attributed to discrepancies in the precision of DVEs, which were performed by multiple midwives with varying levels of expertise. Additionally, it is reasonable to postulate that the area of cervical dilatation does not conform to a perfect circle, which may influence the accuracy of DVE.

This study describes a methodology for a comprehensive visualization of the cervix, including observations of advanced dilatation with both ruptured and intact membranes, achieved despite

the particular challenges in visualizing the cervix using TPUS at dilatations of greater than 8 cm that reported in several previous studies.^{19,20,25,29,30} This was particularly notable in cases with a low fetal head station where visualizing the posterior part of the cervix became progressively more challenging as cervical dilatation advanced. Where cervical dilatation exceeded 8 cm ($n = 16/147, 11\%$), we found that cine-loop capability allowed for a slower replay video speed and hence an accurate visualization of the cervical rim.

In advanced labor, accurately measuring cervical dilatation becomes complex due to fetal skull shadowing, which makes distinguishing the cervix challenging, especially when the cervix is thin. In clinical examinations with DVE, Yuce et al.¹⁹ reported higher precision at greater degrees of cervical dilatation. However, from our investigation, TPUS emerges as a valuable tool for objectively assessing cervical dilation throughout labor, spanning from small to large cervical dilatations.

This study is unusual for its inclusion of a substantial number of participants who underwent successful cervical examinations using both 2D transperineal ultrasonographic and traditional methods during active labor. Conducted at a diverse London tertiary care facility that manages over 5000 deliveries annually, our research is generalizable to a broader laboring population.

However, the study has limitations that require acknowledgment. One limitation stems from the time gap between DVE and subsequent TPUS assessments due to the inherent challenges of conducting ultrasound evaluations promptly after clinical assessments. The study inclusion criteria required patients to undergo TPUS within a maximum timeframe of 1 hour after a clinical evaluation. Consequently, 96 participants were excluded from the study

due to fatigue, which necessitated a phase of relaxation between the two procedures, or due to perceived inadequacies in analgesia, leading to requests for extended time intervals despite the availability of ultrasound operators. Nonetheless, discrepancies between DVE and TPUS within 1 hour are minimal, due largely to the slower cervical dilatation progression in nulliparous women compared with multiparous women, with an estimated progress rate of 0.5 cm per hour.

Furthermore, inter-observer variability was assessed using the same ultrasound cine-loop videos reviewed by two different operators. Although this method presents challenges, namely, that evaluating cine-loop videos is complex due to their length, detail richness, and the challenges in delineating the cervical rim, it could allow more reliable measurement in the labor room. Given the good intraclass correlation between DVE and TPUS and high inter-observer agreement, we consider that multiple ultrasound assessments of the cervix by TPUS technique can feasibly reduce the frequency of DVE, which might reduce discomfort and avoid the risk of ascending vaginal infections, particularly during prolonged labor or in cases of preterm gestation.

5 | CONCLUSION

This study represents a large prospective cohort of participants undergoing ultrasound during active labor. The results support intrapartum two-dimensional transperineal ultrasound as a reliable method for evaluating the cervix at various dilatations with both ruptured and intact membranes. We observed a high degree of consistency between DVE values and TPUS measurements of cervical dilatation, with relatively low inter- and intra-observer variability.

AUTHOR CONTRIBUTIONS

Arwa Hanidu wrote the paper, Arwa Hanidu and Mariya Kovalenko performed the intrapartum ultrasound assessments and collected the data, Giulia Zamagni and Lorenzo Monasta analyzed the data, and ALL authors reviewed and approved the final version and submission.

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CONFLICT OF INTEREST STATEMENT

The views expressed are those of the author(s) and not necessarily those of the NHS, Imperial College London, the NIHR or the Department of Health.

ETHICS STATEMENT

The SONO-PREDICT study received ethical approval from the UK Research Ethics Committee (Leicester Research Ethics Committee, Reference: 20/EM/0298) on February 18, 2021 and the local Joint Research Compliance Office (Reference: 20QC6287).

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