IMPERIAL

# The SONO-PREDICT Study

## Ultrasound Prediction of Delivery Mode: Can the First Stage Prediction Model be Further Improved?

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Thesis Submitted to Imperial College London for the Degree of Doctor of Philosophy

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Co-Supervisor: Miss Sana Usman

# Statement of Originality and Copyright Declaration

I confirm that the work presented has not been accepted for any degree and is not currently under consideration for any degree other than the Doctor of Philosophy programme at Imperial College London. I affirm that this thesis predominantly embodies the outcomes of my independent research efforts, except where explicitly acknowledged through appropriate citations. I guarantee that there are no instances of plagiarism and that all sources have been accurately represented and duly acknowledged.

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**Declaration of Applicant Contribution**

The preliminary foundation and rationale for the study were developed by Professor Christoph Lees and Miss Sana Usman. The collaborative effort of the study team

culminated in the formulation of the research design and protocol. My responsibilities primarily included the development and writing of the protocol, submission to the research ethics committee, and making necessary adjustments as required. Furthermore, I was directly responsible for participant recruitment, conducting intrapartum ultrasound assessments, and overseeing the management of data- its collection, recording, and storage. The statistical analysis for chapters 3, 4, and 5 was conducted by independent statisticians working with the research group in both face-to- face and virtual meetings with myself, Professor Lees, and Miss Usman. The analysis evolved as we developed further ideas. I collated the data and wrote the interpretations for review with the research team.

# Acknowledgement

The achievements documented in this dissertation were made possible through the extensive support and assistance from a diverse group of individuals. At this point, I would like to express my profound gratitude and appreciation to all those who were instrumental in the realisation of this doctoral research.

I extend my deepest gratitude to Professor Christoph Lees, who has been an exemplary supervisor with significant expertise in ultrasound imaging. His substantial support, adaptability, and continues encouragement have been invaluable throughout this academic journey. My sincere appreciation is also extended to my day-to-day supervisor, Miss Sana Usman, for her constant guidance, assistance, and understanding during the research years. Additionally, I am indebted to my fellow researcher, Dr. Mariya Kovalenko, whose assistance and kindness throughout the research period have been immensely helpful.

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My heartfelt gratitude is extended to the Saudi government for its financial support for providing the necessary resources throughout my doctoral studies. Lastly, my most sincere thanks are reserved for both my immediate and extended family for their unwavering support and patience, and for viewing me as a trailblazer in this endeavour.

‘This Ph.D. dissertation is dedicated to my cherished mother, whose resilience, endurance, and tenacity continually inspired me. She passed away during the writing-up phase of my thesis, while looking forward to my accomplishments. This work is also dedicated to my beloved father, who exemplifies strength, decorum, magnanimity, and interpersonal skills. Despite facing health challenges, he has continually provided me with support and encouragement.’



# Collaborators

During the course of my doctoral studies, I actively engaged in collaborations with the following centers:

1- **Clinical Epidemiology and Public Health Research Unit, Institute for Maternal and Child Health IRCCS "Burlo Garofolo", Trieste, Italy; and Unit of Fetal Medicine and Prenatal Diagnosis, Institute for Maternal and Child Health IRCCS "Burlo Garofolo" and Department of Medicine, Surgery and Health Sciences, University of Trieste, Trieste, Italy:** Dr. Lorenzo Monasta, holding a DSc in Epidemiology, an MSc in Health Sciences, and an MSc and a BSc in Statistical Demographic Sciences, serves as the principal investigator at IRCCS Ospedale Infantile Burlo Garafolo. Along with his team, Dr. Monasta contributed essential and sophisticated statistical analyses to the SONO-PREDICT study (Chapter 3, and 4) and to the research on intrapartum ultrasound for cervical dilatation: inter- and intra-observer agreement (Chapter 5). This collaboration involved productive engagements with Professor Tamara Stampalija and her team at the University of Trieste (Chapter 4).

2- **Institute of Clinical and Molecular Medicine, Norwegian University of Science and Technology, Trondheim, Norway; and Department of Obstetrics and Gynecology, St. Olavs Hospital, Trondheim, Norway:** Our collaborative efforts with Professor Kjell Salvesen and Miss Ingrid Volloyhaug centered on the application of three-dimensional (3D) transperineal ultrasound for visualising the pelvic floor during pregnancy and childbirth.

3- **Urogynaecology department, Imperial College Healthcare NHS Trust, and Urogynaecology department, East Sussex Healthcare NHS Trust:** Professor Vik Khullar, a consultant gynaecologist and urogynaecologist with significant experience, specialises in bladder and pelvic organ problems secondary to Ehlers Danlos Syndrome (EDH) and serves as the head of the department at St. Mary's Hospital, London. Miss Victoria Asfour, a consultant gynaecologist and obstetrician with over 15 years of experience, specialises in urogynaecology, focusing on incontinence, prolapse, pelvic floor dysfunction post-childbirth, and issues related to intercourse.

   Our collaboration focused on investigating whether the urinary catheter balloon is visible below the fetal head (termed 'low balloon') during intrapartum ultrasound assessments, aiming to establish the significance of this finding in relation to the mode of delivery, the duration of labour, and immediate post-partum urinary complications (Chapter 6).

4- **Section of Women's Mental Health, Institute of Psychiatry, Psychology and Neuroscience, King's College London, UK:** In an exemplary collaborative effort, I worked alongside Dr. Fiona Challacombe and her team to examine the perspectives of parents, pregnant women, and health care providers on disseminating information about predicting delivery modes using intrapartum ultrasound and clinical assessments. This study also aimed to understand both the immediate and long-term psychological impacts (Chapter 8).

# Scientific Papers

1. Intrapartum ultrasound for cervical dilatation: inter and intra-observer agreement.

   Arwa HANIDU, Mariya KOVALENKO, Sana USMAN, Lorenzo MONASTA, Giulia ZAMAGNI, Tamara STAMPALIJA, Christoph LEES. https://doi.org/10.1111/aogs.14970.

2. Determining the psychological impact of delivery mode prediction using ultrasound and clinical assessment.

   Arwa Hanidu, Tania U Djongianto, Mariya Kovalenko, Esha Gupta, Megan Jansen, Sana Usman, Karen Joash, Fiona L Challacombe, Christoph Lees. Submitted on 11th December 2023, accepted on 21st December 2023, and published on 03rd February 2024. https://doi.org/10.1002/uog.2760.

3. Predicting the mode of delivery based on ultrasound and clinical assessments: views of parents and health care professionals.

   Djongianto Tania, Hanidu Arwa, Kovalenko Mariya, Gupta Esha, Jansen Megan, Usman Sana, Joash Karen, Challacombe Fiona, Lees Christoph. It will be submitted to Archives of Women's Mental Health (In Progress).

4. The sonopartogram.

   Usman S, Hanidu A, Kovalenko M, Hassan WA, Lees C. Am J Obstet Gynecol. 2023 May;228(5S): S997-S1016. Epub 2023 Mar 15. PMID: 37164504. https://doi.org/10.1016/j.ajog.2022.06.027.

5. Intrapartum ultrasound training using optical ultrasound simulation.

   Am J Obstet Gynecol. Anna E. CLARK, Neysa PATEL, Mariya KOVALENKO, Arwa HANIDU, Sana USMAN, Christoph LEES. 2023**.** Published on March 2024. https://doi.org/10.1016/j.ajog.2023.08.025.

**6.** Ultrasound visualisation of the urinary catheter balloon in active labour.

Mariya KOVALENKO, Victoria ASFOUR, Sana USMAN, Arwa HANIDU, Vik KHULLAR, Christoph LEES MD. It will be submitted to European Journal of Obstetrics & Gynecology and Reproductive Biology (In Progress).

# Book Chapter Arising from This Thesis

1- **Chapter Name:** Role of Ultrasound in the Labour Room.

**Book Title:** The Management of Labour, 4th Edition.

**Authors:** Mariya Kovalenko, Sana Usman, Arwa Hanidu, Christoph Lees.

The book has, over its last three editions, become a highly respected and widely utilised resource for postgraduates as well as practitioners in India. We anticipate that this edition will also be well-received. The book is scheduled to be launched at the Annual AICC-RCOG conference on September 19, 2024, in Kolkata. Dr. Ranee Thakar, the current president of the Royal College of Obstetricians and Gynaecologists (RCOG), has graciously agreed to release the book during the inaugural function. The conference will take place at the Royal Bengal Hotel from September 19-21, 2024. Further details can be accessed on the conference website at https://www.aiccrcog2024.com.

# Presentations and Posters Arising from This Thesis

OP: Oral Presentation, EP: Electronic Poster

1. The effect of population in comparing prediction of labour outcome using clinical and ultrasound parameters. International Society of Ultrasound in Obstetrics and Gynecology (ISUOG, 15-17 October 2021, Virtual), EP.
2. Prognostic value of initial & repeat digital vaginal and ultrasound assessments & the likelihood of intrapartum Caesarean delivery (ICD) (ISUOG, 15-17 October 2021, Virtual), EP.
3. Can labour prediction models be further improved with combining different centre datasets? (ISUOG, 15-17 October 2021, Virtual), EP.
4. The “intrapartum app”: prediction of vaginal delivery from first and repeat assessment. The international Study Group on Labour and Delivery Sonography (ISLANDS, 1-2 April 2022, Rome, Italy), OP.
5. Using the “intrapartum app” to estimate duration of labour (ISLANDS, 1-2 April 2022, Rome, Italy), OP.
6. Presence of a low urinary catheter balloon in intrapartum transperineal ultrasound-does it matter? (ISLANDS, 1-2 April 2022, Rome, Italy), OP.
7. The “intrapartum app”: prediction of vaginal delivery from first and repeat assessment (ISUOG, 16-18 September 2022, London, UK), OP.
8. Using the “intrapartum app” to estimate duration of labour (ISUOG, 16-18 September 2022, London, UK), EP.
9. Presence of a low urinary catheter balloon in intrapartum transperineal ultrasound-does it matter? (ISUOG, 16-18 September 2022, London, UK), EP.

10. The “intrapartum app”: prediction of vaginal delivery from first and repeat assessment. British Maternal and Fetal Medicine Society (BMFMS, 16-18 November 2022, Birmingham, UK), OP.
11. Using the “intrapartum app” to estimate duration of labour (BMFMS, 16-18 November 2022, Birmingham, UK), OP.
12. Presence of a low urinary catheter balloon in intrapartum transperineal ultrasound-does it matter? (BMFMS, 16-18 November 2022, Birmingham, UK), OP.
13. Intrapartum ultrasound for cervical dilatation: inter- and intra-observer agreement (ISLANDS, 31 March and 1 April 2023, London, UK), OP.
14. The pelvic floor imaging in labour – a starting point (ISLANDS, 31 March and 1 April 2023, London, UK), OP.
15. The pelvic floor in labour (ISLANDS, 31 March and 1 April 2023, London, UK), OP.
16. Indwelling urinary catheter balloon below the fetal head in active labour (ISLANDS, 31 March and 1 April 2023, London, UK), OP.
17. Predicting delivery mode using the intrapartum app: preliminary data from a clinical setting (ISLANDS, 31 March and 1 April 2023, London, UK), OP.
18. Predicting delivery mode using the intrapartum app: a survey of patient and professional views (ISLANDS, 31 March and 1 April 2023, London, UK), OP.
19. The ‘SONO-PREDICT’ Study: Ultrasound prediction of delivery mode: can the first-stage prediction model be further improved? (Birth Conference, 14-16 December 2023, Dubai, UAE), OP.
20. Intrapartum ultrasound for cervical dilatation: inter- and intra-observer agreement (Birth Conference, 14-16 December 2023, Dubai, UAE), EP.

21. Pelvic floor dimensions in the second stage of labour in relation to mode of birth (Birth Conference, 14-16 December 2023, Dubai, UAE), EP.
22. Ultrasound parameters during the second stage of labour in relation to mode of delivery (Birth Conference, 14-16 December 2023, Dubai, UAE), EP.
23. Predicting delivery mode using the intrapartum app: preliminary data from a clinical setting (Birth Conference, 14-16 December 2023, Dubai, UAE), EP.
24. Predicting delivery mode using the intrapartum app: a survey of and professional views (Birth Conference, 14-16 December 2023, Dubai, UAE), EP.
25. Developing intrapartum ultrasound training modules with an optical ultrasound simulation system (Birth Conference, 14-16 December 2023, Dubai, UAE), OP.
26. The SONO-PREDICT Study: Ultrasound prediction of delivery mode: can the first-stage prediction model be further improved? (ISLANDS, 19-20 April 2024, Reykjavik, Iceland), OP.
27. A pilot survey, United Kingdom trainee perspectives on intrapartum ultrasound (ISLANDS, 19-20 April 2024, Reykjavik, Iceland), OP.
28. Pelvic floor dimensions in the second stage of labour related to mode of birth (ISLANDS, 19-20 April 2024, Reykjavik, Iceland), OP.
29. External validation of a delivery mode model based on ultrasound and maternal parameter (ISLANDS, 19-20 April 2024, Reykjavik, Iceland), OP.
30. The SONO-PREDICT Study: Ultrasound prediction of delivery mode: can the first stage prediction model be further improved? (BMFMS, 25-26 April 2024, Liverpool, UK), EP.
31. Intrapartum ultrasound for cervical dilatation: inter- and intra-observer agreement (BMFMS, 25-26 April 2024, Liverpool, UK), EP.

32. Ultrasound parameters in the second stage of labour related to mode of birth (BMFMS, 25-26 April 2024, Liverpool, UK), EP.
33. Pelvic floor dimensions in the second stage of labour related to mode of birth (BMFMS, 25-26 April 2024, Liverpool, UK), EP.
34. Predicting delivery mode using the intrapartum app: preliminary data from a clinical setting (BMFMS, 25-26 April 2024, Liverpool, UK), EP.
35. Predicting delivery mode using the intrapartum app: a survey of and professional views (BMFMS, 25-26 April 2024, Liverpool, UK), EP.

# Training and Scientific Trips and Seminars

1- Basic Intrapartum Ultrasound Techniques. Invited speaker for Journal Club Meeting, London, 9th March 2022.

2- Intrapartum Ultrasound Physics and Techniques. Invited speaker for Southwest Webinar, organised by the University of Bristol, 26th April 2022.

3- Norway Scientific Trip for Pelvic Floor Training Session. A collaboration with international experts at the University of Trondheim, Norway led by Professor Salvesen offered an in-depth at the 3D/4D intrapartum ultrasound of the pelvic floor in the first and second stages of labour, 20th, 21st, and 22nd May 2022.

4- Italy Scientific Trip for Statistical Analysis, 22nd and 23rd May 2023. A collaboration with a remarkable team of statisticians from the Institute for Maternal and Child Health, IRCCS Burlo, Trieste, Italy led by Professor Lorenzo Monasta and Professor Tamara Stampalija .

# Abbreviations

| | |
|---|---|
| AoP | Angle of Progression |
| AC | Abdominal Circumference |
| AFI | Amniotic Fluid Index |
| AUCA | Anterior Uterocervical Angle |
| AUC | Area Under the Curve |
| ACOG | American College of Obstetricians and Gynaecologists |
| BPD | Biparietal Diameter |
| BMI | Body Mass Index |
| CSOG | Canadian Society of Obstetrics and Gynaecology |
| CTG | Cardiotocography |
| CU | Cerebral-Umbilical |
| CPR | Cerebral-Placental Ratio |
| CUR | Cerebral-Umbilical Ratio |
| CL | Cervical Length |
| CI | Chief Investigator |
| CD | Cervical Dilatation |
| CRL | Crown-Rump Length |
| CCC | Confirmation of Capacity and Capability |
| DVE | Digital Vaginal Examination |
| DOA | Direct Occiput Anterior |
| DOP | Direct Occiput Posterior |
| DASS | Depression, Anxiety and Stress Scale |
| ePartogram | Electronic Partogram |
| EFW | Estimated Fetal Weight |
| FGR | Fetal Growth Restriction |
| FOC | Fear of Childbirth |
| FL | Femur Length |
| 4D | Four-Dimensional |
| GA | Gestational Age |

| | |
|---|---|
| GDM | Gestational Diabetes Mellitus |
| HPD | Head-Perineum Distance |
| HSD | Head-Symphysis Distance |
| HRA | Health Regulator Authority |
| HC | Head Circumference |
| IUGR | Intrauterine Growth Restriction |
| ICD | Intrapartum Caesarean Delivery |
| ICC | Intraclass Correlation Coefficient |
| IQR | Interquartile Range |
| ISUOG | International Society of Ultrasound in Obstetrics and Gynaecology |
| JRCO | Joint Research Compliance Office |
| LCG | labour Care Guide |
| LOT | Left Occiput Transverse |
| LOA | Left Occiput Anterior |
| LOP | Left Occiput Posterior |
| MCA | Middle Cerebral Artery |
| MRI | Magnetic Resonance Imaging |
| MLA | Midline Angle |
| MDAU | Maternity Day Assessment Unit |
| MSD | Mean Gestational Sac Diameter |
| NICE | National Institute for Health and Care Excellence |
| NICU | Neonatal Intensive Care Unit |
| NPV | Negative Predictive Value |
| OSA | Occiput-Spine Angle |
| OPUS | Optical Ultrasound Stimulation |
| PPROM | Preterm Pre-Labour Rupture of Membrane |
| PTSD | Post-Traumatic Stress Disorder |
| PI | Pulsatility Index |
| PD | Progression Distance |
| PPV | Positive Predictive Value |

| | |
|---|---|
| QCCH | Queen Charlotte's and Chelsea Hospital |
| ROT | Right Occiput Transverse |
| ROA | Right Occiput Anterior |
| ROP | Right Occiput Posterior |
| REC | Research Ethics Committee |
| ROC | Receiver Operating Characteristic |
| RCOG | Royal College of Obstetricians and Gynaecologists |
| SDP | Single Deepest Pocket |
| sPTB | Spontaneous Preterm Birth |
| SPSS | Statistical Package for the Social Sciences |
| SSD | Skin-Skull Distance |
| TA | Transabdominal |
| TAUS | Transabdominal Ultrasound |
| TV | Transvaginal |
| TVUS | Transvaginal Ultrasound |
| TP | Transperineal |
| TPUS | Transperineal Ultrasound |
| 3D | Three-Dimensional |
| UA | Umbilical Artery |
| UC | Umbilical Cerebral |
| UCR | Umbilical-Cerebral Ratio |
| VD | Vaginal Delivery |
| W-DEQ | Wijma Delivery Expectancy/Experience Questionnaire |
| WHO | World Health Organisation |

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# Abstract

**Background:** This study aimed to develop a predictive model for intrapartum Caesarean delivery (ICD) in nulliparous women during the active first stage of labour using clinical and ultrasound parameters.

**Methods:** SONO-PREDICT is a prospective longitudinal observational cohort study conducted at Queen Charlotte's and Chelsea Hospital from 2021 to 2023, including nulliparous women with singleton, cephalic pregnancies at term. Transabdominal ultrasound assessed fetal head position, amniotic fluid volume, and fetal Doppler measurements. Transperineal ultrasound measured head-perineum distance (HPD), caput succedaneum, and moulding. Ultrasounds were conducted following digital vaginal examinations.

**Results:** Out of 241 participants, 239 were evaluable, 202 (85%) underwent second assessments. ICD was necessary for 84 (35%). The interval from the onset of active labour to delivery was significantly shorter in participants who delivered vaginally compared to those who required ICD (median duration: 11.8 hours vs. 14.6 hours; $p < 0.001$). The primary predictors at the first labour assessment were HPD and cervical dilatation ($p = 0.003$ and $p = 0.015$, respectively). In the context of repeat assessments, HPD at both assessments and its changes, changes in caput succedaneum, and cervical dilatation at both evaluations and its changes were key variables ($p = 0.023$, $p < 0.001$, $p = 0.012$, $p = 0.007$, $p = 0.015$, $p < 0.001$, and $p < 0.001$, respectively). Multivariate logistic regression analysis of the single assessment model (n = 239) included HPD and cervical dilatation, yielding an AUC of 0.68. For the repeat assessments model (n = 202), incorporating initial HPD and caput succedaneum and cervical dilatation and its changes, achieved an AUC of 0.89.

**Conclusion:** Single-assessment model demonstrates feasibility and provides reasonable accuracy in predicting intrapartum caesarean delivery. However, incorporating repeat clinical and ultrasound assessments significantly enhances predictive value. HPD, caput succedaneum, and cervical dilatation emerge as the most predictive parameters for ICD.

# CHAPTER 1

# Introduction

*Our team recently published a paper titled 'The Sonopartogram' in the American Journal of Obstetrics and Gynaecology (AJOG). This comprehensive expert review discusses the assessment of labour progress using intrapartum ultrasound techniques and explores its potential role in the management of labour and delivery. The paper was published on March 15, 2023.*
*Usman, S., Hanidu, A., Kovalenko, M., Hassan, W. A., & Lees, C. (2023). The sonopartogram. American journal of obstetrics and gynecology, 228(5S), S997–S1016. https://doi.org/10.1016/j.ajog.2022.06.027*

## 1.1 Labour Management: Standard Approach

Digital vaginal examination (DVE) is a routinely employed method utilised in labour management, applied universally at regular intervals to guide decision-making regarding labour progress. DVE acts as a diagnostic tool to evaluate cervical dilatation, effacement, and the position and station of the fetus within the maternal pelvis. Despite its widespread utility, DVE is subjective to significant inter- and intra-observer variability;[1,2,3] discrepancies in the estimates of cervical dilatation by two clinicians have reached or exceeded 2 cm in 11% of cases.[2] This method can also be intrusive and uncomfortable for the patient,[4,5,6] potentially increasing the risk of infections, chorioamnionitis and endometritis, and may accelerate delivery timelines in cases of preterm labour.[7,8] Moreover, DVE is contraindicated in certain conditions, including placenta previa and preterm pre-labour rupture of membranes (PPROM).

It can be particularly distressing for patients with tokophobia, a history of sexual violence, or conditions such as post-traumatic stress disorder (PTSD) or vaginismus, in such instances, medical protocols typically stipulate minimising the use of DVE unless critically necessary.[9] DVE is employed either independently or as part of the partogram, which is typically a pre-printed paper chart. This chart enables birth attendants to graphically document observations related to both the mother and the fetus, thereby informing clinical decision-making.[10]

Although not universally implemented, in many clinical sittings the outcomes of vaginal examinations are recorded on the partogram. Historically, labour monitoring in maternity settings utilised the partogram, which was initially based on the labour curves conceptualised by Friedman in the 1950s.[11,12,13] Subsequent modifications have enhanced its utility.[14-18]

In light of concerns over significant maternal and fetal morbidity, the World Health Organisation (WHO) updated its intrapartum care guidelines in 2018,[19] an advancement from its 1994 guidelines[20] redefining the parameters for slow labour progression. These revised guidelines represent a paradigm shift towards enhancing the childbirth experience, facilitating the introduction of the WHO labour care guide (LCG).[21] This updated partogram has been reported to augment labour management outcomes within hospital environments.[19] Further refinements to the original WHO partogram have led to creation of versions that are deemed more intuitive and, consequently, favoured by healthcare and midwifery professionals.[22,23]

The evolution of partogram use has culminated in the development of a digital, interactive electronic partogram (ePartogram),[24] which incorporates a clinical decision support system based on WHO labour protocols to trigger reminders for clinicians to record maternal and fetal metrics during labour. This ePartogram has been reported to improve adherence to recommended labour observations, subsequently enhancing the quality of care and reducing fetal complications. Further validation in various maternity environments remains essential. Despite these advancements, the partogram primarily aids in identifying arrested labour progress and directing specific obstetrical interventions and is not intended for predicting labour outcomes.

In 2022, we published a comprehensive expert review titled 'The Sonopartogram'[25] in the American Journal of Obstetrics and Gynaecology (AJOG), this review meticulously chronicles the developments and advancements in partogram technology, with particular focus on the globally significant integration of ultrasound in labour management.

## 1.2 Intrapartum Ultrasound

Over the past two decades, the application of ultrasound during labour, termed 'intrapartum ultrasound', has seen significant expansion. It was introduced in 1977[26] when Lewin D. reported the efficacy of ultrasound imaging in evaluating fetal head station by correlation the position of the fetal head with the tip of the coccygeal bone. Since then, a substantial body of literature on the use of ultrasound in labour has developed. This growth is driven by the increased demand for more reliable methods of labour assessment and the improved availability of ultrasound equipment in delivery suites. Ultrasound in labour initially employed for basic assessments such as detecting the fetal heartbeat, determining fetal presentation, and estimating amniotic fluid volume, its use has now expanded to more advanced applications, including assessing the fetal head position and station, measuring cervical dilatation and length, and predicting the mode of delivery with increased objectivity and precision.

Intrapartum ultrasound has propelled the field of obstetrics into a discipline increasingly governed by objective assessments of labour progression. It has diminished the reliance on subjective clinical estimations of fetal head descent, traditionally visualised along an imaginary line between the ischial spines. additionally, it facilitates more precise measurements of cervical dilatation.

Nonetheless, the adoption of intrapartum ultrasound is met with some resistance. A primary concern is the potential over-dependence on technological solutions, which may undermine traditional obstetric skills. The definitive clinical value of intrapartum ultrasound remains to be established. Moreover, the routine application of advanced ultrasound techniques during labour has not been comprehensively validated by robust evidence, as these methods have yet to be thoroughly assessed through large-scale prospective studies.

### 1.2.1 Transabdominal Ultrasound Technique

**Fetal Head and Spine Position**

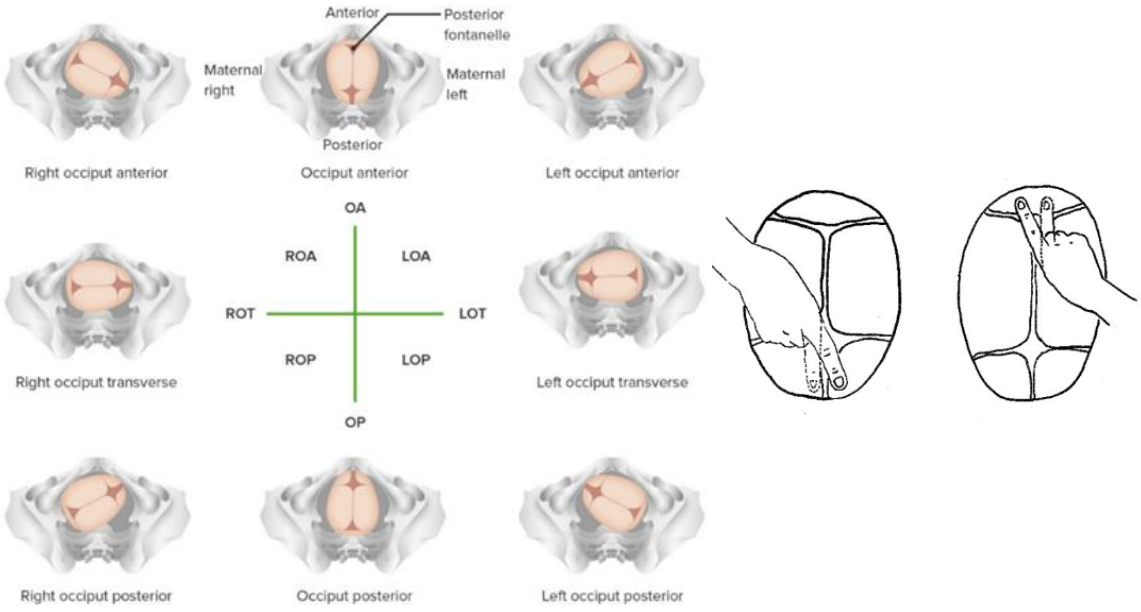
The orientation of the fetal head during labour significantly influences the course of labour, particularly in cases presenting with protraction or arrest disorders. DVE is predominantly used during labour to assess labour progress, including the fetal head position, through palpation of the fetal fontanelles (Figure 1).[27,28] Akmal S. et al.[29] reported that DVE failed to correctly identify the fetal head position in 27% of cases, and further indicated that in 34% of instances, the clinician was unable to ascertain the position of the fetal head.[30] In cases where the position could be determined, only half showed an agreement within a 45-degree range.[30] The rate of concordance improved with cervical dilatation, rising from 21% at 3-4 cm to 44% at 8-10 cm.[30] Ghi T. et al.[31] noted that an incorrect diagnosis of occiput position occurred in 13% of cases assessed digitally.

Sherer D. et al.[32,33] examined the relationship between ultrasound-determined fetal head position and clinical examination in labouring women with a cervical dilatation of at least 4 cm. A discrepancy between DVE and abdominal ultrasound was noted in 76% of cases. Even allowing for an agreement of +/- 45 degrees, discrepancies occurred in 53% of the cases. Senior physicians demonstrated greater accuracy compared to junior doctors; however, significant levels of disagreement persisted, ranging from 69% to 45% among more experienced physicians.[32,33]

In contrast, extensive literature reviews have reported that the transabdominal ultrasound (TAUS) technique is considered the ‘gold standard’, offering superior performance in assessing fetal head position,[29-33] malposition,[39] malpresentation,[39] or asynclitism,[34] with a higher accuracy rate than digital method.[29-41] TAUS demonstrates good inter- and intra-observer agreement, with statistically significant variabilities

($p < 0.001$).[42] Ultrasonography requires a shorter learning curve relative to traditional clinical examinations,[43] and its adoption has been widely encouraged and recommended.[44]

***Figure 1.*** *Variations of the Fetal Occiput Position through Palpation of the Fetal Fontanelles.*[27,28]




The TAUS technique is straightforward to be performed and based on our observations, birth attendants with basic ultrasound proficiency can easily conduct sonographic evaluation for both the fetal head and spine positions. It involves positioning the patient supine with a voided bladder and placing the ultrasound probe transversely over the maternal abdominal region. The ultrasound probe is then moved longitudinally to identify the fetal spine in different positions (Figure 2). Subsequently, the ultrasound probe is placed distally on the maternal suprapubic region in an axial plane, allowing for a clear visualisation of the fetal head. The position of the fetal head is ascertained by locating the posterior fontanelle (occiput) relative to a conventional 12-hour clock face (Figure 3 and 4), with 24 divisions[30] (representing

half-hour increments), the measurements are approximated to the nearest hour, corresponding to 30-degree segments. The ultrasound probe can be rotated longitudinally to provide additional data including the degree of fetal neck flexion.

Fetal head positions are categorised as occiput anterior ($10 \leq OA \leq 2$ o'clock), occiput posterior ($4 \leq OP \leq 8$ o'clock), left occiput transverse ($2 < LOT < 4$ o'clock), and right occiput transverse ($8 < ROT < 10$ o'clock).[40] Key landmarks,[30] including occiput itself, cerebellum and fetal cervical spine for the anterior occiput position (Figure 4 B), the fetal orbits for diagnosing occiput posterior position (Figure 4 C), and midline cerebral echoes for occiput transverse position (Figure 4 D), can be identified beneath the ultrasound probe depending on the fetal head position. Various fetal head positions are illustrated in Figure 5.

Current guidelines recommend the use of ultrasound throughout labour to manage abnormal progress during the first or second stages and to verify the occiput position and station prior to initiation of instrumental delivery.[44] However, DVE and ultrasound should be considered complementary approaches.[45] Given the robust evidence supporting the superiority of TAUS in accurately detecting fetal head position during labour, it is likely that ultrasound will become a standard practice. Acquiring reliable data on what constitutes normal occiput positions in labour will be essential.

***Figure 2.*** *Intrapartum Transabdominal Ultrasound (TAUS) Technique for Assessing Fetal Spine Position.*[25] ***A,*** *Ultrasound probe orientation on the maternal abdominal region giving a cross-sectional view of the fetus;* ***B****, Schematic diagram representing possible positions of the fetal spine in four categories;* ***C,*** *Schematic diagram representing possible positions of the fetal spine in correlation with a 12-hour clock face; and* ***D,*** *the spine position at the 4 o'clock position; E, the spine position at the 2 o'clock position; and F, the spine position at the 6:30 o'clock position. (The ultrasound images from the SONO-PREDICT study, informed consent for publication was obtained from the participant).*

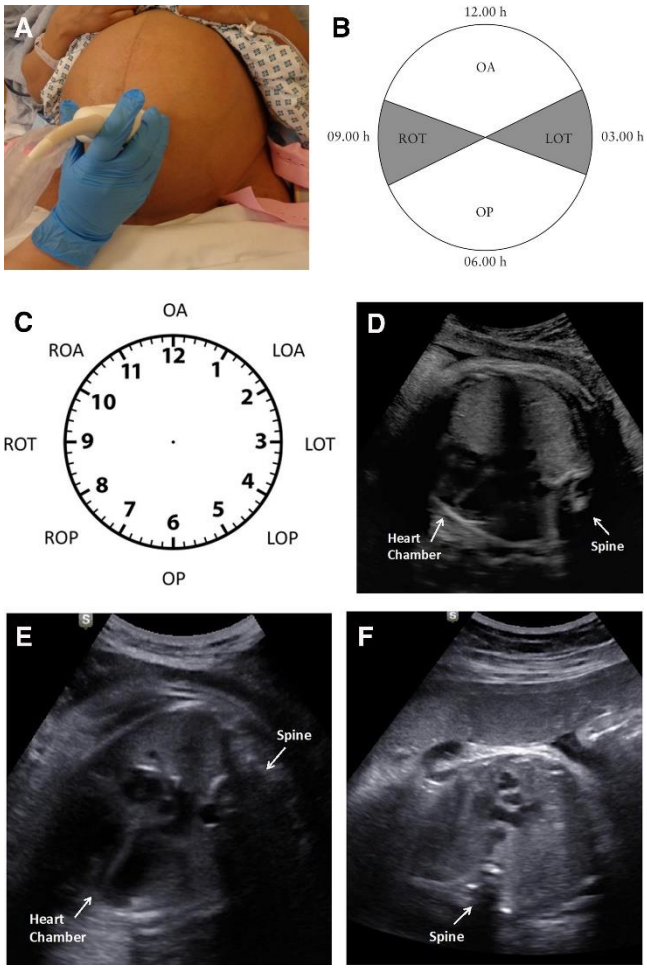



***Figure 3.*** *Variations of the Fetal Occiput Position Relative to a Conventional 12-hour Clock (This fetal head position diagram created for the SONO-PREDICT study).*

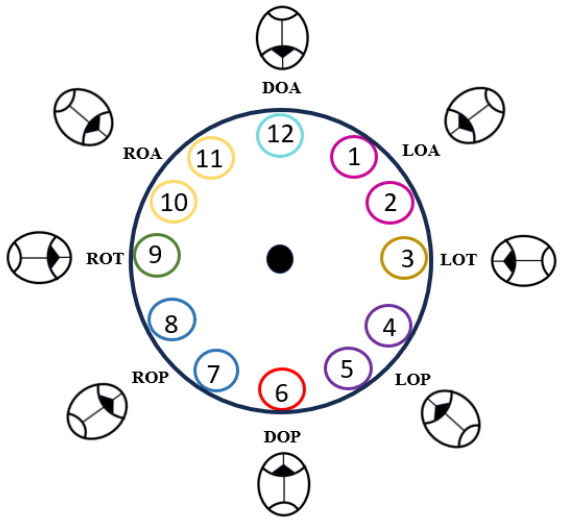


***Figure 4.*** *Intrapartum Transabdominal Ultrasound (TAUS) Technique for Assessing Fetal Head Position.*[25] ***A,*** *Ultrasound probe orientation in the transverse plane on the maternal suprapubic region;* ***B,*** *Cervical vertebra seen at the 12 o'clock position showing occiput anterior position of the fetal head;* ***C,*** *both fetal orbits are seen at the anterior view, the occiput at 6 o'clock position demonstrating occiput posterior position; and* ***D,*** *Midline cerebral echo is seen and either side of the midline are the thalami, and the cerebellum is posterior related to the occiput, this represents the left occiput transverse. (The ultrasound images from the SONO-PREDICT study, informed consent for publication was obtained from the participant).*

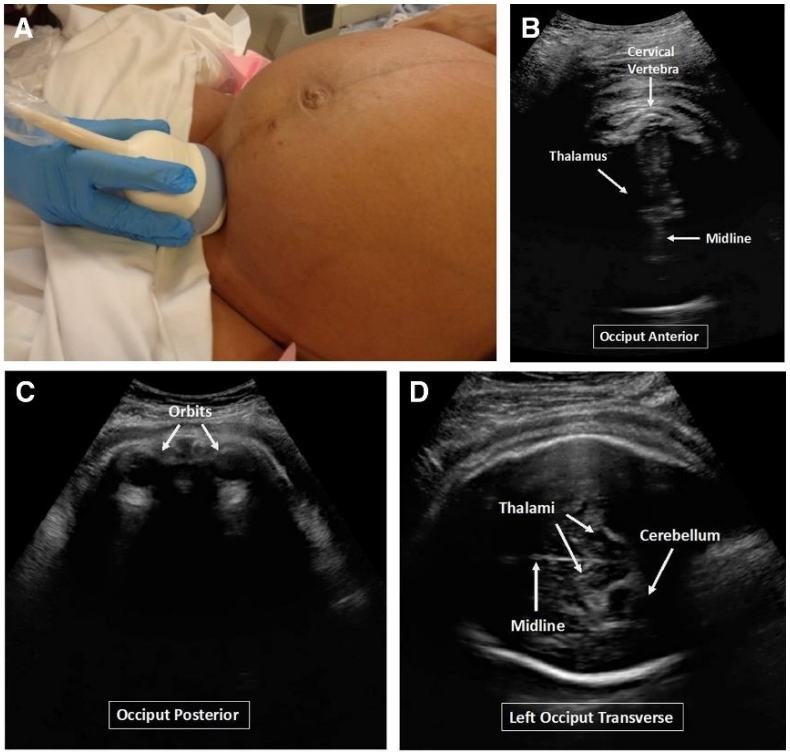
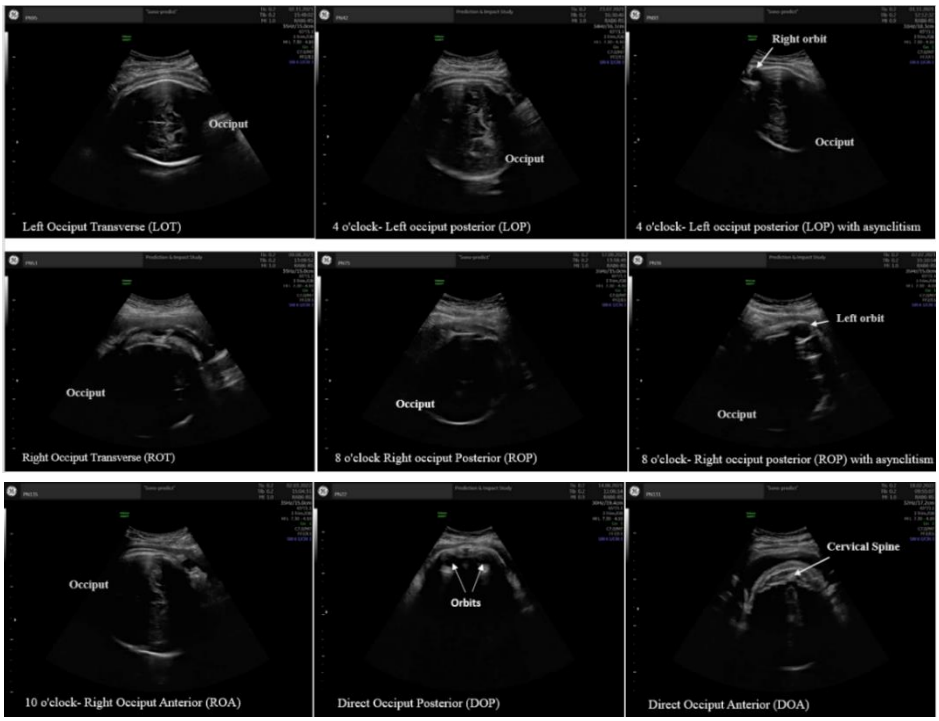



***Figure 5.*** *Variations of the Fetal Head Position Using Transabdominal Ultrasound (TAUS) Technique during First Stage of Labour. (The ultrasound images from the SONO-PREDICT study).*



**Fetal Doppler**

During labour, uterine contractions may compress uterine arteries or the umbilical cord, leading to significant reductions in uteroplacental or umbilical cord blood flow. Such reductions can induce fetal hypoxia. The primary goal of monitoring fetal health during labour is to detect fetuses experiencing hypoxia. Notably, over 20% of annual global neonatal deaths are connected to complications related to intrapartum hypoxia.[46,47] It is important to note that many of these complications occur in pregnant women considered to be low risk at term.[48,49]

Cardiotocography (CTG) continues to be the predominant method for assessing fetal well-being during labour, despite its relatively low specificity for detecting fetal distress. This limitation is the subject of considerable debate.[50-54] Additionally, the use of CTG has not demonstrably improved perinatal outcomes.[55-57] The interpretation of CTG results is subjective and shows low consistency and agreement among, and between, different observers.[55-60] Moreover, it has limited capacity to accurately identify fetuses that are genuinely hypoxic.[55-60]

Recognising the need to predict labour outcomes and manage intrapartum Caesarean deliveries effectively is essential for the appropriate allocation of resources and for reducing incidents that result in hypoxia and other immediate and long-term complications. In the quest of continuous, non-invasive methods to monitor fetal status with greater specificity for identifying fetal compromise, both reflectance pulse oximetry and Doppler ultrasonography of fetal hemodynamics offer considerable promise.[62,63]

Fetal pulse oximetry, a technique currently under review,[61] facilitates measuring fetal oxygen saturation during labour, enhancing the assessment of fetal well-being.[62,63] The use of intrapartum Doppler velocimetry for the fetal middle cerebral artery (MCA) and umbilical artery (UA) proves valuable in identifying changes in

fetal circulation indicative of oxygen stress. The efficacy of intrapartum fetal Doppler velocimetry in predicting adverse perinatal outcomes in complex pregnancies has been thoroughly investigated.[64,65] Strong correlations exist between cerebral Doppler results and fetal hypoxia, particularly in cases of absent end-diastolic flow in the aorta or umbilical artery at various stages of pregnancy.[66,67] The primary responsibility of obstetricians is to accurately predict fetal distress while minimising unnecessary operative interventions.

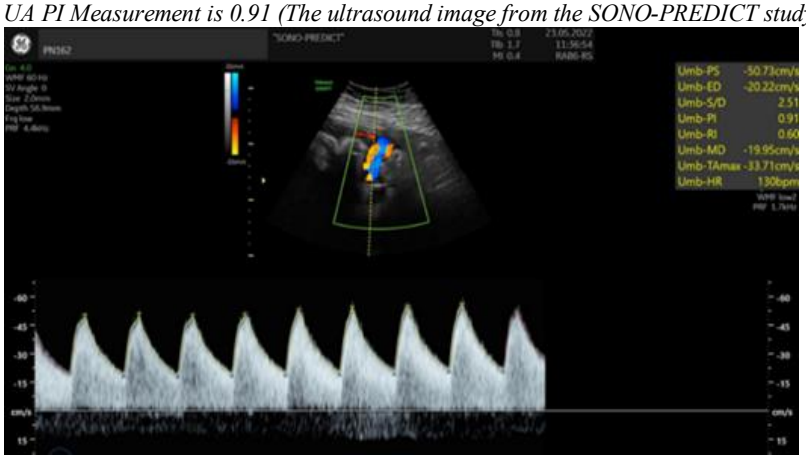
A 2004 study aimed to concurrently use CTG, pulse oximetry, and MCA and UA Doppler assessments during the first stage of labour to explore fetal circulation at various stages of hypoxia and to examine blood flow changes in the brain and peripheral tissues.[68] The findings indicated that this approach facilitates earlier detection of fetal deterioration and provides a more rapid prediction of fetal compromise, revealing a strong correlation between pulse oximetry, Doppler ultrasonography, and fetal morbidity.[68] Fetal Doppler assessments have been postulated to have a role in determining the need for delivery due to fetal distress in both preterm and term babies.[69-71]

**Umbilical Doppler and Middle Cerebral Artery Doppler**

The primary methods for evaluating placental function and fetal well-being antepartum include the analysis of Doppler waveforms from the UA and MCA.[72] The foundational physical principle behind Doppler ultrasound technology is the Doppler effect, which describes the change in frequency of ultrasound waves as they are transmitted and then received between two objects, with at least one in motion.[73,74] In obstetric applications, the stationary component is the ultrasound probe, and the dynamic reflectors are the red blood cells circulating within the uterofetoplacental system, generating the reflected echo signals.[73]

The UA Doppler provides valuable insights into arterial blood flow characteristics and is a well-established method for monitoring high-risk pregnancies complicated by impaired placentation.[75-78] The use of Doppler ultrasound in this context is recognised for reducing the risk of perinatal mortality by approximately 29%.[76] UA Doppler measurements should ideally be performed on a free-floating loop of the umbilical cord, away from both the placental and fetal abdominal insertions, to avoid any potential compression that might alter cord resistance and disrupt normal blood flow.[79] UA Doppler measurements obtained near the placental insertion show lower resistance compared to those taken near the abdominal insertion.[79] Figure 6 depicts the measurement of the UA Doppler. Adverse neonatal outcomes are more prevalent in fetuses exhibiting abnormal UA resistance indices,[80] even among those that are normally sized and appropriately developed.[81] Systematic reviews, however, suggest that relying solely on UA Doppler velocimetry is insufficient for predicting adverse perinatal outcomes.[82,83]

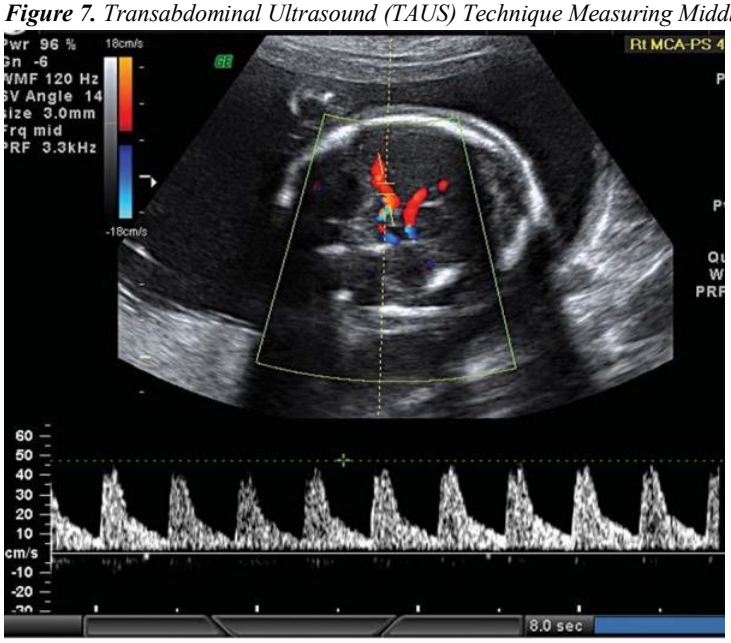
***Figure 6.*** *Transabdominal Ultrasound (TAUS) Technique Measuring Umbilical Artery (UA) Doppler. The UA PI Measurement is 0.91 (The ultrasound image from the SONO-PREDICT study)*




The MCA is crucial for evaluation due to its direct link with fetal hypoxia during labour, as evidenced by lower MCA values.[84] These findings indicate a relationship between MCA Doppler indices and fetal well-being, underscoring the importance of MCA Doppler assessment in identifying well-grown fetuses at risk of intrapartum compromise.

For precise measurement of the MCA Doppler, an axial plane of the fetal head that includes the thalami and cavum septum pellucidum should be visualised. This imaging facilitates the observation of the circle of Willis using either colour or power Doppler techniques. The MCA Doppler should ideally be measured at its origin from the internal carotid artery. It is important to place the sample volume at the centre of the artery and to maintain the angle between the ultrasound beam and the direction of blood flow as close to $0^0$ as feasible to ensure accurate measurement data (Figure 7).[85]

***Figure 7.*** *Transabdominal Ultrasound (TAUS) Technique Measuring Middle Cerebral Artery (MCA) Doppler.*[85]




**Cerebral-Umbilical and Umbilical-Cerebral Ratios**

The cerebral-umbilical (CU) ratio, also known as the cerebral-placental (CP) ratio, is calculating by combining the resistance indices of both the UA and MCA, expressed as the MCA pulsatility index (PI) to UA PI. Initially described in 1987, this ratio was observed to frequently fall below 1 in pregnancies impacted by fetal growth restriction (FGR) or hypertensive disorders.[86] It was noted that there was a significant increase of Caesarean deliveries for fetuses with a low CP ratios.[87] A retrospective study in Brisbane, Australia, found that infants born by emergency Caesarean or instrumental delivery for fetal compromise had the lowest median CPR compared to those delivered by other methods.[88] A low CPR at 35-37 weeks gestation correlates with higher intrapartum complication risks.[88] It has been suggested that a low CP ratio measured early in labour is significantly associated with fetuses that later require emergency delivery due to presumed intrapartum fetal distress, whereas a high CP ratio may protect against fetal compromise during labour.[89] The CP ratio is valuable tool for detecting fetuses at risk of adverse outcomes, thereby

facilitating early identification, monitoring, and management.[90] It has gained recognition as a rapid and effective method for assessing fetal well-being, surpassing the predictive capabilities of both CTG and the biophysical profile in well-grown fetuses.

Conversely, the umbilical-cerebral (UC) ratio uses the same fetal Doppler components but invert the calculation, expressing the UA PI to MCA PI. This metric is particularly sensitive in differentiating abnormal Doppler changes.[91] However, recent studies have indicated no significant differences between the UC ratio and CP ratio in predicting the need for operative delivery due to presumed fetal compromise.[92,93] A study comparing the prognostic accuracy of CP ratio with UC ratio in predicting short-term adverse perinatal outcomes in growth-restricted fetuses found no substantial differences between the two, nor any significant advantage of UC ratio over the CP ratio in this context.[94]

**Amniotic Fluid Volume**

Estimating amniotic fluid volume is pivotal in monitoring fetal well-being and managing pregnancy outcomes. Variations in amniotic fluid volume, whether excessive or insufficient, are indicative of potential complications that may impact fetal development. Fetal urine production, initiating around the 10$^{th}$ week of gestation, significantly contributes to the amniotic fluid volume, particularly during the second and third trimesters. Concurrently, fetal swallowing commences, facilitating amniotic fluid circulation.[95,96]

Clinicians typically measure amniotic fluid volume using the amniotic fluid index (AFI) or the single deepest vertical pocket (SDP) technique.[97,98] An AFI exceeding 24 cm or an SDP greater than 8 cm suggests polyhydramnios, potentially associated

with fetal anomalies including gastrointestinal obstructions, genetic abnormalities, musculoskeletal disorders, and congenital diaphragmatic hernias.[98] In contrast, oligohydramnios is characterised by an AFI less than 5 cm or an SDP below 2 cm[99], and is associated with severe fetal complications including renal agenesis, obstructions in the genitourinary tract, and intrauterine growth restriction (IUGR).[100,101] Intrapartum assessment of amniotic fluid volume is as vital as monitoring fetal heart rate to identify potential risks, including meconium-stained amniotic fluid and the necessity for Caesarean delivery due to fetal distress.[102,103] Monitoring amniotic fluid volume during labour provides essential insights into potential complications in subsequent stages of labour and delivery.[104]

Recent studies underscore the association between a reduced AFI and adverse perinatal outcomes, evidenced by low APGAR scores (< 7/10 at 5 minutes post-birth).[105] Further research indicates that a low AFI (≤ 5 cm) is correlated with factors such as the mode of delivery, low birth weight, diminished APGAR score at 1 minute,[106] an increased likelihood of operative delivery, meconium-stained amniotic fluid, a higher probability of neonatal intensive care unit (NICU) admissions, and generally lower APGAR scores.[107] Figure 8 and 9 depict the techniques for measuring amniotic fluid volume using AFI and SDP methods.

***Figure 8.*** *Amniotic Fluid Volume: Measurement of the Amniotic Fluid Index (AFI). The AFI measurement is 10.67 cm.*[108]

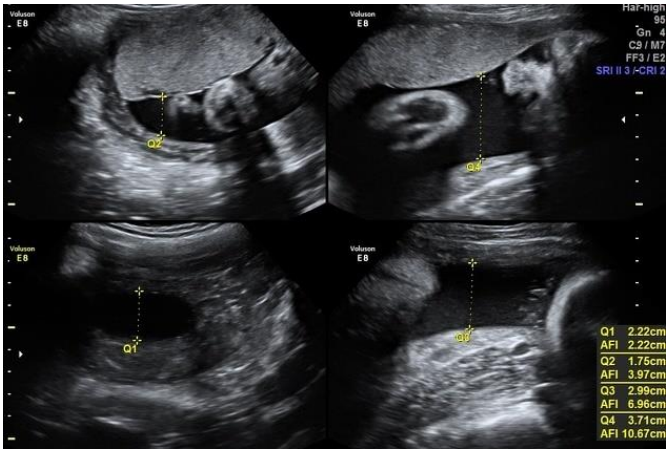
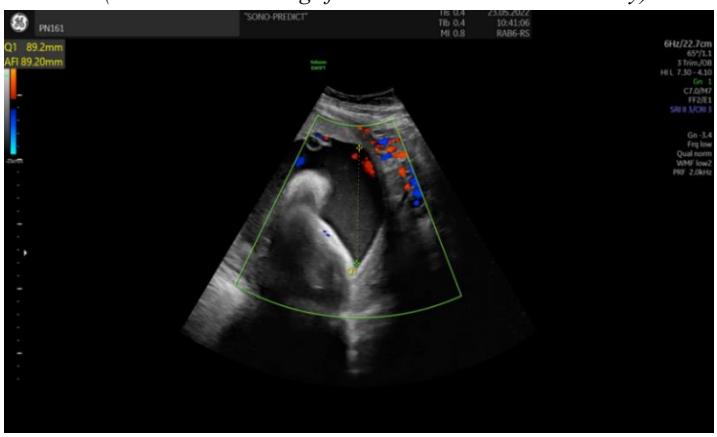



***Figure 9.*** *Amniotic Fluid Volume: Measurement of the Single Deepest Pocket (SDP). The SDP measurement is 8.9 cm. (The ultrasound image from the SONO-PREDICT study).*




## Cervical Length

Cervical length (CL) and its dynamic changes serves as crucial predictors of a successful vaginal delivery outcomes. Preterm birth, the leading cause of perinatal mortality and morbidity, has a global incidence estimated at 5-18%.[109,110] The International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) recommends for cervical ultrasound assessment between 18+0 and 24+0 weeks of gestation for all pregnant women.[111] For individuals with a CL of less than 25 mm, prophylactic administration of vaginal progesterone is recommended to mitigate the risk of preterm birth.[111]

TAUS offers shorter scanning durations and minimal patient discomfort compared to transvaginal ultrasound (TVUS) when assessing CL.[112,113] A prospective cohort study involving routine second-trimester fetal anomaly scans employing both TA and TV techniques found no significant differences in mean CL measurements between the approaches.[114] Another study evaluating preinduction CL measurement via TVUS, transperineal ultrasound (TPUS), and TAUS in terms of delivery time[115] found that all techniques correlated with Bishop scores, and TAUS is a viable initial tool for CL evaluation.[113] However, TAUS was less effective in accurately predicting the timing of vaginal delivery compared to TPUS and TVUS techniques.[116] Screening for a short cervix in nulliparous women could be conducted using TAUS, reducing the need for invasive TVUS in over 3/4 of cases.[116] This technique has demonstrated predictive value for preterm delivery.[117]

Nonetheless, studies indicate that TAUS tends to underestimate CL measurements compered to TVUS when the later exceeds 34 mm and overestimate it when TV CL is less than 34 mm.[118] TAUS shows low sensitivity in predicting a short cervix, and relying solely on TAUS for CL assessment could lead to missed diagnosis.[118] Additionally, the accuracy of CL measurements via TAUS can be influenced by maternal factors including bladder fullness and body mass index (BMI).[119]

A standardised approach to measuring TA CL is essential, as variability in measurement protocols likely affects the accuracy of CL measurements, contributing to significant inter- and intra-observer variability. Further research is required to validate these findings, particularly during labour.

In an intrapartum setting, where women are in established labour, the cervix is, by definition, dilating; therefore, measuring cervical length is not relevant.

### 1.2.2 Transvaginal Ultrasound Technique

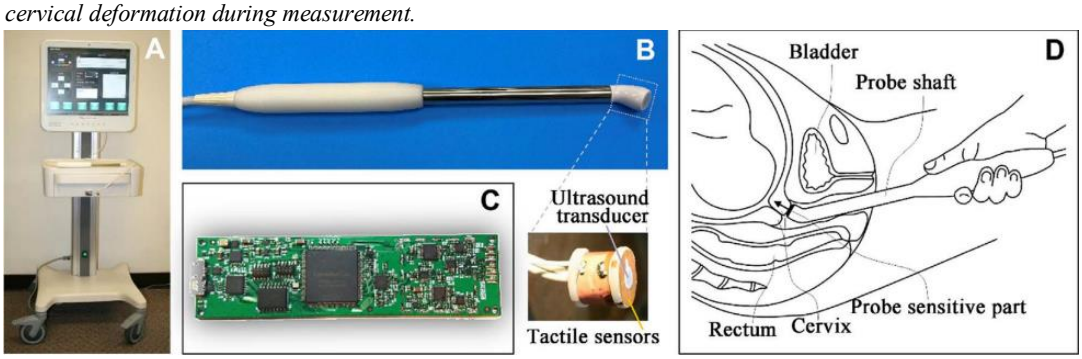
Historically, the assessment of spontaneous preterm birth (sPTB) risk in nulliparous women relied on clinical symptoms and medical risk factors, mainly through reported symptoms. Preterm labour is characterised by regular uterine contractions and progressive cervical changes occurring between 22+0 and 36+6 weeks of gestation.[120,121] sPTB is a major contributor to perinatal morbidity and mortality. To improve risk assessment, more objective methods such as TVUS have been developed, offering higher predictive accuracy.

Studies underscore the effectiveness of CL measurements via TVUS in enhancing labour induction decisions. TVUS-derived CL measurements outperform Bishop scores in predicting Caesarean delivery after labour induction.[122] Additionally, assessing both the posterior cervical angle and CL via TVUS has shown greater sensitivity in predicting labour dystocia than Bishop scores.[123]

Research has also examined the anterior uterocervical angle (AUCA) through TVUS for its impact on cervical pressure.[124] A wider AUCA increases the risk of sPTB by intensifying direct cervical pressure, while a narrower AUCA may be protective.[124] AUCA measurements provide greater precision than CL measurement method,[124] and combining AUCA and CL measurements via TVUS offers superior sPTB prediction. [125] Nonetheless, implementation of a universal TVUS screening programme for CL in singleton pregnancies without prior sPTB history, including treatment for CL≤ 25 mm, has not significantly reduced sPTB incidence.[126] An innovative study by Vladimir E. et al.[127] suggests that measuring cervical elasticity via a transvaginal tactile ultrasound could be cost-effective strategy for predicting sPTB (Figure 10).

Integrating quantitative TVUS into the traditional clinical prediction models significantly enhances risk prediction accuracy as pregnancy progresses.[128] However, in our intrapartum study, TVUS was not utilised.

***Figure 10.*** *Design and Application of Transvaginal Cervical Tactile Ultrasound.* [127]
***A,*** *Cervix monitor device;* ***B****, Cervical probe with a single transducer and four sensors;* ***C,*** *Printed circuit board; and* ***D,*** *Positioning of the cervical probe during data acquisition, with the arrow indicating the direction of cervical deformation during measurement.*



### 1.2.3 Transperineal Ultrasound Technique

In the TPUS technique, the first application was developed by Lewin D. in 1977,[129] who utilised this method to assess the cervix in a cohort of 100 pregnant women. He devised a method to avoid direct scanning on the sensitive and contoured perineal skin. The patients were positioned in a supine posture, mirroring the setup used in conventional abdominal echotomography.[129] A standard, water-filled balloon was strategically placed between the patient's thighs and subsequently compressed gently through the patient's adduction.[129] This arrangement enabled comprehensive anteroposterior scanning. Although the cervix was generally well visualised, Lewin noted that in two initial attempts, the imaging was unsuccessful.[129]

In 1990, Mahony B. et al.[130] conducted comparative research between translabial ultrasound findings and DVEs. They reported excellent agreement in measurements of CL, albeit a notable discrepancy in assessing cervical dilatation between the two methods. Subsequently, in 1995, Richey S. et al.[131] calculated the distance from the fetal skull to the perineum along the sagittal plane, thereby introducing the term 'transperineal' ultrasound as opposed to 'translabial' ultrasound.

Further exploration of TPUS occurred in clinical research documented in 1996.[132] Voskresinsky S. utilised this ultrasound technique to study the biomechanics of labour, presenting detailed imagery of the fetal head at different stages of labour via TP ultrasonography. Despite the formalisation of the research into a thesis, it garnered minimal attention, attributed primarily to its publication in Russian.

TPUS is a non-invasive, objective, straightforward, and reproducible method of examination, presenting less discomfort than DVE in assessing labour progress.[6,133] To

perform the TPUS technique effectively, the ultrasound transducer should be positioned between the labia majora or more caudally at the level of the fourchette. The woman should assume a semi-recumbent position with legs and knees flexed, ensuring an empty bladder.[44] This assessment can be conducted swiftly by applying gentle pressure on the maternal perineal soft tissue to generate high-resolution images. A substantial body of literature now supports the use of the TPUS technique for determining fetal head position,[42,134] fetal head station,[135] cervical dilatation,[136] caput succedaneum,[137] and fetal moulding.[138]

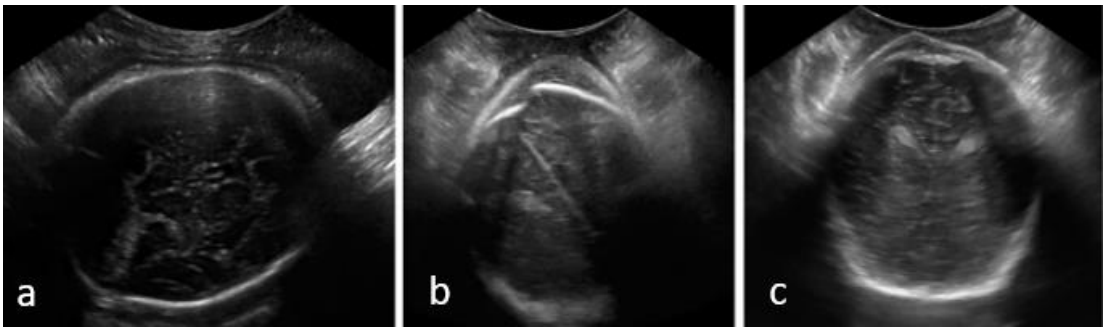
**Fetal Head Position**

The gold standard for assessing the position of the fetal head is the TAUS technique. However, when the fetal head station is too low, TPUS can proficiently evaluate its position (Figure 11).[42,134,139] The TAUS technique faces challenges in accurately determining the orientation of the fetal head relative to the maternal pelvis, particularly at low stations. This difficulty primarily stems from reliance on the midline cerebral echo, which may not always be readily visualised.[32,39,42]

Ghi T. et al.[42] demonstrated that when employing the TPUS technique, the orientation of the fetal head was easily assessable relative to a clock face, once the midline was defined. However, visualisation of intracranial anatomical structures, such as the thalami and orbits, was often obscured; occasionally, visualisation of the midline was obstructed by shadowing from the maternal symphysis pubis.[42] Nonetheless, the application of specific techniques and appropriate angling of the ultrasound probe could mitigate these issues.[140] This demands a higher level of operator's proficiency,[140] as the skills required for the operator increase with the fetal head becoming more asynclitic, particularly in terms of probe manipulation to adequately visualise

the midline structures.[141] Both TA and TP ultrasound techniques are complementary in assessing fetal head position. Therefore, it is advisable to integrate both techniques to achieve a comprehensive and accurate determination of the fetal head position.[142]

***Figure 11.*** *Transperineal Ultrasound (TPUS) Technique for Assessing Fetal Head Position.*[139]
***a,*** *Fetal occiput in the right transverse ROT at 8:30 o'clock position;* ***b,*** *Fetal occiput in the right anterior ROA at 10:30 o'clock position; and* ***c,*** *Fetal occiput in the direct anterior DOA at 12:00 o'clock position.*



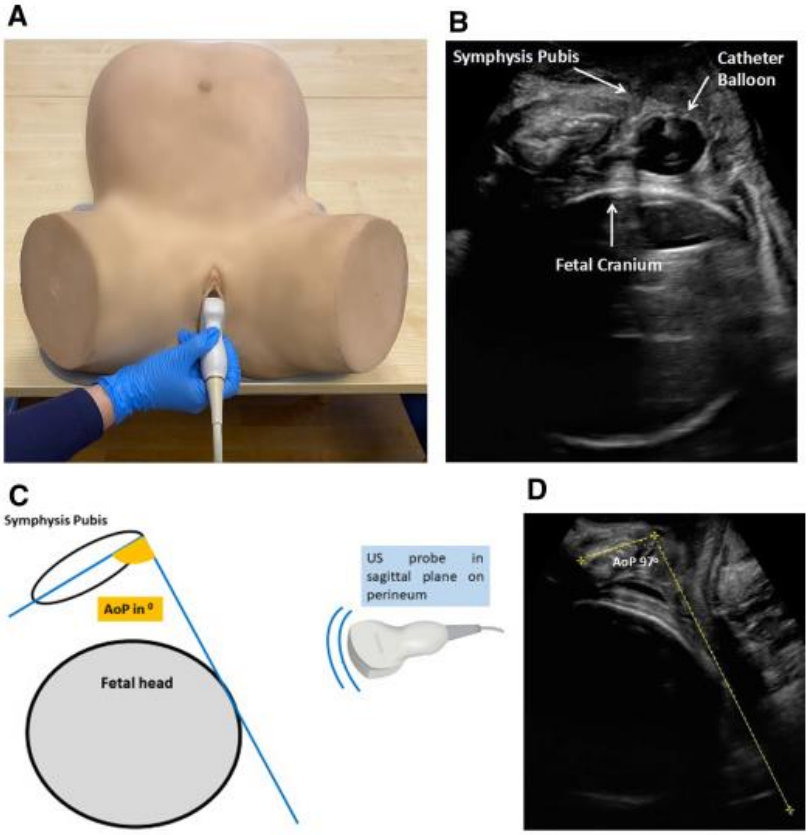

**Fetal Head Station**

The TPUS technique allows for objective assessment of the fetal head station during labour. Several quantitative sonographic parameters have been proposed for this purpose.[42,135,143-150]

- **Angle of Progression or Angle of Descent**

The angle of progression (AoP), originally termed the angle of head descent,[151] is defined as the angle formed between the longitudinal axis of the pubic bone and a line extending from the lowest point of the pubis tangentially to the deepest bony part of the fetal skull. Measuring the AoP is straightforward, involving the placement of the ultrasound probe between the maternal labia majora in a midsagittal plane[44] (Figure 12).

***Figure 12.*** *Measurement of the Angle of Progression (AoP) Using Transperineal Ultrasound Technique.*[25] ***A,*** *Ultrasound probe orientation in the midsagittal plane;* ***B,*** *Ultrasound image depicting the landmarks for measuring the AoP: identification of the maternal symphysis pubis and the contour of the fetal cranium. The maternal indwelling urinary catheter balloon can be seen in this image;* ***C,*** *Illustration of the measurement of the AoP; and* ***D****, The AoP demonstrated is 97°. (Figures and images from the SONO-PREDICT study).*




Barbera A. et al.[135] were the first to characterise this angle, demonstrating that the fetal head station could be quantified in terms of an angle. Traditionally, the determination of fetal head descent during labour relies on locating the lowest part of the fetal head within the pelvic canal. This positioning is assessed relative to an imaginary line drawn through the ischial spines, corresponding to the 0 station.[152] Stations situated above this line are spaced 1 cm apart and denoted by negative numbers, descending to '-5' at the pelvic inlet. Conversely, once the fetal head descends past this reference line, the stations below are similarly spaced by 1 cm increments, labeled from '+1 to +5', marking the level of the perineum.[153]

Barbera A. F. et al.[149] conducted another study employing computed tomography (CT) imaging of the pelvis, during which they meticulously examined the ischial spines as well as the upper and lower boundaries of the symphysis pubis. Their findings indicated that an AoP of 99° aligned with the ischial spines, while an AoP exceeding 120° was associated with a higher likelihood of successful vaginal birth. Additionally, they noted a weak correlation between lower fetal stations measured by TPUS and findings from clinical pelvic examinations.[149] The ischial spines are situated 3 cm inferior to the infrapubic line.[147,154,155]

Bamberg C. et al.[156] used magnetic resonance imaging (MRI) to explore the relationship between the AoP and the ischial spines, revealing a correlation with an AoP of 120° to the interspinal pane, which is a line between the ischial spines. Subsequently, in 2013, Tutschek B. et al.[144] compared various ultrasound measurement parameters and determined that the level of the ischial spines aligns with an AoP of 116°. In 2016, a study utilising three-dimensional (3D) renderings of CT pelvimetry images determined that the distance from the ischial spines to the infrapubic line measured 2.6 cm, and an AoP of > 110° was found to correspond to the level of ischial spines.[157] Variations across different studies could stem from differences in study populations, modalities, definitions, and computational models employed.[156]

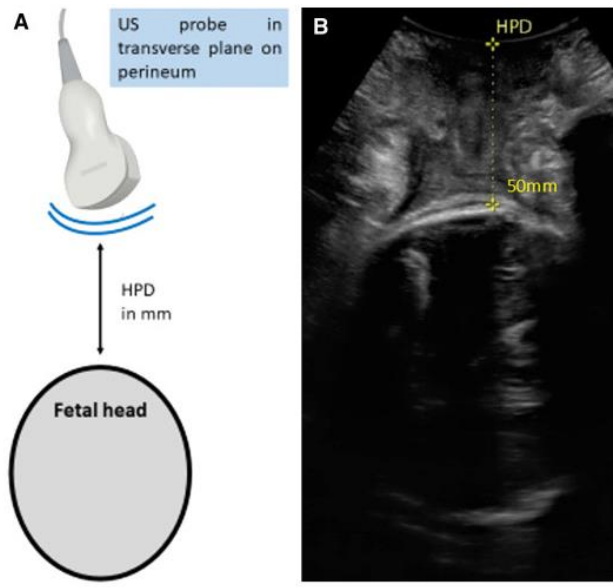
Numerous observational studies have demonstrated that the AoP can serve as a predictive tool for labour outcomes prior to labour induction, during admissions assessments, and throughout the first and second stages of labour.[158-167] Nonetheless, there remains ongoing debate concerning the optimal cut-off level for operative vaginal delivery, with recommended angles ranging from approximately 120° to 146° across various studies.[135,148,168-170] The predictive value of AoP may also vary between fe-

tuses in occiput anterior and occiput posterior positions.[171] However, predicting labour outcomes cannot rely solely on the AoP; information about the fetal station and position is essential.[151] Additionally, consideration should be given to the direction of the head, presentation, and fetal attitude.[151]

- **Head-Perineum Distance**

Eggebø T. M. et al.[145] first described a straightforward technique to measure the descent of the fetal head by positioning the ultrasound probe transversely above the posterior fourchette and compressing the soft tissue completely against the pubic bone. This technique measures the shortest distance from the edge of the ultrasound probe to the fetal skull, termed the head-perineum distance (HPD). The HPD, expressed in millimetres, represents the portion of the birth canal yet to be traversed by the fetus, corresponding to the distance between the maternal perineum and the fetal skull,[145] as illustrated in Figure 13. The HPD measurement is easy to perform, even for operators with minimal ultrasound experience, and its repeatability has been consistently validated.[145,172]

***Figure 13.*** *Measurement of the Head-Perineum Distance (HPD) Using Transperineal Ultrasound Technique with Ultrasound Probe Orientation in the Transverse Plane.*[25]
***A,*** *Illustration of the measurement of the HPD; and* ***B,*** *Transperineal ultrasound scan for obtaining the HPD in millimetres. The HPD measurement is 50 mm. (Image from the SONO-PREDICT study).*



The predictive value of HPD has been evaluated in various clinical settings, including labour induction and cases of labour dystocia during both the first and second stages of labour.[159,165,166] However, HPD should not be directly equated with the clinical assessment of fetal head station, as it does not account for the curvature of the birth canal.[166]

Research by Maticot-Baptista D. et al.[173] in 2009 demonstrated that an HPD of 38 mm corresponds to the midcavity station. Kahrs B. H. et al.[164] identified a correlation between an HPD of 35 mm and head station of 0. Additional studies have associated an HPD of 60 mm with the fetal head at the pelvic inlet, 36 mm with the level of the ischial spines, and 20 mm with the pelvic outlet.[144,151] Kasbaoui S. et al.[174] noted that an unengaged head corresponds to an HPD of 68 mm, with a midcavity station at 38 mm. Variations in HPD findings across these studies may be attributed to inaccuracies in distance measurement due to insufficient compression of the maternal perineal soft tissue.

In the 2011 study, Torkildsen E. A. et al.[166] observed that an HPD of ≤ 40 mm, was associated with a high likelihood of successful vaginal delivery, a finding consistent with Eggebø's 2013 research.[165] Furthermore, in 2017, Kahrs B. H. et al.[164] reported that a HPD greater than 35 mm was predictive of an increased likelihood of Caesarean delivery. They also identified a significant correlation between an HPD > 35 mm and lower umbilical cord pH levels.[164]

- **Head-Symphysis Distance**

The measurement of head-symphysis distance (HSD) has been proposed as a viable parameter for assessing the fetal head station during labour.

This parameter quantifies the distance from the lower boundary of the symphysis pubis to the nearest point of the fetal skull, measured along the infrapubic line[175] (Figure 14). In 2013, Youssef A. et al.[150] highlighted the utility of HSD particularly when the fetal head is positioned at lower stations or beneath the infrapubic line, demonstrating a strong correlation with the AoP. Youssef A. et al.[175] further identified HSD as a predictor for the need for operative interventions. Subsequent research by Dall'Asta A. et al.[176] in 2019 and Hadad S. et al.[159] in 2021 corroborated the predictive value of HSD in determining the likelihood of spontaneous vaginal delivery.

Tutschek B. et al.[144] conducted a comparative analysis of various ultrasound parameters assessing fetal head station, juxtaposing them against traditional digital palpation methods. Their findings suggest that parameters evaluating head descent were largely consistent, with data indicating that an HSD of 34 mm corresponds to the level of the ischial spines.[144] This comparison, detailed in Table 1, underscores the reliability of HSD in clinical assessment. However, Ghi T. et al.[44] have noted that despite its potential, the application of HSD in research remains limited, and its clinical utility is not as well-documented as other established parameters. In the current intrapartum study, HSD measurements were not conducted.

***Table 1.*** *Conversion Table for Transperineal Ultrasound Parameters Assessing Fetal Head Descent, Including Angle of Progression, Head-perineum Distance, and Head-Symphysis Distance.*[144]

| ITU head station (cm) | Angle of progression (°) | HPD (mm) | HSD (mm) |
|---|---|---|---|
| −3 | 84 | 54 | a |
| −2 | 95 | 48 | 48 |
| −1 | 106 | 42 | 41 |
| 0 | 116 | 36 | 34 |
| 1 | 127 | 31 | 27 |
| 2 | 138 | a | a |
| 3 | 148 | a | a |
| 4 | 159 | a | a |
| 5 | 170 | a | a |

- **Fetal Head Direction**

Henrich W. et al.[147] introduced the concept of head direction as a surrogate indicator of head station, defining it as the angle formed between the longest discernible axis of the fetal head and the longitudinal axis of the pubic symphysis, observed via mid-sagittal transperineal ultrasonography (Figure 14). This method was employed to monitor the direction of the fetal head relative to the maternal symphysis pubis prior to initiating vacuum extraction procedures.

The orientation of the fetal head was systematically categorised into three distinct directions: head down (angle less than 0 degrees), horizontal (angle between 0 and 30 degrees), and head up (angle exceeding 30 degrees)[42,147] (Figure 15). The authors documented a progressive and noticeable alteration in head direction as it descended toward the pelvic floor, following the J curve of the birth canal, transitioning from a downward to horizontal to an upward direction. Notably the head up direction just prior to operative vaginal delivery was associated with a higher likelihood of an easy and a successful delivery.[147] In the current intrapartum study, the assessment of fetal head direction was not conducted.

***Figure 14.*** *Transperineal Ultrasound (TPUS) Technique Measuring Head Station, this Assessment Measured Along Line of Head Direction.*[44,144]
*Angle of Progression, Head–Symphysis Distance, Infrapubic Plane and Ischial Plane, are Also Demonstrated.*

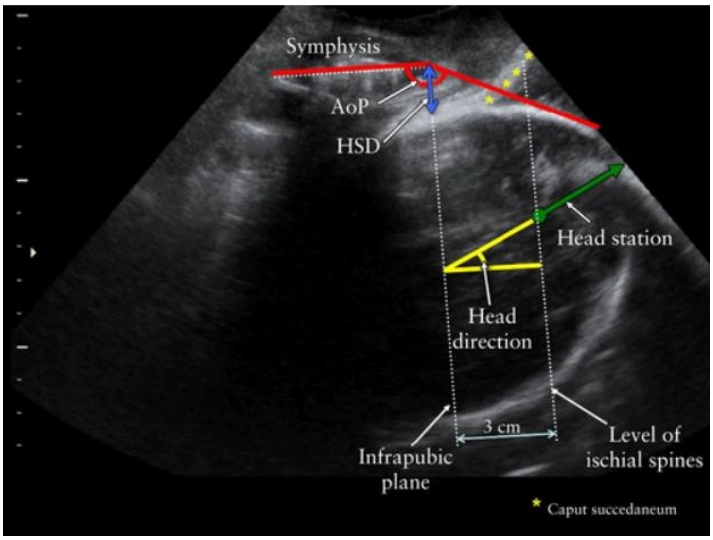
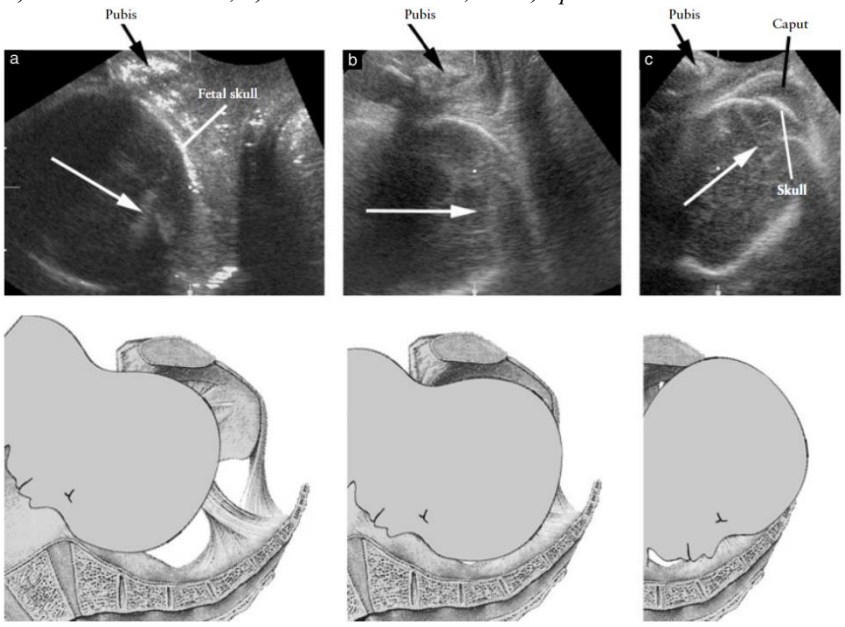



***Figure 15.*** *Categorisation of Fetal Head Direction Using Transperineal Ultrasound (TPUS) Technique in Midsagittal Plane Compared with Visual Schematics.*[42]
***a,*** *Downward direction;* ***b,*** *Horizontal direction; and* ***c,*** *Upward direction.*



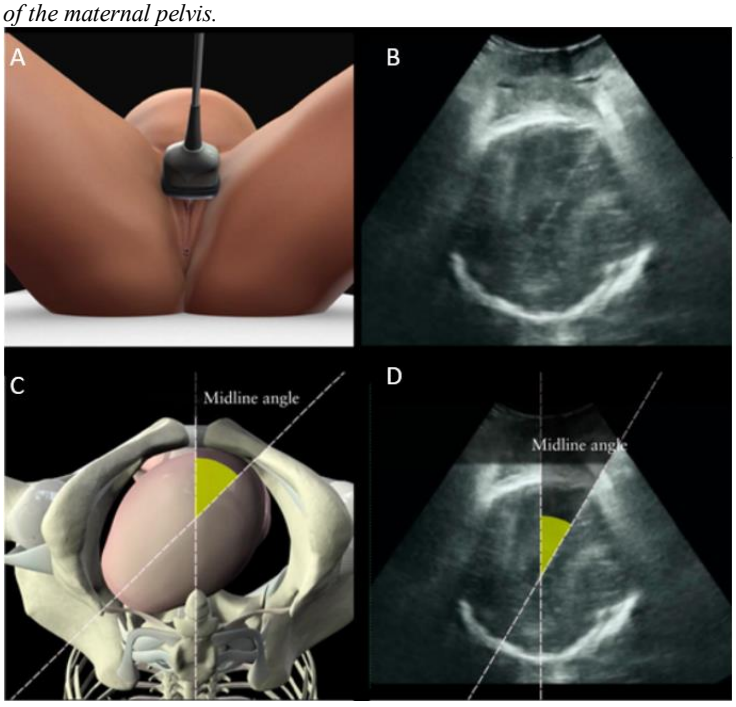

- **Midline Angle**

The midline angle (MLA), first described by Ghi T. et al.[42] is defined as the angle between the midline of the two fetal cerebral hemispheres and the anteroposterior

axis of the maternal pelvis. This measurement is obtained using TPUS in the transverse plane, as depicted in Figure 16. The study identified a significant correlation between the clinically assessed head station and the rotation of the head, as indicated by the MLA.[42] It was observed that an MLA of ≥ 45° typically coincides with the fetal head being in a downward or horizontal orientation, corresponding to a head station of ≤ +2 cm.[42] Conversely, an MLA < 45° generally indicates that the fetal head is oriented upward, corresponding to a head station of ≥ +3 cm.[42]

The MLA and fetal head position effectively represent two aspects of the same concept. While the MLA is originally defined in relation to the maternal pelvic, the fetal head position can also be identified using clock face orientations, commonly employed in TAUS technique. In the current intrapartum study, the assessment of the midline angle was conducted to enhance our understanding and support potential future publications, although this parameter was not mandated by the study protocol.

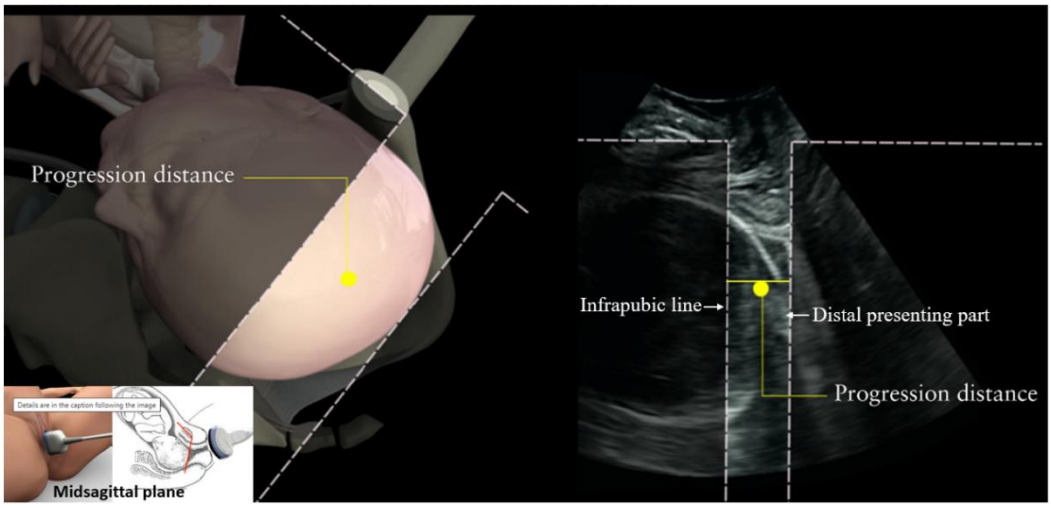
***Figure 16.*** *Transperineal Ultrasound (TPUS) Technique Measuring the Midline Angle (MLA).*[44]
***A,*** *Ultrasound transducer is positioned in the transverse plane between the labia majora on the maternal perineal region;* ***B,*** *Ultrasound image demonstrates the fetal midline echo;* ***C,*** *Structural model illustrated the midline of the two fetal cerebral hemispheres and the anteroposterior axis of the maternal pelvis; and* ***D,*** *Ultrasound image demonstrated the angle between the midline of the two fetal cerebral hemispheres and the anteroposterior axis of the maternal pelvis.*



- **Progression Distance**

Progression distance (PD) is a parameter proposed for assessing fetal head station during labour. Initially introduced in 2005 by Dietz H. P. and Lanzarone V.,[143] PD is specifically defined as the shortest distance from the infrapubic line to the distal presenting part (Figure 17)[44]. However, PD has not been extensively utilised in observational studies, and its clinical use is not established as other parameters such as AoP. Moreover, AoP is simpler to measure, accommodates the curved nature of the birth canal, and is considered a more suitable parameter for evaluating head station than PD.[44] In the present intrapartum study, the assessment of progression distance was not conducted.

***Figure 17.*** *Transperineal Ultrasound (TPUS) Technique Measuring the Progression Distance (PD).*[44] *Ultrasound transducer is positioned in the midsagittal plane between the labia majora on the maternal Perineal Region. The yellow line is the PD, the shortest distance from the infrapubic line to the distal presenting part.*



**Cervical Dilatation**

Evaluating cervical dilatation during active labour via TPUS proves both feasible and reproducible. The technique for visualising the cervix is straightforward, entailing the placement of the ultrasound probe along the midsagittal plane at the perineum. This facilitates the observation of the fetal head and, partially, the symphysis pubis on the screen (Figure 18). The probe is then rotated 90° counterclockwise, with the probe marker directed rightward to obtain a transverse plane view (Figure 19). Adjustments include tilting the transducer rearward to visualise the rectal area, then forward until the rectum is no longer visible, subsequently revealing the cervix at the internal os anteriorly (Figure 20). Cervical dilatation can be assessed using either anteroposterior (AP) or transverse measurements of cervical dimensions, or a combination thereof.

***Figure 18.*** *Transperineal Ultrasound (TPUS) Technique to Measure Cervical Dilatation During Labour.* ***a,*** *Ultrasound probe orientation in the midsagittal plane at the maternal perineum between the labia majora. The red circle indicates the probe marker; and* ***b,*** *Ultrasound image depicting the landmarks, showing the symphysis pubis and the contour of the fetal cranium. (Images from the SONO-PREDICT study).*

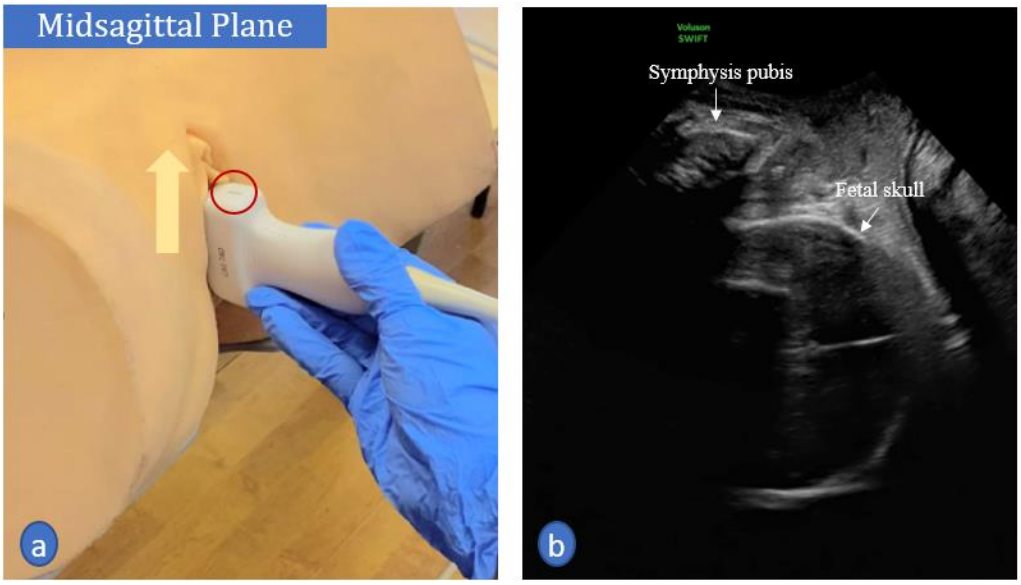


***Figure 19.*** *Transperineal Ultrasound (TPUS) Technique to Measure Cervical Dilatation During Labour.*
***a,*** *Ultrasound transducer is rotated 90º counterclockwise to obtain true transverse plane. The red circle indicates transducer marker; and* ***b,*** *Ultrasound image demonstrating the fetal skull and the maternal perineal area. (Images from the SONO-PREDICT study).*

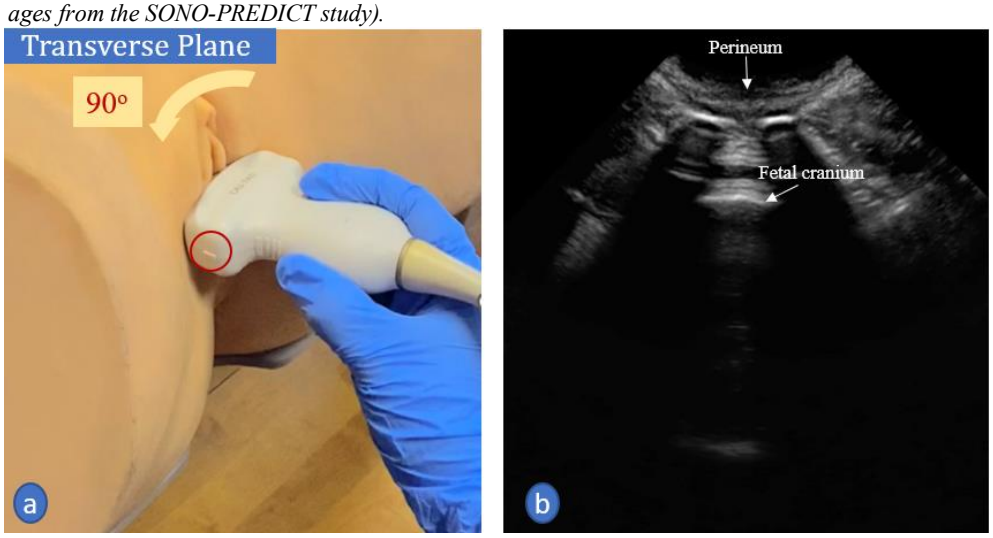
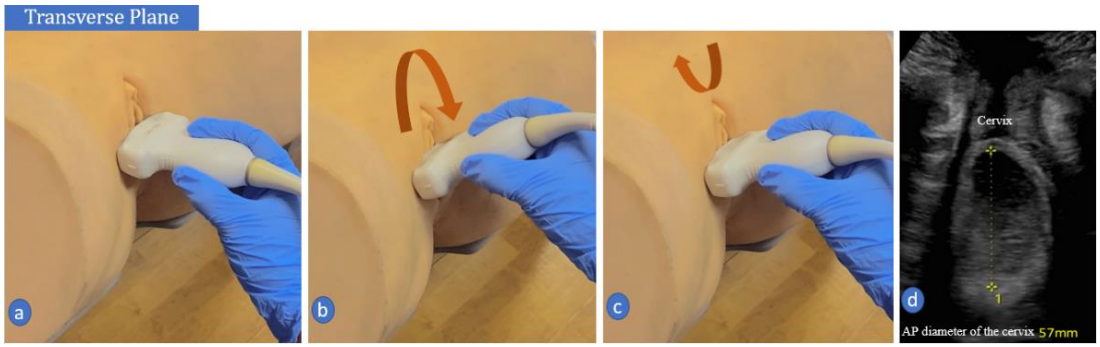



***Figure 20.*** *Transperineal Ultrasound (TPUS) Technique and Ultrasound Probe Movements to Assess the Cervix During Labour.*
***a,*** *Ultrasound transducer is positioned in the true transverse plane;* ***b,*** *The ultrasound transducer is tilted posteriorly to visualise the rectum;* ***c,*** *The ultrasound transducer is then gradually tilted back anteriorly until the rectum is kept out of view and the next clearly visualised region is the cervix; and* ***d,*** *Ultrasound image demonstrating the cervical dilatation is measured at 57 mm. Both the anterior and the posterior rims of the cervix are clearly visible. The anterior lip is the closest to the ultrasound transducer. (Images from the SONO-PREDICT study).*




Two-dimensional (2D) TPUS technique, utilised for measuring cervical dilatation was first described in 2013 by Hassan W. A. et al.,[177] involving 21 nulliparous women with a singleton fetus in cephalic presentation to quantify cervical dilatation before and after clinical examination. This study reported that measuring the cervix

by this technique achieves close agreement with DVE, primarily quantifying the anteroposterior diameter of the cervix;[177] a measurement subsequently widely adopted in observational studies.[178-180]

Zimerman A. et al.[181] conducted research in 2009 using a three-dimensional (3D) TPUS technique to assess cervical dilatation during labour. Their prospective observational study on 52 labouring women revealed that 3D TP ultrasonographic measurements of the cervical mean, maximal diameter and inner cervical area are feasible, reproducible, and demonstrate a positive correlation with clinical cervical examination.

Between 2013 and 2014, Benediktsdottir S. et al.,[136] conducted measurements on two cervical dimensions in 86 labouring women at term. They compared the clinical assessment of the cervix with the 2D TPUS while also assessing intra-observer consistency of ultrasound measurements. Their findings indicated that cervical dilatation was successfully assessed in 71% women, showing cervical dilatation approximately 1 cm less than those obtained from clinical evaluations but displayed good intra-observer agreement. The intra-observer interclass correlation coefficient (ICC) was 0.99 (95 % CI: 0.97-0.99).[136]

Several studies have demonstrated that cervical dilatation measured through TPUS technique significantly correlates with clinical findings.[136,178-185] However, other research has indicated that while feasible, this technique becomes more challenging in the advanced stages of labour.[185]

In the present study, we utilised TPUS to assess cervical dilatation among nulliparous women during the active first stage of labour. Detailed findings from this assessment elaborated in Chapter 5.

**Caput Succedaneum**

Caput succedaneum, characterised by a soft subcutaneous bulge on the fetal skull, can be assessed using TPUS in the midsagittal plane (Figure 21). This condition manifests as a palpable swelling and poses challenges for quantitative assessment via clinical vaginal examinations due to its subjective nature. Several studies have indicated that the presence of caput succedaneum may reduce the precision of digital assessments.[29,33,186] Barbera A. F. et al.[135] in 2009 demonstrated that positioning the TPUS probe in the sagittal plane facilitates clear identification of caput succedaneum. In 2013, Gilboa Y. et al.[187] investigated its presence using TPUS during the prolonged second stage of labour, establishing a correlation with clinical outcomes. They quantified the thickness by drawing a vertical line from the outer surface of the fetal skull to the uppermost skin edge, with an average reported thickness of 21.9 mm (range, 14-40 mm), found no significant impact of caput succedaneum on delivery mode or neonatal outcomes.[187]

In 2015, Hassan W. A. et al.[137] compared clinical assessments of caput succedaneum with ultrasound measurements of the skin-skull distance (SSD), defining its absence when SSD was less than 10 mm. Their findings underscored a significant correlation with digital evaluations and demonstrated notable repeatability in ultrasound assessments. They observed a higher incidence of Caesarean section in women with an SSD of 10 mm or more, although the study was underpowered and calls for further investigation.

***Figure 21.*** *Transperineal Ultrasound (TPUS) Technique for Assessing Caput Succedaneum.*
***a,*** *Ultrasound probe is placed in the midsagittal plane; and* ***b,*** *Ultrasound image demonstrating caput succedaneum. The caput succedaneum is seen as a fluid soft tissue swelling of the scalp. This can be measured as the distance between the skull contour and the tip of the fetal skin in millimetres, here it is measured at 14.6 mm. (Images from the SONO-PREDICT study).*




**Fetal Moulding**

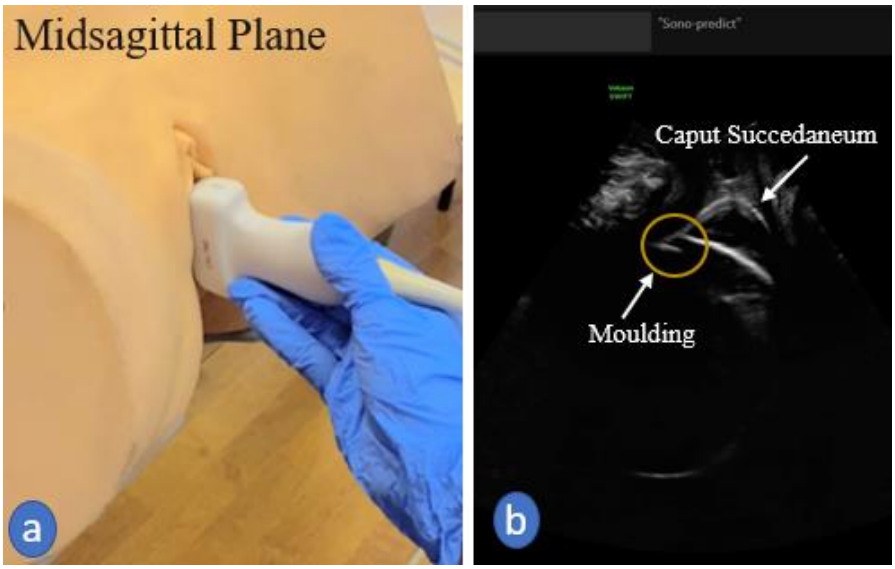
Moulding refers to the alteration in the shape of the fetal head due to external compressive forces applied to the cranial vault,[25] which can be evaluated using TPUS in the midsagittal plane (Figure 22). The initial ultrasound recognition of fetal moulding was by Carlan S. J. et al.[188] in 1991, who observed it during pregnancy and prelabour using transabdominal ultrasound. In 2009, Barbera A. F. et al.[135] illustrated that TPUS with the probe positioned in the sagittal plane effectively identifies the formation of fetal moulding.

In 2020, Iversen J. K. et al.[138] in a study of 144 nulliparous women experiencing protracted second-stage labour, aimed to characterise ultrasound-assessed fetal head moulding and explore its relationships with fetal positioning and mode of delivery. They detected fetal moulding in 55% of these women, noting it more frequently in occiput anterior than non-occiput anterior positions (69 of 117 [59%] vs. 10 of 27

[37%]; $p = 0.04$).[138] The study categorised moulding observable by TPUS into occipitoparietal, frontoparietal, or parietoparietal, depending on the known fetal position. However, occipitoparietal moulding was commonly observed, yet no significant correlations were identified between occipitoparietal moulding and the mode of delivery.[138]

***Figure 22.*** *Transperineal Ultrasound (TPUS) Technique Detecting Fetal Moulding.*

***a,*** *Ultrasound probe is placed in midsagittal plane; and* ***b,*** *Ultrasound image indicating the presence of caput succedaneum and cranial moulding. (Images from the SONO-PREDICT study).*



### 1.2.4 Ultrasound-Based Prediction of Labour Outcomes

- **Pre-Labour and First Stage of Labour**

In 2006, Gomes F. et al.[189] explored the correlation between the sonographic determination of CL via a transvaginal approach and the Bishop score concerning the duration of labour induction. Their findings indicated a significant association between the CL and the Bishop score, validating its utility in predicting delivery within the first 24 hours.[189] Notably, the induction duration was considerably longer in nulliparous women, with no significant correlation between the women's age or weight and the duration of induction.[189]

A subsequent 2007 study consolidated evidence concerning the occipitoposterior position of the fetal head and its implications for maternal and neonatal outcomes.[190] It highlighted the pivotal role of ultrasonography in accurately assessing fetal head position, crucial for planning vaginal instrumental deliveries, as endorsed by the Canadian Society of Obstetrics and Gynaecology (CSOG). In 2011, Torkildsen E. A. et al.[166] employed TPUS to evaluate 110 nulliparous women at term with a singleton fetus in cephalic presentation, diagnosed with a prolonged first stage of labour. This assessment focused on the fetal head station by measuring HPD and AoP using both 2D and 3D ultrasound techniques. The results demonstrated similar predictive capabilities for both techniques regarding labour outcomes, with satisfactory intra-observer repeatability and agreement.[166, 191]

Further investigation by Torkildsen E. A. et al.[192] examined the prognostic value of ultrasound-assessed occipitoposterior position in predicting the likelihood of vaginal delivery and the duration of labour. The findings suggested that most fetuses in these positions during the first stages are likely to rotate spontaneously, facilitating vaginal delivery.[192]

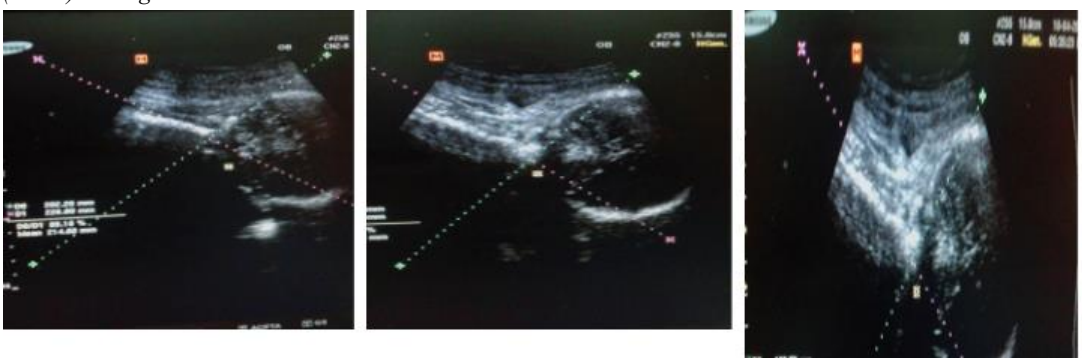
In 2013, Eggebø T. M. et al.[165] conducted research involving 150 nulliparous women with singleton pregnancies in cephalic presentation at term, experiencing a prolonged first stage of labour, across Stavanger university hospital in Norway and Addenbrooke's hospital in United Kingdom. This study assessed whether TPUS measurements of the HPD and AoP could predict vaginal delivery and length of labour. The findings supported the significant predictive value of these measurements.[165] Eggebø's team also explored in 2015 whether the fetal head position detected by TAUS correlates with the necessity for Caesarean section, confirming a significant association.[193] The occiput posterior position may serve as a valuable predictor of labour dystocia, potentially resulting in adverse neonatal outcomes.[194]

Consequently, Eggebø T. M. et al.[195] developed a predictive model incorporating maternal attributes and intrapartum ultrasound parameters to predict the likelihood of vaginal birth among 122 nulliparous women in the first stage of labour. Prolonged labour was categorised based on local protocol, and participants were divided into testing (n = 61) and validation (n = 61) cohorts. They employed multivariable logistic regression to establish a risk score, differentiating outcomes between Caesarean and vaginal deliveries. Predictive variables included dichotomised measures HPD (cut-off ≤ 40 mm, > 40 mm), caput succedaneum (cut-off < 10 mm, ≥ 10 mm), and occiput posterior position (no, yes), alongside continuous variables of maternal age, gestational age, and body mass index. The analysis concluded that the risk model effectively predicts vaginal birth in the first stage of labour among nulliparous women showed an area under the curve (AUC) of 0.85.[195]

Monitoring the descent of the fetal head by TPUS technique during the early active phase has proven feasible in predicting Caesarean delivery for non-progressive la-

bour.[196] A study quantified the fetal occiput-spine angle (OSA) in 400 term, uncomplicated singleton pregnancies with occipitoanterior positioning using TAUS during active labour to evaluate its influence on labour progression and outcomes (Figure 23).[197] Results indicated significantly extended durations of the first and second labour stages, alongside increased Caesarean section rates and both maternal and fetal complications in women with OSA less than 126°.[197]

***Figure 23.*** *Different Measurements of the Fetal Occiput-Spine Angle (OSA) Using Transabdominal Ultrasound (TAUS) During Active Labour.*[197]



In 2020, Erlik U. et al.[198] investigated whether fetal head PD measurements could predict delivery mode in 87 nulliparous women at term ≥ 37 weeks of gestation during the first stage of labour. Their findings revealed significant differences in PD during both rest and pushing phases between those who underwent vaginal delivery versus Caesarean section with a *p-value* at rest of 0.01 and during pushing of 0.015, suggesting its utility in predicting delivery method.[198]

Additional research on 221 women with single cephalic pregnancies who underwent 2D TP ultrasonography to measure AoP and HPD,[199] showed that AoP significantly correlated inversely with the occurrence of vaginal delivery during the first and second stages of labour ($p = 0.017$), whereas HPD showed a direct correlation with the occurrence of surgical delivery in the second stage of labour ($p < 0.003$).[199] The study

concluded that AoP and HPD, as assessed by intrapartum TP ultrasonography, are linked with labour duration and can help predict delivery mode alongside clinical parameters.[199]

In 2024, an expert review by Eggebø and Hjartardottir[151], underscored the efficacy of intrapartum ultrasound in objectively assessing labour progress and predicting outcomes. The review noted that ultrasound assessments of fetal descent provide clinical insights into the condition of both the labouring woman and fetus. These insights are enhanced when combined with data on fetal position and presentation. However, reliance on a single ultrasound parameter does not guarantee the success of instrumental delivery and understanding fetal station, position, head direction, presentation, and attitude is essential.[151] The authors emphasised the critical importance of acquiring this knowledge; however, they highlighted that the primary focus should be on how clinicians can effectively utilise this information, underscoring the necessity for continued research in this domain.[151]

- **Second Stage of Labour**

In 2013, Ghi T. et al.[158] conducted a 3D TPUS on 71 nulliparous women at the onset of the active second stage of labour and subsequently every 20 minutes for assessing AoP and MLA. These parameters were consistently linked with the type of delivery, suggesting their potential utility in predicting delivery mode.[158] Variations in AoP, PD, and HPD values were notable different in patients delivering before or after 60 minutes from the onset of the active second stage of labour.[171] making these parameters significant predictors of the stage's duration.[171]

Youssef A. et al.[175] demonstrated that measuring the HSD during the second stage of labour could predict the necessity for operative delivery.[175] In 2014, Masturzo B.

et al.[200] hypothesised that intrapartum sonography during the prolonged second stage of labour could decrease the rate of operative deliveries. Their research, involving 62 term pregnant women with uncomplicated cephalic presentations in OA head position, indicated that ultrasonographic detection of the fetal head's upward orientation strongly predicts spontaneous vaginal delivery.[200]

AoP has proven to be an accurate and objective parameter in predicting the mode of delivery and the interval time to delivery,[201] it is successfully predicting around 80% of effective instrumental deliveries,[202] delivery mode and complicated operative deliveries,[203] and can predict spontaneous vaginal delivery.[204] A 2019 study sought to assess the predictive value of TA and TP sonographic measurements for spontaneous vaginal delivery among 109 nulliparous women experiencing prolonged second stage of labour.[176] The researchers found that the AoP, HPD, and MLA, anterior occiput position, and HSD could prognosticate the likelihood of spontaneous vaginal delivery.[176] Additionally, AoP, HPD, HSD, and non-occiput posterior position were instrumental in predicting the mode of delivery and duration of pushing efforts.[159]

A systematic review and meta-analysis comprising eight prospective cohort studies on 887 pregnant women focused on the diagnostic efficacy of TPUS measured AoP during the second stage of labour. This review concluded that AoP could predict spontaneous vaginal delivery in singleton pregnancies at term with cephalic presentation.[205]

The application of intrapartum ultrasonography significantly enhanced the decision-making of the appropriate delivery mode during the second stage of labour[206,207] and decreased failed vacuum extraction and Caesarean section rates, without affecting the outcomes of neonates.[207]

in 2024, Skinner S. M. et al.[208] reported that utilising ultrasound before operative vaginal delivery correlated with a decrease in infants born in an unexpected position and reduced neonatal morbidity.

A recent prospective cohort study conducted at the Academic Hospital of Rennes, France, involving 286 women, evaluated the predictive value of HPD measured during the second stage of labour in determining the mode of delivery.[209] The findings indicate that an HPD of less than 44 mm is predictive of vaginal delivery, offering optimal diagnostic performance and aiding in the timely initiation of pushing efforts.[209] In the same year, 2023, Nallet C. et al.[210] found that a higher fetal head station, measured as HPD is associated with failed midcavity vacuum-assisted delivery and recommended measuring HPD prior to undertaking such procedures.

In 2024, a prospective observational study from Greece conducted over one year assessed the AoP and HPD in 82 women during the second stage of labour.[211] The study aimed to explore potential predictors of delivery mode. The findings suggest that ultrasound may improve diagnostic approaches to abnormal labour progression and predict the necessity for operative vaginal or Caesarean delivery.[211]

## 1.3 Hypothesis and Aims of the Thesis

**Hypothesis:** The study, described in this thesis, hypothesises that intrapartum ultrasound techniques can predict labour outcomes and the mode of delivery in nulliparous women at term (37-42 weeks of gestation) with a singleton fetus in cephalic presentation during the active first stage of labour.

**Primary Aims:** The SONO-PREDICT study aims to collect data to test and further develop the previously derived proof-of-principle labour prediction model for nulliparous women. By integrating clinical assessments and maternal characteristics with intrapartum ultrasound prognostic parameters, the study seeks to enhance the external predictive model for intrapartum Caesarean delivery, duration of labour, and labour outcomes.

**Secondary Aims:** The SONO-PREDICT study aims to develop simulation modules for intrapartum ultrasound aimed at educating practitioners in intrapartum sonography. These modules will facilitate the practice and repetition of these skills, providing the benefit of immediate feedback and evaluation.

Additionally, it aims to investigate the impact of receiving predictive information regarding labour outcomes and the mode of delivery on women's birthing experiences. This includes evaluating both the immediate and long-term psychological effects on women, gathering prospectives from pregnant women, parents, and healthcare providers. Insights gained are anticipated to support enhanced informed decision-making processes regarding labour and delivery methods. The study also aims to explore the prevalence of depression and anxiety, examining both the immediate and prolonged psychological ramifications of accessing such predictive information during lab

# CHAPTER 2

# SONO-PREDICT: Intrapartum Caesarean Delivery Model: General Methods

## 2.1 SONO-PREDICT Study Protocol

### 2.1.1 Study Design

This study was a prospective longitudinal observational cohort design, in which nulliparous women at term (37- 42 weeks of gestation) with a singleton fetus in cephalic presentation were recruited during the active first stage of labour.

### 2.1.2 Study Rationale and Hypothesis

This study hypothesises that intrapartum ultrasound techniques can predict labour outcomes and the mode of delivery in nulliparous women at term presenting with a singleton fetus in cephalic presentation during the first stage of labour. The SONO-PREDICT study aims to gather data to test and develop a previously established proof-of-principle labour prediction model tailored for nulliparous women. By integrating clinical assessments and maternal characteristics with intrapartum ultrasound predictive parameters through multiple labour assessments, this study also seeks to enhance the external predictive model for intrapartum Caesarean delivery, duration of labour, and labour outcomes.

### 2.1.3 Study Objectives

1. To determine the rate of intrapartum Caesarean delivery (ICD).
2. To test and develop the predictive model for labour outcomes and duration in nulliparous women by incorporating additional clinical and ultrasound data collected during active labour.
3. To improve the external predictive model for ICD, duration of labour, and labour outcomes.

4. To evaluate the characteristics and accuracy of the predictive model using repeat ultrasound assessments during active labour.

5. To examine the psychological impact of providing predictive information about the likelihood of delivery mode and labour outcomes on women's birthing experiences.

6. To develop simulation modules for the practical application of intrapartum ultrasound techniques.

### 2.1.4 Study Recruitment

Prior to initiating participant recruitment, a poster announcing the SONO-PREDICT study was exhibited on the website of Imperial College Healthcare NHS Trust and Imperial College London. The project manager convened a structured briefing with midwives and medical team in the labour ward to elucidate the study objectives and streamline the recruitment and informed consent process. Participants were identified by the project manager, with a strategic focus on prenatal recruitment, primarily targeting participants at the Maternity Day Assessment Unit (MDAU) and maternity triage .

However, prenatal recruitment proved to be ineffective, resulting in limited patient enrolment and an increased risk of patient loss. Consequently, the recruitment strategy was revised to focus on individuals in the labour ward and birth centre, providing sufficient time for potential participants to consider their participation. Recruitment was conducted during period of minimal discomfort (between uterine contractions), ensuring a more conducive environment for informed decision-making.

### 2.1.5 Study Inclusion and Exclusion Criteria

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| ○ Age range: 18-44 years<br>○ Cephalic presentation<br>○ Nulliparous women<br>○ Singleton pregnancy<br>○ Active labour as defined by NICE[223] (regular painful contractions and/or progressive cervical dilatation from 4 cm)<br>○ Gestational age at term (37-42 weeks) | ○ Individuals younger than 18 years of age<br>○ Presence of life threatening maternal or fetal compromise necessitating immediate medical intervention and/or delivery<br>○ Women deemed by the researcher as incapable of providing fully informed consent for study participation<br>○ Non-cephalic presentations<br>○ Multiple pregnancies<br>○ Multiparous women<br>○ Absence of established labour<br>○ Preterm gestation (< 37 weeks) |

### 2.1.6 Study Centre

The study was conducted at a single centre, Queen Charlotte's and Chelsea Hospital (QCCH), which is part of the Imperial College Healthcare NHS Trust (Figure 24).

***Figure 24.*** *Queen Charlotte's and Chelsea Hospital, London, UK.*



### 2.1.7 Study Consent, Information Sheet, and Explanatory Leaflet

Participants were approached by the project manager, who provided them with an information sheet (Appendix 3) and a comprehensive explanatory information leaflet (Appendix 5), allowing sufficient time for them to consider their participation. The participant's right to decline participation without providing justification was respected and considered paramount.

Women who expressed interest in participating completed the consent form (Appendix 4) prior to enrolment. Three copies of the consent form were generated: one was given to the participant, another was filed within their health records, and the third was retained in the study file for the chief investigator (CI). Contact information was made available, enabling participants to reach out the project manager, the research team, or, if necessary, the CI should they have any inquiries.

Participants retained the right to withdraw from the study at any point without providing justification, and without compromising their entitlement to further treatment.

### 2.1.8 Study Ethical Approval

The study coordination centre underwent evaluation by the Leicester Research Ethics Committee (REC) and the Health Regulator Authority (HRA) on December 4, 2020. Approval was subsequently granted by the Leicester REC on February 5, 2021, and by the HRA on February 18, 2021 (Appendix 1). Confirmation of capacity and capability (CCC) was received from the participating NHS Trust on May 15, 2021. Additionally, the research was registered on December 11, 2020, on the Clinical Trials.gov website, (Clinical Trial Registration NCT04635410), Unique Protocol ID: 283692. The website URL is https://register.clinicaltrials.gov.

### 2.1.9 Study Dataset

| Maternal Characteristics | Intrapartum Labour Parameters | Ultrasound Parameters |
|---|---|---|
| ○ Gestational age<br>○ Body mass index<br>○ Maternal age<br>○ Maternal ethnicity | ○ Rupture of membranes Yes/No: If Yes: Time<br>○ Spontaneous onset of labour Yes/No: If Yes: Time<br>○ Induction of labour with Prostaglandins Yes/No: If Yes: Time at insertion of Prostaglandin<br>○ Syntocinon Yes/No: If Yes: Time<br>○ Epidural analgesia Yes/No: If Yes: Time<br>○ Cervical dilatation assessed via digital vaginal examination | ○ Fetal head position<br>○ Amniotic fluid volume<br>○ Fetal Doppler<br>○ Head-perineum distance<br>○ Caput succedaneum<br>○ Fetal moulding |

### 2.1.10 Study Power Calculation

Recruitment commenced following the receipt of the CCC. The infrastructure, including research personnel, ultrasound equipment, and the database, was established in advance to ensure that routine clinical services remain unimpeded.

Power calculations[217] for the intrapartum Caesarean delivery prediction model indicated the need for approximately 12 variables of interest necessitating 10 participants per variable for statistical reliability,[218,219] accompanied by an estimated Caesarean section rate of 25%[220,221] (the event, the primary outcome currently in the United

Kingdom).[166,325] Thus, a minimum of 480 participants was required. The calculation: (12 variables) x (10 events) x (100/25 estimated Caesarean section rate) = 480 participants. In the SONO-VE study,[222] 269 participants were successfully recruited, necessitating an additional 211 fully evaluable participants. However, the recruitment target was set at 240 participants to accommodate approximately 10% for incomplete data or study withdrawals.

### 2.1.11 Data Collection and Confidentiality

Measurements were captured in real-time during examinations and stored within a secure database on the Imperial College Healthcare NHS Trust's shared server. Patient identities were protected rigorously by only study identification numbers, which facilitated precise data access and archival in an NHS-compliant system. When necessary, data were transmitted within the European Union in a pseudo anonymised manner, using only identification numbers to ensure patient confidentiality. The CI guaranteed strict confidentiality of participants data in compliance with the Data Protection Act, implementing essential measures such as secure databases and secure internet-based research interfaces. The database's entry page, accessible only post-login by investigators, prevented any querying of previously entered data, thereby reinforcing data integrity and confidentiality.

### 2.1.12 Data Storage and Archiving

Data are intended to be preserved for a duration of 10 years, in alignment with the data archiving policies of Imperial College London. Given the innovative nature of this research, substantial efforts are anticipated in refining methodologies and developing models. This necessitates that the data undergo thorough scrutiny over this extended period to facilitate the evaluation of the model.

## 2.2 Study Methods and Materials

### 2.2.1 Study Ultrasound Machine

For the SONO-PREDICT study, a GE Voluson$^{TM}$ SWIFT portable ultrasound device was utilised. This device features a curved, real-time four-dimensional (4D) and a 2-5 MHz wideband three-dimensional (3D) convex ultra-light volume probe (Figure 25). The inclusion of a combined 3D/4D ultrasound transducer, supplemented by two-dimensional (2D) imaging capabilities and the cine-loop technique, facilitated the attainment of superior image resolution.

***Figure 25.*** *The SONO-PREDICT Study Machine: GE Voluson$^{TM}$ SWIFT. (The machine was specifically purchased for and dedicated to the SONO-PREDICT study).*



### 2.2.2 Intrapartum Ultrasound Assessment

In the SONO-PREDICT study, each participant underwent a minimum of one ultrasound assessment during active labour following the clinical examination. Cervical dilatation, fetal head descent, and fetal head position were assessed by healthcare professionals, in accordance with the guidelines provided by the National Institute for Health and Care Excellence (NICE).[223] Fetal head descent was classified according to the World Health Organisation (WHO) criteria, with ischial spines serving as the reference point: 0 (level with the ischial spines), -5 cm at the pelvic inlet, and +5 cm at the pelvic outlet.[224]

The admission ultrasound imaging including transabdominal and transperineal techniques were applied for assessing fetal head position and station, amniotic fluid volume, fetal Doppler, caput succedaneum, and fetal moulding. Subsequent ultrasound assessments were performed as necessitated by the clinical context, typically at intervals ranging from two to six hours, though occasionally extended based on the patient's condition. To mitigate bias in clinical management, healthcare professionals, including midwives and obstetricians, were blinded to the ultrasound findings, which were also withheld from the parents. However, blinding the ultrasound operator to the clinical observations was not practicable for this research.

- **Transabdominal Ultrasound Technique**

During active labour, transabdominal ultrasound (TAUS) assessments were performed. Participants were positioned supine with a voided bladder. The ultrasound probe was initially placed transversely over the maternal abdominal region and then moved longitudinally to identify the fetal spine in various positions. Subsequently, the probe was positioned distally on the maternal suprapubic region in an axial plane,

allowing visualisation of the fetal head (Figure 26). The TAUS technique facilitated multiple assessments: evaluation of the fetal heartbeat, quantification of the amniotic fluid volume, which was measured as single vertical deepest pool (SDP), Doppler measurements for both umbilical and middle cerebral arteries, and determination of both fetal spine and head positions. The position of the fetal head is determined by locating the posterior fontanelle (occiput) in relation to a conventional 12-hour clock face. The categorisation of fetal head positions and the corresponding key landmarks were comprehensively elucidated in Chapter 1 (Figure 27, 28, and 29).

The ultrasound transducer was adjusted across multiple scanning planes as required by the sonographic acquisitions. After each use, the transducer was sanitised using medical sterile wipes and sprays, a regimen scrupulously adhered to before any subsequent examinations.

***Figure 26.*** *Transabdominal Ultrasound (TAUS) Technique Conducted During Active Labour.*
*(Informed consent for publication was obtained from the participant during conducting the 'SONO-PREDICT' study).*



***Figure 27.*** *Transabdominal Ultrasound (TAUS) Technique Conducted During Active Labour.*
***a,*** *Ultrasound image demonstrating the fetal heart and spine;* ***b,*** *Ultrasound image depicting the detection of the fetal heartbeat;* ***c,*** *Ultrasound image illustrating the fetal spine position in a different cross-sectional view; and* ***d,*** *Calculation of the amniotic fluid volume, expressed in terms of the single vertical deepest pool (Images from the SONO-PREDICT Study).*




***Figure 28.*** *Variations of Fetal Head Positions Assessed Using Transabdominal Ultrasound (TAUS) Technique Conducted during Active Labour. (Images from the SONO-PREDICT Study).*

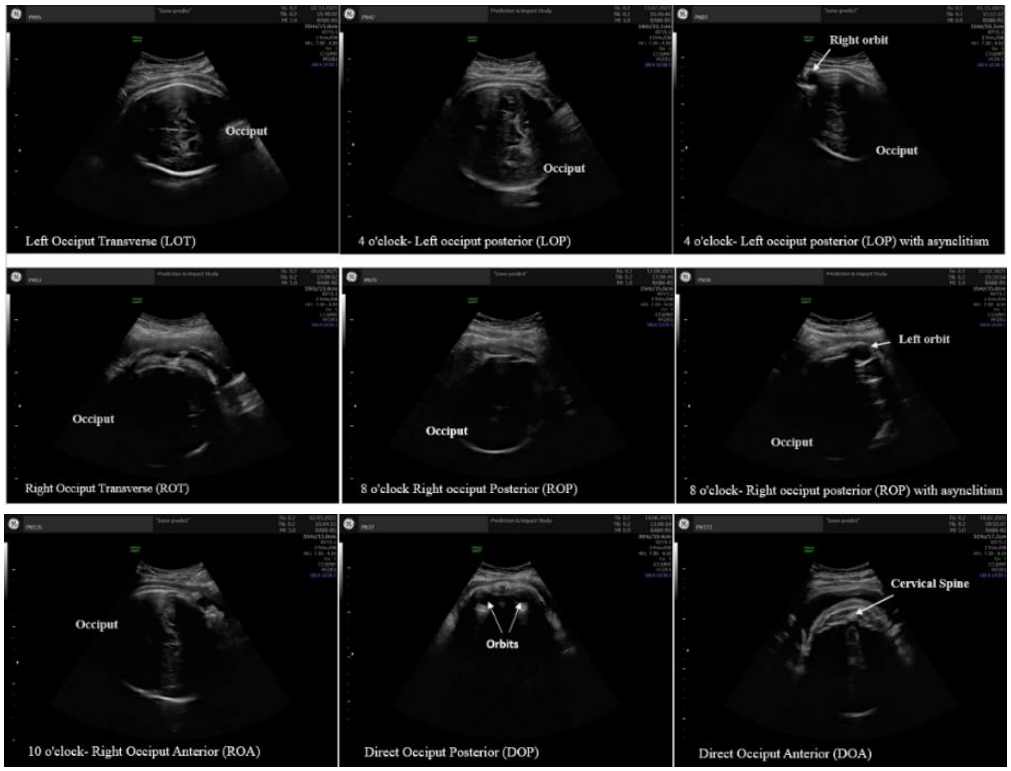
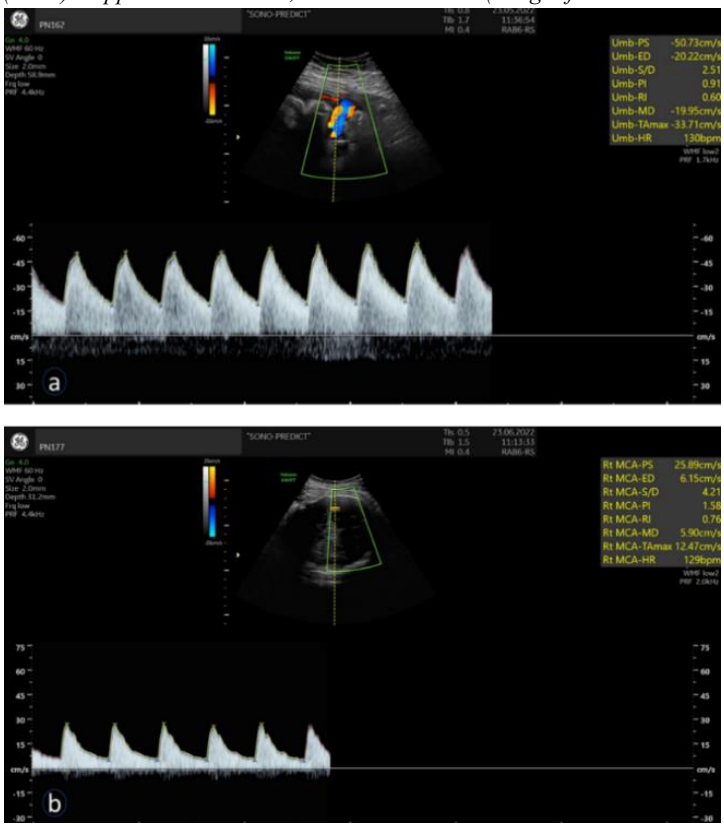


***Figure 29.*** *Fetal Doppler Measurements During Active Labour by Transabdominal Ultrasound (TAUS) Technique.* ***a,*** *Umbilical artery (UA) Doppler measurement, UA-PI is 0.91; and* ***b,*** *Middle cerebral artery (MCA) Doppler measurement, Rt MCA PI is 1.58 (Images from the SONO-PREDICT Study).*

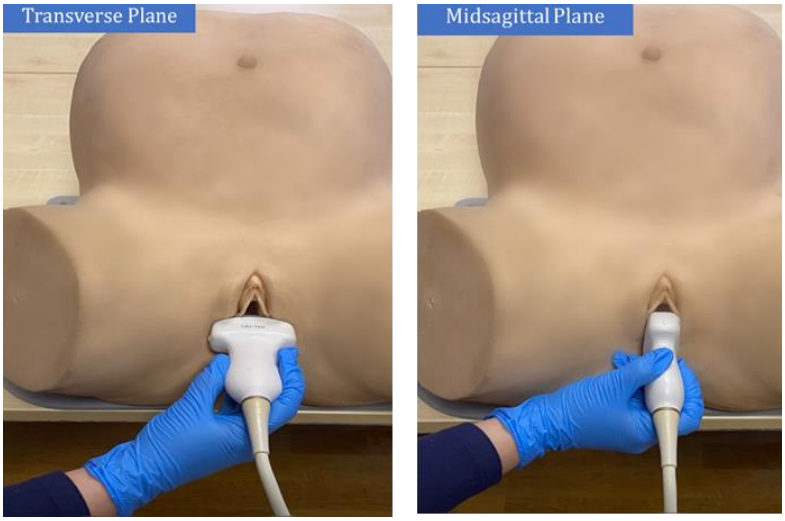



- **Transperineal Ultrasound Technique**

During the transperineal ultrasound (TPUS) examination, participants were positioned supine with their hips and knees flexed, and their bladder evacuated. The researcher's manipulating hand was sheathed in a medical glove. Sterile gel was applied onto the ultrasound transducer, which was then encased in a medical glove. Sterile lubricant was subsequently applied to the glove-encased transducer. The ultrasound transducer was positioned between the labia majora at the level of the posterior fourchette, utilising both transverse and midsagittal planes for imaging (Figure 30). Rigorous hygienic protocols were adhered to throughout the procedure. The ultrasound transducer was decontaminated using sterilising agents, including sterile

wipes and sprays; this cleaning process was meticulously repeated prior to each subsequent use.

***Figure 30.*** *Transperineal Ultrasound (TPUS) Technique in both Transverse and Midsagittal Planes.*




In the SONO-PREDICT study, the TPUS technique was employed to evaluate the fetal head station by measuring head-perineum distance (HPD) in transverse plane, caput succedaneum, and fetal moulding in midsagittal plane (Figure 31).

While the primary objective of this research centered on the specific parameters mentioned above, a comprehensive evaluation of labour parameters was also conducted. These included angle of progression (AoP), cervical dilatation (CD), and midline angle (MLA) (Figure 32).

***Figure 31.*** *Transperineal Ultrasound (TPUS) Images Obtained During Active Labour.*
***a,*** *Head-perineum distance (HPD) is measured at 40 mm;* ***b,*** *Caput succedaneum is measured at 16.2 mm; and* ***c,*** *Fetal moulding is indicated by the white circle. (Images from the SONO-PREDICT Study).*

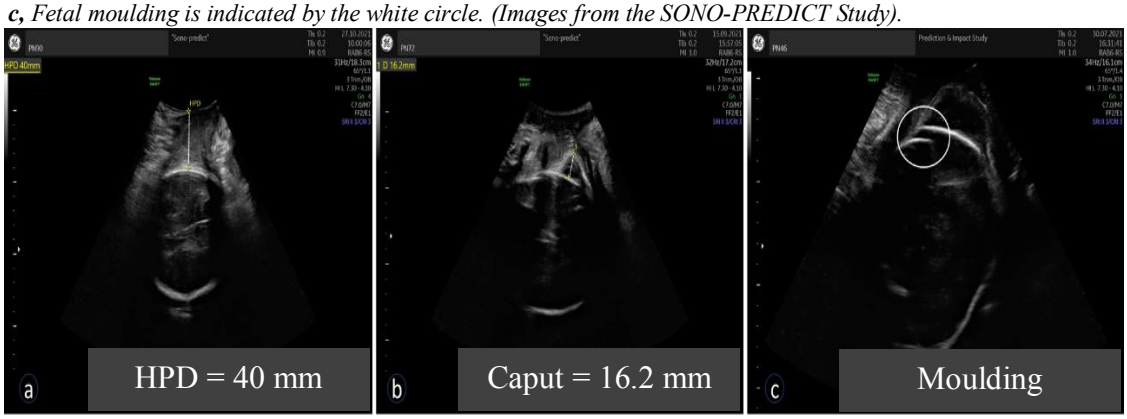



***Figure 32.*** *Transperineal Ultrasound (TPUS) Images Obtained During Active Labour.*
***a,*** *Angle of progression (AoP) is measured at 111°;* ***b,*** *Cervical dilatation (CD) is determined by measuring the anteroposterior diameter of the cervix, measured at 4.4 cm; and* ***c,*** *Midline angle (MLA) is measured at 14.29°, fetal head position is at 12:30 o'clock position. (Images from the SONO-PREDICT Study).*



# CHAPTER 3

# SONO-PREDICT: Intrapartum Caesarean Delivery Model: Statistical Methods and Results

## 3.1 Introduction

In 2015, the first intrapartum prediction model utilising a one-time ultrasound assessment during active labour was published.[195] This model integrated both transabdominal and transperineal ultrasound techniques to predict the mode of delivery, with vaginal birth designated as the primary outcome. It incorporated eight predefined predictors, including maternal characteristics such as maternal age, body mass index (BMI), gestational age (GA), and cervical dilation (CD), the latter assessed by either a midwife or an obstetrician. Additionally, it accounted for the presence of prolonged labour as defined by national guidelines. The study utilised intrapartum ultrasound to evaluate fetal head station, encompassing measurements of head-perineum distance (HPD), caput succedaneum, and the presence of posterior fetal occiput position.[195]

The study was conducted at two medical centres: Stavanger University Hospital, Norway, and Addenbrooke's Hospital, Cambridge, UK. A cohort of 122 nulliparous women with a live singleton pregnancy in cephalic presentation at term (≥ 37 weeks) in the active first stage of labour were recruited between 2012 and 2013. The study population was divided into a testing set (n = 61) and a validation set (n = 61).[195]

The results demonstrated that a dichotomized score, including HPD (cut-off ≤ 40 mm), caput succedaneum (cut-off < 10 mm), occiput posterior position, and prolonged labour, was significantly associated with vaginal delivery (VD) ($p$ = 0.03). Patients with a risk score above the median had a more than tenfold increase in the odds of experiencing a VD compared to those with scores below the median, achieving an area under the curve (AUC) of 0.85 (95% CI: 0.678-1.000).

In contrast, a continuous score, including maternal age, GA, and BMI, did not predict VD in the validation set ($p = 0.10$).[195] This model serves as a proof-of-concept and highlights the need for further refinement to enhance predictive accuracy. Despite the small patient cohort, the feasibility of the model was demonstrated through its application to the validation set.

Despite significant advancements in maternal and perinatal care, digital vaginal examination (DVE) remains the standard method for assessing labour progress, although its reproducibility is inconsistent and has seen minimal evolution over the past century. Discussions with labouring women about their expectations and decision-making processes during labour predominantly rely on traditional clinical assessments and the physician's experience level. Traditionally, labour progress is manually recorded on a partogram, a graphical representation that includes both maternal and fetal observations designed to recognise a failure of labour progress and to guide specific obstetrical interventions.

Significant developments in the partogram technology have occurred[14,15-21,224] since Friedman first described labour progress by developing his labour curve in 1954,[11] culminating in the introduction of the electronic partogram (ePartogram),[24] a paperless, interactive tool designed to enhance the ease and efficiency of labour monitoring. Although the partogram documents maternal and fetal conditions and identifies stalled labour progress, it was not intended to predict labour outcomes, and its use has not significantly impacted maternal and neonatal morbidity.[225]

The introduction of the Sonopartogram in 2014,[226] an ultrasound based partogram, marks a significant advancement. This concept entails a comprehensive, multipa-

rameter, non-intrusive ultrasound-based assessment of labour progress. Unlike assessments based solely on clinical examination, it offers a more objective recording of labour progress. Objective measurements enhance the accuracy of predicting labour outcomes and delivery modes, potentially reducing neonatal and maternal morbidity associated with childbirth.[227] Additionally, there is growing parental interest in understanding the likelihood of vaginal delivey.[228-230] Moreover, the early identification of labour cases requiring interventions allows for more effective allocation of resources and staff within the labour ward.

Ultrasound in labour, first recognised as early as 1977,[26] has come to the forefront in the past two decades due to a persistent demand for a more reliable method of labour assessment coupled with the broader availability of ultrasound on the delivery suites. Transabdominal ultrasound technique remains a cornerstone technique for identifying fetal heartbeat, fetal presentation and lie, multiple gestations, and determining placental location. Transperineal ultrasound technique, first described in clinical research in a 1996,[132] is acceptable[231] and, in recent years, the enhancement of both transabdominal and transperineal ultrasound techniques has become more prevalent in delivery suites, providing a precise and objective assessment of various parameters, including fetal head position,[30,41] cervical dilatation,[177] fetal head station,[147,232] the degree of caput succedaneum[137,187] and moulding,[233] the attitude and flexion of the fetal head,[234] thereby facilitating an estimation that aids in predicting the mode of delivery.[164,171,195, 235]

The International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) recommends the use of ultrasound during labour, particularly in cases of slow progress or arrest of labour in the first and second stages, determining fetal head position

and station prior to performing instrumental vaginal deliveries, and in cases of fetal head malpresentation.[44]

To monitor labour progress, birth attendants including midwives and obstetricians conduct regular clinical evaluations, adhering to local national guidelines and also based on the patient's specific condition. In the SONO-PREDICT study, we aimed to evaluate the utility of repeat clinical and ultrasound assessments in predicting labour outcomes and the likelihood of intrapartum Caesarean delivery (ICD), also referred to as emergency Caesarean section (ECS), among nulliparous women at term with a singleton fetus in cephalic presentation during the active phase of the first stage of labour.

## 3.2 Statistical Methods

At descriptive analysis, categorical variables were expressed as percentages, while continuous variables were reported as median and interquartile range (IQR), depending on the Shapiro-Wilk normality test results, as normality assumption was not satisfied. Group differences were assessed using the Chi-square test or the Fisher's exact test when at least one frequency < 5 was found, for the categorical variables, and Wilcoxon-Mann-Whitney test or the Student's t-test for continuous variables. The significance level was set at alpha = 0.05. All the analyses were performed using Stata 18. Univariate logistic regressions were estimated to identify potential risk factors for the outcome of interest i.e., ICD.

As a second step, multivariable logistic regression was performed, including all significant predictors at univariate and known potential confounders (maternal age, BMI, maternal ethnicity, GA at delivery) regardless of their statistical significance. Moreover, stepwise selection was applied to obtain a more compact model, retaining only significant predictors. Descriptive statistical analysis, univariate and multivariate logistic regression analyses were utilised to identify and test all prognostic factors significantly associated with ICD incidence.

Despite some predictors being significant in the full model, they may be omitted if they do not markedly improve model fit. This constitutes a statistical consideration. Conversely, the stepwise selection process may retain some factors in the compact model even if insignificant in the full model, exploring the implications on statistical performance of a more streamlined model. Nonetheless, for thorough interpretation of each variable's influence on outcomes, our team's statisticians recommended focusing on the full model.

All relevant predictive variables were evaluated including GA, maternal age, BMI, maternal ethnicity, CD, fetal head position, caput succedaneum, HDP, fetal moulding, umbilical-cerebral ratio (UCR), and cerebral-umbilical ratio (CUR). Owing the high correlation between UCR and CUR, only UCR was retained to enhance the model explanatory power, as indicated by the highest $R^2$ value.

In the SONO-PREDICT study, some data were missing relating to the fetal Doppler measurements, specifically the MCA Doppler values. Fetal Doppler measurements were occasionally unrecorded when the fetal head was positioned too low or at an inappropriate angle, complicating the measurement of the MCA Doppler within the fetal brain. This presents a technical challenge associated with the depth of the fetal head within the maternal pelvis.

Model performance was estimated in terms of area under the ROC curve (AUC), with 95% confidence intervals (CI). In addition, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were reported for three different probability cut-offs ($p$ = 0.5, an arbitrary cut-off, and the one associated with the highest Youden Index). Typically, an effective model demonstrates a high level of both sensitivity and specificity. The Youden index cut-off, maximising the combined total of sensitivity and specificity, is generally considered optimal. Our team's statisticians consistently recommended this criterion across all models to standardise our methodological approach. A model exhibiting an AUC of at least 0.80 is deemed to demonstrate good performance. Conversely, an AUC of 0.50 indicates performance equivalent to random guessing, representing the minimal achievable level of discriminative ability.

In the maternal age, a traditional cut-off of 35 years was applied, as the age distribution did not indicate specific cut-offs, given that age was not significant predictor of ICD. For the categorisation of BMI, the classifications were recorded as follows: BMI < 18.5, which included four individuals classified as underweight, were insufficient in number to justify a separate category, $18.5 \leq BMI \leq 24.9$ (normal weight), $25 \leq BMI \leq 29.9$ (overweight), and $BMI \geq 30$ (obesity).

Fetal head position was considered a continuous variable ranging from 0 to 6 (occiput anterior [OA] to occiput posterior [OP]), with no distinction made between left and right. This approach, treating the variable as continuous while blinding laterality, allows for a more nuanced, 'shaded' representation.

## 3.3 Results

The SONO-PREDICT study is a single-centre, prospective longitudinal observational cohort study with the primary outcomes included ICD and time to delivery and secondary outcomes comprised neonatal metrics such as APGAR scores, cord gases, admission to the neonatal unit within 24 hours, and neonatal morbidity. In the SONO-VE study (2015-2018),[222] our team modified the primary outcome from that of the original model published in 2015,[195] selecting an outcome of importance to parents (Caesarean delivery),[236,237] and typically the less common outcome is used to determine the sample size. It is important to note that vaginal delivery serves as the dichotomous counterpart to the Caesarean section, both representing binary outcomes.

From 17 May 2021 to 20 March 2023, 948 participants were screened, 563 were approached, and 241 participants consented to and were recruited for the SONO-PREDICT study. Of these, 239 were evaluable after 2 participants withdrew consent (Figure 33). Demographic characteristics of the participants included nulliparous women aged 18–44 years (mean age, 30 years and 2 months), with a mean GA of 39 weeks and 5 days and mean BMI of 24.4 kg/m$^2$ (range, 18–47 kg/m$^2$). Maternal ethnicity distribution of the SONO-PREDICT population is represented in Figure 34.

A total of 202 participants (85%) underwent second intrapartum ultrasound assessments, while 37 (15%) had a first intrapartum ultrasound assessment. Overall, 441 ultrasound evaluations were conducted during the active first stage of labour (Figure 35). An ICD was deemed necessary for 84 participants (35%), with mean birth weights of 3440 g for babies requiring ICDs compared to 3296 g for those undergoing VDs (Figure 36). Additionally, repeat intrapartum ultrasound scans were conducted in 75 of these 84 participants (89%).

Intrapartum ultrasound assessment was performed both with and without epidural anaesthesia, and with both intact and ruptured membranes. During the first ultrasound assessment, 123/239 participants (51%) did not receive an epidural, and 42/239 (18%) had intact membranes. During the second ultrasound assessments, 32/202 participants (16%) had not received epidural anaesthesia, and 193/202 (96%) had ruptured membranes (Figure 37).

The mean interval between clinical examinations and ultrasound assessments during labour was 1.48 hours (range, 0.05-5.59 hours), while the mean time between the first and second ultrasound assessments was 4.39 hours (range, 1.31-6.29 hours). Transabdominal (TA) and transperineal (TP) ultrasound techniques were conducted with a median completion time of 12.38 minutes (range, 10.7 minutes-22.56 minutes).

The analysis was constrained by missing data related only to the MCA Doppler measurements. Consequently, in the single assessment model, 239 participants were included in the analysis when excluding Doppler assessments, whereas analysis incorporated fetal Doppler values included 174 participants. Similarly, in the repeat assessment model, analysis without Doppler measurements comprised 202 participants, while those including fetal Doppler values involved 154 participants.

***Figure 33.*** *The SONO-PREDICT Study Population.*

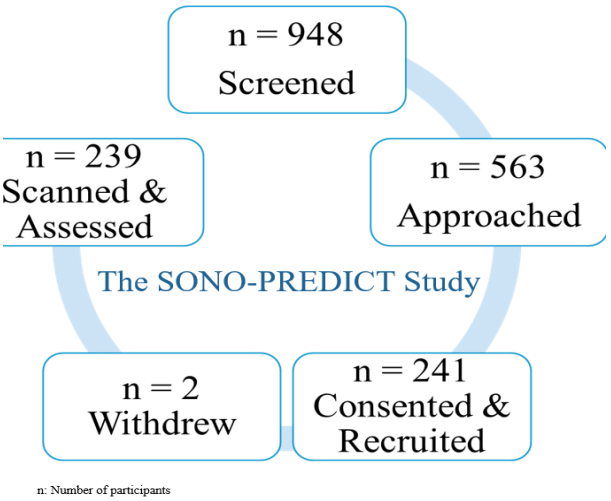



***Figure 34.*** *The SONO-PREDICT: Maternal Ethnicity Distribution.*

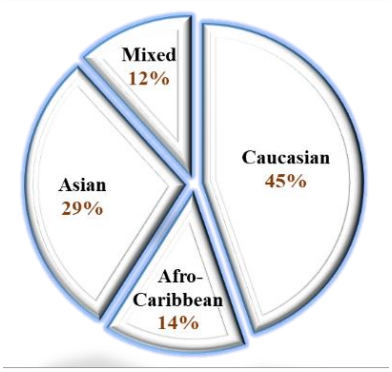



***Figure 35.*** *The SONO-PREDICT: Number of Participants Received the First and Second Ultrasound Scans, and the Total of Ultrasounds Conducted during Active Labour.*

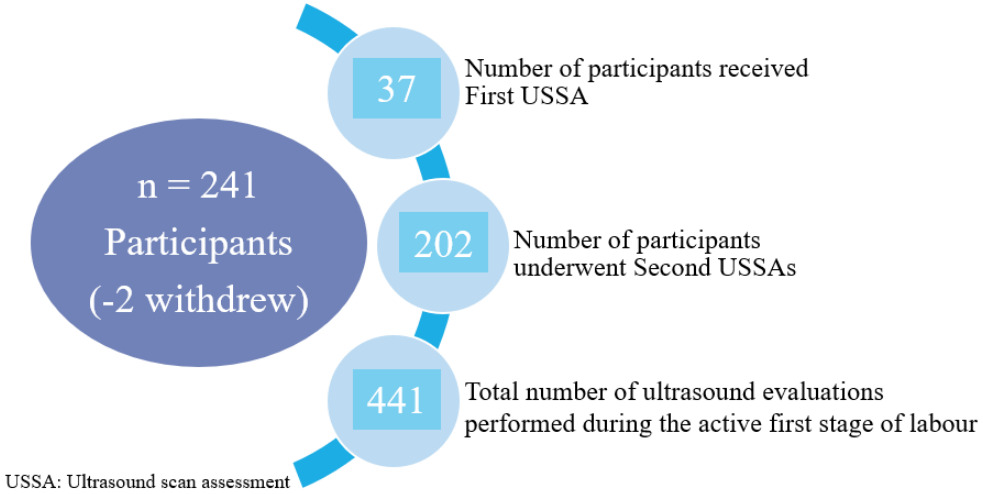


***Figure 36.*** *The SONO-PREDICT: Delivery Mode Rates with the Mean Birth Weights.*

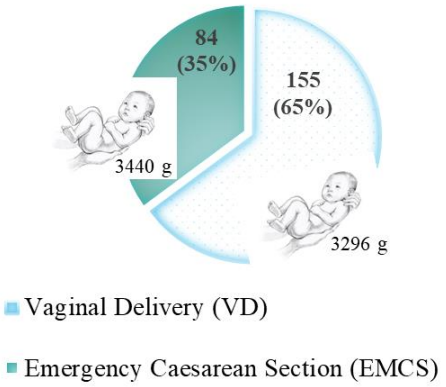
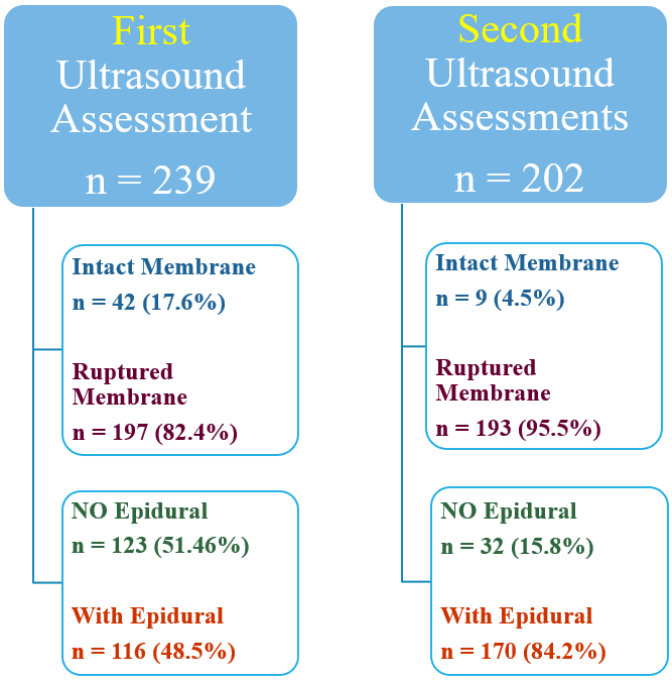



***Figure 37.*** *The SONO-PREDICT: Epidural Anaesthesia and Membrane Status during Ultrasound Assessments in the Active First Stage of Labour.*



### 3.3.1 SONO-PREDICT: Single Assessment Model Descriptive Analysis and Univariate Logistic Regression Analysis

Descriptive statistics were calculated for the overall sample of 239 participants. Categorical variables were represented as percentages, while continuous variables were presented as median and IRQ. This analysis facilitated a comprehensive understanding of the relationships between the tested variables and the incidence of ICD (Table 2).

***Table 2.*** *The SONO-PREDICT: Descriptive Statistical Analysis.*

| Variables | Type of delivery VD N=155 | ECS N=84 | p-value |
|---|---|---|---|
| **Age, median (IQR)** | 32 (28-34) | 31 (29-35) | 0.646 |
| **BMI class, n(%)** | | | 0.497 |
| BMI<18.5 (Underweight) | 3 (1.9) | 1 (1.2) | |
| 18.5<=BMI<25 (Normal weight) | 88 (556.8) | 42 (50.0) | |
| 25<=BMI<30 (Overweight) | 46 (29.7) | 33 (39.3) | |
| BMI>=30 (Obesity) | 18 (11.6) | 8 (9.5) | |
| **Ethnicity, n(%)** | | | 0.174 |
| Caucasian | 70 (45.2) | 35 (41.7) | |
| Afro-Caribbean | 17 (11.0) | 17 (20.2) | |
| Asian | 48 (31.0) | 26 (31.0) | |
| Mixed | 20 (12.9) | 6 (7.1) | |
| **GA (weeks), median (IQR)** | 40 (39-41) | 40.2 (39-41.1) | 0.473 |
| **HPD scan 1 (mm), median (IQR)** | 47 (43-54) | 51 (46.5-56) | ***0.004*** |
| **HPD scan 2 (mm), median (IQR)** | 45 (39-50) | 51 (46-57) | ***<0.001*** |
| **HPD change (mm/h), median (IQR)** | 1.3 (0.6-2.7) | 1.2 (0.2-1.7) | ***0.044*** |
| **Head Position scan 1 (clock face hours), median (IQR)** | 3 (2-4) | 3 (3-4) | 0.758 |
| **Head Position scan 2 (clock face hours), median (IQR)** | 3 (2-5) | 3 (3-4) | 0.538 |
| **Head Position change (clock face hours/h), median (IQR)** | 0 (-0.1-0.2) | 0 (0-0.2) | 0.860 |
| **Caput scan 1 (mm), median (IQR)** | 10.2 (7.4-14.2) | 10.7 (7.0-13.8) | 0.839 |
| **Caput scan 2 (mm), median (IQR)** | 14.7 (11.5-18.1) | 13.8 (10.0-17.1) | 0.145 |
| **Caput change (mm/h), median (IQR)** | 1.1 (0.5-1.7) | 0.5 (0.3-1.2) | ***0.003*** |
| **Cervical dilatation scan 1 (cm), median (IQR)** | 4 (2-5) | 3 (2-4) | ***0.004*** |
| **Cervical dilatation scan 2 (cm), median (IQR)** | 8 (5-10) | 4 (2-5) | ***<0.001*** |
| **Cervical dilatation change (cm/h), median (IQR)** | 0.8 (0.4-1.4) | 0.3 (0-0.4) | ***<0.001*** |
| **UC ratio, median (IQR)** | 0.64 (0.59-0.75) | 0.67 (0.60-0.78) | 0.581 |
| **Moulding, n(%)** | 139 (89.7) | 73 (86.9) | 0.518 |
| **Length of labour (h), median (IQR)** | 11.8 (9.4-15.4) | 14.6 (11.5-19.8) | ***<0.001*** |
| **Epidural, n(%)** | 154 (99.4) | 81 (96.4) | 0.126 |

During the first intrapartum ultrasound assessment, a direct relationship between HPD and ICD was observed. The median HPD was 51 mm (IQR: 46.5–56 mm) in the ICD group, compared to 47 mm (IQR: 43–54 mm) in the VD group, with a statistically significant difference ($p = 0.004$). Conversely, the relationship between CD and ICD was inverse. Median CD was 3 cm (IQR: 2–4 cm) in the ICD group versus

4 cm (IQR: 2–5 cm) in the VD group ($p$ = 0.004). The relationships between these variables and the mode of delivery are depicted in Figure 38 and 39.

Additionally, the duration from the onset of active labour to the delivery of the baby was notably shorter in patients who experienced VD compared to those who underwent ICD, with median durations of 11.8 hours (9.4-15.4 h) and 14.6 hours (11.5-19.8 h), respectively ($p$ < 0.001).

***Figure 38.*** *The SONO-PREDICT: First Ultrasound Assessment: Relationship between HPD and Delivery Mode. ICD: Intrapartum Caesarean Delivery; VD: Vaginal Delivery; and HPD: Head-Perineum Distance.*

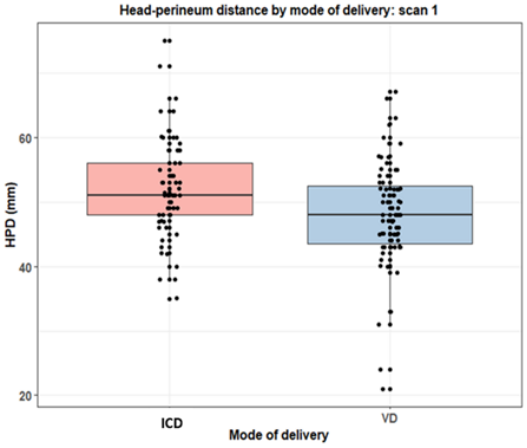
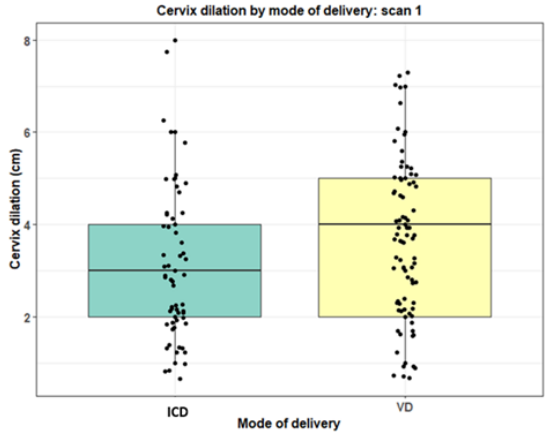



***Figure 39.*** *The SONO-PREDICT: First Ultrasound Assessment: Relationship between Cervical Dilatation and Delivery Mode.*
*ICD: Intrapartum Caesarean Delivery; VD: Vaginal Delivery.*



Univariate logistic regression analysis for the single assessment model was estimated to identify potential risk factors for the ICD (Table 3). The findings indicated that specific factors significantly influenced delivery outcomes and were strongly correlated with ICD. Significant correlations were observed both for the fetal head station, focusing on HPD measurements, and CD, with *p-values* of 0.003, 0.015, respectively.

***Table 3.*** *The SONO-PREDICT: Univariate Logistic Regression Analysis of the Single Assessment Model.*

| Variables | Univariate regression | | | |
|---|---|---|---|---|
| | OR | 95% CI | p-value | AUC [95% CI] |
| **Age>=35** | 1.09 | [0.59; 2.01] | 0.776 | 0.51 [0.45; 0.57] |
| **BMI class (ref. BMI<25)** | | | | 0.55 [0.48; 0.62] |
| 25<=BMI<30 (Overweight) | 1.52 | [0.85; 2.70] | 0.155 | |
| BMI>=30 (Obesity) | 0.94 | [0.38; 2.33] | 0.895 | |
| **Ethnicity (ref. Caucasian)** | | | | 0.57 [0.52-0.62] |
| Afro-Caribbean | 2.00 | [0.91-4.39] | 0.084 | |
| Asian | 1.08 | [0.58-2.03] | 0.802 | |
| Mixed | 0.60 | [0.22-1.63] | 0.316 | |
| **GA (weeks)** | 1.07 | [0.87; 1.32] | 0.515 | 0.53 [0.45; 0.61] |
| **HPD scan 1 (mm)** | 1.05 | [1.02; 1.09] | ***0.003*** | 0.62 [0.54; 0.69] |
| **Head Position scan 1 (clock face hours)** | 0.96 | [0.79; 1.16] | 0.652 | 0.51 [0.44; 0.58] |
| **Caput scan 1 (mm)** | 1.00 | [0.94; 1.06] | 0.967 | 0.51 [0.43; 0.58] |
| **Cervical dilatation scan 1 (cm)** | 0.82 | [0.70; 0.96] | ***0.015*** | 0.61[0.54; 0.68] |
| **UC Ratio** | 1.12 | 0.09; 13.39 | 0.930 | 0.52 [0.44; 0.61] |
| **Moulding** | 0.76 | [0.34; 1.73] | 0.519 | 0.51 [0.47; 0.56] |

### 3.3.2 SONO-PREDICT: Single Assessment Model Multivariate Statistical Analysis

#### 3.3.2.1 Excluding Umbilical-Cerebral Ratio

**Including ALL Prognostic Variables of Intrapartum Caesarean Delivery**

Statistical analysis was conducted on the entire study sample (n = 239); no stepwise selection was performed. Initially, we excluded UC ratios to evaluate potential differences in the results. Comprehensive evaluation of all prognostic variables was undertaken, including maternal age, GA, BMI, maternal ethnicity, HPD, CD, fetal head position, caput succedaneum, and cranial moulding.

Significant predictors for ICD included HPD and CD ($p = 0.008$, $p = 0.017$, respectively), as indicated in Table 4. HPD was identified as a risk factor for ICD, increasing the risk of ICD by 5% per unit increase in HPD, whereas CD exhibited a protective effect, reducing the risk by 17% per unit increase in dilatation. The AUC was 0.68 [95% CI: 0.60-0.75], demonstrating a sensitivity of 51.8% and specificity of 78.7% (Table 5 and Figure 40).

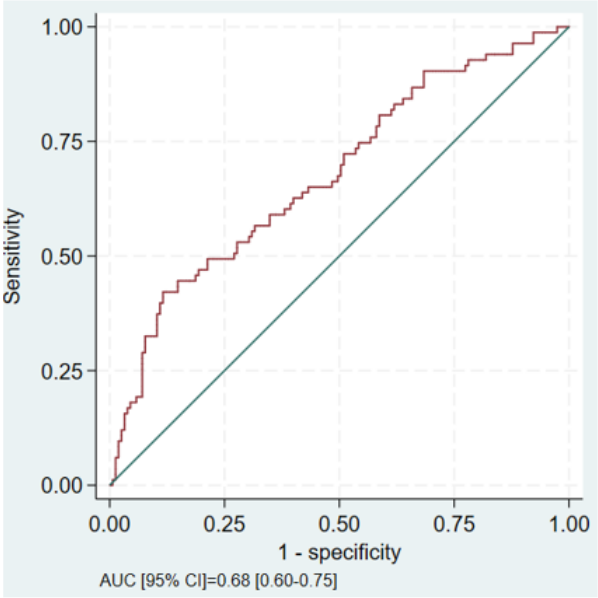
***Table 4.*** *The SONO-PREDICT: Multivariate Logistic Regression Analysis of the Single Assessment Model.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 1.237246 | .4182707 | 0.63 | 0.529 | .637814 | 2.400039 |
| bmi_class | | | | | | |
| 2 | 1.274192 | .4154866 | 0.74 | 0.457 | .6724758 | 2.414312 |
| 3 | .6224042 | .3214345 | -0.92 | 0.359 | .2261923 | 1.712644 |
| ethnicity | | | | | | |
| 2 | 2.163739 | .9566026 | 1.75 | 0.081 | .9096691 | 5.146671 |
| 3 | 1.2062 | .4227933 | 0.53 | 0.593 | .6068186 | 2.397617 |
| 4 | .6323802 | .3355848 | -0.86 | 0.388 | .223497 | 1.789307 |
| GA_weeks | 1.099598 | .1263191 | 0.83 | 0.409 | .8779104 | 1.377267 |
| HPD_scan1 | 1.048814 | .0189685 | 2.64 | 0.008 | 1.012288 | 1.086659 |
| Head_Rotation_scan1 | .9280962 | .0975122 | -0.71 | 0.478 | .7553703 | 1.140318 |
| Caput_scan1 | 1.031544 | .03326 | 0.96 | 0.335 | .9683723 | 1.098836 |
| Cervical_dilatation_s~1 | .8055193 | .0730998 | -2.38 | 0.017 | .674265 | .9623241 |
| Moulding0none1present | .999856 | .4545706 | -0.00 | 1.000 | .4101574 | 2.437386 |
| _cons | .0017679 | .0083866 | -1.34 | 0.182 | 1.62e-07 | 19.29143 |

***Table 5.*** *The SONO-PREDICT: Diagnostic Measures of the Multivariate Logistic Regression Analysis of the Single Assessment Model.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.330 | p=0.449 |
| Sensitivity | 30.1% | 66.3% | 51.8% |
| Specificity | 90.3% | 56.1% | 78.7% |
| PPV | 6.5% | 44.7% | 56.6% |
| NPV | 70.7% | 75.7% | 75.3% |
| Correctly classified | 69.3% | 59.7% | 69.3% |

***Figure 40.*** *The SONO-PREDICT: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Single Assessment Model.*




**Including SELECTED Prognostic Variables of Intrapartum Caesarean Delivery**

A focused multivariate analysis was conducted on the same cohort of 239 participants, employing selective variables through stepwise selection to derive a compact model. This analysis retained factors with substantial effects on ICD, notably cervical dilatation and HPD, while excluding fetal Doppler measurements (UCR) (Table 6). The AUC was 0.63 [95% CI: 0.56-0.71], with a reported sensitivity of 63.9% and specificity of 58.7% (Table 7 and Figure 41).

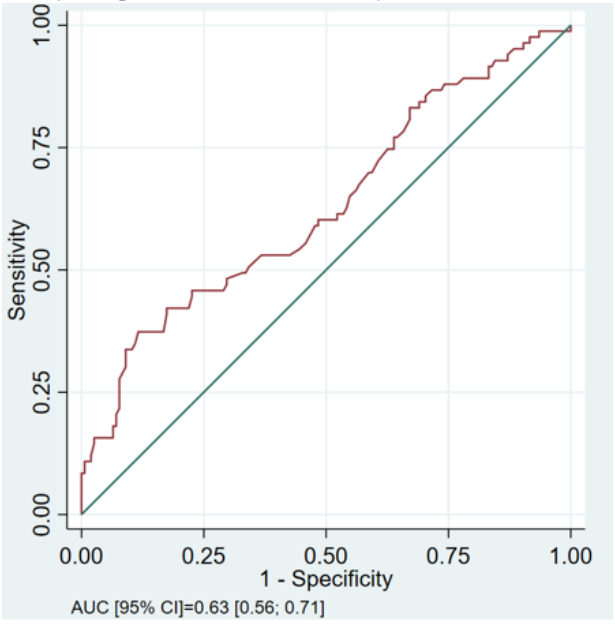
***Table 6.*** *The SONO-PREDICT: Multivariate Logistic Regression Analysis of the Single Assessment Model: Selected Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| Cervical_dilatation_scan1 | .8290365 | .0681937 | -2.28 | 0.023 | .705597 | .974071 |
| HPD_scan1 | 1.048341 | .0177217 | 2.79 | 0.005 | 1.014176 | 1.083657 |
| _cons | .0976731 | .0876086 | -2.59 | 0.010 | .0168377 | .5665875 |

***Table 7.*** *The SONO-PREDICT: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Single Assessment Model: Selected Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.265 | p=0.346 |
| **Sensitivity** | 22.9% | 90.4% | 63.9% |
| **Specificity** | 91.6% | 29.7% | 58.7% |
| **PPV** | 59.4% | 40.8% | 45.3% |
| **NPV** | 68.9% | 85.2% | 75.2% |
| **Correctly classified** | 67.7% | 50.8% | 60.5% |

***Figure 41.*** *The SONO-PREDICT: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery: Selected Variables.*



### 3.3.2.2 Including Umbilical-Cerebral Ratio

**Including ALL Prognostic Variables of Intrapartum Caesarean Delivery**

Multivariate statistical analysis was conducted on a study sample of 174 participants, this time incorporating UC ratios to compare the results and its impact on the incidence of ICD. Both HPD and CD remained significant influencers of ICD prediction ($p$ = 0.002, and $p$ = 0.021, respectively) as presented in Table 8. The inclusion of UCR values yielded similar significance levels and odds ratios (ORs). The AUC was 0.71 [95% CI: 0.63-0.79], with a sensitivity of 58.6% and a specificity of 73.1% (Table 9 and Figure 42).

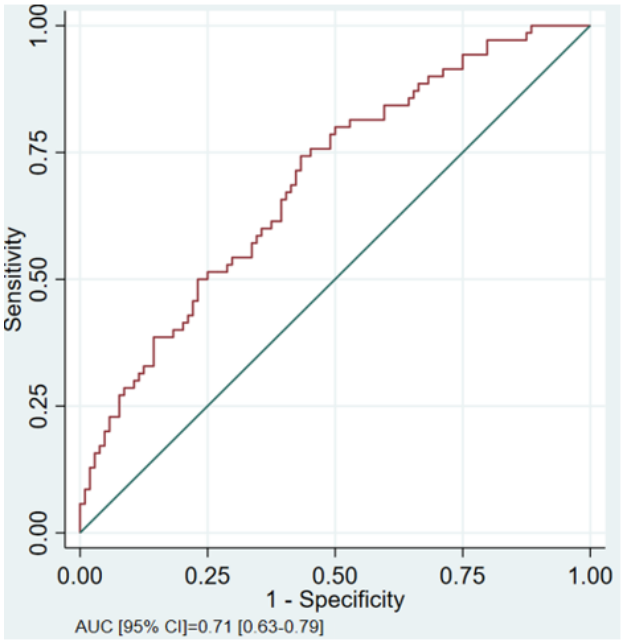
***Table 8.*** *The SONO-PREDICT: Multivariate Logistic Regression Analysis of the Single Assessment Model Including UCR: All Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 1.779838 | .7335862 | 1.40 | 0.162 | .7934971 | 3.992231 |
| bmi_class | | | | | | |
| 2 | 1.050544 | .4068208 | 0.13 | 0.899 | .4918 | 2.244089 |
| 3 | .5195334 | .2989952 | -1.14 | 0.255 | .1681671 | 1.60504 |
| ethnicity | | | | | | |
| 2 | 1.514392 | .7806613 | 0.81 | 0.421 | .5513767 | 4.159377 |
| 3 | 1.32104 | .5292927 | 0.69 | 0.487 | .6023799 | 2.897087 |
| 4 | .4399173 | .2912826 | -1.24 | 0.215 | .1201613 | 1.610562 |
| GA_weeks | 1.056128 | .1407111 | 0.41 | 0.682 | .8134076 | 1.371275 |
| HPD_scan1 | 1.075479 | .02533 | 3.09 | 0.002 | 1.026962 | 1.126289 |
| Head_Rotation_scan1 | 1.004515 | .151501 | 0.03 | 0.976 | .7474433 | 1.350003 |
| Caput_scan1 | 1.045951 | .0410333 | 1.15 | 0.252 | .9685413 | 1.129547 |
| Cervical_dilatation_s~1 | .7691635 | .0871549 | -2.32 | 0.021 | .6159819 | .9604382 |
| UCratio | 1.051316 | 1.464967 | 0.04 | 0.971 | .0684885 | 16.13797 |
| Moulding0none1present | .9146859 | .5298802 | -0.15 | 0.878 | .2938789 | 2.846922 |
| _cons | .0027506 | .015546 | -1.04 | 0.297 | 4.25e-08 | 177.926 |

***Table 9.*** *The SONO-PREDICT: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Single Assessment Model Including UCR: All Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default p=0.5 | Arbitrary p=0.342 | Max Youden Index p=0.448 |
| **Sensitivity** | 44.3% | 75.7% | 58.6% |
| **Specificity** | 81.7% | 51.9% | 73.1% |
| **PPV** | 62.0% | 51.5% | 59.4% |
| **NPV** | 68.6% | 76.1% | 72.4% |
| **Correctly classified** | 66.7% | 61.5% | 67.2% |

***Figure 42.*** *The SONO-PREDICT: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Single Assessment Model Including UCR: All Variables.*




**Including SELECTED Prognostic Variables of Intrapartum Caesarean Delivery**

In the adjusted multivariate analysis involving the same 174 participants cohort, selective inclusion of significant variables, alongside UCR, was pursued (Table 10). The AUC was 0.66 [95% CI: 0.58-0.75], presenting a sensitivity of 37.1% and a specificity of 85.6% (Table 11, Figure 43).

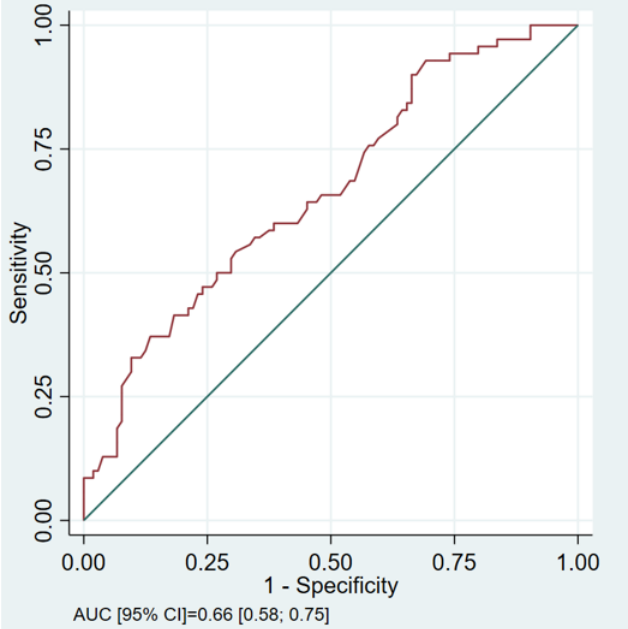
***Table 10.*** *The SONO-PREDICT: Multivariate Logistic Regression Analysis of the Single Assessment Model Including UCR: Selected variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| HPD_scan1 | 1.070511 | .0234468 | 3.11 | 0.002 | 1.025528 | 1.117466 |
| Cervical_dilatation_scan1 | .8074445 | .0811315 | -2.13 | 0.033 | .6631083 | .9831978 |
| _cons | .0473033 | .0545746 | -2.64 | 0.008 | .00493 | .4538767 |

***Table 11.*** *The SONO-PREDICT: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Single Assessment Model Including UCR: Selected Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.291 | p=0.516 |
| Sensitivity | 37.1% | 90.0% | 37.1% |
| Specificity | 82.7% | 33.7% | 85.6% |
| PPV | 59.1% | 47.7% | 63.4% |
| NPV | 66.2% | 83.3% | 66.9% |
| Correctly classified | 64.4% | 56.3% | 66.1% |

***Figure 43.*** *The SONO-PREDICT: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Single Assessment Model Including UCR: Selected Variables.*



### 3.3.3 SONO-PREDICT: Repeat Assessment Model Descriptive Analysis and Univariate Logistic Regression Analysis

In the descriptive analysis of the SONO-PREDICT ICD prediction model, presented earlier in Table 2, the second ultrasound assessment demonstrated a direct correlation between changes in HPD and ICD. During the repeat intrapartum ultrasound assessment, a direct relationship between HPD and ICD was observed. The median HPD was 51 mm (IQR: 46-57 mm) in the ICD group, compared to 45 mm (IQR: 39-50 mm) in the VD group, with a statistically significant difference, ($p < 0.001$). The median HPD change was 1.2 mm/hr (IQR: 0.2-1.7 mm/hr) in the ICD group, compared to 1.3 mm/hr (IQR: 0.6-2.7 mm/hr) in the VD group, with a statistically significant difference noted, ($p = 0.044$) (Table 2 and Figure 44).

Conversely, the relationship between CD and ICD was inverse. Median CD was 4 cm (IQR: 2-5 cm) in the ICD group versus 8 cm (IQR: 5-10 cm) in the VD group, ($p < 0.001$). The relationship between changes in CD and ICD was inverse, the median CD change was 0.3 cm/hr (IQR: 0-0.4 cm/hr) in the ICD group versus 0.8 cm/hr (IQR: 0.4-1.4 cm/hr) in the VD group, showing statistical significance, ($p < 0.001$) (Table 2 and Figure 45). Interestingly, in this descriptive analysis, changes in caput succedaneum demonstrated an inverse relationship with the incidence of ICD. The median change in caput succedaneum was 0.5 mm/hr (IQR: 0.3-1.2 mm/hr) in the ICD group, compared to 1.1 mm/hr (IQR: 0.5-1.7 mm/hr) in the VD group, (Table 2 and Figure 46)

***Figure 44.*** *The SONO-PREDICT: Second Ultrasound Assessments: Relationship between the Changes in HPD and Delivery Mode.*
*ICD: Intrapartum Caesarean Delivery; VD: Vaginal Delivery; HPD: Head-Perineum Distance.*

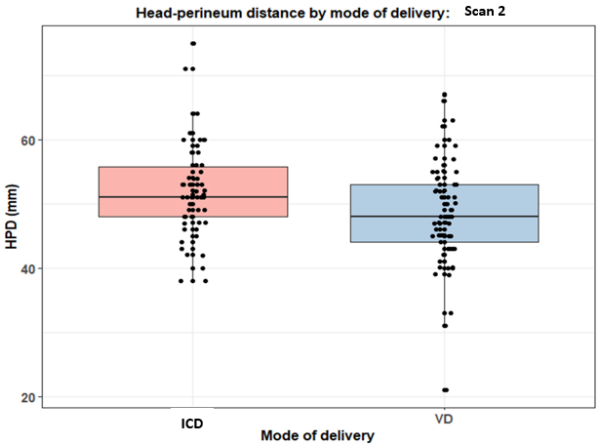



***Figure 45.*** *The SONO-PREDICT: Second Ultrasound Assessments: Relationship between the Changes in Cervical Dilatation and Delivery Mode.*
*ICD: Intrapartum Caesarean Delivery; VD: Vaginal Delivery.*

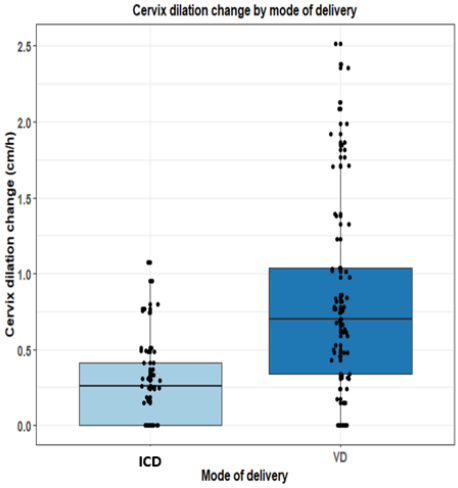
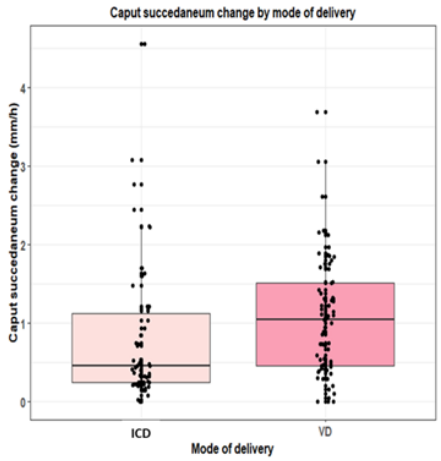



***Figure 46.*** *The SONO-PREDICT: Relationship between the Changes in Caput Succedaneum and Delivery Mode.*
*ICD: Intrapartum Caesarean Delivery; VD: Vaginal Delivery.*



A univariate logistic regression analysis was conducted for the repeat assessment model to identify potential risk factors for ICD (Table 12). This analysis identified significant correlations with delivery outcomes, with particularly strong associations observed in HPD during repeat scan and its changes over time, changes in caput succedaneum, and CD measurements during second labour assessment and their changes over time. The respective *p-values* were < 0.001, 0.012, 0.007, < 0.001, and < 0.001.

***Table 12.*** *The SONO-PREDICT: Univariate Logistic Regression Analysis of the Repeat Assessment Model.*

| Variables | Univariate regression | | | |
|---|---|---|---|---|
| | OR | 95% CI | p-value | AUC [95% CI] |
| **Age>=35** | 1.11 | [0.57; 2.16] | 0.756 | 0.51 [0.45; 0.57] |
| **BMI class (ref. BMI<25)** | | | | 0.54 [0.46; 0.61] |
| 25<=BMI<30 (Overweight) | 1.36 | [0.73; 2.54] | 0.334 | |
| BMI>=30 (Obesity) | 1.05 | [0.41; 2.73] | 0.912 | |
| **Ethnicity (ref. Caucasian)** | | | | 0.56 [0.48; 0.63] |
| Afro-Caribbean | 1.56 | [0.68; 3.57] | 0.290 | |
| Asian | 0.96 | [0.49; 1.90] | 0.918 | |
| Mixed | 0.55 | [0.18; 1.67] | 0.295 | |
| **GA (weeks)** | 1.06 | [0.85; 1.32] | 0.616 | 0.53 [0.44; 0.61] |
| **HPD scan 1 (mm)** | 1.04 | [1.01; 1.08] | ***0.023*** | 0.60 [0.52; 0.68] |
| **HPD scan 2 (mm)** | 1.09 | [1.05; 1.13] | ***<0.001*** | 0.70 [0.63; 0.77] |
| **HPD change (mm/h)** | 0.76 | [0.61; 0.94] | ***0.012*** | 0.58 [0.50; 0.67] |
| **Head Position scan 1 (clock face hours)** | 0.92 | [0.75; 1.14] | 0.466 | 0.51 [0.44; 0.58] |
| **Head Position scan 2 (clock face hours)** | 0.94 | [0.78; 1.14] | 0.531 | 0.53 [0.45; 0.60] |
| **Head Position change (clock face hours/h)** | 1.09 | [0.77; 1.54] | 0.613 | 0.51 [0.43; 0.58] |
| **Caput scan 1 (mm)** | 1.01 | [0.95; 1.07] | 0.714 | 0.51 [0.43; 0.60] |
| **Caput scan 2 (mm)** | 0.96 | [0.91; 1.02] | 0.223 | 0.53 [0.45; 0.60] |
| **Caput change (mm/h)** | 0.58 | [0.39; 0.86] | ***0.007*** | 0.65 [0.57; 0.73] |
| **Cervical dilatation scan 1 (cm)** | 0.81 | [0.69; 0.96] | ***0.015*** | 0.62 [0.54; 0.70] |
| **Cervical dilatation scan 2 (cm)** | 0.62 | [0.54; 0.72] | ***<0.001*** | 0.82 [0.77; 0.87] |
| **Cervical dilatation change (cm/h)** | 0.04 | [0.01; 0.10] | ***<0.001*** | 0.82 [0.77; 0.88] |
| **UC Ratio** | 1.04 | [0.08; 13.49] | 0.975 | 0.53 [0.43;0.62] |
| **Moulding** | 0.79 | [0.26; 2.38] | 0.679 | 0.51 [0.47; 0.55] |

Histograms detailing the frequency distribution of the prognostic variables from the SONO-PREDICT study sample, for both the first and second ultrasound assessments among the two groups (ICD and VD), are presented in Supplemental Data 12.1.

### 3.3.4 SONO-PREDICT: Repeat Assessment Model Multivariate Statistical Analysis

#### 3.3.4.1 Excluding Umbilical-Cerebral Ratio

**Including ALL Prognostic Variables of Intrapartum Caesarean Delivery**

Statistical analysis was conducted on 202 participants who underwent second intrapartum ultrasound assessments. Following the methodology employed in the single assessment model, the repeat assessment model initially excluded UC ratios to evaluate any potential disparities in outcomes and their effects on the incidence of ICD. This analysis encompassed all prognostic factors that could influence the incidence of ICD, including maternal age > 35, GA, BMI, maternal ethnicity, HPD, CD, fetal head position, caput succedaneum, and fetal moulding.

It was observed that HPD and caput succedaneum during the first ultrasound scan, and cervical dilatation measurements at the first scan and its subsequent changes, significantly influenced ICD prediction, ($p$ = 0.034, $p$ = 0.000, $p$ = 0.014, and $p$ = 0.000, respectively) as shown in Table 13. The AUC was 0.89 [95% CI: 0.84-0.93], with a reported sensitivity of 88.0% and a specificity of 74.2% (Table 14 and Figure 47).

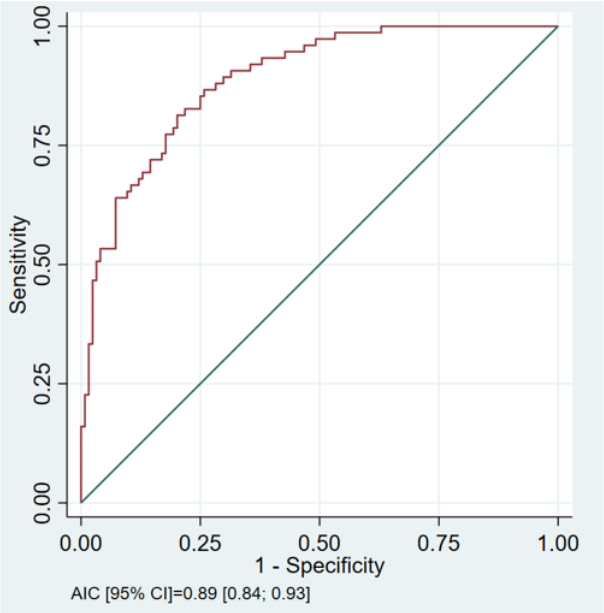
***Table 13.*** *The SONO-PREDICT: Multivariate Logistic Regression Analysis of the Repeat Assessment Model: All Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 1.377753 | .6773359 | 0.65 | 0.515 | .5256548 | 3.611122 |
| bmi_class | | | | | | |
| 2 | .6267231 | .2992898 | -0.98 | 0.328 | .2458029 | 1.597955 |
| 3 | .4781155 | .3355297 | -1.05 | 0.293 | .1208316 | 1.891843 |
| ethnicity | | | | | | |
| 2 | .9198614 | .5548623 | -0.14 | 0.890 | .2820174 | 3.000329 |
| 3 | 1.09408 | .5463248 | 0.18 | 0.857 | .411154 | 2.911343 |
| 4 | .5289182 | .3661017 | -0.92 | 0.357 | .1362109 | 2.053833 |
| GA_weeks | 1.122923 | .1738041 | 0.75 | 0.454 | .8290915 | 1.520889 |
| HPD_scan1 | 1.066674 | .0324111 | 2.12 | 0.034 | 1.005003 | 1.132128 |
| HPD_change_per_hour | .7333396 | .1267998 | -1.79 | 0.073 | .5225479 | 1.029163 |
| Head_Rotation_scan1 | .8357855 | .1430021 | -1.05 | 0.294 | .5976612 | 1.168785 |
| HeadRotation_change_p~c | 1.133941 | .6160654 | 0.23 | 0.817 | .3909637 | 3.288855 |
| Caput_scan1 | 1.242342 | .0694096 | 3.88 | 0.000 | 1.113486 | 1.386111 |
| Caput_change_per_hour | 1.226762 | .3158633 | 0.79 | 0.427 | .7406196 | 2.032008 |
| Cervical_dilatation_s~1 | .7415223 | .0906066 | -2.45 | 0.014 | .5836009 | .942177 |
| CervicalDil_change_pe~r | .0160079 | .0120169 | -5.51 | 0.000 | .0036758 | .0697139 |
| Moulding0none1present | .363156 | .3111326 | -1.18 | 0.237 | .0677375 | 1.94696 |
| _cons | .0036068 | .0235066 | -0.86 | 0.388 | 1.02e-08 | 1272.712 |

***Table 14.*** *The SONO-PREDICT: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Repeat Assessment Model: All Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.411 | p=0.313 |
| Sensitivity | 72.0% | 80.0% | 88.0% |
| Specificity | 82.3% | 80.7% | 74.2% |
| PPV | 71.1% | 71.4% | 67.4% |
| NPV | 82.9% | 87.0% | 91.1% |
| Correctly classified | 78.4% | 80.4% | 79.4% |

***Figure 47.*** *The SONO-PREDICT: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model: All Variables.*




## Including SELECTED Prognostic Variables of Intrapartum Caesarean Delivery

A subsequent analysis on the same cohort of 202 participants focused on selected variables that demonstrated a significant impact on ICD. The model included both cervical dilatation and caput measurements, excluding UCR (Table 15). The AUC was 0.87 [95% CI: 0.82-0.92], with sensitivity and specificity values of 73.3% and 84.7%, respectively (Table 16 and Figure 48).

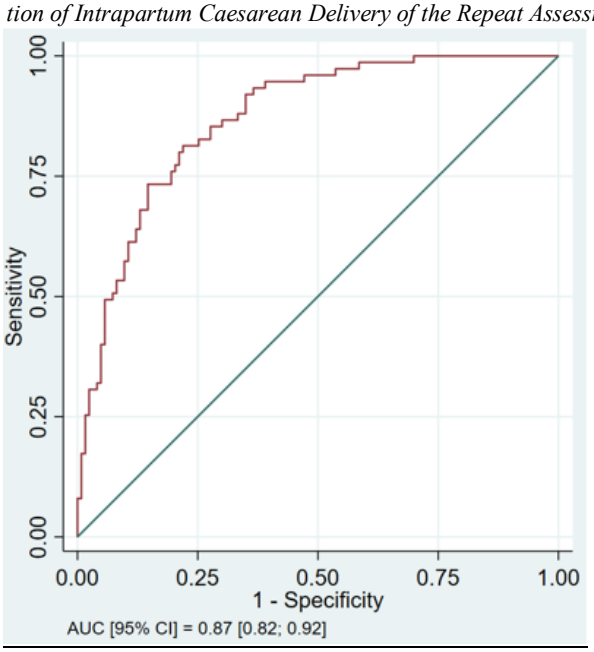
***Table 15.*** *The SONO-PREDICT: Multivariate Logistic Regression Analysis of the Repeat Assessment Model: Selected Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| CervicalDil_change_per_hour | .0215819 | .0142477 | -5.81 | 0.000 | .0059177 | .0787098 |
| Cervical_dilatation_scan1 | .7444468 | .0835731 | -2.63 | 0.009 | .5974149 | .9276653 |
| Caput_scan1 | 1.187829 | .0574076 | 3.56 | 0.000 | 1.080477 | 1.305847 |
| _cons | 1.828724 | .9310591 | 1.19 | 0.236 | .6741794 | 4.960447 |

***Table 16.*** *The SONO-PREDICT: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Repeat Assessment Model: Selected Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.286 | p=0.315 |
| Sensitivity | 73.3% | 92.0% | 73.3% |
| Specificity | 80.6% | 65.3% | 84.7% |
| PPV | 69.6% | 61.6% | 74.3% |
| NPV | 83.3% | 93.1% | 84.0% |
| Correctly classified | 77.9% | 75.4% | 80.4% |

***Figure 48.*** *The SONO-PREDICT: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model: Selected Variables.*




Further analysis explored whether an exclusive focus on cervical dilatation measurements (dilatation and its changes), could enhance the predictive capability of the model. This indicated a reduction in model performance, with an AUC of 0.84 [95% CI: 0.78-0.89] (Table 17 and Figure 49). Conversely, the exclusion of the cervical dilatation parameter (based only on the change in cervical dilatation), diminished the

model efficacy, leading to a further decline in the AUC to 0.83 [95% CI: 0.77-0.88], a decrease from both the compact model incorporating selected prognostic parameters (AUC = 0.87) and the model focusing solely on cervical dilatation measurements (AUC = 0.84) (Figure 50).

***Table 17.*** *The SONO-PREDICT: Analysis of the Repeat Assessment Model: Focusing on the Cervical Dilatation Measurements.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| Cervical_dil~1 | .8427006 | .086313 | -1.67 | 0.095 | .6894291 | 1.030047 |
| CervicalDil_~r | .0402475 | .022807 | -5.67 | 0.000 | .0132552 | .1222051 |
| _cons | 5.257246 | 2.255293 | 3.87 | 0.000 | 2.267793 | 12.18746 |

***Figure 49.*** *The SONO-PREDICT: ROC Showing the Relationship between Prognostic Factors with Retaining Cervical Dilatation Measurements and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model.*

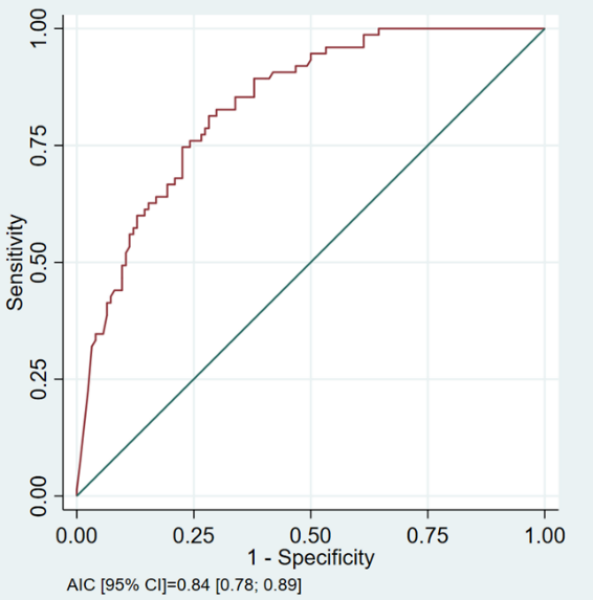
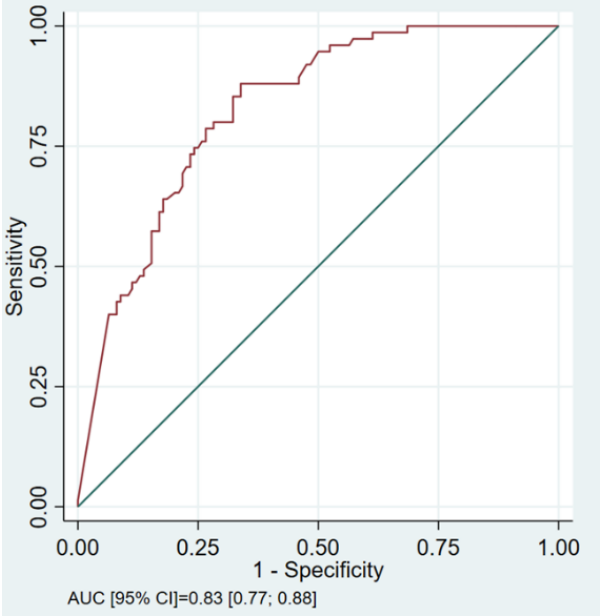


***Figure 50.*** *The SONO-PREDICT: ROC Showing the Relationship between Prognostic Variables with Removing Cervical Dilatation and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model.*




### 3.3.4.2 Including Umbilical-Cerebral Ratio

**Including ALL Prognostic Variables of Intrapartum Caesarean Delivery**

Statistical analysis involved a sample of 154 participants, incorporating UC ratios for comparative assessments. Significant factors influencing ICD prediction included both HPD and caput succedaneum measurements in the first ultrasound assessment, and cervical dilatation during the first ultrasound and its subsequent changes, with respective *p-values* of 0.015, 0.000, 0.030, and 0.000 (Table 18). The inclusion of UC ratios yielded similar significance levels and odds ratios (ORs). The AUC [95% CI] was 0.87 [0.82-0.93], demonstrating a sensitivity of 86.4% and a specificity of 75.0% (Table 19 and Figure 51).

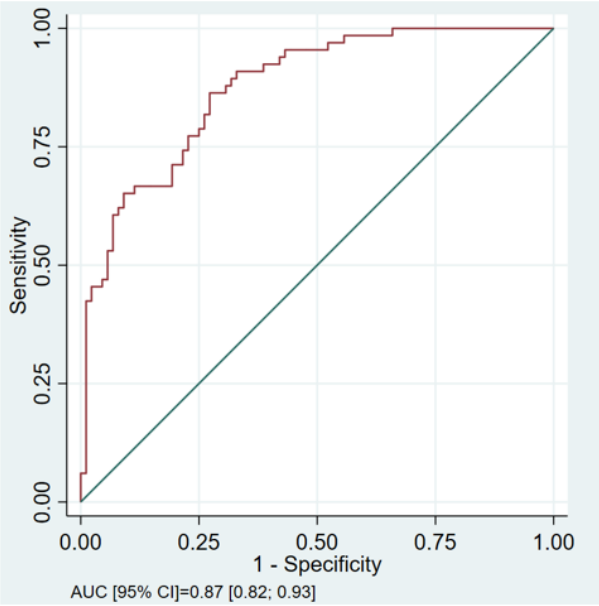
***Table 18.*** *The SONO-PREDICT: Multivariate Logistic Regression Analysis of the Repeat Assessment Model Including UCR: All Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 1.619115 | .8809984 | 0.89 | 0.376 | .5573382 | 4.703665 |
| bmi_class | | | | | | |
| 2 | .3861816 | .2084941 | -1.76 | 0.078 | .1340416 | 1.112611 |
| 3 | .4044117 | .3141116 | -1.17 | 0.244 | .0882439 | 1.853372 |
| ethnicity | | | | | | |
| 2 | .7315754 | .485337 | -0.47 | 0.638 | .1993244 | 2.685083 |
| 3 | 1.215442 | .6473817 | 0.37 | 0.714 | .4279158 | 3.452314 |
| 4 | .3970759 | .303713 | -1.21 | 0.227 | .0886771 | 1.778015 |
| GA_weeks | 1.114225 | .1908249 | 0.63 | 0.528 | .7965153 | 1.558662 |
| HPD_scan1 | 1.094197 | .0403418 | 2.44 | 0.015 | 1.017918 | 1.176193 |
| HPD_change_per_hour | .7140796 | .1346407 | -1.79 | 0.074 | .4934595 | 1.033337 |
| Head_Rotation_scan1 | .9516379 | .212825 | -0.22 | 0.825 | .6139152 | 1.475146 |
| HeadRotation_change_p~c | 1.321364 | .8450967 | 0.44 | 0.663 | .3772458 | 4.628287 |
| Caput_scan1 | 1.241935 | .0756613 | 3.56 | 0.000 | 1.102153 | 1.399445 |
| Caput_change_per_hour | 1.406959 | .4184925 | 1.15 | 0.251 | .7854092 | 2.520384 |
| Cervical_dilatation_s~1 | .7393989 | .1030561 | -2.17 | 0.030 | .562652 | .9716676 |
| CervicalDil_change_pe~r | .0227185 | .018184 | -4.73 | 0.000 | .0047323 | .1090647 |
| UCratio | .4430624 | .7789105 | -0.46 | 0.643 | .0141267 | 13.89602 |
| Moulding0none1present | .4605996 | .4048175 | -0.88 | 0.378 | .0822638 | 2.578922 |
| _cons | .0013153 | .0096772 | -0.90 | 0.367 | 7.18e-10 | 2408.356 |

***Table 19.*** *The SONO-PREDICT: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Repeat Assessment Model Including UCR: All Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.353 | p=0.408 |
| **Sensitivity** | 74.2% | 89.4% | 86.4% |
| **Specificity** | 78.4% | 71.6% | 75.0% |
| **PPV** | 72.1% | 70.2% | 72.2% |
| **NPV** | 80.2% | 90.0% | 88.0% |
| **Correctly classified** | 76.6% | 79.2% | 79.9% |

***Figure 51.*** *The SONO-PREDICT: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery Including UCR of the Repeat Assessment Model: All Variables.*



**Including SELECTED Prognostic Variables of Intrapartum Caesarean Delivery**

Analysis of the same cohort of 154 participants, incorporating UCR and focused on selected variables that significantly impacted ICD incidence was conducted (Table 20). While HPD was significant in the previous full repeat model, it was omitted from this compact model due to its limited impact on model fit. The resulting AUC was 0.84 [95% CI: 0.78-0.90], with reported sensitivity and specificity values of 78.8% and 77.3%, respectively (Table 21 and Figure 52).

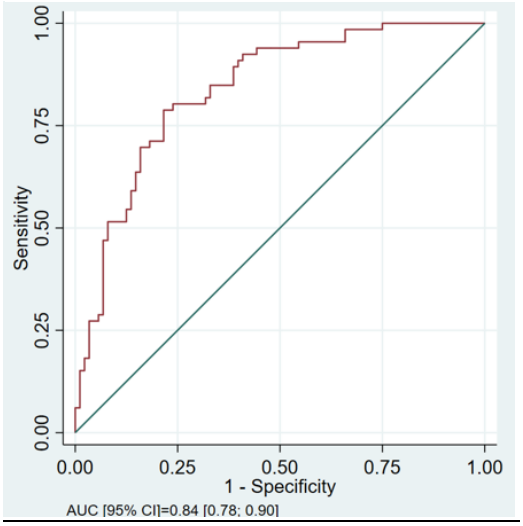
***Table 20.*** *The SONO-PREDICT: Multivariate Logistic Regression Analysis of the Repeat Assessment Model Including UCR: Selected Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| CervicalDil_change_per_hour | .0329117 | .0227549 | -4.94 | 0.000 | .0084886 | .1276041 |
| Cervical_dilatation_scan1 | .7468481 | .0916247 | -2.38 | 0.017 | .587226 | .9498593 |
| Caput_scan1 | 1.159797 | .0574955 | 2.99 | 0.003 | 1.052409 | 1.278142 |
| _cons | 2.204743 | 1.190339 | 1.46 | 0.143 | .7652352 | 6.352153 |

***Table 21.*** *The SONO-PREDICT: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Repeat Assessment Model Including UCR: Selected Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.343 | p=0.477 |
| Sensitivity | 72.7% | 89.4% | 78.8% |
| Specificity | 78.4% | 61.4% | 77.3% |
| PPV | 71.6% | 63.4% | 72.2% |
| NPV | 79.3% | 88.5% | 82.9% |
| Correctly classified | 76.0% | 73.4% | 77.9% |

***Figure 52.*** *The SONO-PREDICT: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery Including UCR of the Repeat Assessment Model: Selected Variables.*



# CHAPTER 4

# Intrapartum Caesarean Delivery: Model Development and External Validation

## 4.1 Introduction

The SONO-VE study[222] represents the first external validation of the original 2015 predictive model from two populations (Cambridge and Norway).[195] SONO-VE aimed to assess the model's efficacy in predicting labour outcomes and mode of delivery within a different population. Our team observed a decrement in performance when the original 2015 predictive model[195] was applied to a different population, compared to its application in the original internal validation set of the same population. Notably, variables influence differed between the SONO-VE dataset[222] and the original model,[195] and corrections to the case-mix did not improve the model's accuracy. The model tended to underestimate the probability of vaginal delivery, and area under the receiver operating characteristics curve (AUC) was more affected by regression coefficients than by population homogeneity.

The challenges observed during this first external validation were multiple. The primary outcome of the original model was vaginal delivery (VD), and this was changed to an intrapartum Caesarean delivery (ICD) in the SONO-VE study[222] as a more relatable outcome. This modification could have skewed the findings, as Caesarean sections are less common, thereby necessitating a larger sample size to adequately assess the effects of the predictors. The original model incorporated eight predefined predictors: maternal age, body mass index (BMI), gestational age (GA), cervical dilatation (CD), the presence of prolonged labour, head-perineum distance (HPD), caput succedaneum, and the presence of posterior fetal occiput position.

In the original 2015 predictive model,[195] the authors utilised a mixed dataset of 122 participants from 2 hospitals, divided into a development set of 61 and a validation set of 61. The development set recorded vaginal births in 41 participants and Caesarean deliveries in 20 cases, hence the calculated sample size required was 213,

derived from: (8 prognostic parameters) x (20 events) x (100/75 vaginal birth frequency rate), markedly higher than the 61 included in the validation set. Employing a commonly advised threshold of 10 events per variable[326] for initial robust model development, the calculations yield: (8 prognostic parameters) x (10 events) x (100/75 Caesarean section frequency rate) = 107, indicating a shortfall of 46 participants in the original model validation set. Therefore, an increased sample size is necessary to accurately evaluate the effects of the variables. Furthermore, a higher incidence of prolonged labour was recorded in the original model[195] compared to the SONO-VE study,[222] where recruitment occurred earlier in labour, underscoring the original model's limited generalisability and necessitating adjustments to better accommodate different population characteristics.

The SONO-VE study[222] also conducted an interim analysis to facilitate variable selection for clinical risk prediction models, improve the accuracy of sample size estimates, and evaluate the feasibility of these models. Following a backward variable selection methodology, the multivariable analysis, utilising a single ultrasound assessment model (n = 264), which included GA, HPD, CD measurements along with caput succedaneum, yielded an AUC of 0.72. A repeat ultrasound assessment model (n = 214), incorporating changes in cervical dilatation and caput succedaneum, achieved an AUC of 0.78 (Table 22).[222]

***Table 22.*** *The SONO-VE: Multivariate Single and Repeat Assessment Models.*[222]

| **Predictor** | **Single scan** | **Repeat scan** |
|---|---|---|
| Gestational age (weeks) | 1.20 (0.96-1.52) | 1.21 (0.93-1.59) |
| HPD scan 1 (mm) | 1.05 (1.00-1.10) | 1.07 (1.01-1.14) |
| Cervical dilatation scan 1 (cm) | 0.79 (0.66-0.92) | 0.77 (0.63-0.94) |
| Caput succedaneum scan 1 (mm) | 1.09 (1.05-1.13) | 1.05 (1.01-1.10) |
| Change in cervical dilatation per hour (cm) | | 0.07 (0.03-0.19) |
| Change in caput succedaneum per hour (mm) | | 1.15 (0.96-1.40) |
| | | |
| **AUC** | 0.76 | 0.83 |
| **Optimism-corrected AUC** | 0.72 | 0.78 |

The performance of the original predictive model[195] in a different cohort of labouring woman, characterised by geographical and temporal differences, remains poor. Thus, conducting external validation is essential to assess the model's applicability in accurately predicting labour outcomes and modes of delivery.

This chapter outlines the development of the intrapartum Caesarean delivery prediction model and its external validation using data from the SONO-VE and Trieste studies. Similar methodological approaches are employed, incorporating the same prognostic parameters as those utilised in the SONO-PREDICT study. Collaboration with Professor Tamara Stampalija's intrapartum research group in Trieste, Italy, facilitates the validation of SONO-PREDICT for predicting intrapartum Caesarean delivery in a distinct population. This ongoing study aims to utilise data from current participants to enhance the external validation model.

## 4.2 Statistical Methods

In the descriptive analysis, categorical variables were reported as percentages, while continuous variables as median with interquartile range (IQR), as normality assumption was not satisfied. Differences between groups were evaluated using the Chi-square test or the Fisher's exact test, applied when any expected cell frequency was less than 5, for categorical variables, and the Wilcoxon-Mann-Whitney test for continuous variables. Univariate logistic regression models were estimated to identify potential risk factors associated with the outcome of interest, 'intrapartum Caesarean delivery'. Multivariable logistic regression was subsequently conducted, incorporating all significant predictors identified in the univariate analysis as well as potential confounders (such as maternal age, BMI, maternal ethnicity, and GA at delivery) irrespective of their statistical significance. A stepwise selection method was applied to obtain a more compact model, retaining only significant predictors.

Data form clinical and ultrasound assessments, derived from different populations, facilitated the validation of the logistic regression model initially developed using the combined and Trieste studies. Specifically, predicted probabilities from the developed model were applied to the other datasets to evaluate model's generalisability.

Model performance was estimated in terms of AUC, with 95% confidence intervals (CI). Additionally, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were reported for three different probability cut-offs ($p$ = 0.5, an arbitrary cut-off, and the one associated with the highest Youden Index). The significance level was set at alpha = 0.05. All analyses were performed using Stata 18.

## 4.3 Results

### 4.3.1 SONO-VE: Single Assessment Model Descriptive Analysis and Univariate Logistic Regression Analysis

Between 2015 and 2018, a cohort of 270 participants was enrolled, among which 269 were assessable following a single withdrawal of consent. ICD was deemed necessary for 79 participants (29%). Data on HPD and/or caput succedaneum measurements were absent for five participants (2%), resulting in an analysis based on 264 participants from the first ultrasound scan assessment and 212 from the second.

Descriptive statistics were generated for the entire sample of 269 participants. Categorical variables were expressed as frequencies and percentages, while continuous variables were described as medians with IQR. This analytical approach facilitated a deeper understanding of the relationships between the tested variables and the incidence of ICD.

The descriptive analysis revealed a significant direct association between HPD and the incidence of ICD. During the first ultrasound evaluation for the ICD group, the median HPD was 55.8 mm (IQR: 48.0-60.0 mm), which contrasted with the VD group that recorded a median of 48.0 mm (IQR: 44.5-52.7 mm), with a *p-value* of < 0.001. Conversely, an inverse relationship was observed between CD and ICD. In the first ultrasound assessment for the ICD group, the median CD was 2 cm (IQR: 1-3 cm), compared to the VD group where the median CD was 4 cm (IQR: 2-6 cm), with *a p-value* of < 0.001 (Table 23). The duration from the onset of active labour to childbirth was significantly shorter for participants undergoing VD [11.7 hours (IQR: 8.8-14.6 hours)] compared to those necessitating ICD [15.1 hours (IQR: 10.9-18.5 hours)], with a statistically significant difference (*p < 0.001)*, as documented in Supplemental Data 12.2.

***Table 23.*** *The SONO-VE: Descriptive Statistical Analysis.*

| Variables | ECS No N=190 | ECS Yes N=79 | p-value |
|---|---|---|---|
| **Age, median (IQR)** | 31 (28-34) | 31 (28-36) | 0.519 |
| **BMI class, n(%)** | | | 0.475 |
| 18.5<=BMI<25 (Normal weight) | 110 (57.9) | 47 (59.5) | |
| 25<=BMI<30 (Overweight) | 57 (30.0) | 19 (24.1) | |
| BMI>=30 (Obesity) | 23 (12.1) | 13 (16.5) | |
| **Ethnicity, n(%)** | | | 0.372 |
| Caucasian | 108 (56.8) | 37 (46.8) | |
| Afro-Caribbean | 16 (8.4) | 10 (12.7) | |
| Asian | 59 (31.1) | 30 (38.0) | |
| Mixed | 7 (3.7) | 2 (2.5) | |
| **GA (weeks), median (IQR)** | 40.1 (39.0-41.0) | 40.3 (39.1-41.1) | 0.296 |
| **HPD scan 1 (mm), median (IQR)** | 48.0 (44.5-52.7) | 55.8 (48.0-60.0) | ***<0.001*** |
| **HPD scan 2 (mm), median (IQR)** | 43.2 (39.0-49.0) | 50.6 (44.6-56.0) | ***<0.001*** |
| **HPD change (mm/h), median (IQR)** | 1.22 (0.41-2.29) | 0.46 (0.00-1.47) | ***0.001*** |
| **Head Position scan 1 (clock face hours), median (IQR)** | 3 (4-2) | 3 (2-4) | 0.688 |
| **Head Position scan 2 (clock face hours), median (IQR)** | 3 (2-5) | 3 (2-4) | 0.265 |
| **Head Position change (clock face hours/h), median (IQR)** | 0 (-0.19-0.19) | 0 (0-0) | 0.411 |
| **Caput scan 1 (mm), median (IQR)** | 0 (0-10.8) | 0 (0-10.0) | 0.657 |
| **Caput scan 2 (mm), median (IQR)** | 12.0 (0.0-18.9) | 12.3 (0.0-17.6) | 0.440 |
| **Caput change (mm/h), median (IQR)** | 0.72 (0-2.8) | 0.2 (0-3.2) | 0.435 |
| **Cervical dilatation scan 1 (cm), median (IQR)** | 4 (2-6) | 2 (1-3) | ***<0.001*** |
| **Cervical dilatation scan 2 (cm), median (IQR)** | 7 (4-10) | 4 (2-5) | ***<0.001*** |
| **Cervical dilatation change (cm/h), median (IQR)** | 0.6 (0.3-1.1) | 0.2 (0-0.5) | ***<0.001*** |
| **UC Ratio, median (IQR)** | 0.61 (0.46-0.83) | 0.66 (0.51-0.88) | 0.206 |
| **Moulding, n(%)** | 41 (21.8) | 13 (16.5) | 0.404 |

Univariate logistic regression analysis on the single assessment model identified two prognostic variables significantly associated with the necessity for ICD. Notably, evaluations of head station, including HPD values and cervical dilatation were significantly associated with emergency Caesarean delivery, as indicated by a *p-value* of $< 0.001$, for both correlations (Table 24).

***Table 24.*** *The SONO-VE: Univariate Logistic Regression Analysis of the Single Assessment Model.*

| Variables | Univariate regression OR | 95% CI | p-value | AUC [95% CI] |
|---|---|---|---|---|
| **Age>=35** | 1.64 | [0.90-3.00] | 0.106 | 0.55 [0.49- 0.60] |
| **BMI class (ref. BMI<25)** | | | | 0.54 [0.47- 0.61] |
| 25<=BMI<30 (Overweight) | 0.78 | [0.42-1.45] | 0.434 | |
| BMI>=30 (Obesity) | 1.32 | [0.62-2.83] | 0.471 | |
| **Ethnicity (ref. Caucasian)** | | | | 0.56 [0.49-0.63] |
| Afro-Caribbean | 1.82 | [0.76-4.37] | 0.178 | |
| Asian | 1.48 | [0.83-2.64] | 0.180 | |
| Mixed | 0.83 | [0.17-4.19] | 0.826 | |
| **GA (weeks)** | 1.13 | [0.92-1.40] | 0.244 | 0.54 [0.46- 0.62] |
| **HPD scan 1 (mm)** | 1.11 | [1.07-1.15] | ***<0.001*** | 0.71 [0.63- 0.78] |
| **Head Position scan 1 (clock face hours)** | 1.04 | [0.87; 1.24] | 0.685 | 0.51 [0.46-0.56] |
| **Caput scan 1 (mm)** | 0.99 | [0.96-1.03] | 0.623 | 0.52 [0.45- 0.57] |
| **Cervical dilatation scan 1 (cm)** | 0.77 | [0.66-0.87] | ***<0.001*** | 0.65 [0.58- 0.71] |
| **UC Ratio** | 2.18 | [0.56-8.47] | 0.264 | 0.57 [0.46- 0.67] |
| **Moulding** | 0.71 | [0.35-1.41] | 0.322 | 0.53 [0.48- 0.58] |

### 4.3.2 SONO-VE: Single Assessment Model Multivariate Statistical Analysis

#### 4.3.2.1 Excluding Umbilical-Cerebral Ratio

**Including ALL Prognostic Variables for Intrapartum Caesarean Delivery**

Statistical analysis was conducted on a sample of 264 participants. UC ratios were initially excluded to evaluate potential differences in the results and their impact on the incidence of ICD. All prognostic factors potentially influencing ICD incidences, including maternal age, GA, BMI, maternal ethnicity, HPD, CD, fetal head position, caput succedaneum, and moulding were considered. The adjusted $R^2$ of the multivariate model was 0.253.

Significant predictors of ICD were identified as BMI (overweight class 2, 25 ≤ BMI ≤ 29.9), GA, HPD, and CD measurements, with *p-values* of 0.045, 0.044, 0.000, and 0.005, respectively (Table 25). The AUC was 0.78 [95% CI: 0.72-0.84], demonstrating a sensitivity of 62.7% and a specificity of 83.2% (Table 26 and Figure 53).

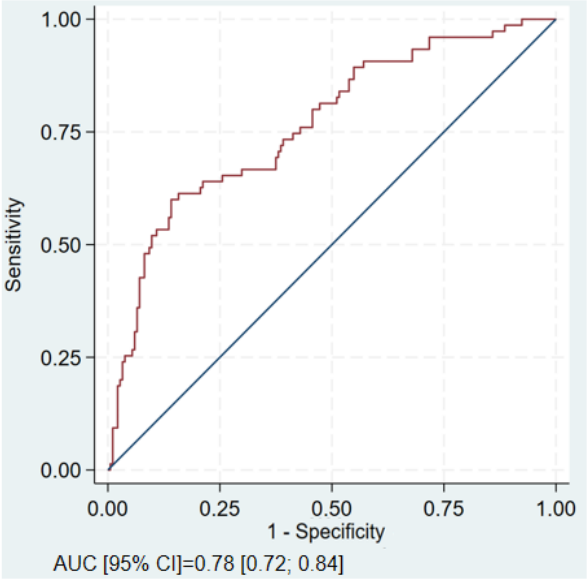
***Table 25.*** *The SONO-VE: Multivariate Logistic Regression Analysis of the Single Assessment Model: All Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 1.878616 | .7191785 | 1.65 | 0.100 | .8871111 | 3.978305 |
| bmi_class | | | | | | |
| 2 | .4679852 | .1773101 | -2.00 | 0.045 | .2227045 | .9834112 |
| 3 | .8687846 | .4297704 | -0.28 | 0.776 | .329488 | 2.290786 |
| ethnicity | | | | | | |
| 2 | 2.57457 | 1.479929 | 1.65 | 0.100 | .8344728 | 7.943231 |
| 3 | 1.771116 | .6388909 | 1.58 | 0.113 | .8733634 | 3.591693 |
| 4 | 1.122477 | 1.004931 | 0.13 | 0.897 | .1941395 | 6.489947 |
| GA_weeks | 1.292783 | .1646642 | 2.02 | 0.044 | 1.007178 | 1.659376 |
| HPD_scan1 | 1.085123 | .0244974 | 3.62 | 0.000 | 1.038156 | 1.134215 |
| Head_Rotation_scan1 | 1.085259 | .116446 | 0.76 | 0.446 | .8794295 | 1.339262 |
| Caput_scan1 | 1.049606 | .0267344 | 1.90 | 0.057 | .9984942 | 1.103335 |
| Cervical_dilatation_scan1 | .776349 | .0701642 | -2.80 | 0.005 | .6503211 | .9268003 |
| Moulding0none1present | 1.016948 | .4352931 | 0.04 | 0.969 | .4394927 | 2.35313 |
| _cons | 2.28e-07 | 1.21e-06 | -2.88 | 0.004 | 6.78e-12 | .0076403 |

***Table 26.*** *The SONO-VE: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Single Assessment Model: All Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default p=0.5 | Arbitrary p=0.305 | Max Youden Index p=0.375 |
| Sensitivity | 41.3% | 70.7% | 62.7% |
| Specificity | 93.5% | 70.7% | 83.2% |
| PPV | 72.1% | 49.5% | 60.3% |
| NPV | 79.6% | 85.5% | 84.5% |
| Correctly classified | 78.4% | 70.7% | 77.2% |

***Figure 53.*** *The SONO-VE: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Single Assessment Model: All Variables.*




## Including SELECTED Prognostic Variables for Intrapartum Caesarean Delivery

Analysis was conducted on the same cohort of 264 participants focused on selected variables, excluding UCR (Table 27). Notably, BMI class 2 and gestational age were not significant in this compact model, whereas caput emerged as a significant factor. The AUC was 0.75 [95% CI: 0.68-0.81], with a sensitivity of 60.0% and specificity of 90.0% (Table 28 and Figure 54).

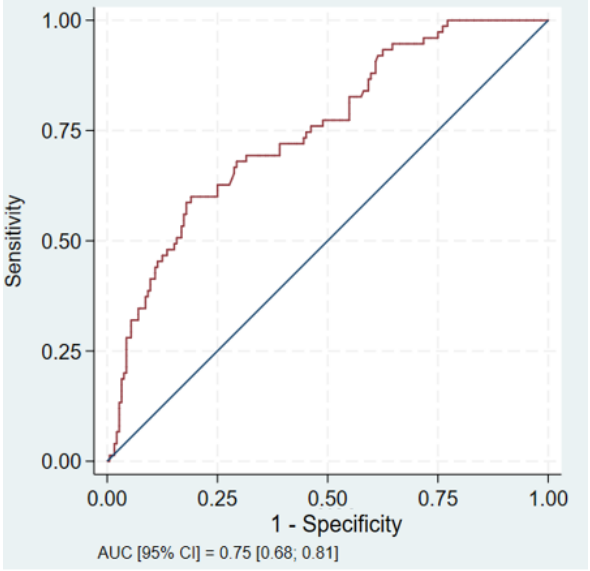
***Table 27.*** *The SONO-VE: Multivariate Logistic Regression Analysis of the Single Assessment Model: Selected Variables.*

| cs | Odds ratio | Std. err. | z | P>\|z\| | [95% conf. | interval] |
|---|---|---|---|---|---|---|
| Cervical_dilatation_scan1 | .7770044 | .0659756 | -2.97 | 0.003 | .6578816 | .9176967 |
| HPD_scan1 | 1.087085 | .0225674 | 4.02 | 0.000 | 1.043741 | 1.132228 |
| Caput_scan1 | 1.050266 | .0246903 | 2.09 | 0.037 | 1.002971 | 1.09979 |
| _cons | .0100856 | .0119526 | -3.88 | 0.000 | .0009884 | .1029127 |

***Table 28.*** *The SONO-VE: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Single Assessment Model: Selected Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.267 | p=0.288 |
| Sensitivity | 33.3% | 72.0% | 60.0% |
| Specificity | 92.9% | 60.9% | 90.0% |
| PPV | 65.8% | 42.9% | 56.3% |
| NPV | 77.4% | 84.2% | 83.2% |
| Correctly classified | 75.7% | 64.1% | 74.9% |

***Figure 54.*** *The SONO-VE: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Single Assessment Model: Selected Variables.*




#### 4.3.2.2 Including Umbilical-Cerebral Ratio

**Including ALL Prognostic Variables of Intrapartum Caesarean Delivery**

Statistical analysis was performed on a sample of 127 participants, incorporating UC ratios to facilitate a comparative evaluation. Within this single assessment model, no parameter demonstrated statistical significance, with cervical dilatation nearing significance ($p$ = 0.058) in predicting ICD (Table 29). The AUC was 0.76 [95% CI: 0.67-0.85]), with a sensitivity of 85.7% and specificity of 52.9% (Table 30 and Figure 55).

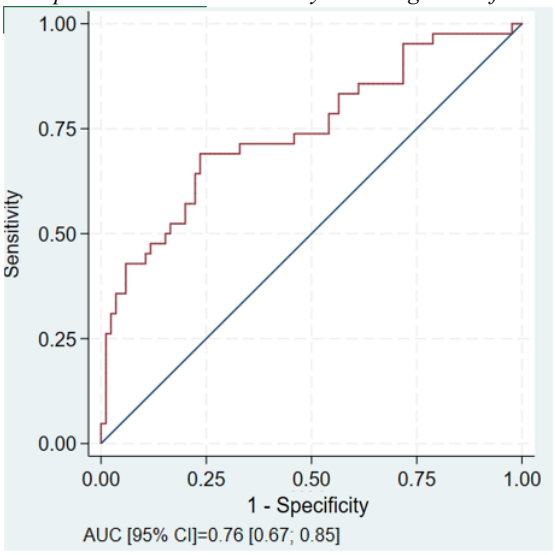
***Table 29.*** *The SONO-VE: Multivariate Logistic Regression Analysis of the Single Assessment Model: Including UCR: All Variables.*

| cs | Odds ratio | Std. err. | z | P>\|z\| | [95% conf. | interval] |
|---|---|---|---|---|---|---|
| age_over35 | 1.706776 | .9220379 | 0.99 | 0.322 | .5920234 | 4.920557 |
| bmi_class | | | | | | |
| 2 | .4816272 | .2549695 | -1.38 | 0.168 | .1706443 | 1.359347 |
| 3 | 2.145304 | 1.47332 | 1.11 | 0.266 | .5583585 | 8.242605 |
| ethnicity | | | | | | |
| 2 | 3.068108 | 2.294344 | 1.50 | 0.134 | .7084978 | 13.28626 |
| 3 | 1.549788 | .7727856 | 0.88 | 0.380 | .5832163 | 4.118272 |
| 4 | .7659469 | .9307699 | -0.22 | 0.826 | .0707666 | 8.290276 |
| GA_weeks | 1.17422 | .2006922 | 0.94 | 0.347 | .8399745 | 1.64147 |
| HPD_scan1 | 1.048051 | .0329606 | 1.49 | 0.136 | .9854004 | 1.114685 |
| Head_Rotation_scan1 | 1.005629 | .0787043 | 0.07 | 0.943 | .8626199 | 1.172346 |
| Caput_scan1 | 1.046616 | .0401698 | 1.19 | 0.235 | .9707735 | 1.128385 |
| Cervical_dilatation_scan1 | .7604495 | .1098764 | -1.90 | 0.058 | .5729032 | 1.009391 |
| Moulding0none1present | .6779275 | .4816323 | -0.55 | 0.584 | .1684414 | 2.728461 |
| UCratio | 1.557768 | 1.294786 | 0.53 | 0.594 | .3054927 | 7.94337 |
| _cons | .0000647 | .0004667 | -1.34 | 0.181 | 4.73e-11 | 88.62247 |

***Table 30.*** *The SONO-VE: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Single Assessment Model Including UCR: All Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.312 | p=0.235 |
| **Sensitivity** | 42.9% | 71.4% | 85.7% |
| **Specificity** | 90.6% | 61.2% | 52.9% |
| **PPV** | 69.2% | 47.6% | 47.4% |
| **NPV** | 76.2% | 81.3% | 88.2% |
| **Correctly classified** | 74.8% | 64.6% | 63.8% |

***Figure 55.*** *The SONO-VE: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery Including UCR of the Single Assessment Model: All Variables.*



**Including SELECTED Prognostic Variables of Intrapartum Caesarean Delivery**

The analysis was performed on the same cohort of 127 participants focused on selected variables significantly impacting ICD incidence, including fetal Doppler values (UCR) (Table 31). In this compact model, cervical dilatation and BMI (obesity class 3, BMI ≥ 30 ) were significant predictors of ICD. The AUC was 0.67 [95% CI: 0.57-0.77], with a sensitivity of 85.7% and specificity of 38.8% (Table 32 and Figure 56).

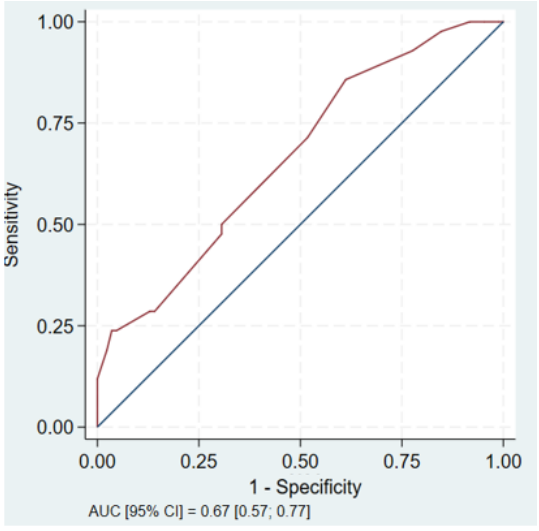
***Table 31.*** *The SONO-VE: Multivariate Logistic Regression Analysis of the Single Assessment Model: Including UCR: Selected variables.*

| cs | Odds ratio | Std. err. | z | P>\|z\| | [95% conf. | interval] |
|---|---|---|---|---|---|---|
| Cervical_dilatation_scan1 | .7548286 | .0885844 | -2.40 | 0.017 | .5997275 | .950042 |
| 3.bmi_class | 4.59683 | 2.745137 | 2.55 | 0.011 | 1.426059 | 14.81765 |
| _cons | .8385323 | .2957005 | -0.50 | 0.618 | .420099 | 1.67374 |

***Table 32.*** *The SONO-VE: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Single Assessment Model: Including UCR: Selected Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default p=0.5 | Arbitrary p=0.323 | Max Youden Index p=0.214 |
| Sensitivity | 23.8% | 71.4% | 85.7% |
| Specificity | 95.3% | 48.2% | 38.8% |
| PPV | 71.4% | 40.5% | 40.9% |
| NPV | 71.7% | 77.4% | 84.6% |
| Correctly classified | 71.7% | 55.9% | 54.3% |

***Figure 56.*** *The SONO-VE: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery Including UCR of the Single Assessment Model: Selected Variables.*



### 4.3.3 SONO-VE: Repeat Assessment Model Descriptive Analysis and Univariate Logistic Regression Analysis

Descriptive statistics were generated for the entire cohort of 269 participants. The repeat ultrasound assessment demonstrated a direct correlation between HPD and ICD. The median HPD was 50.6 mm (IQR: 44.6-56.0 mm) in the ICD group, compared to 43.2 mm (IQR: 39.0-49.0 mm) in the VD group, with a statistically significant difference, ($p < 0.001$). The rate of change in median HPD in the ICD group was 0.46 mm/hr (IQR: 0.00-1.47 mm/hr), compared to 1.22 mm/hr (IQR: 0.41-2.29 mm/hr) in the VD group, with a *p-value* of 0.001.

Conversely, an inverse relationship was observed between CD and ICD. Median CD was 4 cm (IQR: 2-5 cm) in the ICD group versus 7 cm (IQR: 4-10 cm) in the VD group ($p < 0.001$). During the second labour assessments, the rate of change in median CD in the ICD group was 0.2 cm/hr (IQR: 0-0.5 cm/hr), compared to 0.6 cm/hr (IQR: 0.3-1.1 cm/hr) in the VD group, with a *p-value* of < 0.001, as presented earlier in Table 23.

Univariate logistic regression analysis was performed on the repeat assessment model to identify potential risk factors associated with ICD (Table 33). This analysis demonstrated that certain factors had a statistically significant impact on delivery outcomes and were strongly associated with the incidence of intrapartum Caesarean delivery. Notably, significant associations were observed in HPD and CD measurements during repeat ultrasound evaluations, as well as in their changes, with *p-values* of < 0.001, 0.004, < 0.001, and < 0.001, respectively.

***Table 33.*** *The SONO-VE: Univariate Logistic Regression Analysis of the Repeat Assessment Model.*

| Variables | Univariate regression | | | |
|---|---|---|---|---|
| | OR | 95% CI | p-value | AUC [95% CI] |
| **Age>=35** | 1.63 | [0.84-3.15] | 0.143 | 0.54 [0.48-0.61] |
| **BMI class (ref. BMI<25)** | | | | 0.53 [0.46-0.61] |
| 25<=BMI<30 (Overweight) | 0.79 | [0.41-1.54] | 0.489 | |
| BMI>=30 (Obesity) | 1.26 | [0.51-3.10] | 0.621 | |
| **Ethnicity (ref. Caucasian)** | | | | 0.57 [0.50-0.65] |
| Afro-Caribbean | 2.37 | [0.89-6.36] | 0.086 | |
| Asian | 1.43 | [0.77-2.66] | 0.262 | |
| Mixed | 0.53 | [0.06-4.68] | 0.566 | |
| **GA (weeks)** | 1.14 | [0.90-1.45] | 0.259 | 0.55 [0.46-0.63] |
| **HPD scan 1 (mm)** | 1.08 | [1.04-1.13] | ***<0.001*** | 0.66 [0.58-0.74] |
| **HPD scan 2 (mm)** | 1.14 | [1.09-1.19] | ***<0.001*** | 0.75 [0.68-0.83] |
| **HPD change (mm/h)** | 0.70 | [0.55-0.89] | ***0.004*** | 0.64 [0.56-0.72] |
| **Head Position scan 1 (clock face hours)** | 0.99 | [0.82; 1.21] | 0.953 | 0.48 [0.41-0.56] |
| **Head Position scan 2 (clock face hours)** | 0.89 | [0.74-1.06+ | 0.181 | 0.55 [0.47-0.63] |
| **Head Position change (clock face hours/h)** | 0.76 | [0.41-1.39] | 0.368 | 0.53 [0.45-0.60] |
| **Caput scan 1 (mm)** | 1.00 | [0.96-1.05] | 0.909 | 0.50 [0.44-0.56] |
| **Caput scan 2 (mm)** | 0.99 | [0.96; 1.02] | 0.566 | 0.53 [0.45-0.69] |
| **Caput change (mm/h)** | 0.99 | [0.87-1.12] | 0.850 | 0.54 [0.45-0.61] |
| **Cervical dilatation scan 1 (cm)** | 0.79 | [0.68-0.93] | ***0.003*** | 0.61 [0.54-0.68] |
| **Cervical dilatation scan 2 (mm)** | 0.64 | [0.55-0.74] | ***<0.001*** | 0.79 [0.73-0.85] |
| **Cervical dilatation change (cm/h)** | 0.08 | [0.03-0.20] | ***<0.001*** | 0.78 [0.71-0.84] |
| **UC Ratio** | 1.32 | [0.29-6.02] | 0.716 | 0.53 [0.41-0.64] |
| **Moulding** | 0.72 | [0.35-1.49] | 0.375 | 0.53 [0.47-0.58] |

### 4.3.4 SONO-VE: Repeat Assessment Model Multivariate Statistical Analysis

#### 4.3.4.1 Excluding Umbilical-Cerebral Ratio

**Including ALL Prognostic Variables of Intrapartum Caesarean Delivery**

A total of 214 participants underwent repeat intrapartum ultrasound scans. However, data were incomplete for two participants, resulting in 212 participants being included in the final analysis. The statistical analysis was conducted on this cohort to estimate the repeat assessment model, initially excluding UCR. This analysis included all prognostic factors potentially influencing ICD incidence, including maternal age, GA, BMI, maternal ethnicity, HPD, CD, fetal head position, caput succedaneum, and fetal moulding.

Significant predictors of ICD were identified as maternal age > 35 years, maternal ethnicity (Asian group 3, comprising 74/212 participants [34%]), GA, HPD in the first ultrasound scan, caput succedaneum in the first scan, and cervical dilatation in the first scan along with its subsequent changes, with *p-values* of 0.014, 0.043, 0.038, 0.038, 0.019, 0.018, and 0.000, respectively (Table 34). The AUC was 0.85 [95% CI: 0.79-0.90], demonstrating a sensitivity of 87.7% and a specificity of 70.8% (Table 35 and Figure 57).

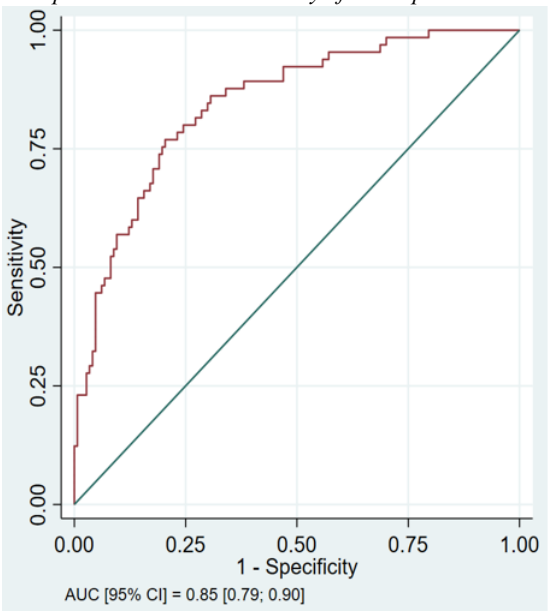
***Table 34.*** *The SONO-VE: Multivariate Logistic Regression Analysis of the Repeat Assessment Model: All Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 3.10562 | 1.426417 | 2.47 | 0.014 | 1.262379 | 7.640236 |
| bmi_class | | | | | | |
| 2 | .4988836 | .2265056 | -1.53 | 0.126 | .2048955 | 1.214691 |
| 3 | .7896536 | .5259957 | -0.35 | 0.723 | .2140145 | 2.9136 |
| ethnicity | | | | | | |
| 2 | 1.968695 | 1.454624 | 0.92 | 0.359 | .4626422 | 8.377448 |
| 3 | 2.490866 | 1.123673 | 2.02 | 0.043 | 1.028865 | 6.030346 |
| 4 | .7493502 | .9120567 | -0.24 | 0.813 | .0689703 | 8.141564 |
| GA_weeks | 1.410538 | .2334868 | 2.08 | 0.038 | 1.01973 | 1.951122 |
| HPD_scan1 | 1.061399 | .0304664 | 2.08 | 0.038 | 1.003334 | 1.122823 |
| HPD_change_per_hour | .8672461 | .1556236 | -0.79 | 0.427 | .6100956 | 1.232784 |
| Head_Rotation_scan1 | .977038 | .1343967 | -0.17 | 0.866 | .7461467 | 1.279377 |
| HeadRotation_change_p~c | .3938908 | .2599049 | -1.41 | 0.158 | .1080734 | 1.435597 |
| Caput_scan1 | 1.090447 | .0402911 | 2.34 | 0.019 | 1.01427 | 1.172346 |
| Caput_change_per_hour | 1.209116 | .1365486 | 1.68 | 0.093 | .9690349 | 1.508677 |
| Cervical_dilatation_s~1 | .7599416 | .08827 | -2.36 | 0.018 | .6052155 | .9542242 |
| CervicalDil_change_pe~r | .0589503 | .0356335 | -4.68 | 0.000 | .0180286 | .1927566 |
| Moulding0none1present | 1.423746 | .754575 | 0.67 | 0.505 | .5038509 | 4.023121 |
| _cons | 7.41e-08 | 5.10e-07 | -2.38 | 0.017 | 1.02e-13 | .0538472 |

***Table 35.*** *The SONO-VE: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Repeat Assessment Model: All Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.295 | p=0.268 |
| **Sensitivity** | 61.5% | 83.1% | 87.7% |
| **Specificity** | 91.2% | 73.5% | 70.8% |
| **PPV** | 75.5% | 58.1% | 57.0% |
| **NPV** | 84.3% | 90.8% | 92.9% |
| **Correctly classified** | 82.1% | 76.4% | 75.9% |

***Figure 57.*** *The SONO-VE: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model: All Variables.*



**Including SELECTED Prognostic Variables of Intrapartum Caesarean Delivery**

Further analysis was conducted on the same cohort (n = 212) retained only variables with *p-values* < 0.05, excluding UC ratios (Table 36). Changes in caput succedaneum measurements, which was not significant in the full predictive model, emerged as a significant factor in this compact model, with a *p-value* of 0.031. The resulting AUC was 0.83 [95% CI: 0.77-0.88]), with a sensitivity of 83.1% and a specificity of 69.4% (Table 37 and Figure 58).

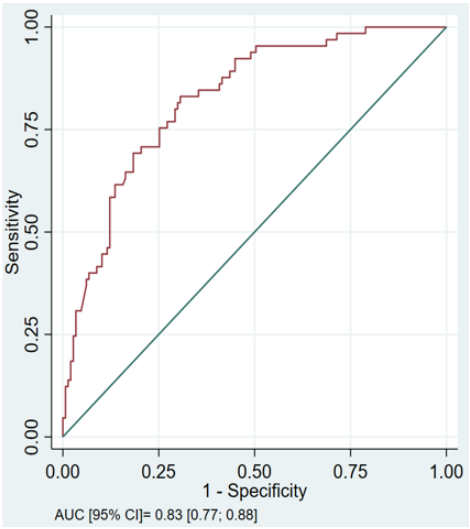
***Table 36.*** *The SONO-VE: Multivariate Logistic Regression Analysis of the Repeat Assessment Model: Selected Variables.*

| Caesarean_Section | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| Maternal_age_35plus | 2.620269 | 1.090246 | 2.32 | 0.021 | 1.159248 | 5.922641 |
| Caput_change_per_hour | 1.236815 | .1221178 | 2.15 | 0.031 | 1.019203 | 1.50089 |
| CervicalDil_change_per_hour | .0531568 | .0280804 | -5.56 | 0.000 | .0188758 | .1496963 |
| Cervical_dilatation_scan1 | .691533 | .0711375 | -3.59 | 0.000 | .5652627 | .8460099 |
| Caput_scan1 | 1.084335 | .0370636 | 2.37 | 0.018 | 1.014071 | 1.159467 |
| _cons | 2.278402 | .8323196 | 2.25 | 0.024 | 1.113472 | 4.662099 |

***Table 37.*** *The SONO-VE: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Repeat Assessment Model: Selected Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.286 | p=0.288 |
| **Sensitivity** | 52.3% | 80.0% | 83.1% |
| **Specificity** | 87.8% | 70.8% | 69.4% |
| **PPV** | 65.4% | 54.7% | 54.6% |
| **NPV** | 80.6% | 88.9% | 90.3% |
| **Correctly classified** | 76.9% | 73.6% | 73.6% |

***Figure 58.*** *The SONO-VE: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model: Selected Variables.*



A focused analysis on only the influence of cervical dilatation and its changes revealed an AUC of 0.79 [95% CI: 0.73-0.85] (Table 38 and Figure 59). Omitting this parameter and focusing only on its changes yielded an AUC of 0.78 [95% CI: 0.71-0.84] (Figure 60).

***Table 38.*** *The SONO-VE: Analysis of the Repeat Assessment Model with Retaining the Cervical Dilatation Measurements.*

| Caesarean_Section | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| Cervical_dilatation_scan1 | .7949624 | .066942 | -2.72 | 0.006 | .6740138 | .9376146 |
| CervicalDil_change_per_hour | .0818116 | .0386455 | -5.30 | 0.000 | .0324139 | .2064897 |
| _cons | 2.898082 | 1.02082 | 3.02 | 0.003 | 1.45306 | 5.780134 |

***Figure 59.*** *The SONO-VE: ROC Showing the Relationship between the Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model with Retaining the Cervical Dilatation Parameter.*

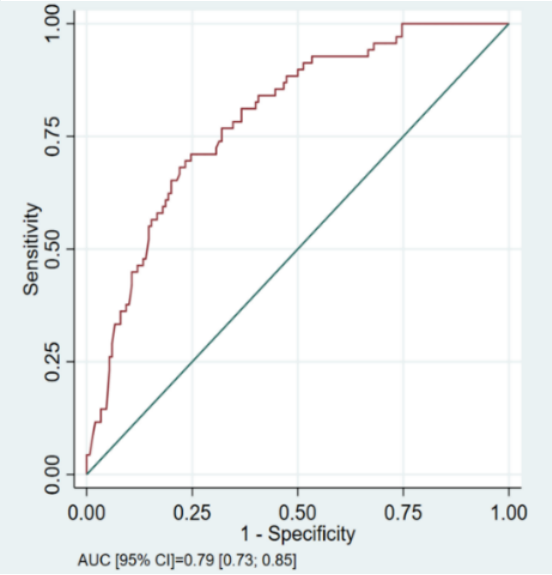
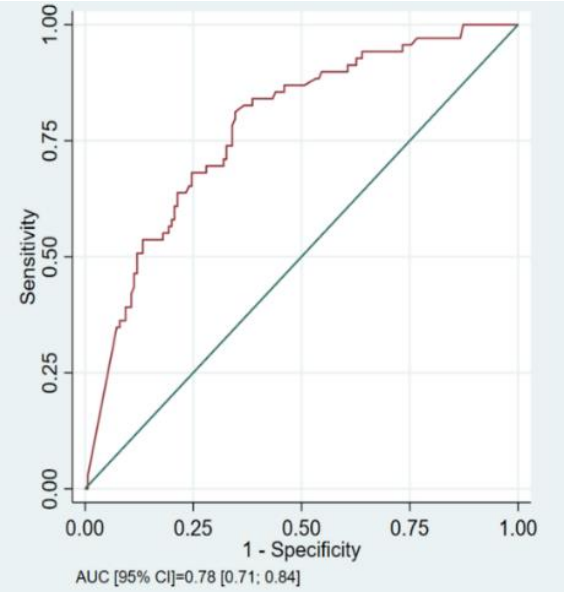


***Figure 60.*** *The SONO-VE: ROC Showing the Relationship between the Prognostic Factors and Prediction of Intrapartum Caesarean Delivery with Removing the Cervical Dilatation Parameter.*




#### 4.3.4.2 Including Umbilical-Cerebral Ratio

**Including ALL Prognostic Variables of Intrapartum Caesarean Delivery**

A statistical analysis included UCR was conducted on sample size of 107 participants. Maternal ethnicity (Asian group 3, accounting for 47/107 participants [44%]), and cervical dilatation change were significantly influenced the prediction of ICD ($p$ = 0.044 and $p$ = 0.000, respectively) (Table 39). The AUC was 0.85 [95% CI: 0.77-0.93], with a sensitivity of 73.5% and a specificity of 85.5% (Table 40 Figure 61).

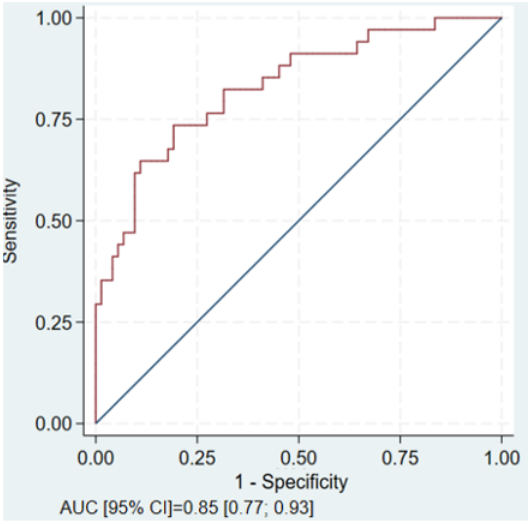
***Table 39.*** *The SONO-VE: Multivariate Logistic Regression Analysis of the Repeat Assessment Model Including UCR: All Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 3.589061 | 2.571605 | 1.78 | 0.075 | .8812205 | 14.61763 |
| bmi_class | | | | | | |
| 2 | .4372284 | .2992438 | -1.21 | 0.227 | .1143238 | 1.672168 |
| 3 | 1.571462 | 1.374683 | 0.52 | 0.605 | .2829371 | 8.728064 |
| ethnicity | | | | | | |
| 2 | 2.086763 | 1.892721 | 0.81 | 0.417 | .3527135 | 12.34594 |
| 3 | 3.882906 | 2.61072 | 2.02 | 0.044 | 1.03954 | 14.5035 |
| 4 | 1 | (empty) | | | | |
| GA_weeks | 1.53761 | .3778182 | 1.75 | 0.080 | .949928 | 2.488866 |
| HPD_scan1 | 1.003418 | .0453542 | 0.08 | 0.940 | .9183488 | 1.096367 |
| HPD_change_per_hour | 1.179121 | .2813525 | 0.69 | 0.490 | .7386718 | 1.882198 |
| Head_Rotation_scan1 | .8955449 | .1889257 | -0.52 | 0.601 | .5922655 | 1.354123 |
| HeadRotation_change_per_hour_rec | .6483281 | .6328889 | -0.44 | 0.657 | .0956894 | 4.392644 |
| Caput_scan1 | .9950647 | .0523942 | -0.09 | 0.925 | .8974952 | 1.103241 |
| Caput_change_per_hour | 1.080202 | .1922258 | 0.43 | 0.665 | .7621331 | 1.531015 |
| Cervical_dilatation_scan1 | .8494538 | .1818894 | -0.76 | 0.446 | .558311 | 1.292419 |
| CervicalDil_change_per_hour | .032774 | .0318914 | -3.51 | 0.000 | .0048669 | .2207025 |
| UCratio | 1.820723 | 1.973704 | 0.55 | 0.580 | .2175317 | 15.23931 |
| Moulding0none1present | .8040708 | .6970867 | -0.25 | 0.801 | .1470103 | 4.397855 |
| _cons | 3.67e-08 | 3.64e-07 | -1.72 | 0.085 | 1.31e-16 | 10.30996 |

***Table 40.*** *The SONO-VE: Diagnostic Measures of Multivariable Logistic Regression Analysis of the Repeat Assessment Model Including UCR: All Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.385 | p=0.437 |
| **Sensitivity** | 70.6% | 76.5% | 73.5% |
| **Specificity** | 88.4% | 79.7% | 85.5% |
| **PPV** | 75.0% | 65.0% | 71.4% |
| **NPV** | 85.9% | 87.3% | 86.8% |
| **Correctly classified** | 82.5% | 78.6% | 81.6% |

***Figure 61.*** *The SONO-VE: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model Including UCR: All Variables.*



**Including SELECTED Prognostic Variables of Intrapartum Caesarean Delivery**

The analysis performed on the same cohort of 107 participants with including only statistically significant factors along with UC ratios (Table 41). This analysis yielded an AUC of 0.78 [95% CI: 0.68-0.87], with a sensitivity of 70.6% and a specificity of 76.7% (Table 42 and Figure 62).

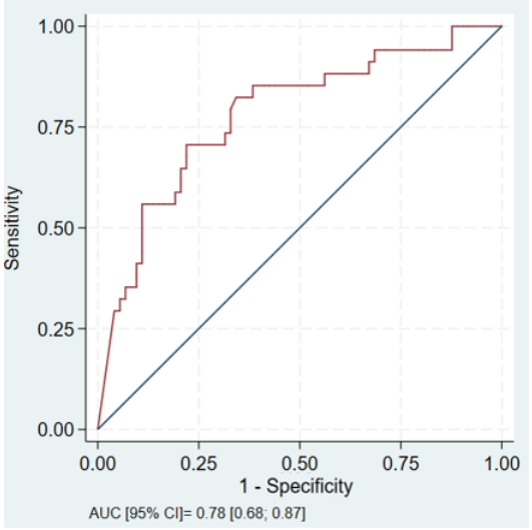
***Table 41.*** *The SONO-VE: Multivariate Logistic Regression Analysis of the Repeat Assessment Model Including UCR: Selected variables.*

| cs | Odds ratio | Std. err. | z | P>\|z\| | [95% conf. | interval] |
|---|---|---|---|---|---|---|
| CervicalDil_change_per_hour | .0743737 | .0521644 | -3.71 | 0.000 | .0188106 | .294061 |
| _cons | 1.622228 | .5787793 | 1.36 | 0.175 | .806157 | 3.264405 |

***Table 42.*** *The SONO-VE: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Repeat Assessment Model Including UCR: Selected Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.318 | p=0.288 |
| Sensitivity | 52.9% | 82.4% | 70.6% |
| Specificity | 89.0% | 65.8% | 76.7% |
| PPV | 69.2% | 52.8% | 58.5% |
| NPV | 80.3% | 88.9% | 84.9% |
| Correctly classified | 77.6% | 71.0% | 74.8% |

***Figure 62.*** *The SONO-VE: ROC between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model Including UCR: Selected Variables.*



### 4.3.5 Combined Study (SONO-VE and SONO-PREDICT): Single Assessment Model Descriptive Analysis and Univariate Logistic Regression Analysis

When we analysed the SONO-VE study, we observed a significant impact of demographic factors, including maternal age, BMI, and maternal ethnicity, on the incidence of ICD. This effect was not apparent in the SONO-PREDICT study. We conducted a comparative analysis of the demographic cohorts from SONO-VE (n = 269) and SONO-PREDICT (n = 239). Table 43 demonstrates significant differences in maternal ethnicity between the two study populations ($p$ = 0.001).

***Table 43.*** *Comparative Analysis of Population Demographics between the SONO-VE and SONO-PREDICT Studies.*

| Variables | Cohort SONO-VE N=269 | SONO-PREDICT N=239 | p-value |
|---|---|---|---|
| **Age, median (IQR)** | 31 (28-34) | 32 (29-35) | 0.462 |
| **Advanced age (>=35 years), n(%)** | 61 (22.7) | 60 (25.1) | 0.533 |
| **BMI class, n(%)** | | | 0.604 |
| BMI<18.5 (Underweight) | 6 (2.2) | 4 (1.7) | |
| 18.5<=BMI<25 (Normal weight) | 151 (56.1) | 130 (54.4) | |
| 25<=BMI<30 (Overweight) | 76 (28.3) | 79 (33.1) | |
| BMI>=30 (Obesity) | 36 (13.4) | 26 (10.9) | |
| **Ethnicity, n(%)** | | | ***0.001*** |
| Caucasian | 145 (53.9) | 105 (43.9) | |
| Afro-Caribbean | 26 (9.7) | 34 (14.2) | |
| Asian | 89 (33.1) | 74 (31.0) | |
| Mixed | 9 (3.3) | 26 (10.9) | |
| **GA (weeks), median (IQR)** | 40.1 (39.0-41.0) | 40.0 (39.0-41.0) | 0.329 |

The demographic characteristics of the participants of the combined study (SONO-VE and SONO-PREDICT) included nulliparous women aged 18-44 years (mean age, 31 years and 1 month), with a mean gestational age of 40 weeks and mean BMI of 25 kg/m$^2$ (range, 18-47.3 kg/m$^2$).

Statistical analysis encompassed 508 participants from both studies to explore the relationship between tested variables and the incidence of ICD. In 163 participants (32%), an ICD was deemed necessary, with mean birth weights of 3448 g for ICD babies versus 3364 g for VD babies (Figure 63).

A total of 416 participants (82%) underwent second intrapartum ultrasound assessments, while 92 (18%) had a first intrapartum ultrasound evaluation. A total of 924 ultrasound evaluations were conducted during the active first stage of labour. Figures 64 and 65 illustrate the population distribution with first and second assessments and maternal ethnicity distribution, respectively.

***Figure 63.*** *The Combined Study: Delivery Mode Rates and Mean Birth Weights.*

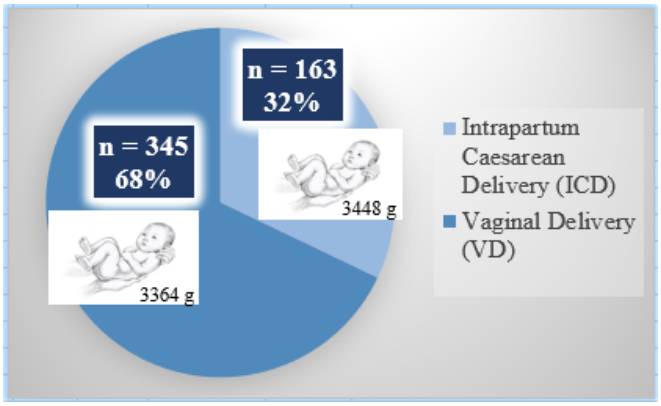



***Figure 64.*** *Flow-Chart of the Combined Study Population.*

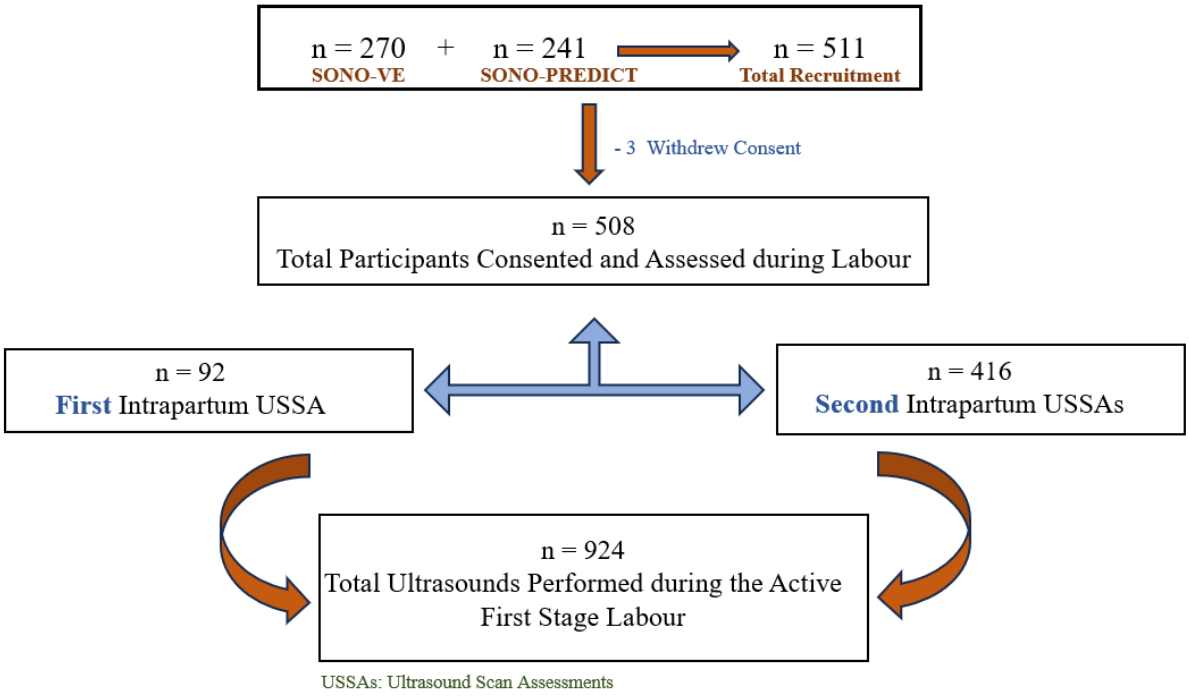
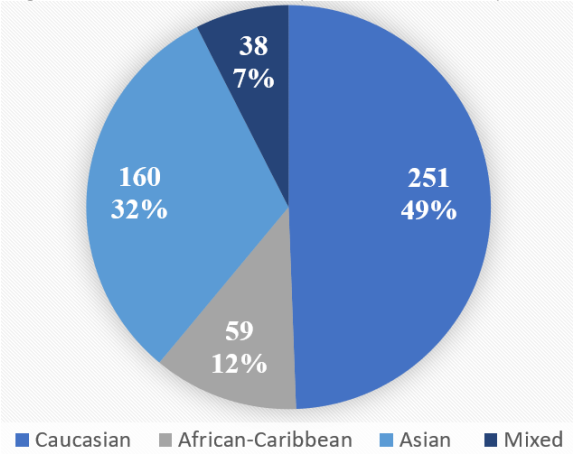


***Figure 65.*** *The Combined Study: Maternal Ethnicity Distribution.*




Descriptive analysis indicated that specific factors, notably fetal head station expressed as HPD measurements during both labour assessments and their subsequent changes (ICD: 52.9 mm; 50.8 mm; and 0.9 mm/hr versus VD: 47.9 mm; 43.6 mm; and 1.2 mm/hr) respectively, changes in caput succedaneum (ICD: 0.5 mm/hr versus VD: 0.9 mm/hr), and cervical dilatation measurements across both labour assessments and their subsequent changes (ICD: 2 cm; 4 cm; and 0.2 cm/hr versus VD: 4 cm; 7 cm; and 0.7 cm/hr) respectively, were significantly associated with ICD, as evidenced by *p-values* of < 0.001, < 0.001, < 0.001, 0.034, < 0.001, < 0.001, and < 0.001, respectively (Table 44). Additionally, the duration from the onset of active labour to the delivery of the baby was longer in participants who had ICD compared to those who underwent VD (median: 15.1 hours, [IQR: 10.9-18.5] versus 11.7 hours [IQR: 8.8-14.6], respectively; ($p$ < 0.001) (Table 44).

Univariate logistic regression analysis for the single assessment model indicated that specific factors, notably maternal ethnicity (Afro-Caribbean, group 2), HPD, and CD measurements significantly influenced ICD incidence, with *p-values* of 0.017, < 0.001, and < 0.001, respectively (Table 45).

***Table 44.*** *The Combined Study: Descriptive Statistical Analysis.*

| Variables | ECS | | |
|---|---|---|---|
| | No N=345 | Yes N=163 | p-value |
| **Age, median (IQR)** | 31 (28-34) | 31 (28-35) | 0.816 |
| **BMI class, n(%)** | | | 0.512 |
| BMI<18.5 (Underweight) | 9 (2.6) | 1 (0.6) | |
| 18.5<=BMI<25 (Normal weight) | 192 (55.7) | 89 (54.6) | |
| 25<=BMI<30 (Overweight) | 103 (29.9) | 52 (31.9) | |
| BMI>=30 (Obesity) | 41 (11.9) | 21 (12.9) | |
| **Ethnicity, n(%)** | | | 0.060 |
| Caucasian | 178 (51.6) | 72 (44.2) | |
| Afro-Caribbean | 33 (9.6) | 27 (16.6) | |
| Asian | 107 (31.0) | 56 (34.4) | |
| Mixed | 27 (7.8) | 8 (4.9) | |
| **GA (weeks), median (IQR)** | 40 (39-41) | 40.3 (39.1-41.1) | 0.235 |
| **HPD scan 1 (mm), median (IQR)** | 47.9 (43.4-53.9) | 52.9 (47.0-59.1) | ***<0.001*** |
| **HPD scan 2 (mm), median (IQR)** | 43.6 (39.0-49.5) | 50.8 (45.4-56.0) | ***<0.001*** |
| **HPD change (mm/h), median (IQR)** | 1.2 (0.5-2.4) | 0.9 (0-1.6) | ***<0.001*** |
| **Head Position scan 1 (clock face hours), median (IQR)** | 3 (2-4) | 3 (2-4) | 0.676 |
| **Head Position scan 2 (clock face hours), median (IQR)** | 3 (2-5) | 3 (2-4) | 0.642 |
| **Head Position change (clock face hours/h), median (IQR)** | 0 (-0.2-0.2) | 0 (0-0) | 0.642 |
| **Caput scan 1 (mm), median (IQR)** | 7.3 (0-13) | 7.2 (0-13.2) | 0.716 |
| **Caput scan 2 (mm), median (IQR)** | 13.9 (7.0-18.4) | 13.5 (7.7-17.2) | 0.273 |
| **Caput change (mm/h), median (IQR)** | 0.9 (0.1-2.0) | 0.5 (0.1-1.5) | ***0.034*** |
| **Cervical dilatation scan 1 (cm), median (IQR)** | 4 (2-5) | 2 (2-4) | ***<0.001*** |
| **Cervical dilatation scan 2 (cm), median (IQR)** | 7 (5-10) | 4 (2-5) | ***<0.001*** |
| **Cervical dilatation change (cm/h), median (IQR)** | 0.7 (0.4-1.2) | 0.2 (0-0.4) | ***<0.001*** |
| **UC Ratio, median (IQR)** | 0.64 (0.54-0.77) | 0.67 (0.58-0.80) | 0.209 |
| **Moulding, n(%)** | 180 (52.5) | 86 (52.8) | 0.953 |
| **Length of labour (h), median (IQR)** | 11.7 (8.8-14.6) | 15.1 (10.9-18.5) | ***<0.001*** |
| **Epidural, n(%)** | 333 (96.5) | 158 (96.9) | 0.810 |

***Table 45.*** *The Combined Study: Univariate Logistic Regression Analysis of the Single Assessment Model.*

| Variables | Univariate regression | | | |
|---|---|---|---|---|
| | OR | 95% CI | p-value | AUC [95% CI] |
| **Age>=35** | 1.35 | [0.88; 2.07] | 0.169 | 0.53 [0.49; 0.57] |
| **BMI class (ref. BMI<25)** | | | | 0.52 [0.47; 0.56] |
| 25<=BMI<30 (Overweight) | 1.13 | [0.74; 1.71] | 0.572 | |
| BMI>=30 (Obesity) | 1.14 | [0.64; 2.05] | 0.651 | |
| **Ethnicity (ref. Caucasian)** | | | | 0.57 [0.52-0.62] |
| Afro-Caribbean | 2.02 | [1.14-3.60] | ***0.017*** | |
| Asian | 1.29 | [0.85-1.98] | 0.233 | |
| Mixed | 0.73 | [0.32-1.69] | 0.465 | |
| **GA (weeks)** | 1.10 | [0.95; 1.27] | 0.221 | 0.53 [0.48; 0.59] |
| **HPD scan 1 (mm)** | 1.07 | [1.05; 1.10] | ***<0.001*** | 0.66 [0.60; 0.71] |
| **Head Position scan 1 (clock face hours)** | 0.82 | [0.52; 1.30] | 0.401 | 0.51 [0.46; 0.57] |
| **Caput scan 1 (mm)** | 1.00 | [0.98; 1.03] | 0.770 | 0.51 [0.46; 0.56] |
| **Cervical dilatation scan 1 (cm)** | 0.79 | [0.72; 0.87] | ***<0.001*** | 0.63 [0.58; 0.68] |
| **UC ratio** | 1.79 | [0.55; 5.81] | 0.332 | 0.54 [0.48; 0.61] |
| **Moulding** | 1.01 | 0.70; 1.47 | 0.953 | 0.50 [0.45; 0.55] |

### 4.3.6 Combined Study (SONO-VE and SONO-PREDICT): Single Assessment Model Multivariate Statistical Analysis

#### 4.3.6.1 Excluding Umbilical-Cerebral Ratio

**Including ALL Prognostic Variables of Intrapartum Caesarean Delivery**

A cohort of 508 participants underwent their first ultrasound assessment during active labour, with analysis performed on 503 participants due to missing data on either HPD or caput succedaneum in five cases. We initially excluded UCR to explore potential differences in outcomes. All prognostic variables potentially influencing the incidence of ICD were tested, including maternal age, GA, BMI, maternal ethnicity, HPD, CD, fetal head position, caput succedaneum, and moulding.

Significant predictors of ICD included maternal ethnicity (Afro-Caribbean, group 2), GA, HPD, caput succedaneum, and cervical dilatation, with *p-values* of 0.013, 0.054, 0.000, 0.013, and 0.000, respectively (Table 46). The AUC was 0.72 [95% CI: 0.67-0.77], demonstrating a sensitivity of 65.8% and a specificity of 66.7% (Table 47 and Figure 66).

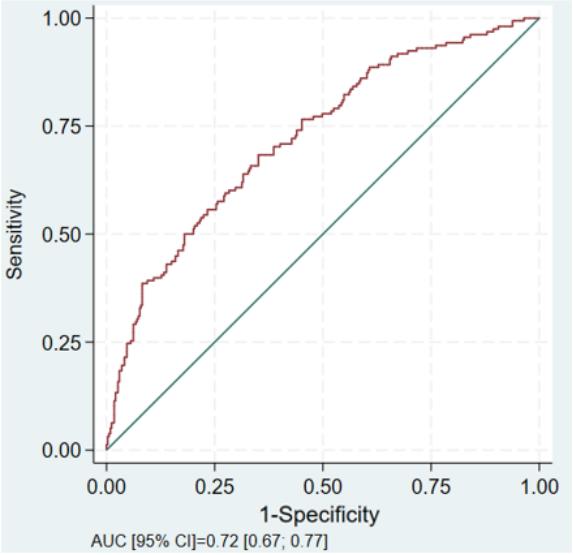
***Table 46.*** *The Combined Study: Multivariate Logistic Regression Analysis of the Single Assessment Model Excluding UCR: All Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 1.491227 | .3689333 | 1.62 | 0.106 | .918236 | 2.421771 |
| bmi_class | | | | | | |
| 2 | .8272588 | .1985981 | -0.79 | 0.430 | .5167677 | 1.324303 |
| 3 | .7612136 | .2640493 | -0.79 | 0.432 | .3856935 | 1.502349 |
| ethnicity | | | | | | |
| 2 | 2.350252 | .8119662 | 2.47 | 0.013 | 1.1941 | 4.625811 |
| 3 | 1.430377 | .3519267 | 1.45 | 0.146 | .8831262 | 2.316745 |
| 4 | .7078081 | .3196993 | -0.77 | 0.444 | .2920445 | 1.715466 |
| GA_weeks | 1.17512 | .0986038 | 1.92 | 0.054 | .9969154 | 1.38518 |
| HPD_scan1 | 1.067703 | .0147782 | 4.73 | 0.000 | 1.039128 | 1.097064 |
| Head_Rotation_scan1 | .999324 | .07323 | -0.01 | 0.993 | .8656267 | 1.153671 |
| Caput_scan1 | 1.04702 | .0192761 | 2.50 | 0.013 | 1.009913 | 1.08549 |
| Cervical_dilatation_s~1 | .783675 | .0480526 | -3.98 | 0.000 | .694933 | .8837493 |
| Moulding0none1present | 1.087454 | .2571346 | 0.35 | 0.723 | .6841312 | 1.728551 |
| _cons | .000033 | .0001148 | -2.97 | 0.003 | 3.61e-08 | .0301631 |

***Table 47.*** *The Combined Study: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Single Assessment Model Excluding UCR: All Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.298 | p=0.327 |
| Sensitivity | 35.4% | 70.3% | 65.8% |
| Specificity | 91.7% | 61.4% | 66.7% |
| PPV | 66.7% | 45.9% | 47.9% |
| NPV | 75.3% | 81.6% | 80.7% |
| Correctly classified | 73.8% | 64.2% | 66.4% |

***Figure 66.*** *The Combined Study: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Single Assessment Model Excluding UCR: All Variables.*




**Including SELECTED Prognostic Variables of Intrapartum Caesarean Delivery**

Further analysis was conducted on the same cohort of 503 participants, utilised stepwise selection to derive a more compact model, retaining only significant predictors and excluding UCR (Table 48). Gestational age was not retained in this compact model. The AUC was 0.71 [95% CI: 0.66-0.75], with a sensitivity of 54.4% and a specificity of 77.6% (Table 49 and Figure 67).

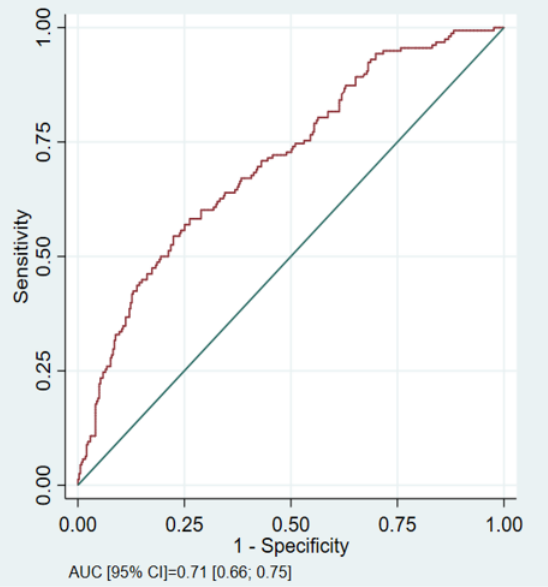
***Table 48.*** *The Combined Study: Multivariate Logistic Regression Analysis of the Single Assessment Model Excluding UCR: Selected Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| Caput_scan1 | 1.044675 | .0169952 | 2.69 | 0.007 | 1.011891 | 1.078522 |
| HPD_scan1 | 1.065303 | .013821 | 4.88 | 0.000 | 1.038556 | 1.092739 |
| Cervical_dilatation_scan1 | .7842502 | .0466082 | -4.09 | 0.000 | .6980194 | .8811335 |
| 2.ethnicity | 1.832334 | .5574857 | 1.99 | 0.047 | 1.009317 | 3.326457 |
| _cons | .0285908 | .0208554 | -4.87 | 0.000 | .0068442 | .119435 |

***Table 49.*** *The Combined Study: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Single Assessment Model Excluding UCR: Selected Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.241 | 0.383 |
| Sensitivity | 27.9% | 80.4% | 54.4% |
| Specificity | 92.0% | 43.4% | 77.6% |
| PPV | 62.0% | 39.8% | 53.1% |
| NPV | 73.2% | 82.6% | 78.5% |
| Correctly classified | 71.6% | 55.1% | 70.2% |

***Figure 67.*** *The Combined Study: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Single Assessment Model Excluding UCR: Selected Variables.*



#### 4.3.6.2 Including Umbilical-Cerebral Ratio

**Including ALL Prognostic Variables of Intrapartum Caesarean Delivery**

This statistical analysis was conducted with a cohort of 301 participants. There was missing data for 117 participants in the SONO-VE and 85 participants in the SONO-PREDICT, primarily due to difficulties in measuring MCA Doppler signals owing to low fetal head positions. UCR values were incorporated to enhance comparability of results.

Significant factors influencing ICD prediction were HPD, caput succedaneum, and cervical dilatation, with *p-values* of 0.001, 0.014, and 0.001, respectively (Table 50). The incorporation of UCR yielded similar significance levels and comparable odds ratios. The AUC was 0.72 [95% CI: 0.66-0.78], with a sensitivity of 49.1% and a specificity of 83.1% (Table 51 and Figure 68).

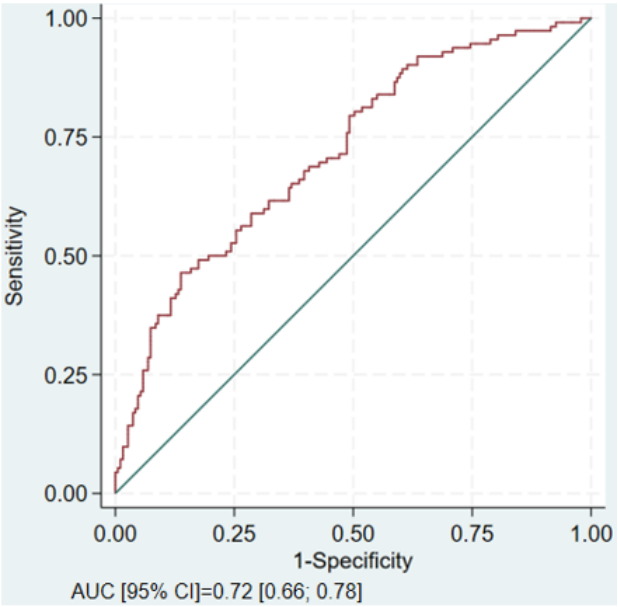
***Table 50.*** *The Combined Study: Multivariate Logistic Regression Analysis of the Single Assessment Model Including UCR: All Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 1.615704 | .506294 | 1.53 | 0.126 | .8742399 | 2.98602 |
| bmi_class | | | | | | |
| 2 | .805455 | .2421692 | -0.72 | 0.472 | .4468048 | 1.451994 |
| 3 | .9590309 | .4023605 | -0.10 | 0.921 | .4214167 | 2.182496 |
| ethnicity | | | | | | |
| 2 | 1.8527 | .7715666 | 1.48 | 0.139 | .8190637 | 4.190756 |
| 3 | 1.389873 | .4229698 | 1.08 | 0.279 | .7654823 | 2.523568 |
| 4 | .520502 | .2941045 | -1.16 | 0.248 | .1719727 | 1.57538 |
| GA_weeks | 1.105419 | .1132309 | 0.98 | 0.328 | .9043496 | 1.351195 |
| HPD_scan1 | 1.063583 | .0189562 | 3.46 | 0.001 | 1.027071 | 1.101393 |
| Head_Rotation_scan1 | 1.033437 | .1123728 | 0.30 | 0.762 | .835078 | 1.278913 |
| Caput_scan1 | 1.06325 | .0266094 | 2.45 | 0.014 | 1.012355 | 1.116704 |
| Cervical_dilatation_scan1 | .7613489 | .0652595 | -3.18 | 0.001 | .6436096 | .900627 |
| UCratio | 1.461318 | .977922 | 0.57 | 0.571 | .393655 | 5.424672 |
| Moulding0none1present | 1.11549 | .3478241 | 0.35 | 0.726 | .6054107 | 2.055328 |
| _cons | .0003637 | .0015681 | -1.84 | 0.066 | 7.78e-08 | 1.699693 |

***Table 51.*** *The Combined Study: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Single Assessment Model Including UCR: All Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.277 | p=0.471 |
| Sensitivity | 44.6% | 82.1% | 49.1% |
| Specificity | 85.7% | 42.9% | 83.1% |
| PPV | 64.9% | 46.0% | 63.2% |
| NPV | 72.3% | 80.0% | 73.4% |
| Correctly classified | 70.4% | 57.5% | 70.4% |

***Figure 68.*** *The Combined Study: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Single Assessment Model Including UCR: All Variables.*




**Including SELECTED Prognostic Variables of Intrapartum Caesarean Delivery**

Focusing on selected significant variables impacting ICD with incorporating UC ratios, the analysis conducted on the same cohort of 301 participants (Table 52). The AUC was 0.69 [95% CI: 0.63-0.75], with a sensitivity of 45.5% and a specificity of 84.7% (Table 53 and Figure 69).

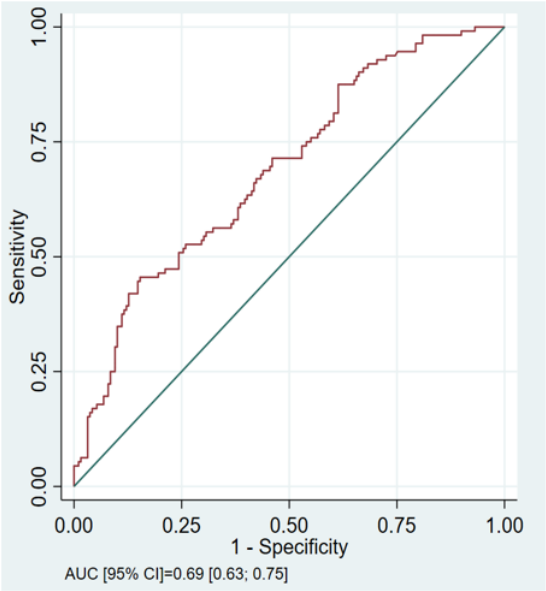
***Table 52.*** *The Combined Study: Multivariate Logistic Regression Analysis of the Single Assessment Model Including UCR: Selected Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| HPD_scan1 | 1.062708 | .0174567 | 3.70 | 0.000 | 1.029038 | 1.097479 |
| Caput_scan1 | 1.065919 | .0232263 | 2.93 | 0.003 | 1.021355 | 1.112428 |
| Cervical_dilatation_scan1 | .758041 | .0631964 | -3.32 | 0.001 | .6437684 | .8925976 |
| _cons | .0385453 | .0355008 | -3.54 | 0.000 | .0063387 | .2343905 |

***Table 53.*** *The Combined Study: Diagnostic Measures of Multivariable Logistic Regression Analysis of the Single Assessment Model Including UCR: Selected Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.343 | p=0.466 |
| **Sensitivity** | 39.3% | 70.5% | 45.5% |
| **Specificity** | 87.3% | 54.0% | 84.7% |
| **PPV** | 64.7% | 47.6% | 63.8% |
| **NPV** | 70.8% | 75.6% | 72.4% |
| **Correctly classifie** | 69.4% | 60.1% | 70.1% |

***Figure 69.*** *The Combined Study: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Single Assessment Model Including UCR: Selected Variables.*



### 4.3.7 Combined Study (SONO-VE and SONO-PREDICT): Repeat Assessments Model Univariate Logistic Regression Analysis

A univariate logistic regression analysis was performed for the repeat assessment model to identify potential risk factors associated with ICD. The analysis revealed that specific factors significantly influenced delivery outcomes and were strongly correlated with ICD. Notably, maternal ethnicity (Afro-Caribbean, group 2), HPD in both ultrasound assessments and its changes, and cervical dilatation across both ultrasound assessments and its changes over time were significantly correlated with ICD, with *p-values* of 0.032, < 0.001, < 0.001, < 0.001, < 0.001, < 0.001, and < 0.001, respectively (Table 54).

***Table 54.*** *The Combined Study: Univariate Logistic Regression Analysis of the Repeat Assessment Model.*

| Variables | Univariate regression | | | |
|---|---|---|---|---|
| | OR | 95% CI | p-value | AUC [95% CI] |
| **Age>=35** | 1.35 | [0.85; 2.16] | 0.204 | 0.53 [0.48; 0.57] |
| **BMI class (ref. BMI<25)** | | | | 0.51 [0.46; 0.56] |
| 25<=BMI<30 (Overweight) | 1.07 | [0.68-1.68] | 0.765 | |
| BMI>=30 (Obesity) | 1.16 | [0.60-2.23] | 0.660 | |
| **Ethnicity (ref. Caucasian)** | | | | 0.56 [0.51; 0.62] |
| Afro-Caribbean | 1.99 | [1.06-3.72] | ***0.032*** | |
| Asian | 1.20 | [0.76-1.90] | 0.434 | |
| Mixed | 0.65 | [0.25-1.68] | 0.370 | |
| **GA (weeks)** | 1.09 | [0.93-1.28] | 0.281 | 0.53 [0.48; 0.59] |
| **HPD scan 1 (mm)** | 1.06 | [1.03-1.09] | ***<0.001*** | 0.62 [0.57; 0.68] |
| **HPD scan 2 (mm)** | 1.11 | [1.08; 1.14] | ***<0.001*** | 0.73 [0.68; 0.78] |
| **HPD change (mm/h)** | 0.74 | 0.63; 0.87 | ***<0.001*** | 0.61 [0.55; 0.66] |
| **Head Position scan 1 (clock face hours)** | 1.01 | [0.89; 1.15] | 0.914 | 0.51 [0.46, 0.56] |
| **Head Position scan 2 (clock face hors)** | 0.92 | [0.81; 1.05] | 0.214 | 0.53 [0.47; 0.58] |
| **Head Position change (clock face hours/h)** | 0.82 | [0.52; 1.30] | 0.401 | 0.51 [0.46; 0.57] |
| **Caput scan 1 (mm)** | 1.02 | [0.99-1.05] | 0.327 | 0.53 [0.47; 0.58] |
| **Caput scan 2 (mm)** | 0.99 | [0.97; 1.02] | 0.489 | 0.53 [0.48; 0.59] |
| **Caput change (mm/h)** | 0.91 | [0.81; 1.03] | 0.151 | 0.56 [0.51; 0.62] |
| **Cervical dilatation scan 1 (cm)** | 0.81 | [0.73-0.91] | ***<0.001*** | 0.61 [0.56; 0.67] |
| **Cervical dilatation scan 2 (cm)** | 0.63 | [0.57; 0.69] | ***<0.001*** | 0.79 [0.75; 0.84] |
| **Cervical dilatation change (cm/h)** | 0.06 | [0.03; 0.11] | ***<0.001*** | 0.80 [0.76; 0.84] |
| **UC ratio** | 1.22 | [0.34-4.38] | 0.760 | 0.53 [0.46; 0.59] |
| **Moulding** | 1.06 | [0.71-1.60] | 0.769 | 0.51 [0.46-0.56] |

### 4.3.8 Combined Study (SONO-VE and SONO-PREDICT): Repeat Assessments Model Multivariate Statistical Analysis

#### 4.3.8.1 Excluding Umbilical-Cerebral Ratio

**Including ALL Prognostic Variables of Intrapartum Caesarean Delivery**

A statistical analysis was conducted on 414 participants (SONO-VE: n = 212; SONO-PREDICT: n = 202) who received second ultrasound assessments. Fetal Doppler measurements assessing the UCR were excluded. This analysis included a wide array of prognostic factors, including maternal age, GA, BMI, maternal ethnicity, HPD, cervical dilatation, fetal head position, caput succedaneum, and fetal moulding.

Significant predictors of ICD included maternal age >35 years, HPD during the first ultrasound assessment, first caput succedaneum measurements and their changes, and cervical dilatation values from the first ultrasound scan and their subsequent changes ($p$ = 0.033, $p$ = 0.001, $p$ = 0.000, $p$ = 0.044, $p$ = 0.000, and $p$ = 0.000), respectively (Table 55). The analysis yielded an AUC of 0.86 [95% CI: 0.82-0.89], with a reported sensitivity of 80.0% and specificity of 78.2% (Table 56 and Figure 70).

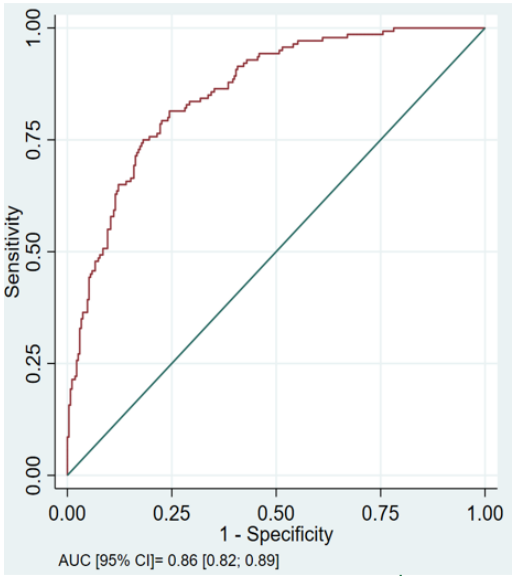
***Table 55.*** *The Combined Study: Multivariate Logistic Regression Analysis of the Repeat Assessment Model Excluding UCR: All Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 1.973412 | .6279447 | 2.14 | 0.033 | 1.057701 | 3.681902 |
| bmi_class | | | | | | |
| 2 | .6567684 | .2020204 | -1.37 | 0.172 | .3594055 | 1.200162 |
| 3 | .6891516 | .3171687 | -0.81 | 0.419 | .2796184 | 1.698493 |
| ethnicity | | | | | | |
| 2 | 1.333162 | .5798457 | 0.66 | 0.509 | .5684091 | 3.126833 |
| 3 | 1.635618 | .5169371 | 1.56 | 0.120 | .8803587 | 3.038814 |
| 4 | .5592094 | .3138372 | -1.04 | 0.300 | .1861515 | 1.679896 |
| GA_weeks | 1.217087 | .1303217 | 1.83 | 0.067 | .9866834 | 1.501293 |
| HPD_scan1 | 1.066579 | .0206034 | 3.34 | 0.001 | 1.026952 | 1.107735 |
| HPD_change_per_hour | .8200457 | .095783 | -1.70 | 0.089 | .6522528 | 1.031004 |
| Head_Rotation_scan1 | .9223995 | .0940258 | -0.79 | 0.428 | .7553547 | 1.126386 |
| HeadRotation_change_per_hour_rec | .6980748 | .2707258 | -0.93 | 0.354 | .3264306 | 1.492839 |
| Caput_scan1 | 1.135714 | .0322796 | 4.48 | 0.000 | 1.074177 | 1.200776 |
| Caput_change_per_hour | 1.216265 | .118266 | 2.01 | 0.044 | 1.005217 | 1.471623 |
| Cervical_dilatation_scan1 | .751164 | .0591846 | -3.63 | 0.000 | .6436773 | .8765999 |
| CervicalDil_change_per_hour | .043013 | .0180947 | -7.48 | 0.000 | .0188589 | .0981033 |
| Moulding0none1present | 1.036027 | .3208016 | 0.11 | 0.909 | .5646768 | 1.900825 |
| _cons | .0000394 | .0001749 | -2.28 | 0.022 | 6.55e-09 | .236888 |

***Table 56.*** *The Combined Study: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Repeat Assessment Model Excluding UCR: All Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.250 | p=0.452 |
| **Sensitivity** | 67.1% | 90.0% | 80.0% |
| **Specificity** | 85.6% | 64.6% | 78.2% |
| **PPV** | 70.7% | 56.8% | 65.5% |
| **NPV** | 83.5% | 92.6% | 88.3% |
| **Correctly classified** | 79.3% | 73.2% | 78.3% |

***Figure 70.*** *The Combined Study: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model Excluding UCR: All Variables.*



**Including SELECTED Prognostic Variables of Intrapartum Caesarean Delivery**

Further analysis was conducted on the same cohort of 414 participants, focusing on selected influential factors while excluding the UCR (Table 57). In this compact model, maternal age >35 years was not retained. The resulting AUC was 0.80 [95% CI: 0.76-0.85], with a reported sensitivity of 80.7% and specificity of 72.3% (Table 58 and Figure 71).

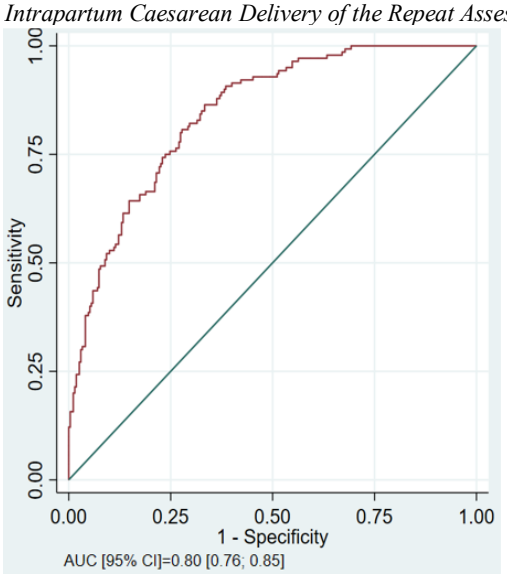
***Table 57.*** *The Combined Study: Multivariate Logistic Regression Analysis of the Repeat Assessment Model Excluding UCR: Selected Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| CervicalDil_change_per_hour | .0425795 | .0168262 | -7.99 | 0.000 | .0196259 | .0923785 |
| Caput_scan1 | 1.111119 | .0264149 | 4.43 | 0.000 | 1.060534 | 1.164116 |
| Caput_change_per_hour | 1.196647 | .1053273 | 2.04 | 0.041 | 1.007034 | 1.421961 |
| Cervical_dilatation_scan1 | .7396492 | .0552706 | -4.04 | 0.000 | .6388802 | .8563123 |
| HPD_scan1 | 1.05025 | .0178331 | 2.89 | 0.004 | 1.015873 | 1.085791 |
| _cons | .2019893 | .1873329 | -1.72 | 0.085 | .0328012 | 1.243846 |

***Table 58.*** *The Combined Study: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Repeat Assessment Model Excluding UCR: Selected Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default p=0.5 | Arbitrary p=0.241 | Max Youden Index p=0.333 |
| Sensitivity | 62.1% | 90.0% | 80.7% |
| Specificity | 85.2% | 61.6% | 72.3% |
| PPV | 68.5% | 54.8% | 60.1% |
| NPV | 81.3% | 92.3% | 87.9% |
| Correctly classifie | 77.4% | 71.3% | 75.2% |

***Figure 71.*** *The Combined Study: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model Excluding UCR: Selected Variables.*



An additional analysis was performed to determine whether focusing exclusively on the cervical dilatation parameter and its changes could enhance model performance. This approach demonstrated increased statistical significance, with an AUC of 0.81 [95% CI:_0.77-0.85] (Table 59 and Figure 72). Conversely, removing the cervical dilatation parameter and focusing only on its changes resulted in reduced model performance, yielding an AUC of 0.80 [95% CI: 0.76-0.85] (Figure 73).

***Table 59.*** *The Combined Study: Analysis of the Repeat Assessment Model: Focusing on Cervical Dilatation Measurements.*

| Caesarean_Section | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| Cervical_dilatation_scan1 | .8229352 | .0522001 | -3.07 | 0.002 | .7267292 | .9318772 |
| CervicalDil_change_per_hour | .0604099 | .0215602 | -7.86 | 0.000 | .0300134 | .1215909 |
| _cons | 3.752433 | 1.007662 | 4.92 | 0.000 | 2.216843 | 6.351713 |

***Figure 72.*** *The Combined Study: ROC Showing the Relationship between Prognostic Factors with Retaining Cervical Dilatation Parameter and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model.*

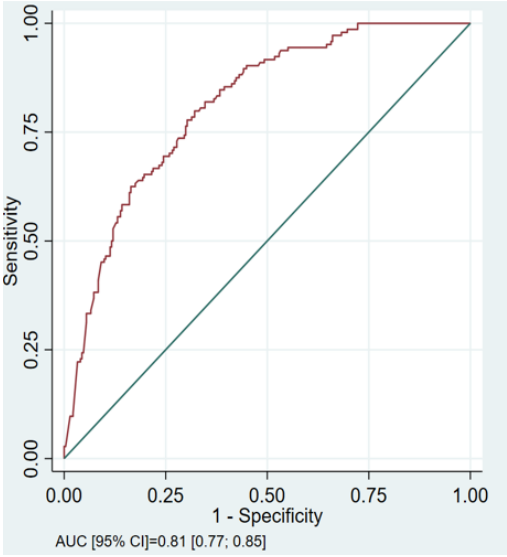
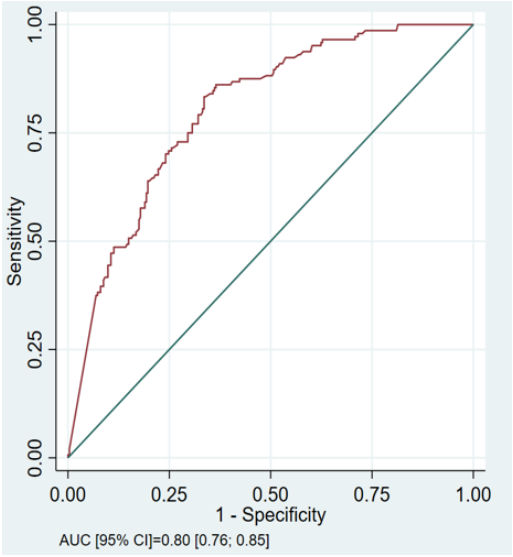


***Figure 73.*** *The Combined Study: ROC Showing the Relationship between Prognostic Variables with Removing Cervical Dilatation Parameter and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model.*




#### 4.3.8.2 Including Umbilical-Cerebral Ratio

**Including ALL Prognostic Variables of Intrapartum Caesarean Delivery**

Statistical analysis was performed on a total of 261 participants (SONO-VE: n = 107; SONO-PREDICT: n = 154), this time including UC ratios to compare the results. Significant predictors included HPD during the first ultrasound scan, caput succedaneum in the first assessment, and cervical dilatation during the first ultrasound scan and its changes ($p = 0.011$, $p = 0.002$, $p = 0.020$, and $p = 0.000$), respectively (Table 60). The analysis yielded an AUC of 0.83 [95% CI: 0.78-0.88], with a reported sensitivity of 78.0% and specificity of 78.9% (Table 61 and Figure 74).

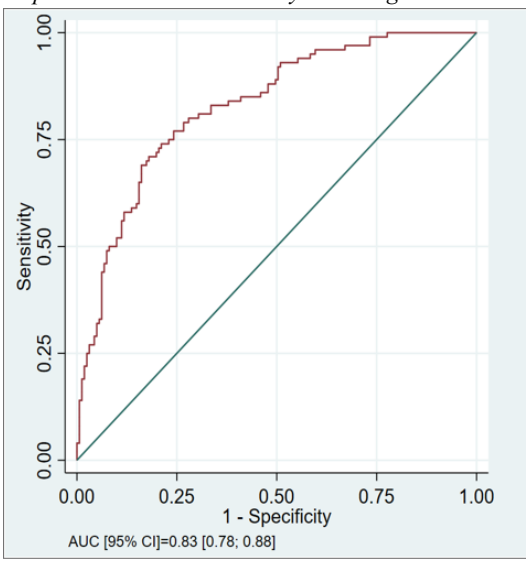
***Table 60.*** *The Combined Study: Multivariate Logistic Regression Analysis of the Repeat Assessment Model Including UCR: All Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 1.655378 | .6242437 | 1.34 | 0.181 | .7905126 | 3.466456 |
| bmi_class | | | | | | |
| 2 | .5501855 | .2050585 | -1.60 | 0.109 | .2650084 | 1.142243 |
| 3 | .7671674 | .4182897 | -0.49 | 0.627 | .2635006 | 2.233565 |
| ethnicity | | | | | | |
| 2 | 1.165264 | .5888326 | 0.30 | 0.762 | .4328066 | 3.137289 |
| 3 | 1.904139 | .7259679 | 1.69 | 0.091 | .9019272 | 4.019999 |
| 4 | .462691 | .3029058 | -1.18 | 0.239 | .1282456 | 1.66932 |
| GA_weeks | 1.185767 | .1505345 | 1.34 | 0.180 | .9245671 | 1.520759 |
| HPD_scan1 | 1.063833 | .0260481 | 2.53 | 0.011 | 1.013986 | 1.116132 |
| HPD_change_per_hour | .8921854 | .1230995 | -0.83 | 0.408 | .6807856 | 1.16923 |
| Head_Rotation_scan1 | .9916092 | .1403529 | -0.06 | 0.953 | .7513824 | 1.30864 |
| HeadRotation_change_per_hour_rec | 1.062251 | .5194818 | 0.12 | 0.902 | .4073394 | 2.770114 |
| Caput_scan1 | 1.114344 | .0393854 | 3.06 | 0.002 | 1.039763 | 1.194275 |
| Caput_change_per_hour | 1.10636 | .1498928 | 0.75 | 0.456 | .8483466 | 1.442845 |
| Cervical_dilatation_scan1 | .7810351 | .0829161 | -2.33 | 0.020 | .6343157 | .9616912 |
| CervicalDil_change_per_hour | .0536469 | .0269441 | -5.82 | 0.000 | .0200461 | .1435687 |
| UCratio | 1.09548 | .9062813 | 0.11 | 0.912 | .2164776 | 5.543655 |
| Moulding0none1present | 1.032462 | .4028615 | 0.08 | 0.935 | .480551 | 2.218241 |
| _cons | .0001008 | .0005348 | -1.74 | 0.083 | 3.09e-09 | 3.292235 |

***Table 61.*** *The Combined Study: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Repeat Assessment Model Including UCR: All Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default p=0.5 | Arbitrary p=0.393 | Max Youden Index p=0.449 |
| **Sensitivity** | 68.0% | 81.0% | 78.0% |
| **Specificity** | 83.2% | 72.7% | 78.9% |
| **PPV** | 71.6% | 64.8% | 69.6% |
| **NPV** | 80.7% | 86.0% | 85.2% |
| **Correctly classifie** | 77.4% | 75.9% | 78.5% |

***Figure 74.*** *The Combined Study: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery Including UCR: All Variables.*



**Including SELECTED Prognostic Variables of Intrapartum Caesarean Delivery**

The analysis was conducted on the same cohort of 261 participants, incorporating only the most significant ICD predictors alongside the UCR (Table 62). The resulting AUC was 0.81 [95% CI: 0.76-0.87], demonstrating a sensitivity of 76.0% and a specificity of 73.9% (Table 63 and Figure 75).

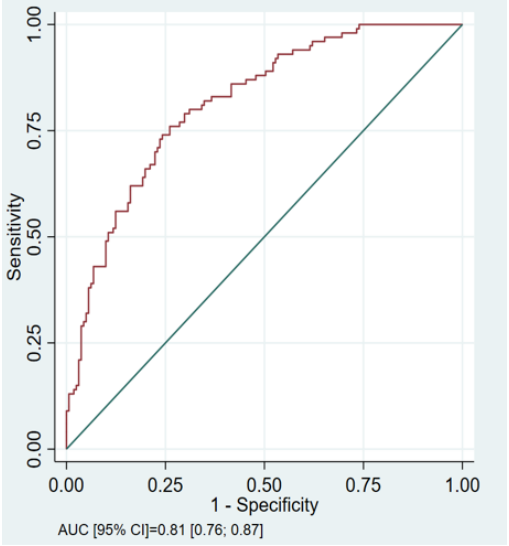
***Table 62.*** *The Combined Study: Multivariate Logistic Regression Analysis of the Repeat Assessment Model Including UCR: Selected variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| Cervical_dilatation_scan1 | .7823737 | .0761205 | -2.52 | 0.012 | .6465426 | .9467413 |
| HPD_scan1 | 1.047046 | .0213468 | 2.25 | 0.024 | 1.006032 | 1.089732 |
| CervicalDil_change_per_hour | .0619666 | .0289436 | -5.95 | 0.000 | .0248071 | .1547888 |
| Caput_scan1 | 1.086291 | .029801 | 3.02 | 0.003 | 1.029424 | 1.146298 |
| _cons | .2613904 | .2931464 | -1.20 | 0.232 | .0290186 | 2.354521 |

***Table 63.*** *The Combined Study: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Repeat Assessment Model Including UCR: Selected Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.385 | p=0.404 |
| Sensitivity | 62.0% | 90.2% | 76.0% |
| Specificity | 83.2% | 33.3% | 73.9% |
| PPV | 69.7% | 44.5% | 64.4% |
| NPV | 77.9% | 85.1% | 83.2% |
| Correctly classifie | 75.1% | 54.5% | 74.7% |

***Figure 75.*** *The Combined Study: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Repeat Assessment Model Including UCR: Selected Variables.*



### 4.3.9 Trieste Study: Statistical Methods and Results

#### Challenges with Trieste Dataset

A significant limitation of the Trieste dataset was the availability of only 53 complete datasets from the second ultrasound scan, representing approximately 51% of the total cohort. This scarcity necessitated the consideration of multiple imputation strategies to address the missing data. Extensive imputation introduces inherent biases and computational challenges, particularly when the proportion of missing data is substantial. Consequently, the integrity of the second ultrasound assessments is compromised, as only 53 participants having complete data for the variables of interest at the second ultrasound scan, and merely 8% of these participants underwent an ICD. Given the low outcome prevalence and significant missing data, validation of the model using this dataset was unfeasible. Multivariate analysis was therefore limited to the first ultrasound assessment model, which contained the most complete dataset.

#### Statistical Methods

Our initial approach involved validating a logistic regression model for ICD prediction using the Trieste dataset. This model was originally developed with data from the combined study (SONO-VE and SONO-PREDICT) and was subsequently applied to the Trieste dataset. Performance of a model on external datasets can vary, attributed to variations in predictor prevalence, distribution, and inter-variable relationships, which may impair the generalisability of findings. Applying a model trained on one dataset (combined study) to another (Trieste) without re-estimating the model parameters on the new dataset involves assumptions about the uniformity of relationships across studies, which might not always hold true.

**Revised Strategy and Improved Outcomes**

In response to these challenges, we re-estimated the logistic regression model directly on the Trieste dataset employing the same predictive equation used with the combined study. This adjustment improved model performance, illustrating the benefit of adapting model parameters to the dataset's unique characteristics, thereby enhancing predictive accuracy and overall model performance.

**Recruitment and Demographics**

The Trieste study commenced recruitment on January 1, 2023. As of the June 1, 2024, 113 participants were approached, with 107 consenting to participate. Of these, 106 were evaluable following one withdrawal. Participants were primarily nulliparous women, aged between 19 and 44 years, with a mean age of 31 years and 4 months. The average gestational age at recruitment was 40 weeks, and the mean BMI was 24.23 kg/m$^2$ (range, 18-35.5 kg/m$^2$).

Of the participants, 61 (58%) underwent repeat intrapartum ultrasound assessments, while the remaining 45 (42%) had a single assessment. A total of 167 ultrasound evaluations were conducted during the first stage of labour. For 10 participants (9%) ICD was deemed necessary. Babies born via Caesarean section had a mean birth weight of 3634 g, compared to 3331g for those delivered vaginally. The median time to complete ultrasound assessments was 10 minutes (range, 8-12 minutes), with an average interval of approximately 2.12 hours between the first and second ultrasound assessments (range, 0.23-8.2 hours).

### 4.3.10 Trieste Study: Single Assessment Model Descriptive Analysis and Univariate Logistic Regression Analysis

Descriptive statistics were conducted for a cohort of 106 participants, utilising univariate models to evaluate each potential predictor. This analytical approach provided an understanding of the relationships between the variables and the incidence of ICD. The results of these descriptive analyses, as presented in Table 64, indicated that no individual factor was significantly associated with the occurrence of ICD. The application of univariate analysis to the single assessment model corroborated these findings, confirming the absence of significant correlations between the examined factors and ICD incidence. However, fetal moulding was marginally significant, with a *p-value* of 0.056 (Table 65).

***Table 64.*** *The Trieste Study: Descriptive Statistical Analysis.*

| Variables | ECS No N=96 | ECS Yes N=10 | p-value |
|---|---|---|---|
| **Age, median (IQR)** | 32 (27-35) | 31 (25-39) | 0.710 |
| **BMI class, n(%)** | | | 0.239 |
| BMI<25 (Normal weight) | 69 (71.9) | 6 (60.0) | |
| 25<=BMI<30 (Overweight) | 17 (17.7) | 4 (40.0) | |
| BMI>=30 (Obesity) | 10 (10.4) | 0 | |
| **Ethnicity, n(%)** | | | 0.239 |
| Caucasian | 88 (91.7) | 8 (80.0) | |
| Afro-Caribbean | 3 (3.1) | 0 | |
| Asian | 5 (5.2) | 2 (20.0) | |
| **GA (weeks), median (IQR)** | 40.0 (39.1-40.7) | 40.6 (39.6-41.0) | 0.211 |
| **HPD scan 1 (mm), median (IQR)** | 46.0 (41.0-51.5) | 50.9 (46.9-54.9) | 0.081 |
| **HPD change (mm/h), median (IQR)** | 2.44 (1.34-5.54) | 1.15 (0.35-2.07) | 0.077 |
| **Head Position scan 1 (clock face hours), median (IQR)** | 5 (2-5) | 5 (3-5) | 0.340 |
| **Head Position change (clock face hours/h), median (IQR)** | 0 (0-0) | 0 (0-0) | 0.988 |
| **Caput scan 1 (mm), median (IQR)** | 0 (0-10.7) | 0 (0-9.0) | 0.715 |
| **Caput change (mm/h), median (IQR)** | 0.48 (0-5.63) | 3.69 (0.55-7.89) | 0.478 |
| **Cervical dilatation scan 1 (cm), median (IQR)** | 5 (3-7) | 5.5 (4-7) | 0.463 |
| **Cervical dilatation change (cm/h), median (IQR)** | 1.0 (0.6-1.7) | 0.6 (0-0.7) | 0.075 |
| **UC Ratio, median (IQR)** | 0.69 (0.53-0.85) | 0.57 (0.49-0.79) | 0.555 |
| **Moulding, n(%)** | 14 (14.7) | 4 (40.0) | 0.066 |

***Table 65.*** *The Trieste Study: Univariate Logistic Regression Analysis of the Single Assessment Model.*

| Variables | Univariate regression | | | |
|---|---|---|---|---|
| | OR | 95% CI | p-value | AUC [95% CI] |
| **Age>=35** | 1.89 | [0.49-7.26] | 0.143 | 0.57 [0.40-0.74] |
| **BMI class (ref. BMI<25)** | | | | 0.60 [0.44-0.77] |
| 25<=BMI<30 (Overweight) | 2.71 | [0.69-10.67] | 0.155 | |
| BMI>=30 (Obesity) | - | - | - | |
| **Ethnicity (ref. Caucasian)** | | | | 0.57 [0.44-0.71] |
| Afro-Caribbean | - | - | - | |
| Asian | 4.40 | [0.73-26.42] | 0.105 | |
| **GA (weeks)** | 1.60 | [0.81-3.16] | 0.178 | 0.62 [0.44-0.81] |
| **HPD scan 1 (mm)** | 1.07 | [0.99-1.15] | 0.105 | 0.67 [0.48-0.86] |
| **Head Position scan 1 (clock face hours)** | 1.25 | [0.81-1.94] | 0.315 | 0.59 [0.43-0.75] |
| **Caput scan 1 (mm)** | 0.99 | [0.90-1.08] | 0.767 | 0.53 [0.37-0.69] |
| **Cervical dilatation scan 1 (cm)** | 1.09 | [0.84-1.42] | 0.514 | 0.57 [0.38-0.76] |
| **UC Ratio** | 0.18 | [0.29-6.02] | 0.716 | 0.60 [0.30-0.91] |
| **Moulding** | 3.85 | [0.96-15.43] | 0.056 | 0.63 [0.46-0.79] |

### 4.3.11 Trieste Study: Single Assessment Model Multivariate Statistical Analysis Excluding Umbilical-Cerebral Ratio

### Including ALL Prognostic Variables of Intrapartum Caesarean Delivery

We re-estimated the logistic regression model directly on the Trieste dataset using the same equation employed on the combined study. The statistical analysis included a cohort of 96 participants, after excluding data from 10 participants due to incompleteness. UCR data were not considered in this analysis. We assessed all prognostic factors potentially influencing ICD incidences, including maternal age, GA, BMI, maternal ethnicity, HPD, CD, fetal head position, caput succedaneum, and fetal moulding.

Significant predictors identified included maternal ethnicity (Asian group 3, representing 7 out of 96 participants [7%]) and HPD measurements, with *p-values* of 0.023 and 0.028, respectively. Cranial moulding was marginally significant, with a *p-value* of 0.057 (Table 66). The AUC was 0.86 [95% CI: 0.74-0.98], demonstrating a sensitivity of 90.0% and a specificity of 71.5% (Table 67, Figure 76).

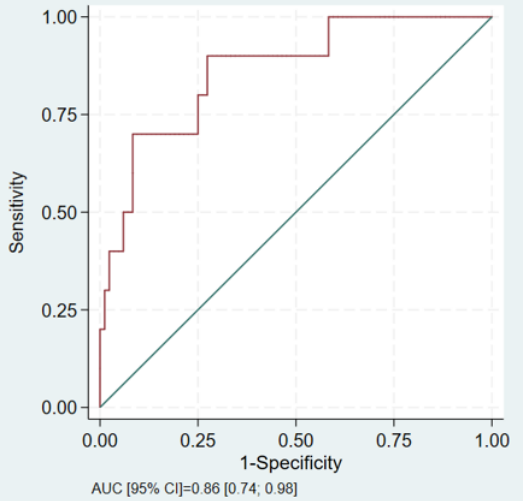
***Table 66.*** *The Trieste Study: Multivariate Logistic Regression Analysis of the Single Assessment Model: All Variables.*

| cs | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 2.495838 | 2.282077 | 1.00 | 0.317 | .4158316 | 14.98012 |
| bmi_class | | | | | | |
| 2 | 4.021603 | 3.56589 | 1.57 | 0.117 | .7073801 | 22.86365 |
| 3 | 1 | (empty) | | | | |
| ethnicity | | | | | | |
| 2 | 1 | (empty) | | | | |
| 3 | 19.97297 | 26.34408 | 2.27 | 0.023 | 1.505632 | 264.9515 |
| GA_weeks | 2.352145 | 1.11365 | 1.81 | 0.071 | .9299357 | 5.949428 |
| HPD_scan1 | 1.150452 | .0736053 | 2.19 | 0.028 | 1.014866 | 1.304151 |
| Head_Rotation_scan1 | .9255209 | .2555083 | -0.28 | 0.779 | .5387599 | 1.589927 |
| Caput_scan1 | .960927 | .0624089 | -0.61 | 0.539 | .846073 | 1.091372 |
| Cervical_dilatation_scan1 | 1.183636 | .2490783 | 0.80 | 0.423 | .7836021 | 1.787889 |
| Moulding0none1present | 8.615103 | 9.755938 | 1.90 | 0.057 | .9361392 | 79.28307 |
| _cons | 2.42e-20 | 4.93e-19 | -2.22 | 0.026 | 1.19e-37 | .0049283 |

***Table 67.*** *The Trieste Study: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Single Assessment Model: All Variable.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.111 | p=0.077 |
| Sensitivity | 20.0% | 80.0% | 90.0% |
| Specificity | 98.8% | 75.0% | 71.5% |
| PPV | 66.7% | 27.6% | 27.3% |
| NPV | 91.2% | 96.9% | 98.4% |
| Correctly classified | 90.4% | 75.5% | 73.4% |

***Figure 76.*** *The Trieste Study: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Single Assessment Model: All Variables.*




**Including SELECTED Prognostic Variables of Intrapartum Caesarean Delivery**

Subsequent analysis focused on a subset of variables selected through a stepwise process from the same cohort of 96 participants, excluding fetal Doppler measurements (UCR). Fetal moulding emerged as a significant factor, whereas the previously significant effect of maternal ethnicity group 3 was not maintained (Table 68). The AUC was 0.78 [95% CI: 0.66-0.88], with a sensitivity of 100.0% and specificity of 60.7% (Table 69, Figure 77).

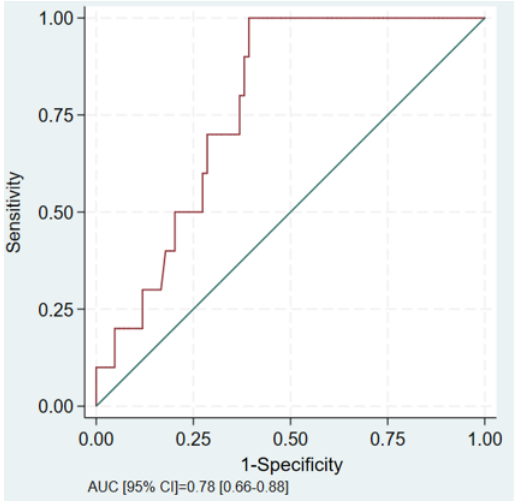
***Table 68.*** *The Trieste Study: Multivariate Logistic Regression Analysis of the Single Assessment Model: Selected Variables.*

| cs | Odds ratio | Std. err. | z | P>\|z\| | [95% conf. | interval] |
|---|---|---|---|---|---|---|
| Moulding0none1present | **6.517901** | **5.388371** | **2.27** | **0.023** | **1.289486** | **32.94571** |
| HPD_scan1 | **1.107868** | **.0513923** | **2.21** | **0.027** | **1.011585** | **1.213317** |
| _cons | **.0005573** | **.0013532** | **-3.09** | **0.002** | **4.78e-06** | **.0649897** |

***Table 69.*** *The Trieste Study: Diagnostic Measures of Multivariate Logistic Regression Analysis of the Single Assessment Model: Selected Variables.*

| Measures | Optimal probability cut-off | | |
|---|---|---|---|
| | Default | Arbitrary | Max Youden Index |
| | p=0.5 | p=0.089 | p=0.079 |
| **Sensitivity** | 10.0% | 90.0% | 100.0% |
| **Specificity** | 100.0% | 61.9% | 60.7% |
| **PPV** | 100.0% | 22.0% | 23.3% |
| **NPV** | 90.3% | 98.1% | 100.0% |
| **Correctly classified** | 90.4% | 64.9% | 64.9% |

***Figure 77.*** *The Trieste Study: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery of the Single Assessment Model: Selected Variables.*

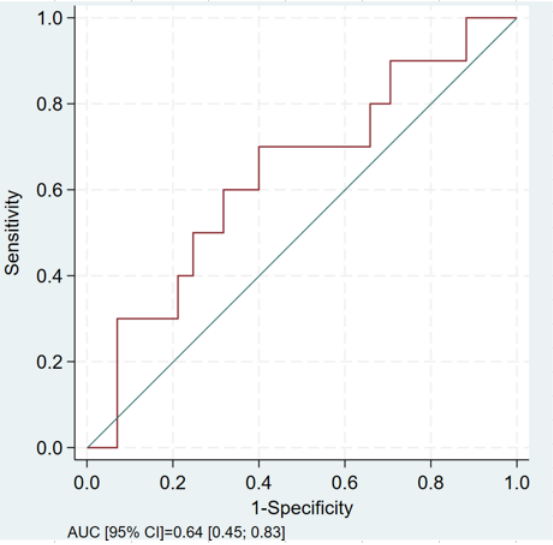


### 4.3.12 External Validation Utilising the Trieste Dataset

We validated our logistic regression model for ICD using the Trieste dataset. Specifically, we trained the model on data from the combined study and subsequently applied the obtained predicted probabilities to the Trieste dataset. Unlike prior analysis, this external validation did not yield tables comparable to those in other sections due its distinct methodological approach. Instead of estimating a model directly from the validation data, we applied probabilities predicted by models trained on the combined study to new data from Trieste. Consequently, we did not generate tables with estimated odds ratios (ORs) and assumed that the relationship between the outcome and covariates remained consistent across samples.

The application of the model developed on the combined study to the Trieste dataset resulted in diminished model predictive performance, with an AUC of 0.64 [95% CI: 0.45-0.83] (Figure 78), compared to its performance on the combined study dataset, AUC = 0.72 [95% CI: 0.67-0.77].

***Figure 78.*** *The Trieste Study: ROC Showing the Relationship between Prognostic Factors and Prediction of Intrapartum Caesarean Delivery: External Validation Model.*



### 4.3.13 Trieste Study: Repeat Assessment Model Univariate Logistic Regression Analysis

Univariate logistic regression analysis was performed on the repeat assessment model to identify potential risk factors associated with ICD. This analysis identified one factor that significantly influenced delivery outcomes and exhibited a strong correlation with the incidence of ICD. Notably, gestational age demonstrated a significant correlation, with a *p-value* of 0.038 (Table 70).

***Table 70.*** *The Trieste Study: Univariate Logistic Regression Analysis of the Repeat Assessment Model.*

| Variables | Univariate regression | | | |
|---|---|---|---|---|
| | OR | 95% CI | p-value | AUC [95% CI] |
| **Age>=35** | 1.79 | [0.29-11.0] | 0.529 | 0.56 [0.34-0.77] |
| **BMI class (ref. BMI<25)** | | | | 0.56 [0.35-0.78] |
| 25<=BMI<30 (Overweight) | 1.9 | [0.30-11.90] | 0.493 | |
| BMI>=30 (Obesity) | - | - | - | |
| **Ethnicity (ref. Caucasian)** | | | | 0.55 [0.38-0.71] |
| Afro-Caribbean | - | - | - | |
| Asian | 2.45 | [0.23-26.38] | 0.460 | |
| **GA (weeks)** | 3.58 | [1.08-11.94] | ***0.038*** | **0.78 [0.61-0.94]** |
| **HPD scan 1 (mm)** | 1.10 | [0.98-1.23] | 0.109 | 0.73 [0.57-0.90] |
| **HPD change (mm/h)** | 0.61 | [0.33-1.15] | 0.130 | 0.72 [0.52-0.93] |
| **Head Position scan 1 (clock face hours)** | 1.25 | [0.81-1.95] | 0.315 | 0.59 [0.43-0.75] |
| **Head Position change (clock face hours/h)** | 1.22 | [0.54-2.73] | 0.634 | 0.50 [0.36-0.64] |
| **Caput scan 1 (mm)** | 0.94 | [0.78-1.12] | 0.470 | 0.58 [0.41-0.74] |
| **Caput change (mm/h)** | 1.05 | [0.86-1.28] | 0.617 | 0.60 [0.29-0.92] |
| **Cervical dilatation scan 1 (cm)** | 1.24 | [0.77-2.03] | 0.377 | 0.63 [0.36-0.89] |
| **Cervical dilatation change (cm/h)** | 0.33 | [0.08-1.46] | 0.144 | **0.72 [0.50-0.94]** |
| **UC Ratio** | 0.15 | [0.00-185.58] | 0.599 | 0.61 [0.25-0.97] |
| **Moulding** | 2.94 | [0.46-18.79] | 0.255 | 0.59 [0.38-0.81] |

### 4.3.14 Summary of Results from the Prediction Studies

Overall, our investigations and statistical analysis of the datasets have elucidated that fetal head station, assessed through head-perineum distance, caput succedaneum measurements, and cervical dilatation measurements, emerged as the most prognostic indicators of intrapartum Caesarean delivery when evaluated during active labour. Maternal age > 35, GA, and maternal ethnicity were also significant in some studies across both predictive models (single and repeat). A comprehensive summary of these findings is presented in Table 71.

***Table 71.*** *Summary of the Findings from Four Studies: SONO-VE, SONO-PREDICT, Trieste, and Combined.*

| Study Name | Number of Participants | Prognostic Parameters of ICD in the Single Assessment Model, Excluding UCR | Prognostic Parameters of ICD in the Single Assessment Model, Including UCR | Prognostic Parameters of ICD in the Repeat Assessment Model, Excluding UCR | Prognostic Parameters of ICD in the Repeat Assessment Model, Including UCR |
|---|---|---|---|---|---|
| **SONO-VE** | n = 269 | n = 264 full model<br>▪ **BMI (Class 2, Overweight)**<br>▪ **Gestational Age**<br>▪ **Head-Perineum Distance**<br>▪ **Cervical Dilatation**<br><br>n = 264 compact model<br>▪ Head-Perineum Distance<br>▪ Caput Succedaneum<br>▪ Cervical Dilatation | n = 127 full model<br>▪ No significant predictors of ICD were identified; however, cervical dilatation was on the border with a *p-value* of 0.058<br><br>n = 127 compact model<br>▪ Cervical Dilatation<br>▪ BMI (obesity class 3, BMI ≥ 30 ) | n = 212 full model<br>▪ **Maternal Age > 35**<br>▪ **Maternal Ethnicity (Asian)**<br>▪ **Gestational Age**<br>▪ **Head-Perineum Distance in 1st Scan**<br>▪ **Caput Succedaneum in 1st Scan**<br>▪ **Cervical Dilatation in 1st and its Change**<br><br>n = 212 compact model<br>▪ Maternal Age > 35<br>▪ Caput Succedaneum in 1st Scan and its Change<br>▪ Cervical Dilatation in 1st and its Change | n = 107 full model<br>▪ Maternal Ethnicity (Asian)<br>▪ Cervical Dilatation Change<br><br>n = 107 compact model<br>▪ Cervical Dilatation Change |
| **SONO-PREDICT** | n = 239 | n = 239 full model<br>▪ **Head-Perineum Distance**<br>▪ **Cervical Dilatation**<br><br>n = 239 compact model<br>▪ Head-Perineum Distance<br>▪ Cervical Dilatation | n = 174 full model<br>▪ Head-Perineum Distance<br>▪ Cervical Dilatation<br><br>n = 174 compact model<br>▪ Head-Perineum Distance<br>▪ Cervical Dilatation | n = 202 full model<br>▪ **Head-Perineum Distance in 1st Scan**<br>▪ **Caput Succedaneum in 1st Scan**<br>▪ **Cervical Dilatation in 1st and its Change**<br><br>n = 202 compact model<br>▪ Caput Succedaneum in 1st Scan<br>▪ Cervical Dilatation in 1st and its Change | n = 154 full model<br>▪ Head-Perineum Distance in 1st Scan<br>▪ Caput Succedaneum in 1st Scan<br>▪ Cervical Dilatation in 1st and its Change<br><br>n = 154 compact model<br>▪ Caput Succedaneum in 1st Scan<br>▪ Cervical Dilatation in 1st and its Change |
| **Trieste** | n = 106 | n = 96 full model<br>▪ **Maternal Ethnicity (Asian)**<br>▪ **Head-Perineum Distance**<br><br>n = 96 compact model<br>▪ Moulding<br>▪ Head-Perineum Distance | ▪ ---------- | ▪ ---------- | ▪ ---------- |
| **Combined** (SONO-VE + SONO-PREDICT)<br>'KEY MODEL' | n = 508 | n = 503 full model<br>▪ **Maternal Ethnicity (Afro-Caribbean)**<br>▪ **Gestational Age**<br>▪ **Head-Perineum Distance**<br>▪ **Caput Succedaneum**<br>▪ **Cervical Dilatation**<br><br>n = 503 compact model<br>▪ Maternal Ethnicity (Afro-Caribbean)<br>▪ Head-Perineum Distance<br>▪ Caput Succedaneum<br>▪ Cervical Dilatation | n = 301 full model<br>▪ Head-Perineum Distance<br>▪ Caput Succedaneum<br>▪ Cervical Dilatation<br><br>n = 301 compact model<br>▪ Head-Perineum Distance<br>▪ Caput Succedaneum<br>▪ Cervical Dilatation | n = 414 full model<br>▪ **Maternal Age > 35**<br>▪ **Head-Perineum Distance in 1st Scan**<br>▪ **Caput Succedaneum in 1st Scan and its Change**<br>▪ **Cervical Dilatation in 1st and its Change**<br><br>n = 414 compact model<br>▪ Head-Perineum Distance in 1st Scan<br>▪ Caput Succedaneum in 1st Scan and its Change<br>▪ Cervical Dilatation in 1st and its Change | n = 261 full model<br>▪ Head-Perineum Distance in 1st Scan<br>▪ Caput Succedaneum in 1st Scan<br>▪ Cervical Dilatation in 1st and its Change<br><br>n = 261 compact model<br>▪ Head-Perineum Distance in 1st Scan<br>▪ Caput Succedaneum in 1st Scan<br>▪ Cervical Dilatation in 1st and its Change |

UCR: Umbilical-cerebral ratio; ICD: Intrapartum Caesarean Delivery; BMI: Body mass index

# CHAPTER 5

# Intrapartum Ultrasound for Cervical Dilatation: Inter- and Intra-Observer Agreement

*Intrapartum ultrasound for cervical dilatation: inter and intra-observer agreement.*
*Arwa HANIDU, Mariya KOVALENKO, Sana USMAN, Lorenzo MONASTA, Giulia ZAMAGNI, Tamara STAMPALIJA, Christoph LEES. Revised manuscript was submitted on 09 August 2024 to the Acta Obstetricia et Gynecologica Scandinavica (AOGS).*

## 5.1 Introduction

Digital vaginal examination (DVE) is used worldwide to assess fetal head descent, cervical effacement and dilatation, and fetal head position before and during labour. However, it can be uncomfortable[4,272] and may cause more pain than a transperineal ultrasound (TPUS) examination, leading to poor tolerance, especially among women in labour.[6] Furthermore, DVE can be associated with ascending infections, including chorioamnionitis and endometritis, as well as a shortened time to delivery in cases of preterm labour.[273] It may not be a reliable method for assessing fetal head position,[274] cervical dilatation,[2] or fetal head station.[1] Moreover, DVE is a notoriously subjective technique with frequently reported poor inter- and intra-observer agreement.[1,2,3] 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 labour progress. Various techniques, including mechanical, electromagnetic, and electronic sensors, in addition to DVE, can be employed to measure cervical dilatation.[275] 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 localisation. Over the last two decades, advanced ultrasound techniques have increasingly been used on delivery suites. These techniques can objectively determine fetal head position,[30,41] cervical dilatation,[177] fetal head station,[147] fetal head attitude and flexion,[234] and allow an estimate towards prediction of delivery mode.[164,171,235] TPUS reduces the need for invasive DVE and is associated with lower rates of intrapartum fever and chorioamnionitis.[276]

There is a scarcity of literature concerning ultrasound measurement of cervical dilatation during active labour. However, some studies have reported the reproducibility of ultrasound as an effective diagnostic tool, producing measurements that highly correlate with DVE.[136, 178,181,182,185, 277] 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 labour and corresponding DVE values, with evaluating the validity of the two-dimensional (2D) cine-loop ultrasound technique for enhancing the visualisation 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 repeat ultrasound measurements of cervical dilatation during active labour.

## 5.2 Materials and Methods

A prospective longitudinal observational cohort study was conducted from May 2021 to November 2022 in the labour ward of an inner-centre maternity unit in London, UK, included TPUS assessment of cervical dilatation. The SONO-PREDICT study received ethical approval from the UK Research Ethics Committee (Leicester Research Ethics Committee, Reference: 20/EM/0298, dated 02/18/2021) and the local Joint Research Compliance Office (Reference: 20QC6287). Informed consent was individually obtained from each participant prior to study inclusion. Consent was obtained during the early stage of labour, 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 labour as defined by NICE[223] (regular painful contractions and/or progressive cervical dilatation from 4 cm), including both spontaneous and induced labour, 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 in the delivery suite in accordance with standard management of labour.[223]

TPUS was conducted within 60 minutes 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 60 minutes. The ultrasound operators were not involved in the clinical management of labour, 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 wideband three-dimensional (3D) convex ultra-light volume probe. A 3D/4D probe was utilised with 2D acquisitions to achieve maximum image resolution. DVEs and TPUS assessments were performed both with and without epidural anaesthesia, 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 visualise the cervix involved positioning the ultrasound probe along the midsagittal plane at the perineum. This approach resulted in the visualisation of the fetal head outline on the ultrasound screen and often a portion of the symphysis pubis. The ultrasound transducer was then rotated 90° counterclockwise, 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 79 a-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 80 a-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 anteroposterior (AP) diameter

with the clearest cervical rim on cine-loop (Figure 81 a-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.

***Figure 79.*** *Transperineal Ultrasound (TPUS) Technique for Measuring Cervical Dilatation during Labour.*
***a,*** *Ultrasound transducer is rotated 90° counterclockwise to obtain the transverse plane orientation; and* ***b,*** *Ultrasound image demonstrating the fetal skull and the maternal perineal area. (Images from the SONO-PREDICT Study).*

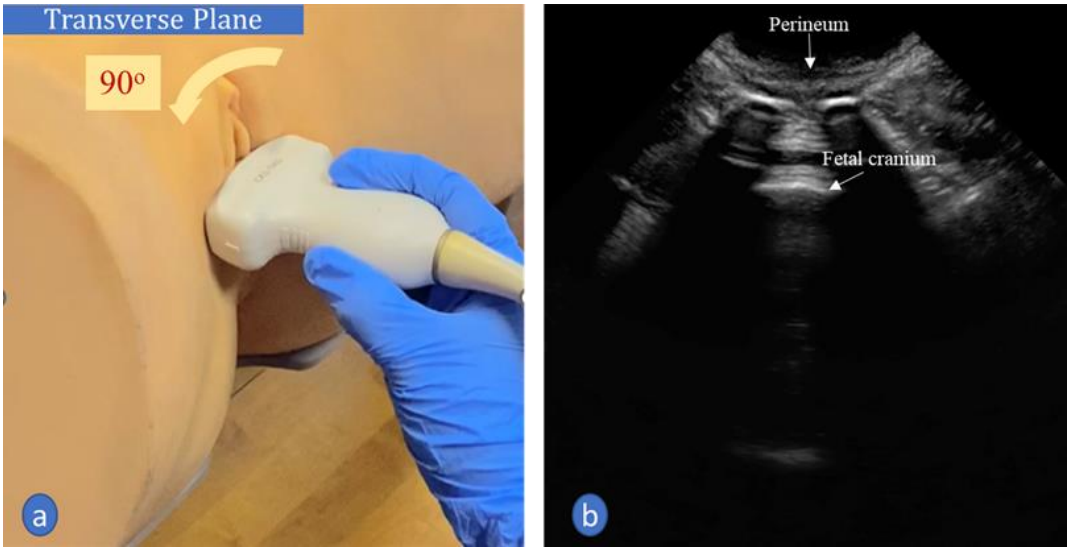



***Figure 80.*** *Transperineal Ultrasound (TPUS) Technique and Ultrasound Probe Movements to Measure Cervical Dilatation during Active Labour.*
***a,*** *Ultrasound transducer is positioned in true transverse plane;* ***b,*** *Ultrasound transducer is tilted posteriorly to visualise the rectum; and* ***c,*** *Ultrasound transducer is gradually tilted back anteriorly until clearly visualise the region of interest, 'the cervix'. (Images from the SONO-PREDICT Study).*

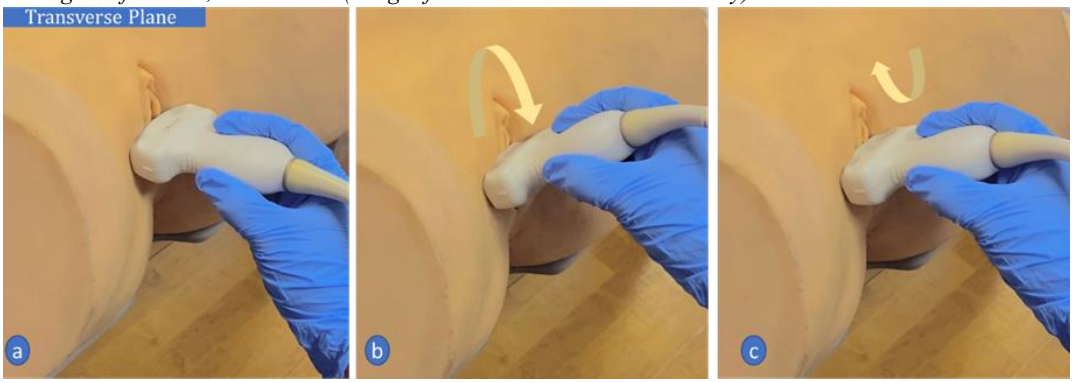
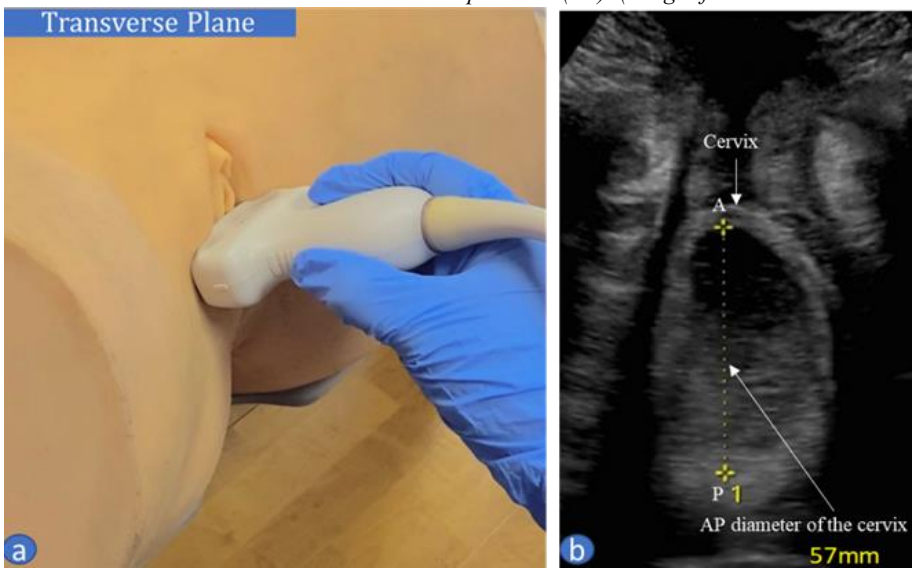
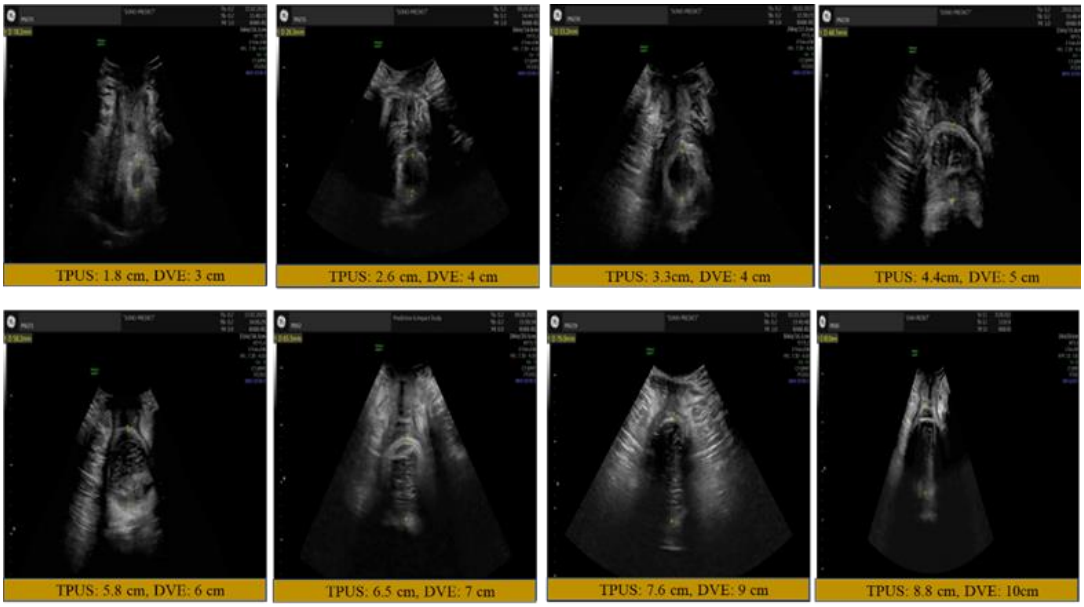


***Figure 81.*** *Transperineal Ultrasound (TPUS) Technique for Measuring Cervical Dilatation during Active Labour.* ***a,*** *Ultrasound transducer is inclined towards the anterior direction, the well-observed area following the rectum at the internal os level is 'the cervix'; and* ***b,*** *Ultrasound 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. Abbreviation: anteroposterior (AP). (Images from the SONO-PREDICT Study).*



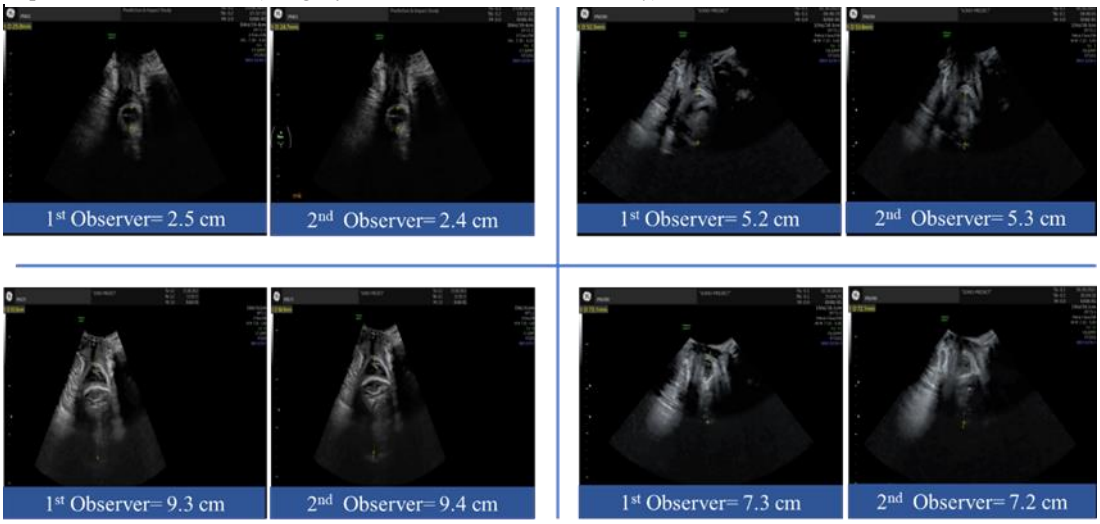

Once the cervix was identified, measurements of the AP diameter at different dilatations were obtained (Figure 82). Inter-observer measurement variability was assessed through repeat observations by A.H. and M.K. (Figure 83). Intra-observer variability was evaluated by A.H. In both cases, the cervical dilatation measurement (AP diameter) was assessed offline using the 2D cine-loop videos that had been recorded and saved on the ultrasound device.

***Figure 82.*** *Ultrasound Images Demonstrating Different Cervical Dilatation Measurements Assessed by Transperineal Ultrasound Technique Gathered from Eight Nulliparous Women during Active Labour. Ultrasound Images were Captured at Various Depths and Focal Points. (Images from the SONO-PREDICT Study).*




*Digital vaginal examination, DVE; Transperineal ultrasound, TPUS*

***Figure 83.*** *Four Ultrasound Image Sets Demonstrating Inter-Observer Variability of Cervical Dilatation Measurements Assessed by Two Observers during Active Labour. Ultrasound Images were Captured at Various Depths and Focal Points. (Images from the SONO-PREDICT Study).*



## 5.3 Statistical Analysis

The relationship between the DVE and TPUS 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 were 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.

## 5.4 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/m$^2$ (range, 18–47 kg/m$^2$).

**Association Between DVE and TPUS Measurements**: Among the 206 participants who provided consent from May 2021 to November 2022, 96 participants (47%) were excluded due to the time interval exceeding 60 minutes between the DVE and TPUS scan. Consequently, the analysis included data from 110 participants, comprising 147 observations from multiple ultrasound assessments undertaken at a median of 27.2 minutes from the DVE (range, 4-50 minutes). Thirty-seven participants (34%) underwent repeat ultrasound assessments of the cervix during the active phase of labour. The TPUS assessment was conducted with a median completion time of 4.75 minutes (range, 2-7 minutes).

The cervix was visible in 147 observations of cervical dilatation, with 83% showing cervical dilatation < 8 cm, 17% ≥ 8 cm. In 57% of the observations, the membranes were ruptured (Figure 84). The association between DVE and TPUS measurements is depicted in a bubble chart (Figure 85 a), 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%). This indicates that the value between DVE and TPUS was within 1 cm in 118 observations (80%). An absolute difference of 2-4 cm was demonstrated in 20% of the observations. The Bland-Altman plot (Figure 85 b) 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% CI = 0.75–0.90; $p < 0.001$).

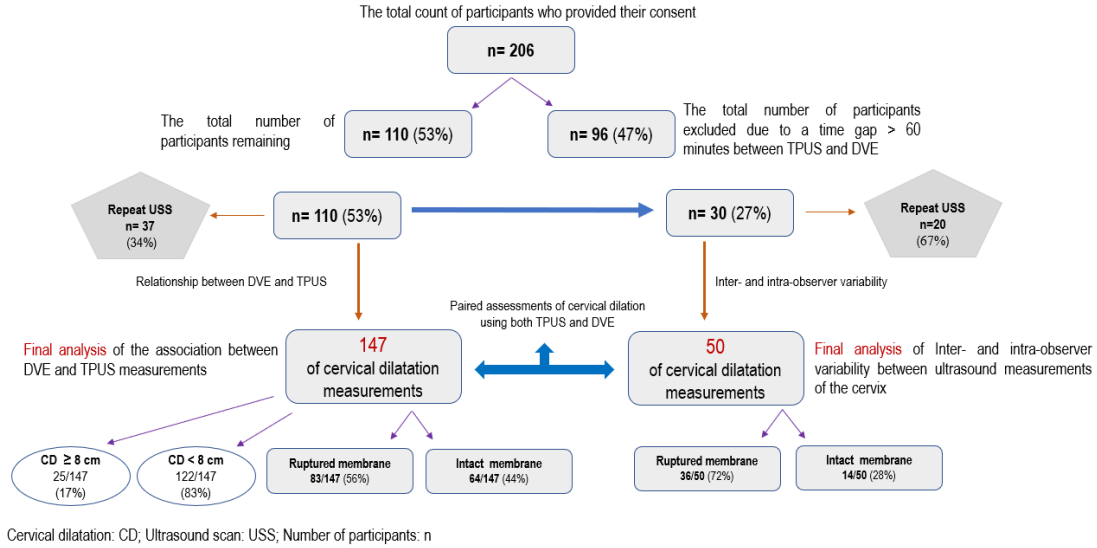
**Inter- and Intra-Observer Variability for TPUS Measurements of the Cervix**:

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 participants (67%) underwent paired ultrasound assessments of the cervix during active labour (Figure 84).

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 86).

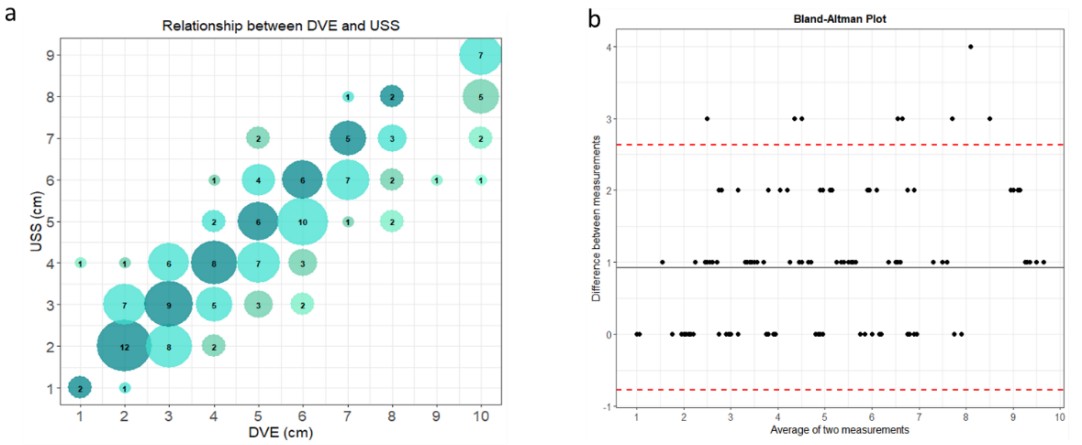
For intra-observer agreement the mean difference in the first ultrasound scan was 0.01 cm (95% LOA = -0.29 to 0.30 cm) with an ICC of 0.995 (95% CI = 0.989–0.998; $p < 0.001$). Similar results were obtained with the repeat ultrasound assessments. The mean difference in the second ultrasound scan was -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 87).

***Figure 84.*** *Flow-Chart Showing the Study Cohort.*




Cervical dilatation: CD; Ultrasound scan: USS; Number of participants: n

***Figure 85.*** *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; and* ***b,*** *Bland-Altman plot with calculation of the mean difference of inter-method agreement between DVE and USS.*




| Absolute difference | n (%) |
|---|---|
| 0 cm | 50 (34.0) |
| 1 cm | 68 (46.3) |
| 2 cm | 20 (13.6) |
| 3 cm | 8 (5.4) |
| 4 cm | 1 (0.7) |

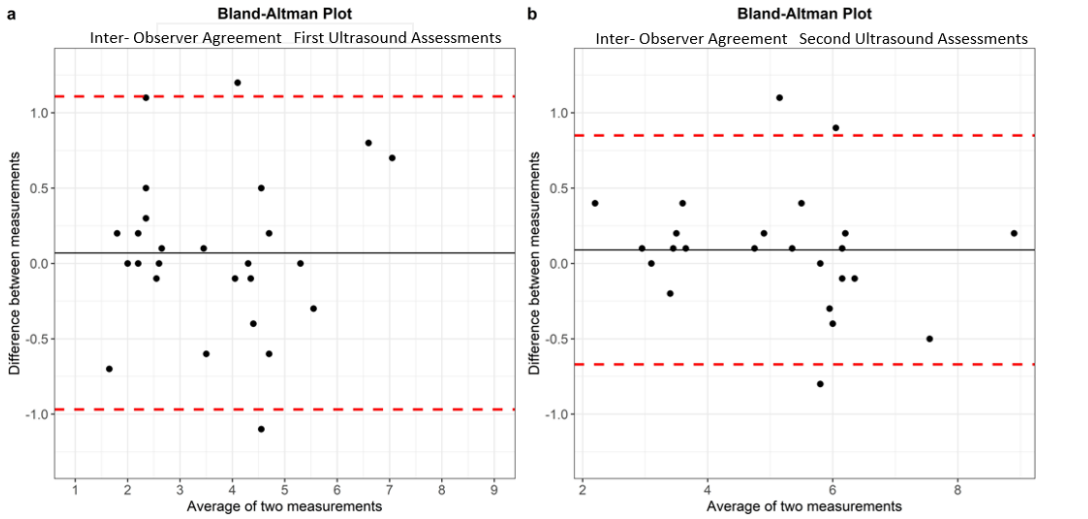
Digital vaginal examination, DVE; Ultrasound scan, USS;
Number of patients, n; %, the percentage

| Mean difference | [95% Limits of Agreement] |
|---|---|
| -0.925 | [-0.777; 2.628] |

| Intraclass correlation coefficient (ICC) | ICC 95% CI | p-value |
|---|---|---|
| 0.85 | [0.75; 0.90] | ***<0.001*** |

Statistical significance is set at an alpha value of 0.05

***Figure 86. Inter-Observer Agreement:*** *Bland-Altman Plot of Differences in 2D Ultrasonographic Measurements of Cervical Dilatation of the Anteroposterior Diameter between Two Observers.*
***a,*** *Inter-observer agreement in the first ultrasound assessment; and* ***b,*** *Inter-observer agreement in the second ultrasound assessments.*

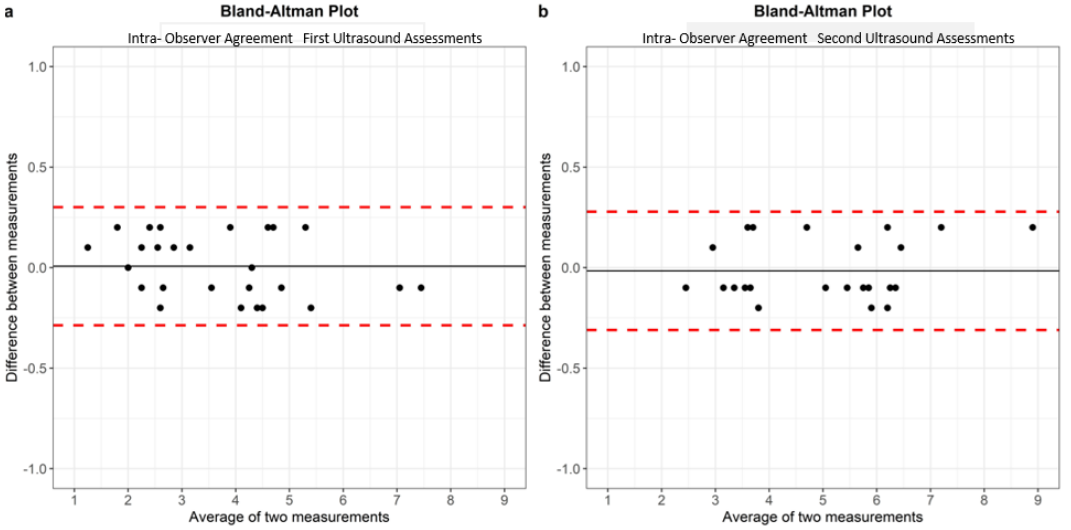



| Mean difference | [95% Limits of Agreement] | Intraclass correlation coefficient (ICC) | ICC 95% CI | p-value |
|---|---|---|---|---|
| 0.07 cm | [-0.96; 1.10] | 0.939 | [0.870; 0.972] | ***<0.001*** |

| Mean difference | [95% Limits of Agreement] | Intraclass correlation coefficient (ICC) | ICC 95% CI | p-value |
|---|---|---|---|---|
| 0.09 cm | [-0.67; 0.85] | 0.969 | [0.933; 0.986] | ***<0.001*** |

***Figure 87. Intra-Observer Agreement:*** *Bland-Altman Plot of Differences in 2D Ultrasonographic Measurements of Cervical Dilatation of the Anteroposterior Diameter Assessed by One Observer with a Time Interval of 10 Days between Each Set of Ultrasound Measurements.*

***a,*** *Intra-observer agreement in the first ultrasound assessment; and* ***b,*** *Intra-observer agreement in the second ultrasound assessments.*




| Mean difference | [95% Limits of Agreement] | Intraclass correlation coefficient (ICC) | ICC 95% CI | p-value |
|---|---|---|---|---|
| 0.01 cm | [-0.29; 0.30] | 0.995 | [0.989; 0.998] | ***<0.001*** |

| Mean difference | [95% Limits of Agreement] | Intraclass correlation coefficient (ICC) | ICC 95% CI | p-value |
|---|---|---|---|---|
| -0.02 cm | [-0.31; 0.28] | 0.996 | [0.990; 0.998] | ***<0.001*** |

## 5.5 Discussion

The main findings of this study show that intrapartum 2D transperineal ultrasound is a feasible technique for evaluating cervical dilatation during active labour 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 dilatations, with ultrasound images enhanced by the addition of cine-loop videos. Importantly, there was a robust inter- and intra-observer consensus in both the first and second transperineal ultrasound 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 W. A. et al.[177] 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.[178-180]

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[278]. In contrast, Connell P. et al.[182] 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.[136,181,183]

Importantly, Wiafe Y. A. et al.[183] found no significant difference in measurements of cervical dilatation between the anteroposterior and transverse approach.

Zimerman A. L. et al.[181] conducted a one-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 labour, 3D TPUS may prove to be more effective than other methods. While we did not utilise it in this study, this technique may provide a clearer visualisation 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 S. et al.[136], two cervical dimensions were examined in 86 participants. They compared DVE with TPUS while also assessing intra-observer consistency of ultrasound measurements. Their findings indicated that TPUS measurements showed cervical dilatation approximately 1 cm less than those obtained from clinical evaluations but displayed good intra-observer agreement. In our study, most of 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 standardised in respect of anteroposterior 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 labours.[275] Transperineal ultrasound, when used in conjunction with traditional clinical assessment, has demonstrated superior accuracy compared to DVE.[279] It not only enhances the precision of cervical measurements but also offers a non-invasive approach, which many women prefer over traditional examinations, making a strong argument for its incorporation into intrapartum care.[44,184,280] Furthermore, using transperineal ultrasound reduces the potential infection risks associated with DVE.[276] Implementing ultrasound assessment may diminish the need for repetitive clinical examinations, particularly during the early stages of labour, consequently optimising the efficiency of labour monitoring processes in an objective manner and holding significant implications for clinical practice.[179,277]

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 visualisation of the cervix, including observations of advanced dilation with both ruptured and intact membranes, achieved despite the particular challenges in visualising of the cervix using transperineal ultrasound at dilatations of greater than 8 cm that reported in several previous studies.[136,179,184,277,279] This was particularly notable in cases with a low fetal head station where visualising 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 visualisation of the cervical rim.

In advanced labour, 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 T. et al.[277] reported higher precision at greater degrees of cervical dilatation. However, from our study, transperineal ultrasound emerges as a valuable tool for objectively assessing cervical dilation throughout labour, 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 labour. Conducted at a diverse London tertiary care facility that manages over 5,000 deliveries annually, our research is generalisable to a broader labouring 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 one hour after a clinical evaluation. Consequently, ninety-six 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 one hour are minimal, due largely to the slower cervical dilatation progression in

nulliparous women compared to 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 labour room. Given the good intraclass correlation between DVE and TPUS measurements and high inter-observer agreement, we consider that multiple ultrasound assessment 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 labour or in cases of preterm gestation.

## 5.6 Conclusion

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

# CHAPTER 6

# Ultrasound Visualisation of the Urinary Catheter Balloon during Active Labour

*This work, presented in this chapter, is intended for submission to the European Journal of Obstetrics & Gynecology and Reproductive Biology. Dr Victoria Asfour, Consultant Urogynaecologist at East Sussex Healthcare NHS Trust, and Professor Vik Khullar, Professor of Practice in Urogynaecology at St Mary's Hospital, Imperial College Healthcare NHS Trust, have contributed to this work.*

## 6.1 Introduction

In the management of women receiving regional anaesthesia during labour, the routine employment of intrapartum urinary catheters is a prevalent practice. International guidelines[223,281,282] support monitoring bladder function throughout labour, recommending approaches that include patient-initiated voiding, intermittent catheterisation, or the use of indwelling catheters. The principal aim of catheterisation is to mitigate the risk of urinary retention, both peripartum and postpartum.[283]

In a prior study, SONO-VE,[222] our research team made a novel observation during transperineal ultrasound scans. Specifically, in certain cases, there was a clear visualisation of the catheter balloon positioned between the fetal head and a probe placed transperineally along the midsagittal plane. This observation led to a further investigation into the potential correlation between the lower positioning of the catheter balloon, the incidence of intrapartum haematuria, and labour outcomes.

The objectives of the retrospective review of ultrasound imaging in the SONO-PREDICT were to determine the prevalence of catheter balloons positioned at a lower level during intrapartum transperineal ultrasound and to examine any potential associations with intrapartum haematuria, labour outcomes, and/or postpartum urinary retention.

## 6.2 Materials and Methods

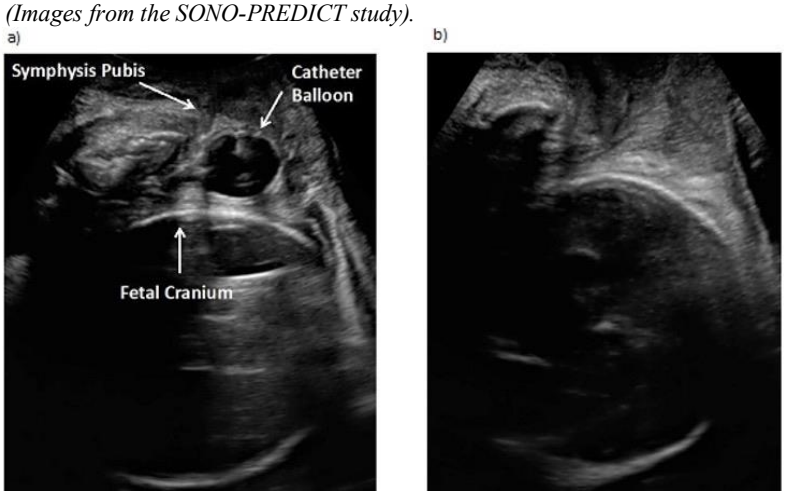
The methodology of the SONO-PREDICT study, encompassing the inclusion and exclusion criteria, recruitment strategies, and intrapartum ultrasound assessment techniques, is delineated in detail in Chapter 2.

In brief, intrapartum transperineal ultrasound was utilised to assess parameters including fetal head station, cervical dilatation, caput succedaneum, and fetal moulding. From transperineal ultrasound evaluation capturing images along the midsagittal plane and complemented by cine-loop videos, it was possible to retrospectively ascertain the presence of a low-positioned catheter balloon. A low indwelling catheter balloon was defined as being positioned below the fetal head, as observed in one or two transperineal ultrasound assessments (Figure 88 a). In instances where the catheter balloon could not be visualised on transperineal ultrasound, it was considered to be positioned high (Figure 88 b).

Ultrasound images and videos were subsequently reviewed by two investigators proficient in intrapartum ultrasound imaging (A.H. and M.K.).

It is important to note that this research was conducted independently of any clinical decisions made during the intrapartum period. Moreover, participants were not apprised of the ultrasound findings throughout this time. The care provided during labour was in strict adherence to and compliance with the guidelines issued by the National Institute for Health and Care Excellence (NICE).[223]

***Figure 88.*** *Intrapartum Transperineal Ultrasound Images in the Midsagittal Plane.*
***a,*** *Low urinary catheter balloon visualised caudal to the symphysis pubis.*
***b,*** *Urinary catheter balloon is located above the fetal head, not visualised on the transperineal ultrasound.*
*(Images from the SONO-PREDICT study).*




A retrospective evaluation of electronic patient records was conducted to assess the incidence of documented intrapartum haematuria and immediate postpartum urinary retention during the inpatient care period. Haematuria was characterised by either the visible presence of blood in the indwelling catheter or the detection of microscopic haematuria through urinary dipstick analysis, performed by the clinical care team when applicable.

Postpartum urinary retention was identified as the inability to achieve urinary voiding within 6 hours after the removal of an indwelling urinary catheter. Exclusion of postpartum urinary retention was determined by recording two voiding volumes exceeding 150 ml each. Any urinary symptoms, such as sensations of incomplete bladder emptying or urinary incontinence, were noted in the clinical care records.

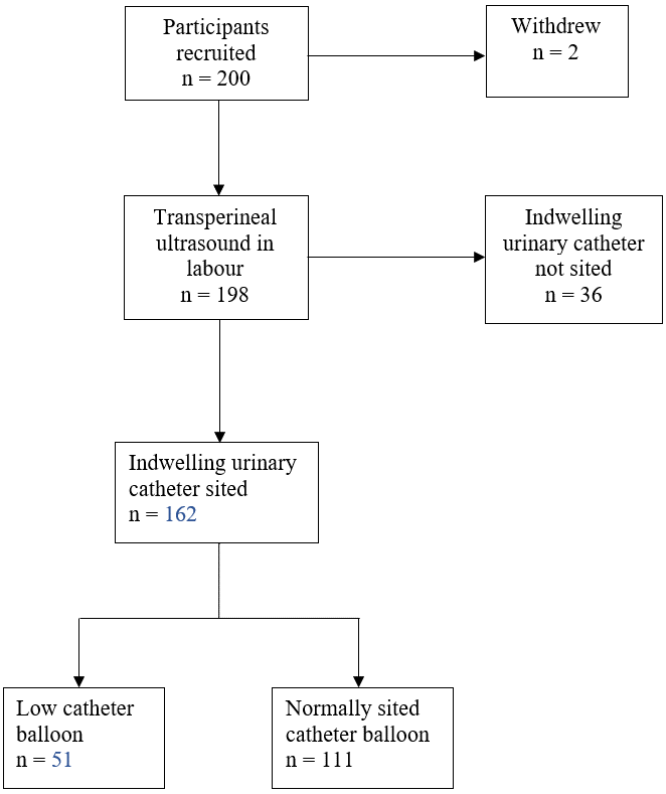
Data entry into a Microsoft Excel spreadsheet was conducted contemporaneously with the ultrasound assessments, with each participant being uniquely identified by their assigned study number. Information pertaining to immediate postpartum outcomes were retrospectively extracted from electronic patient records, accessible online.

A Chi-square test was employed to assess the difference in the incidence of intrapartum haematuria between two categories: low-positioned and normally positioned catheter balloons. Furthermore, to examine the impact of the urinary catheter balloon's location on the mode of delivery, a 3 x 2 Chi-square test was utilised. The influence of catheter balloon placement on the duration of labour was evaluated using a one-way Analysis of Variance (ANOVA). Results were deemed significant at a *p-value* of less than 0.05.

## 6.3 Results

Two hundred participants were consecutively recruited for the SONO-PREDICT study from May 2021 to November 2023. Among them, two participants withdrew their consent, leaving a cohort of 198 individuals who underwent at least one ultrasound examination during active labour. Within this cohort, 82% (162/198) had an indwelling urinary catheter inserted during their labour. A low-positioned indwelling urinary catheter balloon was observed in 31% (51/162) of these participants (Figure 89).

***Figure 89.*** *Flow-Chart of the Study Participants.*




As illustrated in Table 72, the range of cervical dilatations assessed in participants who underwent one or two transperineal ultrasound evaluations during labour is reported. Notably, the catheter balloon was most frequently observed in a low position at a cervical dilatation of 4 cm (20%, 10/51).

***Table 72.*** *Low Catheter Balloons Seen at Corresponding Cervical Dilatations during Intrapartum Transperineal Ultrasound (TPUS) Assessments.*

| Cervical Dilatation (cm) | Ultrasound findings of a low balloon (n = 51) |
|---|---|
| <1 | 0 |
| 1 | 4 (7.8%) |
| 2 | 9 (17.6%) |
| 3 | 8 (15.7%) |
| 4 | 10 (19.6%) |
| 5 | 8 (15.7%) |
| 6 | 3 (5.9%) |
| 7 | 6 (11.8%) |
| 8 | 2 (3.9%) |
| 9 | 0 |
| 10 | 1 (2.0%) |

Intrapartum haematuria was detected in 17% (28/162) of participants with an indwelling urinary catheter. Within the subgroup with a low-positioned catheter balloon, haematuria was observed in 29% (15/51), compared to 12% (13/111) in those where the balloon was not visualised ($X^2$, $p = 0.0057$). Moreover, postpartum urinary retention or incomplete bladder evacuation was noted in 4% (6/162) of participants with an indwelling urinary catheter.

In instances where a low-positioned urinary catheter balloon was observed, occurrences of urinary retention and incomplete bladder evacuation were documented. Two percent (1/51) of participants with a low catheter balloon placement experienced postpartum urinary retention and incomplete bladder evacuation, compared to 5% (5/111) in cases where the catheter balloon was high ($X^2$, $p = 0.43$). These findings are depicted in Table 73. In situations where a urinary catheter balloon was not

visible/high during labour, 3% (3/111) of the participants demonstrated urinary retention, and 2% (2/111) reported symptoms of postpartum incomplete bladder emptying.

***Table 73.*** *Haematuria and Urine Retention in Participants with Low Catheter Balloon.*

| | Labour | Postnatal |
|---|---|---|
| **Transperineal Ultrasound Scan** | **Haematuria** | **Urine Retention** |
| **Low Balloon (n = 51)** | 15 (29%) | 1 (2%) |
| **Balloon not visible/high (n = 111)** | 13 (12%) | 5 (5%) |
| **Chi-Square Test** | $X^2$, $p=0.0057$ | $X^2$, $p=0.43$ |

A comparative analysis of delivery outcomes was conducted among three groups: those with a low-positioned catheter balloon, those in whom the indwelling catheter balloon was not visualised/high, and those without an indwelling catheter (Table 74). The mean labour duration was notably longer in the low indwelling catheter balloon group (n = 51) at 998 minutes, compared to 801 minutes in cases where the catheter balloon was not visible (n = 111). The shortest mean duration of labour was recorded in instances where no catheter was used, at 730 minutes (n = 36); ($p$ = 0.0055).

The incidence of interventions during labour necessitating emergency Caesarean section was noted to be 35% (18/51) in the group with the low-positioned catheter balloon, 33% (37/111) in the cohort where the balloon was not visualised/high, and 42% (15/36) in participants without an indwelling catheter. To elucidate the relationship between the placement of catheter balloon (either low, not visible /high, or absent) and the mode of delivery (either vaginal birth or emergency Caesarean section), a multi-way contingency table Chi-Square analysis was conducted as shown in Table 74. This analysis revealed no significant correlation between the method of delivery and the positioning of the catheter balloon ($p$ = 0.66).

***Table 74.*** *Comparison of Labour Outcomes Differentiated between Site of the Catheter Balloon.*

| **Labour outcomes** | | **No Catheter (n = 36)** | **Low Balloon (n = 51)** | **Balloon not Visible/High (n = 111)** | |
|---|---|---|---|---|---|
| **Duration of labour** | Mean (minutes) | 730 | 998 | 801 | ANOVA $p$= 0.0055 |
| **Mode of delivery** | Vaginal Birth (Spontaneous Vaginal Delivery or Assisted Vaginal Delivery) | 21 (58%) | 33 (65%) | 74 (67%) | $X^2$, $p$= 0.66 |
| | Emergency Caesarean Section | 15 (42%) | 18 (35%) | 37 (33%) | |

## 6.4 Discussion

In one-third of the cohort, a low prevalence of indwelling urinary catheter balloon positioning was observed. Approximately one-third of this subgroup exhibited concurrent haematuria during labour. The average duration of labour was longer in participants with low-positioned catheter balloons compared to those with high-positioned balloons. No correlation was identified between the presence of low indwelling urinary catheter balloons and either the mode of delivery or immediate urinary retention.

To the best of our knowledge, there is a lack of published literature regarding the placement of urinary catheter balloons, their outcomes during labour, and associated urinary complications, both with and without the aid of intrapartum ultrasound visualisation. Given the novelty of this area of research, a comparison with pre-existing data is not feasible.

A low-positioned urinary catheter balloon was observed in third of women during labour, constituting a frequent intrapartum occurrence across various stages of cervical dilatation. Intrapartum haematuria was found to be associated with low catheter balloon, while no relationship was noted between a low catheter balloon and either the mode of delivery or immediate urinary retention.

We propose a potential mechanism of these observations. If the catheter balloon is inadvertently positioned beneath the fetal head, it may become entrapped as the head descends and impacts against the symphysis pubis. This entrapment could prevent the fetal head from advancing past the pubic symphysis, potentially impeding its descent. Such a scenario could lead to mucosal injury, which may account for the haematuria observed. Upon detection, repositioning the urinary catheter above the

fetal head can be achieved either through manual adjustment or by deflating the balloon, advancing the catheter further, and then re-inflation.

Interestingly, the association was found between a low catheter balloon and an extended duration of labour. Whether this is due to the low catheter balloon causing an obstruction or a consequence of prolonged labour that results in the catheter balloon moving towards the bladder neck remains unclear. However, this observation warrants further investigation.

The association and investigation of catheterisation techniques during labour, with respect to intrapartum haematuria, remain unexplored territories. The prevalence of haematuria throughout pregnancy is estimated to be approximately 3%,[284] attributed to pre-renal, renal, and post-renal factors.[285] The specific causes of haematuria during labour are not well-documented; however, it is acknowledged that bladder trauma, occurring in cases of obstructed labour, represents a significant etiological factor.[286,287] This trauma arises from the compression of the bladder between the fetal head and the symphysis pubis during episodes of obstructed labour.

The relationship between the positioning of the catheter balloon beneath the fetal head and a predisposed antenatal hypermobile blabber neck, potentially a risk factor for postpartum stress incontinence, remains unclear.[288] This investigation may illuminate a potential mechanism for urethral and urethral sphincter damage that could precipitate stress urinary incontinence, particularly in scenarios where the fetal head exerts pressure on the bladder and urethra.[289]

While the specific position of the bladder neck was not directly assessed, the presence of a low catheter balloon serves as an indirect marker. There is an established link between increased bladder neck mobility, damage to the levator ani muscle, and

the subsequent development of urinary incontinence over time.[290] Prior research has identified a correlation between increased bladder neck mobility and vaginal delivery,[291] although this association was not evident in the current study when using a low catheter balloon as an indicator.

The prospective methodology, characterised by standardised imaging of consecutively recruited participants, stands as a strength of this investigation. However, the ultrasound evaluation of catheter balloon placement, although informed by insights from a prior study and was not its primary objective, but the retrospective analysis of consecutive patients, conducted without systematic exclusions, lends robustness to the study design.

The primary limitation of this study is the absence of long-term postpartum follow-up, which precludes the reporting on sustained pelvic floor outcomes associated with a lowered position of the bladder neck. Nonetheless, this research establishes a foundation for future investigations, advocating for the inclusion of objective assessments in subsequent studies.

## 6.5 Conclusions

During active labour, one-third of the indwelling urinary catheter balloons have been visualised below the fetal head. Intrapartum haematuria occurs more frequently in cases with a low urinary catheter balloon; however, there is no association with postpartum urinary retention. Although the placement of the urinary catheter balloon does not influence the mode of delivery, a lower balloon position is associated with a prolonged duration of labour.

# CHAPTER 7

# Intrapartum Prediction Application for Vaginal Delivery: Testing and Improvement

*This work was presented at the following conferences: International Study Group on Labour and Delivery Sonography (ISLANDS) 2022, Rome, Italy; British Maternal and Fetal Medicine Society (BMFMS) 2022, Birmingham, UK; and International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) in 2022, London, UK.* https://doi.org/10.1002/uog.24996. https://doi.org/10.1002/uog.25395.

## 7.1 Background

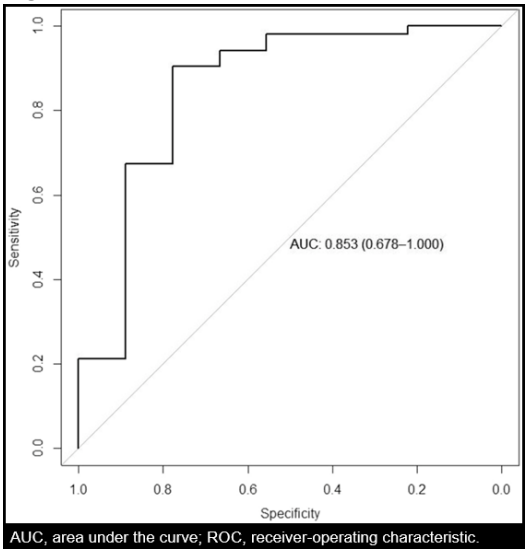
Ultrasound technology, a long-established diagnostic tool, harbors significant potential for facilitating non-invasive evaluations during labour. Its application has been predominantly confined to determining fetal heartbeat, fetal presentation and lie, the presence of multiple gestations, and the placenta's location. In the past two decades, however, the adoption of advanced ultrasound techniques in delivery suites has markedly increased. These techniques now capable of objectively assessing fetal head position,[30,41] cervical dilatation,[177] fetal head station,[147] fetal head attitude and flexion,[234] and predicting the mode of delivery.[164,171,235]

Despite multiple modifications in intrapartum care practices, a reduction in the frequency of Caesarean deliveries remains elusive.[292] The precise prediction of delivery mode in nulliparous women may herald a significant paradigm shift in obstetrical practice. A nuanced understanding variations in labour duration is of great importance for the implementation of individualised care strategies during labour management. Such strategies aim to mitigate various complications, including operative delivery, postpartum haemorrhage, perineal lacerations, sepsis, the necessity for neonatal resuscitation, and prolonged hospital stays.

The first labour prediction model was published in 2015,[195] encompassing a cohort of 122 nulliparous women. Labour classification within this cohort adhered to existing national guidelines, identifying instances of protracted labour. This study utilised maternal characteristics and ultrasound techniques including transabdominal and transperineal, alongside digital vaginal examination (DVE), to measure specific parameters including fetal head position, head-perineum distance (HPD), caput succedaneum, and cervical dilatation.

The cohort was divided into two primary sets: testing and validation with a risk score being developed through multivariable logistic regression analysis, designating vaginal birth as the intended outcome. Notably, the study elucidated a significant correlation between the dichotomized score including (HPD, caput, occiput posterior position, and prolonged labour) and the occurrence of vaginal delivery ($p$ = 0.03).[195] The prediction of vaginal birth leverages this risk score, revealing that subjects with scores surpassing the median value exhibited a tenfold increased probability of vaginal deliveries compared with participants with a score below the median (Figure 90).

***Figure 90.*** *ROC between the Dichotomized Score and Prediction of Vaginal Delivery.*[195]




AUC, area under the curve; ROC, receiver-operating characteristic.

The study posited that a risk score based on maternal characteristics in conjunction with intrapartum ultrasonographic findings, was effective despite the constrained sample size.[195] This predictive model demonstrates the capacity for predicting vaginal delivery in nulliparous women during the first stage of labour. Should this model undergo validation within a broader study sample, it could facilitate timely Caesarean interventions for individuals experiencing prolonged labour with a reduced likelihood of vaginal delivery and promises to provide reassurance to expectant mothers.

The potential to predict delivery mode could profoundly inform future decisions regarding the allocation of resources and staffing within delivery settings, ensuring optimal preparedness and resource availability.[195]

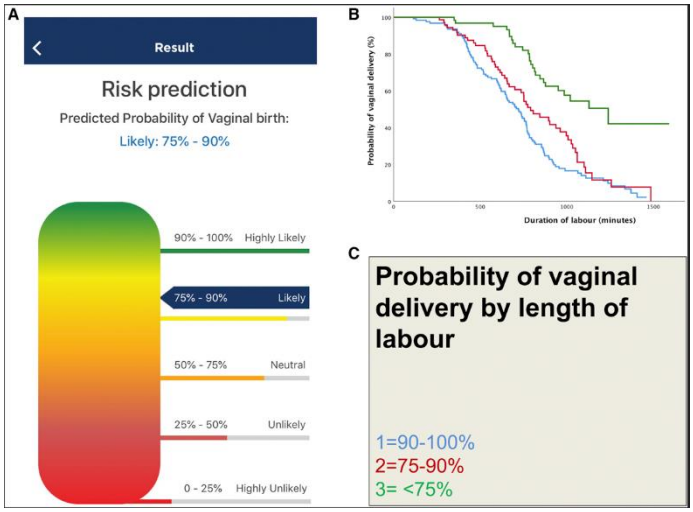
Subsequently, the intrapartum prediction application designed to operationalise this first prediction model was launched exclusively for research purposes on both Apple and Android platforms.[293,294] The primary objective was to evaluate the applicability of this predictive model, now reformulated as an application, across a diverse obstetric population. In 2019, a first investigation utilising the intrapartum app was conducted to determine the predictive capacity of vaginal delivery within an obstetric cohort distinct from that which informed the first model.[235]

Nulliparous women at term (37-42 weeks) were recruited during active labour into a prospective observational study, SONO-VE.[222] Transabdominal ultrasound was used to assess fetal head position, while a fetal head station (HPD), caput succedaneum, and moulding were assessed by transperineal ultrasound approach. Cervical dilatation was documented via DVE. Maternal and labour parameters, including maternal age, gestational age (GA), body mass index (BMI), and presence or absence of prolonged labour, were recorded on the predictive app. Ultrasound operators were not involved in the clinical management of labour, and both the ultrasound operators and attending midwives were blinded to each other's assessments to ensure unbiased results.[235]

The original model categorised the likelihood of vaginal delivery into five bands: highly likely (90-100%), likely (75-90%), neutral (50-75%), unlikely (25-50%), and highly unlikely (0-25%). The probability of vaginal delivery was analysed in relation

to the length of labour, employing Kaplan-Meier curves. These curves were constructed to compare the likelihood of vaginal delivery within three simplified categories: highly likely, likely and neutral, and unlikely, reclassified as high, medium, and low likelihood, respectively (Figure 91).[235]

***Figure 91.*** *Intrapartum Prediction of Delivery Mode App.* [235]
***A,*** *Results page of the intrapartum app displaying predictions about the likelihood of vaginal delivery;* ***B,*** *Kaplan–Meier curves comparing the likelihood of vaginal delivery as predicted by the app with the duration of labour; and* ***C,*** *Percentages of the likelihood of having vaginal delivery within the three simplified categories (high, medium, and low).*




This was the first report on an intrapartum app,[235] underscoring its potential to predict outcomes within an obstetric population distinct from that of the original model's development. The study highlighted that both the feasibility and precision of this model are now ready for evaluation in subsequent prospective studies[235].

The objectives of our work in this chapter were to evaluate the predictive application model, grounded on a new and large prospective cohort study, by utilising maternal characteristics and data derived from multiple intrapartum ultrasound examinations. This work also aimed to appraise the efficacy of both single and repeat ultrasound assessments during active labour in predicting delivery mode within the intrapartum predictive app. Additionally, it aimed to estimate the duration of labour by predicting the likelihood of vaginal delivery utilising data from the intrapartum predictive app.

## 7.2 Materials and Methods

Data from two prospective observational cohort studies: SONO-VE[222] (2015-2018) and SONO-PREDICT (2021-2022) were utilised, conducted at a large inner-city maternity unit in London, UK. Both studies received ethical approval from the UK Research Ethics Committee (REC) and local Joint Research Compliance Office (JRCO). The ethical approvals were as follows: SONO-VE: REC (Ref: 15/LO/0227) and JRCO (Ref: 14HH2428); SONO-PREDICT: REC (Ref: 20/EM/0298) and JRCO (Ref: 20QC6287).

Nulliparous women with a singleton fetus in cephalic presentation were recruited at 37-42 weeks of gestation while in active labour as defined by NICE[223] (regular painful contractions and/or progressive cervical dilatation from 4 cm) for inclusion in the studies. Informed consent was obtained individually from each participant prior to their inclusion in the study. Consent was obtained during the early stages of labour, allowing participants sufficient time to understand the study's aims and procedures and to make an informed decision regarding their involvement.

Transabdominal ultrasound (TAUS) technique (Figure 92), was conducted with women in a supine position, employing various imaging planes to assess fetal head and spine positions, perform Doppler assessments of the umbilical artery (UA) and middle cerebral artery (MCA), and quantify the amniotic fluid volume.

The transperineal ultrasound (TPUS) technique (Figure 93), was employed with women in a supine position, hips and knees flexed, and an empty bladder. This method was utilised to measure HPD (transverse plane), detect caput succedaneum (midsagittal plane), and assess the degree of fetal head moulding (midsagittal plane).

Cervical dilatation was meticulously documented concurrently with the corresponding DVE. Ultrasound assessments were repeated alongside subsequent DVEs. Maternal and labour parameters were meticulously recorded and input into the intrapartum predictive app (Figure 94). The recorded parameters included maternal age, maternal BMI, GA, the presence of prolonged labour (Yes-No), clinically assessed cervical dilatation, and the ultrasound findings including HPD, caput succedaneum, and presence of occiput posterior position (Yes-No). The app's algorithm processed these inputs to generate a predictive probability of vaginal birth, stratified into five main prognostic categories: highly likely (90-100%), likely (75-90%), neutral (50-75%), unlikely (25-50%), and highly unlikely (0-25%).

***Figure 92.*** *Transabdominal Ultrasound (TAUS) Technique Utilised for Assessing Fetal Head Position, Evaluating Fetal Doppler, and Examining Amniotic Fluid Volume during Active Labour. (The SONO-PREDICT study, informed consent for publication was obtained from the participant).*



***Figure 93.*** *Transperineal Ultrasound (TPUS) Technique in Both Midsagittal and Transverse Planes Utilised for Assessing Head-Perineum Distance, Caput Succedaneum, and Moulding during Active Labour.*

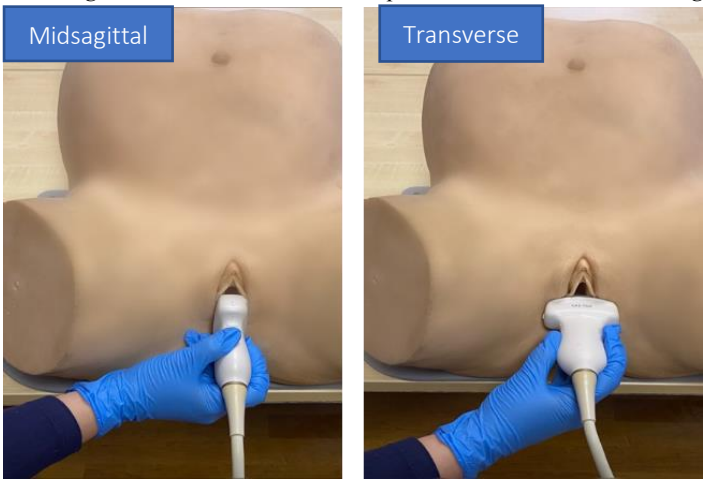
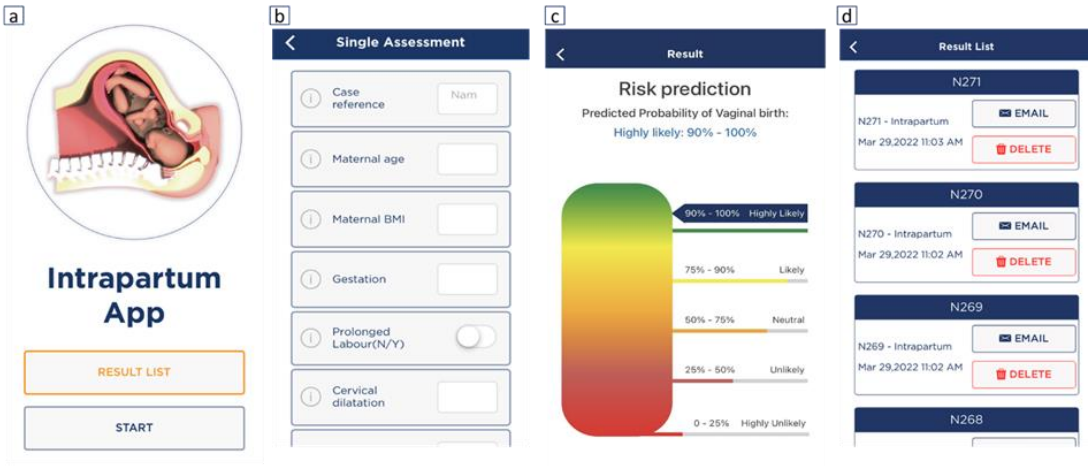


***Figure 94.*** *Intrapartum Prediction Application.* ***a,*** *Front Screen of the App;* ***b,*** *Input Data Screen;* ***c,*** *Displaying Result Screen of the Likelihood of Vaginal Delivery; and* ***d,*** *Screen Showing Stored Results.*[229]



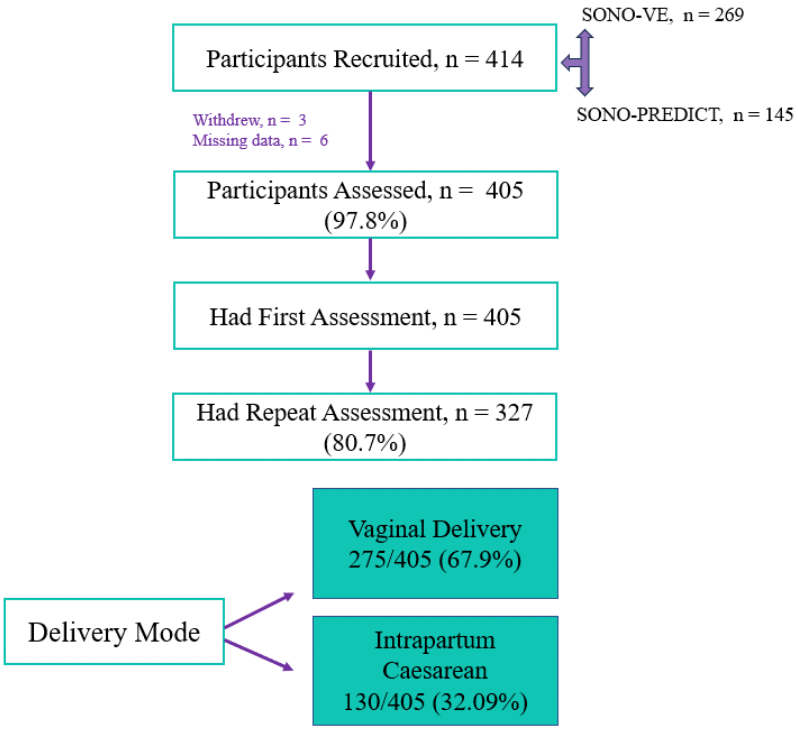

Statistical analyses were conducted using Microsoft Excel (MS) to compare the probability of vaginal delivery as assessed during the first and repeat ultrasound evaluations, categorised into the five risk groups mentioned. MS Excel was also utilised to calculate the average duration of labour and to facilitate comparative analyses of labour duration estimates. These estimates were divided into two main groups based on the predictive probability of a vaginal birth: the HIGH likelihood group (>50%) [including highly likely (90-100%), likely (75-90%), and neutral (50-75%)], and LOW likelihood group (<50%) [including unlikely (25-50%), and highly unlikely (0-25%)].

## 7.3 Results

Data were sourced from two prospective observational cohort studies conducted at the same institution, Imperial College Healthcare NHS Trust: SONO-VE[222] (2015-2018, 269 participants) and SONO-PREDICT (2021-2022, 145 participants). The studies encompassed maternal and labour data from 414 nulliparous women, of whom 3 withdrew consent and 6 had missing data. These data were consecutively recorded and entered into the intrapartum predictive application. Of the participants analysed, 81% (327/405) underwent repeat ultrasound assessments. An intrapartum Caesarean delivery (ICD) was required for 32% (130/405) of the cases (Figure 95).

The demographic profile of the participants included nulliparous women from diverse ethnic backgrounds, aged between 18 and 42 years, with a mean age of 32 years. The average gestational age at the time of the study enrollment was 41 weeks. The participants had a mean BMI of 24.6 $kg/m^2$ (range, 18-47 $kg/m^2$)

***Figure 95.*** *Flow-Chart of the Study Population.*




The predictive application generated the probability percentages of the likelihood of vaginal delivery across five categories: highly likely, likely, neutral, unlikely, and highly unlikely during the first ultrasound assessment, which were 70%, 77%, 56%, 38%, and 43%, respectively, while in the second ultrasound assessments, the corresponding probabilities were 84%, 51%, 48%, 43%, and 17%. The average probability percentages across both assessments for these five bands were 77%, 64%, 52%, 41%, and 30%, respectively. Considering the mean percentage probability of vaginal delivery derived from multiple labour assessments could improve the predictive accuracy of the prediction of delivery mode application (Table 75 and Figure 96).

The length of labour was shorter for those participants predicted to have a HIGH (>50%) likelihood of vaginal delivery.

**First labour assessment:** The average predicted labour duration for the HIGH likelihood group was 773 minutes (range, 55-2825 minutes), with 70% (264/377)

achieving vaginal delivery. In the LOW (<50%) likelihood group, the average duration was 871 minutes (range, 418-2358 minutes), with 39% (11/28) achieving vaginal delivery (Table 76).

**Repeat labour assessments:** For the HIGH likelihood group, the average predicted labour duration was 756 minutes (range, 55-2362 minutes), with 73% (198/272) achieving vaginal delivery. In contrast, the LOW likelihood group had an average duration of 903 minutes (range, 288-2495 minutes), with 35% (19/55) achieving vaginal delivery (Table 76).

Notable differences were observed in the average durations and the rates of vaginal births between the two groups. The average predicted labour duration for both assessments in the HIGH likelihood group was 765 minutes, compared to the actual labour duration of 721 minutes in the same group. For the LOW likelihood group, the average predicted labour duration was 887 minutes versus an actual labour duration of 903 minutes (Table 76).

***Table 75.*** *The Predictive App Percentages of the Probability of Vaginal Delivery during First and Repeat Labour Assessments.*

| First assessment - The five app categories | 90-100% | 75-90% | 50-75% | 25-50% | 0-25% |
|---|---|---|---|---|---|
| Expected vaginal delivery (n) | 247 | 82 | 48 | 21 | 7 |
| Actual vaginal delivery (n) | 174 | 63 | 27 | 8 | 3 |
| Actual Intrapartum Caesarean delivery (n) | 73 | 19 | 21 | 13 | 4 |
| The app precentage of the likelihood of vaginal delivery % | 70% | 77% | 56% | 38% | 43% |
| | | | | | |
| Repeat assessments - The five app categories | 90-100% | 75-90% | 50-75% | 25-50% | 0-25% |
| Expected vaginal delivery (n) | 183 | 45 | 44 | 37 | 18 |
| Actual vaginal delivery (n) | 154 | 23 | 21 | 16 | 3 |
| Actual Intrapartum Caesarean delivery (n) | 29 | 22 | 23 | 21 | 15 |
| The app precentage of the likelihood of vaginal delivery % | 84% | 51% | 48% | 43% | 17% |

***Figure 96.*** *Prediction of Delivery Mode: The Intrapartum Predictive App during First and Second Labour Assessments.*

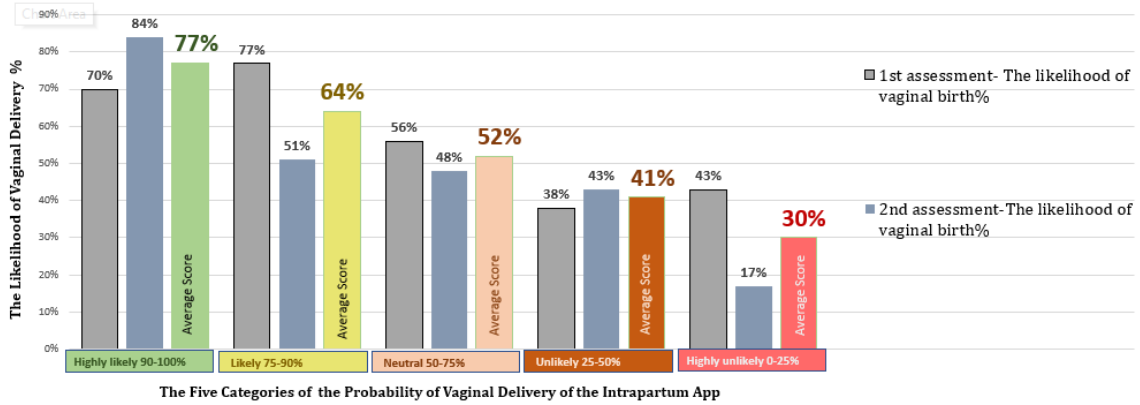



***Table 76.*** *The Average Predicted and Actual Duration of Labour for Both HIGH and LOW Groups during the First and Second Labour Assessments.*

| The App's Probability of Vaginal Delivery | HIGH | LOW |
|---|---|---|
| 1st assessment-number of participants (n) | 377 | 28 |
| 1st assessment-average predicted labour length (min) | **773** (55-2825) | **871** (418-2358) |
| 2nd assessment-number of participants (n) | 272 | 55 |
| 2nd assessment-average predicted labour length (min) | **756** (55-2362) | **903** (288-2495) |

| | |
|---|---|
| Average actual labour length of vaginal delivery (min) | 721 |
| Average actual labour length of emergency Caesarean delivery (min) | 903 |

## 7.4 Discussion

In this segment of the research, we demonstrated the feasibility of utilising an intrapartum predictive application to evaluate the efficacy of the original prediction model in an app format across diverse prospective obstetric populations. Our findings elucidate the acceptability of this model within a sizable prospective cohort. Notably, our investigation suggests that conducting repeat ultrasound assessments may enhance the accuracy of the intrapartum predictive application, despite its initial development being grounded on a single labour assessment. Using the mean score of both first and repeat assessments could improve the performance of the intrapartum predictive app. Moreover, the classification of the likelihood of vaginal delivery provided by the predictive intrapartum app offers valuable insights into labour duration, with a progression from HIGH to LOW likelihood correlating with extended labour durations.

DVE is recognised as the fundamental method for diagnosis the onset of labour and monitoring its progression. The resulting data are meticulously charted on a partogram, a graphical representation that delineates the typical length and duration of labour, originally derived from Friedman's labour curves.[11-13] The development of the partogram has been advanced in the subsequent decades.[14-18]

Nevertheless, the universal applicability of the partogram remains a subject of considerable debate.[295-297] This discourse reached its zenith with a unified consensus statement from the American College of Obstetricians and Gynaecologists (ACOG) and the Society of Maternal-Fetal Medicine, which, in 2014, promulgated novel guidelines for labour management.[298] An electronic partogram (ePartogram) has been introduced in the form of a mobile application. This application is designed to enhance both the convenience and efficacy of utilisation[24] and is embedded with a

clinical decision support mechanism, devised through an algorithm that integrates the World Health Organisation's guidelines for labour management.

Comparing ultrasound-based prediction applications in labour directly with the partogram is not feasible, given that the partogram was not designed for predicting risks. Its effectiveness in monitoring the progression of labour has also been questioned.[297] Nonetheless, in the absence of alternative means for assessing labour, the partogram is most prevalently employed tool.[299] Meanwhile, the application of intrapartum ultrasound for prediction purposes is still primarily confined to research contexts.

The evaluation of labour progress via intrapartum ultrasound, utilising different methods and techniques, is posited to play a central role in the management of labour and delivery. Our research team has outlined the conceptualisation of an ultrasound-based partogram, termed the sonopartogram,[226] predicted on a non-invasive ultrasound assessment using both transabdominal and transperineal ultrasound techniques. The sonopartogram provided a proof-of-concept based on a synthesis of labour parameters, derived from both traditional clinical examination and ultrasonographic assessment. Our team has recently extensively deliberated on the inquiry regarding the potential utility of a specific amalgamation of clinical examinations and ultrasound parameters in evaluating labour progress and predicting labour outcomes.[25]

The aim of this investigation was to utilise a real-time application for predicting the mode of delivery, incorporating both first and repeat assessments. The original predictive model was created based on a one-time assessment, with a primary focus on vaginal delivery as the outcome. However, our investigation included 414 nullipa-

rous women who participated in two prospective observational studies where intrapartum Caesarean delivery was the primary outcome. It is not anticipated that this factor will have a significant impact on our results, considering that these outcomes are binary and inversely related.

Our aim also focused on predicting the duration of labour via the real-time predictive app. This metric was not included in the original predictive model on which the application was developed. To facilitate this analysis and ensure a sufficient number of participants in each category, the likelihood bands were simplified from five to two bands: HIGH (greeter than 50%) and LOW (less than 50%) probability of the likelihood of vaginal delivery.

The impact of having the predictive information of labour outcomes has been thoroughly analysed with parents and healthcare professionals.[228-230] In addition, the significance of knowing the potential duration of labour to women and their willingness to endure a longer labour if it meant a higher likelihood of vaginal delivery have been explored in greater depth in Chapter 8.[229,230]

Having completed the predictive data analysis and established multivariable models (as elaborated in Chapter 3 and 4), we have identified the most predictive parameters for anticipating intrapartum Caesarean delivery. Following the external validating of this model, our next endeavour involves development a predictive intrapartum Caesarean delivery app. This initiative aims to transform theoretical insights into a practical application, featuring risk stratification categories such as LOW, MEDIUM, and HIGH, which predict the likelihood of intrapartum Caesarean delivery.

## 7.5 Conclusion

The findings of this chapter demonstrate that multiple clinical and ultrasound assessments may improve the accuracy of the intrapartum prediction app, even though it was originally developed based on a single assessment model. Furthermore, utilising an average score derived from both first and repeat assessments could enhance its performance. The categorisation of the likelihood of vaginal delivery provides valuable insights into labour duration, indicating that labour duration increases as the probability of vaginal delivery decreases from HIGH to LOW.

# CHAPTER 8

# The Psychological Impact of Predicting Delivery Mode Based on Ultrasound and Clinical Examinations: Views of Parents and Healthcare Professionals

*This Chapter represents a collaborative work between Imperial College London (supervised by Professor Christoph Lees) and King's College London (spearheaded by Dr Fiona Challacombe, a clinical Psychologist) and her specialist team. It includes two distinct sections. The first section, an online survey, will be submitted to the Archives of Women's Mental Health. The second section, a clinical cohort study, was submitted to Ultrasound in Obstetrics & Gynecology (UOG) on 11th of December 2023, underwent revision on 21st of December 2023, and was accepted for publication on 26th of January 2024.*

*Hanidu, A., Djongianto, T. U., Kovalenko, M., Gupta, E., Jansen, M., Usman, S., Joash, K., Challacombe, F. L., & Lees, C. (2024). Determining psychological impact of delivery mode prediction obtained from ultrasound and clinical assessment. Ultrasound in obstetrics & gynecology: the official journal of the International Society of Ultrasound in Obstetrics and Gynecology, 64(2), 261–263. https://doi.org/10.1002/uog.27601.*

## 8.1 Introduction

Parents and healthcare professionals often face significant anxiety associated with childbirth, primarily due to the uncertainties surrounding this process. These uncertainties include the timing and duration of labour, the safety of the delivery process, and the method of delivery chosen. While the immediate outcomes of delivery are critically important, the expectations and experiences related to labour and birth significantly influence parent-child bonding, postnatal psychological state, and the recovery of both mothers and their partners. Subjectively perceived adverse birth experiences can trigger psychological reactions ranging from low mood and mild stress to severe post-traumatic stress disorder (PTSD).

Emergency Caesarean sections and instrumental deliveries are associated with increased symptoms of anxiety and depression.[300] A woman's first labour experience profoundly shapes her views and future childbirth decisions.[213] Traumatic birth experiences are significant predictors of childbirth-related fear.[214] Moreover, research has shown that postpartum depression and anxiety can severely disrupt mother-child bonding.[215] Consequently, a negative or traumatic birth experiences may have a long-lasting effect on woman's interpersonal relationships and various aspects of her life.

The unpredictable nature of childbirth events, particularly those occurring during and prior to labour, presents significant challenges to a woman's coping abilities. A clear correlation exists between the unpredictability of childbirth and the fear of childbirth (FOC), particularly among women with pre-existing fears, as demonstrated in a meta-analysis of 25 studies.[216] Various factors contribute to this fear, including fear of the unknown, risk of injury, anticipated pain, loss of control, and

concerns about receiving adequate support from healthcare providers.[216] Two main factors that moderate this fear are the quality and clarity of information about childbirth provided and the level of support from healthcare professionals. Additionally, an awareness of potential adverse birth outcomes is a critical component of this fear.[216] Fear of the unknown and the unpredictable are key factors among pregnant women experiencing FOC.[301]

Pregnant women are often encouraged to create a birth plan, outlining their preferences for the birthing experience. However, the process of advance planning may have the disadvantage in some women of setting expectations that are discrepant with reality.[302] Research indicates that birth plans have mixed effects on enhancing the birthing experience, and their overall utility remains unclear. While birth plans may reduce the incidence of pregnancy complications and improving obstetric outcomes, they can subjectively lead to less satisfactory birthing experiences.[303] However, another study found that women who had formulated a birth plan reported improved subjective birthing experiences and an enhanced sense of control during childbirth.[304]

Women's sense of control and choice in childbirth appears to be important in their overall experience. Antenatal education with an open discussion on the unpredictable nature of labor and different modes of delivery has a positive effect on women's FOC and perceived ability to cope with pain during labour.[305] Notably, a strong preference for vaginal birth in women who experience emergency Cesarean delivery has been associated with FOC postnatally.[306] Hence, the concept of predictability is of particular significance. The issue of how this might interact with women's perceptions of the importance of choice during pregnancy is an important one.

A combination of intrapartum ultrasound and clinical examinations has been used recently to develop a predictive model for vaginal birth.[195] An application based on this model, which utilises a traffic light system to categorise the likelihood of vaginal delivery, is currently available exclusively for research purposes.[293,294] This app also provides insights into the expected duration of labour.[235] The acceptability of abdominal and transperineal ultrasound techniques during active labour has been confirmed.[228] However, the impact of predictive information on the birthing experiences of women and their partners requires further investigation. Additionally, the perspectives of healthcare professionals, including obstetricians and midwives, on the use of birth prediction in labour management are vitally important.

The first part of this study was designed to comprehensively explore and understand the perspectives of both parents and healthcare professionals regarding the receipt of predictive information during labour. An online survey served as our primary data collection method, aiming to gather a diverse range of opinions and insights on the use and efficacy of predictive data in facilitating informed decisions about labour and delivery processes. The second part involved employing validated questionnaires to assess levels of depression and anxiety, examining both the immediate and prolonged psychological impacts of this predictive information on women during active labour.

## 8.2 Materials and Methods

Ethical approval for this study was obtained on the 23rd of July 2021 by the London–Harrow Research Ethics Committee (REC), under IRAS number 296778 and REC number 21/LO/0432.

### 8.2.1 Online Survey for Parents and Healthcare Professionals

Participants were recruited via social media, flyers, and posters at an inner-city London hospital, and directly by the research team positioned in the Maternity Day Assessment Unit (MDAU). The MDAU provides day-assessment services for women beyond 20 weeks of gestation. The recruitment targeted healthcare professionals, including obstetricians and midwives, as well as pregnant women, new parents, and their partners up to one year postpartum. The recruitment materials featured a direct link and a QR code to facilitate easy access to the study.

The study utilised the online platform Qualtrics XM to guide participants through an informational sheet and a confidential consent form. Based on their responses to an initial screening question, participants were directed to the appropriate survey, either for parents or healthcare professionals. The surveys included both rating scales and open-ended questions.

Healthcare professionals offered insights into the utility of predictive data from both clinical and patient perspectives. Parents provided accounts of their own or their partner's childbirth experiences, focusing on the type of delivery, levels of anxiety, and confidence prior to labour. They also expressed their views on the importance of predictive data. Participants rated their experiences on various aspects of the de-

livery and the perceived benefits of having such predictions on a scale of 0-10 (Appendix 13). These ratings underwent between-group comparisons using Mann-Whitney U tests.

### 8.2.2 Clinical Cohort Study

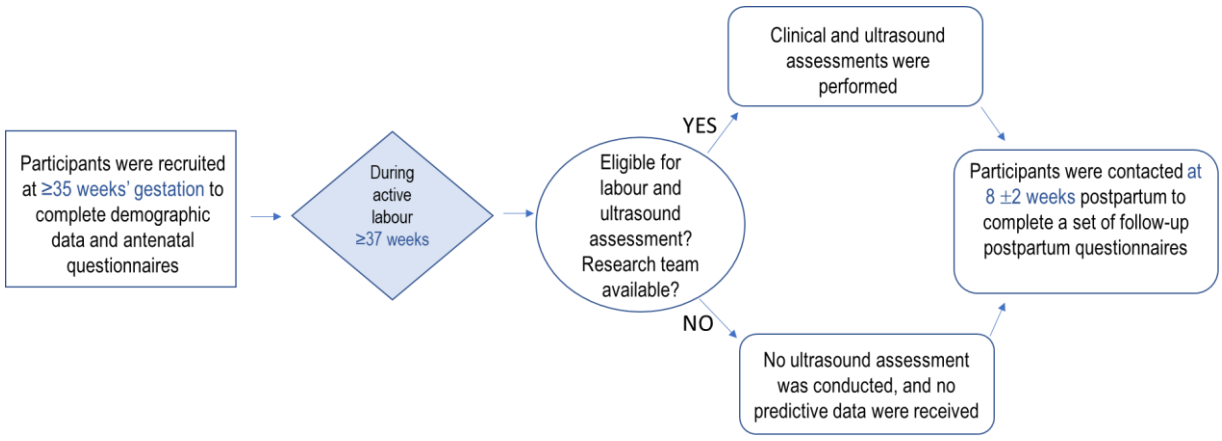
A research team approached women antenatally to confirm their eligibility based on predefined inclusion criteria. After being informed about the study, the participants were given a tablet to complete the consent form and antenatal questionnaires. Researchers were on hand to assist with any technical issues or inquiries during this initial process. Upon arrival at the delivery suite, a consenting participant was reassessed by an available research team member to re-evaluate eligibility for labour and ultrasound assessments. If deemed eligible, both clinical and ultrasound assessments were conducted. During active labour, cervical dilatation (CD) was assessed via digital vaginal examination (DVE), followed by an ultrasound assessment. The transabdominal ultrasound (TAUS) method evaluated fetal head position, amniotic fluid volume, and fetal Doppler measurements, while the transperineal ultrasound (TPUS) technique assessed fetal head station by measuring head-perineum distance (HPD), caput succedaneum, and fetal moulding.

Subsequently, labour data were entered into the intrapartum prediction application to obtain predicted outcomes. The intrapartum predictive application's output provided probabilities of vaginal birth, categorised as highly likely (90-100%), likely (75-90%), neutral (50-75%), unlikely (25-50%), or highly unlikely (0-25%).

This predictive data was then communicated to the participants and their partners by a research team specifically trained in intrapartum ultrasound imaging. It is im-

portant to note that the ultrasound results and predictive information were not disclosed to the medical team to prevent any influence on clinical decision-making. Participants provided their email addresses and were contacted at 8±2 weeks postpartum to complete a set of follow-up postpartum questionnaires. As a token of appreciation, participants received a £10 voucher. Figure 97 illustrates the various stages of the clinical cohort study.

***Figure 97.*** *Recruitment Process of the Clinical Cohort Study*




### 8.2.3 Inclusion and Exclusion Criteria

| Inclusion Criteria-Antenatal | Inclusion Criteria- Intrapartum |
|---|---|
| • Nulliparous women<br>• Live singleton pregnancy<br>• Cephalic presentation<br>• Gestation ≥ 35 weeks<br>• Age ≥ 18 years old | • Participants who provided consent antenatally<br>• Cephalic presentation<br>• Gestation ≥ 37 weeks<br>• Active labour as defined by NICE[223] (regular painful contractions and/or progressive cervical dilatation from 4 cm) |
| Participants who did not meet the inclusion criteria, those unable to adequately understand verbal or written information in English, or individuals with specific communication needs were excluded from the study. | |

### 8.2.4 Validated Psychometric Questionnaires Utilised for the Clinical Cohort Study (Appendix 14)

#### Measures Administrated Solely during the Antenatal Period:

- **Fear of Birth Scale (FOBS):** Participants were asked, "How do you feel right now about the approaching birth?". Their responses were recorded using two visual analogue scales: (a) ranging from 'calm' to 'worried' (FOBS Worry), and (b) from 'no fear' to 'strong fear' (FOBS Fear).[307]

#### Measures Administrated during both Antenatal and Postnatal Periods:

- **Depression, Anxiety and Stress Scale (DASS):** The DASS, a 21-item self-report questionnaire, evaluates levels of depression, anxiety, and stress. It has demonstrated satisfactory internal consistency across subscales in a sample of pregnant women: depression (0.84), anxiety (0.77), and stress (0.86). This questionnaire was integrated into both antenatal and postnatal questionnaires.[308] Postnatal DASS scores were compared with antenatal scores using the Wilcoxon Signed-Ranks tests. The median difference between antenatal and postnatal DASS scores for each subgroup was determined and compared using the Mann-Whitney U tests and Statistical Package for the Social Sciences (SPSS).
- **Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ):** This questionnaire, validated and commonly used for assessing FOC, was employed in its validated English version, adapted from the original Dutch.[309] The W-DEQ consists of 33 items that evaluate antenatal fear of labour and childbirth (W-DEQ A), focusing on women's cognitive and emotional anticipations. Responses are scored on a 1-6 scale, with higher scores indicating greater FOC, and a score of 85 or above indicating extreme FOC. For postnatal assessments, participants evaluated their childbirth experience using the validated post-labour version (W-DEQ B).

## 8.3 Results

### 8.3.1 Online Survey

Between April and August 2022, a total of 85 respondents participated in the online survey, consisting of 50 parents and 35 healthcare professionals (Table 77).

- **Parental Survey**

Parents were asked to rate their opinions on different aspects of their most recent or upcoming labour and childbirth experience. Evaluations included their anxiety levels concerning childbirth, potential changes to the mode of delivery during labour, their preference for knowing the delivery method beforehand, and the impact of receiving predictive information on their confidence. The usefulness of such information was rated on a scale from 0 to 10. Notably, participants were given the flexibility to respond only to questions they felt comfortable answering, omitting any they preferred to avoid (Table 78).

Parents were also invited to share, in free text responses, any additional information they found beneficial during pregnancy and labour, as well as any concerns about receiving predictive information. Their responses are summarised in Table 79. Twenty-eight percent of participants (14/50) expressed a desire for a more comprehensive understanding of different sensations experienced during labour and a more clarity of what to anticipate on the day of labour. One respondent stated she would have appreciated knowing the expected duration of labour. The primary advantage identified by parents in receiving predictive information was an enhanced sense of preparedness, (e.g., "…know how long I'd be spending at the hospital", "choice of pain relief", and "help with birth plan").

Eight percent of respondents (4/50) had specific concerns regarding the receipt of predictive data: four percent (2/50) indicated that such information could induce

stress, especially among those with a strong preference for a particular type of delivery. Others expressed doubts about the accuracy of the predictions, and one raised the concern of becoming excessively focused on details and it might lead to overthinking. Overall, parents believed that access to this predictive information in advance would improve their psychological preparedness for labour and childbirth, enable better arrangements for the care of existing children, and potentially reduce anxiety surrounding the birthing process.

***Table 77.*** *Demographic Characteristics of Participants in the Online Survey.*

| **Parents** | N = 50 | | | |
|---|---|---|---|---|
| | Pregnant women | Partners | Postnatal women | Prefer not to disclose |
| N | 26 | 6 | 11 | 7 |
| Age | | | | |
| *Range* | 24-39 | 34-42 | 27-38 | 27-51 |
| Weeks pregnant | | | | |
| *Range* | 7-40 | - | - | - |
| Ethnicity | | | | |
| *White* | 5 | 2 | 2 | 1 |
| *Mixed or multiple ethnic groups* | 0 | 1 | 1 | 0 |
| *Asian or Asian British* | 10 | 2 | 2 | 1 |
| *Black, African, Caribbean, or Black British* | 4 | 0 | 0 | 0 |
| *Arab* | 6 | 1 | 6 | 5 |
| *Other* | 1 | 0 | 0 | 0 |
| Employment | | | | |
| *Full-time* | 13 | 5 | 3 | 0 |
| *Part-time* | 5 | 1 | 1 | 1 |
| *Self-employed* | 3 | 0 | 1 | 1 |
| *Home maker* | 2 | 0 | 0 | 1 |
| *Student* | 1 | 0 | 3 | 3 |
| *Unemployed* | 2 | 0 | 1 | 0 |
| *Prefer not to say* | 0 | 0 | 2 | 1 |
| **Healthcare professionals** | N = 35 | | | |
| | Midwives | | Obstetricians | |
| N | 8 | | 27 | |
| Gender | | | | |
| *Male* | 0 | | 7 | |
| *Female* | 8 | | 20 | |
| Years worked in profession | | | | |
| *Median* | 9.50 | | 9.00 | |
| *Range* | 3-10 | | 1-10 | |

***Table 78.*** *Responses from Parents to the Online Survey.*

| Questions | N=50 | Mean (SD) |
|---|---|---|
| How anxious do you feel about delivery? (0-10) | 37 | 4.95 (2.39) |
| How anxious do you feel about knowing or not knowing the birth delivery mode (vaginal or caesarean)? (0-10) | 38 | 5.05 (2.71) |
| How confident do you feel that you were going to deliver by this mode? (0-10) | 32 | 6.24 (2.41) |
| How confident do you feel in your ability to cope during labour? (0-10) | 38 | 5.47 (2.61) |
| Would you want to know (the delivery mode)? | 33 | |
| YES (%) | 29 (87.9%) | - |
| NO (%) | 4 (12.1%) | - |
| How helpful would it be to know (the delivery mode)? (0-10) | 33 | 6.74 (2.89) |

***Table 79.*** *Themes Identified in Open Responses in the Online Survey for Parents.*

| Themes | Responses *(quotes in italics)* |
|---|---|
| **There is a lack of clarity during labour** | Would have liked clearer understanding of different sensations during labour |
| | More clarity on what would happen on day of labour |
| | Would have liked to know how long labour would take |
| **Prediction information helpful for preparation** | *"…know how long I'd be spending at the hospital"* |
| | *"choice of pain relief"* |
| | *"help with birth plan"* |
| | Preparing mentally for upcoming birth |
| | Reducing anxiety |
| | Planning childcare arrangements |
| **Concerns about prediction** | Prediction may be inaccurate |
| | Having prediction may lead to overthinking |
| | Having prediction may be stressful if have strong preference for one delivery mode and prediction does not align with preference |

- **Healthcare Professionals' Survey**

A total of 35 healthcare providers participated in the study, including 27 obstetricians and 8 midwives. They were asked to rate various aspects of the predictive information provided. Specifically, their evaluations focused on their confidence in disclosing such prognostic data to women in labour, their opinions on whether these women would wish to be informed of such details, and the perceived utility of this information for both the expectant mothers and their labour management strategies. Responses were measured on a scale from 0 to 10.

A statistically significant difference was observed between the two professional groups in terms of their confidence in presenting and disclosing the predictive information to parents, with obstetricians exhibiting a higher level of confidence compared to midwives (mean = 7.00/10 vs. 5.13/10; $p = 0.009$). However, both groups held similar views regarding the utility of the prediction information, there was no difference between them regarding how helpful they perceived this information to be for the woman and for their own work. Descriptive statistics for these evaluations are provided in Table 80.

Additionally, a thematic analysis of the open-ended questions from the healthcare professionals' survey, including representative quotations, is detailed in Table 81. In general, both groups acknowledged the potential impact of these prognostic information on women and labour management. Notably, obstetricians demonstrated greater confidence in the accuracy of these predictions compared to midwives.

***Table 80.*** *Responses from Healthcare Professionals to the Online Survey.*

| Questions | Midwives (n = 8) | Obstetricians (n = 27) |
|---|---|---|
| How confident would you feel disclosing prediction information? (0-10) | | |
| Mean (SD) | 5.13* (1.81) | 7.00* (2.02) |
| Range | 2-8 | 1-9 |
| What is the lowest percentage accuracy rating you would feel comfortable disclosing the prediction information to women? | | |
| Mean (SD) | 61.3 (25.88) | 62.10 (30.01) |
| Range | 30-100 | 10-100 |
| Do you think pregnant women would want to know (the prediction information)? | | |
| Yes (%) | 6 (75%) | 20 (74.1%) |
| Maybe (%) | 2 (25%) | 6 (22.2%) |
| No (%) | 0 (0.0%) | 1 (3.7%) |
| How helpful would this be for the pregnant woman? (0-10) | | |
| Mean (SD) | 6.33 (2.29) | 7.27 (1.97) |
| Range | 2-9 | 1-9 |
| How helpful would this be in doing your work (0-10)? | | |
| Mean (SD) | 5.56 (2.50) | 6.96 (1.88) |
| Range | 1-9 | 2-10 |
| What is the lowest % accuracy rating you would use this prediction information in the pregnant women's management of care? | | |
| Mean (SD) | 65.00 (27.00) | 66.50 (25.02) |
| Range | 30-100 | 0-100 |

*$P < 0.05$

***Table 81.*** *Themes Identified in Open Responses in the Online Survey for Healthcare Professionals**

| | Midwives | Obstetricians |
|---|---|---|
| **Accuracy** | Doubts about accuracy | High accuracy of the instrument |
| | *"Labour is more than an algorithm"* | *"The patient should have all the information"* |
| | | *"Would give women realistic expectations"* |
| **Impact on care in labour** | Support in decision-making. | Possible impact on care in labour |
| | | *"It could lead to additional uncertainty and potentially over-intervention"* |
| **Impact on woman** | Women want to prepare | Women will want to know |
| | Women may fixate or be disheartened | Could improve satisfaction with care |
| | *"some women will be upset, and this could fracture the relationship of mother/midwife."* | *"They would find it easier than routine discussions if % are used."* |
| | *"This opens up the conversation of 'risk'. However, I do not believe a woman can be reduced to a risk number"* | |
| | It could be a help or a hindrance | |
| **Organisational planning** | On an organisational level | May help manage workloads |
| | *"Normalising for high-risk women"* | |
| | *"Should be a birth plan option"* | |
| **Influence on management** | *"It could influence care and women not to persist with labour"* | *"May influence management and compromise choice"* |
| | *"this tool will further medicalise the management of birth"* | *"More c-sections"* |

*Themes not italicized, quotes in italics.

### 8.3.2 Clinical Cohort Study

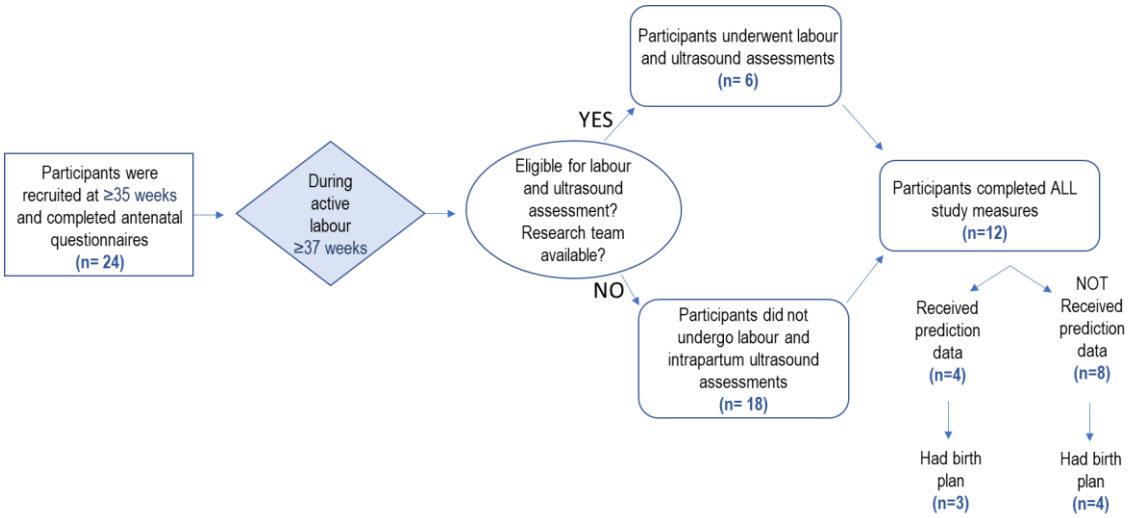
Of the 24 participants who completed the antenatal measures, 6 (25%) underwent intrapartum ultrasound and received predictive information. The remaining 18 participants (75%) did not undergo assessment during labour for various reasons, including arrival at the labour ward prior to 37 weeks of gestation, non-cephalic fetal presentation, reluctance towards scanning, a late decision to opt for a Caesarean section, or the unavailability of the research team outside their scheduled working hours.

Twelve out of the twenty-four participants (50%) completed all study measures. Demographic characteristics of these participants, including nulliparous women aged between 22 and 37 years, with a mean age of 30.25 years (Table 82). Amongst them, 4 (33%) had previously undergone intrapartum ultrasound and received the associated predictive information (Figure 98).

***Table 82.*** *Demographic Characteristics of Participants who Completed All Clinical Study Measures.*

| | Had Prediction Information | Did not have Information |
|---|---|---|
| Age | | |
| Mean (SD) | 31.35 (3.42) | 31.20 (4.45) |
| Ethnicity (%) | | |
| White | 4 (100.0%) | 4 (50.0%) |
| Mixed or multiple ethnic groups | 0 | 0 |
| Asian or Asian British | 0 | 3 (37.5%) |
| Black, African, Caribbean or Black British | 0 | 1 (12.5%) |
| Employment status (%) | | |
| Full-time | 4 (100.0%) | 5 (62.5%) |
| Part-time | 0 | 1 (12.5%) |
| Self-employed | 0 | 1 (12.5%) |
| Homemaker | 0 | 0 |
| Prefer not to say | 0 | 1 (12.5%) |
| Relationship status (%) | | |
| Married/Partner | 3 (75.0%) | 7 (87.5%) |
| Divorced | 0 | 1 (12.5%) |
| Prefer not to say | 1 (25.0%) | 0 |
| Past miscarriage | | |
| Yes | 0 | 2 (25.0%) |
| IVF for current pregnancy? | | |
| No | 4 (100.0%) | 8 (100.0%) |
| Prefer not to answer | 0 | 0 |

***Figure 98.*** *Flow-Chart of the Clinical Cohort Study Population and Recruitment Process.*




Two groups were established for the clinical study: Group 1, which received predictive information, and Group 2, which did not. Prenatally, both groups exhibited high levels of childbirth fear, as evidenced by the scores on the FOBS and W-DEQ (Table 83). Group 1 demonstrated significant changes and decrease in DASS scores from antenatal to postnatal, except in the Anxiety subscale ($p$ = 0.283), with observed changes in total DASS ($p$ = 0.008), Depression ($p$ = 0.004), and Stress ($p$ = 0.048) scores (Table 83). Conversely, Group 2 showed significant changes and postnatal increase in all DASS subscales except Anxiety ($p$ = 0.214), with observed changes in the total DASS ($p$ = 0.012), Depression ($p$ = 0.012), and the Stress ($p$ = 0.017) scores (Table 83).

Among the participants who received predictive information, 3 out of 4 (75%) were assessed as highly likely to have a vaginal delivery, and 1 out of 4 (25%) received a neutral prediction. All these participants (4/4, 100%) ultimately underwent vaginal deliveries. Conversely, among those who did not receive the predictive data (8/12, 67%), 4 out of 8 (50%) delivered vaginally, and the remaining 4 out of 8 (50%) underwent Caesarean sections (Table 83).

***Table 83.*** *Psychometric Outcomes of Receiving Predictive Information on Delivery Mode Via Intrapartum Ultrasound Prediction Application.*

| | Had Prediction Information 4/12 (33%) | Did not Have Information 8/12 (67%) |
|---|---|---|
| **Birth Plan** | | |
| Had birth plan (%) | 3 (75.0%) | 4 (50.0%) |
| **Measures** | | |
| **WDEQ** | | |
| Scale (1-6) | | |
| Range of scores (33-198) | | |
| WDEQ-A | | |
| Median (Range) | 98.50 (89-116) | 99 (64-122) |
| N above cutoff of 85 (%) | 4 (100.0%) | 6 (75.0%) |
| WDEQ-B | | |
| Median (Range) | 102.50 (71-141) | 108.5 (73-134) |
| **FOBS** | | |
| Scale (0-100) | | |
| Range of scores (0-100) | | |
| Worry | | |
| Median (Range) | 65.5 (30-70) | 61 (20-91) |
| Fear | | |
| Median (Range) | 65.5 (60-80) | 68.5 (20-93) |
| **DASS** | | |
| Scale (0-3) | | |
| Range of subscale scores (0-21) | | |
| Range of total scores (0-63) | | |
| Total | | |
| Pre | | |
| Median (Range) | 13.5 (6-23) | 9.00 (0-19) |
| Post | | |
| Median (Range) | 5 (3-23) | 21.5 (3-48) |
| Anxiety | | |
| Pre | | |
| Median (Range) | 5.5 (0-8) | 2 (0-10) |
| Post | | |
| Median (Range) | 0.5 (0-9) | 3.5 (0-13) |
| Depression | | |
| Pre | | |
| Median (Range) | 3.00 (0-5) | 1 (0-3) |
| Post | | |
| Median (Range) | 0 (0-4) | 5 (1-13) |
| Stress | | |
| Pre | | |
| Median (Range) | 6.5 (3-10) | 4.5 (0-8) |

| | | |
|---|---|---|
| Post | | |
| Median (Range) | 4.5 (3-8) | 10.5 (2-20) |
| **Experience of birth** | | |
| Type of birth | | |
| Vaginal (%) | 4 (100.0%) | 4 (50.0%) |
| Caesarean (%) | 0 | 4 (50.0%) |
| Prediction information | | |
| Highly likely | 3 | - |
| Neutral | 1 | - |
| Anxiety in labour Scale (0-100) | | |
| Median (Range) | 45 (10-100) | 73.5 (45-100) |
| Confidence in coping during labour Scale (0-100) | | |
| Median (Range) | 45.5 (0-87) | 63.5 (30-95) |
| Birth differed from plan? | | |
| Yes (%) | 3 (75.0%) | 6 (75.0%) |
| How upset about differing? Scale (0-100) | | |
| Median (Range) | 32 (15-50) | 54.5 (0-100) |
| No (%) | 0 (0.0%) | 2 (25.0%) |
| Prefer not to say (%) | 1 (25.0%) | 0 (0.0%) |
| Recommends/would have liked prediction info (%) | 2 (50.0%) | 6 (75.0%) |
| **How helpful was…** | | |
| Having prediction info? (0-100) | | |
| Median (Range) | 54.5 (19-80) | - |
| Not having prediction info? (0-100) | | |
| Median (Range) | - | 24 (0-50) |

WDEQ, Wijma Delivery Expectancy/Experience Questionnaire (WDEQ-A is the original version while the WDEQ-B is the adapted postnatal version); FOBS, Fear of Birth Scale; DASS, Depression Anxiety and Stress Scale. Increasing WDEQ and FOB scores indicate greater fear of childbirth. Increasing DASS scores denote increasing levels of depression, anxiety and stress.

## 8.4 Discussion

This study represents the first investigation of the perspectives of both parents and healthcare professionals regarding the reception of birth prediction information and examines the psychological impact of providing such birth prognostic data to women during the active first stage of labour. The online survey revealed a pronounced interest among women in knowing their likelihood of either a vaginal or Caesarean delivery. The majority of healthcare professionals (obstetricians and midwives) concurred that such prognostication was appreciated by women and considered it beneficial for both the patients and their own clinical practice. However, it was noted that midwives exhibited less confidence in delivering these predictions. A comparative analysis between women who were received the prediction and those who did not, revealed an association between the provision of this information and improved psychological outcomes post-delivery.

Parents who responded to the survey, including both nulliparous and multiparous women and their partners, demonstrated a substantial interest in receiving predictive information, particularly concerning the predicted mode of delivery prior to labour. This was primarily for the purpose of enhanced preparedness. These findings resonate the theme of unpredictability in childbirth identified by Sheen K. and Slade P.,[216] specifically highlighting the fear of the unknown and its key role in the development of FOC. Providing a prediction for the mode of delivery would mitigate a significant unknown in childbirth, thereby understandably reducing anxiety surrounding the birth.

There was a general consensus on the usefulness of having such information. It was widely agreed that this knowledge would aid in planning practical arrangements and alleviating anxiety surrounding birth. These observations align with the findings of

Wilkinson M. et al.[228] who evaluated the acceptance of intrapartum ultrasound among nulliparous women in the early stages of labour.

Both obstetricians and midwives demonstrated congruent perspectives on women's desire for information and their own confidence in providing such data. Notably, both professional groups indicated a preference for a higher accuracy percentage for predictions to be utilised in care management, with the lowest acceptable percentages being 67% for obstetricians and 65% for midwives. They considered lower accuracy thresholds adequate for disclosure, at 62% for obstetricians and 61% for midwives. Both professional groups expressed concern about the potential impact of the prediction on the management of care, agreeing that it may limit choice in labour.

Midwives, in particular, exhibited more ambivalence concerning the utility of prediction for women, rating its helpfulness lower than obstetricians. They voiced apprehension about the possibility of prediction ultrasounds becoming routine, potentially leading to further medicalisation of birth management. Wilkinson M. et al.[228] also found similar concerns during focus group discussions with midwives. Given that the medicalisation of birth is a debated issue in midwifery,[331] an exploration into the views of healthcare professionals and parents from diverse cultural backgrounds, particularly those averse to the medicalisation of childbirth, would constitute a compelling extension of this research.

A notable point in the current study is the absence of concerns among midwives regarding skill attrition due to the utilisation of ultrasound, a significant issue highlighted in Wilkinson's study.[228] This may be indicative of an increasing utilisation and endorsement of intrapartum ultrasound within the healthcare professional community.

This study is subject to a number of limitations. Firstly, the sample size was relatively small, constrained by the study being conducted at a single centre, which may affect its generalisability. Secondly, the study materials were exclusively available in English language, thereby limiting our ability to capture perspectives from non-native English speakers. This constraint potentially introduces a cultural bias into our sample. However, we did capture a wide range of ethnic backgrounds in our sample (online surveys). It would thus be an interesting extension of this research to replicate this study more globally to gauge attitudes towards receiving prediction information before active labor, given the high acceptability of intrapartum ultrasound among women globally.[133,280]

Furthermore, the study did not investigate the participants' history of pregnancy complications, a factor that could have significantly influenced their attitudes towards receiving predictive information. Moreover, all participants who received the predictive information underwent vaginal deliveries, whereas those who did not receive the information had a distribution of 50% vaginal deliveries and 50% Caesarean sections, however, the limited power of the clinical cohort study (n = 24, with 12 out of 24 receiving the predictive information) could affect these results, which necessitates further investigation.

Nonetheless, considering the novelty of advanced techniques of intrapartum ultrasound, we believe this study serves as a sufficient initial step in gauging general attitudes toward receiving predictive information before active labour and examining psychological impact of receiving such information, which showed association with lower postnatal depression, stress, and anxiety compared to antenatal scores.

## 8.5 Conclusion

This study investigated the attitudes of parents and healthcare professionals towards the utility of ultrasound during labour and the reception of predictive delivery outcome information. Notably, all respondents seemed receptive to the idea of having an intrapartum ultrasound assessment and receiving prediction information before active labour. Parents felt that knowing this information beforehand would be helpful in preparing for the upcoming birth and reducing anxiety around it. However, there were differences in opinion between obstetricians and midwives regarding the use of this predictive information in labour management.

These findings can begin to inform a strategy for more widespread implementation of intrapartum ultrasound for predicting the delivery mode before active labour. However, more diverse views must be considered, such as those from parents and healthcare professionals with different cultural backgrounds before any concrete recommendations can be made. Nonetheless, the study results highlight the important potential that addressing the unpredictability of labour outcomes through predictive data could enhance the birth experience and improve postpartum mental health.

# CHAPTER 9

# Obstetric Ultrasound and Intrapartum Ultrasound Training and Simulation

*(Intrapartum Ultrasound Training Using Optical Ultrasound Simulation, AJOG, 2024)*
*Clark, A. E., Patel, N., Kovalenko, M., Hanidu, A., Usman, S., & Lees, C. (2024). Training for intrapartum sonography using optical ultrasound simulation. American journal of obstetrics and gynecology, 230(3S), S913–S916. https://doi.org/10.1016/j.ajog.2023.08.025*

## 9.1 Introduction

Diagnostic ultrasound imaging is pivotal in obstetrics and gynaecology. As a precise, straightforward, and safe modality, it is universally applicable, suitable for both developed and developing regions. Proper education of healthcare professionals who perform ultrasonographic procedures is essential. The International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) advocates for excellence in practices, education, and research in women's healthcare imaging.[310]

In the United States and Europe, the integration of ultrasound training within OB-GYN residency programmes is well-established, recognising the essential need for foundational skills in ultrasound for obstetric practitioners to provide appropriate care in emergencies.[311,312] Obstetricians must exhibit proficiency in performing, understanding, and interpreting pelvic ultrasound assessments.[313,314] The Royal College of Obstetricians and Gynaecologists (RCOG)'s most recent curriculum update equates ultrasound proficiency with other crucial procedural competencies, such as laparoscopy and Caesarean section.[315,316]

The effectiveness of ultrasound critically depends on the operator's skill in managing the equipment and accurately procuring and interpreting imagery. Mastery in this field necessitates relentless practice for optimal results.

To this end, a plethora of theoretical and practical ultrasound training sessions, courses, and seminars have been diligently attended throughout the Ph.D. journey to master a myriad of advanced methodologies and techniques in ultrasonographic imaging.

## 9.2 Transabdominal and Transvaginal Ultrasound Training

The period of ultrasound training extended from July to November 2020 and included both day and night shifts. The training was conducted in the main ultrasound department at Queen Charlotte's and Chelsea Hospital, London, UK. The programme incorporated theoretical components utilising ultrasound textbooks, hospital imaging protocols, and scientific sonographic articles and guidelines.[317-320] Additionally, practical training conducted within a formally supervised setting, aiming to equip trainees with the skills necessary to perform ultrasound evaluations across the three trimesters of pregnancy. Upon completion of the programme, a comprehensive evaluation focused on the application of ultrasound procedures on actual patients was conducted; the assessment reports were subsequently submitted to the supervisors at Imperial College London for final consideration.

### 9.2.1 Ultrasound in the First Trimester

Ultrasound examinations in the first trimester are not universally required. However, in cases of high-risk factors such as advanced maternal age, multiple pregnancies, or clinical concerns like irregular menstrual cycles or vaginal bleeding, multiple ultrasounds may be advised based on the clinical judgment. Ideally, the initial ultrasound should be scheduled between 10+0 and 13+6 weeks.[317] Ultrasounds conducted prior to ten weeks are common and can provide precise assessments for most clinical decisions.[318]

Ultrasound in the first trimester serves various medical purposes, including experiencing pelvic pain, the possibility of ectopic or multiple pregnancies, vaginal bleeding, the suspicion of trophoblastic disease, evaluation for anomalies in fetal growth, measurement of nuchal translucency, analysis of pelvic masses or abnormalities in uterus, ascertain precise gestational age, and monitor cardiac activity.[317,318]

**The training programme in the first trimester covered topics such as:**

1. Understanding the ultrasound characteristics of early normal pregnancy, including gestational sac, yolk sac, and embryo.
2. Identifying criteria for fetal viability.
3. Diagnosing ectopic and molar pregnancy.
4. Performing biometric measurements: Crown-Rump Length (CRL) and Mean Gestational Sac Diameter (MSD).
5. Determining chorionicity and amnionicity in multiple pregnancies.
6. Identifying detectable fetal abnormalities in the first trimester.

### 9.2.2 Ultrasound in the Second Trimester

The second trimester anatomy scan is standard for assessing fetal anatomy and identifying potential anomalies. If only one ultrasound is to be performed during pregnancy, it should ideally take place between 18-22 weeks to detect any abnormalities.[319] This scan provides insights into the number of fetuses, gestational age, and placental location, and is crucial for diagnosing congenital abnormalities and maternal pelvic pathology.[320]

**The training programme in the second trimester covered topics such as:**

1. Assessing fetal position and movement.
2. Evaluating Amniotic Fluid Index (AFI) and placental location.
3. Conducting fetal biometry, including Biparietal Diameter (BPD), Head Circumference (HC), Abdominal Circumference (AC), Femur Length (FL) and Estimated Fetal Weight (EFW).
4. Performing detailed anatomical survey.
5. Examining umbilical cord insertions.

### 9.2.3 Ultrasound in the Third Trimester

The third trimester growth scan is crucial for monitoring pregnancy progression and detecting fetal and maternal pathologies; typically conducted between 28 and 42 weeks. According to the National Institute for Heath and Care Excellence (NICE),[321] third trimester ultrasound in uncomplicated pregnancies are only recommended when clinical necessary.

**The training programme for the growth scan in the third trimester focused on:**

1. Measuring fetal biometry.
2. Evaluating fetal lie, presentation, and position.
3. Calculating AFI.
4. Identifying placental location and abnormalities.
5. Assessing umbilical artery Doppler.

Throughout the training, the emphasis was on transabdominal ultrasound examinations; however, transvaginal ultrasound was also incorporated for specific clinical scenarios such as suspected placenta previa or when detailed measurements of the cervical length were required.

## 9.3 Intrapartum Ultrasound Training

Several training sessions, led by Professor Christoph Lees and Miss Sana Usman, focussed on transabdominal and transperineal ultrasound techniques during labour. These sessions took place in the labour ward of Queen Charlotte's and Chelsea Hospital, utilising a research portable ultrasound device. The objectives were multifaceted: to review established guidelines and published techniques on ultrasound in labour, to explore their practical applications, and to understand the indications for ultrasound evaluations during labour.[44]

These sessions also facilitated introductions to the labour ward staff, fostering a sense of familiarity, and included detailed instructions on patient recruitment in the labour ward and provided insights into the concept of transperineal ultrasound techniques. A significant emphasis was placed on evaluating the progression of labour using a transabdominal approach to primarily determine the position of the fetal head and spine, and a transperineal approach for assessing head station. Several quantitative sonographic parameters were practiced and measured during labour, including Head-Perineum Distance (HPD), Angle of Progression (AoP), Midline Angle (MLA), Progression Distance (PD) and Head–Symphysis Distance (HSD), along with the detection of caput succedaneum and moulding.

During the data collection period from 2021 to 2023, I had the opportunity to provide training to my colleague, Dr Mariya Kovalenko, focused on imparting both fundamental and advanced ultrasonography practices. Additionally, I dedicated time to educate several midwives in basic ultrasound techniques, specifically focusing on their application during labour to ascertain the position of the fetal head.

## 9.4 Intrapartum Ultrasound Training Using Optical Ultrasound Stimulation

### 9.4.1 Introduction and Objective

In recent years, the utilisation of intrapartum ultrasound has been a substantial increase, favoured for its reliability, precision, and patient preference compared to conventional clinical assessments.[44] Ultrasound provides a non-invasive methods to monitor labour progression and guide clinical decisions, particularly in assessing fetal head position prior to initiating assisted vaginal birth.[44,322] However, educating practitioners poses logistical challenges; limitations in labour room, related to maintaining patient privacy, and ensuring infection control, complicate bedside teaching of intrapartum ultrasound.

Simulation training is increasingly recognised as an important component in medical education offering a standardised and immersive learning experience that emulates real-time situations in an appropriate environment away from the patient's bedside.[323] Recognising its significance, our team initiated the development of simulation modules for intrapartum ultrasound in 2022, aiming to allow practitioners to practise and refine their skills, with the advantage of receiving immediate feedback and evaluation.

### 9.4.2 Technical Description

The compact ultrasound simulator, Volutracer OPUS (optical positioning ultrasound simulator) (Medge Platforms, NY), was utilised for this training. OPUS enables users to explore actual 'cloud-based' ultrasound volumes on their computers using a scanning pad, webcam, and replica probe, while receiving real-time feedback and guidance[323] (training classroom, Figure 99). The simulator's analytics evaluate probe

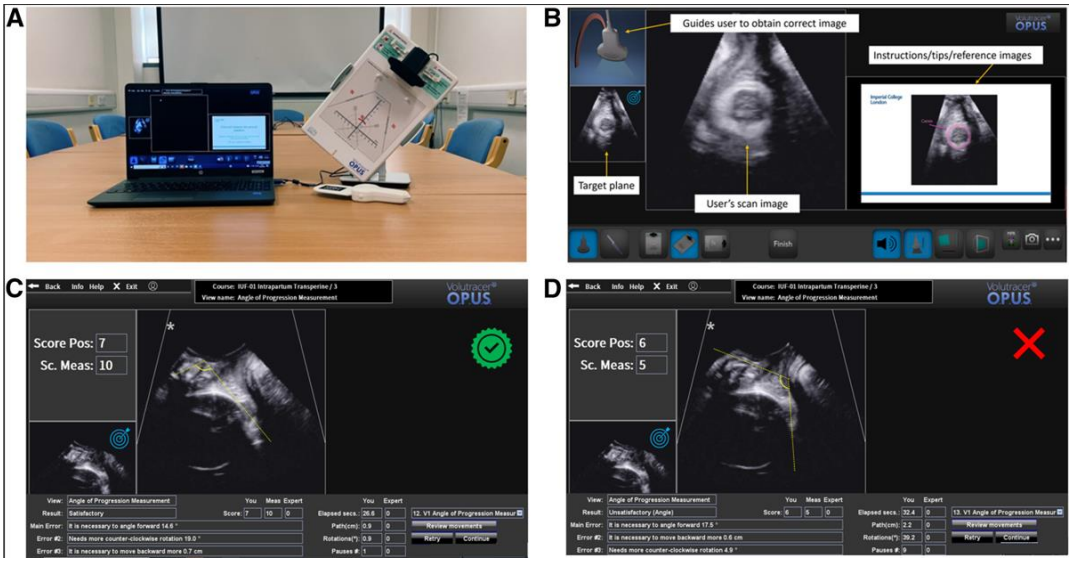
movements in six degrees of freedom and help users accurately acquire images, guiding them to perform the necessary probe adjustments to capture the target plane (Figure 100 A-D). OPUS has been proven to enhance the efficiency and accuracy of image acquisition for novices in both transabdominal and transvaginal ultrasound training.[324]

To adapt OPUS for transperineal ultrasound simulation, several modifications were necessary. The scanning pad was positioned vertically to mimic real-life probe positioning and rotated 45° to facilitate the 90-degree probe transitions between sagittal and transverse planes (Figure 100 A).

***Figure 99.*** *Intrapartum Ultrasound Simulation: Training Classroom.*

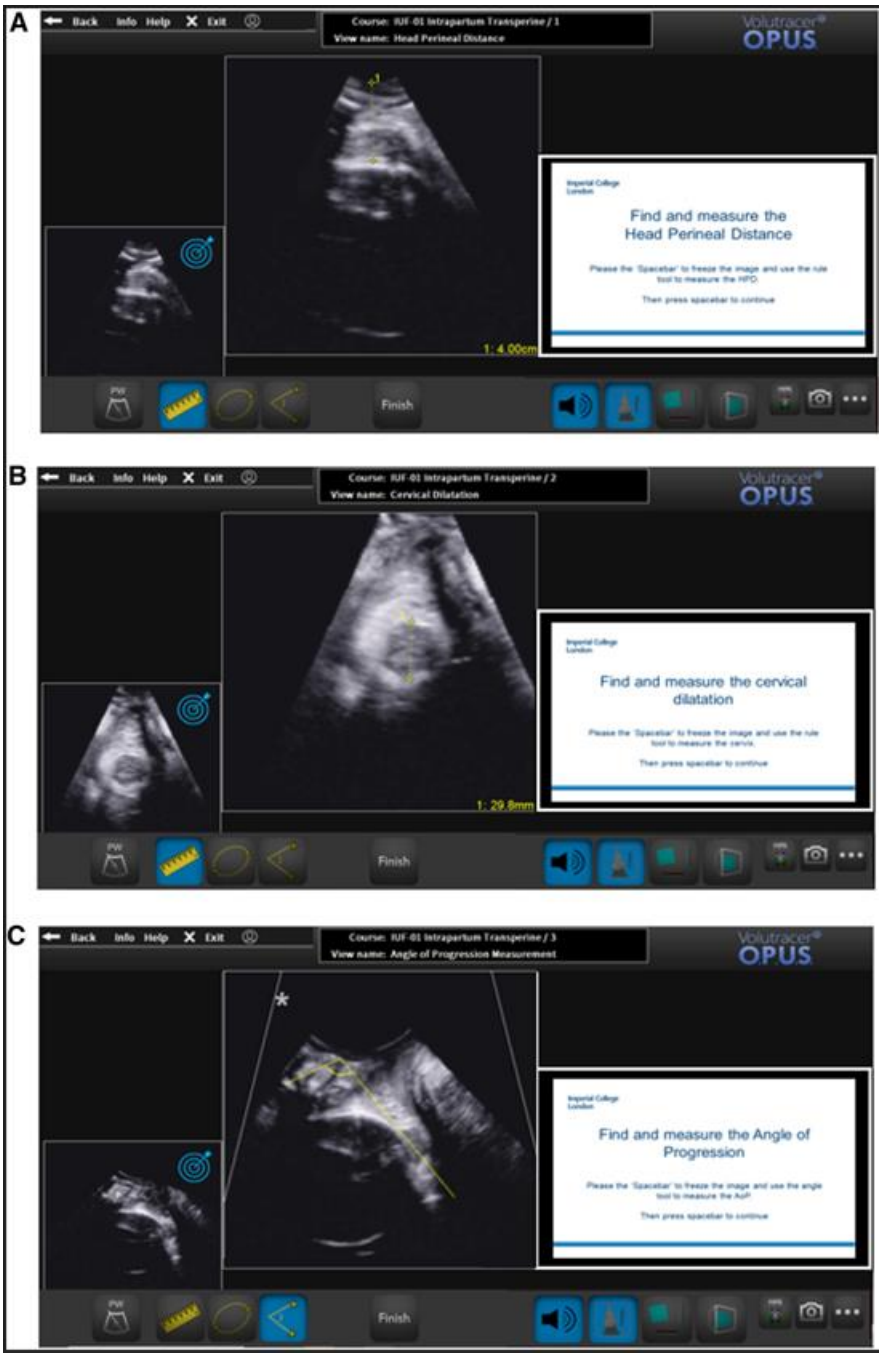


***Figure 100.*** *The Components and Functionalities of the Intrapartum Ultrasound Simulator.*[332]
***A,*** *Scanning pad, webcam, and a replica probe;* ***B,*** *The user interface of the intrapartum simulator, which displays the target plane and the main scan image. This image which shows cervical dilatation, accompanied by instructions for probe movements and a reference image;* ***C,*** *The angle of progression intrapartum module, demonstrating an acceptable image and measurement with a score of ≥7/10, along with simulator feedback; and* ***D,*** *The angle of progression intrapartum module displaying an unacceptable image and incorrect measurement, scoring <7/10, also accompanied by simulator feedback.*




Anonymised high-resolution three-dimensional (3D) transperineal ultrasound volumes were obtained from women at all stages of active labour. Participants were positioned supine, with hips and knees flexed, maintaining an empty bladder. The widest sector angle was selected to encompass the entire maternal pelvis, extending from the symphysis pubis anteriorly to the puborectalis muscle posteriorly. Four structured training modules were developed, each including theoretical background videos and guided exercises. These modules focused on three critical parameters measurements: HPD, cervical dilatation, and AoP (Figure 101 A-C). This approach aimed to familiarise practitioners with the most commonly monitored transperineal ultrasound parameters of labour progression.

***Figure 101.*** *The OPUS Intrapartum Module Demonstrates:* ***A,*** *Head-Perineum-Distance;* ***B,*** *Cervical Dilatation; and* ***C,*** *Angle of Progression Measurements.*[332]




Each training module includes a 'target plane' or 'gold standard' image; successfully aligning with this plane grants the user a maximum accuracy score of 10/10. Discretional limits (or tolerances) were established for each target plane; these represent the allowable distances in each of the six directions of movement away from the target plane, measured in millimetres per degree.

If the probe is positioned within or exactly at the tolerance limits, the resulting image is scored ≥ 7/10 and deemed acceptable by the simulator (Figure 100 C). Conversely, any image acquired with the probe moving beyond these established tolerances is considered unacceptable and receives score of < 7/10 (Figure 100 D). Setting appropriate tolerances proved challenging; too restrictive a limit could render obtaining an acceptable image nearly impossible, whereas too overly generous limits allow the simulator to accept an incorrect view, thereby compromising the integrity of the training module. Six free scan modules were developed to mimic 'real-life' scanning, facilitating unsupervised practice and enabling users to scan without simulator guidance.

For an ultrasound image to be displayed on the screen and to adjust according to the position of the probe, the webcam must detect the probe tracker sign. If the probe moves beyond the boundaries of the camera's field of view, the display of the image will be interrupted; this is considered a limitation.

We anticipate that the use of transperineal ultrasound in labour rooms will become more widely adopted as an adjunct to clinical examination, aiding the decision-making process during labour care. Ultrasound assessment may be preferred over digital vaginal examination in cases involving preterm labour, rupture of membranes, and placenta praevia. We have introduced a portable, home-based ultrasound simulation system that allows trainees the flexibility to practise at their own pace and convenience, offering a range of realistic scenarios to reinforce correct plane identification and accurate measurement attainment.

# CHAPTER 10

# Research Discussion and Projects Future Work

| ***Study Name*** | ***Study Timeline*** |
|---|---|
| ***2015 model*** *to predict vaginal delivery, 2-centre study (Stavanger, Norway) and (Cambridge, United Kingdom)* | *2012-2013* |
| *The **SONO-VE** study, single centre (London, UK)* | *2015-2018* |
| *The **SONO-PREDICT** study, single centre (London, UK)* | *2021-2023* |
| *The **combined study** (SONO-VE study SONO-PREDICT study)* | *Analysed in 2024* |
| *The **Trieste study**, single centre (Trieste, Italy)* | *January 2023- June 2024* |

## 10.1 Intrapartum Caesarean Delivery Research

To date, the accurate prediction of delivery mode and informed decision-making during labour have primarily depended on the clinical evaluations and the experiential knowledge of birth attendants. Emergency Caesarean sections, particularly those performed during advanced stages of labour, are associated with an increased incidence of complications such as damage to surrounding structures, postpartum haemorrhage, sepsis, and prolonged hospital stays.[238-242] The ability to predict the delivery mode could offer significant reassurance to women, especially first-time mothers who experience anxiety and stress during labour. Such reassurance may also contribute to the reduction in labour duration, particularly among women with a fear of childbirth (FOC).[243] However, research focused on predicting delivery mode using advanced ultrasound techniques in conjunction with clinical assessments during active labour remains markedly scarce. The majority of studies have predominantly focused on evaluating maternal and fetal parameters prior to the onset of labour.[244]

Observational studies have examined variations in head station, quantified by head-perineum distance (HPD), comparing women who required intrapartum Caesarean sections with those who achieved vaginal delivery. Women who underwent vaginal delivery consistently demonstrated a shorter HPD, indicating a greater descent of the fetal head, compared to those who required emergency Caesarean delivery.[146,165,166,271] Our findings align with these observations.

The current SONO-PREDICT study, as reported in this thesis, demonstrated that HPD serves as an important prognostic indicator for intrapartum Caesarean delivery (ICD) among nulliparous women in the active first stage of labour, irrespective of whether the assessment was first or second.

HPD significantly influenced the prediction of ICD in most study analyses. It was identified as a risk factor for ICD, with a 5% increase in ICD risk associated with each incremental increase in HPD. Among eighty-four participants (35%) who required ICD, seventy-five participants (89%) underwent a second ultrasound assessments. During these assessments, HPD measurements remained unchanged in 16% (12/75) and increased in 44% (33/75) of the cases experiencing ICD. Meanwhile, in those who underwent vaginal delivery (VD) and had repeat ultrasound assessments, HPD measurements remained unchanged in 8% (10/127) and increased in 21% (27/127) of the cases. Similar observations were noted in the SONO-VE study,[222] where 87% (69/79) of the women who underwent ICD had second ultrasound scans. Their HPD values were consistently higher than those in the VD group, with a mean difference of 5 mm higher at the first ultrasound assessments and remained higher or increased in 29% (20/69) of cases, showing a mean difference of 8 mm at the second ultrasound assessments.

In the Trieste study, despite a low rate of emergency Caesarean sections (9%, 10/106) among the sample, HPD was a significant factor for ICD during the first ultrasound assessments. Moreover, among the women who underwent a second ultrasound assessment (60%, 6/10), half (3/6) reported no changes in HPD, while the remaining half exhibited minimal changes. HPD consistently played a significant role in predicting ICD in the combined study (SONO-VE and SONO-PREDICT), across both single and repeat assessment models, regardless of the inclusion of the umbilical-cerebral ratio (UCR). Each unit increase in HPD was associated with a 6% increase in the risk of ICD, identifying it as a notable risk factor.

Cervical dilatation (CD), assessed by digital vaginal examination (DVE), was strongly associated with the incidence of ICD in both the SONO-VE and SONO-PREDICT studies. Conversely, in the Trieste study, CD was not a significant factor

when analysed using a single assessment model. This discrepancy may be attributed to the Trieste team's recruitment restrictions, which were limited to low-risk pregnancies, excluding conditions such as diabetes or fetal growth restriction (FGR), and thus resulted in a lower incidence of ICD within the sample. This selection bias could potentially affect the accuracy of the results.

In the SONO-PREDICT study, CD progressed very slowly among those undergoing ICD, with a median of 0.3 cm/hr (IQR: 0-0.4 cm), compared to the vaginal delivery group, which had a median of 0.8 cm/hr (IQR: 0.4-1.4 cm). Additionally, 45% (34/75) of participants experienced no change in their CD values. Cervical dilatation was a strong protective factor both at the initial assessment and in terms of its change over time. The risk of ICD decreased by 26% for each unit increase in cervical dilatation at the first assessment, and by 98% for each unit increase in cervical dilatation change. A similar pattern was observed in the SONO-VE study,[222] where CD progressed more rapidly in those who achieved vaginal delivery, with a mean change per hour of 0.8 cm, compared to 0.3 cm in the ICD group. The combined study (SONO-VE and SONO-PREDICT) corroborated these findings, demonstrating that CD was consistently a significant factor for ICD across both single and repeat assessment models.

The SONO-PREDICT study examined the prognostic significance of caput succedaneum, revealing notable differences between participants undergoing ICD and VD. Multivariable analysis from repeat assessment models, both with and without UCR, identified caput measurement during the first ultrasound scan as a significant predictor, with each unit increase raising ICD risk by 19% ($p = 0.000$).

These findings align with Hassan's study,[137] which reported that among 63 participants with caput measurement ≥10 mm, 24 (38%) underwent Caesarean section

compared to 5 out of 59 (8%) of participants with caput measurement <10 mm, ($p$ < 0.01). However, Gilboa Y. et al.[187] found no statistically significant relationship between caput succedaneum and delivery mode or neonatal outcomes.

Furthermore, in the SONO-PREDICT study, caput measurements generally increased in repeat assessments for both groups, with only a few cases maintaining the same values as in the first assessments. In contrast, the SONO-VE study[222] reported a tendency for caput succedaneum size to decrease in second ultrasound scans among those undergoing either ICD or VD. This reduction in caput measurements was not observed in the SONO-PREDICT study, where no decrease was noted in subsequent ultrasound assessments. The SONO-VE study[222] further indicated ambiguous prognostic significance of caput succedaneum, with minimal differences noted between the ICD and VD groups. However, the multivariable analysis suggested that first measurements of caput succedaneum, along with its subsequent changes, might enhance predictive accuracy.[222]

In the Trieste study, caput succedaneum was not identified as a significant factor for ICD; however, an increased caput measurement consistently emerged as a significant predictive indicator in respect of increasing the risk of ICD in the combined study (SONO-VE and SONO-PREDICT). The risk of ICD increased by 11% for each unit increase in the initial caput measurement and by 20% for each unit increase in caput change when analysing the repeat assessment model. This prognostic significance was evident across the entire analysis, both in single and repeat assessment models (with UC ratios: $p = 0.014$, and without: $p = 0.013$), (with UC ratios: $p = 0.002$, and without: $p = 0.000$), respectively.

The prognostic significance of cranial moulding was explored in our investigations. Fetal moulding was determined to be non-significant in influencing ICD outcomes

in the SONO-VE, SONO-PREDICT, and combined studies, corroborating the findings from the 2020 study by Iversen J. K. et al.,[138] which demonstrated no substantial associations between fetal moulding and delivery modes. Nonetheless, increased moulding was identified as a significant predictive marker for increasing the risk of ICD in the Trieste study, particularly within the single assessment compact model, as evidenced by a *p-value* of 0.023. The differing results of the Trieste study, compared to others, may be attributed to its small sample size, with only 9% of participants undergoing an ICD.

Fetal head position frequently changes during labour and is often only ascertained shortly before birth.[245] Predicting labour outcomes based solely on a single sonographic assessment of fetal head position, either prior to induction or at the onset of spontaneous labour, is currently impractical and overly ambitious.[246]

In the SONO-PREDICT study, among the 35% (84/239) of participants who underwent ICD, the rate of unchanged position of the fetal head was higher in the ICD group compared to those who delivered vaginally [48% (36/75) vs. 23% (29/127)]. This finding was consistent with both the SONO-VE[222] and Trieste studies. Although several studies have underscored the significance of fetal head position in predicting the mode of delivery,[193,247-249] our analyses across all four studies (SONO-VE, SONO-PREDICT, Trieste, and combined) did not demonstrate a significant association between fetal head position and delivery mode. In our current analysis, we assessed the significance of fetal head position, initially treating it as a continuous variable (0-6, ranging from occiput anterior [OA] to occiput posterior [OP], irrespective of laterality). Additionally, we conducted further analysis of the combined study (SONO-VE and SONO-PREDICT) by evaluating this factor as a categorical variable (OP versus non-OP), as detailed in Supplemental Data 12.3.

Neither approach demonstrated a significant predictive value. Nonetheless, further research is necessary to validate these findings.

The role of fetal Doppler measurement has highlighted a heightened risk of Caesarean deliveries for fetuses with a low cerebral-umbilical ratio (CUR), otherwise known as cerebral-placental ratio (CPR).[87] A retrospective study in Brisbane, Australia, found that infants born by emergency Caesarean or instrumental delivery for fetal compromise had the lowest median CPR compared to those delivered by other methods.[88]

A low CPR at 35-37 weeks gestation correlates with higher intrapartum complication risks.[88] It has been suggested that a low CPR, measured early in labour, is significantly associated with fetuses that later require emergency deliverydue to presumed intrapartum fetal distress, whereas a high CPR may protect against fetal compromise during labour.[89] However, recent studies have indicated no significant differences between the CPR and UCR in predicting the need for operative delivery due to presumed fetal compromise.[92,93]

Interestingly, data analyses from the SONO-VE, SONO-PREDICT, and combined studies indicated that whether the UCR was included or not, the performance of both single and repeat assessment models for predicting ICD was quite similar. The including of Doppler measurements in the analyses, however, reduced the sample size due to data loss, occasionally leading to certain factors emerging as significant, which were not deemed significant when the Doppler values were excluded.

Utilising a variety of parameters obtained from clinical examinations and ultrasound assessments during active labour, the application of both first and second assessments, along with the analysis of both single and repeat assessment models, aids in predicting ICD. In the SONO-PREDICT study, the area under the curve

(AUC) values were 0.68 and 0.89 for single and repeat assessment models, respectively; in the SONO-VE study, these values were 0.78 and 0.85; and in the combined study, they were 0.72 and 0.86. Notably, the AUC for the repeat assessment model in the SONO-PREDICT study was 0.21 higher than that for the single assessment model, 0.07 higher in the SONO-VE, and 0.14 higher in the combined study. These findings suggest that a model incorporating repeat clinical and ultrasound assessments could significantly enhance clinical outcomes compared to those based solely on a single labour evaluation.

The original 2015 predictive model developed using data from two populations (Cambridge and Norway),[195] was designed to predict labour outcomes based on a single assessment, demonstrated a reasonable level of accuracy, as evidenced by an AUC of 0.85. However, its generalisability and applicability were limited by the relatively small sample size and the prevalence of prolonged labour among participants. In the current investigations, we tested and evaluated the most predictive factors for ICD in a larger and different cohort of nulliparous women during the active first stage of labour. These investigations involved conducting multiple labour assessments, including the measurement of the fetal Doppler, assessed as UCR.

We utilised both intrapartum clinical evaluations and ultrasonography to predict labour outcomes and the mode of delivery. Our findings revealed that the three main prognostic indicators for ICD were identified: HPD, caput succedaneum, and CD measurements, along with their observed changes during subsequent assessments. Additionally, body mass index (BMI), maternal age, gestational age (GA), maternal ethnicity, and fetal moulding also emerged as significant predictors for ICD in some of the analysed studies. These factors require further investigation to validate their predictive accuracy.

In the UK, the Caesarean section rate among nulliparous women aged over 35 stands at 38%, increasing to 50% for those over 40.[250] A linear relationship has been identified between maternal age and the likelihood of emergency Caesarean delivery.[251] The SONO-VE and combined studies corroborate these findings, highlighting maternal age as a significant indicator for ICD in the repeat assessment model analyses.

Maternal ethnicity also emerged as a predictive factor for ICD in both the SONO-VE and combined studies (SONO-VE and SONO-PREDICT), as well as in the single assessment model in the Trieste study. However, neither maternal age nor maternal ethnicity were identified as significant factors in the SONO-PREDICT study.

Despite both the SONO-VE and SONO-PREDICT studies being conducted at the same maternity centre, Queen Charlotte's and Chelsea Hospital (QCCH), discrepancies in results were attributed to significant differences in maternal ethnicity, as evidenced by a *p-value* of 0.001, and may also be due to differences in the timing of the research (SONO-VE: 2015-2018; SONO-PREDICT: 2021-2023), which could have influenced the outcomes.

Studies have indicated that maternal BMI,[252] estimated fetal weight (EFW)[253-255] and maternal ethnicity[256] are associated with an increased frequency of Caesarean deliveries. Some of these factors emerged as significant in both the SONO-VE and Trieste studies; notably, BMI (overweight class 2, $25 \leq BMI \leq 29.9$), and maternal ethnicity (Asian mothers, group 3), although not representing a large population [SONO-VE: 34% (74/212), and Trieste: 7% (7/96)], had a significant impact on ICD incidence. Maternal ethnicity (Afro-Caribbean mothers, group 2) was a significant indicator for ICD in the combined study (SONO-VE and SONO-PREDICT), representing approximately 12% (59/508) of the sample. Of these, 46% (27/59) of Afro and Caribbean women experienced ICD.

These findings align with recent studies reporting that Caesarean deliveries were highest among Asian and black women.[327,328] However, in the SONO-PREDICT study, maternal characteristics (maternal age, GA, BMI, and maternal ethnicity), along with UCR, cranial moulding, and fetal head position, were found to have minimal impact on the estimation of ICD.

Epidural anaesthesia is considered the gold standard for labour analgesia and is highly effective in mitigating pain during labour.[257,258] This technique involves a central nerve blockade through the administration of a local anaesthetic into the lower spinal area, near the nerves that transmit pain signals from the contracting uterus and birth canal. In the SONO-PREDICT study, we evaluated the impact of epidural anaesthesia on labour outcomes, comparing it with cases where no analgesia was used. Results indicated that while epidural analgesia was associated with a prolonged labour duration (mean duration: 853 vs. 789 minutes), it did not influence the frequency of ICD, aligning with numerous preceding studies demonstrating that effective pain relief during active labour does not adversely affect Caesarean section rates.[259,260]

The World Health Organisation (WHO) supports the use of epidural anaesthesia, highlighting its significant role in enhancing maternal pain scores and overall satisfaction. Additionally, epidural anaesthesia is associated with reduced incidences of post-traumatic stress disorder (PTSD) and postnatal depression, potentially contributing to diminished severe maternal morbidity.[261-265] Despite these benefits, some studies have reported that epidural analgesia may hinder labour progression and increase the incidence of ICDs.[266-270] One particular study reported a 3.7-fold increase in the likelihood of Caesarean delivery among participants who received an epidural.[267]

However, recent research published in 2022 by Chen Y. et al.[329] reported that the use of epidural labour analgesia is associated with a decreased rate of Caesarean section and improved maternal and neonatal outcomes in nulliparous women with gestational diabetes mellitus (GDM). Another study from the same year by Deepak D. et al.[330] suggested that epidural analgesia effectively alleviates labour pain in nulliparous women, without increasing the rates of Caesarean section or instrumental vaginal delivery, and does not affect the duration of the first stage of labour, however, it slightly prolongs the duration of the second stage of labour.[330] Nonetheless, our analyses of the SONO-PREDICT, SONO-VE, Trieste, and combined studies indicate that the use of epidural anaesthesia was not associated with an increase in the incidence of ICD.

The median durations from the onset of active labour to the delivery of the baby were notably shorter in participants who experienced VD compared to those who underwent ICD, as observed across all four studies: SONO-VE (11.7 vs. 15.1 hours), SONO-PREDICT (11.8 vs. 14.6 hours), Trieste (5.1 vs. 8.5 hours), and the combined analyses (11.7 vs. 15.1 hours), with a *p-value* of $< 0.001$.

The primary strength of our investigation lies in the substantial sample sizes employed in the SONO-PREDICT study (n = 239) and the combined study (n = 508). Moreover, the blinding of birth attendants to ultrasound findings played a crucial role in mitigating potential biases, thereby ensuring that the predictive ultrasound data did not influence decisions in labour management.

Nonetheless, the SONO-PREDICT study exhibits some limitations related to it being undertaken under very busy conditions in the clinical area. A significant consideration relates to the inconsistency in the timing of intrapartum ultrasounds among participants; for instance, the first ultrasound assessment for patient (A) was

performed at 4 cm dilation, whereas for patient (B), it was conducted at 6 cm dilation. There was also considerable variability in the intervals between the clinical and ultrasound assessments, as well as between first and subsequent ultrasound evaluations. Consequently, measurements of ultrasound parameters at different stages of labour (early, middle, or late) exhibited significant differences.

In the SONO-VE study,[222] recruited participants were at earlier stages of labour compared to the original 2015 prediction model,[195] resulting in higher HPD and reduced incidences of caput succedaneum.

To mitigate this issue, we recommend adopting a standardised protocol for timing of recruiting participants and conducting intrapartum ultrasound assessments. Ultrasounds could ideally be performed at regular intervals of 2-4 hours, independent of DVE. This approach would address the observed delays in clinical assessments, which can extend the interval between ultrasound assessments to beyond four hours. Future studies should aim to ensure regular ultrasound assessments throughout the active phase of labour at specified intervals to improve the accuracy of predictive information. The reproducibility of the predictive model, a primary goal of our investigations, is likely to be influenced by these timing variations.

An additional limitation is the omission of second intrapartum ultrasound assessments for several participants; thirty-seven underwent only first ultrasound evaluation due to factors including fatigue, perceived inadequacies in analgesia, or decisions to proceed with a Caesarean section, thus precluding further assessments. Moreover, delays in performing DVE contributed to the unavailability of the research team outside scheduled hours, leading to missed assessments.

The SONO-PREDICT study was conducted within the same maternity unit as the SONO-VE study,[222] which involved a population that exhibited slight demographic

differences, only significant in maternal ethnicity ($p = 0.001$). The external validity of the predictive model requires rigorous testing across diverse centres and populations, incorporating varied ethnic backgrounds and a range of pelvic anatomies. Such investigations are essential to verify the model's generalisability and practical applicability across different clinical sittings.

A dedicated research team from Trieste, Italy, is actively involved in these investigations. Although the sample size of the Trieste study was relatively small, its findings provide preliminary evidence supporting the broader applicability of the predictive model for ICD.

In the context of intrapartum Caesarean delivery, predictive models based on a single assessment during labour provide a reasonable basis for predicting the necessity for an emergency Caesarean section. However, the inclusion of multiple clinical and ultrasound evaluations significantly improves the accuracy of these predictions. The application of a multivariable model, which integrates repeat assessments, has proven both feasible and superior to models that rely solely on a single evaluation.

Three key predictive parameters identified in the SONO-PREDICT study were head-perineum distance, caput succedaneum, and cervical dilatation, as measured during the first ultrasound assessment, along with their subsequent changes observed during the second ultrasound evaluation.

We consider the combined study (SONO-VE and SONO-PREDICT) as the 'key model', as it is based on the largest sample (n = 508), focusing on full models during both labour assessments without incorporating UC ratios, these models achieved the best overall performance. Notably, it demonstrates the highest sensitivity and positive predictive value (PPV), which are essential for identifying as many true cases as possible and ensuring that when an emergency Caesarean section (ECS) is

predicted, it is indeed warranted. In this 'key model', six key predictive parameters for ICD were identified: maternal age, gestational age, maternal ethnicity (Afro-Caribbean), head-perineum distance, caput succedaneum, and cervical dilatation observed during the first ultrasound assessment, along with their subsequent changes during the second ultrasound evaluation.

## 10.2 Ph.D. Journey Challenges

**Embarking on a Novel Research Endeavour**

As an international student with a background in Radiological medicine, undertaking an intrapartum obstetric study represented a formidable challenge, necessitating starting from scratch. My initial responsibilities involved meticulous preparation of ethics applications and extensive literature reviews, both of which were time-consuming and demanding. Acclimatising to a new clinical environment and establishing effective communication with midwives and labour ward staff added further complexity. Following approval from the Research Ethics Committee (REC), the Health Regulator Authority (HRA), and the Confirmation of capacity and capability (CCC) from the participating NHS Trust, the recruitment phase commenced.

Our initial aim was to recruit primarily from the labour ward and birth centre; however, frequent meetings with the head of midwifery and the birth centre lead proved challenges as they were hesitant to involve a study they perceived as medically intrusive to the natural birth process. Despite approaching numerous patients, many declined to participate. Nonetheless, recruitment was primarily successful in the labour ward. This process required meticulous attention to ensure participants eligibility and consent, involving detailed explanations of the research aims and procedures, coupled with the execution of detailed intrapartum ultrasound assessments. The research entailed multiple assessments during active labour, requiring me to wait for the next clinical assessment to offer the subsequent ultrasound scans, which were sometimes declined by participants after a lengthy wait of 4-6 hours.

These responsibilities often extended my working hours beyond 12 hours per day, leading to depleted energy by the end of the day.

This intense period of data collection continued for more than 2 years before transitioning to the thesis writing up phase. Figure 102 illustrates the intrapartum research challenges encountered.

My role extended beyond patient recruitment and assessment; I actively assisted the labour ward and healthcare providers in assessing labouring women. This involved utilising ultrasound for various diagnostic purposes, including detecting fetal heartbeat, evaluating amniotic fluid index, assessing fetal spine and head positions, presentation, and station, as well as cervical dilatation. Additionally, I provided translation services for many patients and their partners, enhancing communication and care delivery within the clinical sittings. Undertaking such intrapartum research is immensely challenging, dealing with nulliparous labouring women, their partners, medical teams, and midwives.

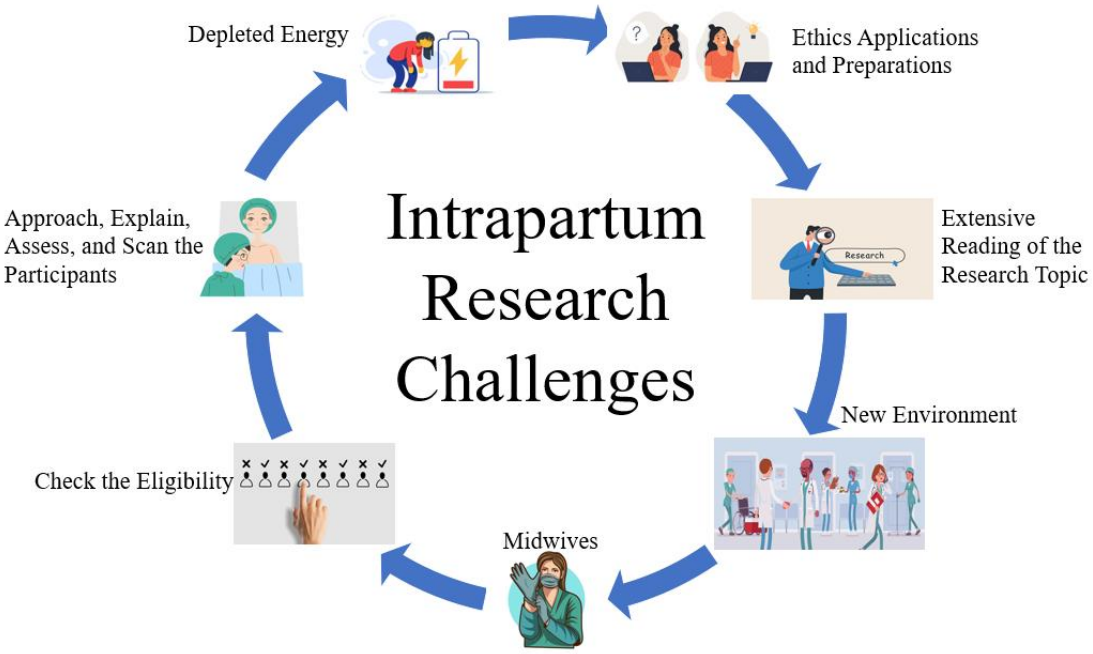
There is not specific time for subsequent clinical assessments, although they are usually conducted every four hours, they primarily depend on the patient's condition. This necessitates constant vigilance on the labour ward board to monitor whether the vaginal examination has been completed for your participants. Often, birth attendants conducted examinations without notifying us or without our realising it. In addition, on several occasions, decisions regarding delivery were made before the patient could undergo the subsequent ultrasound assessment, leading to general reluctance among patients to proceed with it.

Throughout the course of my Ph.D. journey, which was fraught with numerous challenges, the unwavering support of Professor Christoph Lees was indispensable. His presence and guidance were constant, assisting me at every phase of my research, from the recruitment process to fostering introductions with the labour ward staff.

His encouragement, even in the smallest of achievements, provided continues support. Additionally, Miss Sana Usman played a pivotal role in guiding me throughout my journey. Her seasoned advice and empathetic understanding were crucial in navigating the complexities of my research. Dr. Mariya Kovalinko's warmth, kindness, and invaluable support further enriched my experience.

I am profoundly grateful to this remarkable team, whose camaraderie made me feel as though I was among family and made my Ph.D. journey easier and complete. Their collective contribution was not only instrumental in my academic endeavours but also provided a profound sense of belonging and encouragement.

***Figure 102.*** *Main Challenges during the Ph.D. Journey.*



## 10.3 Future Directions

### Prediction Model for Intrapartum Caesarean Delivery

**Main research:** Further refinement on the external predictive model for ICD requires comprehensive validation through trials across multiple maternity centres and diverse population groups. This should include participants from various ethnic backgrounds and encompass a range of pelvic anatomies and morphologies. The protocol for participant recruitment and the timing of intrapartum ultrasound evaluation should be meticulously standardised, entailing multiple assessments at consistent intervals, irrespective of DVE. While HPD, Caput succedaneum, and CD have been recognised as significant predictors of ICD, further research that focusing more on maternal characteristics and fetal moulding is crucial to ascertain their predictive validity.

### Intrapartum Ultrasound Measuring Cervical Dilatation

**Chapter 5:** Ongoing research is necessary to validate the capability of transperineal ultrasound technology to accurately measuring cervical dilatation with high resolution. Special attention should be given to the timing interval between digital vaginal examination and transperineal ultrasound scan assessment. Additionally, it is essential to enhance the precision of both inter- and intra-observer variability through real-time ultrasound, performed by various ultrasound-trained practitioners. Further studies should involve multiple ultrasound assessments of cervical dilatation using both two-dimensional (2D) and three-dimensional (3D) transperineal ultrasonography. Moreover, these studies should include detailed measurements of mean and maximal cervical diameters, as well as the internal cervical area.

**Intrapartum Ultrasound Visualisation of the Catheter Balloon**

**Chapter 6:** Our novel research provides a groundwork for subsequent studies aimed at promoting objective evaluations in future inquiries. Future efforts should assess the prevalence of urinary catheter balloons positioned at lower levels using intrapartum transperineal ultrasound and examine any associated outcomes, including intrapartum haematuria, labour outcomes, and postpartum urinary retention and complications. Investigations should also include long-term postpartum follow-up focusing on enduring pelvic floor outcomes associated with a lowered bladder neck position.

**Intrapartum Prediction Application for Delivery Mode**

**Chapter 7:** For future work, our team conducted an initial online survey comprised of six healthcare professionals and four parents (focus group comments, Appendix 15) to enhance the predictive capabilities of the intrapartum app. The aim was to understand the preferences of healthcare professionals and parents regarding potential suggestions or modifications to future prediction applications. This included preferred likelihood bands, the threshold levels deemed practical by participants for making informed decisions, participants demographics, application content, and its design, thereby informing the refinement of future predictive applications.

Having completed the predictive data analyses and established multivariable models (as elaborated in Chapter 3 and 4), we have identified the most predictive parameters for anticipating intrapartum Caesarean delivery. Following the external validating of this model, our next endeavour involves development a predictive intrapartum Caesarean delivery app.

**The Psychological Impact of Knowing Prediction Information**

**Chapter 8:** Our exploratory study into the perceptions of both parents and healthcare professionals regarding receiving predictive information during labour and examining both the immediate and prolonged psychological impacts of this information, highlights the need for further research. Future studies should involve large sample size and be conducted across multiple centers to enhance generalisability. Study materials better to be available in multiple languages to include non-native English speakers, thereby reducing cultural bias. Future investigations should also consider the participants' history of pregnancy complications, which may significantly influence their attitudes towards receiving predictive information.

**Intrapartum Ultrasound Training Using Optical Ultrasound Stimulation**

**Chapter 9:** Future efforts will concentrate on improving the modules by integrating a transabdominal simulation package and an extensive library of free-scan modules. These enhancements will include the first and second stages of labour, showcasing different fetal head positions, stations, and cervical dilatations to enhance practitioner proficiency. The introduction of a 360-degree probe will facilitate a more realistic viewing perspective and eliminate interruptions due to 'out of view' issues.

# CHAPTER 11

# Appendices

## Appendix 1: Research Ethics Committee Approval Letter.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Professor Christoph Lees
Imperial College Healthcare NHS Trust, Centre for Fetal Care
Queen Charlotte's and Chelsea Hospital
Du Cane Road London
W12 0HS

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

18 February 2021

Dear Professor Lees

**HRA and Health and Care Research Wales (HCRW) Approval Letter**

| | |
|---|---|
| **Study title:** | **Ultrasound Prediction of Delivery Mode: can the first stage prediction model be further improved?** |
| **IRAS project ID:** | **283692** |
| **Protocol number:** | **20QC6287** |
| **REC reference:** | **20/EM/0298** |
| **Sponsor** | **Imperial College London, Joint Research Compliance Office** |

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

**How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?**
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in NorthernIreland and Scotland.

**How should I work with participating non-NHS organisations?**
HRA and HCRW Approval does not apply to non-NHS organisations. You should work withyour non-NHS organisations to obtain local agreement in accordance with their procedures.

**What are my notification responsibilities during the study?**

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reportingexpectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light ofchanges in reporting expectations or procedures.

**Who should I contact for further information?**
Please do not hesitate to contact me for assistance with this application. My contact detailsare below.

Your IRAS project ID is **283692**. Please quote this on all correspondence.Yours sincerely,
Barbara Cuddon Approvals Specialist

Email: approvals@hra.nhs.uk

# Appendix 2: The Sponsorship Letter.

Imperial College London

NHS
Imperial College Healthcare
NHS Trust

Research Governance and Integrity Team
Academic Health Science Centre
Imperial College London and
Imperial College Healthcare NHS Trust
Room 221, Level 2, Medical School Building
Norfolk Place,
London W2 1PG
02075949832
cheuk-fung.wong@imperial.ac.uk
https://www.imperial.ac.uk/joint-research-compliance-off ice/

**Cheuk Fung Wong**
Research Governance and Quality Assurance Manager

16/10/2020

Professor Christoph Lees
Imperial College Healthcare NHS Trust,
Centre for Fetal Care,
Queen Charlotte's and Chelsea Hospital

Dear Professor Christoph Lees

**RE:** Ultrasound Prediction of Delivery Mode: can the first stage prediction model be further improved?

**Research Governance and Integrity Team Reference number: 20QC6287**

This is to confirm that the above-named research project utilises human participants, their organs, tissue and/or data as defined under the sponsorship requirements of the UK policy framework for health and social care (2017), incorporating the Medicines for Human Use (Clinical Trials) Regulations 2004.

On behalf of Imperial College of Science, Technology and Medicine, we undertake to act as the identified Research Sponsor for this project.

This letter confirms:

- The research proposal has been discussed, assessed and registered with the Research Governance and Integrity Team, Imperial College Academic Health Science Centre, Imperial College London and provisional sponsor approval granted.
- The Chief Investigator has undergone a process of scientific critique commensurate with the scale of the project.
- Indemnity and insurance arrangements have been put in place to cover the project.
- Resources and support are available to the research team to aid delivery of the research as proposed.
- Management, monitoring and reporting responsibilities for the research have been approved.
- Imperial College will undertake and enforce those sponsor duties set out in the UK policy Framework for Health and Social Care.

**Imperial College Sponsorship is conditional on the project receiving applicable ethical and regulatory approval for all research related aspects of its conduct. It is also conditional on successful contract and agreement negotiations and sign off via the Joint Research Office, where relevant, and before the study commences.**

A copy of the ethics approval letter **must** be sent to the Research Governance Manager prior to the study commencing. Sponsorship is dependant on obtaining R&D Office approval for all NHS sites where the research is being conducted.

Yours sincerely

Cheuk Fung Wong

Digitally signed by Cheuk Fung Wong
Date: 2020.10.16 14:00:11 +01'00'

# Appendix 3: Patients Information Sheet of the SONO-PREDICT Study.

At the start of your labour, we will perform an ultrasound scan along-side the vaginal examination for the cervical assessment. Details of the scan will be provided in a separate patient information leaflet: Ultrasound scans in labour: what to expect. We will perform a transabdominal ultrasound scan similar to the dating (3 months) and anomaly scan (5 months) you may have had done. Transperineal scanning will involve placing a disinfected probe with a sterile probe cover between the labia (not in the vagina) for 1-2 minutes without undue pressure. Following the ultrasound scan, we will advise you of the likelihood of a vaginal delivery.

It is important to note that if a research team is not available when you attend in labour or if there is a change in delivery plans, it is possible you may not receive the scan and hence the delivery prediction.

At 12 weeks following your delivery, we will ask you to complete the online questionnaire asking you how you felt about receiving the prediction information as well as asking you to complete the psychological measures online again.

**Who is funding this study?**
This study is sponsored by Imperial College London. It is being jointly organised by the Department of Obstetrics at the Imperial College London and the Institute of Psychiatry, Psychology and Neuroscience at Kings' College London.

**Does the study have ethical approval?**
The study has been reviewed and approved by xxxx. The REC number is xxxx

**What are the possible disadvantages and risks of taking part?**
There is no known risk of harm to the baby from the ultrasound scan. You may experience slight discomfort when the probe is placed, though this is usually considered less than the discomfort experienced with vaginal examinations. We will also be asking you to reflect on your experience during pregnancy and labour. There is a very small chance you may become upset if you voluntarily disclose any experience that was particularly stressful or unhappy. You are free to withdraw at any stage or not answer a specific question.

**What if new information becomes available?**
Sometimes during the course of a research study, new information becomes available about the treatment that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to continue in the study you may be asked to sign an updated consent form. Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study.

Where participants are willing to be identified for information dissemination purposes, we will keep a separate online secure database and we will email any relevant publications to them.

**What will happen if I don't want to carry on with the study?**
You can withdraw from the study at any time and you do not need to give a reason. If you withdraw, we will ask you if we can still use your data that we have obtained so far for the study, but you do not have to agree to this, and if you do not agree, we will destroy all data we have obtained about you for the purposes of the study.

payments, reimbursement of expenses or any other benefits or incentives for taking part in this research. The findings from your ultrasound will only be used in your care if this will impact your clinical care.

**Who is funding this study?**
Imperial College London will act as the main sponsor for this study. Delegated responsibilities will be assigned to the NHS trust taking part in this study.

**Does the study have ethical approval?**
The study has been reviewed and approved by ……. The REC reference number is ……
The research has been registered with the Clinical Trials website clinicaltrials.gov.

**What are the possible disadvantages and risks of taking part?**
There is no known risk of harm to the baby from the ultrasound scan. You may experience slight discomfort when the probe is placed, though this is usually considered less than the discomfort experienced with vaginal examinations.

**What will happen if I don't want to carry on with the study?**
You can withdraw from the study at any time and you do not need to give a reason. If you withdraw, we will ask you if we can still use your data that we have obtained so far.

**What if something goes wrong?**
Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for a legal action.

**What can I do if I have any complaints or concerns?**
If you have a concern about any aspect of this study, you should ask to speak to the researcher, Arwa Hanidu, who will do her best to answer your questions. If you wish to complain or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Chief Investigator (Professor Christoph Lees, email: christoph.lees@nhs.net)

If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office, 510A, 5th Floor Lab Block, Charing Cross Hospital, Fulham Palace Road, London, W6 8RF. Tel +44 (0) 203 311 0205 Fax: +44 (0) 203 311 0203.

The normal NHS complaint mechanisms are also available to you. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure, details of which can be accessed by contacting PALS- Patient Advice and Liaison Service: Telephone: +44 (0) 203 313 0088 (service available 9.00am - 5.00pm Monday to Friday Email: pals@imperial.nhs.uk).

**Will my data in this study be kept confidential?**
Imperial College London is the sponsor for this study, and it will act as the data controller. This means that Imperial College is responsible for looking after your information and using it properly. Imperial College will keep your personal data for 10 years after the study has completed in relation to primary research data. In this research project, we will need to use

information from you and from your medical records. This information will include your initials, NHS number, name, contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

You will be given an individual study number and we will only use information that we need for the research study. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. We will also follow all privacy rules. Anonymised information will be sent to Europe confidentially for analysing. We must follow our rules about keeping your information safe. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We will retain collected data if you withdraw from the study or lose capacity. If you do not want this to happen, tell us and we will stop. We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. You can find out more about how we use your information by visiting www.hra.nhs.uk/information-about-patients, or asking one of the research team, or sending an email to [arwa.hanidu18@imperial.ac.uk] and [arwa.hanidu@nhs.net]

**Complaint**

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

**Legal basis**

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

**Information transfers**

There may be a requirement to transfer your information between research team members or to European countries outside the UK. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial

College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

**Sharing your information with others**

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties. Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third-party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

**What will happen to the results of the research study?**

We intend to use the results of this study in future pregnancy management. We intend to publish the results in local and international journals and meetings or conferences, in addition to publication on websites. You will not be identified in any report or publication. Participants will be provided with a lay summary of the main findings and details of any publications.

**Who will be doing the research?**

The research group consists of Ms Arwa Hanidu (Project Manager, Honorary Research Fellow in Obstetrics and Gynaecology Ultrasound, Imperial College London), Professor Christoph Lees (Consultant in Obstetrics and Fetal Medicine, Imperial College London), Dr Sana Usman (Clinical Research Fellow in Maternal and Fetal medicine, Imperial college London), or suitably qualified researcher under their supervision. If you would like to contact us, please email the Project Manager, Ms Arwa Hanidu: [arwa.hanidu18@imperial.ac.uk] or [arwa.hanidu@nhs.net] for further information.

# Appendix 4: Consent Form of the SONO-PREDICT Study.

## Consent Form for Research Participants

### Using ultrasound and clinical assessments to predict delivery

Thank you for opting to take part in this study. Please ensure you have read the Patient Information Sheet. Please feel free to ask the researcher any questions you may have about the study.

This is the consent form, which confirms that you are happy to participate in the study and understand what this entails. You will be given a copy of this form in addition to the Patient Information Sheet to keep.

**Patient ID number: ……**

**Name of Principal Investigator: ……**

To confirm agreement with each of the statements below, please initial in the box.

1. I confirm that I have read and understand the patient information sheet dated ..... version ..... for the above study and have had the opportunity to ask questions which have been answered fully. ☐

2. I understand that my participation is a voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that sections of any of my medical notes may be looked at by responsible individuals from Imperial College London, from NHS Trust or from regulatory authorities. I give permission for these individuals to access my records that are relevant to this research. ☐

4. I understand that fully anonymised data will be shared with a statistician within the European Union for the purposes of data analysis. The key for the study number will be held at Imperial College and not shared with a third party. ☐

5. I agree to take part in this research study and agree to have transabdominal and transperineal ultrasound scans performed around the same time of vaginal assessment. I am aware that these procedures may be done at recurring time intervals.

1. I understand that my images and data will be stored for up to 10 years according to Imperial College London policy and may be used in future ethically approved studies. ☐

2. I agree to my collected data being retained if I withdraw from the study or lose capacity. ☐

3. I agree that the details and outcome of my pregnancy may be followed via the local hospital birth registry. ☐

4. I agree to be informed via email of any publications of the results from the study. My email is…… ☐

5. I understand a copy of this signed consent form, containing my full name, will be sent to the Principal Investigator (PI).

**Contact for Further Information:**

The researchers and doctors mainly conducting the study in the UK are Ms Arwa Hanidu (project manager, honorary research fellow in Obstetrics and Gynaecology Ultrasound, Imperial College London), Professor Christoph Lees (Chief Investigator, Consultant Obstetrician, Imperial College) and Dr Sana Usman (Day to Day supervisor, Clinical Research Fellow in Maternal and Fetal Medicine).

Ms Arwa Hanidu can be contacted during working hours by email: arwa.hanidu18@imperial.ac.uk

**Participant's name (BLOCK CAPITALS): …….**

**Signature: ..... Date: …….**

**Investigator taking consent ……..**

**Signature: ..... Date: …….**

Copy: CI Copy: Participant Copy: Hospital notes

**Appendix 5: Standard Care Leaflet of Intrapartum Ultrasound.**

**Having an Ultrasound Scan on the Labour Ward: information for women and their birth partners.**

## What is an ultrasound?

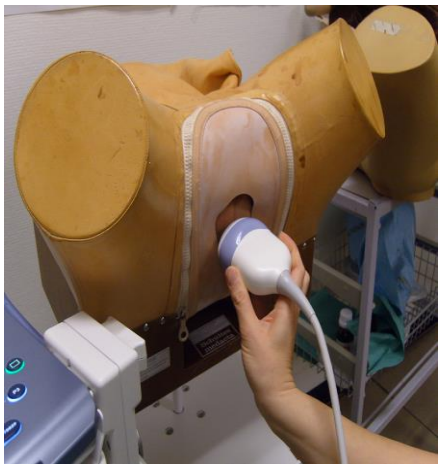
An ultrasound scan is a procedure that uses sound waves to create a picture of part of the inside of the body. The scan on labour ward is similar to the scan that women have during pregnancy to produce real-time visual images of the developing baby in the womb. Ultrasound imaging is not painful, very safe and takes approximately 10 minutes to complete.

## Why do you need the ultrasound?

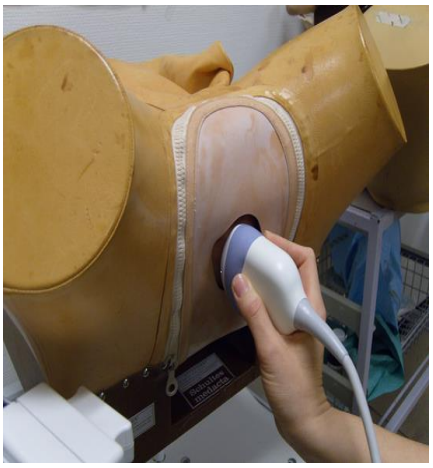
As well for standard assessment of which way up the baby is and the heartbeat, ultrasound scanning could be used in assessing the progress of labour, and potentially in predicting how women may deliver.

Two techniques will be used to do this, the transabdominal ultrasound method where the probe is placed on a mother's abdomen. It will be used to look at the fluid around the baby, the position of the baby's head and also to study the blood flow pattern of the baby. This is similar to the 12 week dating and 20 week anomaly scan you may have had in pregnancy.

The second is the transperineal method where the probe is placed between labia but not inside the vagina, for 1-2 minutes without exerting undue pressure to assess the labour progress and to predict the delivery mode (Figure 1).



Transverse (horizontal)



Sagittal (vertical)

**Figure 1:** Transperineal ultrasound technique with the 2 common views: Transverse (horizontal) and Sagittal (vertical).

## Do you have any questions?

If you have any queries, you can contact Ms. Arwa Hanidu, honorary research fellow in Obstetrics and Gynaecology, Imperial College London.

Ms. Arwa Hanidu can be contacted during working hours by email: arwa.hanidu18@imperial.ac.uk

**Appendix 6: The SONO-PREDICT Study Recruitment Poster.**

Imperial College Healthcare NHS Trust

Imperial College London

# Pregnant?



We are recruiting first time pregnant women

**We are using safe, non-invasive ultrasound imaging as well as clinical assessments in labour to help us understand the likelihood of Caesarean delivery in labour**

**Interested?**

**Please contact Ms Arwa Hanidu**

**Email: arwa.hanidu18@imperial.ac.uk**

Improving ultrasound-based prediction of delivery mode - supervised by Professor C. Lees, Professor P. Bennett, Dr S. Usman (Imperial College London). Version 2_31st January 2021.

## Appendix 7: Information Sheet for Research Participants (Chapter 8, the Online Survey).

# Information Sheet for Research Participants

## Title of study: Study 1 - An online survey of parents and healthcare professionals' views on knowing the birth delivery mode

**What is the purpose of this study?**
We know that uncertainty about whether a birth will be vaginal or Caesarean can be difficult for some women. A research team at Imperial has developed a method of being able to predict the likelihood of vaginal delivery and length of labour while the woman is in labour, which is presented in an easy to understand format. The aim of the present study is to explore the perspective of women, partners and healthcare professionals, on the potential impact of having this information using a one-off anonymous online survey.

The study is being carried out by Imperial College Healthcare NHS Trust joint with King's College London Psychiatry department. Understanding gained from the study will help inform how the prediction information could best be used and conveyed to women and healthcare professionals (HCPs).

Before deciding to participate, it is important for you to understand why the research is being done and what it will involve. This patient information sheet gives you the purpose of the study and more detailed information about the conduct of the study and what will happen to you if you take part. Please get in contact if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. You are free to withdraw at any time without explanation.

**Why have I been invited?**
We are inviting participation from women who are currently pregnant and their birth partners, as well as parents up to 1 year post-delivery. We are also inviting Healthcare Professionals (Obstetricians and Midwives) of any grade and area of work within the discipline to take part in the study.

**Do I have to take part?**
A decision to take part in this study is entirely voluntary and It is entirely your decision to take part or not. Your responses to the online survey will be collected anonymously and no identifiable data will be collected. You are also free to withdraw from the study at any time, without giving any reason. This will not affect the standard of care you receive or any future care.

**Are there any benefits for taking part?**
Whilst there are no immediate benefits for those people participating in this study, it is hoped that this work will help inform future studies on the psychological impact of knowing the likelihood of having a vaginal or Caesarean birth early on in labour. Additionally, we hope that the information you provide may help shape and improve care provided in labour in the future.

**What will I have to do?**
If you decide to participate, you will be asked to follow an online link where a copy of this information sheet and consent form will be available to read. If you agree to take part, you will be asked to sign an online consent form to confirm you agree to participate. You will then

be directed towards a series of questions including demographic details. You will be asked about your views about having the prediction information regarding the delivery mode.

**Who is funding this study?**
This study is sponsored by Imperial College London. It is being jointly conducted by the Department of Obstetrics and Fetal Medicine at Imperial College London and the Institute of Psychiatry, Psychology and Neuroscience at Kings' College London.

**Does the study have ethical approval?**
The study has been reviewed and approved by xxxx. The REC number is xxxx

**What are the possible disadvantages and risks of taking part?**
We will be asking pregnant and postnatal women and partners to reflect on how this may be relevant to their experience during pregnancy. There is a very small chance you may become upset if you voluntarily disclose any experience that was particularly stressful or unhappy. You are free to withdraw at any stage or not answer a specific question.

**What will happen if I don't want to carry on with the study?**
You can withdraw from the study at any time and you do not need to give a reason. The data that you have given so far will be destroyed. This will not affect the standard of care you receive or any future care.

**What if something goes wrong?**
Imperial College London holds insurance policies, which apply to this study. If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Mr Christoph Lees, Email: christoph.lees@nhs.net). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

**Will my taking part in this study be kept confidential?**
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. We will follow ethical and legal practice and all information about you will be handled in confidence. Information will be collected by one of the research team members.

**What will happen to the results of the research study?**
We intend to use the result of this study in future pregnancy management. We intend to publish the results in local and international journals and meetings. You will not be identified in any report or publication.

**Who will be doing the research?**

The UK research group consists of Ms Megan Jansen (Trainee Clinical Psychologist, King's College London), Ms Sana Usman (Research Associate in Fetal and Maternal Medicine, Imperial College Ms Arwa Hanidu (Project Manager and Honorary Research Fellow in Obstetrics and Gynaecology Ultrasound, Imperial College),), Professor Christoph Lees

(Consultant in Obstetrics and Fetal Medicine, Imperial College), Dr Fiona Challacombe (NIHR Lecturer and Clinical Psychologist, King's College London), The statistician and data analyst collaborators include Dr Cedric Ginstet (BRC Lecturer in Statistical Modelling, King's College London and Dr John Hodsoll (CTU Statistician, King's College London).

If you would like to contact us, please email Ms Sana Usman on sana.usman@nhs.net

## Appendix 8: Information Sheet for Research Participants (Chapter 8, the Clinical Cohort Study).

# Information Sheet for Research Participants

## Title of study: Study 2 - A cohort study looking at the psychological effects of knowing the delivery mode

**What is the purpose of this study?**
Women planning a vaginal birth in hospital do not know how likely it is that this will be the way they give birth or if they will have Caesarean section in labour. Previous research has shown that this can cause anxiety for some women. Our research group has developed a way of predicting the likelihood of a vaginal delivery once women are in labour. The aim of the present study is to investigate from the point of view of women and partners, any benefits or impacts on the experience of labour from having this knowledge. The study also aims to develop a better understanding of people's perceptions to help inform future studies on the psychological impact of knowing the likelihood of having a vaginal or Caesarean birth. We hope that the information you provide may help shape and improve care provided in labour in the future.

Before deciding to participate, it is important for you to understand why the research is being done and what it will involve. This patient information sheet gives you the purpose of the study and more detailed information about the conduct of the study and what will happen to you if you take part. Take time to decide whether or not you wish to take part. You are free to withdraw at any time without explanation.

The study is being carried out by the Imperial College Healthcare NHS Trust.

**Why have I been invited?**
We are inviting women who are currently around 36 weeks pregnant (35-37 weeks) and not booked for an elective Caesarean section to take part in our study.

**Do I have to take part?**
A decision to take part in this study is entirely voluntary and It is entirely your decision to take part or not. Any decision regarding your participation will be kept confidential between you and the research team. You are also free to withdraw from the study at any time, without giving any reason. This will not affect the standard of care you receive or any future care.

**Are there any benefits for taking part?**
Information from the scans may influence the management of your pregnancy. Additionally, we hope that the information you provide may help shape and improve care provided in labour in the future.

**What will I have to do?**
If you decide to participate, you will be asked to follow an online link where a copy of this information sheet and consent form will be available to read. If you agree to take part, you will be asked to sign an online consent form to confirm you agree to participate. You will then be directed towards a series of questions to fill in online including demographic details. You will also be asked to complete some standard questionnaires about your general mood and feelings towards childbirth.

At the start of your labour, we will perform an ultrasound scan along-side the vaginal examination for the cervical assessment. Details of the scan will be provided in a separate patient information leaflet: Ultrasound scans in labour: what to expect. We will perform a transabdominal ultrasound scan similar to the dating (3 months) and anomaly scan (5 months) you may have had done. Transperineal scanning will involve placing a disinfected probe with a sterile probe cover between the labia (not in the vagina) for 1-2 minutes without undue pressure. Following the ultrasound scan, we will advise you of the likelihood of a vaginal delivery.

It is important to note that if a research team is not available when you attend in labour or if there is a change in delivery plans, it is possible you may not receive the scan and hence the delivery prediction.

At 12 weeks following your delivery, we will ask you to complete the online questionnaire asking you how you felt about receiving the prediction information as well as asking you to complete the psychological measures online again.

**Who is funding this study?**
This study is sponsored by Imperial College London. It is being jointly organised by the Department of Obstetrics at the Imperial College London and the Institute of Psychiatry, Psychology and Neuroscience at Kings' College London.

**Does the study have ethical approval?**
The study has been reviewed and approved by xxxx. The REC number is xxxx

**What are the possible disadvantages and risks of taking part?**
There is no known risk of harm to the baby from the ultrasound scan. You may experience slight discomfort when the probe is placed, though this is usually considered less than the discomfort experienced with vaginal examinations. We will also be asking you to reflect on your experience during pregnancy and labour. There is a very small chance you may become upset if you voluntarily disclose any experience that was particularly stressful or unhappy. You are free to withdraw at any stage or not answer a specific question.

**What if new information becomes available?**
Sometimes during the course of a research study, new information becomes available about the treatment that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to continue in the study you may be asked to sign an updated consent form. Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study.

Where participants are willing to be identified for information dissemination purposes, we will keep a separate online secure database and we will email any relevant publications to them.

**What will happen if I don't want to carry on with the study?**
You can withdraw from the study at any time and you do not need to give a reason. If you withdraw, we will ask you if we can still use your data that we have obtained so far for the study, but you do not have to agree to this, and if you do not agree, we will destroy all data we have obtained about you for the purposes of the study.

**What if something goes wrong?**
Imperial College London holds insurance policies, which apply to this study. If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Professor Christoph Lees, Email: Christoph.lees@nhs.net). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

**Will my taking part in this study be kept confidential?**
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. We will follow ethical and legal practice and all information about you will be handled in confidence. Information will be collected by one of the research team members.

All information that is collected about you during the course of the research will be kept strictly confidential. All electronic data about you will be stored on a secure Imperial College NHS Trust departmental database. This is a confidential computer system, which requires a specific password for access and can only be viewed by authorised persons.

**What will happen to the results of the research study?**
We intend to use the result of this study in future pregnancy management. We intend to publish the results in local and international journals and meetings. You will not be identified in any report or publication.

**Who will be doing the research?**

The UK research group consists of Ms Megan Jansen (Trainee Clinical Psychologist, King's College London), Ms Sana Usman (Research Associate in Fetal and Maternal Medicine, Imperial College), Ms Arwa Hanidu (Project Manager and Honorary Research Fellow in Obstetrics and Gynaecology Ultrasound, Imperial College), Professor Christoph Lees (Consultant in Obstetrics and Fetal Medicine, Imperial College), Dr Fiona Challacombe (NIHR Lecturer and Clinical Psychologist, King's College London), The statistician and data analyst collaborators include Dr Cedric Ginstet (BRC Lecturer in Statistical Modelling, King's College London and Dr John Hodsoll (CTU Statistician, King's College London).

If you would like to contact us, please email Ms Sana Usman: sana.usman@nhs.net

## Appendix 9: Consent Form (Chapter 8, the Online Survey).

# Consent Form for Research Participants

# Study 1 - An online survey of parents and healthcare professionals' views on knowing the birth delivery mode

**Study Identification Number: ……**

Thank you for opting to take part in this study. Please ensure you have read the patient information sheet. Please feel free to ask the researcher any questions you may have about the study.

This is the consent form, which confirms that you are happy to participate in the study and understand what this entails.

**Patient Study number: …….**

To confirm agreement with each of the statements below, please initial in the box.

1. I confirm that I have read, understood and have had time to consider the information sheet for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is a voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that my study data may be looked at by responsible individuals from the research staff, study sponsor, NHS Trust, or from regulatory authorities. ☐

4. I understand that my data will be collected for this study and may be used to help develop new research, and that data protection regulations will be observed and strict confidentiality maintained. I understand that anonymous data may be shared with researchers external to Imperial College, and study commercial partners. ☐

5. I understand and agree that my data relating to the study being stored electronically on secure databases in the Department of Obstetrics and Fetal Medicine at Imperial College London. ☐

6. I understand that my data will be stored for up to 10 years according to Imperial College policy and may be used in future ethically approved studies. ☐

1. I agree to my research data to be accessed by responsible persons from Imperial College London, Imperial College NHS Trust and regulatory authorities in order to ensure that the study is being conducted correctly. ☐

2. I confirm agreement to take part in the above study. I understand a copy of this signed consent form, containing my full name, will be sent to the main supervisor. ☐

**Participant's name (BLOCK CAPITALS): …….**

**Signature: ..... Date: ……**

**Contact for Further Information:**

The UK research group consists of ), Ms Megan Jansen (Trainee Clinical Psychologist, King's College London)Ms Sana Usman (Research Associate in Fetal and Maternal Medicine, Imperial College), Ms Arwa Hanidu (Project Manager and Honorary Research Fellow in Obstetrics and Gynaecology Ultrasound, Imperial College Professor Christoph Lees (Consultant in Obstetrics and Fetal Medicine, Imperial College), Dr Fiona Challacombe (NIHR Lecturer and Clinical Psychologist, King's College London),. The statistician and data analyst collaborators include Dr Cedric Ginstet (BRC Lecturer in Statistical Modelling, King's College London and Dr John Hodsoll (CTU Statistician, King's College London).

If you would like to contact us, please email Ms Sana Usman on sana.usman@nhs.net

## Appendix 10: Consent Form (Chapter 8, the Clinical Cohort Study).

# Consent Form for Research Participants

# Study 2 - A cohort study looking at the psychological effects of knowing the delivery mode

**Study Identification Number: ……**

Thank you for opting to take part in this study. Please ensure you have read the patient information sheet. Please feel free to ask the researcher any questions you may have about the study.

This is the consent form, which confirms that you are happy to participate in the study and understand what this entails.

**Patient Study number: …….**

To confirm agreement with each of the statements below, please initial in the box.

1. I confirm that I have read, understood and have had time to consider the information sheet for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is a voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that my clinical information and study data may be looked at by responsible individuals from the research staff, study sponsor, NHS Trust, or from regulatory authorities; I give permission for these individuals to have access to my records such as hand-held maternity and hospital notes or contact my GP for relevant information which are not obtainable from my notes. ☐

4. I understand that my medical data will be collected for this study and may be used to help develop new research, and that data protection regulations will be observed and strict confidentiality maintained. I understand that anonymous data may be shared with researchers external to Imperial College, and study commercial partners. ☐

5. I agree to take part in the above study and agree to have transabdominal and transperineal ultrasound scans performed in the event cervical assessment is deemed necessary or when I am thought to be in labour. ☐

1. I understand and agree that the images and data relating to the study being stored electronically on secure databases in the Department of Metabolism, Digestion and Reproduction at Imperial College Healthcare NHS Trust. ☐

2. I understand that my images and data will be stored for up to 10 years according to Imperial College policy and may be used in future ethically approved studies. ☐

3. I agree to my research notes and data to be accessed by responsible persons from Imperial College London, Imperial College NHS Trust and regulatory authorities in order to ensure that the study is being conducted correctly. ☐

4. I understand that if I lose capacity to consent whilst I am a participant in the study, all previous data and tissue collected with consent will be retained and used, but no further data collection or procedures will be carried out. ☐

5. I agree that the details and outcome of my pregnancy may be followed via the local hospital birth registry. ☐

6. I confirm agreement to take part in the above study. I understand a copy of this signed consent form, containing my full name will be sent to the main supervisor ☐

**Participant's name (BLOCK CAPITALS): …….**

**Signature: ..... Date: …….**

**Contact for Further Information:**

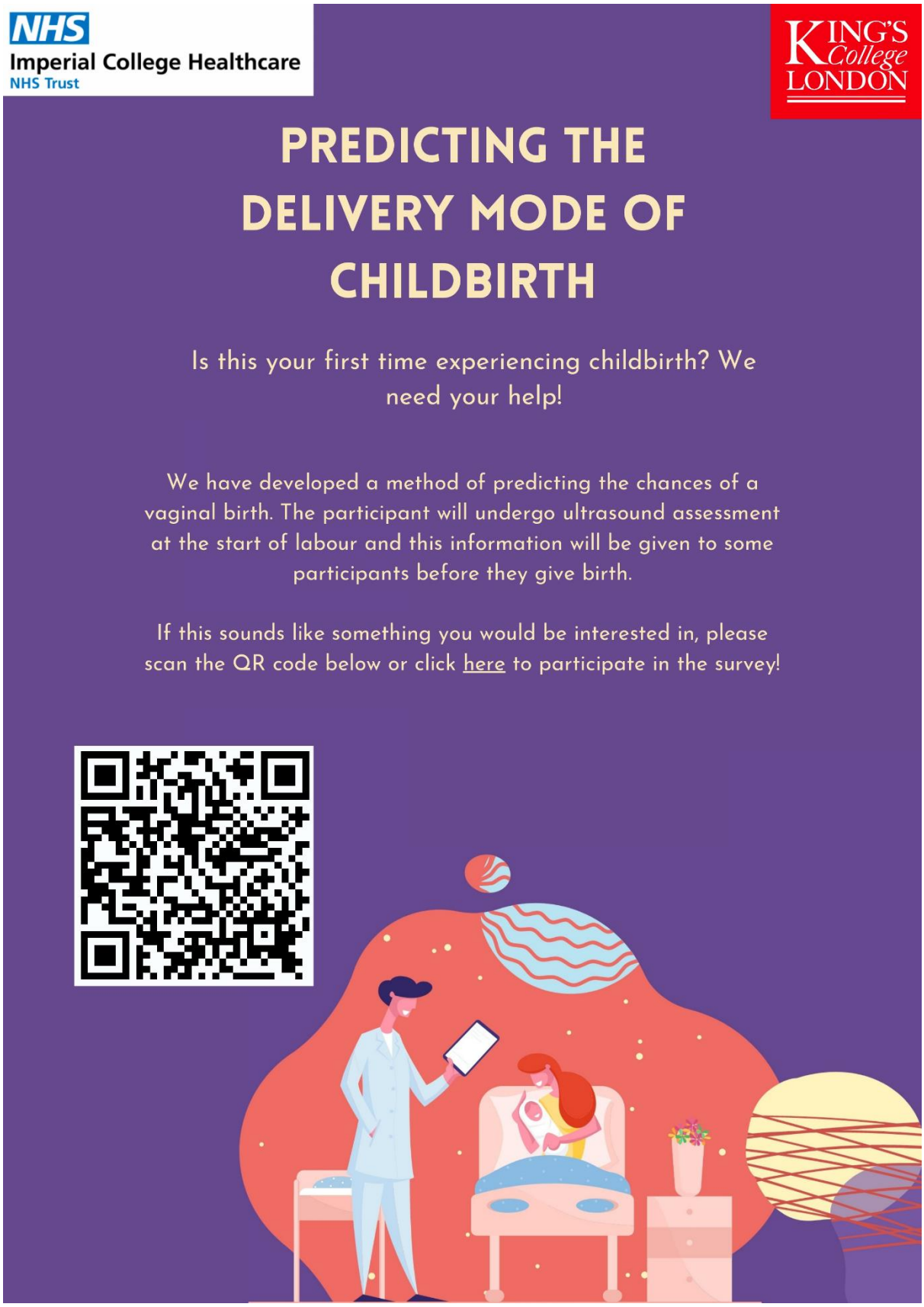
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If you would like to contact us, please email Ms Sana Usman on sana.usman@nhs.net

**Appendix 11: Recruitment Leaflet (Chapter 8, the Online Survey).**



**Appendix 12: Recruitment Leaflet (Chapter 8, the Clinical Cohort Study).**



# Appendix 13: The Online Survey of the Psychological Impact Study, (Chapter 8).

## 13.1 Online Survey for healthcare professionals.

**Prediction Information**
The following questions ask about a hypothetical situation.

Imagine if healthcare professionals were able to predict the likelihood of the delivery mode of either a vaginal (spontaneous or instrumental) or Caesarean with reasonable accuracy of around 84% through an algorithm including information from an ultrasound scan and clinical assessments at the start of labour. Please note the start of labour is as indicated by the NHS guidelines.

How confident would you feel disclosing this prediction information to the pregnant women?
*Slider Scale - On a scale from 0-10 with 0 being not at all confident and 10 being very confident*

Please explain your answer, what factors make you feel more or less confident to disclose this information?
*Free Text Box*

What is the lowest percentage accuracy rating, you feel comfortable disclosing the prediction information to women?
*Drop down options (0-9, 10-19, 20-29, 30-39, 40-49, 50-59, 60-69, 70-79-80-89-90-100)*

Do you think pregnant women would want to know?

- *Yes*
- *No*
- *Maybe*

Please explain your answer
*Free Text Box*

How helpful would this be for the pregnant women?
*Slider Scale – On a scale from 0-10 with 0-not helpful at all, 5 being neither helpful nor unhelpful (indifferent) and 10 being very helpful.*

Please explain your answer including any possible reasons why this would be helpful/unhelpful.
*Free Text Box*

How helpful would this be in doing your work?
*Slider Scale – On a scale from 0-10 with 0-not helpful at all and 10 being very helpful.*

Please explain your answer including possible reasons why this would be helpful/unhelpful.

*Free Text Box*

Can you think of any advantages of having his prediction information about delivery mode? You might want to think about different patient groups or clinical scenarios such as high risk patients those with diabetes or at an older age, for example.
*Free Text Box*

Can you think of any disadvantages of having this prediction information about delivery mode? You might want to think about different patient groups or clinical scenarios such as high risk patients those with diabetes or at an older age, for example.
*Free Text Box*

If you were given the prediction information, what difference would this make for you in your own work?
*Slider Scale – On a scale from 0-10 with 0-no difference at all and 10 being very different.*

Please explain your answer, including any areas where differences or no differences might occur.
*Free Text Box*

If you were given the prediction information, what difference would this make for the pregnant women?
*Slider Scale – On a scale from 0-10 with 0-no difference at all and 10 being very different.*

Please explain your answer, again including any areas where differences or no differences might occur.
*Free Text Box*

What is the lowest percentage accuracy rating, would you use this prediction information in the pregnant women's management of care?
*Drop down options (0-9, 10-19, 20-29, 30-39, 40-49, 50-59, 60-69, 70-79-80-89-90-100)*

## 13.2 Online Survey for Pregnant/Postnatal Mothers and Partners.

**Pregnancy Experience**
The following questions will ask you about your experience of when you or your partner was pregnant. For those who have given birth in the last year, please try to think back to you or your partner's experience at the time, rather than reflecting on what you now know since the delivery.

How anxious **overall** do/did you feel during you or your partner's pregnancy?
*Slider Scale - On a scale from 0-10 with 0 being not at all and 10 being extremely anxious*

Please explain your answer, what factors made you feel more or less anxious?
Open Text Box

Did you know what type of delivery (vaginal or caesarean) you were having?

- Yes
- No
- Maybe

If you answered yes or maybe to the question above, how confident did/do you feel that you were going to deliver by this mode?
*Slider Scale - On a scale from 0-10 with 0 being not at all confident and 10 being very confident*

How anxious do/did you feel about knowing or not knowing the birth delivery mode (vaginal or caesarean)?
*Slider Scale - On a scale from 0-10 with 0 being not at all and 10 being extremely anxious*

On average, how confident do/did you feel in your ability to cope during the labour and delivery?
*Slider Scale - On a scale from 0-10 with 0 being not at all confident and 10 being very confident*

Were there any factors that made you feel more or less confident about the delivery?
Open Text Box

Is/was there anything that you would have liked to have known during the pregnancy?
*Open Text Box*

Any other comments about you or your partner's pregnancy experience?
*Open Text Box*

**Prediction Information**
The following questions ask about a hypothetical situation.

Imagine if healthcare professionals were able to predict the likelihood of the delivery mode (Vaginal delivery including instrumental or Caesarean delivery) with reasonable accuracy through an ultrasound scan and a clinical assessment at the start of labour.

Would you want to know?

- *Yes*
- *No*

Please explain your answer
*Free Text Box*

How helpful would this be for you?
*Slider Scale – On a scale from 0-10 with 0-not helpful at all and 10 being very helpful.*

Please explain your answer
*Free Text Box*

Can you think of any advantages of having his prediction information about delivery mode?
*Free Text Box*

Can you think of any disadvantages of having this prediction information about delivery mode?
*Free Text Box*

If you were given the prediction information, what difference would this make for you or your partner?
*Free Text Box*

# Appendix 14: The Clinical Cohort Study Questionnaire, (Chapter 8).

## 14.1 Fear of Birth Scale.

How do you feel right now about the approaching birth?
Please mark with an X on the lines below.

Calm ——————————————————— Worried

No fear ——————————————————— Strong fear

**14.2 Depression, Anxiety and Stress Scale.**

# DASS21

Name: Date:

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you **over the past week**. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree or a good part of time
3 Applied to me very much or most of the time

| | | | | | |
|---|---|---|---|---|---|
| 1 (s) | I found it hard to wind down | 0 | 1 | 2 | 3 |
| 2 (a) | I was aware of dryness of my mouth | 0 | 1 | 2 | 3 |
| 3 (d) | I couldn't seem to experience any positive feeling at all | 0 | 1 | 2 | 3 |
| 4 (a) | I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion) | 0 | 1 | 2 | 3 |
| 5 (d) | I found it difficult to work up the initiative to do things | 0 | 1 | 2 | 3 |
| 6 (s) | I tended to over-react to situations | 0 | 1 | 2 | 3 |
| 7 (a) | I experienced trembling (e.g. in the hands) | 0 | 1 | 2 | 3 |
| 8 (s) | I felt that I was using a lot of nervous energy | 0 | 1 | 2 | 3 |
| 9 (a) | I was worried about situations in which I might panic and make a fool of myself | 0 | 1 | 2 | 3 |
| 10 (d) | I felt that I had nothing to look forward to | 0 | 1 | 2 | 3 |
| 11 (s) | I found myself getting agitated | 0 | 1 | 2 | 3 |
| 12 (s) | I found it difficult to relax | 0 | 1 | 2 | 3 |
| 13 (d) | I felt down-hearted and blue | 0 | 1 | 2 | 3 |
| 14 (s) | I was intolerant of anything that kept me from getting on with what I was doing | 0 | 1 | 2 | 3 |
| 15 (a) | I felt I was close to panic | 0 | 1 | 2 | 3 |
| 16 (d) | I was unable to become enthusiastic about anything | 0 | 1 | 2 | 3 |
| 17 (d) | I felt I wasn't worth much as a person | 0 | 1 | 2 | 3 |
| 18 (s) | I felt that I was rather touchy | 0 | 1 | 2 | 3 |
| 19 (a) | I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat) | 0 | 1 | 2 | 3 |
| 20 (a) | I felt scared without any good reason | 0 | 1 | 2 | 3 |
| 21 (d) | I felt that life was meaningless | 0 | 1 | 2 | 3 |

### 14.3 WIJMA Delivery Expectancy/Experience Questionnaire: Versions A & B.

Version A was used in the pre-labour questionnaires. Version B was used in the post-labour questionnaires.

**The Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ): version A**

**Instruction**

This questionnaire is about feelings and thoughts women may have at the prospect of labour and delivery. The answers to each question appear as a scale from 1 to 6. The outermost answers (1 and 6 respectively) correspond to the opposite extremes of a certain feeling or thought.

Please complete each question by drawing a circle around the number belonging to the answer which most closely corresponds to **how you imagine** your labour and delivery will be. Please answer **how you imagine** your labour and delivery will be - not the way you hope it will be

| How do you think your labour and delivery will turn out as a whole? | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Extremely fantastic** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all fantastic** |
| **Extremely frightful** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all frightful** |

| How do you think you will feel <u>in general</u> during the labour and delivery? | | | | | | | |
|---|---|---|---|---|---|---|---|
| Extremely lonely | 1 | 2 | 3 | 4 | 5 | 6 | Not at all lonely |
| Extremely strong | 1 | 2 | 3 | 4 | 5 | 6 | Not at all strong |
| Extremely confident | 1 | 2 | 3 | 4 | 5 | 6 | Not at all confident |
| Extremely afraid | 1 | 2 | 3 | 4 | 5 | 6 | Not at all afraid |
| Extremely deserted | 1 | 2 | 3 | 4 | 5 | 6 | Not at all deserted |
| Extremely weak | 1 | 2 | 3 | 4 | 5 | 6 | Not at all weak |
| Extremely safe | 1 | 2 | 3 | 4 | 5 | 6 | Not at all safe |
| Extremely independent | 1 | 2 | 3 | 4 | 5 | 6 | Not at all independent |
| Extremely desolate | 1 | 2 | 3 | 4 | 5 | 6 | Not at all desolate |
| Extremely tense | 1 | 2 | 3 | 4 | 5 | 6 | Not at all tense |
| Extremely glad | 1 | 2 | 3 | 4 | 5 | 6 | Not at all glad |
| Extremely proud | 1 | 2 | 3 | 4 | 5 | 6 | Not at all proud |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Extremely relaxed | 1 | 2 | 3 | 4 | 5 | 6 | Not at all relaxed |
| Extremely happy | 1 | 2 | 3 | 4 | 5 | 6 | Not at all happy |
| **How do you think you will feel during the labour and delivery?** | | | | | | | |
| Extreme panic | 1 | 2 | 3 | 4 | 5 | 6 | No panic at all |
| Extreme hopelessness | 1 | 2 | 3 | 4 | 5 | 6 | No hopelessness at all |
| Extreme longing for the child | 1 | 2 | 3 | 4 | 5 | 6 | Not longing for the child at all |
| Extreme self-confidence | 1 | 2 | 3 | 4 | 5 | 6 | No self-confidence at all |
| Extreme trust | 1 | 2 | 3 | 4 | 5 | 6 | No trust at all |
| Extreme pain | 1 | 2 | 3 | 4 | 5 | 6 | No pain at all |
| **What do you think will happen when labour is most intense?** | | | | | | | |
| I will behave extremely badly | 1 | 2 | 3 | 4 | 5 | 6 | I will not behave badly at all |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **I will totally lose control of myself** | **1** | **2** | **3** | **4** | **5** | **6** | **I will not lose control of myself at all** |

| **How do you imagine it will feel the very moment you deliver the baby?** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Extremely funny** | **1** | **2** | **3** | **4** | **5** | **6** | **Not funny at all** |
| **Extremely natural** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all natural** |
| **Extremely self-evident** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all self-evident** |
| **Extremely dangerous** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all dangerous** |

| **Have you, during the last month, had fantasies about the labour and delivery, for example...** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **.fantasies that your child will die during labour/delivery?** | | | | | | | |
| **Never** | **1** | **2** | **3** | **4** | **5** | **6** | **Very often** |
| **.fantasies that your child will be injured during labour/delivery?** | | | | | | | |
| **Never** | **1** | **2** | **3** | **4** | **5** | **6** | **Very often** |

Would you please now check that you have not forgotten to answer any questions.

**The Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ): version B**

The answers to each question appear as a scale from 1 to 6. The outermost answers (1 and 6 respectively) correspond to the opposite extremes of a certain feeling or thought.

Please complete each question by drawing a circle around the number belonging to the answer which most closely corresponds to **how you now think** your labour and delivery will be. Please answer **how you now think** your labour and delivery will be - not the way you wish it would have been.

| How do you think your experience your labour and delivery as a whole? | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Extremely fantastic** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all fantastic** |
| **Extremely frightful** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all frightful** |

| How do did you will feel <u>in general</u> during the labour and delivery? | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Extremely lonely** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all lonely** |
| **Extremely strong** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all strong** |
| **Extremely confident** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all confident** |
| **Extremely afraid** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all afraid** |
| **Extremely deserted** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all deserted** |
| **Extremely weak** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all weak** |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Extremely independent** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all independent** |
| **Extremely desolate** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all desolate** |
| **Extremely tense** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all tense** |
| **Extremely glad** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all glad** |
| **Extremely proud** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all proud** |
| **Extremely abandoned** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all abandoned** |
| **Totally composed** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all composed** |
| **Extremely relaxed** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all relaxed** |
| **Extremely happy** | **1** | **2** | **3** | **4** | **5** | **6** | **Not at all happy** |

| **What did you feel during the labour and delivery?** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Extreme panic** | **1** | **2** | **3** | **4** | **5** | **6** | **No panic at all** |
| **Extreme hopelessness** | **1** | **2** | **3** | **4** | **5** | **6** | **No hopelessness at all** |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Extreme self-confidence | 1 | 2 | 3 | 4 | 5 | 6 | No self-confidence at all |
| Extreme trust | 1 | 2 | 3 | 4 | 5 | 6 | No trust at all |
| Extreme pain | 1 | 2 | 3 | 4 | 5 | 6 | No pain at all |
| **What happened when the labour was most intense?** | | | | | | | |
| I will behave extremely badly | 1 | 2 | 3 | 4 | 5 | 6 | I will not behave badly at all |
| I will dare to totally surrender control to my body | 1 | 2 | 3 | 4 | 5 | 6 | I will not dare to surrender control to my body at all |
| I will totally lose control of myself | 1 | 2 | 3 | 4 | 5 | 6 | I will not lose control of myself at all |
| **How was the very moment you delivered the baby?** | | | | | | | |
| Extremely funny | 1 | 2 | 3 | 4 | 5 | 6 | Not funny at all |
| Extremely natural | 1 | 2 | 3 | 4 | 5 | 6 | Not at all natural |
| Extremely self-evident | 1 | 2 | 3 | 4 | 5 | 6 | Not at all self-evident |

**Have you, during the labour and delivery, fantasies like for example...**

**.fantasies that your child will die during labour/delivery?**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Never** | **1** | **2** | **3** | **4** | **5** | **6** | **Very often** |

**.fantasies that your child will be injured during labour/delivery?**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Never** | **1** | **2** | **3** | **4** | **5** | **6** | **Very often** |

Would you please now check that you have not forgotten to answer any questions.

# Appendix 15: The Initial Online Survey of Healthcare Professionals and Parents to Improve the Predictive Models and Applications.

Online Survey for Healthcare Professionals – Focus Group Comments (n=6)

Title

- Potentially changing the word 'knowing' to 'anticipating' saying 'Healthcare Professionals' views on anticipating the birth delivery mode' instead

Demographics

- Clarify the word 'area' in the question – 'How many years have you worked in this area?'
- Age to include brackets rather than open text box
- Is the survey limited to the UK?
- Include gender in demographics section

Prediction Information

- Information to be added at the start of this section, clarifying the accuracy, what would be regarded as the start of pregnancy and the algorithm only predicting between vaginal (which includes both spontaneous and instrumental) or caesarean.
- Highlight on the 'how helpful would this be for pregnant women/in doing your work' to state that 5 may mean indifferent – not helpful or helpful.
- Perhaps question around are their situations that you can think of in which it would be helpful/not as helpful.
- Physical representation of the risk using a yard stick.
- Felt potentially vignette/scenarios would be helpful to have in the survey for HCP to think about possible benefits and limitations. (i.e., high risk, diabetes, older women, etc)
- Possibly a dropdown menu for the advantages with tick all that apply and an option to write any other options not listed.
- To include questions around what the advantages for are the professional involved, the pregnant women, the profession at large and the service at large.
- To include 'I don't know' as possible answers to questions
- Perhaps questions around what difference would it make to HCP if the accuracy was at 50%, 70%, 90% etc. Where would clinicians feel comfortable using the information from the app?

App

- Change wording of 'risk prediction' at the top of the app to the 'likelihood'. This will ensure it is more user friendly.
- App on first impressions looks predominately red. Distribution of colours to be thought about when presenting to pregnant women.

Online Survey for Pregnant Women – Individual Interviews (n=4)

- To include question around factors that made people feel more or less confident about the delivery.

- I guess a sliding scale is an easy format to work with if you have quite a 'steady' pregnancy, birth and post birth period. For some mums it might be difficult for them to put a number on a period that is full of highs and lows however the survey does give a couple of opportunities to give further details so that is good. - Perhaps we stipulate that the questions say 'on average' to account for these ups and downs.

- This question doesn't feel quite right to me - How anxious do/did you feel about not knowing the birth delivery mode (vaginal, instrumental or caesarean)? - As far as I was concerned, I felt like I did know the birth delivery mode (assuming of course that something didn't happen to change this) – We might need to account for those who have decided the delivery mode already in the survey. I wonder whether we add and reword to the following:
  Did you know what type of delivery (vaginal or caesarean) you were having?
  - Yes
  - No
  - Maybe

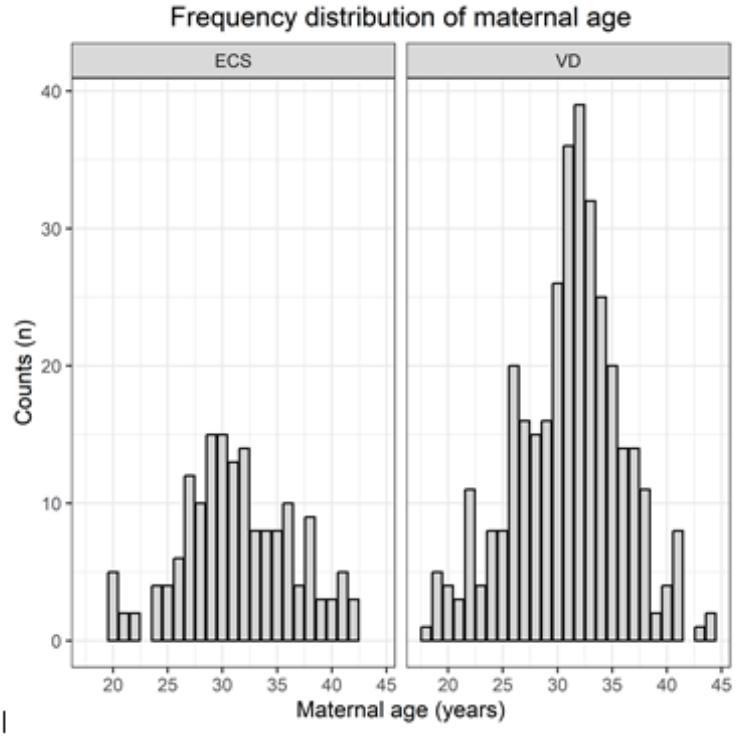
  If you answered yes or maybe to the question above, how confident did you feel that you were going to deliver by this mode?
  *Slider Scale - On a scale from 0-10 with 0 being not at all confident and 10 being very confident*

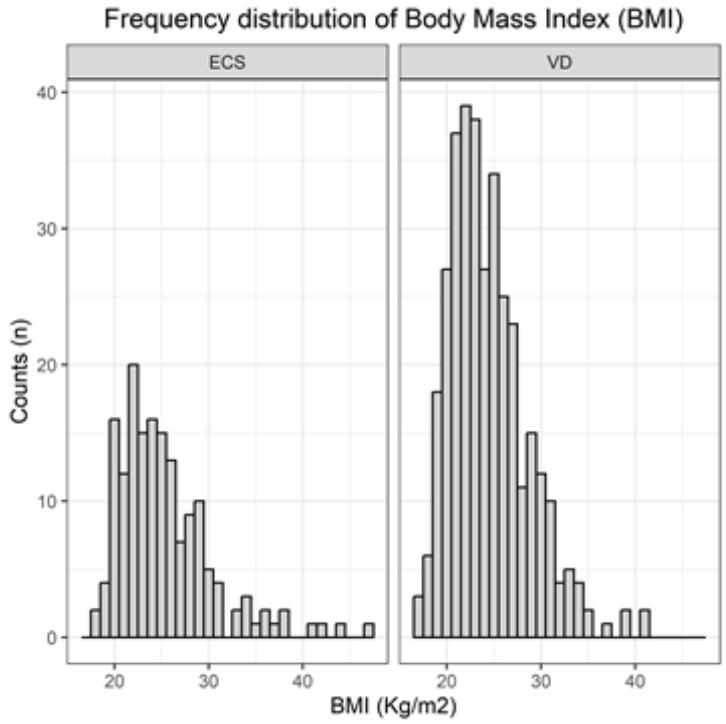
  How anxious do/did you feel about knowing or not knowing the birth delivery mode (vaginal or Caesarean)?
  *Slider Scale - On a scale from 0-10 with 0 being not at all and 10 being extremely anxious*

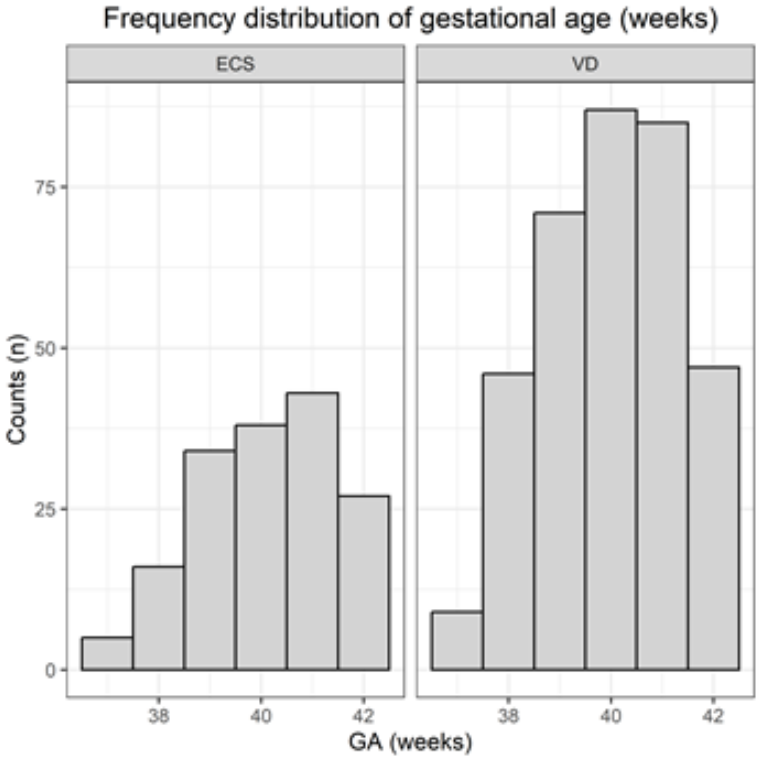
# CHAPTER 12

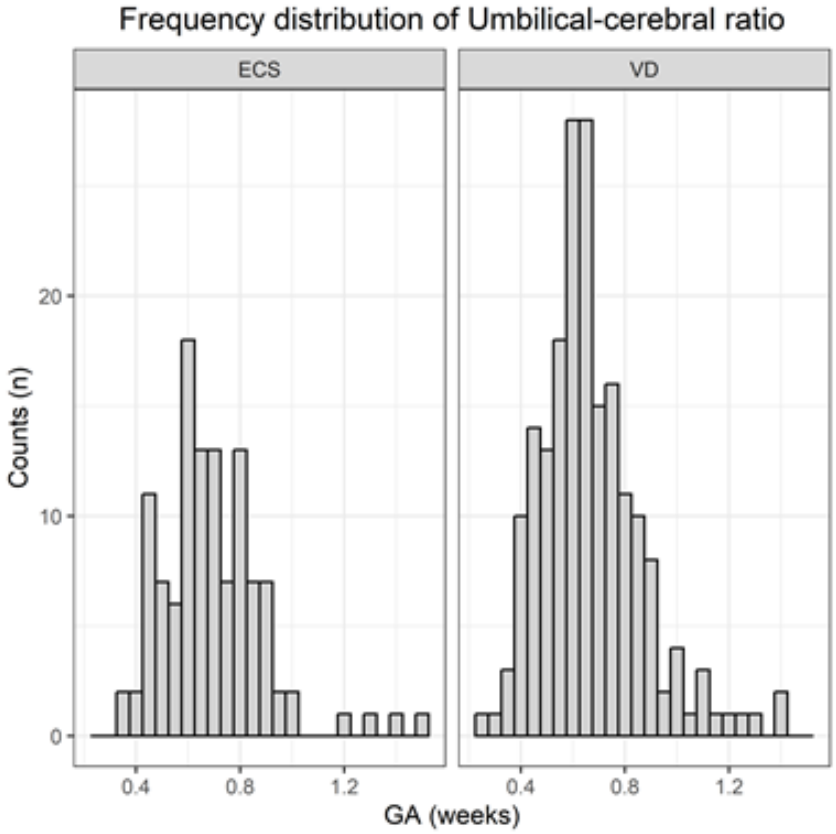
# Supplemental Data

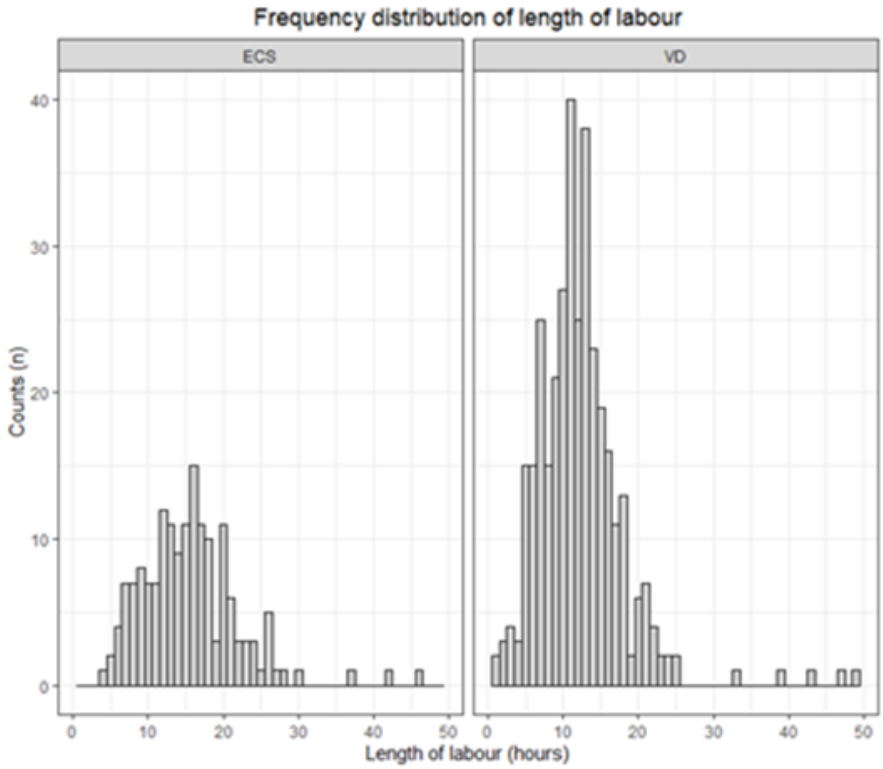
**12.1 Frequency Distribution of Prognostic Variables during the First and Repeat Ultrasound Assessments of the SONO-PREDICT study.**

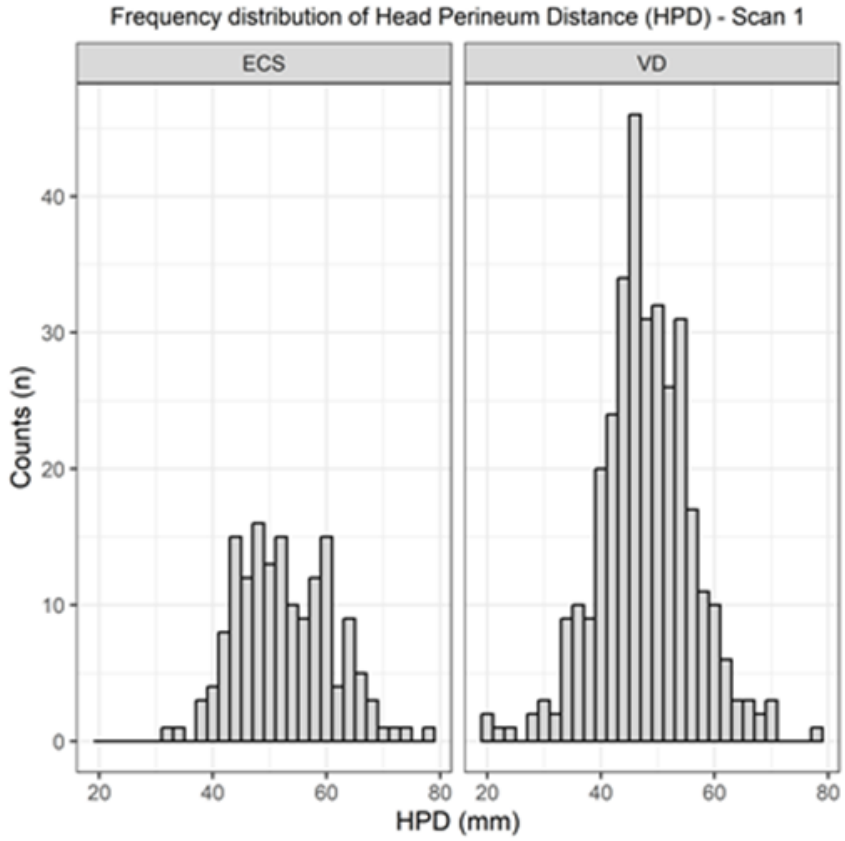


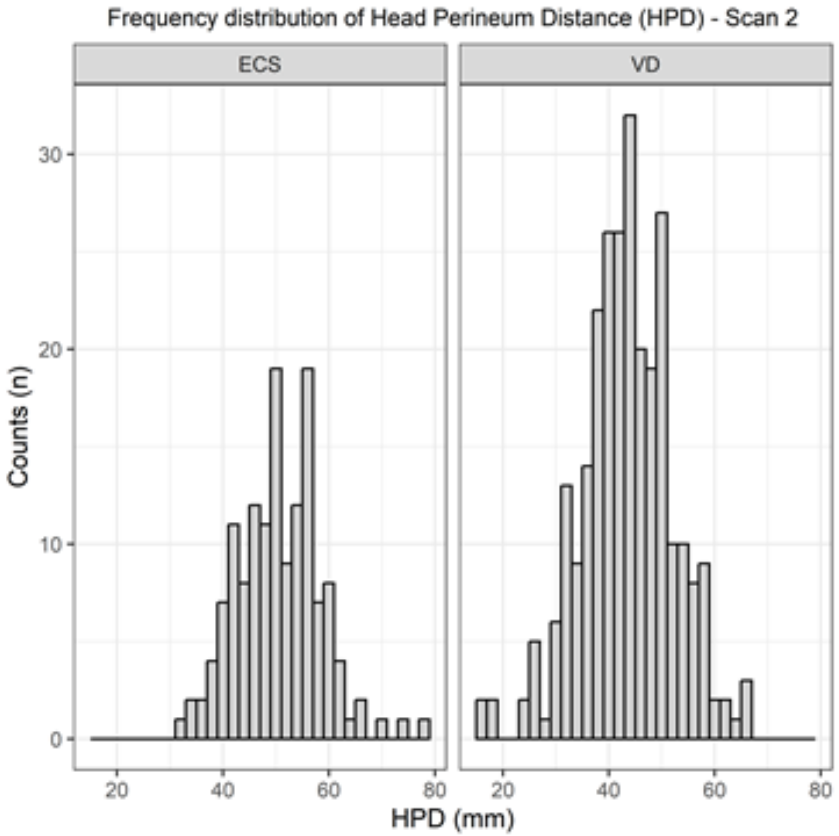



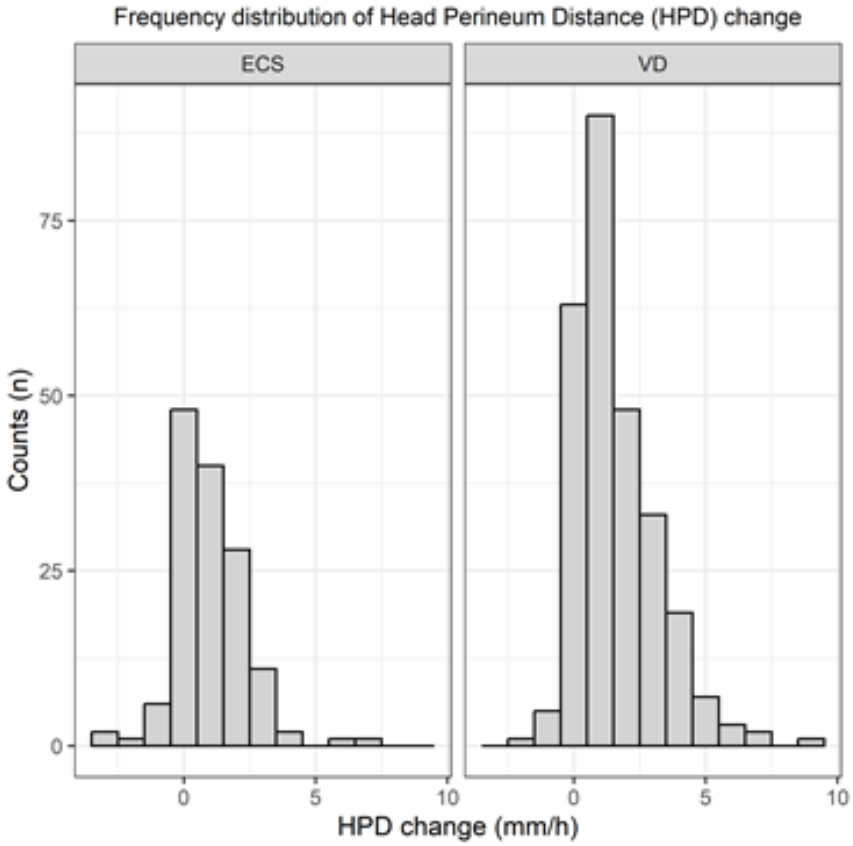

Frequency distribution of gestational age (weeks)
ECS
VD
Counts (n)
0
25
50
75
38
40
42
GA (weeks)

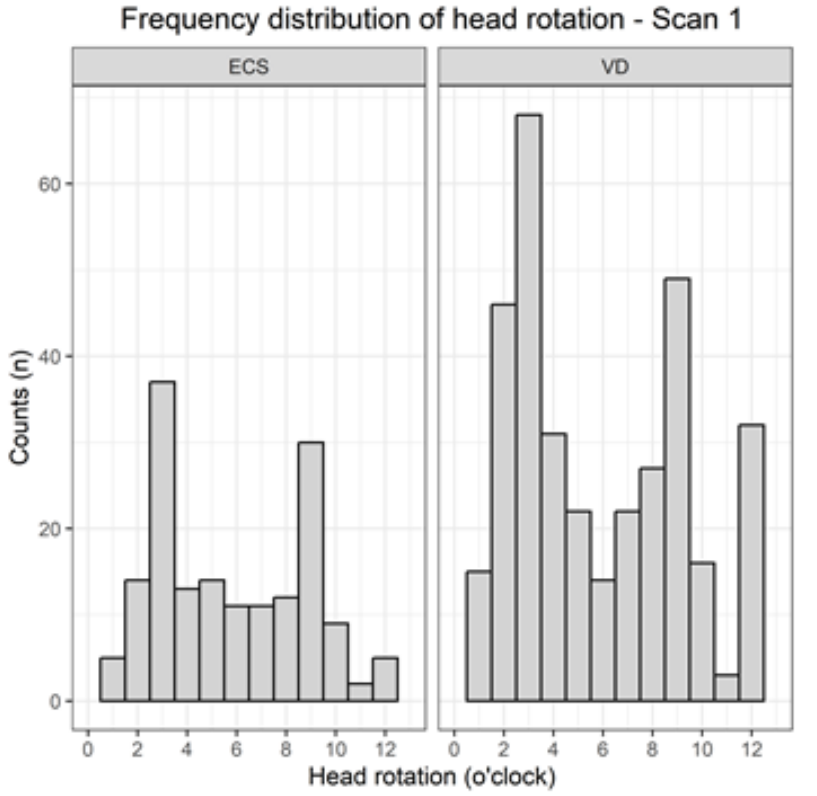

Frequency distribution of Umbilical-cerebral ratio
ECS
VD
Counts (n)
0
10
20
0.4
0.8
1.2
GA (weeks)

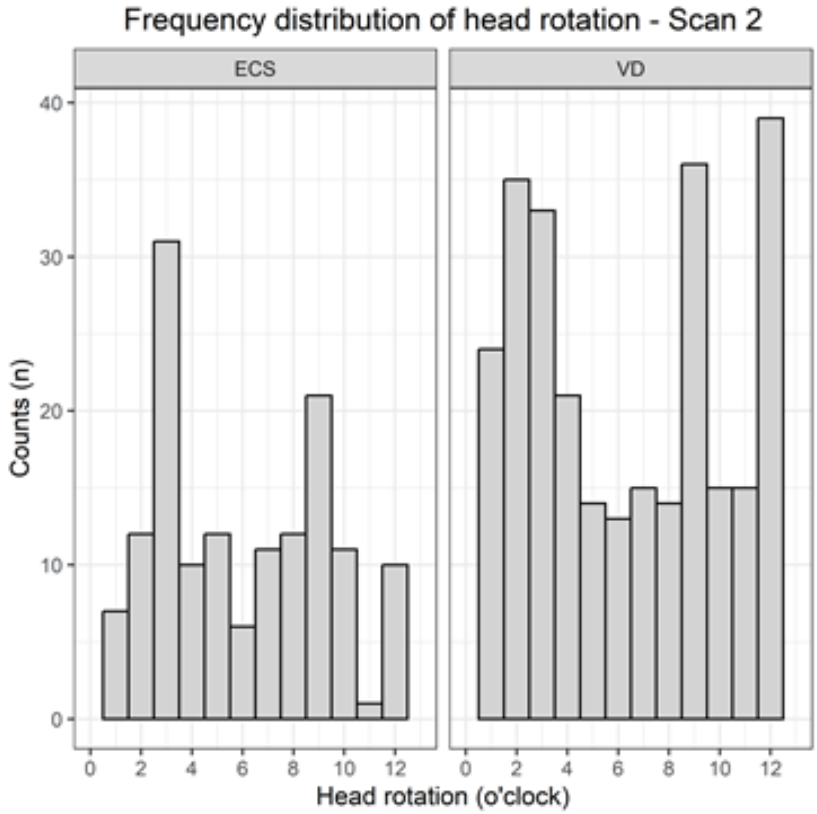

Frequency distribution of length of labour
ECS
VD
Counts (n)
0
10
20
30
40
0
10
20
30
40
50
Length of labour (hours)

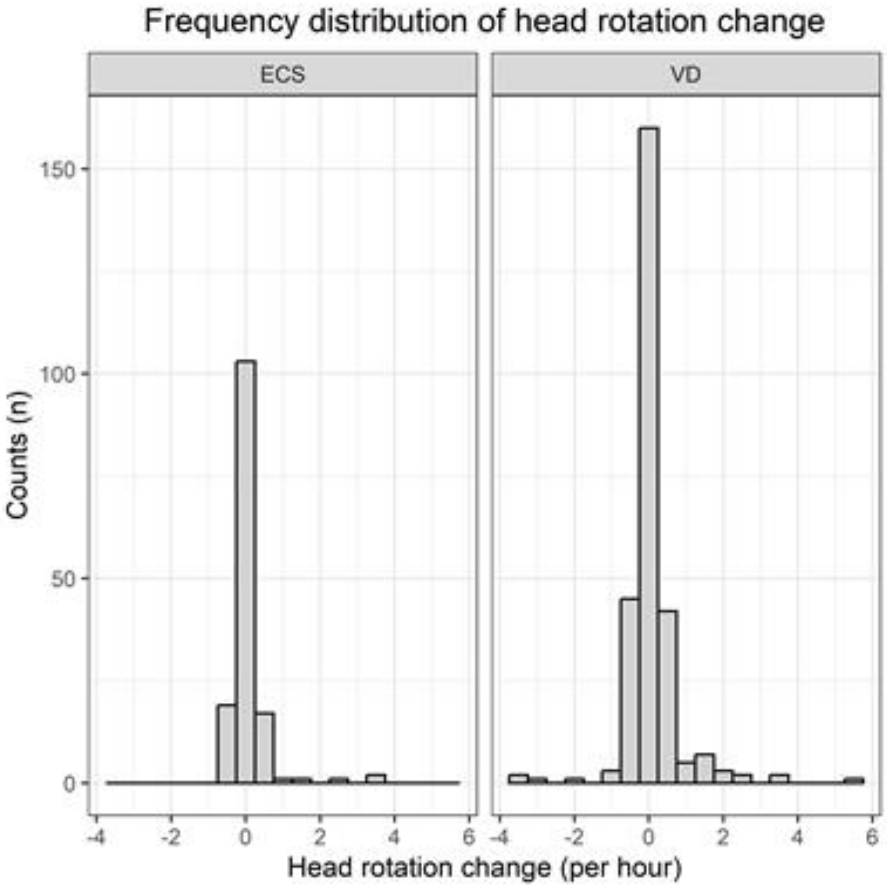

Frequency distribution of Head Perineum Distance (HPD) - Scan 1
ECS
VD
Counts (n)
0
10
20
30
40
20
40
60
80
HPD (mm)

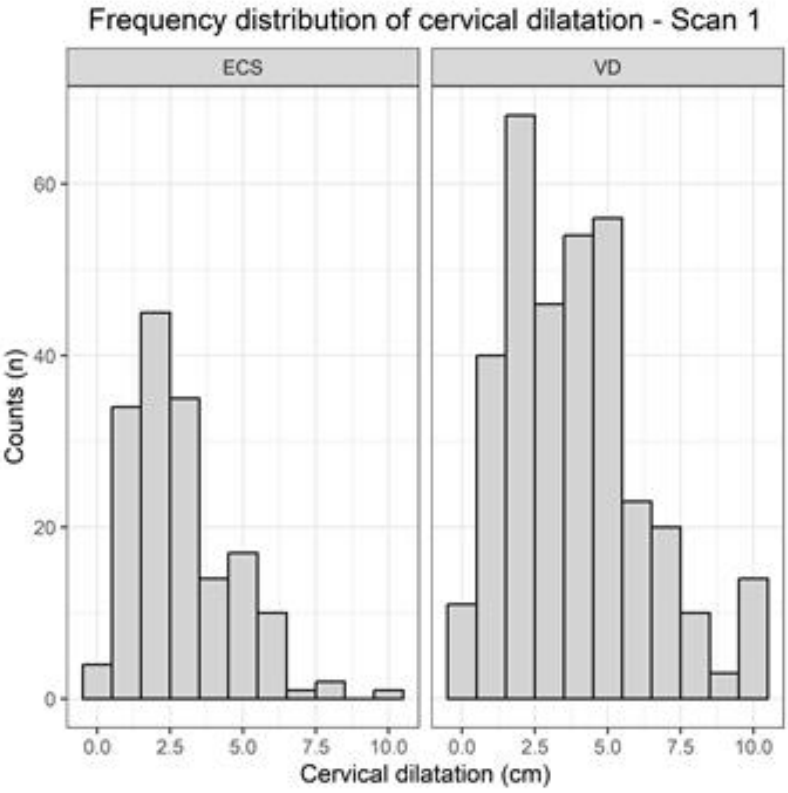

Frequency distribution of Head Perineum Distance (HPD) - Scan 2
ECS
VD
Counts (n)
0
10
20
30
20
40
60
80
HPD (mm)

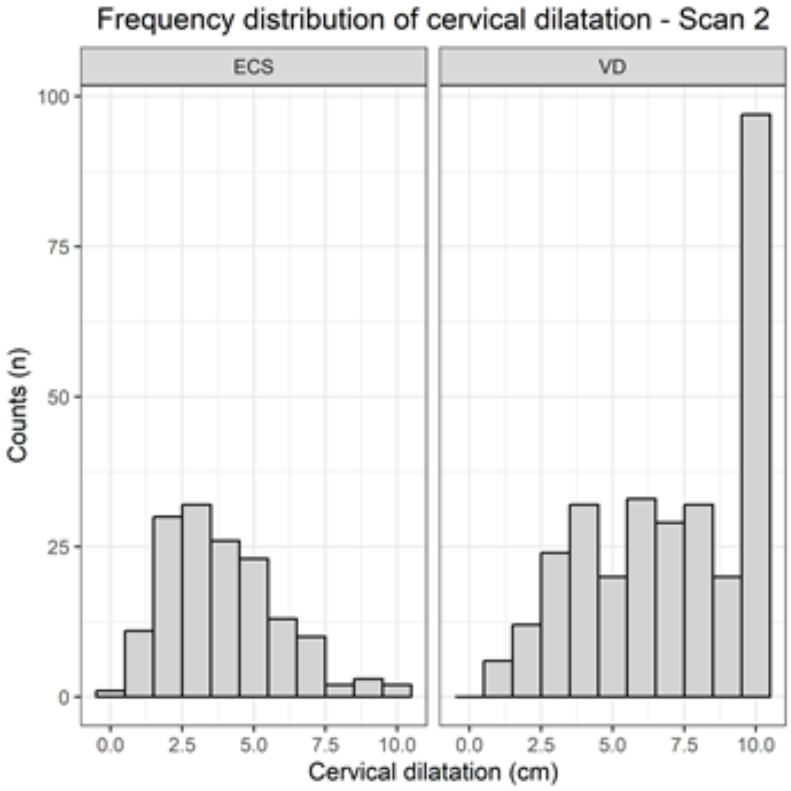

Frequency distribution of Head Perineum Distance (HPD) change
ECS
VD
Counts (n)
0
25
50
75
0
5
10
HPD change (mm/h)

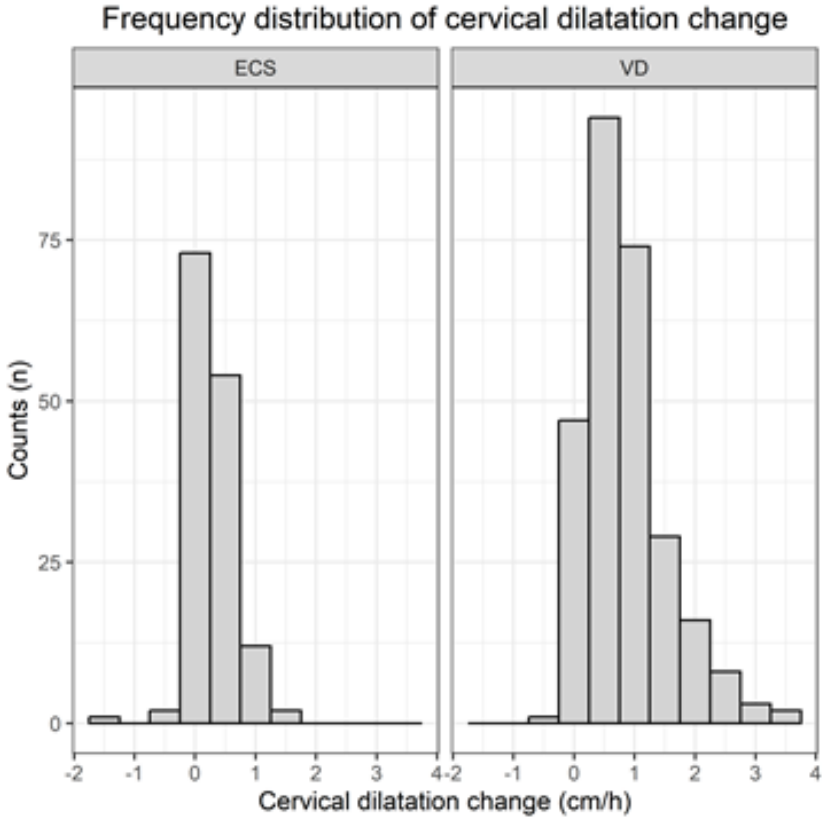

Frequency distribution of head rotation - Scan 1
ECS
VD
Counts (n)
0
20
40
60
0 2 4 6 8 10 12
Head rotation (o'clock)

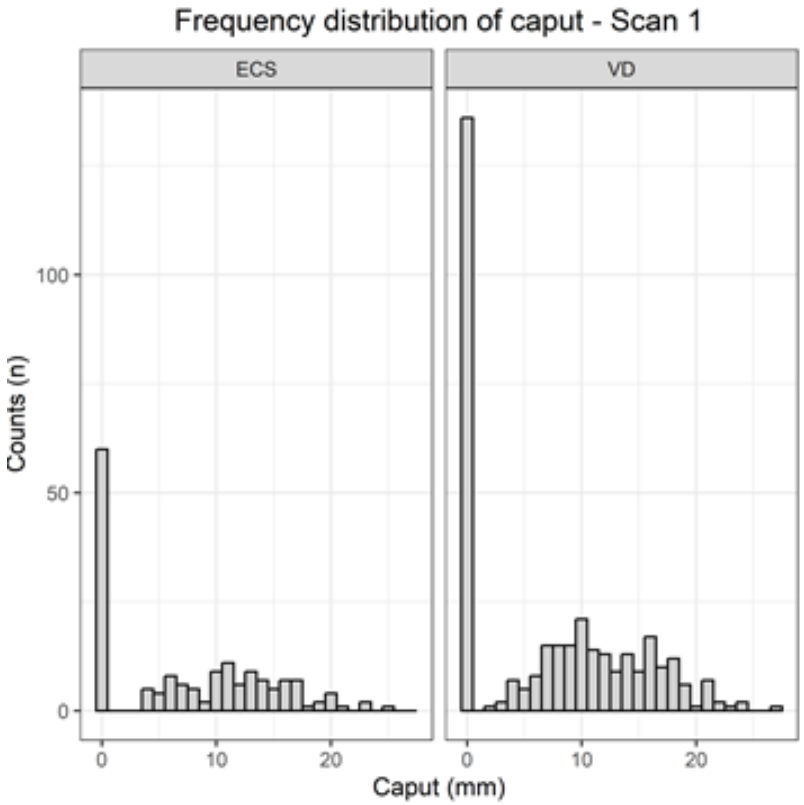

Frequency distribution of head rotation - Scan 2
ECS
VD
Counts (n)
0
10
20
30
40
0 2 4 6 8 10 12
Head rotation (o'clock)

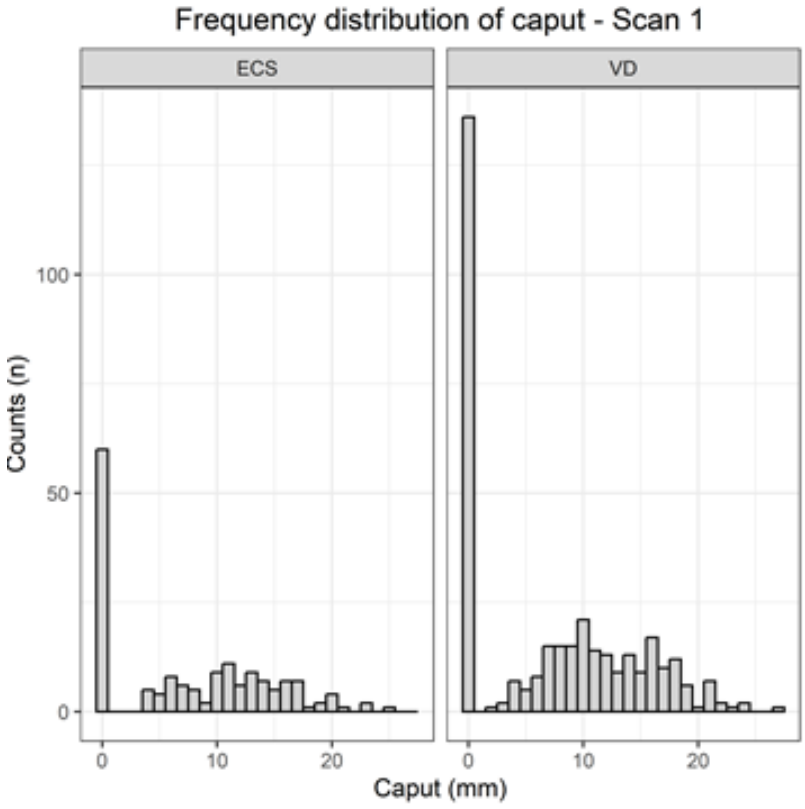

Frequency distribution of head rotation change
ECS
VD
Counts (n)
150
100
50
0
-4
-2
0
2
4
6
Head rotation change (per hour)

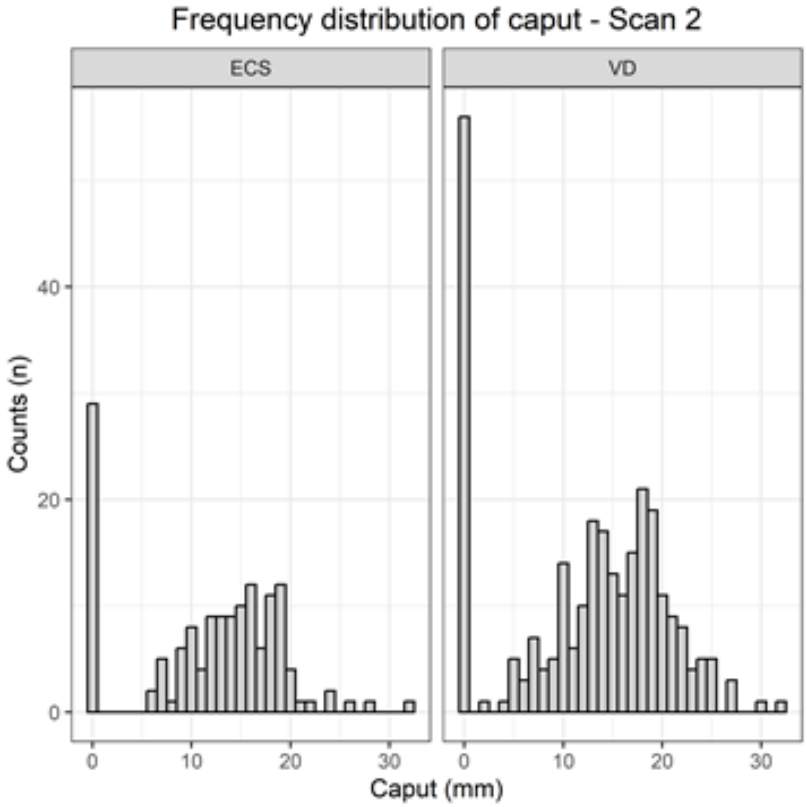

Frequency distribution of cervical dilatation - Scan 1
ECS
VD
Counts (n)
60
40
20
0
0.0
2.5
5.0
7.5
10.0
Cervical dilatation (cm)

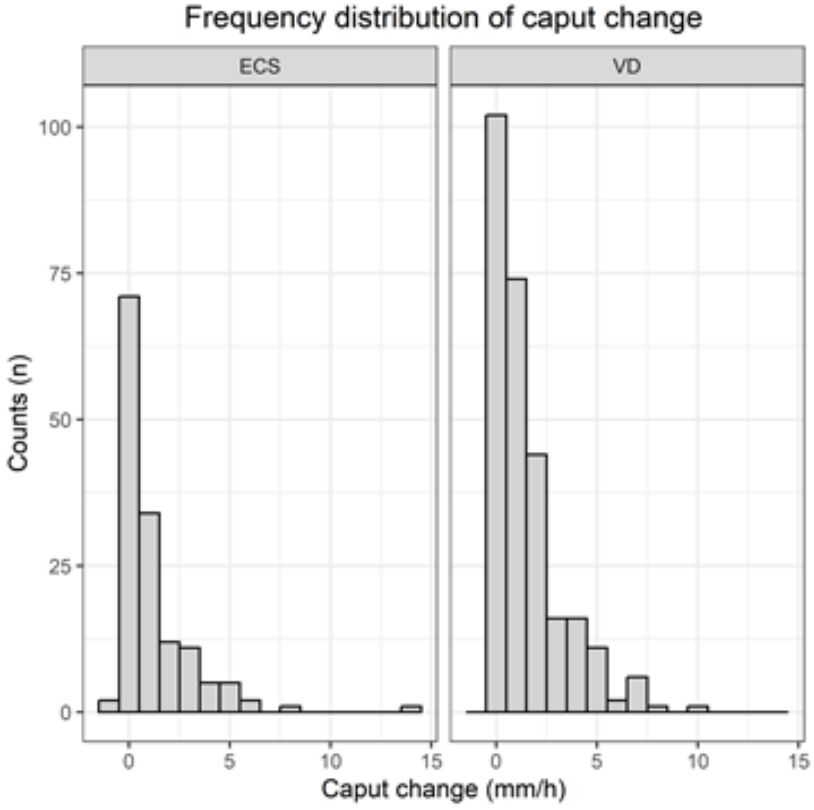

Frequency distribution of cervical dilatation - Scan 2
ECS
VD
Counts (n)
100
75
50
25
0
0.0
2.5
5.0
7.5
10.0
Cervical dilatation (cm)


Frequency distribution of cervical dilatation change
ECS
VD
Counts (n)
75
50
25
0
-2
-1
0
1
2
3
4
Cervical dilatation change (cm/h)


Frequency distribution of caput - Scan 1
ECS
VD
Counts (n)
100
50
0
0
10
20
Caput (mm)


Frequency distribution of caput - Scan 1
ECS
VD
Counts (n)
100
50
0
0
10
20
Caput (mm)


Frequency distribution of caput - Scan 2
ECS
VD
Counts (n)
0
20
40
0
10
20
30
Caput (mm)


Frequency distribution of caput change
ECS
VD
Counts (n)
0
25
50
75
100
0
5
10
15
Caput change (mm/h)

**12.2 SONO-VE: Preliminary Descriptive Statistical Analysis: Excluding Maternal Ethnicity.**

| Variables | ECS | | p-value |
|---|---|---|---|
| | No N=345 | Yes N=163 | |
| **Age, median (IQR)** | 31 (28-34) | 31 (28-35) | 0.816 |
| **BMI class, n(%)** | | | 0.512 |
| BMI < 18.5 (Underweight) | 9 (2.6) | 1 (0.6) | |
| 18.5 ≤ BMI ≤ 24.9 (Normal weight) | 192 (55.7) | 89 (54.6) | |
| 25 ≤ BMI ≤ 29.9 (Overweight) | 103 (29.9) | 52 (31.9) | |
| BMI ≥ 30 (Obesity) | 41 (11.9) | 21 (12.9) | |
| **GA (weeks), median (IQR)** | 40 (39-41) | 40.3 (39.1-41.1) | 0.235 |
| **HPD scan 1 (mm), median (IQR)** | 47.9 (43.4-53.9) | 52.9 (47.0-59.1) | ***<0.001*** |
| **HPD change (mm/h), median (IQR)** | 1.2 (0.5-2.4) | 0.9 (0-1.6) | ***<0.001*** |
| **Head Position scan 1 (clock face hours), median (IQR)** | 5 (3-9) | 5 (3-9) | 0.772 |
| **Head Position change (clock face hours/h), median (IQR)** | 0 (-0.2-0.2) | 0 (0-0) | 0.739 |
| **Caput scan 1 (mm), median (IQR)** | 7.3 (0-13) | 7.2 (0-13.29 | 0.716 |
| **Caput change (mm/h), median (IQR)** | 0.9 (0.1-2.0) | 0.5 (0.1-1.5) | ***0.034*** |
| **Cervical dilatation scan 1 (cm), median (IQR)** | 4 (2-5) | 2 (2-4) | ***<0.001*** |
| **Cervical dilatation change (cm/h), median (IQR)** | 0.7 (0.4-1.2) | 0.2 (0-0.4) | ***<0.001*** |
| **UC Ratio, median (IQR)** | 0.64 (0.54-0.77) | 0.67 (0.58-0.80) | 0.209 |
| **Moulding, n(%)** | 180 (52.5) | 86 (52.8) | 0.953 |
| **Length of labour (h), median (IQR)** | 11.7 (8.8-14.6) | 15.1 (10.9-18.5) | ***<0.001*** |
| **Epidural, n(%)** | 333 (96.5) | 158 (96.9) | 0.810 |

## 12.3 Additional Analysis of the Combined Study (SONO-VE and SONO-PRE-DICT) on Fetal Head Position (Categorical Variable)

- *The Combined Study: First Ultrasound Assessment: Comparison the Frequency Distribution of OP vs non-OP Positions between ICD and VD.*

| OP_scan1 | ICD 0 | 1 | Total |
|---|---|---|---|
| 0 | 252<br>73.04 | 120<br>73.62 | 372<br>73.23 |
| 1 | 93<br>26.96 | 43<br>26.38 | 136<br>26.77 |
| Total | 345<br>100.00 | 163<br>100.00 | 508<br>100.00 |

Fisher's exact = 0.915
1-sided Fisher's exact = 0.491

- *The Combined Study: Repeat Ultrasound Assessments.*

  *Non-OP Positions Were Significantly More Common in the ICD Group (OR = 0.62 [95% CI: 0.40–0.95],* p *= 0.027).*

| OP_scan2 | ICD 0 | 1 | Total |
|---|---|---|---|
| 0 | 154<br>56.20 | 97<br>67.36 | 251<br>60.05 |
| 1 | 120<br>43.80 | 47<br>32.64 | 167<br>39.95 |
| Total | 274<br>100.00 | 144<br>100.00 | 418<br>100.00 |

Fisher's exact = 0.028
1-sided Fisher's exact = 0.017

- *Fetal Head Position Change between the Two Ultrasound Scans.*

  *A Significantly Higher Percentage of Fetuses Always Non-OP in the ICD Group, and a Lower Percentage of Non-OP to OP in the Same Group.*

  *Note: 0=always OP, 1=non-OP to OP, 2=OP to non-OP, 3=always non-OP.*

| pos_change | ICD 0 | 1 | Total |
|---|---|---|---|
| 0 | 55<br>20.07 | 28<br>19.44 | 83<br>19.86 |
| 1 | 65<br>23.72 | 19<br>13.19 | 84<br>20.10 |
| 2 | 24<br>8.76 | 8<br>5.56 | 32<br>7.66 |
| 3 | 130<br>47.45 | 89<br>61.81 | 219<br>52.39 |
| Total | 274<br>100.00 | 144<br>100.00 | 418<br>100.00 |

Fisher's exact = 0.016

- *Fetal Head Position Change between the Two Ultrasound Scans: Univariate Logistic Regression.*

  *The Position Change is No More Significantly Associated with ICD.*

| ICD | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| pos_change | | | | | | |
| 1 | .574176 | .2004789 | -1.59 | 0.112 | .2896276 | 1.138282 |
| 2 | .6547619 | .3075031 | -0.90 | 0.367 | .26081 | 1.643776 |
| 3 | 1.34478 | .3629023 | 1.10 | 0.272 | .7924031 | 2.282215 |
| _cons | .5090909 | .1181882 | -2.91 | 0.004 | .3229865 | .8024285 |

*This discrepancy likely arises from the fact that Fisher's exact test is more sensitive to differences in categorical data distributions, especially with smaller or unbalanced sample sizes. Logistic regression, on the other hand, requires a consistent effect across levels of the predictor and assumes a linear relationship with the log odds of the outcome, which may not fully capture the nuances of categorical changes in position.*

*Therefore, the lack of significance in logistic regression suggests that head position changes may not have a strong or consistent predictive power for ICD on their own.*

*This finding aligns with the idea that persistent OP position at the second scan is a more reliable predictor of ICD than the position change alone.*

- *Clinical Role of OP during the Repeat Labour Assessments.*

  *This Variable Loses Significance when Included in the Final Full Model.*

| ICD | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 1.972859 | .6271186 | 2.14 | 0.033 | 1.058089 | 3.678494 |
| bmi_class | | | | | | |
| 2 | .6504785 | .1997127 | -1.40 | 0.161 | .3563637 | 1.187333 |
| 3 | .6864896 | .3141466 | -0.82 | 0.411 | .279971 | 1.683274 |
| gaweeks | 1.218948 | .1304128 | 1.85 | 0.064 | .9883639 | 1.503327 |
| ethnicity | | | | | | |
| 2 | 1.37362 | .6000566 | 0.73 | 0.467 | .5834783 | 3.233763 |
| 3 | 1.606257 | .5067878 | 1.50 | 0.133 | .8654733 | 2.981099 |
| 4 | .5308752 | .3002957 | -1.12 | 0.263 | .1751864 | 1.608735 |
| HPD1mm | 1.067263 | .0205811 | 3.38 | 0.001 | 1.027677 | 1.108373 |
| HPDchangeh | .8213165 | .0951269 | -1.70 | 0.089 | .654519 | 1.030621 |
| OP_scan2 | .7075965 | .1983126 | -1.23 | 0.217 | .4085319 | 1.22559 |
| Caput1mm | 1.132241 | .0320894 | 4.38 | 0.000 | 1.071062 | 1.196915 |
| Caputchangeh | 1.199559 | .1165023 | 1.87 | 0.061 | .9916357 | 1.451079 |
| Cervdil1cm | .7582503 | .0601566 | -3.49 | 0.000 | .6490552 | .885816 |
| Cervdilchangeh | .0450362 | .0188533 | -7.41 | 0.000 | .0198256 | .102305 |
| Moulding0none1present | .9893731 | .3035455 | -0.03 | 0.972 | .5422586 | 1.805152 |
| _cons | .0000319 | .0001421 | -2.33 | 0.020 | 5.19e-09 | .1963642 |

- *Similarly, replacing it with OP at the First Scan as a Categorical Variable (OP vs. non-OP) and Categorical Change Did Not Yield Significant ORs. Therefore, There Is No Need to Prioritise One Approach Over Another, As the Adjusted Effect Remains Non-Significant Across Both Representations.*

| ICD | Odds Ratio | Std. Err. | z | P>\|z\| | [95% Conf. | Interval] |
|---|---|---|---|---|---|---|
| age_over35 | 2.170768 | .7039686 | 2.39 | 0.017 | 1.14967 | 4.09877 |
| bmi_class | | | | | | |
| 2 | .6552529 | .2052582 | -1.35 | 0.177 | .3546254 | 1.210732 |
| 3 | .7522417 | .3498204 | -0.61 | 0.540 | .3023549 | 1.871534 |
| gaweeks | 1.275582 | .1410734 | 2.20 | 0.028 | 1.026998 | 1.584336 |
| ethnicity | | | | | | |
| 2 | 1.376858 | .6137996 | 0.72 | 0.473 | .5746793 | 3.298773 |
| 3 | 1.710735 | .5555876 | 1.65 | 0.098 | .9051948 | 3.233133 |
| 4 | .5886812 | .3303001 | -0.94 | 0.345 | .1960126 | 1.767976 |
| HPD1mm | 1.07033 | .0211686 | 3.44 | 0.001 | 1.029635 | 1.112635 |
| HPDchangeh | .8115691 | .0952623 | -1.78 | 0.075 | .6447794 | 1.021504 |
| OP_scan1 | .6802549 | .2431799 | -1.08 | 0.281 | .3375835 | 1.370762 |
| pos_change | | | | | | |
| 1 | .5094043 | .193507 | -1.78 | 0.076 | .2419454 | 1.072526 |
| 2 | .3657953 | .2252213 | -1.63 | 0.102 | .1094336 | 1.222716 |
| 3 | 1 | (omitted) | | | | |
| Caput1mm | 1.129762 | .0320663 | 4.30 | 0.000 | 1.068629 | 1.194391 |
| Caputchangeh | 1.190379 | .1175824 | 1.76 | 0.078 | .9808577 | 1.444657 |
| Cervdil1cm | .7610984 | .0609049 | -3.41 | 0.001 | .6506173 | .8903403 |
| Cervdilchangeh | .0447171 | .0188266 | -7.38 | 0.000 | .0195932 | .102057 |
| Moulding0none1present | .986227 | .3072935 | -0.04 | 0.964 | .5354949 | 1.816346 |
| _cons | 5.10e-06 | .0000235 | -2.65 | 0.008 | 6.19e-10 | .0420103 |

# CHAPTER 13

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