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Birgitte Heiberg Kahrs

Can ultrasound predict labour outcome in operative vaginal deliveries?

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Norwegian University of Science and Technology
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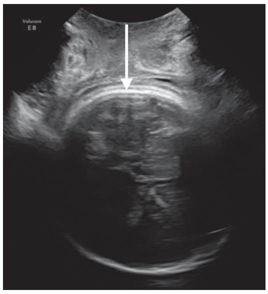

Thesis for the Degree of Philosophiae Doctor

Trondheim, June 2020

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Sammendrag på norsk

Ultralyd før vakumforløsning

I Norge anbefaler man at aktiv trykketid i fødselen ikke skal vare lenger enn en time. Da skal fødselshjelperen vurdere aktiv forløsning, enten ved vakum, tang eller keisersnitt. Valg av forløsningsmetode avgjøres av fosterhodets nivå og innstilling i bekkenet. De fleste foster ligger med ryggen opp i forbindelse med fødsel (bakhodeinnstilling), mens noen har ansiktet opp mot mors mage (stjernekikkere). Denne siste posisjonen er forbundet med økt risiko for en vanskelig forløsning. Dette har man tradisjonelt vurdert ved hjelp av en vaginal undersøkelse. Tidligere studier har vist at vaginal undersøkelse både er subjektiv og upresis og at ultralyd har muligheten til å bedre presisjonene av denne undersøkelsen.
Vi utførte en prospektiv kohortstudie i perioden november 2013 og juli 2016. Syv fødeavdelinger i Europa deltok. Hensikten med studien vår var å vurdere om ultralydundersøkelse ved langsom fremgang i trykketiden kunne forutsi om vakumforløsningen ble vellykket, varigheten av vakuumforløsning, og hvordan det gikk med den nyfødte.

Kvinnene ble inkludert i studien når det oppsto langsom fremgang i trykketiden og de hadde trykket i mer enn 45 minutter. 222 kvinner ble inkluder.
Først undersøkte vi fosterhodets posisjon ved å gjøre ultralyd på magen til kvinnen og deretter satt vi ultralydproben i skjedeåpningen og målte avstanden opp til fosterhodet. Vi målte også om fosterhodet beveget seg i bekkenet når kvinnen trykket. Fødselshjelperen som var ansvarlig for kvinnen gjorde den samme vurderingen ved hjelp av en vaginal undersøkelse. Fødselshjelperen var ansvarlig for fødselen og bestemte forløsningsmetoden. Ultralyd undersøkeren og fødselshjelperen viste ikke om hverandres undersøkelses resultat.

Vi fant at varigheten av vakuumforløsningen var kortere hos kvinner hvor foster hodet sto dypt nede i bekkenet. Hos disse kvinnene var det også mindre risiko for mislykket vakumforløsning enn hos de hvor hodet sto høyere. Hvis fosterhodet sto høyt i bekkenet ved starten av vakumforløsning fant vi at det var økt risiko for lav pH i navlesnoren hos den nyfødte. Videre fant vi at vakumforøsningen gikk raskere og oftere var vellykket hvis fosterhodet lå i en bakhode innstilling. Ved feilinnstillinger roterte ofte fosterhodet spontant til en bakhodeinnstilling under vakumforløsningen. Hvis det var god bevegelse av fosterhodet i bekkenet under aktiv trykking, var dette et positivt tegn for en vellykket og rask vakumforløsning.

Hovedkonklusjonen i denne avhandlingen er at ultralydundersøkelse kan hjelpe fødselshjelperen til å velge den beste forløsningsmetoden.

Navn kandidat: Birgitte Heiberg Kahrs

Institutt: Institutt for Klinisk og molekylær medisin

Hovedveileder: Torbjørn Moe Eggebø

Biveiledere: Erik Andreas Torkildsen og Christoph C. Lees

Finansieringskilde: Samarbeidsorganet Helse Midt-Norge og NTNU

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Summary in English

Safe management of the second stage of labour is of great importance. Unnecessary interventions should be avoided. The numbers of cesarean sections are increasing and the number of operative vaginal deliveries are decreasing globally. Traditionally fetal head station and fetal head position has been determined with digital vaginal examination. Previous studies have shown that ultrasound has the potential to improve the precision of determination of fetal head station and fetal head position. The aim of our study was to evaluate if ultrasound measurements of fetal head station and position could predict duration of vacuum extraction, mode of delivery and neonatal outcome. We also wanted to investigate fetal head rotation during vacuum extraction, and if position influenced duration of vacuum extraction, mode of delivery and neonatal outcome. Finally, we wanted to evaluate if descent of the fetal head during active pushing, assessed with transperineal ultrasound, was associated with duration of vacuum extraction, mode of delivery and neonatal outcome.

We conducted a prospective cohort study between November 2013 and July 2016. Seven European maternity units participated. The women were included when prolonged second stage was diagnosed and a vacuum extraction was considered, after at least 45 minutes of active pushing. A transabdominal and a transperineal ultrasound scan was performed to determine fetal head position and fetal head station. The clinicians in charge of the delivery determined position and station with digital vaginal examination. The ultrasound operators and the clinicians in charge of the delivery were blinded for each other’s results.

223 women were included. One was excluded due to missing information about the main variable (duration of vacuum extractions).

The duration of vacuum extraction was shorter in women with HPD ≤25 mm. Fetal head station measured as HPD could predict mode of delivery. When evaluated together with fetal head position it was even better. If HPD was ≤35 mm and there was an occiput anterior position the chance of a successful vaginal delivery, both spontaneously or operative, was 98%. Even though all women included had a normal

CTG at inclusion, the neonates delivered with HPD >35 mm had significantly more often an umbilical artery pH <7.10.

When examining fetal head rotation during vacuum extraction we found that rotation from occiput transverse to occiput anterior position during vacuum delivery occurred in 74% of cases and from occiput posterior to occiput anterior in 60% of cases. There was a higher conversion rate from vacuum extraction to forceps or cesarean section in the non-occiput anterior group (23%) than in the occiput anterior group (10%). The duration of vacuum extraction was significantly shorter in occiput anterior position. There was no difference in neonatal outcome.

The movement of the fetal head was measured with HPD during active pushing and in rest between contractions. In cases with no or minimal fetal head movement during contractions with active pushing, there was a longer duration of operative vaginal deliveries and a higher rate of cesarean section. There was no difference in neonatal outcome.

The main conclusions from this thesis are that ultrasound measurements done shortly before vacuum extractions were associated with duration of the operative delivery, mode of delivery and that fetal station also was associated with pH in the umbilical artery.

Ultrasound examinations have a potential to reassure clinicians when it is safe to perform a vacuum extraction.

Table of contents

1. Acknowledgements

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My father passed away before I started on this journey, but I know he has been with me every step of the way. You always knew I would do this even long before I knew it myself. There for I dedicate this thesis to you, dad.

2. List of papers

2.1 Paper one

Kahrs, B. H., Usman, S., Ghi, T., Youssef, A., Torkildsen, E. A., Lindtjørn, E., Østborg, T. B., Benediktsdottir, S., Brooks, L., Harmsen, L., Romundstad, P. R., Salvesen, K. Å., Lees, C. C., Eggebø, T. M.

Sonographic prediction of outcome of vacuum deliveries: a multicentre, prospective cohort study.

Am J Obstet Gynecol 2017; 217:69e1-10.

DOI: 10.1016/j.ajog2017.03.009

2.2 Paper two

Kahrs, B. H., Usman, S., Ghi, T., Youssef, A., Torkildsen, E. A., Lindtjørn, E., Østborg, T. B., Benediktsdottir, S., Brooks, L., Harmsen, L., Salvesen, K. Å., Lees, C. C., Eggebø, T. M.

Fetal rotation during vacuum extraction for prolonged labor: a prospective cohort study.

Acta Obstet Gyencol Scand 2018; 97:1-8

DOI: 10.1111/agos.13372

2.3 Paper three

Kahrs, B. H., Usman, S., Ghi, T., Youssef, A., Torkildsen, E. A., Lindtjørn, E., Østborg, T. B., Benediktsdottir, S., Brooks, L., Harmsen, L., Salvesen, K. Å., Lees, C. C., Eggebø, T. M.

Descent of fetal head during active pushing: secondary analysis of prospective cohort study investigating ultrasound examination before operative vaginal delivery.

Ultrasound Obstet Gynecol 2019; 54: 524-529.

DOI: 10.1002/uog.20348

3. Abbreviations

AoP	Angle of progression
AOC	Area under the curve
BMI	Body mass index
CI	Confidence interval
CM	Centimetres
CT	Computer Tomographic
CTG	Cardiotocography
HPD	Head-perineum distance
HR	Hazard ratio
HSD	Head-symphysis distance
ITU	Intrapartum translabial ultrasound
ISUOG	The International Society of Ultrasound in Obstetrics and Gynecology
MI	Mechanical index
MM	Millimetres
OA	Occiput anterior
OP	Occiput posterior
OR	Odds ratio
OT	Occiput transverse
LOT	Left occiput transverse
ROT	Right occiput transverse
ROC	receiver operating characteristics
TI	Thermal index

4. Introduction and background

4.1 History of ultrasound

The history of ultrasound did not start in medicine, but during World War I when it was invented to detect submarines[1]. In medical ultrasound one of the most important contributors was the Scottish physician Sir Ian Donald. He conducted basic research for the development of an ultrasound machine for clinical use[2]. At present ultrasound is now an integrated part of antenatal care. For most women and healthcare workers in obstetrics it is not possible to imagine not being able to use ultrasound[3].

In Norway ultrasound in antenatal care was offered for all pregnant women from 1986[4]. The basis for a national program was the important work by Professor Sturla Eik-Nes. In 1979-1980 he conducted two randomized controlled trails in Ålesund, Norway, and Trondheim, Norway, where women were randomized to two ultrasound scans, gestational week 19 and 32, or ultrasound on clinical indication[5, 6]. This was to evaluate ultrasound as a supplement to standard antenatal care. A study that would be impossible to conduct today. No pregnant women would take the risk of being randomised to only getting ultrasound on medical indication. As a result of these studies the routine scan for all pregnant women in Norway was implemented in gestational age 17-21. The aim of this examination is pregnancy dating and to estimate a date of delivery, counting number of fetuses, locate the placenta and an anatomical examination of the fetus. At present, this is still the only ultrasound examination offered to all pregnant women in Norway during pregnancy.

Ultrasound has had its place in the labour ward, but usually prior to labour. The indications for ultrasound examinations in a labour and delivery department in an academic teaching institution in the USA were assessed over a 4-months period and 68% of the examinations were on non-labouring women[7]. The determination of breech presentation before labour, planned cesarean section or external cephalic version are common indications. It is also used to confirm or exclude intrauterine fetal death when women present with less fetal movement or if the fetal heart tones were not detected with a hand-held Doppler device. The cervix has been examined using ultrasound in situation with threatening preterm labour[8]. Examination of fetal growth, amniotic fluid amount and Doppler examination of fetal and maternal vessels can be performed at the labour ward[9].

In 2006 Yves Ville wrote an editorial in Ultrasound in Obstetrics and Gynecology that ultrasound will be a more and more important tool in obstetrics and that 'we are moving form obstetric ultrasound to ultrasonographic obstetrics'[10]. Ultrasound has given us the possibility to get access to the fetus and the intrauterine environment in a unique manner. In the labour ward, ultrasound during labour is not widely used so far.

Clinical examination by vaginal digital examination during labour has been the method to determine the fetal head position and station. The result of the examination is usually drawn in to a partogram. Most clinicians have experienced that the results of these examination could differ between different midwifes and doctors. Some changes in the partogram are not necessarily an indication that there was progress or lack of progress in labour, but a result of new members of staff starting their shift. Clinical vaginal examination is subjective. This has been demonstrated in several studies. Dupuis et al. showed that by using a birth simulator and during second stage of labour both experienced and unexperienced clinicians were wrong in determining fetal head position and fetal head station[11, 12]. Others have confirmed the same findings both in a randomized controlled trail were the patient was randomized to ultrasound before operative vaginal delivery or standard care[13] and in studies comparing ultrasound and clinical examination in determining fetal head position[14, 15].

One of the major reasons for introducing the ultrasound machine to the labour ward was a need to make a subjective examination more objective. This was first done by Lewine et al. In 1977[16]. The ultrasound probe was placed on the skin, near the sacral tip of the woman, and angled towards her umbilicus. With the obtained image the ultrasound operator could then observe the echo of the sacral tip and the fetal scull and measure a distance, *figure 1*. For clinical use they made a table were clinical assessment was cross-matched with the distance measured.

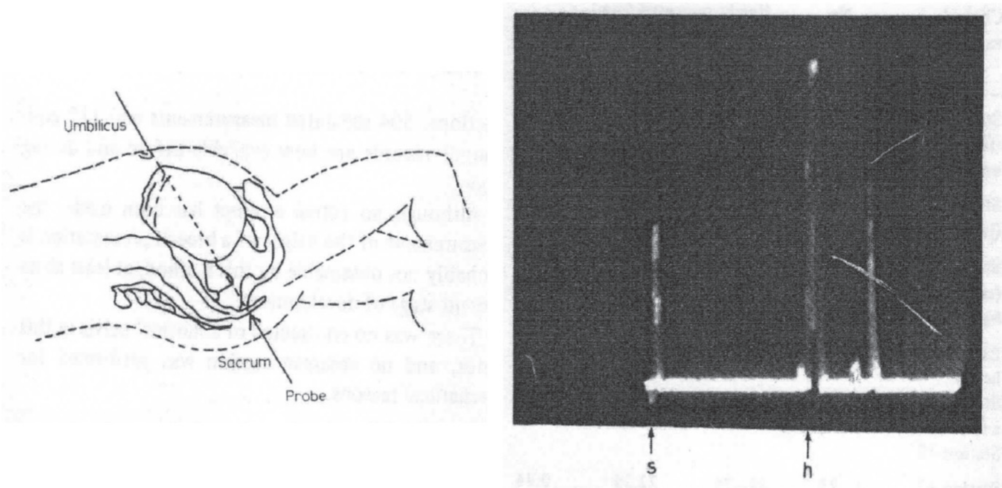

Figure 1. Illustration of the technique suggested by Lewine et al. with corresponding ultrasound image. s: sacral tip, h: fetal skull[16].

In 1996, a thesis was published by Voskresynsky in Russian were a series of drawings with corresponding ultrasound pictures illustrates the process of delivery[17], *figure 2*. This thesis describes the how the cervix changes during spontaneous abortion, labour and after labour.

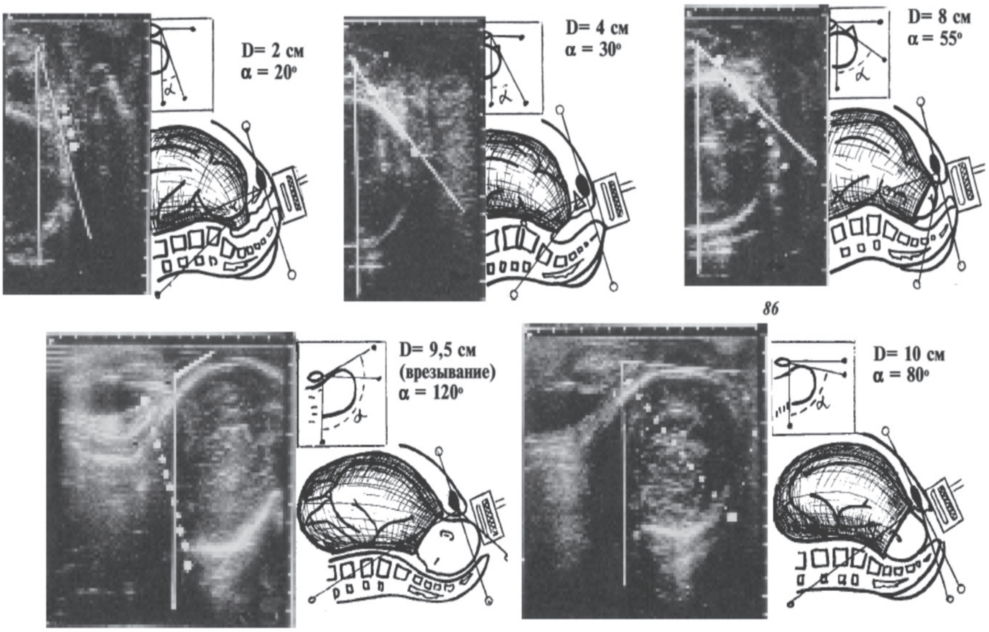

Figure 2. Ultrasound pictures and drawings published by S. L. Voskresynsky[17].

In 2003, Sherer et al. published a method to determine fetal head engagement by using transabdominal ultrasound[18]. In 2004 Dietz et al. published two methods to evaluate fetal head engagement, relating to the fetal head position to the posterior part of the pubic symphysis[19]. After these publications many new methods were suggested and published. Ultrasound during labour increased in popularity and was more and more used. In 2018 The International Society of Ultrasound in Obstetrics and Gynecology, published its Guidelines on intrapartum ultrasound[20]. They recommend using ultrasound during labour in:

- Slow progress or arrest of labour in the first stage of labour
- Slow progress or arrest of labour during the second stage of labour
- Ascertainment of fetal head position and station before considering or performing instrumental vaginal deliveries
- Objective assessment of fetal head malformations

When performing transperineal ultrasound there are two scanning options, transverse and sagittal. Eggebø et al. published in 2006 the Head-perineum distance (HPD)[21], the same year Henrich at al. published the head direction[22] and in 2009 Barbera et al. published the Angle of Progression (AoP)[23]. In the years following more methods were published. Even a sonopartogram has been suggested were the findings recorded are ultrasound findings and not the findings of the traditional digital vaginal exploration[24]. The publishing of several methods indicates that none of them are perfect, all have limitations.

In 2009 Torbjørn Moe Eggebø defended his thesis, 'Ultrasound and labour', on ultrasound before onset of labour and inductions of labour presenting the HPD method[25]. In 2013 Erik Andreas Torkildsen defended his thesis, '*Ultrasound and prediction of prolonged labor'*, on ultrasound and prediction of labour outcome when prolonged first stage of labour was diagnosed[26]. Based on their work, a continues work on this issue was natural and this thesis has been focusing on ultrasound in the second stage of labour.

4.2 Ultrasound methods

4.2.1 Transabdominal ultrasound

Obstetrical transabdominal ultrasound has traditionally been used as a diagnostic tool. A transabdominal ultrasound scan may quickly and accurately give us a lot of information about the fetus. With a single movement of the transducer in an 'upside-down-U' manner we can detect the fetal heart rate, placenta location, amount of amniotic fluid, lie, head position, spine position, attitude and presentation. To determine the fetal head position by transabdominal ultrasound intracranial structures are used, *figure 3*. First the location of the fetal orbits are determined. Then you look for the cerebellum. The choroid plexus always diverges towards the occiput and the cerebral peduncles point towards the occiput. When the fetal head is at a low station it can be difficult to see all these structured and a transperineal scan may be helpful. Also, a transabdominal scan gives information about the fetal size, fetal well-being by looking at fetal movement and Doppler examination and anatomy. But these examinations are not what is performed in labour since they are more time consuming.

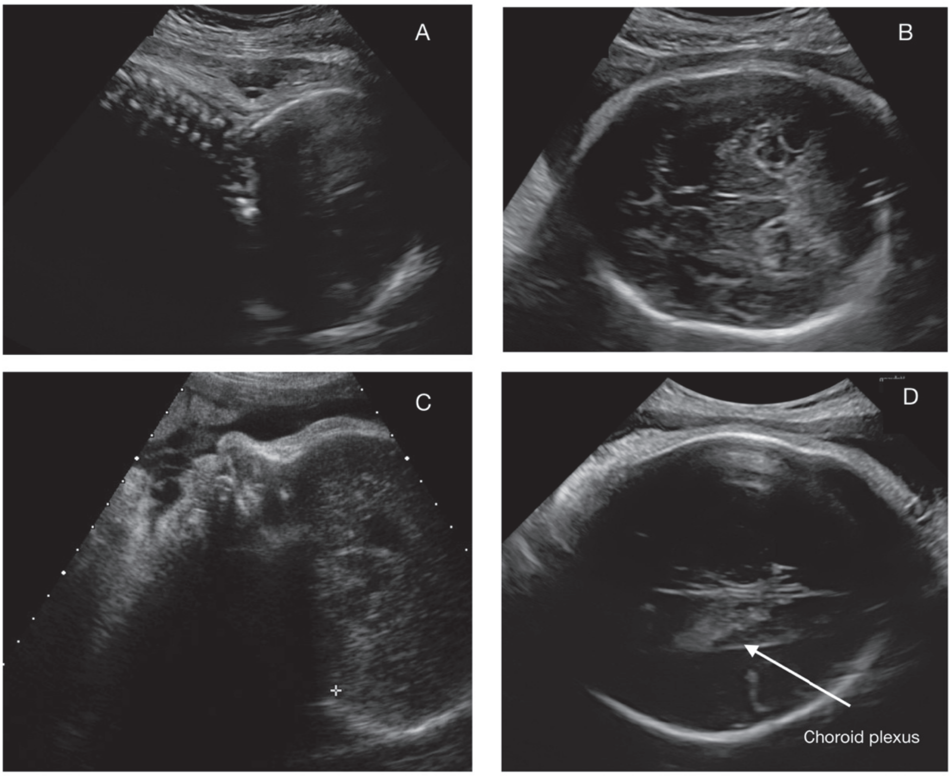

Figure 3. Transabdominal ultrasound. A: Occiput anterior position (sagittal scan), B: left occiput transverse (transverse scan – cerebral peduncles pointing to occiput), C: occiput posterior position (sagittal scan), D: right occiput transverse (transverse scan – choroid plexus diverging towards occiput). Ultrasound image made by Torbjørn Moe Eggebø.

4.2.2.Transperineal ultrasound

Transperineal ultrasound can be performed as a transverse scan or a sagittal scan. The transverse scan is in the frontal plane related to the mother, but transverse related to the perineum. The method is sometimes called translabial ultrasound, but the scanning is not performed trans the labia, but between the labia. Transperineal ultrasound is also done in men when examining the prostate, and the same phrasing should be used in both genders. The perineum is defined anatomically as the diamond-shaped region bounded anteriorly by the lower border of the pubic symphysis and posteriorly by the tip of the os coccyx and laterally by the ischial tuberosities[27], *figure 4*. In anatomy the fibro-muscular tissue between the anterior edge of the anus and the posterior edge of the vaginal is called the tendinous centre of the perineum, and is also known as the perineal body[27]. The term transperineal has be recommended by the journal Ultrasound in obstetrics and gynecology[28].

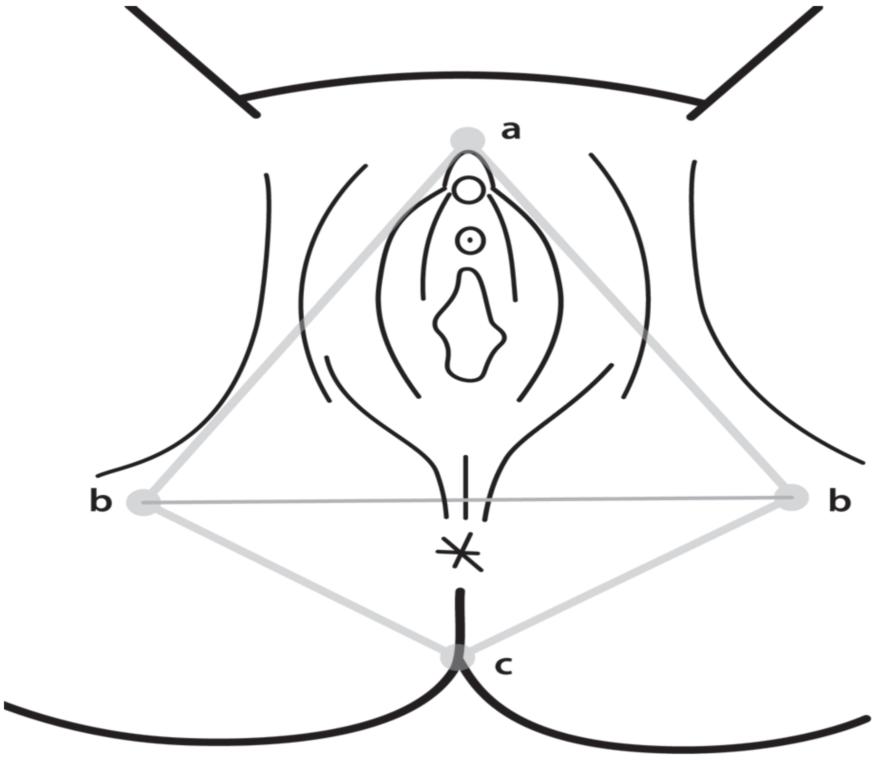

Figure 4. The diamond shaped area of the female perineum. a: pubic symphysis, b: ischial tuberosities, c: os coccyx. Illustration by Morten Dreier.

4.2.2.1 Head-perineum distance

Head-perineum distance (HPD) is measured in a transverse scan. The HPD is measured by placing the transducer in a transverse position in the posterior fourchette and compressing the soft tissue until a resistance in felt. This is done without causing discomfort for the woman. The transducer should be angled until the skull contour is as clear as possible. Then the ultrasound waves are perpendicular to the fetal skull, and the shortest distance between the fetal skull and the transducer can be measured[21], *figure 5*.

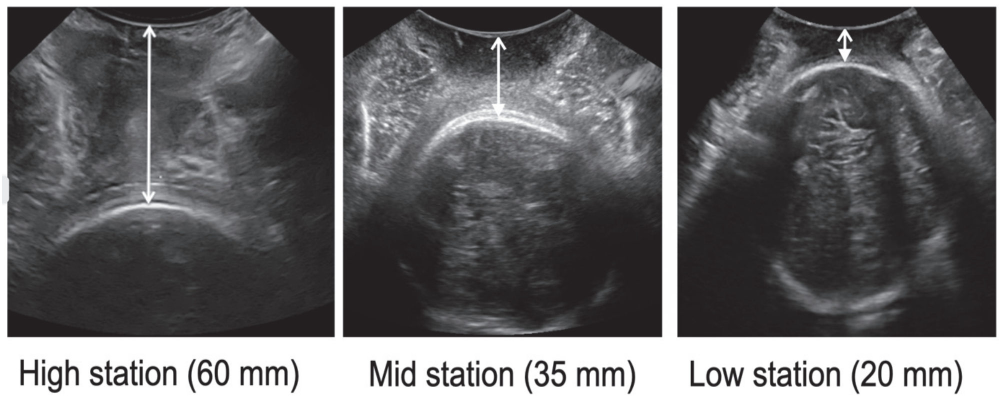

Figure 5. Head-Perineum distance measured according to Eggebø et al. at different stations[21].

4.2.2.2 Angle of Progression

Angle of Progression (AoP) is a sagittal transperineal scan. The AoP is measured in the sagittal plane as the angle between the long axis of the symphysis and a line joining the lower edge of the symphysis to the lower convexity of the fetal skull[23], *figure 6*.

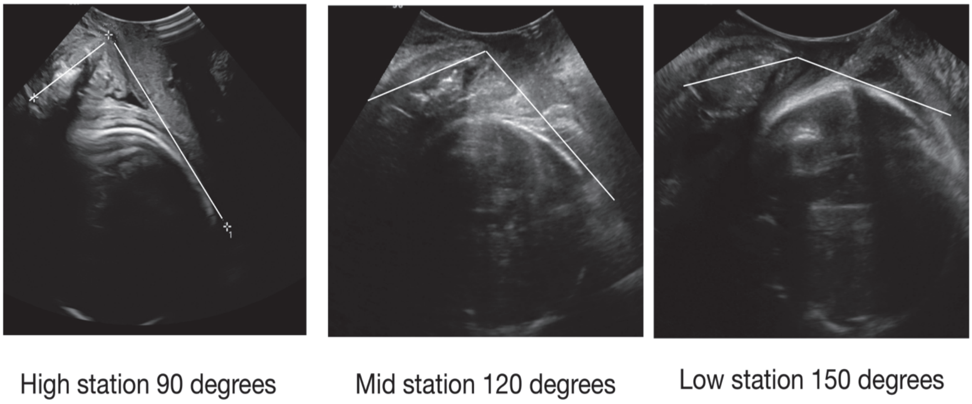

Figure 6. Angles of Progression measured according to Barbera el at.[23] at different stations.

4.2.2.3 Head progression distance

Head progression distance is a sagittal scan using the lower margin of the echogenic core of the symphysis to start a vertical line and the minimal distance from this line to the presenting part is measured in millimetres[19], *figure 7*.

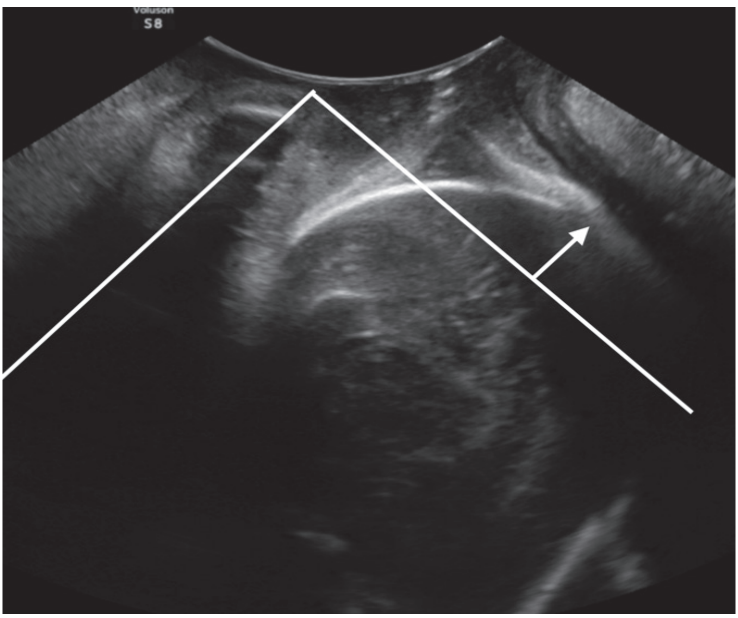

Figure 7. Head progression distance, arrow, measured according to Dietz et al[19].

4.2.2.4 Head symphysis distance

Head symphysis distance (HSD) is a sagittal scan were the distance between the lowest edge of the symphysis and the nearest point of the fetal skull along the infrapubic line is measured[29], *figure 8*.

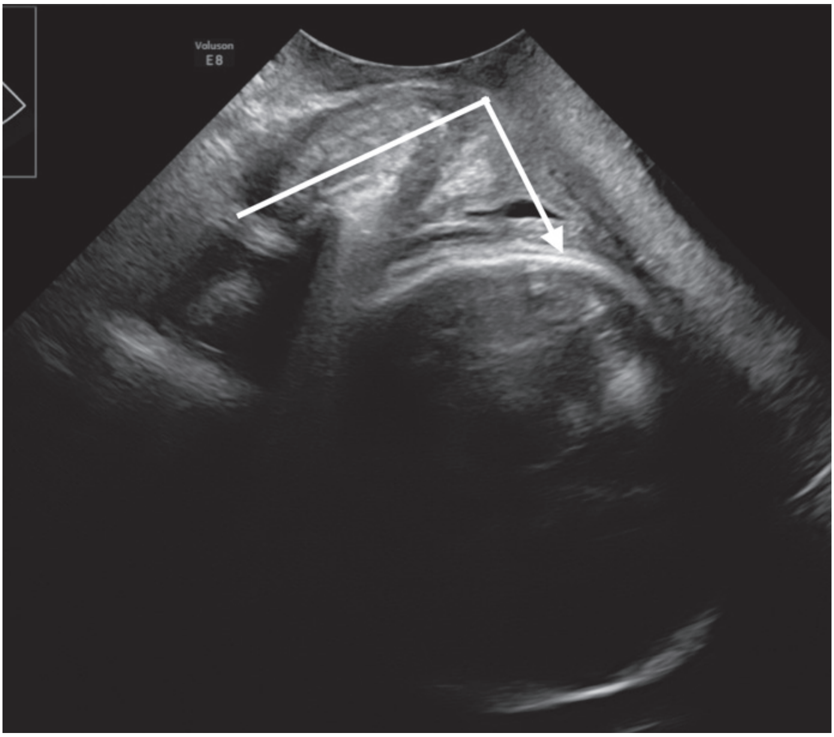

Figure 8. Head symphysis distance, arrow, measured according to Youssef et al[29]

4.2.2.5 Fetal head direction

Head direction is defined as the direction of a line parallel to the widest diameter of the fetal head. This line can be up, down or horizontal[22], *figure 9.*

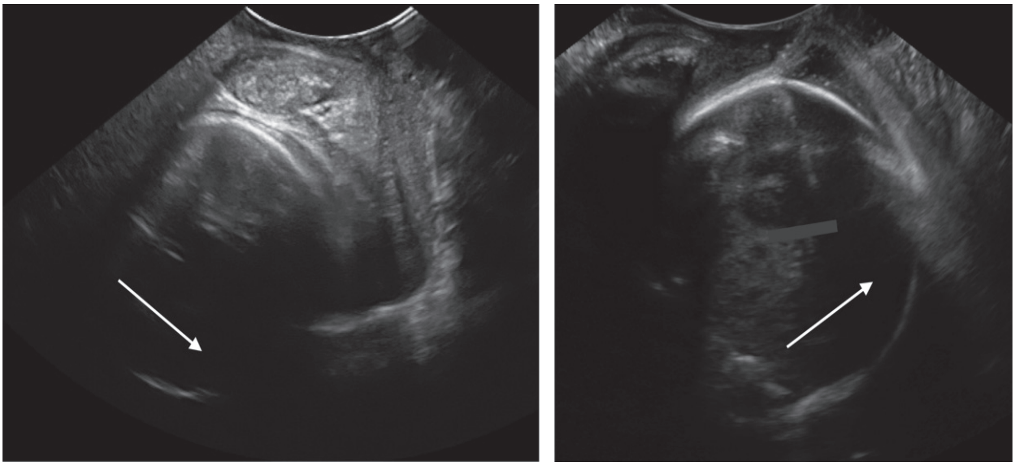

Figure 9. Transperineal ultrasound showing head direction down and head up measured according to Henrich et al[22] .

4.2.2.6 Intrapartum translabial ultrasound (ITU) head station

This is a sagittal scan defining the plan that corresponded with the ischial spines. A three-dimensional computer tomographic (CT) reconstruction and standard pelvimetic measurements of a normal female pelvis was used. By using this reconstructed pelvis with normal measurements, CT correlation with intrapartum translabial ultrasound confirmed that a line parallel to the infrapubic line and three centimetres (cm) caudal to it, indicates the level or plane of the ischial spines[22]. By measuring along the longest visible axis of the fetal head between the intersections with the infrapubic line and the deepest bony part of the fetal head, subtracting three cm for the level of the ischial spines, the station of the fetal head can be calculated. Tutschek et al. called this the Intrapartum Translabial Ultrasound (ITU) head station[30], *figure 10*.

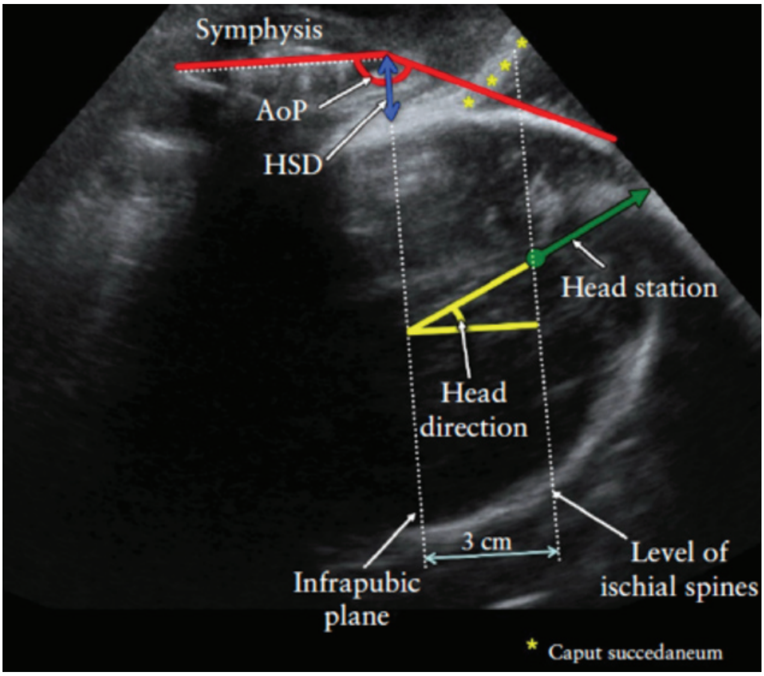

Figure 10. Measuring AoP, Head symphysis distance and Intrapartum Translabial ultrasound (IUT) head station. IUT head station is measured according to Tutschek et al[30].

They also showed a strong linear correlation between ITU and AoP allowing a simple approximate conversion by using this equation:

IUT head station (in cm) = AoP (in degrees) x 0.0937 – 10.911

A conversion table comparing IUT head station, AoP and HPD is published[31], *table 1.*

Table 1. A conversion table comparing IUT head station, AoP and HPD according to Tutschek et al[31]

ITU Head station (cm)	Angle of Progression (°)	Head-perineum distance (mm)
-3	84	54
-2	95	48
-1	106	42
0	116	36
1	127	31
2	138	
3	148	
4	159	
5	170	

4.2.2.7 Midline angle

The midline angle is a transverse transperineal scan to determine fetal head position. The midline of the fetal head is defined as the echogenic line between the two cerebral hemispheres. The midline angle is the angel between this line and the anteroposterior diameter of the pelvis[32], *figure 11.*

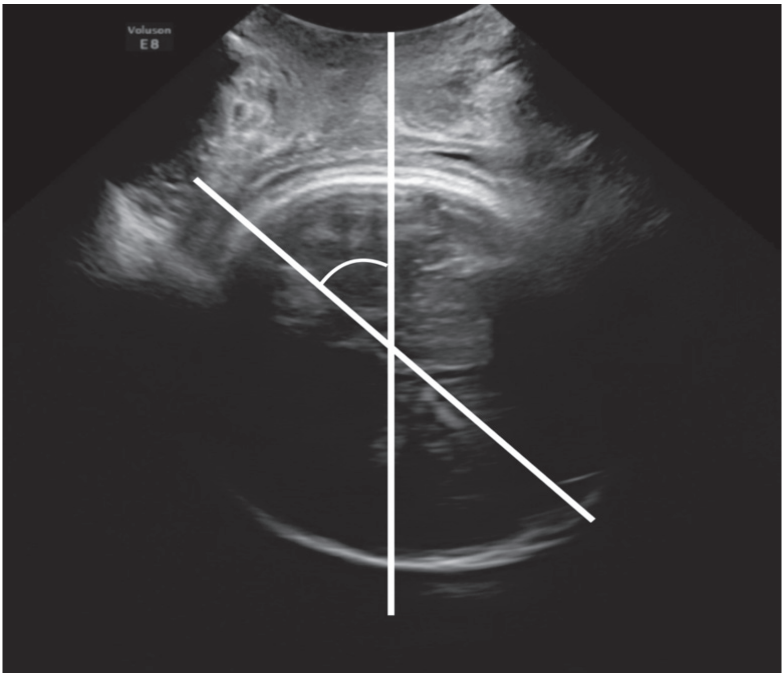

Figure 11. Midline angle measured according to Ghi et al[32].

4.3 The normal labour and labour stages

According to the textbook 'Williams Obstetrics' the greatest impediment to understand normal labour is recognizing its start. The strict definition of labour '*uterine contractions that bring about demonstrable effacement and dilatation of the cervix'* does not help the clinician in determine when labour has actually begun, because this diagnosis is confirmed only retrospectively[33]. This makes prolonged labour even more difficult. When we do not know the start, how do we know when it is too long?

The normal labour is depending on three factors. Power, passage and passenger. Power being the contractions, passage is the maternal pelvis and passenger being the fetus. Normal birth is by the World Health Organization in 1997 defined as: '*A normal birth is spontaneous in onset, low-risk at start of labour and remaining so throughout labour and delivery. The infant is born spontaneously in the vertex position between 37 and 42 completed weeks of pregnancy. After birth both mother and infant are in*

good condition'[34]. When working in obstetrics we know that this is not always the case. And when labour and delivery not progress normally we need to be able to help both mother and fetus to facilitate a safe birth.
In normal labour fetal lie, presentation, attitude and position need to be determined. The fetal lie is the relation of the long axis of the fetus to that of the mother. It is either longitudinally, oblique or transverse. 99% of fetuses at term are in a longitudinally lie[33].
The presenting part is that portion of the fetal body that is either foremost within the birth canal or in close proximity to it. In a longitudinally lie it is either cephalic or breech presentation, and in an oblique or a transverse lie it can be a shoulder. At term the prevalence of cephalic presentation is 96%[33, 35]. The cephalic presentations can be divided into occiput, sinciput, brow and face presentation, with occiput being the most common. Fetal position is the rotation of the presenting part in relation to the maternal pelvis, with occiput anterior being the most common position at birth and two thirds being in the left occiput transverse earlier in labour[36].
Labour is a complicated mechanism, and the movements of the fetal head down the birth canal are called the cardinal movements, which includes seven movments[37]. The first cardinal movement is the engagement of the fetal head into the maternal pelvis. The head is engaged when the maximum diameter of the fetal head has passed the pelvic inlet. The next cardinal movement is descent. This is the downward movement of the fetal head in the maternal pelvis. The descent is what is determined by the fetal head station. The cardinal movement after descent is flexion. The contractions cause flexion of the fetal head forwards so that the chin is coming into contact with the chest. This results into that the suboccipito-bregmatic diameter, the smallest diameter of the fetal head, continues to pass through the birth canal. The nest cardinal movement is internal rotation. The fetal head usually enters the pelvis with the sagittal suture in the transverse diameter of the pelvis, the internal rotation is a gradual turning of the fetal head so that the occiput turns to be behind the symphysis (in an occiput anterior position). The following cardinal movement is

extension. At the level of the pelvic outlet the base of the occiput will come into contact with the inferior margin of the symphysis where the birth canal curves upward and forward. The head is delivered through the maternal vaginal introitus by extension of the flexed position. First to be delivered is the occiput, then with further extension the vertex, forehead, nose, mouth and finally chin. Then the shoulders are delivered by external rotasion[37]. A simpler model only differentiates into four cardinal movements, flexion of the neck, rotation, extension and rotation of shoulders.

Labour is divided into stages. There is no uniform definition of these stages and their duration. A Norwegian publication from 2008 compared eight medical textbooks and seven guidelines all in a Scandinavian languages or English. There was in these textbooks and guidelines no consensus in defining the onset of the different stages of labour or the duration[38]. In 1954 Friedman published an observational study on labour progress and indicated how the normal labour would progress and a curve was made[39]. This is the basis of our partogram which is used today. In 1972 Philpott introduced the alert line and action line. The alert line is set when the women is defined to be in the active phase of labour and the action line is set after four hours[40], *figure 12*. In the delivery unit in Rhodesia where these lines were introduced, 90% of all normal nulliparous women delivered at the left side of this line. The remaining 10% were potentially abnormal. When the cervical dilatation reached the action line the patients were re-assessed for malpresentations or pelvic abnormalities. If these were excluded the woman got adequate analgesia and oxytocin acceleration. Most cases did then deliver and if not, they were delivered by cesarean section after six hours. By having this regime they reduced the number of cesarean sections and they did not have deliveries lasting more than 16 hours[41]. What this tells us today is that it is important to define start of labour and by doing that prolonged labour can be diagnosed correctly and treated.

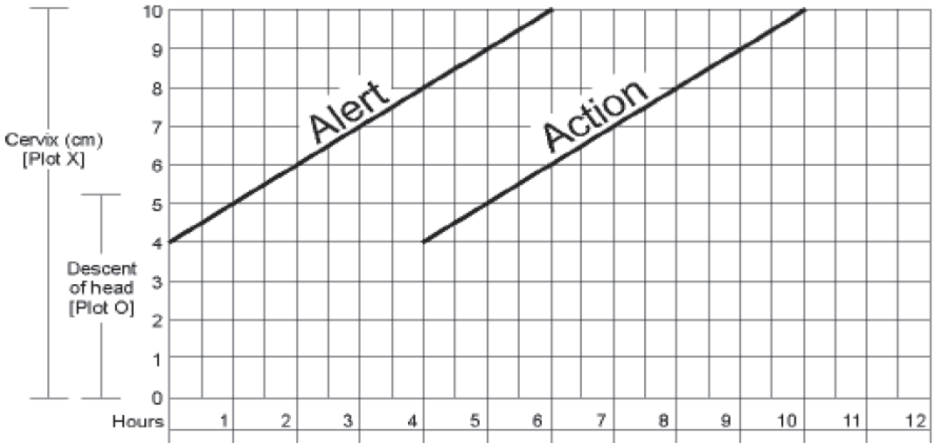

Figure 12. WHO partogram with alert line at start of the active phase of labour when the cervix is dilated four cm, and a four hour action line[34].

4.3.1 Latent phase

The first part of the first stage of labour is the latent phase, often referred to as stage 0, where there is shortening of the cervix, effacement, and some dilatation of the cervix. In this phase the woman is not in active labour. The latent phase can be long and it is important for the woman to get support and rest during this period. This phase can in a nulliparous women last for 20 hours[39]. It is important that the woman is educated about the latent phase and the duration and about how she can rest and be comfortable[42].

4.3.2 First stage of labour

The first stage of labour is divided into a latent phase and an active phase. Until 2018, WHO defined start of active phase when cervix was effaced and dilated four cm, but according to 2018 guidelines, the latent first stage is characterized by painful uterine contractions and cervical dilatation up to five cm for first and subsequent labours. The active first stage is characterized by regular painful uterine contractions, a substantial degree of cervical effacement and more rapid cervical dilatation from five cm until full dilatation for first and subsequent labours[33].

There is no consensus on the duration of the first stage, but WHO recommended until 2018 to use a partogram with alert line at the start of the first stage and an action line parallel to the alert line four hours apart[42, 43]. According to Friedman the mean duration of the first stage was 4.9 hours for nulliparous woman with a standard deviation of 3.4 hours[39]. In the NICE guidelines they use an average of 8 hours for the first stage[42]. The 2018 guideline from WHO say that the duration of active first stage usually does not extend beyond 12 hours in first labours, and usually does not extend beyond 10 hours in subsequent labours. By applying the alert and action lines slow progress can be detected and action can be undertaken. Friedman divided the first stage anomalies in to two groups; protraction and arrest disorders. Protraction is defined as a slow rate of cervical dilatation or decent of the fetal head. For nulliparous women this was less than 1.2 cm dilatation per hour or less than one cm descent per hour. Arrest of labour was defined as complete cessation of dilatation or descent, no dilatation for two hours or no descent for one hour. In 30% of women with protracted labour there was a cephalopelvic disproportion and for arrested labour this number was 45%[39]. This is a quite strict definition, NICE guidelines defines slow progress as less than two cm dilatation in four hours[42]. An alternative, more contemporary partogram, the Zhang-partogram, *figure 13*, defines active labour at six cm for both nulliparous and parous women. According to this curve, absence of dilation for four hours may be normal in early labour, but is prolonged after a dilation of six cm[44].

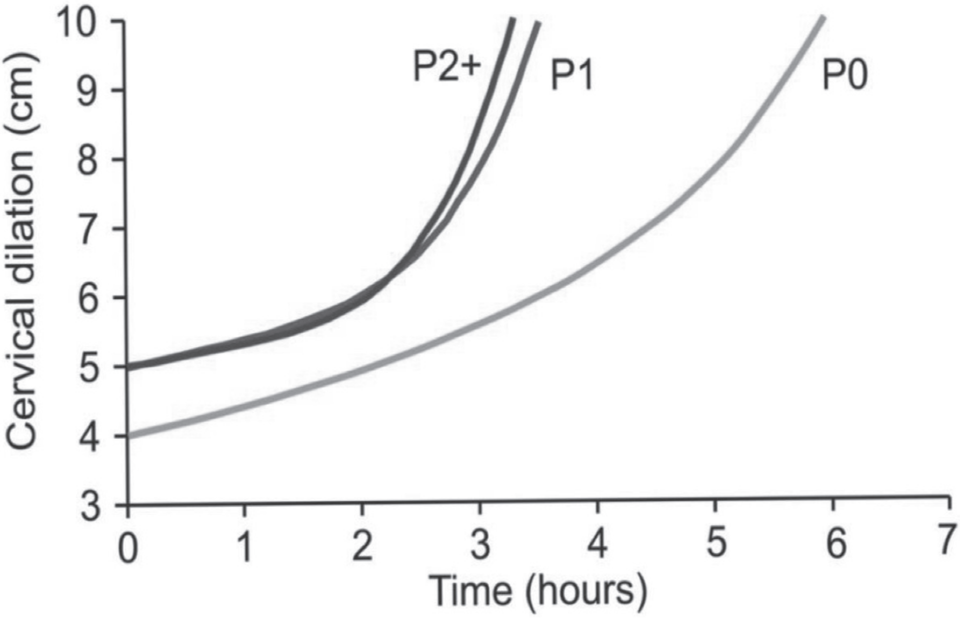

Figure 13. Average labour curves by parity in singleton pregnancies with spontaneous onset of labour at term according to Zhang et al.[44]

4.3.3 Second stage of labour

The second stage of labour starts when the cervix is fully dilated, 10 cm, and ends with the delivery of the new-born. This stage has a defined starting point and end point. The second stage is usually divided into a passive phase and an active phase. During the passive phase the women let the contractions do the work and wait for the fetal head to descent through the birth canal until it is at the pelvic floor. During the passive phase there is often lack of involuntary expulsive contractions. Then the active phase starts, this is the phase of pushing. The duration of the passive and active phase varies in different guidelines. In the Norwegian guidelines the passive phase can last for two hours, if the CTG is reassuring, but the active phase should not exceed one hour[43]. NICE guidelines recommend delivery within two hours of active pushing[42]. Research have shown that the risk of neonatal asphyxia increases after 30 minutes of active pushing [45]. A randomised trail comparing early and delayed pushing included nearly 2000 women. In this trail they did a secondary analysis to determine the maternal and neonatal outcome in prolonged second stage. They wanted to determine if there was a maximum duration of the active second stage. The risk of operative delivery increased 9-fold in the group with 2-3 hours of pushing, and 30-fold after 3 hours of pushing. They concluded that there was hardly any benefit of pushing more than two hours.[46]

4.3.4 Third stage of labour

The third stage of labour is the period between the birth of the new-born and the delivery of the placenta.

4.4 Prolonged second stage

When Friedman described the length of the stages of labour he did not perform any calculations regarding the length of the second stage of labour. This because the variability of the length of the second stage is depending to a considerable degree on the cephalopelvic relationship, the intensity and frequency of the contractions and the cooperation of the patient. He stated: '*The second stage, therefore, is not a matter for consideration here. Its management is left as a clinical art'*[39]. However, birth attendants need definitions of prolonged second stage so that they know when to act or not. Since there is no consensus regarding the maximum length of the second stage national guidelines vary.

There are certain risks related to prolonged second stage of labour; increased risk of operative vaginal delivery, increased risk of cesarean section, third and fourth degree sphincter tears, postpartum haemorrhage, chorioamnionitis, 5-minutes Apgar less than 7, meconium stained amniotic fluid, admission to neonatal intensive care and a longer hospital stay in general[47]. In low income countries prolonged second stage of labour is an important cause of maternal mortality. The main causes of maternal death due to prolonged second stage of labour are; uterine rupture, complications of cesarean section and anaesthesia, postpartum haemorrhage and postpartum sepsis[48].

There are several reasons for prolonged second stage of labour. Mainly they may be defined into four categories; strength of the contractions and the expulsive force, cephalopelvic disproportions, malposition and malpresentation, and finally a combination of these factors.

One factor which may influence the contractions is the use of epidural analgesia. Epidural analgesia has been associated to prolonged labour both the first and the second stage of labour without increasing the rate of cesarean section[49, 50]. Epidural analgesia is more commonly started in women with slow progress, therefore, we do not know if epidural analgesia is the cause of prolonged labour. Maternal position during labour has also showed to influence the contractions. Supine position of the delivering woman leads to less intensity of the contractions than side laying position. While sitting and standing increases the frequency and intensity of the contractions[33]. Low intensity and frequency of contractions can be treated with oxytocin acceleration.

Cephalopelvic disproportion is a mismatch between the size and shape of the maternal pelvis and the fetus. The bony pelvis has been classified into four basic types: gynecoid (55%), android (20%), anthropoid (20%), and platypelloid (5%), *figure 14*.

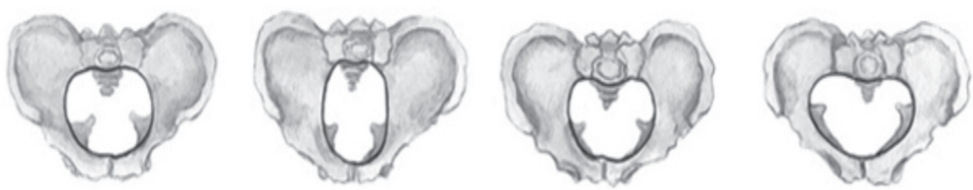

Figure 14. Four basic types of the bony pelvis: gynecoid, anthropoid, android and platypelloid. From: http://steflenk.com/OBSTETRICdolls/07_pelvis.html.

The gynecoid pelvis is optimal for normal delivery. The android (male shaped) pelvis is triangular in shape, narrow in front and associated with dystocia due to failure of head rotation. The android pelvis is more common in African-Caribbean women. The pelvis shape cannot be examined by clinical examinations or with ultrasound, but the subpubic arch angle is associated to pelvic shape and has recently been examined with ultrasound[51, 52].

The fetal head has several important diameters, *figure 15*. The suboccipitobregmatic, number 4 *figure 15*, (occiput anterior position) and submentobregmatic, number 3 *figure 15* (face presentation) are the narrowest, while the occipitofrontal, number 2 *figure 15* (occiput posterior position) is larger and the occipitomental diameter, number 1 *figure 15*, (brow presentation) is the largest. In a brow presentation a vaginal delivery is impossible[33].

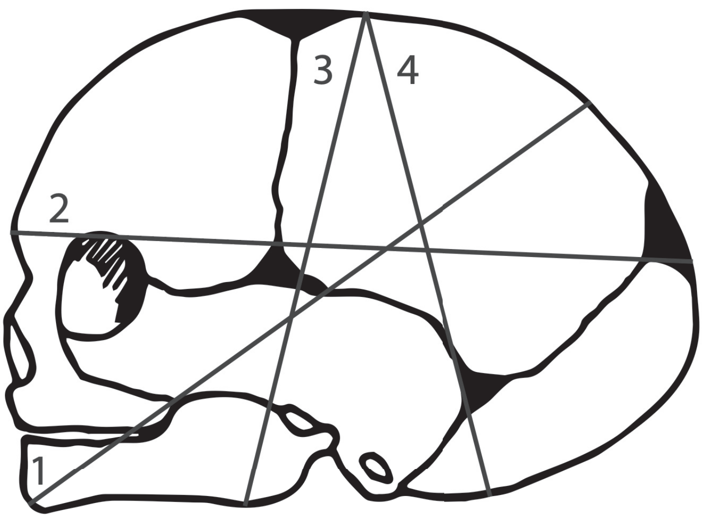

Figure 15. Diameters of fetal head. Number 1 is occipitomental (13.5 cm); 2 is occipitofrontal (11.5 cm), 3 is submentobregmatic (9.5 cm) and 4 is suboccipitobregmatic diameter (9.5 cm). Illustration: Morten Dreier.

The shape of the birth canal and the presentation of the fetal head plays a critical role in the outcome of labour.

Macrosomia, usually defined as a birth weight more than 4500 gr. Irrespectively of gestational age, can also be a cause of cephalopelvic disproportion and a prolonged second stage of labour. Macrosomia affects 2-4 % of fetuses. Maternal diabetes mellitus and gestational diabetes is associated with macrosomia.

The third cause of prolonged second stage is malpresentation and malposition. The fetal presentation describes the lowermost part of the birth canal and can be breech, occiput, sinciput (forehead), brow, or face. With face presentation and the fetal spine anterior a vaginal delivery is impossible, the fetus has to rotate into a position with the fetal chin anteriorly. In a brow presentation a vaginal delivery is only possible with in very small fetus, at term this is an indication for cesarean section. With a compound presentation with an arm lying in front of the head, a vaginal delivery is difficult, and the clinicians should be aware of the possibility of prolonged labour. The fetal position describes the rotation of the fetal head in relation to the maternal pelvis, usually a description of where the occiput is, *figure 16*. This is usually done like a clock with twelve hourly divisions[36, 53], occiput anterior (OA): ≥10.00 and ≤ 2.00, left occiput transverse (LOT): > 2.00 and < 4.00, occiput posterior (OP): ≥ 4.00 and ≤ 8.00, right occiput transverse (ROT) : > 8.00 and < 10.00[36], *figure 17.* Occiput posterior position in active labour is associated with prolonged second stage[33], increased risk of artificial rupture of membranes, acceleration with oxytocin and operative vaginal deliveries[54, 55]. Occiput posterior position at birth is associated with higher risk of anal sphincter rupture[56], low 5-minute Apgar score, low umbilical artery pH and admission to neonatal intensive care unit[54].

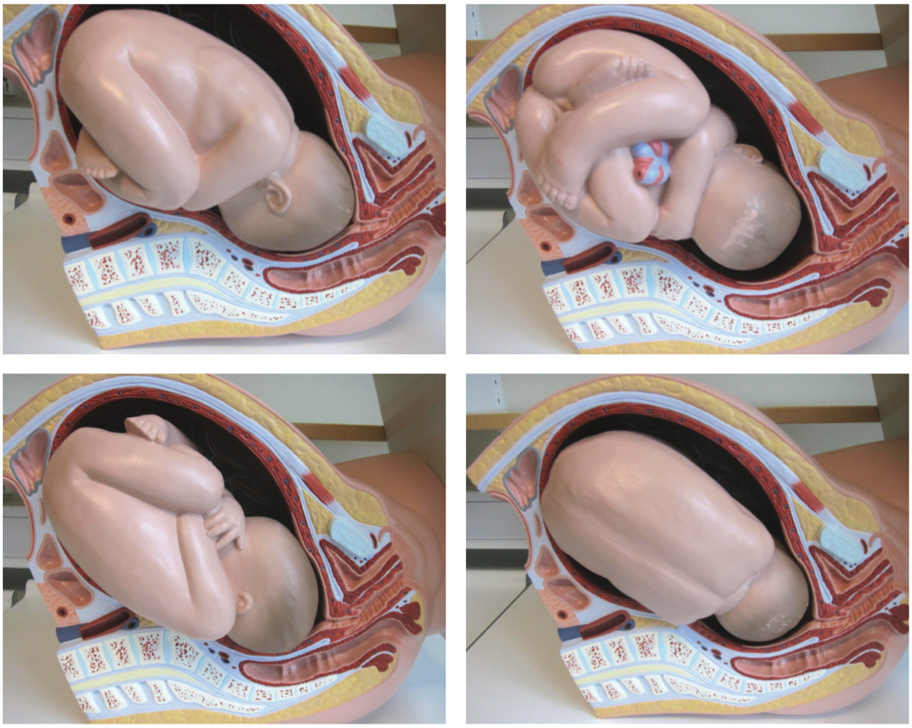

Figure 16. Fetus in occiput anterior, left occiput transverse position, occiput anterior position and right occiput transverse position, photo by Torbjørn Moe Eggebø.

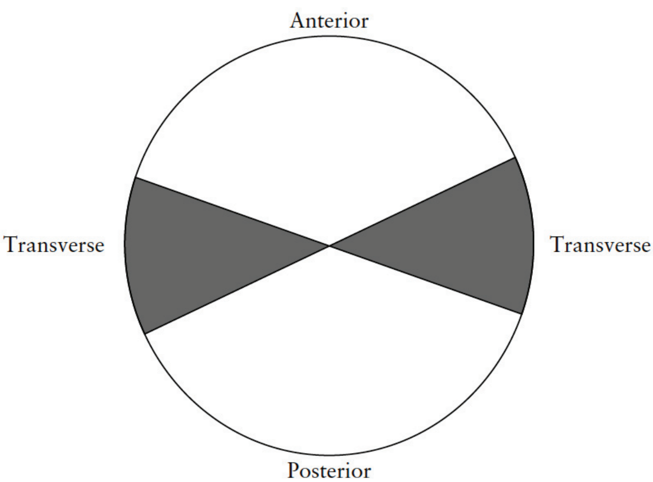

Figure 17. Showing the position of the occiput in on a clock face [36].

When prolonged labour is diagnosed there are several procedures that can be done to prevent arrested labour. Fluid and food intake should be encouraged during active labour[57]. The woman try to stay active since this affects the contractions and the bladder should be emptied regularly[33]. The labouring woman also needs support, and one-to-one support has shown to increase the chance of an uneventful delivery[58]. Artificial rupture of the membranes can shorten labour, but is not recommended to be performed on a regular basis[59, 60]. The membranes should be ruptured before acceleration with oxytocin is started. If the contractions are not sufficient it is possible to make them more sufficient by start acceleration with oxytocin. Acceleration with oxytocin has shown to shorten the duration of labour but does not decrease the number of operative deliveries due to prolonged second stage of labour [61-63]. Oxytocin is a potent drug and the sensitivity of the woman to the drug is very individual. A too high doses can lead to overstimulation of the muscles in the uterus and can reduce the blood perfusion of the placenta. This can compromise the fetus[61]. If prolonged second stage is diagnosed and the contractions are sufficient or there is acceleration with oxytocin and the woman has a good pushing technique, there is a point where the last option is to deliver the woman with an operative delivery.

4.5 Operative deliveries in the second stage of labour

Operative deliveries can be divided into operative vaginal deliveries, by vacuum extraction or forceps, or cesarean section. In both cases a decision has been made to end the delivery, either due to maternal indications or fetal indications.

4.5.1 Operative vaginal deliveries in the second stage of labour

4.5.1.1 Vacuum extraction

Vacuum extraction was first described in 1705 by Dr James Young, an English surgeon. However, it did not gain widespread use until the 1950s, after the publication of several studies by the Swedish obstetrician Dr. Tage Malmstrom[64]. The prevalence of vacuum extractions differs in different parts of the world. In the United Kingdom the rates of both vacuum extractions and forceps deliveries have been stable at between 10-13%[65] and in Norway the same numbers are 9%[66]. An underuse of vacuum extractions is reported from other parts of the world, and there are less than 1% operative deliveries in Sub Saharan Africa[67]. In a birth cohort of more than 22 million vaginal deliveries in the USA, the rate of vacuum deliveries declined from 5.8% in 2005 to 4.1% in 2013. The authors worry that the art of operative vaginal deliveries will disappear and women will not get an alternative to late second stage cesarean sections[68].

The indication for vacuum extraction can be fetal, maternal or due to prolonged second stage. Fetal indication have to do with presumed fetal compromise. The maternal indications are when the mother has a medical condition that could worsen if the second stage is too long and the Valsalva maneuverer should be avoided, for instance cardiac disease or epilepsy. The indication of prolonged second stage is depending on the local definition of prolonged second stage, but maternal fatigue and exhaustion is also a part of this indication[65].

To perform a safe vacuum extraction some prerequisites, need to be fulfilled[33, 37, 65, 69, 70].

- Cephalic presentation
- The cervix must be fully dilatated and the membranes ruptured
- No more than one-fifth of the head should be palpable on the abdominal palpation
- Fetal head station at level of the ischial spines or below
- Exact position of the fetal head should be determined
- Excessive caput and moulding should be evaluated
- The operator should be willing to abandon the procedure if it does not proceed easily or if the cup dislodges more than three times

Like in all procedures there are some contraindication to perform vacuum extractions. Some are absolute and other are relative[64].

- Absolute contraindications:
  - Underlying fetal disorders: bleeding disorders or demineralisation disorders
  - Failure to fulfil all the requirements for vacuum extraction
  - Abnormalities of labour: malpresentations (breech, face, brow) and a suspicion of cephalopelvic disproportion
  - Gestational age <34 weeks or estimated fetal weight <2500 grams
- Relative contraindications
  - Suspected macrosomia
  - Uncertainty about fetal head position
  - Inadequate anaesthesia

A vacuum extractor is a device with a suction cup attached with tubing to a vacuum source and a handle, which is used to apply traction to the cup. Traction is applied to the fetal head along the axis of the birth canal. There are several cups available. Malmstrom designed a stainless-steel vacuum cup in the 1950s. It has rounded edges and the vacuum tubing and traction chain are attached to the centre of the upper surface of the cup, *figure 18.*

Figure 18. Malmstrom stainless-steel vacuum cup. Photo by Morten Dreier.

Bird modified the Malmstrom vacuum extractor by attaching the vacuum tubing and traction chain on the side of the cup. This allows placement of the cup close and anterior to the occiput in occiput posterior and lateral positions. A soft silicone cup was introduced by Kobayashi, this cup has a stainless-steel valve that allows the release of suction between the contractions without loss of application of the cup to the head. The disposable vacuum extractor, the Kiwi Omnicup™, is a plastic cup and a hand pump-traction system directly applied to the vacuum cup[37], *figure 19.*

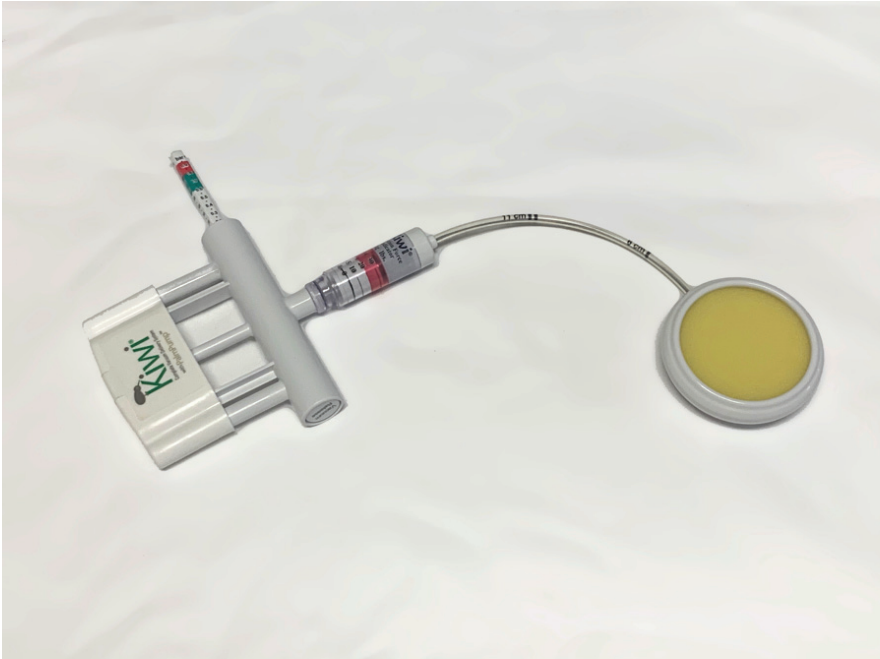

Figure 19. The disposable vacuum extractor, the Kiwi Omnicup™. Photo by Morten Dreier.

Choosing of a cup is depended on the operators own choice and experience. The soft cups are more likely to fail, but are associated with less fetal scalp injury. There are no difference in maternal injury between the cups[71]. The Kiwi Omnicup™ also has a higher failure rate than the metal cups, 34%. There is no difference in fetal scalp trauma[72]. In this study the failure rate for metal cups was 21% which is higher than in other publications.

There is a randomised trail investigating whether to reduce the negative pressure between the contractions, no differences were detected regarding neonatal and maternal outcome[73].

When there is an indication, the prerequisites are met and there are no contraindications a vacuum extraction can be performed. The woman is placed in a lithotomy position, the bladder is emptied and there is adequate analgesia. Correct cup placement and appropriate traction direction are major determinants of the outcome. The flexion point is the place where the vacuum cup should be placed to achieve flexion of the fetal head. The flexion point is on the sagittal suture three cm in front of the posterior fontanel. When the cup is placed correctly on the fetal head before negative pressure is applied any maternal tissue entrapment between the cup and the fetal head should be excluded. The suction is applied by gradually increasing the negative pressure. Effective tractions require a negative pressure of at least 0.6 kg/cm^2 and usually 0.8 kg/cm^2. Traction should be in line with the axis of the pelvis, perpendicular to the plane of the vacuum cup and coordinated with maternal pushing[37]. In occiput anterior positions the cardinal movement at expulsion is extension of the neck, however, in occiput anterior positions this movement starts with flexion and thereafter extension. The traction directions are shown in *figure 20 and 21*.

Figure 20. Traction direction in occiput anterior position, photo by Torbjørn Moe Eggebø.

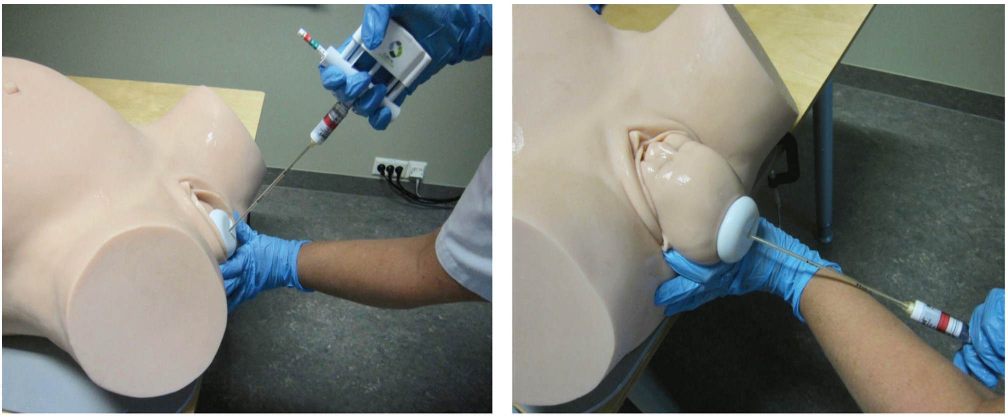

Figure 21. Traction directions in occiput posterior position, photo by Torbjørn Moe Eggebø.

Vacuum extractions are classified according to the fetal head station[64, 69]; outlet, low, mid pelvic and high. High vacuum extractions are above the ischial spines and are not recomended[69]. An outlet vacuum extraction is when the fetal skull is visible in the introitus, has reached the level of the pelvic floor, the sagittal suture is in a direct anteroposterior diameter or in a right or left occiput anterior or posterior position and the rotation is $\leq 45°$. The fetal head station in clinical examination is usually described in relation to the ischial spine from -5 to +5. A low vacuum extraction is when the fetal head is at station +2 or lower. Mid pelvic is when the fetal head is between station 0 and +2[69].

Documentation of the procedure is essential and should contain; indication, fetal head station and position, assessment of the fetal heart rate, ease of application of the vacuum cup, number of attempts, duration of the procedure, neonatal and maternal outcome also including complications[70].

The Royal College of Obstetricians and Gynaecologist stated that *'the goal of operative vaginal deliveries is to mimic spontaneous vaginal delivery, thereby expediting delivery with a minimum of maternal and neonatal morbidity'*[65]. But with all operative procedures there are complications. Vacuum extractions are associated with neonatal complications like scalp trauma and traumatic intra-cranial haemorrhage with subsequent neurodevelopmental delay[74], were as forceps

deliveries have been more associated with maternal complications like anal sphincter tears[56, 75, 76]. These complications might be a part of the increased use of cesarean section and the decrease in operative vaginal deliveries on a global scale[77].
Complication to the neonate can be divided into minor complications with a good prognosis and major complications with a worse prognosis. The minor complications are caput succedaneum, scalp bruising, cephalohematoma and retinal haemorrhage. The major complications are subgaleal haemorrhage and intracranial haemorrhage[78]. Subgaleal haemorrhage is characterised by an accumulation of blood in the subaponeurotic space, beneath the epicranial aponeuroses of the scalp and the periosteum. This condition is dangerous because the large potential space for blood accumulation and the possibility of a life-threatening haemorrhage. These complication are well-known, already in 1969 a case report including nine cases of subgaleal haemorrhage was reported and two of these infants died[79].
One study investigated the neonatal outcome after vacuum extraction in a university hospital setting. The most common indication was prolonged second stage. 913 neonates were delivered with vacuum extraction, 18% had scalp oedema, 11% had cephalohematoma, 5% had skull fractures and 1% had intracranial haemorrhage[78]. A population-based cohort study from Sweden from 1999-2010, investigated cerebral complication among neonates delivered by vacuum extraction. The rate of traumatic intracranial haemorrhage was 0.8/10 000 and the rate of non-traumatic intracranial haemorrhage was 3.8/1000 of the deliveries during this period. 58% of the neonates with traumatic intracranial haemorrhage were delivered with vacuum extraction resulting in an OR of 10.05 (95% CI 4.67-21.65) compared to spontaneous vaginal delivery. 31.5% of the neonates with non-traumatic intracranial haemorrhage were delivered with vacuum extraction, this resulted in an OR of 2.23 (95% CI 1.57-3.16) compared to spontaneous vaginal delivery. Neonates delivered with cesarean section had no increased risk of intracranial haemorrhage[80].
A prospective cohort study from two university hospitals in England recruited 393 women delivered with operative delivery at full cervical dilatation, 184 were

delivered with operative vaginal delivery and 209 with cesarean section. All were delivered due to prolonged second stage of labour. Five years after the delivery they received two questionnaires investigating the neurological development of the child. The cohort were divided into three groups; operative vaginal delivery (127 cases), cesarean section after failed operative vaginal delivery (73 cases) and immediate cesarean section without attempt of operative vaginal delivery (65 cases). There were no differences in general health problems within the three groups besides, hearing problems which was higher in the operative vaginal delivery group compared with the immediate cesarean section group, OR 3.68 (95% CI 1.22-11.1). There was no difference in neurological development between the groups[74]. In the same cohort they investigated the short term and long term maternal and neonatal outcome. Regarding maternal morbidity, there was more blood loss and prolonged hospital stay more than six days in the cesarean section group. In the group operative vaginal delivery there was a 5% risk of a third-degree sphincter tear. 24% of the cesarean sections got an extension of the uterine incision to the cervix, vagina and broad ligaments. There were significantly more cases of neonatal trauma in the operative vaginal group and the cesarean section after failed operative vaginal delivery, that in the immediate cesarean section group, but there were few cases with serious neonatal trauma[81]. When they compared successful operative vaginal delivery and failed operative vaginal delivery there were more neonatal trauma and maternal trauma when more than one instrument was used and if more than three pulls had occurred. In this study they focused on number of pulls and not duration of delivery[82].

A group in California investigated the relationship between mode of delivery and intracranial injury in neonates. Intracranial haemorrhage occurred in 1 of every 860 neonates delivered with vacuum extraction, 1 in every 664 neonates delivered with forceps, 1 in every 256 neonate delivered with forceps after attempt of vacuum and 1 in every 334 neonate delivered with cesarean section after attempt of vacuum extraction[83].

Another serious complication after vacuum extraction is obstetric brachial plexus palsy, a feared complication after shoulder dystocia. This can also occur after vacuum extraction without shoulder dystocia. A population based study from Sweden analysed the result of more than 13 000 vacuum deliveries. Obstetric brachial plexus palsy occurred in 1.1%. The probability of risk increased in relation to the duration of vacuum delivery[84]. Safe operative vaginal deliveries can be a good treatment for prolonged second stage and in low income countries it can save lives[48].

4.4.1.2 Forceps deliveries

The first obstetric forceps were invented by the Chamberlen family in the United Kingdom. They arrived in Britain in 1569 from France, where they fled persecution. The instrument was kept a secret and handed down through the generations for 150 years before it was made public[85, 86]. More than 700 types of obstetric forceps have been described[65, 87]. The obstetric forceps consists of two crossing branches. Each branch has four components: blade, shank, lock and handle. The blades has two curves, the cephalic curve conforms to the shape of the fetal head and the pelvic curve corresponds more or less to the axis of the birth canal[33], figure 22.

Figure 22. Obstetrical forceps, model: Simpsons. Photo by Morten Dreier.

There are three main types; outlet, mid cavity, or rotational forceps, each appropriate to specific situations and requiring different levels of expertise[87]. Outlet and mid cavity forceps are used as tractional devises, the fetal head position should preferably be in an OA position. Kiellands forceps is a rotational forceps, where the fetal head is rotated before the traction is completed[88]. High forceps deliveries is not recommended in modern obstrics[33]. A safe forceps delivery has the same prerequisites as a vacuum extraction.
In some cases, a forceps delivery is preferred over a vacuum extraction[33, 87]:

- Preterm delivery before 34 weeks of gestation
- Known or suspected coagulopathy or thrombocytopenia in the fetus
- Operative vaginal delivery in a woman where maternal medical conditions prelude pushing
- Operative vaginal delivery under general anaesthesia

Benefits of forceps delivery over vacuum extraction is that the forceps is less likely to fail and less likely to cause cephalic hematomas and scalp injury in the neonate[89]. The disadvantage is damage to the maternal pelvic floor, both on short term and long term[76, 90].
The number of forceps deliveries are going down, like all operative vaginal deliveries[87]. The choice of instrument is always up to the operator, since all situations are different, and this should be done with care[65].

4.5.2 Second stage cesarean sections

The first written record of a cesarean section were both mother and child survived happened in Switzerland in 1500, when Jacob Neufer performed the operation on his wife. At that point she had been in labour for several days and had help from thirteen midwifes. After the successful operation the mother gave birth to five more children in the years to come. This was written down 80 years after it is supposed to have happened, and to get it confirmed is impossible[85]. The early cesarean section had a very high maternal mortality. Ferdinand Adolf Kehrer, a German gynaecologist, is known for the first modern cesarean section with a transverse incision in 1881, reducing blood loss and increasing the chance of survival.

The rate of cesarean sections performed differs throughout the world. In 2012 the estimated number of cesarean sections in the world was 23 million[91]. In 2013 the rate of cesarean sections were 32% in the USA, 23% in the United Kingdom and 16% in Norway[66, 92]. And the frequencies are increasing. By avoiding the first one we might reduce the number of cesarean sections[93].

Cesarean sections can be performed before and during labour. Numbers from the Norwegian birth registry shows that about half of all the cesarean sections are performed before onset on labour and half after onset of labour. Unfortunately, there are no information about numbers of cesarean sections performed in the first or the second stage of labour[66].

Cesarean sections have traditionally been divided into elective and emergency cesarean sections. A better classification is prelabour cesarean sections, which can be elective and emergency cesarean sections, and intrapartum cesarean sections, which all are emergency cesarean sections[37].

The indication for second stage cesarean sections can be both fetal and maternal. The fatal indications are usually regarding fetal distress, and the maternal due to failure to progress. A surgery or any form of medical intervention should always have a medical indication. For cesarean section this is not always the case. In a multinational survey, including 373 health facilities in 24 countries, the cesarean section rate was 26% and in 1 % of all cases of cesarean section there was not a medical indication. It was either ‘maternal request’ or no indication was recorded. The rates of cesarean section on ‘maternal request’ differs a lot between countries, with African countries with the lowest rate and some Asian health facilities did cesarean sections on maternal request on more than 10% of all their deliveries[94].

Cesarean sections performed in second stage is always with a fully dilated cervix. Many would claim that an attempt of an operative vaginal delivery should be performed first. If an operative vaginal delivery should be attempted the prerequisites to perform an operative vaginal delivery must be met[33, 37].
The question is if maternal and neonatal outcome would differ from a cesarean section in the first or the second stage? A systematic review and meta analyses included 23 104 women delivered with cesarean section, 18106 during the first stage of labour and 4998 during the second stage of labour. Maternal deaths were significantly more prevalent among women with a second stage cesarean section, OR 7.96 (95% CI 1.61-39.39). Admission rates to the intensive care unit was also higher, OR 7.41 (95% CI 2.47-22.5), as were the transfusion rates, OR 2.60 (95% CI 1.49-2.54). This was also regarding incision extension rates, OR 9.42 (95% CI 2.33-27.59), were the incision in the uterus extended into the cervix and vagina. Obstetric manoeuvres to avoid massive bleeding were also more prevalent in the second stage cesarean section than in the first stage cesarean sections, OR 3.44 (95% CI 1.34-8.55), as were post-operative haemorrhage, OR 2.28 (95% CI 1.01-5.16). Regarding neonatal outcome the death rates here were also higher in the group that underwent second stage cesarean sections, OR 5.20 (95% CI 2.49-10.85). The admission rate to the neonatal intensive care unit were comparable between the groups, OR 1.63 (95% CI 0.91-2.91). The same was for Apgar score <3, OR 2.95 (95%CI 0.77-11-28). Intubation for other reasons than meconium aspiration was more frequent in the second stage cesarean section group, OR 3.02 (95% CI 1.24-7.31). There was no difference in neonatal septicaemia between the groups, OR 1.93 (95% CI 0.63-5.88). Fetal injury was more common in the second stage cesarean section group, OR 5.76 (95% CI 1.27-26.18). They concluded that even though the studies in the meta-analysis are heterogenetic the rates of perinatal, both maternal and neonatal, mortality and morbidity are high and that operative vaginal deliveries, if they are not contraindicated, represent a solution[95].

A population-based cohort study from a university hospital in Canada, including 1623 cesarean sections of which 549 were in the second stage of labour. 84% of the second stage cesarean sections were due to labour dystocia. 110 of the second stage cesarean section were after a failed attempt of an operative vaginal delivery. Regarding maternal morbidity they found more early postpartum haemorrhage and intraoperative trauma in the second stage cesarean section group than in the first stage cesarean section group. The only difference in neonatal morbidity was that there was more asphyxia among the neonate delivered with second stage cesarean section. There was no difference in perinatal outcome, maternal or neonatal, when comparing the group that had an attempt of operative vaginal delivery and not before the cesarean section. They conclude that their low number of complications were due to an universal health service and that operative deliveries were performed by experienced obstetricians[96].

A case control study was performed in a large referral hospital in South Africa. The cases were women delivered with second stage cesarean sections and the controls were women delivered with cesarean section due to prolonged first stage of labour. Women with a previous cesarean section were not included. Data on pregnancy, labour, surgery and puerperium were collected and all women were contacted by phone after two weeks to identify clinical problems arising after discharge. There were 39 women in each group. In the second stage cesarean section group seven were done after an unsuccessful attempt of operative vaginal delivery. In 31% of the cases (12) and none of the controls the delivery of the fetal head was describes as difficult. In 10 of these a second assistant was required to push the fetal head up from the vagina and in two cases they did a reversed breech delivery. The median blood loss was greater in the cases. 12 cases had a lower segment tear. The operation was significantly longer in the cases than in the controls, 45 vs. 30 minutes. One case had a hysterectomy due to uncontrollable haemorrhage and one of the cases died due to server bleeding, massive transfusions and pulmonary oedema. Neonatal morbidity was also increased after second stage cesarean sections. 5-minutes Apgar

score <7 was found in 18% of cases, and in none of the controls, 44% were admitted to the neonatal intensive care unit in the case group compared to 8% in the control group. There were eight neonates with neonatal encephalopathy in the case group and one in the control group. There were 2 neonatal deaths in the case group. This study has a small sample size and is under powered. The median duration of the second stage was 135 minutes (range 45-355 minutes) and the median time interval from decision to do cesarean section to delivery was 70 minutes (range 10-245 minutes). This can also influence the results of the second stage cesarean section[97].
A cohort for the United Kingdom comprising 393 women delivered with operative delivery in the second stage of labour were followed over time. After three years 283 women answered a questionnaire. 192 women wanted another pregnancy and 140 women had a achieved this. 91 did not want another pregnancy and almost half of them indicated fear of childbirth as a reason for not conserving. 78% of the women who delivered the first time with an operative vaginal delivery had a subsequent vaginal delivery, and 69% whom had a cesarean section had a cesarean section again. Indicating that the result of the first delivery has an impact on later deliveries[98].

There are certain complications related to cesarean sections. They are usually divided into immediate, early and late complications. The immediate complications can be related to the anaesthetic, there can be an acute haemorrhage or damage to the other pelvis organs like the bladder. These are usually discovered right away and handled during the surgery. The early complications can be haemorrhage during the early recovery period, this is either clearly evident like vaginal bleeding or can be more concealed like intra uterine- or intra-abdominal bleeding. Infections can occur in the urinary tract, uterus or the wound. After all abdominal surgery there is a risk of paralytic ileus. Thromboembolic disease is a feared complication and most women usually get thrombosis prophylactics.
The late complications can involve fertility issues. Women after a cesarean section are less likely to have further children. If this is because of the surgery or the

indication of the surgery is unclear. There is also an association between previous cesarean sections and stillbirth. There is a risk of uterine scar rupture of approximately 0.5% is subsequent labours. This can cause significant morbidity and mortality for both mother and neonate. There is also a risk of placenta previa with or without placenta accreta. This risk is increasing with increasing number of cesarean sections, and is the most serious complication[37].

What are the risks involved with of multiple cesarean sections? Over a five-year period in a referral hospital in Saudi Arabia all clinical records of women delivered with cesarean sections were examined for indicators for maternal morbidity. 3191 women were delivered with a cesarean section during this period. Placenta previa and placenta accreta escalated linearly with rising numbers of cesarean sections. When placenta previa was present, placenta accreta coexisted in 50% of women undergoing the fifth cesarean section. In the second cesarean section placenta previa and placenta accreta coexisted in 12% of woman. They conclude that the number of cesarean sections a women undergoes predicts her risk of morbidity. The risk between cesarean section number three and four is almost the same, but the fifth clearly has a higher degree of complications[99].

A case control study from Israel compared 154 women who underwent a cesarean section for the fourth time or more with two control groups. One including 148 women undergoing cesarean section for the second or third time, and the second control group were 132 women who delivered spontaneous vaginally without previous cesarean sections. The authors wanted to investigate pregnancy outcome in these groups. There were no maternal deaths but two from the case group underwent a hysterectomy. Women in the case group had more adhesions. In 10% of the cases the fetal membranes were visible though the uterine wall before incision, in the group of two or three cesarean sections this happened in 8% of women. There were more neonatal complications in the group with higher order cesarean sections; lower mean birth weight, lower gestational age at delivery, lower Apgar scores, more respiratory distress syndrome and more admissions to the neonatal intensive care unit. They conclude that there was little difference between the two cesarean section groups regarding maternal complications but more neonatal complications, mostly related to elective preterm cesarean section. In the paper, which is from 1994, there is no mention of placenta accreta spectrum disorders[100].

Abnormally invasive placenta or placenta accreta spectrum disorders is a situation where the placenta does not detach from the uterine wall after the delivery of the neonate due to ingrowth of placenta tissue into the uterine wall. These terms cover the conditions were the placenta is a true accrete, increta or percreta. Clinically the placenta accreta spectrum is usually divided into a 'simple accreta' where the placenta can be removed manually or with a curettage or the more relevant group with invasion of the uterus. In this group surgical interventions are a necessity. There is a high risk of severe haemorrhage and a maternal mortality up to 7% has been reported. The incidence has increased dramatically over the last decades due to the increased rate of cesarean section. Prenatal diagnosis can reduce the complications is this condition. When the diagnosis is known, the delivery can be planned at the right time, at the right place with the right staff present[101, 102].

5. Hypotheses and aims

The main objective of the study was to investigate if ultrasound methods could predict labour outcome in women with prolonged second stage of labour.

We wanted to test following three null- hypothesis:

- Ultrasound measurements cannot predict outcomes of operative vaginal delivery.
- Ultrasound is not better than digital examination in predicting delivery outcome.
- Movement of fetal head with active pushing is not a predictive factor

5.1 Paper one

The aim was to assess if ultrasound measurements of fetal head position and station could predict duration of vacuum extraction, mode of delivery and fetal outcome in nulliparous women with prolonged second stage of labour.

5.2 Paper two

The aim was to study was to investigate fetal head rotation during vacuum extraction performed due to prolonged second stage of labour in nulliparous women.

5.3 Paper three

The aim was to investigate if movement of the fetal head assessed with transperineal ultrasound during active pushing was associated with duration of operative delivery, mode of delivery and neonatal outcome in nulliparous women with prolonged second stage of labour.

6. Materials and methods

6.1 Study population

The inclusion period was from November 2013 through July 2016. Women were included in 7 delivery departments throughout Europe. A total of 223 women were included at Stavanger University Hospital, Norway (n=135); University Hospital of Bologna, Italy (n=34); Trondheim University Hospital, Norway (n=16).; Queen Charlotte's and Chelsea Hospital, Imperial College Healthcare National Health Service Trust, London, United Kingdom (n=14); Lund University Hospital, Sweden (n=9); Hvidovre University Hospital, Copenhagen, Denmark (n=9); and University Hospital of Parma, Italy (n=6).

The inclusion criteria of the study were:

- Nulliparous
- One live singleton fetus
- Cephalic presentation
- Gestational age ≥37 weeks and <42 weeks
- Diagnosed prolonged second stage and vacuum extraction was considered, after at least 45 minutes of active pushing
- Reassuring cardiotocography (CTG)

The women were included when prolonged second stage was diagnosed and vacuum extraction was considered. After inclusion a transabdominal and transperineal ultrasound examination was performed. All participating centres had experience with ultrasound, both transabdominally and transperineally. All examiners without experience before the study were trained with at least five supervised examinations before the start of the study. All participating women signed an informed consent before they were included in the study.

Since the local protocols regarding prolonged second stage of labour varied between centres, the woman had to push for at least 45 minutes before inclusion. 45 minutes was chosen because the Norwegian guidelines defines prolonged second stage as 60 minutes of active pushing and the delivery should then be expedited[43].
The clinicians in charge of the delivery were examining the women with a digital vaginal examination and determined the fetal head station and position. The fetal head station was described in relation to the ischial spine from -5 to +5[69]. The position was described as a clock face with 12 hourly divisions[36]. The clinicians were blinded for the ultrasound examination and the team performing the ultrasound examinations were not involved with decision making regarding the delivery.

6.2 Ultrasound systems and methods

The ultrasound examinations were performed with GE Voluson *i* (GE Medical Systems, Zipf, Austria) or GE Voluson S6 (GE Medical Systems, Zipf, Austria) in Stavanger, Norway, and GE Voluson *i* (GE Medical Systems, Zipf, Austria) in Trondheim, Norway; Lund, Sweden; Copenhagen, Denmark; and Bologna, Italy. In London, United Kingdom, Samsung PT60A and Samsung HM70 were used and in Parma, Italy, a Samsung WS70 was used (Samsung, Seoul, Republic of Korea).

6.2.1 Transabdominal ultrasound

The transabdominal ultrasound scan was performed to determine the position of the fetal head. The transducer was first placed transversely in the suprapubic region of the maternal abdomen, scanning all parts of the uterus. Further, a longitudinal scan was performed. Landmarks as the fetal spine, the eyes, the thalami, the cerebellum and the choroid plexus were described. The position of the occiput was defined on a clock face[36]. OA was defined as an occiput between ≥10 o’clock and ≤2 o’clock. OP was defined as an occiput between ≥4 o’clock and ≤8 o’clock. LOT was defined as an occiput between >2 o’clock and <4 o’clock. ROT was defined as an occiput between >8 o’clock and >10 o’clock.

6.2.2 Transperineal ultrasound

The transperineal ultrasound scan was used to determine fetal head decent. A curved glove covered transabdominal transducer was used, placed on the perineum. Before the examination the bladder had to be empty. The woman was placed in a semi recumbent position with the legs flexed at the hip and knee at 45-degree and 90-degree angles, respectively. The AoP was measured in the sagittal plane as the angle between the long axis of the symphysis and a line joining the lower edge of the symphysis to the lower convexity of the fetal skull[23]. The HPD was measured by placing the transducer in a transverse position in the posterior fourchette and compressing the soft tissue until a resistance was felt. This was done without causing discomfort for the woman. The transducer was than angled until the skull contour was clear and the shortest distance between the fetal skull and the transducer was measured[21]. In paper one the AoP and HPD was measured in rest between contractions. In paper three the HPD was first measured at rest between contractions and thereafter during maximum contraction and active pushing. The difference was calculated as delta HPD.

6.2.3 Analysing of the ultrasound images

All the ultrasound images where analysed immediately in the delivery room by the ultrasound operators involved in the study. They were all trained in performing the ultrasound examinations, but they were not clinically in charge of the delivery. A paper copy of the ultrasound picture was kept together with the signed informed consent and the study data sheet in a locked cabinet only available for the study investigators and destroyed after finishing the study period. All data were anonymised at this stage.

6.3 Statistical methods

6.3.1 Sample size estimation

Our preliminary clinical experience assessing HPD prior to vacuum extraction suggested that we should set 25 mm for the power calculation, a level corresponding approximately to +2 below the ischial spines. The main outcome of the study was duration of vacuum extraction analysed with survival analyses. The main predictor variable was HPD with a predefined cut-off at 25 mm to discriminate between groups. To identify a hazard ratio (HR) as low as 1.5 with 80% power, 2-sided test, with alpha 5%, one third of the women with distance >25 mm and two third of the women with distance ≤25 mm, we determined that 220 women should be included when expecting 10% censoring due to cesarean sections. The calculations were based on log rank test using the Freedman method.

6.3.2 Paper one

Categorical variables were compared using Chi-square test and linear regression. To evaluate differences in the time interval from start of vacuum extraction to complete delivery according to HPD and AoP, we used Kaplan-Meier methods and Cox regression analyses. The Kaplan-Meier method was used to generate survival plots, and we used HPD 25 mm as cut-off value in accordance with the power analysis. Cox regression was used to calculate HR as an estimate for relative risk of delivery. In the Cox regression analyses we controlled for fetal position, pre-pregnancy body mass index (BMI), maternal age, induction of labour, epidural analgesia, and acceleration with oxytocin, and in an additional analysis we included institution as a covariate. Women with spontaneous vaginal delivery were not included in the survival analysis and cesarean sections were right censored at the time of the decision to perform a cesarean section. Cox regression assumes proportional hazards, and this was evaluated by log minus log plots and test of Schoenfeld residual using the global and detailed ph-test in Stata software. The assumption was satisfied (P=.66). The association between HPD and delivery mode was analysed at five different cut-off levels: ≤20, 21-25, 26-30, 31-35 >35 mm. Since a previous study had found that HPD 35 mm was corresponding to station <0 by clinical examination we focused on 35 mm as a cut-off level and presented test characteristics related to this level[31]. The association between AoP and mode of delivery was analysed at cut-off levels: <120, 120-129, 130-139, 140-149, ≥150°. The association between spontaneous delivery and cesarean section related to HPD and AoP as continuous variables were evaluated using receiver operating characteristics (ROC) curves. These analyses were first performed as intention to treat because cesarean sections performed without a vacuum attempt were included. Thereafter, we did separate analysis that only included cesarean sections performed after a vacuum attempt. The area under the curve was considered to have a discriminatory potential if the lower limit of the confidence interval (CI) was >0.5. A p-value <0.05 was considered statistically significant.

6.3.3 Paper two

The categorical variables were compared using Chi-square test and Cohen's Kappa. To evaluate differences in the time interval from start of vacuum extraction to complete delivery according to fetal head position, we used Kaplan-Meier methods and Cox regression analysis. The Kaplan-Meier method was used to generate survival plots, and we differentiated between OA and non-OA position and compared with log rank test. Cox regression analysis were used to calculate HR as an estimated for relative risk of delivery. In the Cox regression analyses we controlled for fetal position, pre-pregnancy BMI, maternal age, induction of labour, epidural analgesia and acceleration with oxytocin. Cesarean sections and women with duration of vacuum extraction >20 minutes were censored. Cox regression assumes proportional hazards, and this was evaluated by log minus log plots. A p-value <0.05 was considered statistically significant.

6.3.4 Paper three

Cox regression analysis was used to calculated HR as an estimate for relative risk of vaginal delivery over time in women undergoing vacuum extraction, and delta HPD as a continuous variable was used as the test variable. HR >1 indicates shorter survival i.e. duration of operative vaginal delivery with increasing delta HPD. Cesarean sections were censored at the time of the decision to perform cesarean section. We adjusted for pre-pregnancy BMI, maternal age, induction of labour, use of epidural analgesia and acceleration with oxytocin. Confounding effect was set at >10% change in HR of the main test variable. Cox regression assumes proportional hazards, which was evaluated by log minus log plots. The study population was divided according to delta HPD quartile. Mean duration of vacuum extraction in the four quartile groups was estimated using Kaplan-Meier analysis. The association between delta HPD and delivery mode, 5-minutes Apgar score <7 and umbilical artery pH <7.10 were presented descriptively and compared using Chi-square test and Fisher's exact test. A p-value <0.05 was considered statistically significant.

6.3.5 Analysing tools

For the power calculating we used a statistical program (Stata for windows, version 12; StataCorp, College Station, TX). All the data were analysed using the statistical software package SPSS statistics version 23.0-25.0 (IBM corp., Amronk, NY, USA)

6.4 Ethics, safety and registration

6.4.1 Ethical consideration

This was an international multicentre study and the women were handled according to the local guidelines and the study protocol did not interfere with them.

The women participating in this study had an extra ultrasound examination in additional to the routine clinical examinations. The ultrasound examination, both transabdominally and transperineally, only lasted for a few minutes. Only women with a reassuring CTG were included and since the duration of pushing before the ultrasound examination was set to at least 45 minutes of active pushing the examination could be performed before an hour of active pushing. In Norway, this is the moment when operative delivery is considered. Because of this the examination did not delay the delivery. Ultrasound is regarded as safe for women and fetus. When used transperineally the ultrasound probe was covered with a clove and did only have contact with the skin. Studies have showed that transperineal ultrasound is well accepted by the women[103, 104]. Since this was an observational study the women were informed that the ultrasound examination would not interfere with clinical management, and any benefit from the study would be for future women and not for themselves. This was also stated in the informed consent they signed, the women signed before inclusion.

The local ethics committees in each country approved the study. Reference numbers: REK 2012/1865 in Norway; 3348/2013 in Italy; REC reference 15/LO/1341 and IRAS project ID 169478 in UK; DNR 2012/808 in Sweden; and H-4-2014-038 in Denmark.

6.4.2 Medical ultrasound safety

Diagnostic ultrasound has been widely used in clinical medicine for many years with no proven deleterious effects[105]. All the large ultrasound societies; International Society of Ultrasound, in Obstetrics and Gynecology (ISOUG), European Federation of Societies in Ultrasound and Biology (EFSUMB) and the British Medical Ultrasound Society (BMUS) all have safety committees with guidelines and safety statements regarding ultrasound and safety[105-107]. Ultrasound can produce heat, pressure changes and mechanical disturbances in tissue. The ultrasound operator is responsible for the safety of the patient, and should work after the ALARA principle; *as low as reasonably achievable,* when scanning without compromising the diagnostic value of the examination. When low values cannot be achieved the time should be kept as short as possible[105].

To help the clinicians to scan safely, there are two indices displayed on the screen of the ultrasound machine: the thermal index (TI) and mechanical index (MI). The TI is an estimate of the tissue temperature rise in in degrees centigrade, which might be possible under reasonable worse-case conditions. The MI attempts to indicate the probability of non-thermal events occurring within the tissue. In obstetrical ultrasound the TI is the most important one. During an examination there is a potential for adverse effects at high energy levels, the proper control of output levels is mandatory[108, 109]. Every ultrasound operator should know the indication for the examination, be aware of potential risks and know how to use the ultrasound machine in a safe manner.

Ultrasound examinations in this study were performed during delivery, without Doppler and with short examination time [22, 23], therefor the examinations were considered as harmless, even though no research about safety has been performed in active labour.

6.4.3 Data-registration

The study was registered in Clinical Trials (ClinicalTrials.gov) with identifier NCT01878591[110].

The data was registered in SPSS statistics and transferred to a common database. All identifiable information was deleted 2017, according to the ethical approval.

7. Results

223 women were included, and 1 woman was excluded due to missing main outcome, leaving 222 women in the study population. The characteristics of the study population are presented in *table 2* and the feasibility of the ultrasound examination in *figure 23.*

Table 2. Characteristics of the study population n=222

	Median or n (%)	Range
Maternal characteristics		
Maternal age (years)	30	17-43
Pre-pregnant body mass index	24	18-39
Gestational age (weeks)	40	38-42
Labour characteristics		
Induction of labour	73 (33)	-
Epidural analgesia	175 (79)	-
Oxytocin acceleration	170 (77)	-
Characteristics of the new-born		
Birthweight (g),	3657	2152-4930
Apgar score 5 minutes	10	5-10
PH in umbilical artery (n=184)	7.24	6.90-7.43
Birth characteristics		
Bleeding ml	400	100-3400
3^{rd} and 4^{th} degree anal sphincter tears	14 (6)	-

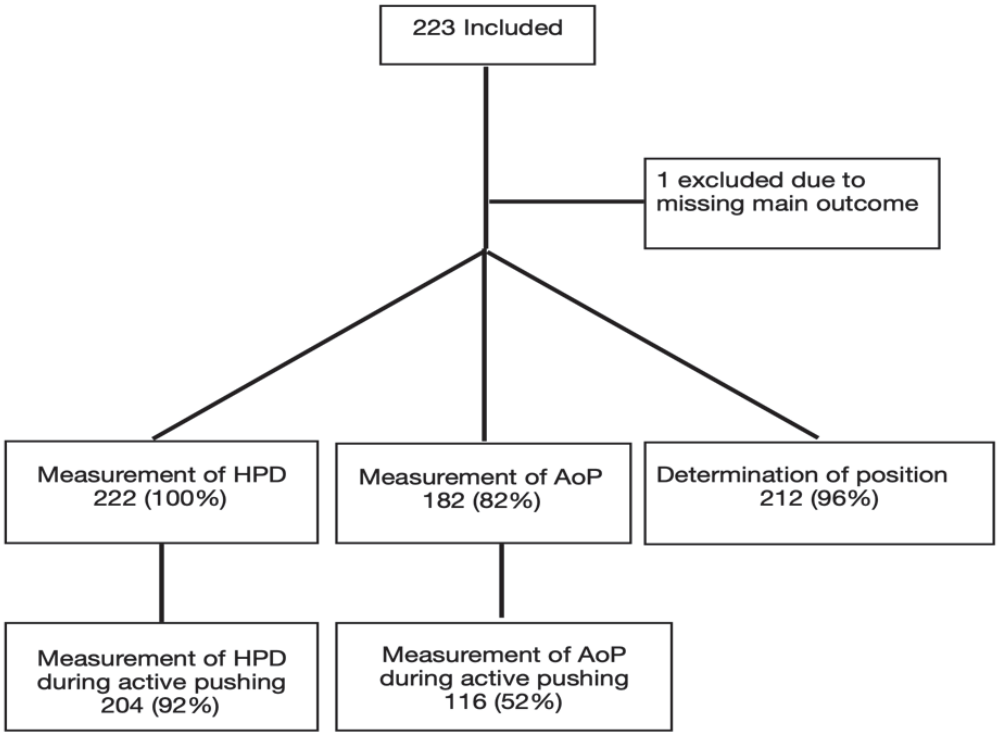

Figure 23. Flowchart illustrating the feasibility of the ultrasound examinations.

7.1 Paper one

Survival analysis were performed in women with a vacuum attempt. The duration of operative delivery was significantly shorter in women with HPD ≤25 mm (log rank test <0.01). The estimated median duration (Kaplan-Meier analysis) in women with HPD ≤25 mm was 6.0 (95% CI, 5.2-6.8) minutes vs. 8.0 (95% CI, 7.1-8.9) minutes in women with HPD >25 mm, figure 24.

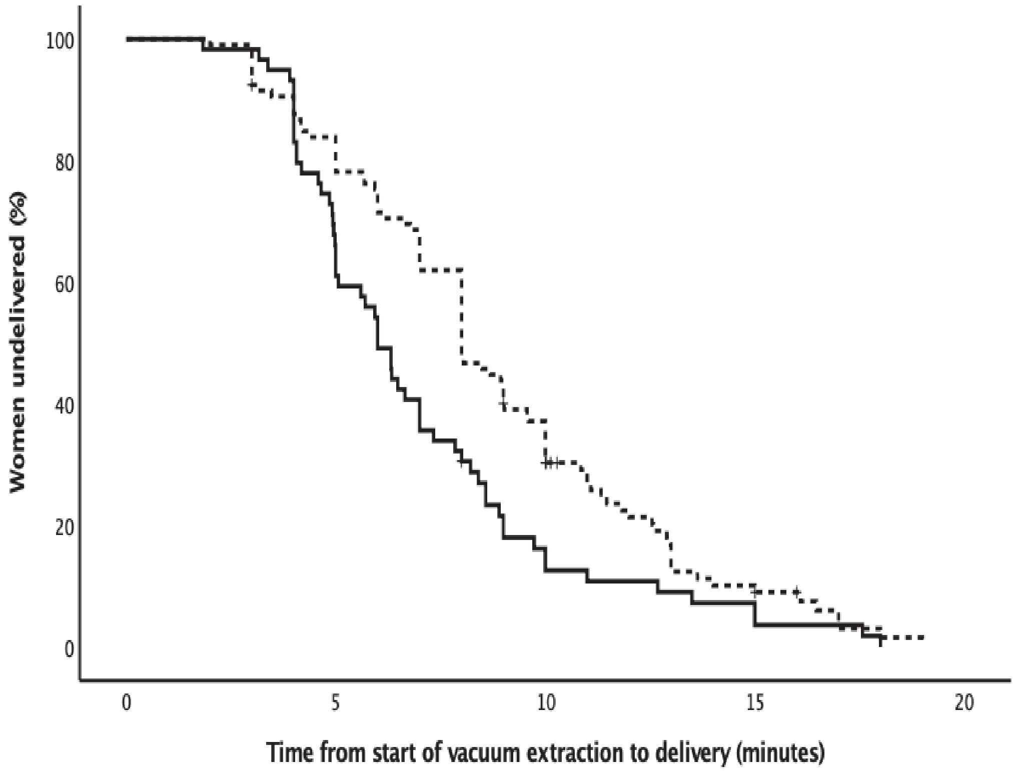

Figure 24. Kaplan–Meier plot of time from start of vacuum extraction to delivery within 20 minutes differentiated into those with head-perineum distance ≤25 mm (——) and head-perineum distance >25 mm (------). Women who were delivered by cesarean were censored at the time when decision to convert to cesarean was done (p <0.01; log Rank test).

The HR in Cox regression analysis was 0.56 (95% CI 0.41-0.78) and adjusted value 0.58 (95% CI, 0.41-0.82). HPD and AoP were analysed as continuous variables in separate analysis. They were both significantly associated with the duration of operative vaginal deliveries after adjusting for covariates Adjusted HR was 0.96 (95% CI, 0.94-0.98) for increasing HPD and 0.98 (95% CI 0.97-0.996) for increasing AoP*, table 3.*

Table 3. Cox regression analysis for predicting duration of vacuum extraction in nulliparous women with slow progress in the second stage of labour. Hazard ratios with CI intervals not crossing 1.0 were assumed significant.

	Unadjusted HR	(95% CI)	Adjusted HR	(95% CI)
Head-perineum distance	0.96	0.94-0.98	0.96	0.94-0.98
Body mass index	1.05	1.004-1.09	1.05	1.01-1.10
Maternal age	0.99	0.97-1.03	1.00	0.96-1.03
Fetal position (n=212)				
Occiput anterior (reference)	1.00	-	1.00	-
Non-occiput anterior	0.46	0.32-0.68	0.56	0.38-0.84
Induction of labour				
No (reference)	1.00	-	1.00	-
Yes	0.97	0.69-1.36	1.10	0.76-1.60
Epidural analgesia				
No (reference)	1.00	-	1.00	-
Yes	0.69	0.47-1.03	0.73	0.49-1.10
Acceleration with oxytocin				
No (reference)	1.00	-	1.00	-
Yes	0.75	0.52-1.09	0.87	0.59-1.29

The centre-adjusted HR for estimate for increasing HPD was 93 (95% CI, 0.91-0.96) when the centres were included in the analyses. Duration of vaginal delivery was >20 minutes in three women and three women had >2 cup detachments. The median duration from the ultrasound examination to delivery was 25 (interquartile range 15-38) minutes. Median HPD in women with fetal head station of 0 at clinical examination was 36 mm, mean 34 mm, range 15-49 mm and interquartile range was 7 mm. Median AoP was in the same group 132°, mean 133°, range 112-164°, and interquartile range 24°. HPD and AoP were correlated (r=0.48). When looking at delivery mode HPD and AoP were categorized into 5 different groups. In woman with HPD ≤25 mm the frequency of cesarean sections was 1% (1/99) vs. 12% (15/122) with HPD >25 mm p <0.01), *figure 25.*

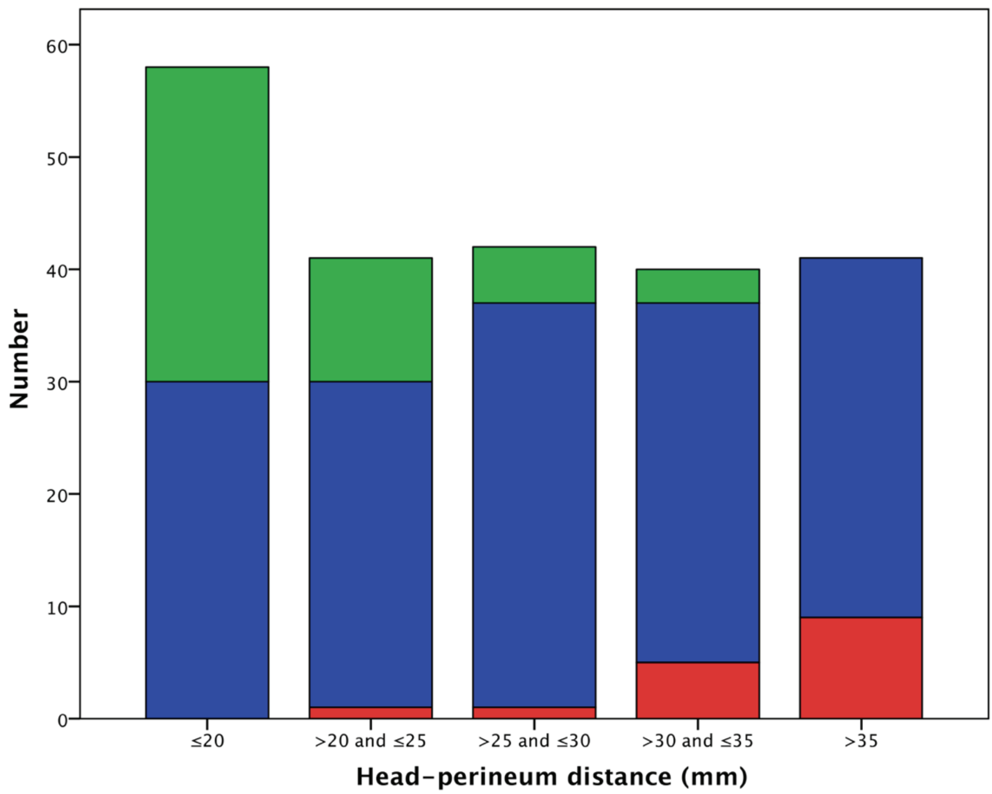

Figure 25. Distribution of spontaneous deliveries (green), operative vaginal deliveries (blue) and cesarean (red) in relation to head–perineum distance in nulliparous women with prolonged second stage of labour.

When using HPD >35 mm as cut-off level, station 0, the sensitivity in prediction cesarean section was 56% (95% CI, 33-77%), false-positive rate was 16% (95% CI, 11-21%), positive predictive value was 22% (95% CI, 12-33%), and negative predictive value was 96% (95% CI 92-98%). HPD and AoP were significantly associated with spontaneous delivery with an area under the ROC curve of 83% (95% CI, 77-89%) and 75% (95% CI, 66-86%) respectively. Only HPD was significantly associated with cesarean sections with an area under the ROC curve of 83% (95% CI, 74-92%) vs. 56% (95% CI 42-69%) for AoP.

The association between HPD and cesarean section were analysed separately among the women with a vacuum attempt. This occurred in 14/173 (8%) of women. The results were similar to the intention to treat analyses. In women with HPD ≤35 mm 7/181 (3.9%) were delivered with cesarean section vs. 9/41 (22%) in women with HPD >35 mm, $p < 0.01$. Ultrasound-assessed position was OA in 73% and non-OA in 23%. There was missing information in 4% of women. In foetuses in OA position 6/162 (3.7%) were delivered with cesarean section, this was 10/50 (20%) in non-OA foetuses, $p < 0.01$. When combining HPD ≤ 35 mm and OA position only 3/138 (2.2%) were delivered with cesarean section and 6/17 (35.3%) with non-OA position and HPD >35 mm were delivered with cesarean section. Regarding neonatal outcome umbilical artery pH was measured in 184/222 (83%) of cases. pH <7.0 was measured in one case. This was a vacuum extraction with HPD 38 mm. pH <7.10 occurred in 10 cases and HPD was >35 mm in 8/40 (20%) vs 2/144 (1.4%) with HPD ≤35 mm, p <0.01. 3 cases had bare excess >12 and of these 2 had an HPD >35 mm.

7.2 Paper two

In paper two, only women with vacuum attempt and known fetal head position determined with ultrasound were included, 165 in total. 121 (73%) of the fetuses were in an OA position, 19 (12%) in an OT position and 25 (15%) in an OP position before vacuum extraction. During the vacuum extraction, 117/119 (98%) remained in OA position and two rotated to OP position. Rotation from OT to OA position occurred in 14/19 (74%) and to OP position in 5/19 (26%). Rotation from OP to OA position occurred in 15/25 (60%), and 10/25 (40%) remained in OP position, *figure 26.*

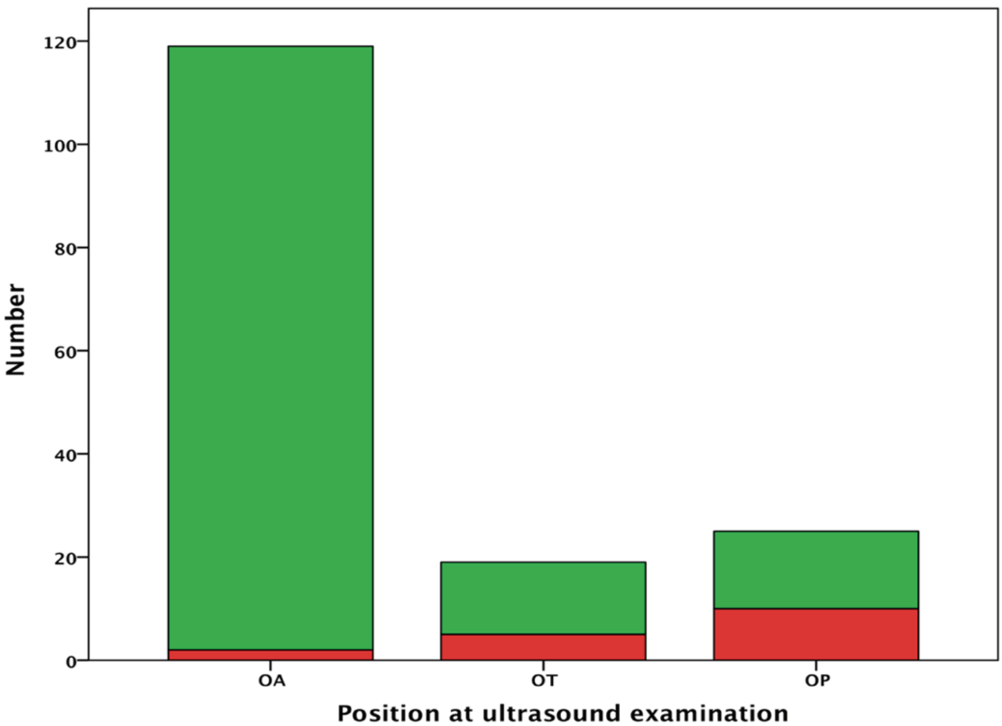

Figure 26. Number of occiput anterior (OA) deliveries at birth (green) and occiput posterior (OP) deliveries (red) at birth stratified into ultrasound assessed fetal head position before vacuum extraction. OT = occiput transverse position.

There was missing information about position at delivery in two women. The duration of vacuum extraction was significantly shorter in fetuses in OA position compared to non-OA position, log rank test <0.01, *figure 27.*

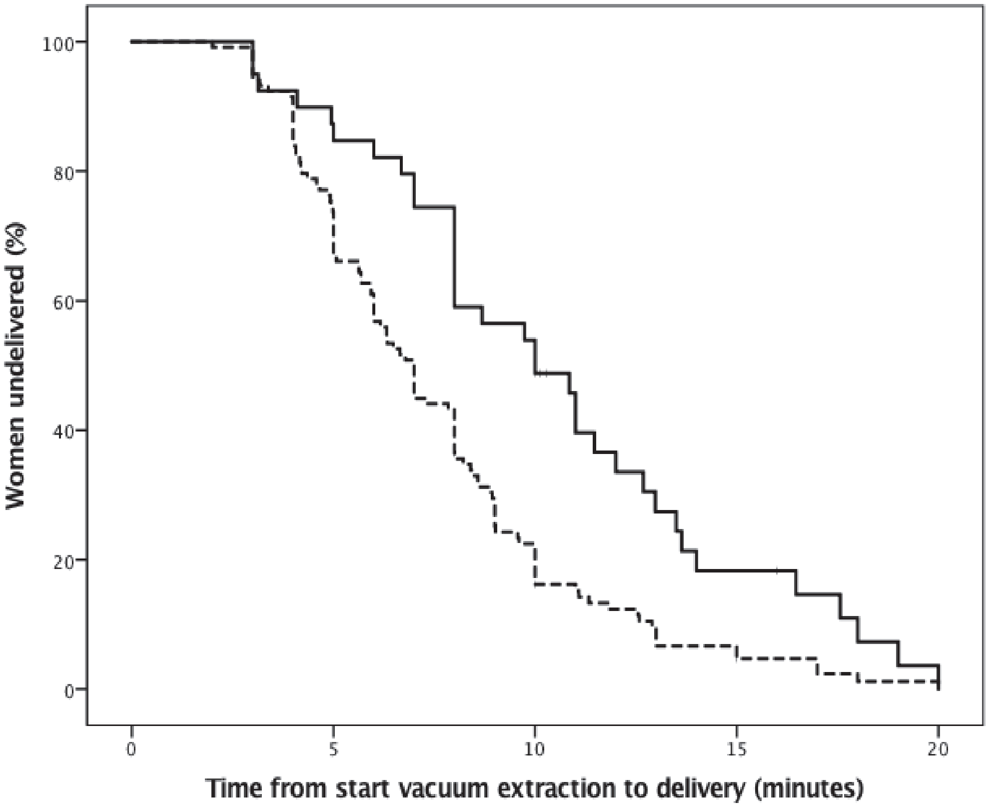

Figure 27. Kaplan Meier plot of time from starting vacuum extraction to delivery differentiated into occiput anterior (OA) (-----) and other (non-OA) positions (——). Log rank test < 0.01. Cesarean section and delivery lasting more than 20 minutes were censored.

The median duration in OA position was seven minutes (95% CI, 6.3-7.7) vs. ten minutes (95% CI 7.8-12.2) in non-OA position. The adjusted HR for vaginal delivery in fetuses starting from a non-OA position analysed with Cox regression analysis was 0.53 (95% CI, 0.36-0.37). Two cases were censored due to vacuum extraction >20 minutes and 14 due to cesarean section. Vacuum extraction was converted to cesarean section or forceps in 6/25 (24%) of fetuses in OP position, in 4/19 (21%) in OT position and 12/121 (10%) in OA position. The conversion rate in the OA group (10%) was significantly different than in the non-OA group (23%), p <0.05. There were no statically significant differences in umbilical artery pH <7.10 between the OA group and the non-OA group, 6 % vs. 5%, *p*=0.76. The clinicians performing the vacuum extractions classified fetal head position with vaginal examination in 139/165 (84%) of women and they agreed with the ultrasound findings in classifying OA position in 87/102 (84%), OT position in 6/15 (40%) and OP position in 12/22 (55%) of cases; Cohen's Kappa 0.42 (95% CI 0.26-0.57). In 70/165 (42%) the clinical examination to determine position was not possible or not agreeing with the ultrasound result. The median duration of time from ultrasound examination to start of delivery was 16 minutes (interquartile range 4-27 minutes).

7.3 Paper three

In this paper we included all women with HPD measured between contraction and during contraction and maximum pushing. The delta HPD was successfully calculated in 204 cases. 46 had a spontaneous delivery, 143 had an operative vaginal delivery, all starting with vacuum extraction, but 7 converted to forceps delivery. 15 were delivered with cesarean section. The population was divided into quartiles according to delta HPD. Duration of vacuum extraction was shorter with increasing delta HPD, and the estimated mean duration of vacuum extraction was 10.0, 9.0, 8.8 and 7.5 minutes in the women with delta HPD in the first to fourth quartile, respectively.
The adjusted HR for vaginal delivery, using delta HPD as a continuous variable was 1.04 (95% CI, 1.01-1.08). Maternal age, pre-pregnancy BMI, use of epidural analgesia, induction of labour and use of acceleration with oxytocin were not confounding factors, *table 4.*

Table 4. The hazard ratio for vaginal delivery after vacuum extraction in nulliparous women with slow progress in the second stage of labour. Hazard ratios with CI intervals not crossing 1.0 were assumed significant.

	Unadjusted HR	95% CI	Adjusted HR	95% CI
Delta HPD	1.04	1.00-1.08	1.04	1.01-1.08
Maternal age	0.99	0.96-1.03	0.99	0.96-1.02
BMI	1.05	1.00-1.09	1.05	1.01-1.10
Epidural	0.69	0.47-1.03	0.76	0.50-1.17
Induction	0.97	0.70-1.36	0.95	0.65-1.14
Acceleration	0.75	0.52-1.09	0.71	0.46-1.08

Mean HPD between contractions was 27 mm (range, 1-49 mm) and mead HPD during contractions was 20 mm (range 0-42 mm), this difference was statistically significant, $p < 0.01$. Mean delta HPD was 7 mm (range, -10 to 37 mm); 185 cases had a positive value, showing positive advancement of the fetal head during active pushing, 13 cases had a negative value and six cases had a delta HPD of 0 mm.

We examined mode of delivery according to the quartile groups. Delta HPD was either negative or ≤2 mm in the lowest quartile. In this group, 7/50 (15%) women were delivered with cesarean section compared with 8/154 (5%) in the other three quartiles, $p < 0.05$*, figure 27.*

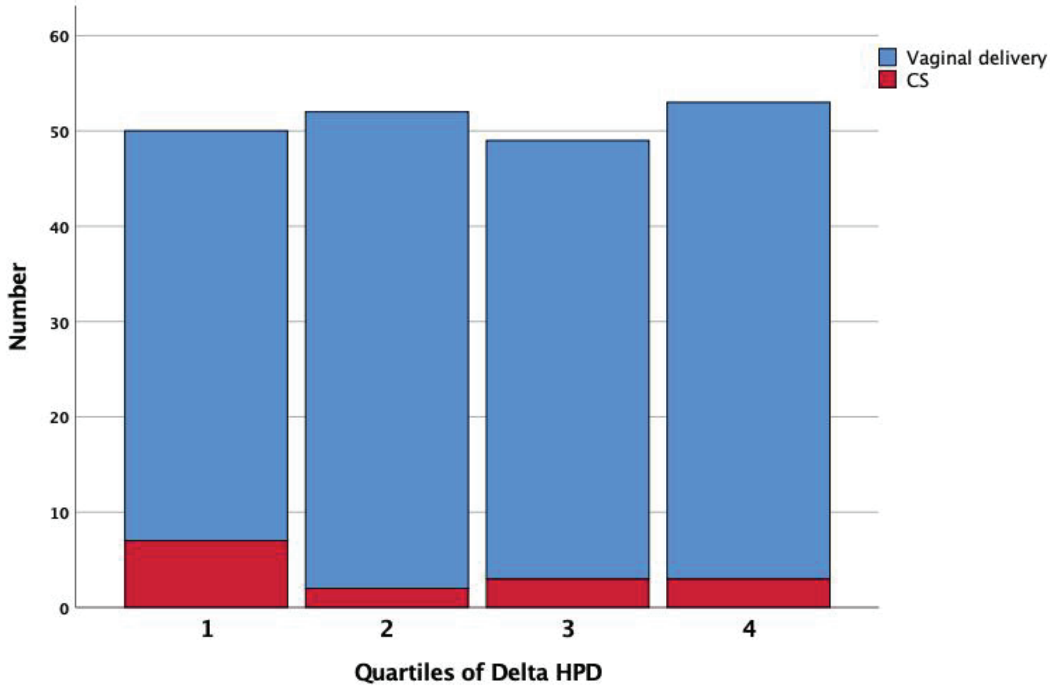

Figure 27. Number of vaginal deliveries and caesarean sections according to the delta-HPD quartiles. Blue: vaginal delivery, red: cesarean section.

There was no association between umbilical artery pH <7.10 or 5 minutes Apgar score <7 and the delta HPD quartile groups. Median duration of vacuum extraction was 8 minutes (range, 2-32 minutes). Median number of contractions during vacuum extraction was 4 (range, 0-14). Whether the vacuum cup detached was recorded in 150 cases; 116 had no detachments, 31 had one or two detachments and in three cases there was three or more detachments. Information about number of contractions during the extraction attempts was available in 12 of 15 women that were delivered by cesarean section. Four of these cases had more than 4 contractions before a decision of cesarean section was made.

8. Discussion

8.1 Main findings

8.1.1 Duration of vacuum extraction

In this study we performed an ultrasound examination on 222 women in the second stage of labour, before vacuum extraction was considered. We found a significant association between ultrasound assessed fetal head station and duration of vacuum extractions.

There is a consensus of current guidance that operative vaginal deliveries should not occur above station 0 or the ischial spines. Ultrasound measured HPD 35 mm corresponds to station 0. The duration of the operative delivery should not exceed 20 minutes[64, 111]. In Sweden they performed a nationwide case-control study involving all the maternity units from 1999 to 2013. All live-borne infants diagnosed with an intracranial haemorrhage after vacuum extraction were included as cases (n=167). For each case there were three vacuum delivered controls without the diagnosis of neonatal intracranial haemorrhage (n=546). In 33% of cases vs. 5% of the controls the duration of vacuum extraction lasted longer than 15 minutes. They concluded that not adhering to the safety recommendations the odds for neonatal intracranial haemorrhage were OR 8.04 (95% CI. 4.49-14.38) after adjusting to possible confounders[112].

In a prospective observational study from California, they investigated 134 vacuum extractions. The duration of vacuum application lasted from 0.5 minutes to 26 minutes. The proportion of fetal complications was less if the duration was less than 10 minutes[113].

In our population we discovered that neonatal outcome differed according to fetal head station assessed with transperineal ultrasound. All women included in the study had a reassuring CTG when they were included, and all operative deliveries were on the indication prolonged second stage. The delivery method was decided by the responsible obstetrician and based on clinical examinations. There was a significant difference in umbilical artery pH <7.10 between the groups that were delivered with HPD >35 mm and the group delivered with HPD ≤35 mm, 20.0% vs. 1.4%. Since most cases of umbilical artery pH <7.10 were delivered with a HPD >35 mm this also stresses the importance of adhering to the safety rule of not performing vacuum extractions above this level.

Additionally, we found that duration of vacuum extraction was significantly longer in fetuses in a non-OA position than in an OA position. When investigating the importance of fetal head movement during contractions, we observed that the longer the delta HPD, the shorter was the duration of vacuum extractions.

8.1.2 Mode of delivery

In our study population comprising 222 women, 47 had a spontaneous delivery, 150 had a vacuum delivery, nine had a forceps delivery and 16 were delivered with cesarean section. 173 had a vacuum attempt and two were delivered with cesarean section without vacuum attempt. Both HPD and AoP predicted the probability of spontaneous delivery, but only HPD predicted the probability of cesarean section. There is an increase in cesarean sections worldwide and if we want to prevent more cesarean sections we need to focus on the prevention of the first one[93]. One way of preventing a second stage cesarean section is by waiting for a spontaneous delivery or to perform an operative vaginal delivery. This has to be done when it is safe and achievable. Ultrasound can be helpful in making this decision. When dividing our study population according to HPD, in the group with HPD ≤35 mm 4% of women were delivered with cesarean section vs. 22% in the group with HPD >35 mm. Studies have shown that clinical assessment of fetal head station and fetal head position are subjective and unreliable, with poor reproducibility[11]. Ultrasound examinations are more precise[13]. We combined ultrasound assessed station and position and found that 35% of women with a HPD >35 mm and a fetal head in a non-OA position ended up with a cesarean section.

Expectant management in the second stage of labour is appropriate if labour is progressing and there is a reassuring CTG. Between 50-80% of fetuses in a malposition will rotate spontaneously[36, 114]. Since there is an increased risk of failed vacuum extractions in an OP position, the clinician should be aware of the higher failure rate. The extraction should follow the cardinal movement. A cesarean section performed after a failed vacuum extraction is associated with adverse fetal and maternal outcome[83, 96], and cesarean section in the second stage of labour is associated with maternal and fetal morbidity and increases risk in the subsequent pregnancy[115]. Since most fetuses do rotate during vacuum extraction, a trail of vacuum extraction may be attempted in OP position if HPD is less than 35 mm.
There are several factors influencing the likelihood of a successful operative vaginal delivery. In a tertiary centre in the United Kingdom they matched the unsuccessful operative vaginal deliveries with the successful operative vaginal deliveries by the same operator. They then compared the unsuccessful with the successful. In their material the failure rate was 6.5%. Birth weight, fetal head malposition and a long second stage had a negative influence on the chance of success. The experience of the operator was of important. The more trained the operator was in operative vaginal deliveries, the less chance of failure when adjusting for the fact that the most senior operators do the most complicated cases[116]. Training in operative vaginal deliveries is important to reduce the second stage cesarean sections.
In another study performed in the United Kingdom 32 women were examined by a specialist registrar in regards to whether performing an operative vaginal delivery or not, and shortly after examined by a consultant. In 44% of cases there was a disagreement of fetal head position and in 88% of cases there was a disagreement on fetal head station. This lead to a different decision and the consultants were more likely to opt for an operative vaginal delivery than the specialist registrar[117].
Digital vaginal examination may be challenging, especially when there is caput succedaneum[12, 14, 118]. Accuracy improves with training and one study documented very good agreement between clinical examinations ultrasound measurements,

however, a specially trained obstetricians did all the clinical examinations in this study[118]. It has also been shown that forceps deliveries are faster than vacuum Transperineal ultrasound has also been used to predict complicated or easy forceps deliveries, in these deliveries both fetal head station and fetal head position is important to know and ultrasound might give the operator that[119]. It has also been shown that forceps deliveries are faster than vacuum extractions and when HPD is >35 mm the failure rate is increased with both instruments[120]
Ultrasound is a helpful tool in decision-making and has potential to improve outcome in women with prolonged second stage. A simple tool to predict a successful vacuum extraction to avoid the failed operative vaginal deliveries ending with cesarean section is a common aim[121-123].

8.1.3 Fetal head position

We observed that most fetuses in a malposition, OP or OT position, assessed with ultrasound before vacuum extraction rotated to OA position during the procedure. The conversion rate from vacuum extraction to forceps delivery or cesarean section was higher in the fetuses with non-OA position than in an OA position. The fetal position can be classified in different ways. We preferred a circle, transformed to a clock face rather than eight equal sectors of 45°[36]. Several studies have compared determination of fetal head position with digital examination or ultrasound. If the fetal head is in an OP position the vaginal examination is found to be incorrect in 50% of cases[14], which is in accordance with our findings. A randomized controlled trail investigating the incidence of incorrect fetal head position before operative vaginal delivery concluded that the ultrasound group had a lower risk of wrong diagnosis than the vaginal examination group, 1.6% vs. 20.2%[13].
In a reproducibility study the interobserver agreement of ultrasound determination of fetal head position was within 15° in 90% of cases, and within 30° of all cases[124]. Determination of fetal head position important before vacuum extraction but may be difficult due to the presence of caput succedaneum and fetal scalp hair which makes

it difficult to identifying the sutures and fontanelles[125]. The vacuum cup should be placed on the flexion point. This point is three cm anterior to the posterior fontanelle or six cm posterior to the anterior fontanelle[64], figure 28.

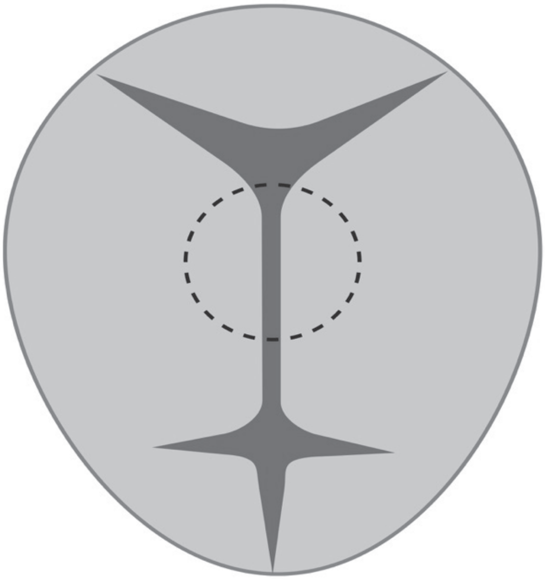

Figure 28. Drawing of the fetal head, with the anterior and posterior fontanelle and the flexion point in front of the posterior fontanelle. Illustration by Morten Dreier.

The cup should not be placed over the fontanelle, thus correct placement of the cup demands accurate knowledge of the fontanels. With incorrect placement of the cup, the risk of cup detachment and harm increases[126]. Since traction should follow the cardinal movement (deflexion in OA position, and flexion first followed by deflexion in OP position), exact knowledge of position is important.

The International Society of Ultrasound in Obstetrics and Gynecology (ISOUG) recommends in their practical guidelines on intrapartum ultrasound to determine fetal head position with ultrasound when labour progress is slow and when operative delivery is considered [20]. Vacuum extraction from an OP position has increased risk of failure with odds ratio of 2.2-2.6 compared with vacuum extraction from an OA position[127, 128].

8.1.4 Movement of the fetal head

When we investigated the change in HPD during active contractions with active pushing, we discovered that this value was negative or 0 mm in 19 women. When we divided the study population in to quartiles according to delta HPD the lowest quartile comprised of the women with negative values and values ≤2 mm. Women with negative or minimal movement of fetal head had a significant increased risk of cesarean section. There are two reasons for this lack of movement, the fetal head is stuck due to cephalopelvic disproportion or inadequate pushing technique with contraction of the levator ani muscle instead of relaxing the pelvic floor when they pushed. This phenomenon is called levator ani muscle coactivation[129].

Movement or descent of the fetal head during pushing may be assessed with intrapartum translabial ultrasound (ITU). This is a scan where the transducer is placed in the mid-sagittal plane below the symphysis. The aim is to visualize the fetal head station, decent and direction during the active phase of the second stage and can be used during active pushing. When doing this scan a line is drawn from the caudal end of the symphysis and is perpendicular to the symphysis, infrapubic line. Then a line indicating the widest part of the fetal head. The head direction is the orientation of the widest part of the fetal head with respect to the infrapubic line. When this line points ventrally at an angle of 30° or more it is considered 'head up'. For lines below 0°, the direction is 'head down', and for the angles in between the direction is 'horizontal'. The decent can also be subjectively be assessed as present yes or no when performing this scan during pushing and to evaluate if the widest part of the fetal head is below the infrapubic line[22]. The head up sign is predictive for successful vacuum extraction on indication prolonged second stage of labour.

In a study of 284 low-risk nulliparous women with a singleton pregnancy the anteroposterior diameter of the levator hiatus was measured with transperineal ultrasound at rest, during maximum pelvic floor contraction and during maximum Valsalva manoeuvre. Levator ani muscle coactivation was defined as a reduction in anteroposterior diameter of the levator hiatus on maximum Valsalva manoeuvre in comparison to rest[129]. The women in the study were recruited before onset of labour. When looking at the association between levator ani muscle coactivation and mode of delivery and duration of labour, they discovered that these women had a longer stage of labour but not more cesarean sections[129]. They also examined this in women undergoing induction of labour and found that women with levator ani muscle coactivation before labour had a longer active second stage of labour but not more operative deliveries[130]. The women in our study were all nulliparous women and 79% had epidural analgesia. They have never been in active labour before and pushing is not always intuitive, especially when they have epidural analgesia. They do not feel the urge to push and might contract their pelvic floor muscles instead of relaxing them. This inadequate pushing technique could be one reason for their prolonged second stage. These women may be helped with ultrasound techniques as visual biofeedback, well known from urogynaecology[131, 132]. This technique is used to learn patients control voluntarily some of the bodily functions. When we do transperineal ultrasound the fetal head is visible on the ultrasound screen. If the women observe the ultrasound screen while she is pushing she can see if the fetal head moves or not and it is possible to coach her. A pilot study has been done with 40 women randomized to sonographic coached pushing with the possibility to see the screen and the other group did the same coaching but could not see the screen. They were enrolled in the active phase of the second stage of labour. The group that could see the screen had a significantly shorter second stage of labour but otherwise there were no differences between the groups[133]. Another study of 26 women in a visual biofeedback group were compared to a control group. They investigated pushing efficacy, perineal tearing, perceived control during childbirth and maternal satisfaction with childbirth and feeling of maternal connectedness with the new born. The pushing efficacy was measured by calculation a delta AoP. This was significantly better in the visual biofeedback group. Mode of delivery did not differ between the groups. The group with the visual biofeedback also had a larger degree of intact perineum and they reported higher levels of maternal connectedness with the new born[134].

8.1.5 Fetal head station

Fetal head station is always determined during digital vaginal examinations of the labouring woman. When Friedman did his graphic analysis of labour he discovered that the fetal head descent happened during the last phase of the first stage of labour[39]. We know that digital examination may be challenging and that clinicians often fail in determining the exact fetal head station[11]. Knowledge about fetal head station is probably the most important factor in predicting if an operative vaginal delivery will be successful or not. In our study HPD and AoP was used to determine fetal head station. The shorter the HPD and the winder the AoP, the shorter the duration of vacuum and the better the chance of a successful vaginal delivery.
Fetal head station in our study, measured as HPD and AoP, influenced all the outcomes. It affected duration of vacuum extraction, mode of delivery and success rate of operative vaginal deliveries. Together with position it was an even stronger indicator.

8.2 Ultrasound methods

8.2.1 Fetal head station

There are several ultrasound methods to evaluate fetal head station. In our study we published the results based on AoP and HPD. The AoP was published by Barbera et al. in 2009[23] and it is the most used ultrasound method determining fetal station. The advantage of this method is that the symphysis is a fixed reference point. In a study of 75 women two different examiners did several measurements of AoP and they found good intra- and inter-observer repeatability, concluding that AoP is consistent and accurate method to use[23]. The problems with AoP is that all the initial studies on the predictive value of AoP were done in fetuses in an occiput anterior position[23, 135]. Not all fetuses are in an OA position, in the beginning of labour only 30% are in an OA position and at the start of the second stage this is increased to 64%[36]. The method should be tested in a population with all positions included. In OP position the third cardinal movement of labour is different with maximal flexion followed by extension. Before flexion begins, the head descends in the birth canal and the AoP increases while HPD remains long[136]. A technical issue regarding AoP is that the line from the lower edge of the symphysis should go along the convexity of the fetal skull. Due to ultrasound physics the ‘dropout’ phenomenon can occur making this part of the skull hard to visualize. ‘Dropout’ occurs when the ultrasound beams are parallel to the object that should be visualised. The whole length of the symphysis should be visualised as horizontal as possible. Sometimes the capsule of the symphysis may be difficult to visualise and to draw an exact line through the symphysis may be challenging.

The HPD method was as published by Eggebø et al. in 2006[21]. The main advantage of HPD is that only one line from the transducer to the fetal skull is used, and the method is therefor easy to perform also for inexperienced ultrasound operators. Since the ultrasound beams reflect the bony edge perpendicular, it gives a clear skull contour. A limitation of the method is that the fetal skull is the only reference point. The soft tissue has to be compressed until a resistance is met against the pubic bones. If the tissue is not compressed firmly, the HPD will be measured incorrectly too long. In the original paper describing the HPD method good intra- and inter-observer repeatability was found[21], this was confirmed in a later study also comparing two- and three dimensional ultrasound [137]. Both these studies were from the same delivery department, Stavanger in Norway, but have been reproduced in study performed in Lund university hospital in Sweden[138]. The soft tissue can easily be compressed also in obese women and the BMI has little influence on HPD measurements if the soft tissue is compressed correctly[139]. HPD has been tested in all fetal positions.

There are other ways to assess fetal head station by performing transperineal ultrasound not used in our study. Dietz et al. published a validation study in 2005 presenting two methods to evaluate fetal head engagement. They were both sagittal scans. For method A, a line was drawn from the inferioposterior margin of the symphysis, parallel to the main transducer axis and the minimal distance from this line to the presenting part was measured in millimetres. The other method, method B, a line was placed at a 90° angle form the central axis of the symphysis, trough the posterior symphysis margin. Head engagement was then measured as the minimum distance between the fetal head and this line. Vaginal assessment of fetal station was in both methods significantly associated[140].

Head progression distance is the same measurement as method A, described by Dietz. The fetal head is related to infrapubic line, which is drawn from the posterior part of the symphysis perpendicular to a line through the symphysis. Head progression distance has shown to have a good correlation to fetal head station in prolonged second stage of labour. Head progression distance is correlated with AoP and AoP is easier to perform. This correlation was best at higher stations and at lower stations AoP This correlation is best at higher stations and at lower stations AoP should be preferred[141].

Head direction was suggested by Henrich et al. in 2006 and was defined as the direction of a line perpendicular to the widest diameter of the fetal head examined with a sagittal transperineal scan. Lack of descent below the infrapubic line with horizontal or downwards head direction were poor prognostic signs for a successful vacuum extraction[22].

According to the World Health Organizations definition, the ischial spines are at mid-pelvis; station 0. The ischial spines cannot be visualized by ultrasound. In 2006 Henrich et al. suggested an objective method of defining the plan which corresponded with the ischial spines[22]. Tutschek et al. called this the Intrapartum Translabial ultrasound (IUT) head station[30]. They also showed a strong linear correlation between ITU and AoP.

A conversion table comparing IUT head station, AoP and HPD is published[31]. ITU station is more complicated than other methods, and therefore not the preferred method to use online in the labour ward.

Maticot-Babtista et al. published in 2009 a method, similar to HPD, called perineum-fetal head distance. They defined high cavity as 50 mm, mid cavity as 38 mm and low cavity as 20 mm[142].

In 2013 Youssef et al. published a new transperineal ultrasound method called the fetal head-symphysis distance (HSD)[29]. This measurement showed high intra- and inter-observer repeatability. HSD also showed a significant negative correlation with both fetal head station with digital examination and AoP. They therefore concluded that HSD was a simple and reliable method to evaluate fetal head station[29]. In the study they only included OA position and HSD cannot be used if the fetal head is above the infrapubic line, which corresponds to stations -3.

A method called the perineum-to-skull distance is similar to HPD, but without the compressing of the soft tissue. A study of 659 patients were perineum-to-skull distance was measured before operative vaginal delivery concluded with that a perineum-to-skull distance ≥40 mm correlated with difficult operative vaginal deliveries[143].

There are several methods to evaluate fetal head station with transperineal ultrasound. In our study we present the results based on two of them, AoP and HPD. When we performed our study, the measurements were done online in the delivery room, both between and during contraction with active pushing. We started with the transabdominal scan and then continued to the transperineal scan and performed both sagittal and transverse transperineal scanning. In a clinical setting with a woman in labour having contraction the ultrasound examination should be fast. Thus, we could not include all published methods, and we only one performed one measurement of HPD and AoP. Our women all had prolonged second stage and a vacuum extraction was considered when the ultrasound was performed, and we did not want to interfere with clinical management of the woman. We performed AoP and HPD because they are simple methods with documented good repeatability and they are widely used. They have been used in similar studies, investigating prolonged first stage of labour[121, 139].

8.2.2 Fetal head position

The fetal head position can be determined with transabdominal and transperineal ultrasound. At high stations the transabdominal approach should be preferred, but at low stations a transperineal approach is better.

When performing a transabdominal scan, the examination should first start with an overview examining the fetal lie, the fetal heartbeat, look at the amniotic fluid amount, the position and presentation. This can be done by making a sweep over the abdomen, performed in an 'upside down U' movement, starting in the lower left quadrant. The fetal head position can be determined more precisely by performing both a transverse and a sagittal scan over the symphysis. The position is determined by identifying certain landmarks like the fetal orbits, cerebral midline echo, cerebral peduncles, cerebellum, choroid plexus and the fetal spine[36, 144, 145].

With the transperineal approach the cerebral midline echo can be identified and the occiput can be easiest determined by observing the cerebellum or the choroid plexus, they diverge towards the occiput. Fetal moulding can also be helpful. In OP position the moulding will be between the parietal bones and therefore in the midline, however, in OA positions the moulding seen will be between the occipital and parietal bones, and not be in the midline, *figure 29*.

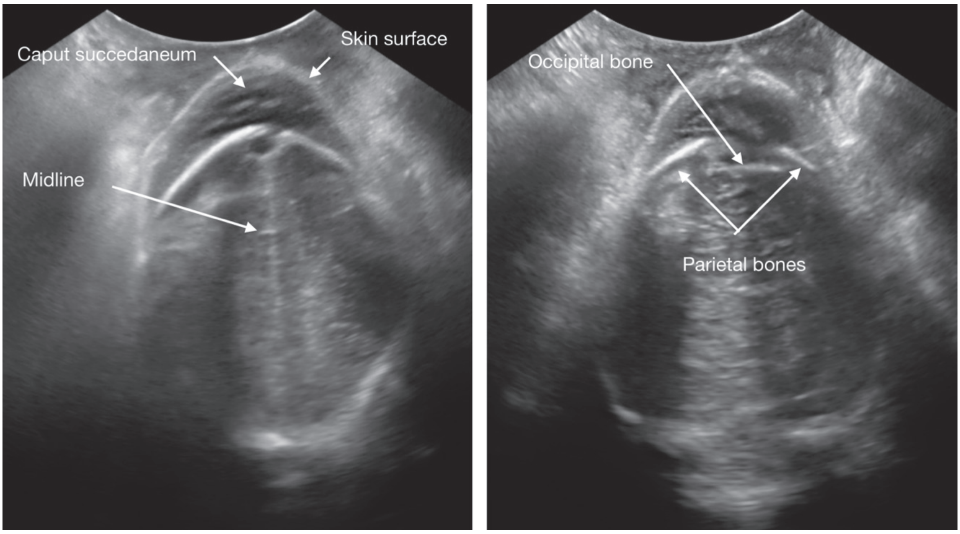

Figure 29. Transverse transperineal scan illustrating, the midline, caput succedaneum, skin surface and the molding where the occipital bone is under the two parietal bones.

In our study we determined the position of the occiput by using a circle, transformed to a clock face rather than eight equal sectors of 45°. A clock face is familiar to everyone and it is easier to relate to that than sectors of 45°. Different methods have been suggested, occipitioposterior or occipitioanterior[146], 8 sectors[15], a clock face with 12 units, 24 units[36, 53, 147]. Our conclusion was that a clock face divided into 12 parts was the most appropriate way to classify position.

8.2.3 Ultrasound vs. digital vaginal examination

Traditionally, fetal head station and position has been evaluated by using digital vaginal examination. In our study the clinicians were not able to determine position in 16% of cases, we found that the digital vaginal agreed with the ultrasound examination regarding fetal head position in 76% of cases. The agreement was better in OA position, 84%, than in OT and OP position, 40% and 55% respectively. Guidelines recommend not to perform a vacuum extraction at station 0 or higher. Station 0 corresponded with HPD 35 mm, and in figure 25 there are several vacuum extractions performed and attempted at HPD higher than 35 mm. This might be due to underestimating fetal head station.

Regarding fetal head station Dupuis et al. in 2005 published a study involving a birth simulator to determine fetal head station. 32 residents and 25 attending physicians were tested. They were presented with 11 possible stations randomly, between -5 to +5. 50-88% of the residents were wrong in determining station depending on position and for the attending physicians the numbers were 36-80%. They were also asked to group the fetal head station according to the four groups; 'high', 'mid', 'low' and 'outlet'. There was still more than 30% error. Group error is potentially dangerous, when a 'high' station is diagnosed as a 'mid' station and an operative vaginal delivery is performed. But also the other way around, when a fetal head is diagnosed as 'high' station when it is 'mid' station or 'low' station and a cesarean section is performed instead of an operative vaginal delivery[11].

Position is also often misdiagnosed. Sherer et al. investigated diagnosis of position with vaginal digital examination vs. ultrasound both in the active first stage of labour and in the second stage of labour. In the first stage of labour 102 patients were examined both with digital vaginal examination and ultrasound, and in 24% of cases there was consistency between the examinations. There was no difference between senior residence or attending physicians[148]. During the second stage of labour 112 patients were examined in the same way and in 65% of cases the result differed between digital vaginal examination and ultrasound. The authors concluded that the accuracy of the examination was increased when ultrasound was performed.

The art of digital vaginal examination is possible to improve. A study including 100 women in labour showed that there was complete agreement on position in 52% of cases and agreement within one unit in 95% of cases and within two units in 98% of cases. A clock face was used to determine position and one unit corresponded with one hour. All the examinations were performed by a trained obstetrician and the ultrasound pictured were examined by a blinded expert in intrapartum ultrasound. When examining fetal head station the clinical examination determined fetal head station from -5 to +5 and the AoP and HPD was determined with ultrasound. The examinations and blinding were the same as for position. The agreement between clinical examination was good for both HPD, Pearson correlation coefficient r=86, and AoP r= 0.77. There was also a good correlation between HPD and AoP, r=0.76. The clinical examination in this study was performed by a trained obstetrician in a structured manner including an abdominal examination and a vaginal examination identifying all the different landmarks to secure the diagnosis. This shows that clinical examination must be trained and structured[118].

8.3 Ultrasound during labour in low resource countries

The implications of the results of research on labour outcome prediction by ultrasound are different in high resource countries vs. low resource countries. The rates of operative deliveries are low. We want to reassure clinicians that vacuum extractions at low stations are safe, and avoiding complications is an important issue in low resource countries. Complications of prolonged and obstructed labour causes 4-13% of maternal deaths in Africa, Asia, Latin America and the Caribbean[149-151]. The rates of cesarean section are increasing. In the WHO statement, published in 2015, they state that cesarean sections are effective in saving maternal and infant lives, but only when they are performed on a medical indication. At a population level, cesarean section rates higher than 10% are not associated with reduction of maternal and neonatal mortality rates[152]. In contrast to the increasing cesarean section rates worldwide, there is a decrease in operative vaginal deliveries in low resource countries. Less than 1% operative deliveries in Sub Saharan Africa[67]. The main causes for not performing operative vaginal deliveries have been found to be; equipment related, staff were not trained or policy issues[153]. Ultrasound might be helpful in changing the attitude towards operative vaginal deliveries and can be used in training of the clinicians. One reason for not preforming operative vaginal delivery is that the clinicians are uncertain of their skills regarding digital vaginal delivery. Ultrasound examinations might reassure clinicians to perform vacuum extractions at low levels.

The ultrasound techniques described in this thesis are all methods which can be used with very basic ultrasound devises. To determine position with a transabdominal scan you need a machine with basic 2D image. To measure HPD you need a machine that can measure one distance and for AoP measurements an angle must be calculated. The methods are also easy to learn for non-experienced examiners.

In a teaching hospital in Ghana a prospective cross-sectional study was performed in 2016. They wanted to investigate if transperineal ultrasound could determine if the fetal head was engaged or not. 201 women were included, and the concluded that the fetal head was at station 0 or the ischial spines if the HPD was 36mm and AoP 101°[154]. This is corresponding with other studies.

Operative vaginal deliveries is a key element in essential obstetric care, and improving maternal and neonatal outcomes will require the scaling up of the use of operative vaginal deliveries with provision of equipment and training operators in areas where they currently are unavailable[67].

In Mulago Hospital in Kampala, Uganda, they did an intervention to increase the use of operative vaginal deliveries and have published an audit covering 18 months after starting the intervention. This is a national referral hospital in Uganda, with approximately 33 000 deliveries per year. They had systematic training of medical staff, both theoretical and practical. They used Kiwi Omnicup™ vacuum extractors, which were donated form a European hospital, and they sterilized them for repeated use. They analysed maternal and neonatal outcome before and after the intervention. The rate of vacuum extractions increased from 0.6-2.6% of deliveries and they declined the rate of intrapartum stillbirth from 34-26 per 1000 births and the rate of uterine ruptures from 1.1-0.8 per 100 births. These were all statistically significant changes. The decision to deliver interval was four hours shorter for vacuum extraction than cesarean section. Maternal deaths due to intrapartum complications was reduced with 11%, and was not statistically significant but has a high clinical significance [155]. This is a very good example of how important it is that the clinicians can perform vacuum extractions.

A perinatal audit from the Maweni Regional Hospital in Kigoma, Tanzania, publishes an audit of all the perinatal deaths over a two-year period. 18.5% of all deaths were related to obstructed labour and this was the second most frequent case after birth asphyxia. Of the perinatal and early neonatal deaths that occurred due to delay in hospital 16% were due to cesarean section being performed when vacuum extraction could be preferred. 13% were cesarean sections performed on a dead fetus and two maternal deaths occurred after cesarean section for obstructed labour on a dead fetus with a fully dilated cervix.[156]

A very important use of ultrasound in the labour ward in low resource countries is to determine if the fetus is alive or not. Performing a cesarean section on a dead fetus usually gives no medical benefit, just a risk of complications. Cesarean section on dead fetuses should only be done in cases with uterine rupture, placenta previa or transverse lie. Ultrasound is a helpful diagnostic tool also for these diagnoses.

While operative vaginal deliveries have decreased in low resource countries the rate of cesarean section has increased. In a study investigating all deliveries at Muhimbili National Hospital, Dar es Salaam, Tanzania, during a 12-year period, the total cesarean section rate increased from 19 to 49%. The only two patients' groups benefitting from the increased rate of cesarean sections were women with twin pregnancies and women with a fetus in breech presentation. In these groups there was a decrease in perinatal mortality. Overall there was a significant increase in maternal mortality and a moderate increase in the perinatal mortality[157]. This trend has been seen in many other low and mid resource countries[158].

Large variations in the frequencies of operative deliveries are not only seen between countries, but large variations are also seen within countries. Especially, in private sectors, the caesarean section rates are much higher than medically indicated. Cesarean sections is considered as a status symbol among rich women, and the poor do not get the interventions needed for them[159].

The next issue is what happens in the subsequent pregnancy? It has been stated that vaginal birth after a cesarean section in a low resource country is associated with high risk for maternal morbidity and morbidity that a repeated cesarean section is to prefer[160]. However, many women have no guaranty that a repeated cesarean section will be available, and delivery in the village next time may end with a life-threatening complication. Thus, it is even more important to avoid the first cesarean section in low resource countries, and by teaching safe operative vaginal deliveries and by using ultrasound to objectify the clinical findings it is possible to reassure the clinicians to make the right decisions.

A feared complication after a cesarean section are placenta accreta spectrum disorders. The incidence is rapidly increasing in middle and low resource countries because of their increase in cesarean sections. The diagnostic options and treatment options which are present in high resource countries are usually not present in middle and low resources countries. A basic routine second trimester scan to evaluate the placenta location if often even not offered. To be able to help these women in the future, we need to know how large the problem is, and teach the healthcare provider how to recognise and to treat the problem when it occurs. National programs and awareness campaigns to avoid the first cesarean section is also necessary to reduce the incidence of placenta accreta spectrum disorders[161].

An ecological study investigating cesarean section rates and maternal and neonatal mortality in low-, medium-, and high-income countries, showed a significant negative correlation between cesarean section rates and maternal and neonatal mortality in low-income countries. This was not observed in medium- and high-income countries[158]. Another study investigating emergency peripartum hysterectomy stated that in low income countries 36% were due to uterine atony and in many cases a consequence of prolonged labour. The maternal mortality after peripartum hysterectomy were higher than in high-income countries[162]. If there was knowledge how to perform operative vaginal deliveries for prolonged second stage, some of these atonic uteri could be avoided[163].

8.4 Strength and limitations

Strengths of this study are the multicentre design, inclusion of only nulliparous women with prolonged second stage of labour, and that the ultrasound examiners and the birth attendant were blinded to each other's findings. The study was conducted in seven delivery departments in five European countries, which increases the external validity of results. Basic ultrasound devices were used, and both midwives and obstetricians performed examinations. Fetal position was routinely examined transabdominally in accordance with recommended principles, and the two most used transperineal methods examining station was used. When possible, measurements were done both between contractions and on maximum contractions with pushing.

Limitations of the study were that some centres had few inclusions and that different vacuum devices were used. All the centres included were university hospitals in a high-resource setting, which reduces the universal generalizability.

The study period was long, from November 2013 through July 2016, with relatively few inclusions per month. The main reason for this was the blinding of the study. The ultrasound examiners had to be present at the delivery unit, but not be on call and involved in clinical care. The integrity of the study relied on the ultrasound examiners not biasing the clinical decision.

Measurements of AoP failed in 18% of the cases when measuring between contractions and in rest and in 48% of cases during pushing. Therefore, we did not calculate a delta AoP for fetal head movement during pushing. Some of the examiners had limited ultrasound experience and too little training for AoP measurements. Especially during pushing, some examiners found AoP measurements challenging and failed to measure both HPD and AoP during the same contraction. Head descent during active pushing were not examined clinically, thus; clinical and ultrasound findings could not be compared in paper three.

In the study women could be included after at least 45 minutes of active pushing. In the Norwegian guidelines operative vaginal delivery is recommended after one hour of active pushing[43]. This period differs from recommendations in other countries and might affect the external validity of the study since the majority of the participants were Norwegian women.

The final decision on delivery method was based on the responsible physician on call, and this was difficult to standardize. This was an observational study, and local guidelines were followed.

In paper two the rotation of the fetal head during vacuum extraction was examined, and it is a limitation that we cannot know if rotation occurred during the procedure or between the ultrasound examination and start of vacuum extraction. However, this seem unlikely since all women were included because of slow progress in the second stage of labour and the median duration ultrasound to instrumental delivery interval was 16 minutes. It was not always possible to determine position with ultrasound before vacuum extraction. When the fetal head is at a low station or in an OT position it can be difficult to see the intracranial structures necessary to determine position with transabdominal ultrasound. Fetal position at low stations can be examined as midline angle at low stations[32], but this was not routinely done in this study. In borderline cases between two positions, for example with an fetal occiput at 2.00 or at 2.30, it can be difficult to classify correctly as an OA or an OT position. Therefore, neither clinical examination nor ultrasound can be considered as a gold standard. However, it is documented that ultrasound is a more precise method than clinical examnation[13, 14]. Regarding fetal head position, another limitation is that we did not record the position of the fetal spine at the level of the four-chamber view. Rotation is more likely from an OP position to an OA position when the fetal spine is in an oblique position in relation to the fetal head[147].

Umbilical artery pH was analysed in 83% of cases as it was not measured routinely in all centres.

We did not record who performed the ultrasound examinations, neither doctors or midwives, since all ultrasound examiners were trained before they could include patients. In our opinion the profession does not matter, as long all measurements are performed correctly.

9. Conclusion

This thesis demonstrated that examinations with ultrasound were feasible during the second stage of labour, 100% successful measurements of HPD and 82% successful measurements of AoP between contractions. Position was successfully assessed with ultrasound in 95% of cases.

We reject our first null-hypotheses because ultrasound examinations predicted outcome of operative vaginal deliveries, both duration and mode of delivery. Position was determined with ultrasound in 96% of cases and with digital vaginal examination in 84%. We have not compared the predictive value of ultrasound examinations and clinical assessments of position and station; thus, we cannot reject the second null-hypothesis.
Minimal or no descent of the fetal head was associated with longer duration of operative vaginal deliveries and cesarean section resulting in the rejection of the third null-hypotheses.

In the first paper, we aimed to investigate if ultrasound measurements of fetal head position and station could predict duration of vacuum extraction, mode of delivery and fetal outcome. We found that ultrasound measurements predicted both duration of operative vaginal deliveries and the likelihood of cesarean section. We also found an association between HPD and neonatal outcome measured as umbilical artery pH despite all vacuum extractions were performed due to prolonged second stage of labour and CTG was reassuring at time of inclusion.
In the second paper we aimed to study fetal head rotation during vacuum extraction Most fetuses rotated from non-OA position to OA position during the procedure. The duration of vacuum extraction from a non-OA position was longer than from an OA position. The failure rate of operative vaginal deliveries was higher when the fetus was in a non-OA position than in an OA position.

In the third paper the aim was to investigate if movement of the fetal head during active pushing was associated with duration of operative delivery, mode of delivery and neonatal outcome. We found that minimal or no fetal head descent, measured as delta HPD, during pushing was associated with longer duration of operative vaginal deliveries and higher frequency of cesarean section. We did not find associations with neonatal outcome.

The main conclusions from this thesis are that ultrasound measurements done shortly before vacuum extractions were associated with duration of the operative delivery, mode of delivery and that fetal station also was associated with pH in the umbilical artery. Ultrasound examinations have a potential to reassure clinicians when it is safe to perform a vacuum extraction.

10. Future perspectives

In 2002 Ugwumadu wrote an Opinion in Ultrasound in Obstetrics and Gynecology about the use of ultrasound in the labour room. He concluded that: *'the clinical application of ultrasound scanning in the labor ward is broadening. Some of the newer indications require further studies to validate its use'*[9]. Since 2002 several studies on this subject have been conducted, some may claim that ultrasound in labour has not been proved to be beneficiary since no randomised controlled trails have been conducted. Adverse maternal and neonatal outcome are fortunately rare, and to be able to detect a reduction in either of these would demand a huge number of included women. Some have tried, but not succeeded, and other studies have been under-powered. If a randomised controlled trail would be conducted it would have to be a large multicentre study. Several observational studies have been performed and show that ultrasound during labour is useful.

There are many ultrasound methods used in the labour ward, indicating that we might not have found the perfect one yet. How should the perfect ultrasound method be? Easy to learn, easy to use, useful in all fetal head stations and in all fetal head positions and acceptable for the woman comes in mind. The methods to determine fetal head station are mostly transperineal scans. A recent letter to the editor of AOGS[164], suggests a method to determine fetal head station by using transabdominal ultrasound. This might be the way forward. If we had a reliable and easy method to determine fetal head station with transabdominal ultrasound we might be able to determine fetal head station and position in one examination. Clinicians might be more comfortable to do a transabdominal examination instead of a transperineal examination, since the transabdominal approach is a more familiar one.

On the other hand we have easy and reliable transperineal methods that are acceptable for the woman. Instead of spending more time on develop new methods we might spend our time on teaching the methods we have. Not only to doctors, midwifes are the ones that spend most of their time with the labouring woman. In obstetrical ultrasound in general midwifes have successfully been trained to perform a variety of ultrasound examination.

In low resource countries we might have the most to gain by introducing ultrasound in labour. If we could increase the number of safe operative vaginal deliveries by reassuring clinicians and reduce late second stage cesarean sections there might be a reduction in future maternal complications.

An operative vaginal delivery is a skill that should be continuously trained. Otherwise, these important skills will disappear. The number of operative vaginal deliveries are declining due to an increase in cesarean sections. The most important issue is not to reduce the cesarean section rate, but to undertake the appropriate intervention at the right time. This might be done by reassuring clinicians that a low level operative vaginal delivery might be a safer option than a cesarean section.
Ultrasound might add more and new knowledge about the labour process and this knowledge and more education may be the most important future perspective for improving quality in obstetrical care.

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Papers I-III

Paper one

OBSTETRICS

Sonographic prediction of outcome of vacuum deliveries: a multicenter, prospective cohort study

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BACKGROUND: Safe management of the second stage of labor is of great importance. Unnecessary interventions should be avoided and correct timing of interventions should be focused. Ultrasound assessment of fetal position and station has a potential to improve the precision in diagnosing and managing prolonged or arrested labors. The decision to perform vacuum delivery is traditionally based on subjective assessment by digital vaginal examination and clinical expertise and there is currently no method of objectively quantifying the likelihood of successful delivery. Prolonged attempts at vacuum delivery are associated with neonatal morbidity and maternal trauma, especially so if the procedure is unsuccessful and a cesarean is performed.

OBJECTIVE: The aim of the study was to assess if ultrasound measurements of fetal position and station can predict duration of vacuum extractions, mode of delivery, and fetal outcome in nulliparous women with prolonged second stage of labor.

STUDY DESIGN: We performed a prospective cohort study in nulliparous women at term with prolonged second stage of labor in 7 European maternity units from 2013 through 2016. Fetal head position and station were determined using transabdominal and transperineal ultrasound, respectively. Our preliminary clinical experience assessing head-perineum distance prior to vacuum delivery suggested that we should set 25 mm for the power calculation, a level corresponding roughly to +2 below the ischial spines. The main outcome was duration of vacuum extraction in relation to ultrasound measured head-perineum distance with a predefined cut-off of 25 mm, and 220 women were needed to discriminate between groups using a hazard ratio of 1.5 with 80% power and alpha 5%. Secondary outcomes were delivery mode and umbilical artery cord blood samples after birth. The time interval was evaluated using survival analyses, and the outcomes of delivery were evaluated using receiver operating characteristic curves and descriptive statistics. Results were analyzed according to intention to treat.

RESULTS: The study population comprised 222 women. The duration of vacuum extraction was shorter in women with head-perineum distance ≤25 mm (log rank test <0.01). The estimated median duration in women with head-perineum distance ≤25 mm was 6.0 (95% confidence interval, 5.2–6.8) minutes vs 8.0 (95% confidence interval, 7.1–8.9) minutes in women with head-perineum distance >25 mm. The head-perineum distance was associated with spontaneous delivery with area under the curve 83% (95% confidence interval, 77–89%) and associated with cesarean with area under the curve 83% (95% confidence interval, 74–92%). In women with head-perineum distance ≤35 mm, 7/181 (3.9%) were delivered by cesarean vs 9/41 (22.0%) in women with head-perineum distance >35 mm (P <.01). Ultrasound-assessed position was occiput anterior in 73%. Only 3/138 (2.2%) fetuses in occiput anterior position and head-perineum distance ≤35 mm vs 6/17 (35.3%) with nonocciput anterior position and head-perineum distance >35 mm were delivered by cesarean. Umbilical cord arterial pH <7.10 occurred in 2/144 (1.4%) women with head-perineum distance ≤35 mm compared to 8/40 (20.0%) with head-perineum distance >35 mm (P < .01).

CONCLUSION: Ultrasound has the potential to predict labor outcome in women with prolonged second stage of labor. The information obtained could guide whether vacuum delivery should be attempted or if cesarean is preferable, whether senior staff should be in attendance, and if the vacuum attempt should be performed in the operating theater.

Key words: cesarean delivery, labor, sonography, transabdominal ultrasound, transperineal ultrasound, umbilical artery blood samples, vacuum extraction

Introduction

The tension between optimizing neonatal outcome while promoting vaginal delivery is nowhere more pertinent than in the management of the second stage of labor. Prolonging the upper limit of what is acceptable for duration of the second stage of labor is found to reduce the frequency of cesarean delivery in nulliparous women.[1] While a higher likelihood of vaginal delivery represents a beneficial maternal outcome, this may not be without risk for the fetus and hence led to concerns from obstetricians.[2] Furthermore, equating vaginal delivery with optimal outcome is simplistic, as complicated vaginal deliveries are associated to damage to the pelvic floor and anal sphincter ruptures.[3,4] No choice is risk neutral and cesarean deliveries at low fetal head station are also associated with risk of maternal and fetal complications.[5-7] So, the goal of obstetric care in the second stage of labor must be to avoid cesarean deliveries where assisted or spontaneous vaginal delivery is likely to be safe and achievable. Unnecessary cesarean delivery has a cumulative effect as it is widely accepted that prevention of the primary cesarean delivery will have an important influence on subsequent deliveries.[8] Sonography has the potential to be helpful in deciscion-making.[9]

There are 130 million births worldwide every year, and 3-14% are operative vaginal deliveries with highest rates in high-resource countries.[10,11] Failed

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Click Video under article title in Contents at **ajog.org** operative deliveries are reported to occur in 6.5% of vacuum extractions.[12] The determinants to achieve successful delivery and avoid fetal and maternal complications rely on both accurate assessments of fetal position and station, and on operator skill.[12] A consensus of current guidance is that operative vaginal delivery is not recommended above station 0 in relation to the ischial spines and that the duration of an operative vaginal delivery should not exceed 20 minutes.[13,14] Obstetrics, however, remains a largely subjective art. In clinical obstetrics the fetal head is considered engaged in the mother's pelvis when the leading part has reached the level of maternal ischial spine (station 0) based on digital examination.[15] Such clinical assessment is subjective, poorly reproducible, and unreliable.[16]

Fetal head position is more precisely examined with ultrasound than with clinical examinations.[17,18] In a transabdominal scan the fetal head is considered engaged when the biparietal diameter is below the maternal pelvic inlet.[19] Using transperineal ultrasound, fetal station can be assessed as head-perineum distance[20-22] or angle of progression.[23] The ischial spines cannot be seen on ultrasound, but station 0 was found to broadly correspond with head-perineum distance around 35 mm and angle of progression around 120 degrees.[24,25]

Prolonged attempts at vaginal delivery and failed operative vaginal deliveries are associated with increased risk of fetal and maternal complications.[26,27] Hence, greater diagnostic precision of fetal position,[18] descent,[28] and attitude[29] is warranted, and the recently described techniques of intrapartum ultrasound have the potential to improve accuracy of assessments[30] and to predict delivery mode.[31] The aim of this study was to assess if ultrasound measurements of fetal position and station can predict duration of vacuum extractions, mode of delivery, and fetal outcome in nulliparous women with prolonged second stage of labor.

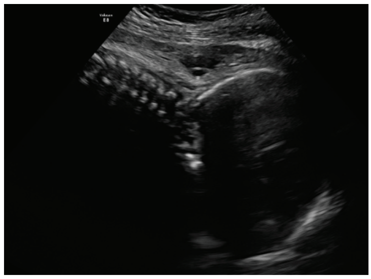
Materials and Methods

We conducted a prospective cohort study in nulliparous women with prolonged second stage of labor. Eligible for inclusion were those with a live singleton fetus in cephalic presentation and gestational age ≥37 weeks and <42 weeks. The second stage of labor was differentiated into a passive phase (<2 hours) and an active phase with pushing. Women were included and examined with ultrasound when the birth attendant diagnosed prolonged second stage of labor after at least 45 minutes of active pushing and vacuum extraction was considered. Repeated ultrasound examinations were not performed. Women were not eligible when fetal compromise was suspected due to abnormal or nonreassuring cardiotocography.

From November 2013 through July 2016, 223 women were recruited at Stavanger University Hospital, Norway (n = 135); University Hospital of Bologna, Italy (n = 34); Trondheim University Hospital, Norway (n = 16); Queen Charlotte's and Chelsea Hospital, Imperial College Healthcare National Health Service Trust, London, United Kingdom (n = 14); Lund University Hospital, Sweden (n = 9); Hvidovre University Hospital, Copenhagen, Denmark (n = 9); and University Hospital of Parma, Italy (n = 6). All participating centers had experience in transperineal scanning, and the ultrasound examiners were trained before the start of the study. The ethics committees approved the study with reference numbers Regional Ethics Committee 2012/1865 in Norway; 3348/2013 in Italy; Research Ethics Committee 15/LO/1341, ID project identification 169478 in the United Kingdom; Diarie Number 2012/808 in Sweden; and H-4-2014-038 in Denmark. All women gave informed written consent and the study was registered in Clinical Trials with identifier NCT01878591.

First a transabdominal scan was performed. Fetal head position was defined using a transabdominal or transperineal scan and categorized into occiput anterior (OA) position (Figure 1 and video clip 1) or non-OA position (posterior or transverse position) (Figures 2 and 3 and video clips 2 to 4). The position was described as a clock face with 12 hourly divisions; positions ≥10 o'clock and ≤2 o'clock were classified as OA.[32] Fetal station was assessed from the

FIGURE 1
Fetus in occiput anterior position



Sagittal transabdominal image with transducer in midline and occiput at 12 o clock.

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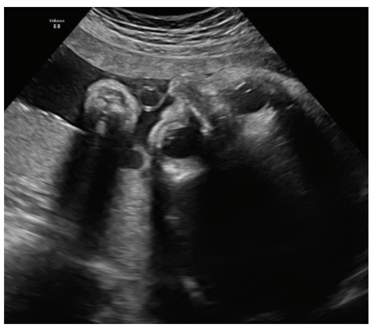
transperineal scan. The woman was placed in a semirecumbent position with the legs flexed at the hips and knees at 45-degree and 90-degree angles, respectively, and a transperineal scan performed after ensuring the bladder was empty (Figure 4). Angle of progression was measured in the sagittal plane as the angle between the longitudinal axis of the pubic bone and a line joining the lowest edge of the pubis to the lowest convexity of the fetal skull (Figure 5 and video clip 5).[23] Head-perineum distance was measured in a transverse transperineal scan (in the axial plane) as the shortest distance from the outer bony limit of the

FIGURE 2
Fetus in occiput posterior position



Transverse transabdominal image with fetal nose at 10 o clock and occiput at 4 o clock.

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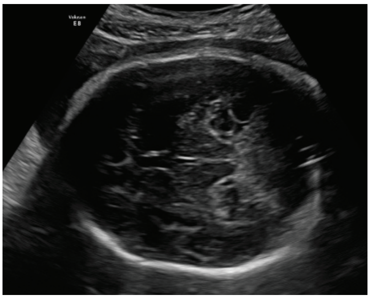
FIGURE 3
Fetus in left occiput transverse position



Transverse transabdominal image with occiput at 3 o clock.

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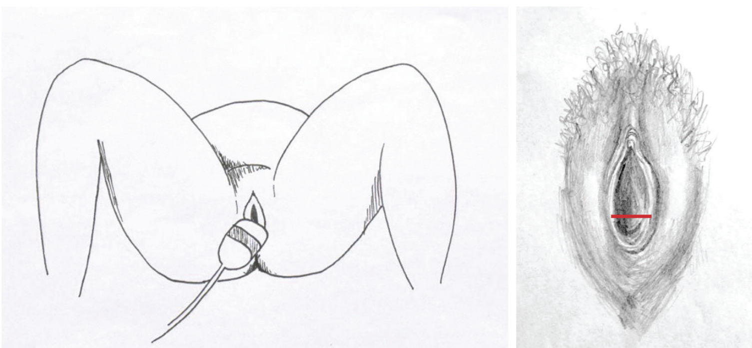
fetal skull to perineum (Figure 6 and video clips 6 and 7). The transducer was placed between the labia majora (in the posterior fourchette), and the soft tissue compressed with firm pressure against the pubic bone without creating discomfort for the woman.[20,22,33,34] The transducer was angled until the skull contour was as clear as possible, indicating that the ultrasound beam was perpendicular to the fetal skull. A cineloop was stored and used to identify the shortest distance possible between the transducer (perineum) and the fetal skull. This distance represents the remaining part of the birth canal for the fetus to pass. The transperineal measurements were done between contractions, and all ultrasound measurements were done online 2-dimensionally in the labor room. Neither the women nor the birth attendant were informed about the ultrasound results. The ultrasound operator was not involved in clinical decisions or management of labor. Both obstetricians and midwives performed ultrasound examinations.

The ultrasound devices used were GE Voluson i (GE Medical Systems, Zipf, Austria) or GE Voluson S6 in Stavanger (GE Medical Systems), Norway, and GE Voluson i in Trondheim, Norway; Lund, Sweden; Copenhagen, Denmark; and Bologna, Italy (GE Medical Systems). In London, United Kingdom, Samsung PT60A and Samsung HM70 were used, and in Parma, Italy, a Samsung WS70 was used (Samsung, Seoul, Republic of Korea). The Malmstrom vacuum cup was the preferred device used in Stavanger and Trondheim, Norway; Lund, Sweden; London, United Kingdom; and Copenhagen, Denmark. In Bologna and Parma, Italy, the Kiwi cup was used. Body mass index was calculated from maternal height and prepregnant weight.

FIGURE 4
Placement of transducer measuring head-perineum distance



Woman is placed in semirecumbent position with legs exed at hips and knees at 45-degree and 90-degree angles, respectively. Transducer placed transverse in posterior fourchette (red line) when head-perineum distance measured and rotated to sagittal plane when angle of progression measured.

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Cord blood was obtained by direct puncture of the umbilical artery without clamping of the cord, and acid-base analysis was performed immediately after collecting the samples. Umbilical artery pH <7.10, known to be associated with adverse neonatal outcome, was used as the cut-off level.[35,36]

The main outcome measure was duration of vacuum extractions. Secondary outcomes were frequencies of spontaneous deliveries, vacuum extractions, cesarean deliveries, and umbilical artery blood samples after birth (pH and base excess).

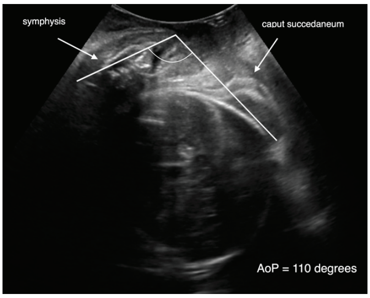
Power analysis

Our preliminary clinical experience assessing head-perineum distance prior to vacuum delivery suggested that we should set 25 mm for the power calculation, a level corresponding approximately to +2 below the ischial spines. The main outcome of the study was duration of vacuum extraction analyzed using survival analyses. The main predictor variable was head-perineum distance with a predefined cut-off at 25 mm to discriminate between the groups. To identify a hazard ratio (HR) as low as 1.5 with 80% power, 2-sided test, with alpha 5%, one third of the women with distance >25 mm and two thirds with distance ≤25 mm, we determined that 220 women should be included when expecting 10% censoring. The calculations were based on log rank test using the Freedman method and performed in a statistical program (Stata for Windows, Version 12; StataCorp, College Station, TX).

Statistical analyses

Variables were compared using χ^2 test and linear regression. To evaluate differences in the time interval from start of vacuum extraction to complete delivery according to head-perineum distance and angle of progression, we used Kaplan-Meier methods and Cox[37] regression analyses. The Kaplan-Meier method was used to generate survival plots, and we used head-perineum distance 25 mm as cut-off value in accordance with the power analysis. Cox regression was used to calculate HR as an

FIGURE 5
Measurement of angle of progression



Sagittal transperineal image illustrating measurement of angle of progression (AoP).

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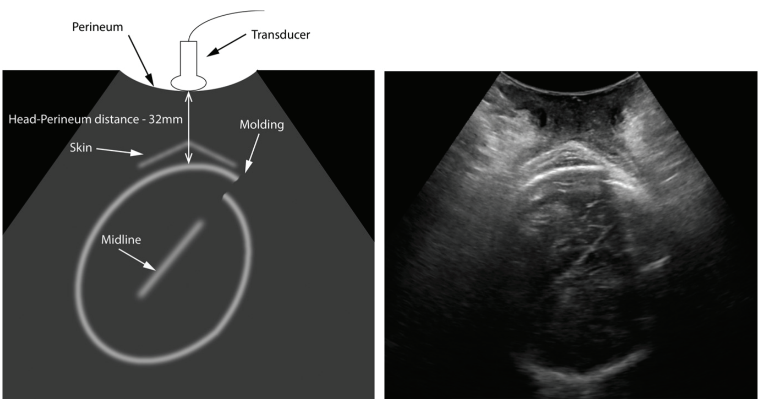
estimate for relative risk of delivery. In the Cox regression analysis we controlled for fetal position, prepregnancy body mass index, maternal age, induction of labor, epidural analgesia, and augmentation with oxytocin, and in an additional analysis we included institution as a covariate. Women with a spontaneous vaginal delivery were not included in the survival analyses and cesarean deliveries were right censored at the time of the decision to perform a cesarean delivery. Cox regression assumes proportional hazards, and this was evaluated by log minus log plots and tests of Schoenfeld residuals using the global and detailed ph test in Stata software. The assumption was satisfied ($P = .66$).

The association between head-perineum distance and delivery mode was analyzed at 5 different cut-off levels: ≤20, 21-25, 26-30, 31-35, >35. In a previous study 35 mm was found to correspond to station <0 by clinical examinations,[24] therefore, we focused on 35 mm as cut-off level and presented test characteristics related to this level. The association between angle of progression and delivery mode was analyzed at cut-off levels: <120, 120-129, 130-139, 140-149, ≥150 degrees. The associations between spontaneous and cesarean delivery related to head-perineum distance and angle of progression as continuous variables were evaluated using receiver operating characteristic (ROC) curves. These analyses were first performed as intention to treat because cesarean deliveries done without a vacuum attempt were included. Thereafter, we did separate analyses that only included cesarean deliveries performed after a vacuum attempt. The area under the curve was considered to have discriminatory potential if the lower limit of the confidence interval (CI) was >0.5. $P < .05$ was considered statistically significant.[38] Data were analyzed with the statistical software package SPSS Statistics, Version 23.0 (IBM Corp, Armonk, NY) and Stata for Windows, Version IC 13.

FIGURE 6
Measurement of head-perineum distance



Transverse transperineal image (frontal plane related to woman) illustrating measurement of head-perineum distance (double arrow). Head midline and molding are seen.

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Results

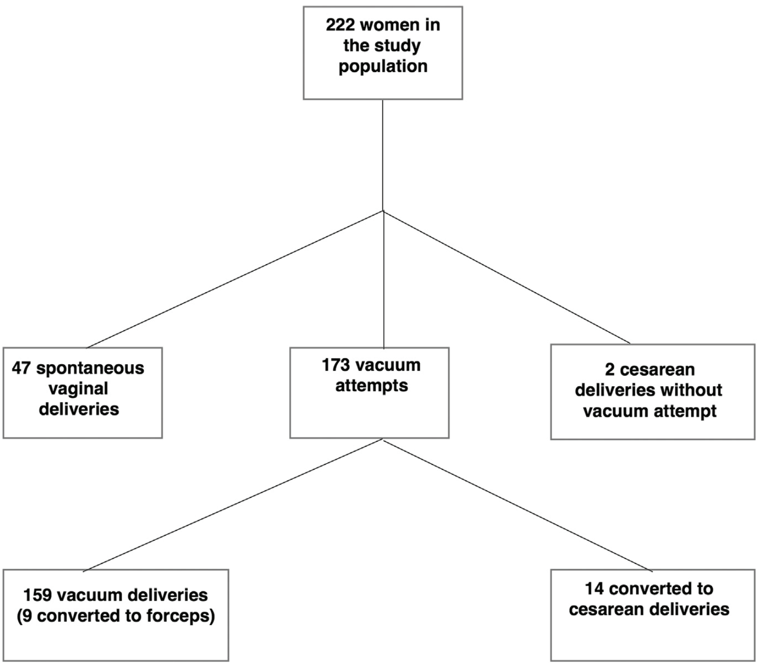
Study population

A total of 223 women were included and 1 woman was excluded because information about the main outcome was missing, leaving 222 women in the study population. Figure 7 is a flow chart illustrating delivery methods. Head-perineum distance was successfully measured in all women and angle of progression was successfully measured in 182/222 (82%). Characteristics of the study population differentiated between women with head-perineum distance ≤25 mm vs >25 mm are presented in Table 1.

Duration of vacuum extraction

Survival analyses were performed in women with a vacuum attempt. The duration of operative delivery was significantly shorter in women with head-perineum distance ≤25 mm (log rank test <0.01) (Figure 8). The estimated median duration (Kaplan-Meier analyses) in women with head-perineum distance ≤25 mm was 6.0 (95% CI, 5.2–6.8) minutes vs 8.0 (95% CI, 7.1–8.9) minutes in women with head-perineum distance >25 mm. The HR in Cox regression analyses was 0.56 (95% CI, 0.41–0.78) and adjusted value 0.58 (95% CI, 0.41–0.82). Head-perineum distance and angle of progression were analyzed as continuous variables in separate analyses. They were both significantly associated with the duration of operative vaginal deliveries after adjusting for covariates. Adjusted HR was 0.96 (95% CI, 0.94–0.98) for increasing head-perineum distance (Table 2) and 0.98 (95% CI, 0.97–0.996) for decreasing angle of progression. The center-adjusted HR estimate for increasing head-perineum distance was 0.93 (95% CI, 0.91–0.96) when the centers were included in the analysis. Duration was >20 minutes in 3 women and 3 women had >2 cup detachments. The median duration from the

FIGURE 7
Study population



Flow chart of study population.

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ultrasound examination to delivery was 25 (interquartile range 15-38) minutes.

Fetal station

Median head-perineum distance in women with fetal head station of 0 from clinical examination was 36 mm, mean 34 mm, range 15-49 mm, and interquartile range 7 mm. Median angle of progression in women with palpated station 0 was 132 degrees, mean 133 degrees, range 112-164 degrees, and interquartile range 24 degrees.

Delivery mode

Head-perineum distance and angle of progression were correlated (r = 0.48). The associations between delivery mode and head-perineum distance and angle of progression were categorized into 5 different groups as presented in Figures 9 and 10. The frequency of cesarean deliveries was 1% (1/99) in women with head perineum distance ≤25 mm vs 12% (15/122) in women with distance >25 mm (P < .01). Using head-perineum distance >35 mm as cut-off level, the sensitivity in predicting cesarean delivery was 56% (95% CI, 33−77%), false-positive rate was 16% (95% CI, 11−21%), positive predictive value was 22% (95% CI, 12−33%), and negative predictive value was 96% (95% CI, 92−98%). Head-perineum distance and angle of progression were significantly associated with a spontaneous delivery with area under the ROC curve 83% (95% CI, 77−89%) (Figure 11) and 75% (95% CI, 66−85%), respectively, but only head-perineum distance was significantly associated with cesarean delivery; area under the ROC curve was 83% (95% CI, 74−92%) for head-perineum distance (Figure 12) vs 56% (95% CI, 42−69%) for angle of progression.

We separately analyzed the association of cesarean delivery with head-perineum distance after a vacuum attempt. This occurred in 14/173 (8%) vacuum extractions and the results were similar to the intention-to-treat analyses. Head-perineum distance was associated with a cesarean with 83% (95% CI, 73−93%) vs angle of progression with 52% (95% CI, 38−66%).

Ultrasound-assessed position was OA in 73% and non-OA in 23% with missing information in 4%. In women with head-perineum distance ≤35 mm 7/181 (3.9%) were delivered by cesarean delivery vs 9/41 (22.0%) in women with head-perineum distance >35 mm (P < .01). In fetuses with OA position 6/162 (3.7%) were delivered by cesarean compared to 10/50 (20.0%) in non-OA position (P < .01). Only 3/138 (2.2%) of fetuses in OA position in combination with head-perineum distance ≤35 mm were delivered by cesarean and 6/17 (35.3%) with non-OA position in combination with head-perineum distance >35 mm were delivered by cesarean.

Umbilical artery blood samples

pH in the umbilical artery were measured in 184/222 (83%) cases. Only 1 newborn had pH <7.0 (pH 6.90 and base excess 18). This baby was delivered by vacuum and head-perineum distance before start of vacuum was 38 mm. pH <7.10 occurred in 10 newborns, and head-perineum distance was >35 mm in 8/40 (20.0%) compared to 2/144 (1.4%) in cases with head-perineum distance ≤35 mm (P < .01). Base excess was >12 in 3 cases in which head-perineum distance was >35 mm in 2.

Comment

Principal ndings

The main finding in our study was a significant association between ultrasound-assessed fetal station and duration of vacuum extraction. Fetal station assessed with head-perineum distance and angle of progression predicted the probability of a spontaneous delivery, but only head-perineum distance predicted cesarean delivery. We observed significant association between low umbilical cord pH and head-perineum distance >35 mm.

The importance of these findings differs in high and low resource countries.

TABLE 1
Characteristics of study population

	Head-perineum distance $\leq$25 n = 99		Head-perineum distance >25 n = 123	
Maternal characteristics				
Maternal age, y	29	20—43	30	17—41
Prepregnant body mass index	23	18—39	24	18—39
Gestational age, wk	40	38—42	40	37—42
Labor characteristics				
Induction of labor	30 (30)	—	43 (35)	—
Epidural analgesia	80 (81)	—	95 (77)	—
Oxytocin augmentation	72 (73)	—	98 (80)	—
Characteristics of newborn				
Birthweight, g	3660	2570—4665	3650	2152—4930
5-min Apgar score	10	7—10	10	5—10
pH in umbilical artery, n = 184	7.24	7.09—7.43	7.24	6.90—7.40
Birth characteristics				
Bleeding, mL	400	100—2000	400	100—3400
Third- and fourth-degree anal sphincter tears	8 (8)		6 (5)	

Values are median, n (%), or range.

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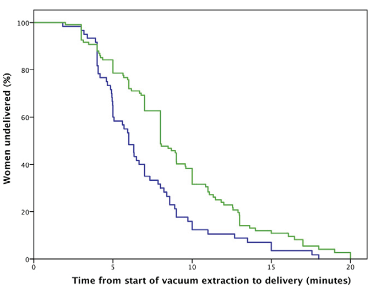
Firstly, the transperineal scan requires little training and can be undertaken with the type of ultrasound equipment frequently found in many delivery units worldwide. Thus, the technique is generalizable. In high-income countries, the benefit of the technique is 3-fold: (1) a previously subjective and unreproducible measurement is converted into an objective and recordable measure; (2) knowledge of the likely difficulty and duration of labor will determine the seniority of the operator and the setting of the delivery; and (3) the likelihood of cesarean delivery can be discussed with the woman and a decision made in advance not to proceed with a potentially futile attempt at vacuum delivery.

In many low- and mid-resource countries there is an increase in cesarean rates and declining use of operative vaginal deliveries, including vacuum.[10,39] In the United States a declining trend is also observed.[40] In low-resource countries cesarean delivery is associated with increased risk of maternal complications and high risk of uterine rupture in subsequent pregnancies.[41] Training of clinicians in vacuum deliveries might reduce the frequency of late-stage cesarean deliveries[40,42] and use of intrapartum ultrasound might add important information and reassure clinicians that a vacuum attempt at low stations has low risk of failure. New studies in low-resource settings are necessary.

FIGURE 8
Duration of vacuum extractions



Kaplan-Meier plot of time from start of vacuum extraction to delivery within 20 minutes differentiated into those with head-perineum distance $\leq$25 mm (blue) and >25 mm (green). Women who were delivered by cesarean were censored at time when decision to convert to cesarean was done ($P < .01$; log rank test).

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Clinical signi cance

We found that head-perineum distance $\leq$20 mm was associated with a high probability of a spontaneous delivery (Figure 9), and birth attendants might be patient in these situations as long as the fetal heart rate is normal. In a previous study head-perineum distance >35 mm corresponded to station $\geq$0,[24] and this finding agreed well with our new study (mean head-perineum distance 34 mm and median head-perineum distance 36 mm at clinically assessed station 0). It is usually not recommended to perform an operative vaginal delivery at levels above this station.[13] We found that the probability of cesarean in women with head-perineum distance >35 mm was 22% and 35% if it was combined with a non-OA position. A failed operative vaginal delivery is associated with risks for the mother and the fetus and a fearful experience for the woman. Our study

TABLE 2
Cox regression analysis for predicting duration of vacuum extraction in nulliparous women with slow progress in second stage of labor

	Unadjusted HR	95% CI	Adjusted HR	95% CI
Head-perineum distance[a]	0.96	0.94–0.98	0.96	0.94–0.98
Body mass index[a]	1.05	1.004–1.09	1.05	1.01–1.10
Maternal age[a]	0.99	0.97–1.03	1.00	0.96–1.03
Fetal position (n = 212)				
Occiput anterior (reference)	1.00	—	1.00	—
Nonocciput anterior	0.46	0.32–0.68	0.56	0.38–0.84
Induction of labor				
No (reference)	1.00	—	1.00	—
Yes	0.97	0.69–1.36	1.10	0.76–1.60
Epidural analgesia				
No (reference)	1.00	—	1.00	—
Yes	0.69	0.47–1.03	0.73	0.49–1.10
Augmentation with oxytocin				
No (reference)	1.00	—	1.00	—
Yes	0.75	0.52–1.09	0.87	0.59–1.29

HR with CI not crossing 1.0 were assumed signi cant.

CI, con dence interval; *HR*, hazard ratio.

[a] Analyzed as continuous variable.

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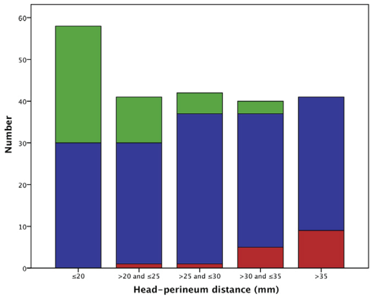
FIGURE 9
Delivery mode related to head-perineum distance



Distribution of spontaneous (green), operative vaginal (blue), and cesarean (red) deliveries in relation to head-perineum distance in nulliparous women with prolonged second stage of labor.

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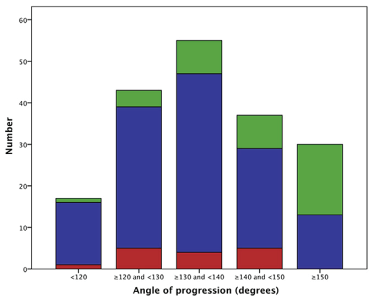
confirms that vacuum deliveries at high station are associated with a high failure risk, but at head-perineum distance levels <35 mm there is very good chance (96%) of a vaginal delivery. Another important finding is that pH <7.10 was more commonly observed among cases with head-perineum distance >35 mm. Although our study did not include fetuses with suspected compromise before start of vacuum, a significantly lower pH in cases with greater head-perineum distance might be explained by the longer duration of vacuum extractions at higher levels.

Research implications

Labor progress in the second stage of labor is evaluated by fetal descent and traditionally assessed by clinical assessment of station.[43] In 1977 Lewin et al[44] assessed fetal head station by ultrasound. They measured the distance from the fetal head to the sacral tip. Barbera et al[23] suggested angle of progression as a measure of head descent and found that an angle of >120 degrees was associated with subsequent spontaneous vaginal deliveries. Sonographically assessed head station has already been shown to be associated with duration of labor and delivery mode in nulliparous women with prolonged first stage.[33,34] Kalache et al[45] evaluated 41 women with prolonged second stage of labor, but included only the 26 women with OA position in the final analyses. They found that angle of progression >120 degrees was associated with a spontaneous delivery or an easy vacuum extraction.[45] Henrich et al[46] studied 20 women and found that head direction with respect to the long axis of the symphysis was associated with a successful operative vaginal delivery. Sainz et al[47] found that angle of progression <105 degrees and head-down direction before vacuum extraction was very unfavorable. Bultez et al[14] measured angle of progression in 235 women immediately before vacuum extraction. Duration of extraction exceeding 20 minutes or detaching of the vacuum cup >3 times were defined as failed vacuum extraction. The area under the ROC curve for predicting failure of vacuum extraction was 67% (95% CI, 57–77%) with optimal cut-off at 146 degrees. Our results cannot be directly compared with this study

FIGURE 10
Delivery mode related to angle of progression



Distribution of spontaneous (green), operative vaginal (blue), and cesarean (red) deliveries in relation to angle of progression in nulliparous women with prolonged second stage of labor.

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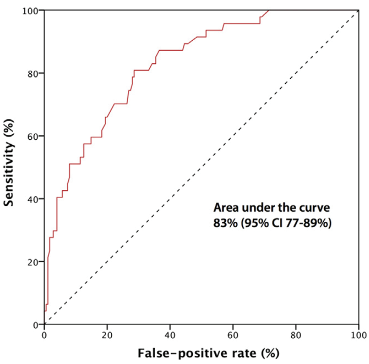
FIGURE 11
ROC-curve illustrating prediction of spontaneous deliveries



Receiver operating characteristic curves for head-perineum distance in prediction of spontaneous deliveries in women with prolonged second stage of labor.

CI, con dence interval.

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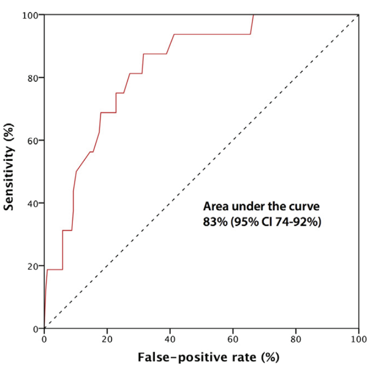
because our prespecified outcome was different. We found that head-perineum distance predicted cesarean delivery with area 83% (95% CI, 74—92%) under the ROC curve. It should be noted that in our study the duration of vacuum extraction exceeded 20 minutes in only 3 women, 3 women experienced >2 detachments, and that the frequency of cesarean after a vacuum attempt was 8%. In the original studies angle of progression was only used in OA fetuses. In our study, all positions were included. The third cardinal movement is different in occiput posterior positions[48,49] and this might explain why angle of progression did not predict cesarean. Because varying cut-off levels for the angle of progression in predicting cesarean deliveries are suggested in previous studies (from 120-146 degrees),[14,45] we decided to investigate angle of progression as a continuous variable.

Head-perineum distance is easy to measure and can be used at all stations. The transabdominal transducer should be placed in the posterior fourchette and pressed until resistance against the pubic arches is achieved. Repeatability has been investigated in a previous study. The intraobserver variation was within 3 mm in 87%, and the interobserver variation was within 3 mm in 61%. The limits of agreement for intraobserver variation were −3.0 to 5.3 mm, and for interobserver agreement −8.5 to 12.3 mm.[20] A randomized study is warranted, but it might be difficult to perform because adverse fetal outcomes are fortunately rare. It is shown that women prefer ultrasound examinations before vaginal examination,[50,51] and maternal experiences of fear and pain might be used as outcomes in a future randomized study.

FIGURE 12
ROC curve illustrating prediction of cesarean deliveries



Receiver operating characteristic curves for head-perineum distance in prediction of cesarean deliveries in women with prolonged second stage of labor.

CI, con dence interval.

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Strengths and limitations

Strengths of this study are the multicenter design, inclusion of only nulliparous women with prolonged second stage in the active phase of labor, and that the ultrasound examiners and the birth attendants were blinded to each other s findings. Limitations of the study were that some centers had few inclusions and that different vacuum devices were used. The study period was long with relatively few inclusions/months because it was often difficult to find ultrasound examiners not involved in the clinical care, and the integrity of the study relied on study examinations not biasing clinical decisions.

In measuring angle of progression, the complete length of the symphysis and the skull contour should be visualized on the same image; this failed in 18% of the cases. Women could be included after 45 minutes of active pushing. In the Norwegian guidelines operative delivery is recommended after 1 hour of active pushing.[52] This period differs from recommendations in many other countries and might affect the external validity of the study since the majority of participants were Norwegian women. The final decision of delivery method was based on subjective considerations of the responsible physician, and difficult to standardize. The study design was observational, and local guidelines should be followed.

Conclusion

In summary, ultrasound measurement in women with prolonged second stage of labor might predict duration of assisted vaginal delivery and the likelihood of cesarean delivery, and was associated with fetal acid-base status. We did not examine the clinical impact of this information nor did we attempt to change clinical decision-making. This work sets the scene for further studies of management in prolonged second stage of labor. ■

Acknowledgment

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Paper two

AOGS ORIGINAL RESEARCH ARTICLE

Fetal rotation during vacuum extractions for prolonged labor: a prospective cohort study

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Key words
delivery, fetal rotation, prolonged labor, ultrasound, vacuum extraction

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Conflict of interest
The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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Abstract

Introduction. The aim of the study was to investigate fetal head rotation during vacuum extraction. *Material and methods.* We conducted a prospective cohort study from November 2013 to July 2016 in seven European hospitals. Fetal head position was determined with transabdominal or transperineal ultrasound and categorized as occiput anterior (OA), occiput transverse (OT) or occiput posterior (OP) position. Main outcome was the proportion of fetuses rotating during vacuum extraction. Secondary outcomes were conversion of delivery method, duration of vacuum extraction, umbilical artery pH <7.10 and agreement between clinical and ultrasound assessments. *Results.* The study population comprised 165 women. During vacuum extraction 117/119 (98%) remained in OA and two fetuses rotated to OP position. Rotation from OT to OA position occurred in 14/19 (74%) and to OP position in 5/19 (26%). Rotation from OP to OA position occurred in 15/25 (60%), and 10/25 (40%) fetuses remained in OP position. Delivery information was missing in two cases. The conversion rate from vacuum extraction to cesarean section or forceps was 10% in the OA group vs. 23% in the non-OA group; $p < 0.05$. The estimated duration of vacuum extraction was significantly shorter in OA fetuses, 7 min vs. 10 min (log rank test $p < 0.01$). There was no significant difference in umbilical artery pH < 7.10 between OA and non-OA position. Cohens Kappa of agreement between clinical and ultrasound assessments was 0.42 (95% CI 0.26–0.57). *Conclusion.* Most fetuses in OP or OT positions rotated to OA position during vacuum extraction, but the proportion of failed vacuum extractions remained high.

Abbreviations: CI, confidence intervals; OA, occiput anterior; OP, occiput posterior; OT, occiput transverse.

Introduction

In early labor approximately 30% of fetuses are in occiput posterior (OP) position (1). At delivery, this is reduced to 5–8% (1) because most OP fetuses will rotate to occiput anterior (OA) position during labor (2). Persistent

Key Message

During vacuum extractions, most fetuses rotate from occiput posterior and occiput transverse position to occiput anterior position.

OP position at delivery is usually due to failure of rotation rather than malrotation from OA position or occiput transverse (OT) position (1,3). Spontaneous rotation is not only influenced by the position of the fetal head, but also by the position of the fetal spine (4). An android shape of the female pelvis with a narrow subpubic arch angle predisposes to persistent OP position (5). Ultrasound is found to be more accurate in diagnosing fetal position than digital examination (6,7).

An OP position in active labor is associated with higher risk of prolonged labor, artificial rupture of membranes, augmentation with oxytocin and operative delivery (8). OP position at delivery is associated with higher risk of anal sphincter rupture (9), low 5-min Apgar score, low umbilical artery pH and admission to neonatal intensive care unit (8).

Many clinicians say that a malpositioned fetus may rotate during vacuum extraction and we hypothesized that this is true. The proportion of fetuses eventually rotating during the procedure is not known. The aim of the study was to investigate fetal head rotation during vacuum extraction.

Material and methods

The present study was part of a multicenter cohort study comprising nulliparous women at term with slow progress in the second stage of labor. We have previously published duration of vacuum extraction related to fetal head station, and in accordance with a power calculation in this study the sample size of 220 women was established (10). Women were not eligible for inclusion if fetal compromise was suspected due to nonreassuring cardiotocography.

The inclusion period was November 2013 to July 2016. The participating centers were Stavanger University Hospital, Norway; University Hospital of Bologna, Italy; Trondheim University Hospital, Norway; Queen Charlotte's and Chelsea Hospital, Imperial College Healthcare NHS Trust, UK; Lund University Hospital, Sweden; Hvidovre University Hospital, Denmark; and University Hospital of Parma, Italy.

In the present study, we included all women with a vacuum attempt. Second stage of labor was differentiated into a passive phase (<2 h) and an active phase with pushing. Women were eligible for inclusion when the birth attendant diagnosed slow progress in second-stage labor according to the local hospital definition, and the ultrasound examination was performed after at least 45 min of active pushing and a vacuum extraction was considered.

The main outcome was the proportion of fetuses rotating in relation to the starting position of the fetal head (OP, OT or OA position) during vacuum extraction. Secondary outcomes were conversion of delivery method, time from start of vacuum extraction to delivery, umbilical artery pH < 7.10 and agreement between clinical and ultrasound assessments.

Fetal head position was defined with transabdominal or transperineal ultrasound and recorded as the position on a 'clock' divided into half-hourly sections (6,11,12). Positions from 2.30 to 3.30 were recorded as left OT and positions from 8.30 to 9.30 as right OT. Positions from 4.00 to 8.00 were recorded as OP, and positions from 10.00 to 2.00 as OA position (13). Transabdominal ultrasound was performed both transversely and longitudinally related to the mother. Landmarks were the cervical spine, orbits, cerebral midline echo, cerebellum and choroid plexus. At low stations, intracerebral structures were sometimes better visualized using a transperineal approach (11,14). All ultrasound examinations were carried out online in the delivery room. Both doctors and midwives performed ultrasound examinations and they were all trained in the procedures before the start of the study. Neither the women in labor nor the responsible birth attendants were informed about results from the ultrasound team, and the ultrasound operators were not involved in clinical decisions or management of labor. The birth attendants in charge of the delivery were the doctors and midwives on call that day. They recorded fetal position based on clinical examination in accordance with the protocol; but were allowed to use ultrasound themselves if needed for decision-making. Active rotation during vacuum extractions was not performed.

The ultrasound devices used were GE Voluson *i* (Stavanger, Trondheim, Lund, Bologna, Copenhagen) or GE Voluson S6 (Stavanger) (GE Medical Systems, Zipf, Austria). In London, Samsung PT60A and Samsung HM70 were used (Samsung Medison, Seoul, Republic of Korea). In Parma, a Samsung WS70 was used (Samsung Medison). In Stavanger, Trondheim, Lund, London and Copenhagen metal vacuum cups were preferred, whereas in Bologna and Parma Kiwi cups were used. Body mass index was calculated from prepregnant weight and maternal height.

Statistical analyses

Categorical variables were compared using chi-squared test and Cohen's Kappa. To evaluate differences in the time interval from start of vacuum extraction to complete delivery according to fetal position, we used Kaplan–Meier methods and Cox regression analyses. The Kaplan–Meier method was used to generate survival plots, and we differentiated between OA and non-OA positions and compared with log rank test. Cox regression analyses were used to calculate hazard ratio as an estimate for relative risk of delivery. In the Cox regression analysis we controlled for fetal position, prepregnancy body mass index, maternal age, induction of labor, epidural analgesia and augmentation with oxytocin.

Cesarean sections and women with duration of vacuum extraction >20 min were censored. Cox regression assumes proportional hazards, and this was evaluated by log minus log plots. Values of p that were <0.05 were considered significant. Data were analyzed with the statistical software package SPSS statistics version 24.0 (IBM SPSS; IBM Corp., Armonk, NY, USA).

Ethical approval

The local ethics committees approved the study with reference numbers REK 2012/1865 in Norway, 3348/2013 in Italy, REC reference 15/LO/1341; IRAS project ID 169478 in UK, DNR 2012/808 in Sweden and H-4-2014-038 in Denmark. All women gave informed written consent, and the study was registered in Clinical Trials with identifier NCT01878591.

Results

The original study population comprised 222 women among whom vacuum delivery was attempted in 173 women. Eight women were excluded because position was not determined with ultrasound. The final study population comprised 165 women, of whom 121 (73%) fetuses were in OA, 19 (12%) in OT and 25 (15%) in OP positions before operative vaginal delivery. Figure 1 demonstrates a flow chart of the study population.

Characteristics of the study population differentiated into OA, OT and OP positions are shown in Table 1. During vacuum extraction, 117/119 (98%) remained in OA and two fetuses rotated to OP position. Rotation from OT to OA position occurred in 14/19 (74%) and to OP position in 5/19 (26%). Rotation from OP to OA position occurred in 15/25 (60%), and 10/25 (40%) fetuses remained in OP position. (Figure 2). There was missing information about position at delivery in two women.

The median time from ultrasound examination to start of delivery was 16 min (interquartile range 4–27 min). The duration of vacuum extraction was significantly shorter in fetuses with OA position compared with non-OA position (log rank test <0.01).

The estimated median duration in OA position was 7 min (95% CI 6.3–7.7) vs. 10 min (95% CI 7.8–12.2) in non-OA position (Figure 3). The adjusted hazard ratio for vaginal delivery in fetuses starting from non-OA positions analyzed with the Cox regression method was 0.53 (95% CI 0 0.36–0.79). Unadjusted and adjusted results from the Cox regression analyses are presented in Table 2. Two cases were censored due to vacuum extraction >20 min and 14 due to cesarean section.

Vacuum delivery was converted to cesarean section or forceps in 6/25 (24%) fetuses in OP position, in 4/19 (21%) in OT position and in 12/121 (10%) in OA position. The conversion rate in the OA group (10%) was significantly different from the conversion rate in the non-OA group (23%); $p < 0.05$.

The number of newborns with umbilical artery pH <7.10 was 7 (6%) in OA and 2 (5%) in non-OA positions, and this difference was not statistically significant; $p = 0.76$.

The clinicians performing vacuum extractions classified position with vaginal examination in 139/165 (84%) of the women and they agreed with ultrasound findings in classifying OA position in 87/102 (84%), OT position in 6/15 (40%) and OP position in 12/22 (55%) cases; Cohen's Kappa 0.42 (95% CI 0.26–0.57).

Discussion

We observed that most fetuses that were in an OP or OT position before the start of vacuum extraction rotated during the procedure, and that malrotation from OA to OP position was rare. The conversion rate from vacuum delivery to different delivery method was more than double in non-OA position compared with OA positions; however, this was not reflected in low umbilical cord pH in the newborn.

Fetal head position can be classified in different ways. We preferred a circle, transformed to a clock face (1) rather than eight equal sectors of 45 degrees. Intrapartum assessment of fetal head position is traditionally performed by digital vaginal examination. Ultrasound examination of fetal head position is easy to learn and reliable in novice hands (15). Several studies have compared vaginal examination and ultrasound. If the fetal head is in OP position, vaginal examination is found to result in incorrect diagnosis in around 50% of cases (6), which is in accordance with our findings. A randomized controlled trial concluded that the incidence of incorrect diagnosis of fetal position before instrumental vaginal delivery was significantly lower in an ultrasound group compared with a vaginal examination group, 1.6% vs. 20.2% (7). In a reproducibility study the interobserver agreement of ultrasound determination of fetal head position was within 15° in 90% of cases, and within 30° of all cases (16).

Fetal head position should be known before performing operative delivery due to slow progress. The vacuum cup should be placed over the flexion point, which in an OP

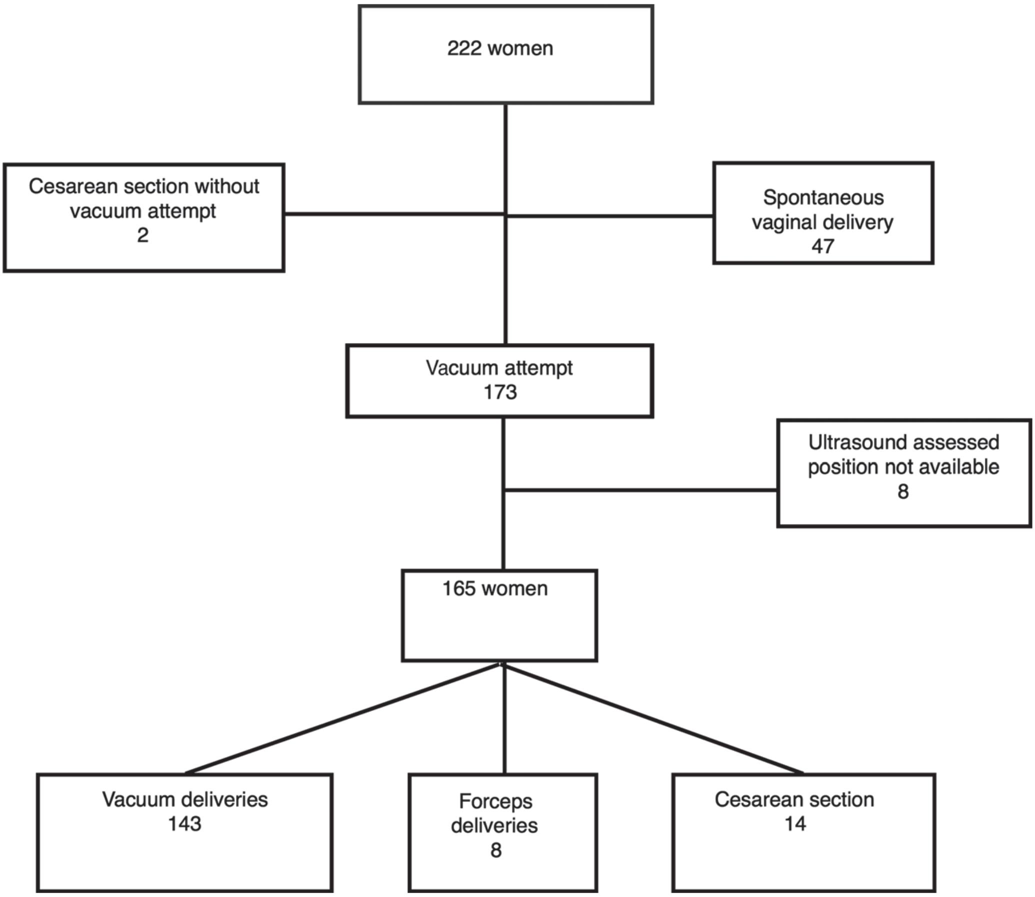

Figure 1. Flow chart of the study population.

position is more posterior compared with fetuses in OA position. When incorrect technique is used, and the cup is incorrectly placed, risk of cup detachment and harm increases (17). The experience of the birth attendant is also related to the failure rate, and continuous training in operative vaginal deliveries is advised (18). Traction should follow the third cardinal movement (deflexion in OA positions, and flexion first then followed by deflexion in OP positions). Exact knowledge of position is also essential for correct placement of forceps.

Both OP and OT positions in the second stage of labor can be managed expectantly or actively. Expectant management early in the second stage is appropriate if the fetal heart rate is reassuring and labor is progressing. Between 50 and 80% of fetuses will spontaneously rotate to OA position (1,2). Active management options include manual rotation, vacuum deliveries, traction forceps, rotational forceps or cesarean section. A success rate of around 90% has been reported using manual rotation, and an increase in rate of spontaneous vaginal delivery of > 50% was observed in the group who underwent manual rotation compared with a group with no intervention (19). Manual rotation has also been advised when the descent of the head is slowing down, as the chance of success is greater than when arrest of labor has occurred (19). An ongoing randomized controlled trial in Australia aims to investigate the effect of manual rotation (20).

In previous studies, vacuum extraction from OP position has an increased risk of failure with odds ratio of 2.2–2.6 compared with vacuum extraction from OA position (21,22). There is an increased risk of adverse maternal and fetal outcome when cesarean section is performed

Table 1. Characteristics of the study population.

	OA position n = 121		OT position n = 19		OP postion n = 25	
	Median or n (%)	Range	Median or n (%)	Range	Median or n (%)	Range
Maternal						
Maternal age (years)	30	19–41	30	22–38	30	17–39
Prepregnant BMI (kg/m^2)	23	18–39	24	18–29	23	18–29
Gestational age (weeks)	40	38–41	41	39–41	40	38–40
Labor						
Induction of labor	38 (31)		7 (37)		9 (36)	
Epidural analgesia	92 (76)		18 (95)		21(84)	
Oxytocin augmentation	90 (74)		17 (90)		21 (84)	
Newborn						
Birthweight (g)	3624	2570–4930	3845	2980–4560	3700	2152–4575
Apgar score at 5 min	9	7–10	10	6–10	10	8–10
pH in umbilical artery	7.24	6.90–7.40	7.26	7.00–7.43	7.23	7.08–7.34
Birth						
Bleeding (mL)	400	100–3400	500	150–1100	400	200–1600
Third- or fourth-degree anal sphincter tears	9 (8)		2 (11)		0 (0)	

BMI, body mass index; OA, occiput anterior; OP, occiput posterior; OT, occiput transverse.

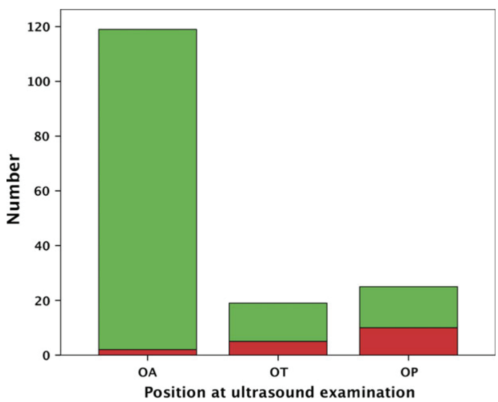

Figure 2. Number of occiput anterior (OA) deliveries at birth (green) and occiput posterior (OP) deliveries (red) at birth stratified into ultrasound-assessed fetal head position before vacuum extraction. OT, occiput transverse position. [Color figure can be viewed at wileyonlinelibrary.com]

after failed operative vaginal delivery (23,24). In our study, we found a higher failure rate in non-OA positions and when using survival methods, the hazard ratio for vaginal delivery was 0.53 from non-OA positions compared with OA positions. However, the majority of fetuses from non-OA positions rotated to an OA position during vacuum extraction and >75% of fetuses starting in non-OA positions were successfully delivered vaginally. Hence, we think that vacuum extraction should be tried also from non-OA positions.

We did not observe differences in umbilical artery pH between the groups. However, the failure rate was high, and we think experienced obstetricians should be available in these situations. The high conversion rate from vacuum to forceps or cesarean section in our study may be due to inclusion of only nulliparous women with slow progress in the second stage of labor.

The failure rate is found to be lower with forceps delivery than with vacuum extraction, especially when the fetus is in OP position (25,26). However, forceps deliveries have higher incidence of anal sphincter tears and a randomized controlled trial showed that anal sphincter function following forceps delivery is more associated with symptoms of altered fecal continence (27). Forceps is also associated with increased risk of damage to the levator ani muscle. A cross-sectional study including 608 women concluded that forceps delivery was significantly associated with pelvic organ prolapse, levator avulsion and larger hiatal areas 15–23 years after first delivery compared with vacuum extraction and spontaneous vaginal delivery (28). The use of rotational forceps should only be used by experienced obstetricians.

Second-stage cesarean sections are associated with increased maternal intraoperative trauma and perinatal asphyxia. According to the Royal College of Obstetricians and Gynaecologists audit figures from 2001, 25% of all cesarean sections due to failure to progress were performed at full dilatation of the cervix. In more than half

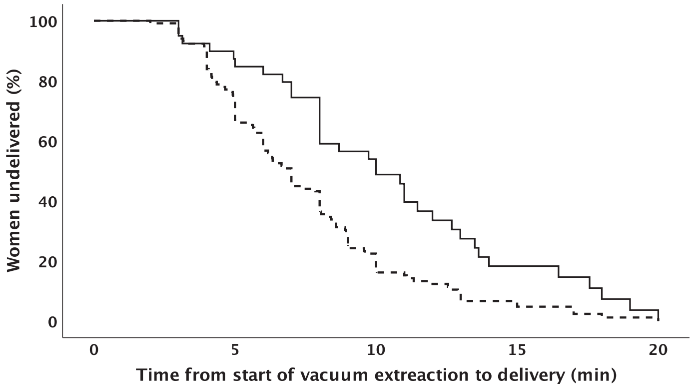

Figure 3. Kaplan–Meier plot of time from starting vacuum extraction to delivery differentiated into occiput anterior (OA) (-----) and other (non-OA) positions (——). Log rank test <0.01. Cesarean section and delivery lasting > 20 min were censored.

Table 2. The hazard ratio for vaginal delivery after vacuum extraction in nulliparous women with slow progress in the second stage of labor.

	Unadjusted HR	95% CI	Adjusted HR	95% CI
Position				
OA (reference)	1.00	–	1.00	–
Non-OA	0.52	0.35–0.76	0.53	0.36–0.79
BMI	1.05	1.01–1.10	1.05	1.00–1.10
Maternal age	0.99	0.95–1.02	0.98	0.94–1.01
Induction				
No (reference)	1.00	–	1.00	–
Yes	0.92	0.65–1.30	0.91	0.63–1.32
Epidural				
No (reference)	1.00	–	1.00	–
Yes	0.73	0.49–1.09	0.80	0.53–1.20
Augmentation				
No (reference)	1.00	–	1.00	–
Yes	0.85	0.58–1.24	0.94	0.63–1.40

BMI body mass index; CI, confidence interval; HR, hazard ratio; OA, occiput anterior.
Hazard ratios with CI intervals not crossing 1.0 were assumed to be significant.

of these cases, no attempt at vaginal delivery was made. Cesarean section after prolonged second stage has been associated with longer surgery time, increased postoperative fever, maternal intraoperative trauma, including higher risk of extension of the uterine incision, and higher composite morbidity (29). Structured training and the need for obstetricians to maintain and develop their vaginal operative delivery skills are necessary to offer safe alternatives to cesarean section in prolonged second stage (30).

In this study, all fetuses had reassuring cardiotocography when the ultrasound was performed. It would not be ethically acceptable to postpone delivery in cases with fetal distress. Our results cannot be generalized to all vacuum deliveries. Malposition is associated with slow progress, and the frequency of OP and OT positions may be lower in fetuses delivered using vacuum extraction due to fetal distress.

Strengths of the study were the multicenter design and that fetal head position was defined with ultrasound. Birth attendants and ultrasound examiners were not aware of each other's findings. An important limitation of the study is that it was impossible to know if a fetus had rotated spontaneously between the ultrasound examination and start of vacuum extraction. However, this seems unlikely as all women were diagnosed with slow progress at inclusion, and the median duration of the ultrasound to instrumental delivery interval was 16 min. Also, eight women were excluded because fetal head position was not determined with ultrasound. When the fetal head is at a low station or in an OT position it can be difficult to see the intracerebral structures necessary to determine position with transabdominal ultrasound. In borderline cases between two positions, for instance if the fetal occiput is at 2.00 or 2.30, it can be difficult to classify it correctly as OA or OT position. Therefore, neither clinical examinations nor ultrasound can be considered as a reference standard. However, it is documented that ultrasound is a more precise method than clinical examinations (6,7). Another limitation is that we did not record the position of the fetal spine at the level of the four-chamber view. Rotation is more likely from OP to OA positions when the fetal spine is in an oblique position in relation to the fetal head (4). Seven centers in five countries included patients. All departments were in university hospitals in a high-resource setting. This may reduce generalizability and external validity.

In conclusion, most fetuses rotate from non-OA to OA position during vacuum delivery, but clinicians should be aware of a high failure rate from non-OA positions.

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Paper three

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Descent of fetal head during active pushing: secondary analysis of prospective cohort study investigating ultrasound examination before operative vaginal delivery

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KEYWORDS: Cesarean section; duration of vacuum extraction; head–perineum distance; second stage of labor; transperineal ultrasound

CONTRIBUTION

What are the novel findings of this work?
Previous studies have shown that ultrasound examination during labor to determine fetal head station and position is more accurate than is digital vaginal examination. This study shows that measuring change in head–perineum distance using transperineal ultrasound during active pushing in women with prolonged second stage of labor provides an objective assessment of fetal head descent.

What are the clinical implications of this work?
Change in head–perineum distance measured using transperineal ultrasound during active pushing can be used to provide objective information to guide decision-making in the labor ward when prolonged second stage of labor is diagnosed.

ABSTRACT

Objectives *To investigate if descent of the fetal head during active pushing is associated with duration of operative vaginal delivery, mode of delivery and neonatal outcome in nulliparous women with prolonged second stage of labor.*

Methods *This was a prospective cohort study of nulliparous women with prolonged second stage of labor, conducted between November 2013 and July 2016 in five European countries. Fetal head descent was measured using transperineal ultrasound. Head–perineum distance (HPD) was measured between contractions and on maximum contraction during active pushing, and the difference between these values (ΔHPD) was calculated. The main outcome was duration of operative vaginal delivery, estimated using survival analysis to calculate hazard ratios (HRs) for vaginal delivery, with values > 1 indicating a shorter duration. HR was adjusted for prepregnancy body mass index, maternal age, induction of labor, augmentation with oxytocin and use of epidural analgesia. Pregnancies were grouped according to ΔHPD quartile, and delivery mode and neonatal outcome were compared between groups.*

Results *The study population comprised 204 women. Duration of vacuum extraction was shorter with increasing ΔHPD. Estimated mean duration was 10.0, 9.0, 8.8 and 7.5 min in pregnancies with ΔHPD in the first to fourth quartiles, respectively, and the adjusted HR for vaginal delivery, using increasing ΔHPD as a continuous variable, was 1.04 (95% CI, 1.01–1.08). Mean ΔHPD was 7 mm (range, −10 to 37 mm). ΔHPD was either negative or ≤ 2 mm in the lowest quartile. In this group, 7/50 (14%) pregnancies were delivered by Cesarean section, compared with 8/154 (5%) of those with ΔHPD > 2 mm ($P < 0.05$). There was no significant association between umbilical artery pH < 7.10 or 5-min Apgar score < 7 and ΔHPD quartile.*

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Conclusion *Minimal or no fetal head descent during active pushing was associated with longer duration of operative vaginal delivery and higher frequency of Cesarean section in nulliparous women with prolonged second stage of labor. © 2019 The Authors. Ultrasound in Obstetrics & Gynecology published by John Wiley & Sons Ltd on behalf of the International Society of Ultrasound in Obstetrics and Gynecology.*

INTRODUCTION

Movement of the fetal head during active pushing is sometimes used as a clinical variable to inform decision-making regarding mode of delivery. Descent of the fetal head during contraction and return of the presenting part between contractions is what clinicians call the 'yo-yo-sign' and is considered to be predictive of successful vaginal delivery. However, evidence of this is not documented in obstetric scientific literature or textbooks. A study has shown that fetal head descent before vacuum extraction, determined subjectively as 'yes' or 'no', could predict outcome of vacuum extraction[1]. Others have investigated the progress of labor using transperineal ultrasound and found a change in fetal head direction during contractions[2].

Examination of fetal head station is traditionally performed by palpation, although digital vaginal examination has been shown to be largely subjective and has poor reproducibility[3]. Ultrasound can be used during the active phase of labor, and the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) has recently published practical guidelines on intrapartum ultrasound. ISUOG recommends determining head position and descent using ultrasound when labor progress is slow and when operative delivery is considered[4]. Studies have shown that transabdominal ultrasound examination can give a more accurate diagnosis of fetal head position and is more reproducible than is digital vaginal examination[5,6]. Head station can also be determined with ultrasound using different methods, such as transperineal ultrasound[1,2,7–10]. It has been shown that women find transperineal ultrasound examination during labor less uncomfortable than they do digital vaginal examination[11,12]. The predictive value of fetal head descent is not mentioned in guidelines with regards to assisted or operative vaginal delivery[13,14].

The aim of this study was to investigate if descent of the fetal head during active pushing, assessed using transperineal ultrasound, is associated with duration of operative vaginal delivery, mode of delivery and neonatal outcome in nulliparous women with prolonged second stage of labor.

METHODS

This is a secondary analysis of a multicenter cohort study of nulliparous women with slow progress in the second stage of labor at term. Duration of vacuum extraction, according to fetal head station and rotation of the fetal head during vacuum extraction, has been reported previously[15,16]. According to a power calculation, which was performed before the multicenter cohort study was undertaken, a study population of 220 women was needed. The main outcome of the primary study was duration of vacuum extraction, which was assessed using survival analyses. Head–perineum distance (HPD) of 25 mm corresponds to station +2 and was used to discriminate between groups. To identify a hazard ratio (HR) as low as 1.5 with 80% power, using a two-tailed test with an α-level of 5%, assuming that one-third of the women would have HPD > 25 mm and two-thirds would have HPD ≤ 25 mm, and anticipating 10% censoring, 220 women needed to be included.

All included women had reassuring cardiotocography at the time of the ultrasound examination. The inclusion period was November 2013 to July 2016. Women were included at six delivery departments in five countries. The participating centers were Stavanger University Hospital, Norway; University Hospital of Bologna, Italy; Trondheim University Hospital, Norway; Queen Charlotte's and Chelsea Hospital, Imperial College Healthcare NHS Trust, UK; Lund University Hospital, Sweden; and Hvidovre University Hospital, Denmark.

Women were included when slow progress in the second stage of labor was diagnosed in accordance with local guidelines. The second stage was divided into a passive phase (< 2 h) and an active phase with pushing. The birth attendant responsible for the delivery made the diagnosis of slow progress, according to the local protocol. An ultrasound examination was performed when the woman had pushed for at least 45 min and vacuum extraction was considered. The cut-off of 45 min was chosen because Norwegian guidelines recommend that vacuum extraction should be considered after 1 h of active pushing. Fetuses were included regardless of position.

HPD was first measured between contractions and thereafter during maximum contraction with active pushing (Figure S1). Descent of the fetal head (ΔHPD) was calculated as the difference between HPD measured between contractions and HPD measured during active pushing. The main outcome was duration of operative vaginal delivery, which was estimated using survival analyses with HRs for vaginal delivery. Additionally, pregnancies were grouped according to ΔHPD quartile, and mode of delivery (vaginal delivery or Cesarean section) and neonatal outcome (pH < 7.10 in the umbilical artery and 5-min Apgar score < 7) were compared between groups.

HPD was measured as described previously[8,15]. When measuring HPD, the woman was placed in a semirecumbent position with the legs flexed at the hips and knees at angles of 45° and 90°, respectively, ensuring that the bladder was empty. HPD was measured as the shortest distance between the outer bony limit of the fetal skull and the perineum in a transverse plane on transperineal ultrasound examination. The transducer was placed in the posterior fourchette between the labia majora, and the soft tissue was compressed with firm pressure against the pubic bone. The transducer was angled until the skull contour was as clear as possible, which indicates that the ultrasound beam is perpendicular to the skull. HPD represents the remaining part of the birth canal through which the fetus has to pass. All ultrasound measurements were performed online in the labor room. A cineloop was used to assure that the shortest distance was measured. The birth attendants in charge of the delivery were blinded to the results of the ultrasound examination, and the ultrasound operators did not influence clinical management. The ultrasound examinations were performed by trained doctors and midwives.

The ultrasound devices used were a GE Voluson *i* (Stavanger, Trondheim, Lund, Bologna, Copenhagen) or GE Voluson S6 (Stavanger) (GE Medical Systems, Zipf, Austria). In London, a Samsung PT60A and a Samsung HM70 were used (Samsung Medison, Seoul, Republic of Korea). In Stavanger, Trondheim, Lund, London and Copenhagen, metal vacuum cups were preferred, whereas, in Bologna, Kiwi cups were used. Body mass index (BMI) was calculated from prepregnant weight and maternal height.

Cord blood was obtained by direct puncture of the umbilical artery, without cord clamping. Acid–base analysis was performed immediately after collecting the sample. The cut-off level of pH < 7.10 was used because this is known to be associated with adverse neonatal outcome[17,18].

The local ethics committees approved the study (reference numbers: REK 2012/1865 in Norway; 3348/2013 in Italy; REC reference 15/LO/1341 and IRAS project ID 169478 in UK; DNR 2012/808 in Sweden; and H-4-2014-038 in Denmark). All women gave written informed consent and the study was registered in Clinical Trials (identifier NCT01878591).

Statistical analysis

Cox regression analysis was used to calculate HRs as an estimate for relative risk of vaginal delivery over time in women undergoing vacuum extraction, and ΔHPD as a continuous variable was used as the test variable. HR > 1 indicates shorter survival i.e. duration of operative vaginal delivery with increasing ΔHPD. Pregnancies that underwent Cesarean section were censored at the time of the decision to perform the Cesarean section. We adjusted for prepregnancy BMI, maternal age, induction of labor, augmentation with oxytocin and use of epidural analgesia. Confounding effect was set at > 10% change in HR of the main test variable. Cox regression assumes proportional hazards, which was evaluated by log-minus-log plots.

The study population was divided according to ΔHPD quartile. Mean duration of vacuum extraction in the four quartile groups was estimated using Kaplan–Meier analysis. The associations between ΔHPD and delivery mode, 5-min Apgar score < 7 and umbilical artery pH < 7.10 were presented descriptively and compared using the chi-square test and Fisher's exact test. Data were analyzed using the statistical software package SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA).

RESULTS

The original study population comprised 222 women. HPD at rest between contractions could be measured in all cases, and HPD during pushing was measured successfully in 204 cases. Figure 1 shows a flowchart of the study population. Forty-six women had spontaneous vaginal delivery, 143 had operative vaginal delivery (all started with vacuum extraction, but seven were converted to forceps) and 15 were delivered by Cesarean section. Table 1 shows the characteristics of the study population.

Duration of vacuum extraction was shorter with increasing ΔHPD, and the estimated mean duration of vacuum extraction was 10.0, 9.0, 8.8 and 7.5 min in pregnancies with HPD in the first to fourth quartiles, respectively. Results of the multivariable Cox regression analyses are presented in Table 2. The adjusted HR for vaginal delivery, using ΔHPD as continuous variable, was 1.04 (95% CI, 1.01–1.08). None of maternal age, BMI, use of epidural analgesia, induction of labor or augmentation with oxytocin had a confounding effect. While BMI influenced the HR for vaginal delivery (dependent variable) in the Cox regression analysis, it did not change the HR for ΔHPD (independent variable), indicating that BMI had no confounding effect on ΔHPD.

Mean HPD between contractions was 27 mm (range, 1–49 mm) and mean HPD during pushing was 20 mm (range, 0–42 mm); this difference was statistically significant ($P < 0.01$). Mean ΔHPD was 7 mm (range, −10 to 37 mm); 185 cases had a positive value, showing positive advancement of the fetal head during pushing, 13 cases had a negative value and six cases had a ΔHPD

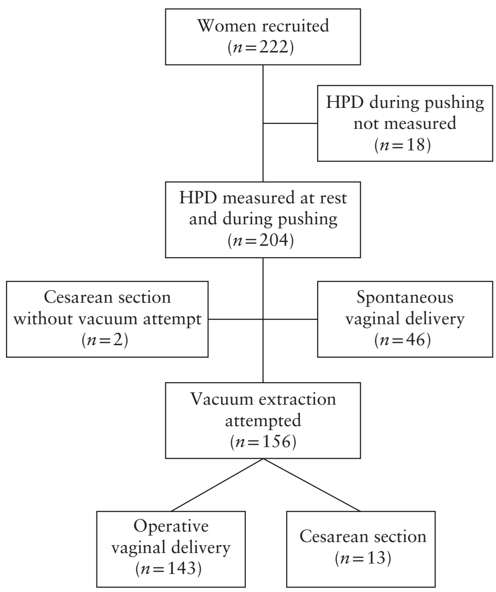

Figure 1 Flowchart summarizing inclusion and delivery outcome of study population of nulliparous women with prolonged second stage of labor. HPD, head–perineum distance.

Table 1 Characteristics of study population of 204 nulliparous women with prolonged second stage of labor

Characteristic	*Value*
Age (years)	30 (17 43)
Prepregnancy BMI	24 (18 39)
Gestational age (weeks)	40 (38 41)
Induction of labor	134 (66)
Epidural analgesia	162 (79)
Oxytocin augmentation	158 (78)
Birth weight (g)	3658 (2152 4930)
5-min Apgar score	10 (5 10)
Umbilical artery pH	7.24 (6.9 7.43)
Postpartum blood loss (mL)	400 (100 3400)
Third- or fourth-degree anal sphincter tear	14 (7)

Data are given as median (range) or *n* (%). BMI, body mass index.

Table 2 Cox regression analysis, showing hazard ratios (HR) for vaginal delivery in nulliparous women with slow progress in second stage of labor

Variable	*Unadjusted HR (95% CI)*	*Adjusted HR (95% CI)*
ΔHPD*	1.04 (1.00 1.08)	1.04 (1.01 1.08)
Maternal age	0.99 (0.96 1.03)	0.99 (0.96 1.02)
Prepregnancy BMI	1.05 (1.00 1.09)	1.05 (1.01 1.10)
Epidural analgesia	0.69 (0.47 1.03)	0.76 (0.50 1.17)
Induction of labor	0.97 (0.70 1.36)	0.95 (0.65 1.14)
Oxytocin augmentation	0.75 (0.52 1.09)	0.71 (0.46 1.08)

*Change in head perineum distance (ΔHPD) calculated as difference between HPD at rest between contractions and HPD on maximum contraction during active pushing. BMI, body mass index.

of 0 mm. We grouped pregnancies according to ΔHPD quartile and examined mode of delivery (Figure 2). ΔHPD was either negative or ≤ 2 mm in the lowest quartile. In this group, 7/50 (14%) women were delivered by Cesarean section, compared with 8/154 (5%) in pregnancies with ΔHPD > 2 mm ($P < 0.05$).

Two neonates had 5-min Apgar score < 7. pH in the umbilical artery was analyzed in 169/204 (83%) cases. One neonate had pH < 7.0 (pH 6.90 and base excess 18) and pH < 7.10 occurred in eight cases. There was no signi cant association between umbilical artery pH < 7.10 or 5-min Apgar score < 7 and ΔHPD quartile.

Median duration of vacuum extraction was 8 min (range, 2 32 min). Median number of contractions during vacuum extraction was four (range, 0 14). Whether the vacuum cup detached was recorded in 150 cases; 116 had no detachments, 31 had one or two detachments and three cases had three or more detachments. Fetal position at delivery was occiput anterior in 92% and occiput posterior in 8% of cases. Dystocia was the indication for all conversions to Cesarean section. Information about the number of contractions during the extraction attempts was available in 12 of 15 pregnancies delivered by Cesarean section. Four of these cases had more than four contractions before Cesarean section was decided.

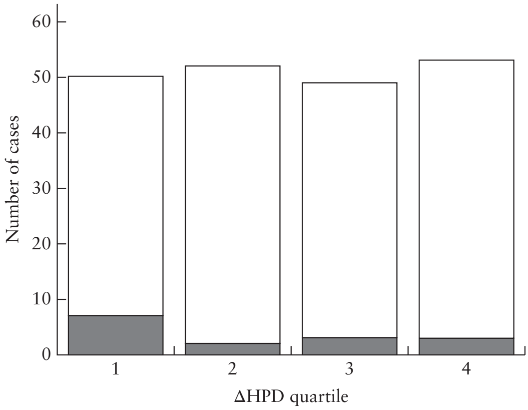

Figure 2 Numbers of vaginal delivery (□) and Cesarean section (■) in nulliparous women with prolonged second stage of labor, according to difference between head perineum distance (HPD) at rest between contractions and HPD on maximum contraction during active pushing (ΔHPD).

DISCUSSION

We found that a greater degree of head descent during active pushing was associated with shorter duration of operative delivery, and that increased frequency of Cesarean section was signi cantly associated with minimal or no fetal head descent. ΔHPD was not associated with umbilical cord pH or low 5-min Apgar score.

In 19 cases, ΔHPD had a negative value or was 0 mm. This may indicate that fetal head descent was obstructed or that the woman had an ineffective pushing technique. We believe that fetal head movement upwards in the birth canal during pushing can be explained by levator ani muscle coactivation instead of relaxation[19,20]. The effect of coactivation on labor has been assessed recently[21,22]. Youssef *et al.* and Kamel *et al.* examined nulliparous women at term before onset of labor and before induction of labor, respectively, and showed that women with coactivation had a signi cantly longer second stage of labor[21,22].

Fetal head descent is visible on the ultrasound screen during examination and visual biofeedback may be a future option to guide women to push more effectively. In a randomized controlled pilot study, 40 women randomized to either sonographic coaching or traditional coaching underwent a transperineal ultrasound at the beginning of the active phase of pushing[23]. The sonographic coaching group observed the progress of the fetal head on the screen, while the other group did not. The sonographic coaching group had a signi cantly shorter second stage of labor[23]. Gilboa *et al.* have shown that women who received visual biofeedback during labor had a more effective pushing technique and felt a stronger connection to the newborn after birth[24]. The evidence level regarding pushing method is, however, low[25]. There was no difference in maternal or neonatal outcome when comparing spontaneous and coached pushing or when comparing delayed and immediate pushing[25,26]. All of these studies investigated pushing at the beginning of the second stage. As we investigated pushing during prolonged second stage of labor, it is possible that women with minimal or no fetal head descent may bene t from coaching and receiving visual biofeedback by transperineal ultrasound.

Most failed operative vaginal deliveries which were converted to Cesarean section occurred in the group with no or minimal descent of the fetal head, but failed operative vaginal delivery also occurred in the other groups. In the fourth quartile, comprising pregnancies with the greatest ΔHPD values, there were three Cesarean sections, two of which had fetal occiput posterior position on ultrasound examination. Occiput posterior position is associated with a higher risk of emergency Cesarean section[27].

Fetal station can be measured with ultrasound using HPD[8], angle of progression (AoP)[7], progression distance[28], head symphysis distance[9], head direction[1] or intrapartum transperineal ultrasound (ITU) head station[2], and good correlation between methods has been found[1,29,30]. Ghi *et al.* assessed progression of the fetal head using AoP from 3D volumes at the beginning of the second stage of labor and every 20 min thereafter. The results showed that women with a wide AoP had a higher incidence of spontaneous vaginal delivery[31]. Henrich *et al.* performed translabial ultrasound (another word for transperineal ultrasound[32]) in women immediately before vacuum extraction[1]. They assessed direction and descent of the fetal head during pushing. The head-up sign was a predictor for successful vacuum extraction in cases with protracted labor. In cases with no descent, vacuum extraction was either dif cult or failed[1]. This is in line with the results of the current study. Tutschek *et al.* recorded transperineal digital videos of the fetal head at rest, during contractions and during voluntary pushing. They found that, between ITU head station of −2 and + 2, the average change in head direction was 10° during contraction, and between ITU head station of + 2 and + 3, there was an increased change of 18°. Time to delivery was shorter when the fetal head was below ITU head station of +2[2].

We found a signi cant association between ΔHPD and duration of operative delivery and failed vaginal delivery leading to Cesarean section. This is in accordance with a study in which AoP was measured in 20 women before vacuum extraction, in which it was found that a change in AoP of more than 15° predicted 73% of successful vacuum extractions[33].

Digital vaginal examination is subjective with poor reproducibility[3]. Position of the fetal head is determined more accurately with transabdominal ultrasound than by digital vaginal examination[5,6]. Fetal head station can also be determined objectively using transperineal ultrasound[8,10]. A signi cant advantage of ultrasound is the possibility to document the ndings by adding an ultrasound image to the patient s chart. While ultrasound should not replace clinical examination, it may add important information and may be helpful in decision-making in the labor room.

The strengths of the present study were the multicenter design, blinding of the ultrasound operators and the midwives and doctors in charge of the delivery, and inclusion of only nulliparous women with prolonged second stage of labor and no signs of fetal distress. A limitation is that only HPD was included as an ultrasound measurement in this study. AoP was measured at rest, but in only a few cases during pushing. It was dif cult to measure both HPD and AoP during the same contraction and, therefore, it was not possible to calculate ΔAoP. Another limitation is that we do not have clinical evaluation of fetal head descent during pushing. Repeatability of HPD measurement was not assessed in the present study, but this has been examined previously[34]. Additionally, umbilical cord pH was analyzed in 83% of cases as it was not measured routinely in all centers. Furthermore, we did not record if the ultrasound examination was performed by a doctor or a midwife.

In conclusion, this study shows that minimal or no fetal head descent measured using transperineal ultrasound during pushing was associated with longer duration of operative delivery and higher frequency of Cesarean section in nulliparous women with prolonged second stage of labor.

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SUPPORTING INFORMATION ON THE INTERNET

The following supporting information may be found in the online version of this article:

Figure S1 Transperineal ultrasound images showing fetal head descent during active pushing.

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