Fetal and Maternal Imaging: Ultrasound Assessment of Labor Parameters

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DECLARATION

"I certify that this work has not been accepted in substance for any degree, and is not concurrently being submitted for any degree other than that of (Doctor of Philosophy) being studied at the Universities of Greenwich and Kent. I also declare that this work is the result of my own investigations except where otherwise identified by references and that I have not plagiarized the work of others".

Signed.........Wassim A Hassan.........

Date.........27/03/2018.........

Signed...

Date...

SCIENTIFIC PAPERS

Hassan WA, Eggebo TM, Ferguson, Lees CC. A simple 2D ultrasound technique to assess intrapartum cervical dilatation: A pilot study. Ultrasound Obstet Gynecol. 2013; 41: 413-418.

Sole first author – Contribution: Devised the concept and developed method of assessment; participated in research design, performed ultrasound assessments and data collection and participated in data analysis, contributed to the writing of the manuscript.

Hassan WA, Eggebo TM, Ferguson M, Gillett A, Studd J, Pasupathy D, Lees CC. A novel method for recording the progress of labor by ultrasound: The Sonopartogram. Ultrasound Obstet Gynecol. 2014; 43:189-94.

Sole first author – Contribution: Devised the concept of a Sonopartogram (together with CCL), Participated in research design, performed ultrasound assessments and data collection, contributed to the writing of the manuscript.

Hassan WA, Eggebo TM, Salvesen KA, Lindtjorn E, Lees CC. Intrapartum assessment of caput succedaneum by transperineal ultrasound: a two-center pilot study. Australian and New Zealand Journal of Obstetrics and Gynaecology. 2015; 55: 401–403.

Sole first author – Contribution: Designed the concept (together with CCL). Performed ultrasound assessments, participated in data collection and analysis, participated in writing the manuscript.

Eggebo TM, **Hassan WA**, Salvesen KA, Lindtjorn E, Lees CC. Sonographic prediction of vaginal delivery in prolonged labor: a two-center study. Ultrasound Obstet Gynecol 2014; 43: 195-201

Second author – Contribution: assisted in study design, performed ultrasound assessments and data collection in UK side, participated in writing and reviewing the manuscript.

Eggebo TM, **Hassan WA**, Salvesen KA, Torkildsen EA, Ostborg TB, Lees CC. Prediction of delivery mode with ultrasound assessed fetal position in nulliparous women with prolonged first stage of labor. Ultrasound Obstet Gynecol; 2014. 46: 606–610

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I dedicate this thesis to

my wife Catalina, my beloved children

Adam, Sara & Alyssia and my parents Abdallah and Wafaa,

for their constant support and unconditional love.

I love you all dearly.

ABSTRACT

Today antenatal ultrasound is a necessary tool for screening and diagnosis of pregnancy. It is extensively used for fetal chromosomal risk assessment, fetal anatomy and biometry, placental localization and fetal head presentation in singleton and multiple pregnancies. It is essential for intrauterine invasive procedures and for the management of growth restricted fetuses.

Ultrasound during labor or "Intrapartum Ultrasound" has been explored widely in the last decade for the assessment of fetal presentation, fetal heart beat localization and more recently in advanced research topics such as monitoring the progress of labor and prediction of mode of delivery.

The overall concept of this thesis was to describe new methods of assessment of parameters of labor by ultrasound. For this purpose, we performed an observational study investigating the use of a novel method for assessing cervical dilatation by ultrasound during labor; a novel method for monitoring the progress of labor "sonopartogram"; assessment of caput succedaneum by transperineal ultrasound and furthermore to analyze the parameters of labor by ultrasound in prediction of mode of delivery. In addition to the above methods we will give an insight on the current established methods for assessment of the progress of labor and will compare these methods to ultrasound.

We applied innovative use of technology such as transperineal ultrasound in monitoring labor progress. Obstetrics has the opportunity to develop into an objectively guided skill. Assessment of fetal head descent no longer needs to rely on an imaginary line drawn between the ischial spines; cervical dilatation could be measured accurately using simple two-dimensional (2D) ultrasound. Monitoring the progress of labor has the opportunity to be performed solely by the means of

ultrasound. Labor characteristics such as head descent, head rotation, caput succedaneum, cervical dilatation when measured by ultrasound could predict the outcome of delivery (i.e. vaginal or caesarean delivery) in women with prolonged labor.

CONTENTS

General Introduction

Worldwide digital vaginal examinations (VE) are considered the "gold standard" method for monitoring the progress of labor and assessment of fetal head descent, cervical ripening and dilatation and fetal head position before and during labor (Friedman 1955; Friedman 1956). However assessment of cervical dilatation by digital VE is imprecise (Buckmann and Libhaber 2007) and the direction of error in the assessment is random (Tufnell et al. 1989). Assessment of fetal head station by digital examination is both subjective and unreliable (Dupuis et al. 2005). Inconsistent findings between examiners cause distress in women and loss of confidence in their care providers (Ying Lai and Levy 2002). Digital VE can be uncomfortable for the patient, especially when the examination is repeated or in the lack of adequate regional analgesia and can have negative psychological sequalae in those so predisposed (Murphy et al. 1986; Clement 1994).

The overall concept of this thesis was to describe new methods for the assessment of labor parameters by ultrasound. For this purpose, we performed an observational study investigating the use of transperineal ultrasound in the depiction of cervical dilatation during labor and comparing these assessments to digital VE (Hassan et al. 2013). Moreover, we described a new method of recording labor progress assessments based on ultrasound only (the "sonopartogram") (Hassan et al. 2014). In doing so we compared sonographic and digital VE measurements of cervical dilatation, fetal head descent and rotation in first stage of labor. We also compared clinical and ultrasound findings of caput succedaneum in first stage of labor and investigated the repeatability of ultrasound measurements (Hassan et al. 2015).

Slow progress of labor is one of the leading causes of cesarean sections (Kolas et al. 2003). Progress of labor is universally monitored by digital VE by assessing cervical dilatation, fetal head station and position (World Health Organisation). In this study we investigated whether transperineal ultrasound assessments of head-perineum distance (HPD) are predictive of vaginal delivery and time remaining in labor in first stage of labor and to compare the predictive value with that of angle of progression (Eggebø et al. 2014). Furthermore, we investigated whether ultrasound assessment of fetal head position is associated with prolonged active first stage of labor (Eggebø et al. 2015).

Pregnancy Introduction

Pregnancy or gestation is the time during which one or more offspring develops inside the uterus of a woman. Pregnancy can occur by sexual intercourse or assisted reproductive technology. Pregnancy is typically divided into three trimesters. The normal human pregnancy length is estimated to be 280 days after the first day of the last menstrual period (Bergsjo et al. 1990). Most commonly and where ultrasound is available, an accurate estimation of pregnancy length is possible by ultrasound assessment of the fetal size and relating it to gestational length (Persson and Weldner 1986). Term pregnancy is commonly acknowledged as 37 to 41 weeks gestation where most of births occur; whereas preterm pregnancy is considered as below 37 weeks gestation (Tucker and McGuire 2004). An overall pregnancy chart is shown in Figure 1. (Haggstrom 2013)

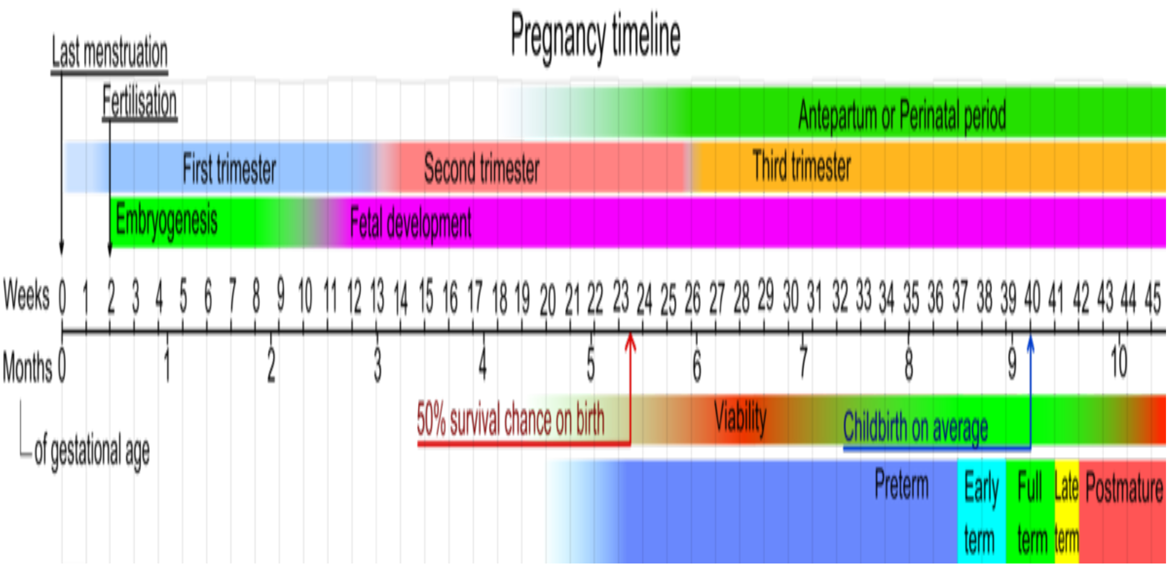


Figure 1: Definition of pregnancy timeline adopted from Haggstrom M. 2013

Pregnancies are classified as high-risk or low-risk. High-risk pregnancies are commonly associated with either maternal, fetal complications or both and women are placed under combined medical and midwifery care; whereas low-risk pregnancies are managed under midwifery care antenatally, during labor and postnatally. Should any maternal or fetal complications arise during pregnancy in low-risk women, these are transferred under consultant care accordingly. Maternal complications during pregnancy include and not restricted to diabetes, thrombophilia disease, hypertension and cardiac conditions. Fetal complications during pregnancy include and not restricted to growth disorders, congenital abnormalities and stillbirth.

As part of their antenatal care pregnant women are offered regular checks, tests including screening for common chromosomal abnormalities, and ultrasound scans. Dating scans are performed between 11 and 14 weeks gestation and anomaly scans done between 18 and 22 weeks gestation.

Pregnant women during pre-labor and labor undergo a series of abdominal and digital vaginal examinations to determine the progress of labor and fetal progress in relation to maternal pelvis. These examinations are performed by either midwives or doctors looking after women. The quantity of these assessments is variable, depending on the several factors such as progress of labor, duration of labor, and medical or surgical interventions during labor and multiple pregnancies.

According to NHS Maternity Statistics- England, there were 646,904 deliveries taking place in NHS hospitals in 2013-14 with a 3.6% drop from 2012-13. Nearly two thirds (61.8 percent, 343,797) of deliveries were spontaneous onset; 13.6 per cent (75,798) were medically induced and 13.2 per cent (73,486) were caesarean onset (Hospital Episode Statistics Analysis, Health and Social Care Information Centre 2015). Interventions during labor and delivery are common and include emergency caesarean deliveries, vaginal instrumental deliveries (forceps, ventouse). In 2013-14 caesarean deliveries accounted for around 26.2% in the UK with a 0.7 percentage point increase from 2012-13 (Hospital Episode Statistics Analysis, Health and Social Care Information Centre 2015).

a) Fetal presentation or presenting part

Fetal presentation refers to leading anatomical part of the fetus which about to be born; this is the portion of the fetus that is felt through the cervix on vaginal examination (Scheer and Nubar 1976). Equally this could be visualized by performing transabdominal or transperineal ultrasound scan (Youssef, Ghi and Pilu 2013). The presenting part of the fetus determines the presentation. Accordingly, in longitudinal lie, the presenting part is the fetal head or the breech, creating cephalic and breech presentations, respectively. When the fetus lies with the long axis transversely, the shoulder is the presenting part, thus a shoulder presentation is felt through the cervix on vaginal examination (Cunningham, MacDonald and Gant 1989).

At or near term the incidence of the various presentations is as follows: 96% for vertex (head); 3.5% for breech; 0.3% face presentation; 0.4% transverse presentation (25).

Christian Leopold (1846-1911) was the first to describe abdominal external palpation and proposed the “fourth Leopold Maneuver” which determines the relationship between the fetal head and the pelvic inlet (Leopold 1894) Figure 2.

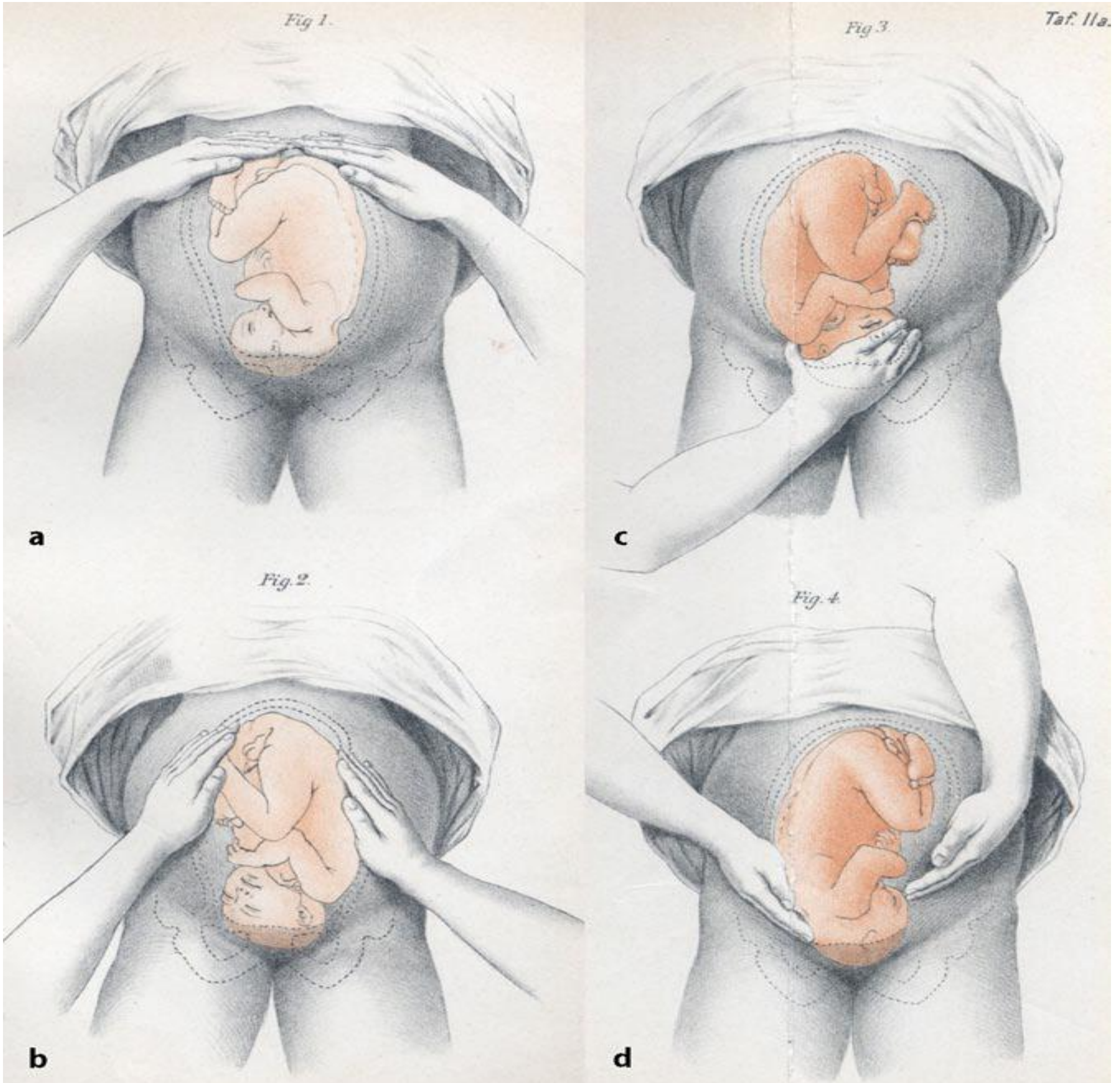


Figure 2: Leopold's maneuvers adopted from www.wikepeida.org (a, fundal grip; b, umbilical grip; c, first pelvic grip; d, second pelvic grip).

Crichton introduced the concept of "fifths palpable" of the fetal head palpable abdominally to quantify fetal head descent by abdominal palpation and vaginal examination (Crichton 1974). This technique requires a full knowledge of- and palpatory access to- the landmarks on the fetal head and on the pelvis: the occiput and the sinciput for the fetal head, and the upper border of the pubic symphysis for the pelvis (Figure 3).

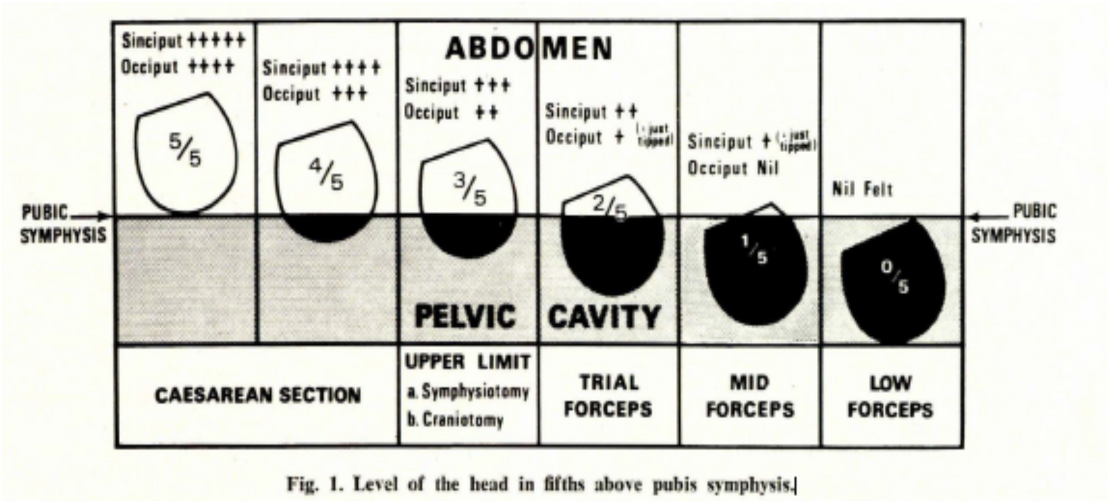


Figure 3: Level of the head in fifths palpable above pubis symphysis adopted from S.A. Medical Journal (Crichton 1974).

These methods have become essential tools in the management of labor and in the conduct of operative vaginal deliveries (Gibbs et al. 2008). However, some pitfalls in the practice has been highlighted such as incorrect alignment of the examiner's hands and arms during abdominal palpation; the fingers must be held parallel to the surface of the abdomen; issues in quantifying the amount of pressure applied by the fingers, and most importantly, the technique is not effective when the occiput is posterior. Moreover, it is known that in clinical practice it is impossible to palpate or ascertain precisely what is the largest diameter of the presenting fetal part (Crichton 1974).

b) Digital vaginal examinations

Digital vaginal examination is considered the "gold standard" for the assessment of labor parameters such as fetal head station, fetal head position or rotation, cervical ripening and dilatation before and during labor (Friedman 1955). These parameters are plotted on a "partogram" or "partograph" Figure 4., a graphic recording of progress of labor together with silent conditions of the mother (Philpott 1972).

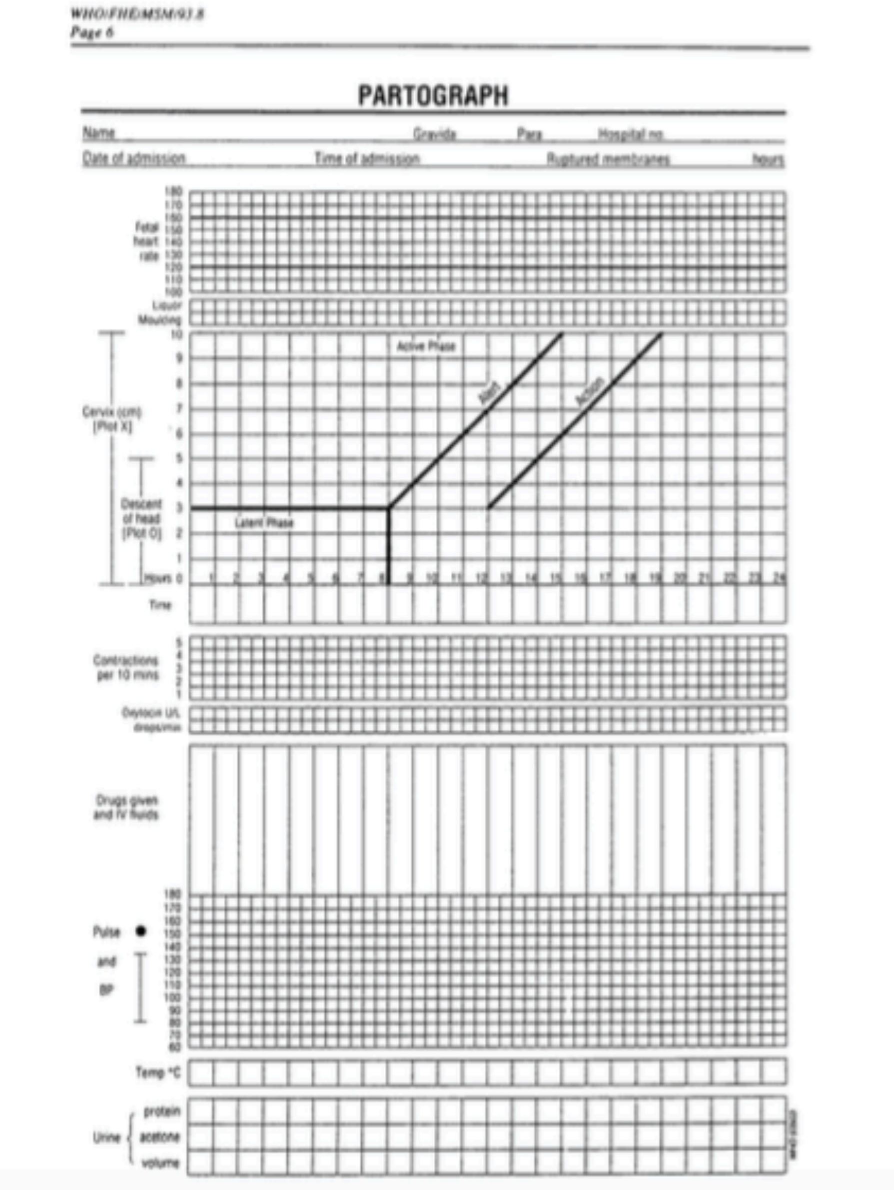


Figure 4: Partograph adopted from World Health Organisation (World Health Organisation 1994).

WHO recommended the use of partograph as a response to high level of maternal and fetal morbidity due to slow progress of labor (World Health Organisation 1994). Correctly used, the partograph certainly improves the management of labor and the outcome of pregnancy at hospital level, and probably even more at health center level (Dujardin 1992).

During labor, women are exposed to serial digital vaginal examinations to monitor labor parameters and progress of labor and are considered a routine part of intrapartum care. Digital vaginal examination is key component in the process of assisted vaginal birth where labor parameters are assessed to determine the application of forceps or ventouse suction and the likelihood of successful vaginal birth.

Although conventionally known and extensively used during labor and prelabor, digital vaginal examinations can be inaccurate and inconsistent (Dupuis et al. 2005; Molina et al. 2010). They are an imprecise measure of monitoring the progress of labor when performed by different examiners (Buckmann and Libhaber 2007; Clement 1994; Tufnell et al. 1989). Inconsistent findings between examiners have been found to cause distress in women and loss of confidence in their care providers (Ying Lai and Levy 2002).

They can be uncomfortable for the patient, especially when the examination is repeated or in the absence of adequate analgesia and can give negative psychological sequalae in those so predisposed (Murphy et al. 1986; Clement 1994). Many women experience vaginal examinations as painful (Bergstrom et al. 1992), distressing and embarrassing (Devane 1996) and invasive (Stuart 2000). They bring up issues of sexual intimacy, invasion of privacy and vulnerability (Warren 1999).

Repeated vaginal examinations also increase the risk of ascending vaginal infection: the probability of chorioamnionitis was found to range from 4% for two vaginal examinations to 10% for 13 vaginal examinations (Westover and Knuppel 1995; Seaward et al. 1997a).

In an RCOG document from 1997, the GMC has received a considerable number of complaints about improper or rough behavior during intimate examinations (Royal

College of Obstetricians and Gynaecologists RCOG 1997). *Menage et al*. suggests that physical pain, feelings of powerlessness, lack of information and unsympathetic attitude by the midwife or the doctor may contribute to psychological trauma; it has been suggested too this might have medico-legal implications (Menage 1996). Despite this, women with prolonged labor are subjected to multiple digital vaginal examinations that often serve little purpose other than documenting a dysfunctional labor. Lewin et al. surveyed 104 primiparous women about their experience of vaginal examinations found that the practice needed to be more sensitive to pain and distress, improve on information giving about possible alternative options and obtaining informed consent (Lewin et al. 2005).

Labor and delivery introduction

Labor and delivery, also known as childbirth is the ending of a pregnancy with one or more babies leaving woman's uterus (Martin 2003). In 2015 there were about 13 million births globally (The World Factbook). About 1.5 million were born before 37 weeks of gestation(Preterm birth Fact sheet No.363), while between 3 and 12% were born after 42 weeks gestation (postdates) (Buck G. and Platt 2011).

Commonly, childbirth is obtained by vaginal delivery where the contents of the uterus (baby and placenta) are exteriorized outside the vagina. This involves three stages: shortening and opening of the cervix, descent and birth of the baby through the birthing canal and delivery of the placenta (Memon and Handa 2013).

A. Assessment of labor progress and labor parameters

a. Cervical dilatation

Cervical dilatation is universally assessed by digital vaginal examinations and plotted on a partogram. It is an essential element of the progress of labor. Labor is established when cervical dilatation is 4 cm coinciding with regular uterine contractions. Regular digital vaginal examinations are required to monitor the progress of labor and cervical dilatation. Healthcare professionals looking after women during labor perform these at 4 hourly intervals. NICE recommends that progress in the first stage of labor should include cervical dilatation of 2cm in 4 hours (NICE 2007). The assessment of the cervix is considered the "cornerstone of the management of labor" (Tufnell et al. 1989) and remains the most accepted method for measuring the progress (Enkin, Keirse and Neilson 2000).

There however remains a high element of inaccuracy in assessing cervical dilatation. In 1989, Tufnel et al. used cervical simulators for a group of experienced midwives (no.36) and obstetricians (no.24) and found that no examiner correct in all cases (Tufnell et al. 1989). Another study by Robson et al in 1991 used also simulators where 52 healthcare professionals (doctors, midwives and students) found significant variation in assessment of effacement and dilatation (Robson 1991). A larger cross-sectional study of 508 women by Buchmann et al., found that clinicians differed in cervical dilatation assessments by 2cm or more in 11% of occasions and most importantly the direction of error is random (Buckmann and Libhaber 2007).

b. Fetal head station

Fetal head station describes the level of the fetal head in the birth canal. This is widely performed by digital vaginal examinations where the level of descent of fetal head is assessed against an imaginary line drawn between the maternal ischial spines and graded between -5 to +5 (-3, -2, -1, 0, +1, +2, +3). Station “0” is considered to be at the level of ischial spines. Where the fetal head reached station “0” or at ischial spines level, it is considered to be “engaged”. Engagement of fetal head is said to have occurred when the largest diameter of the presentation has passed through the pelvic brim (Akmal et al. 2003; Cunningham et al. 2001). Figure 5 shows the fetal head in relation of pelvic prim and expected assessment from digital examination.

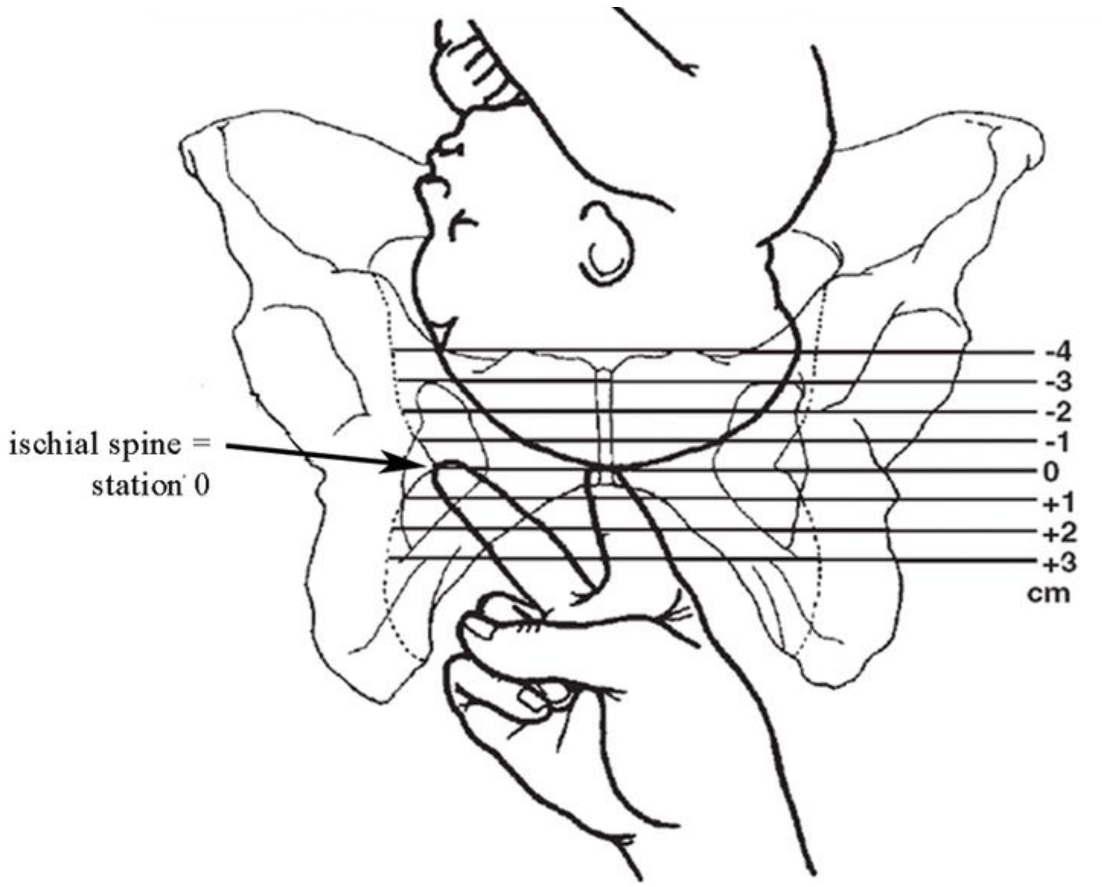


Figure 5: Fetal head station adopted from www.pinterest.com

Dupuis et al. studied the reliability of digital vaginal examinations in assessing fetal head station using a birth canal simulator (Dupuis et al. 2005). Twenty-five (25) experienced obstetricians (average experience 9 years) and 36 less experienced obstetricians (average experience of 2 years) performed the assessment of fetal head station. The canal simulator was equipped with real time sensor and a fetal head mannequin; 11 possible stations were used. Experienced obstetricians palpated incorrectly head stations (in cm) in 36-80% and less experienced obstetricians palpated incorrectly in 50-88%. Interestingly, “high” stations were palpated as “mid” or “low” in 16% and 22.4% respectively. Conversely, true “mid” and “low” stations were falsely palpated as “high” in 18.1% and 17.8% respectively. The mean group error for experienced obstetricians was 34% where for less experienced obstetricians was 30% (Dupuis et al. 2005).

c. Fetal head position or rotation

Fetal position refers to the relation of a presenting part to the right or left side of the maternal birthing canal. Accordingly, with each presentation there may be two positions, right or left. The occiput, chin and sacrum are the determining points in vertex, face and breech presentations respectively (25). Various fetal head positions are shown in Figure 6.

Head position describes the position of the fetal occiput in relation to the maternal pelvis: occiput anterior (OA), occiput posterior (OP), left and right occipitoanterior, left and right occipito-posterior. Antenatally fetal head position is palpated abdominally whereas during labor a combination of abdominal palpation and digital vaginal examinations are used.

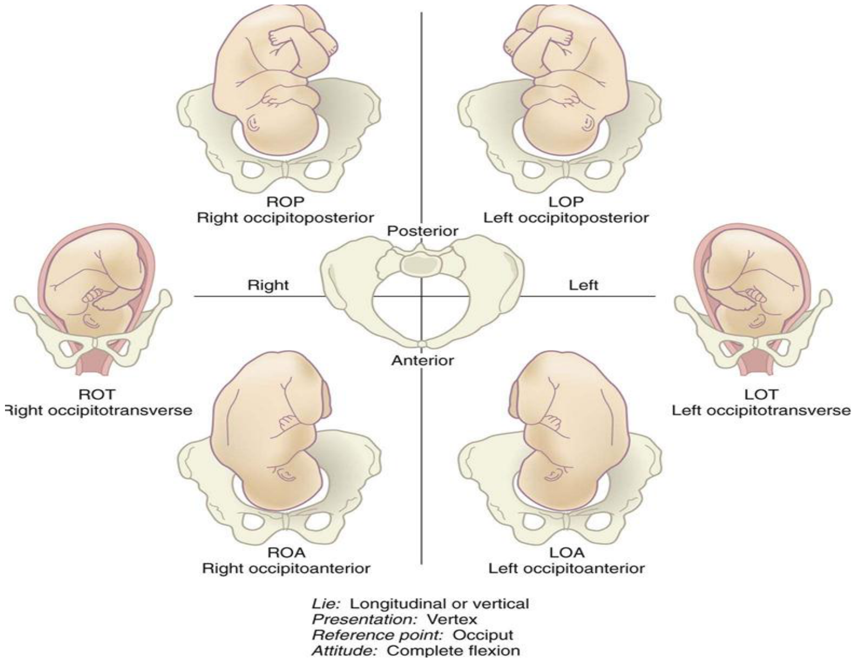


Figure 6: shows various fetal head positions during labor. Adopted from www.nursekey.com

The fetus enters the pelvis in left occiput transverse (LOT) position in 40% of cases compared to 20% in right occiput transverse (ROT) position (Caldwell and Moloy 1938). Occiput anterior positions (LOA &or ROA) represent approximately 20% of occiput presentations. Whereas, occiput posterior positions are found in about 20% of occiput presentations (Caldwell and Moloy 1938).

Akmal et al. investigated the accuracy of fetal head assessment by digital vaginal examination in 496 women in labor and compared this to ultrasound assessment (Akmal et al. 2002). They reported that digital vaginal examination failed to define the fetal head position in 33.5% of cases. In 72.5% of cases where the position was determined, the agreement with ultrasound was in 49.4% of cases only. Correct identification of fetal head position increased with advancing cervical dilatation from 20.5% at 3-4 cm to 44.2% at 8-10cm (Akmal et al. 2002). Although advancing cervical dilatation increased the chance of positive identification of fetal head position, digital vaginal examination failed to identify the correct position in the majority of cases.

Sherer et al. assessed fetal head position in the first stage of labor by comparing digital vaginal examinations to transabdominal ultrasound (Sherer et al. 2002). In 24% of cases only, digital vaginal examinations were consistent with ultrasound (95% confidence interval, 16-33). Furthermore, cervical effacement and ischial spine station significantly affected the accuracy of digital vaginal examinations. The accuracy of digital vaginal examinations was increased to 47% (95% confidence interval, 37-57) when fetal head position assessed by digital vaginal examination was considered correct if reported within ±45 degree of the ultrasound assessment (Sherer et al. 2002).

d. Caput succedaneum

Caput succedaneum is defined as a diffuse swelling of the fetal scalp caused by pressure of the scalp against the dilating cervix during labor. It may extend across the midline (as opposed to cephalhaematoma) and is associated with moulding of the head (Royal College of Obstetricians and Gynaecologists RCOG 2017); Figure 7.

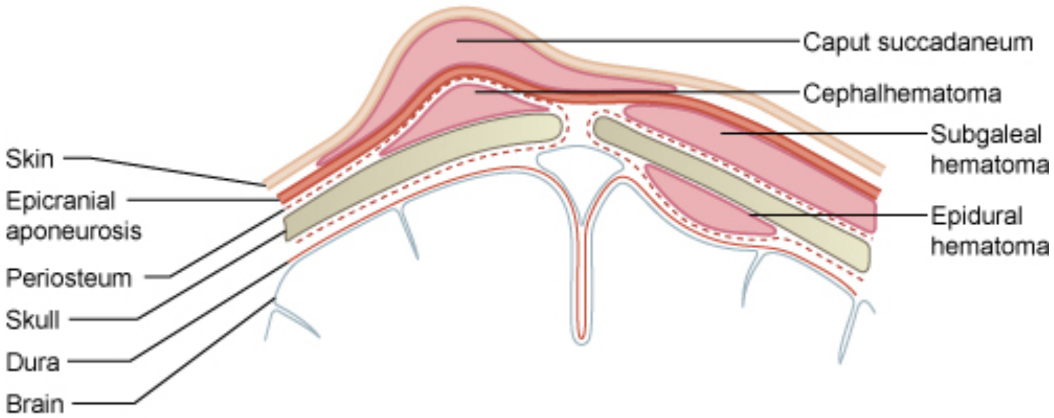


Figure 7: Caput succedaneum. Adopted from RCOG 2017.

Others define it as serosanguinous, subcutaneous and extraperiosteal fluid collection with poorly defined margins caused by the pressure of the presenting part against the cervix during labor (Fraser and Cooper 2009). Caput succedaneum normally has good prognosis and resolves within few days after delivery (Fraser and Cooper 2009). Caput does not only occur in term labor, it has been identified at 28 weeks gestation after rupture of membranes (Bats et al. 2003) and by prenatal ultrasound diagnosis mimicking an encephalocele (Winter, Mack and Cyr 1993).

Caput succedaneum is assessed conventionally during labor by digital vaginal examination (VE) and is usually recorded as either present or absent or being quantified by a number of + values (Smith 2008). Various definitions of caput exist and the key components are a diffuse and palpable welling of the fetal scalp in labor (Fraser and Cooper 2009).

B. Labor progress and slow progress of labor

In a detailed assessment of labor stages NICE defines the following: latent first stage of labor not necessarily continuous where there are painful contractions and some cervical change including cervical effacement and dilatation up to 4 cm. whereas established first stage of labor when contractions are regular and painful coinciding with progressive dilatation from 4 cm (NICE Guidance {CG190} 2014).

Second stage of labor is established when cervical dilatation has reached "full dilatation" before or in the absence of involuntary expulsive contractions. Onset of active second stage of labor is when the baby is visible or expulsive contractions with fully dilated cervix and or active maternal effort following confirmation of full dilatation of the cervix in the absence of expulsive contractions (NICE Guidance {CG190} 2014).

Third stage of labor is defined as the time from the birth of the baby to the expulsion of the placenta and membranes. Active management of 3rd stage of labor involves a package comprising the following components:

- Routine use of uterotonic drugs;
- Deferred clamping and cutting of the cord;
- Controlled cord traction after signs of separation of the placenta.

Physiological (passive) management of the 3rd stage of labor involves a package of care that includes the following components:

- No routine use of uterotonic drugs;
- No clamping of the cord until pulsation has stopped;

- Delivery of the placenta by maternal efforts (NICE Guidance {CG190} 2014).

Widely obstetricians and healthcare professionals looking after women in labor use the classical definitions of labor (Cunningham, MacDonald and Gant 1989); First stage of labor is the stage in which *cervical effacement and dilatation occurs*. It commences when uterine contractions of sufficient frequency, intensity and duration initiate effacement and dilatation of the cervix. First stage of labor ends when the cervix is fully dilated meaning the cervix is sufficiently dilated (about 10cm) to allow passage of the fetal head.

Second stage of labor begins when cervical dilatation is complete or "fully dilated ~10cm) and ends with the delivery of the newborn. Therefore, it is considered the stage of *expulsion of the fetus*. Third stage of labor begins with delivery of the newborn and ends with delivery of the placenta and fetal membranes. The third stage of labor is the stage of separation and expulsion of the placenta (25).

In addition to these classic three stages of labor, there is a period of prelabor and a latent phase of labor that precede active labor (stages 1, 2 and 3). *Hendricks et al.* identified prelabor as the period of increased uterine activity that occurs before labor and could be few days to few weeks before labor. During this time, increased uterine activity facilitates softening of the cervix, cervical effacement and some lesser degree of cervical dilatation (Hendricks 1970).

Most delivery units around the world monitor progress of labor according to the "Friedman's curve" standard. Friedman's curve is used to define "normal" length and pace of labor. If the cervix does not dilate according to these curves, patient may be assigned a diagnosis of "slow progress of labor" (Friedman 1955; Friedman 1956).

Friedman 1955, was the first to describe and monitor the length of labor and on a graph that became famous for it's name "Friedman's curve". Figure 8

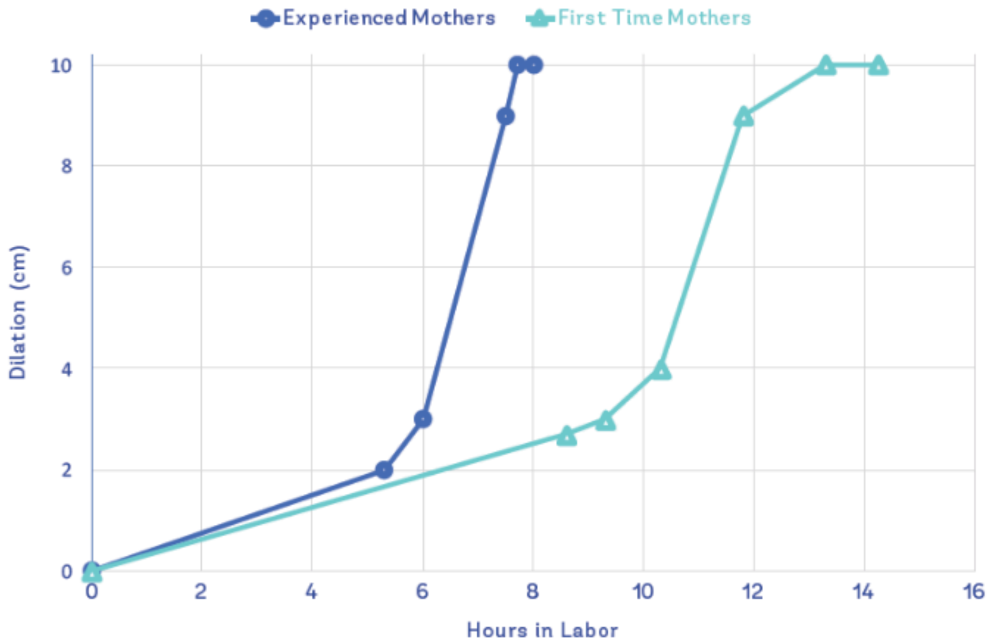


Figure 8: A depiction of Friedman's Curve, based on data from Friedman, E.A. (1955) adopted from evidencebasedbirth.com

Friedman et al found that the average length of time it took first time mothers to get from zero cm to four cm was 8.6hrs (±6 hours). Once cervical dilatation is four cm, labor progress sped up- meaning that they were in "active labor" and on average they dilated three cm per hour (±2cm) until they reached 9 cm. A slight slow down between 9cm and 10cm was noticed. The average length of time it took to get from four cm to ten cm was 4.9hrs (±4 hours). The average length of second stage (pushing) was one hour (±0.8hours). The importance of this study was significant at that time because it was the first study that described labor in a way that has never been done before. Although it was published more than 60 years ago, Friedman's curve still serves as the basis of how most obstetricians define normal labor (Gabbe, Niebyl and Simpson 1986).

NICE recommends that progress in the first stage of labor should include cervical dilatation of 2cm in 4 hours, descent and rotation of the fetal head, changes in strength, duration and frequency of contractions (NICE 2007).

Worldwide several expressions are used for obstructed labor such as labor dystocia, slow or abnormal progression of labor, failure to progress, and first or second stage labor arrest. Dystocia of labor is characterised by slow progress of labor arising from inefficient uterine contractions, abnormal fetal presentation or position, inadequate bony pelvis or abnormalities of the soft tissue of the mother's pelvis.

Slow progress of labor is common in nulliparous women and is associated with considerable maternal and perinatal morbidity and mortality due to infections, uterine rupture and operative deliveries (Ronel et al. 2012; McClure et al. 2009). It has been suggested that up to one third of nulliparous women experience slow progress of labor and particularly delay in first stage of labor (Kjaergaard et al. 2009). In clinical practice identifying the precise cause of slow progress of labor can be challenging. Therefore, "failure to progress" has become an increasingly common description of slow progress of labor and one of the leading causes for caesarean section (Boyle et al. 2013).

Women who had longer labor were more likely to have an infection of the uterus (23.5% vs. 12.5%) and at increased risk of emergency cesarean section (13.5% vs. 6.1%) (Cheng et al. 2010). Another study suggested that mothers who had failure to progress in the first stage of labor were more likely to be anemic after birth (45% vs. 23%) (Sheiner et al. 2002). Women diagnosed with prolonged labor are exposed to higher number of digital vaginal examinations.

Furthermore, Cheng et al. suggested an increased rate of neonatal admissions (babies admitted to the neonatal unit intensive care unit) for babies born after a first stage of labor longer than 30 hours (9.8% vs. 4.7%) in a study of more than 10.000 first-time mothers in the US (Cheng et al. 2010). Also Sheiner et al. concluded that babies born after a prolonged labor were more likely to have Apgar scores <7 at 5 minutes of birth (1.3% vs. 0.2%); no difference in neonatal mortality was noted (Sheiner et al. 2002).

Ultrasound introduction

Ultrasound is a high frequency sound, exceeding the upper limit of the human hearing (20.000 cycles per second -20KHz). Medical ultrasound uses frequencies from 1.000.000 to 40.000.000 HZ (1 to 40 megahertz MHZ). Ultrasound wave is graphically displayed as a sine wave in which the peaks and nadirs represent the areas of compression and rarefaction. Sound waves are characterised by the following parameters: frequency, amplitude, velocity, wavelength. The wave equation: product of wave (λ) and frequency (f) represents the velocity C of the sound wave. $C= \lambda f$.

The velocity through soft tissue is assumed to be constant (1540m/s) hence there is an inverse relationship between frequency and wavelength. Ultrasonic imaging uses frequencies of 2 megahertz and higher; the shorter wavelength allows resolution of small internal details in structures and tissues. The power density is generally less than 1 watt per square centimetre, to avoid heating and cavitation effects in the object under examination. Ultrasound is considered safe in pregnancy and arguably is the most common used diagnostic procedure in obstetrics (Abramowicz 2013).

The use of ultrasound on the labor ward has been for limited purposes including detection of fetal heart, identification of fetal lie or presentation (for example cephalic or breech). Over the last decade intrapartum ultrasound was introduced in researching the parameters of labor progress such as fetal head descent, fetal head position, cervical dilatation, analysis of pelvic diameters and prediction of mode of delivery. Furthermore intrapartum ultrasound was researched in the assessment of the fetal spine, fetal head position and fetal head rotation during first and second stage of labor in the context of diagnosing persistent op position at birth, assisting in the choice of instrumental delivery (Blasi et al. 2010; Akmal et al. 2002; Akmal et al. 2003; Akmal et al. 2004; Ghi et al. 2009a). Transabdominal ultrasound was used at earlier stage where researchers studied fetal spine position, head position, and compared to vaginal examinations in the prelabor and labor. Other studies used transvaginal ultrasound to assess cervical length in the context of prediction of induction of labor and vaginal birth. Subsequently, translabial and transperineal ultrasound were used for assessment of fetal head station, position, and prediction of mode of delivery in first and second stage of labor.

Obstetrics has remained resilient to the “high-tech” developments in the field of medicine over the last three to four decades particularly in the assessment of labor progress. There is an exhaustive use of subjective methods for the determination of labor progress and labor parameters. These, inadvertently, could lead to inaccurate assessments and inappropriate decisions mostly in the management of obstructive labor. Unfortunately, these decisions have significant repercussions on the care of women and on future pregnancies. It is quite obvious there is a need for objective and repeatable measurements of the cervical dilatation and the most obvious imaging technology for this is ultrasound.

Intrapartum ultrasound requires the use of an ultrasound machine provided with 2D probe. The use of ultrasound during labor does not necessarily advocate for the provision of ultra-advanced ultrasound technology and worldwide, most delivery units have the ultrasound machines with 2D transducer and on their premises. Figure 9 shows illustrative depiction of transabdominal and transperineal or translabial ultrasound.

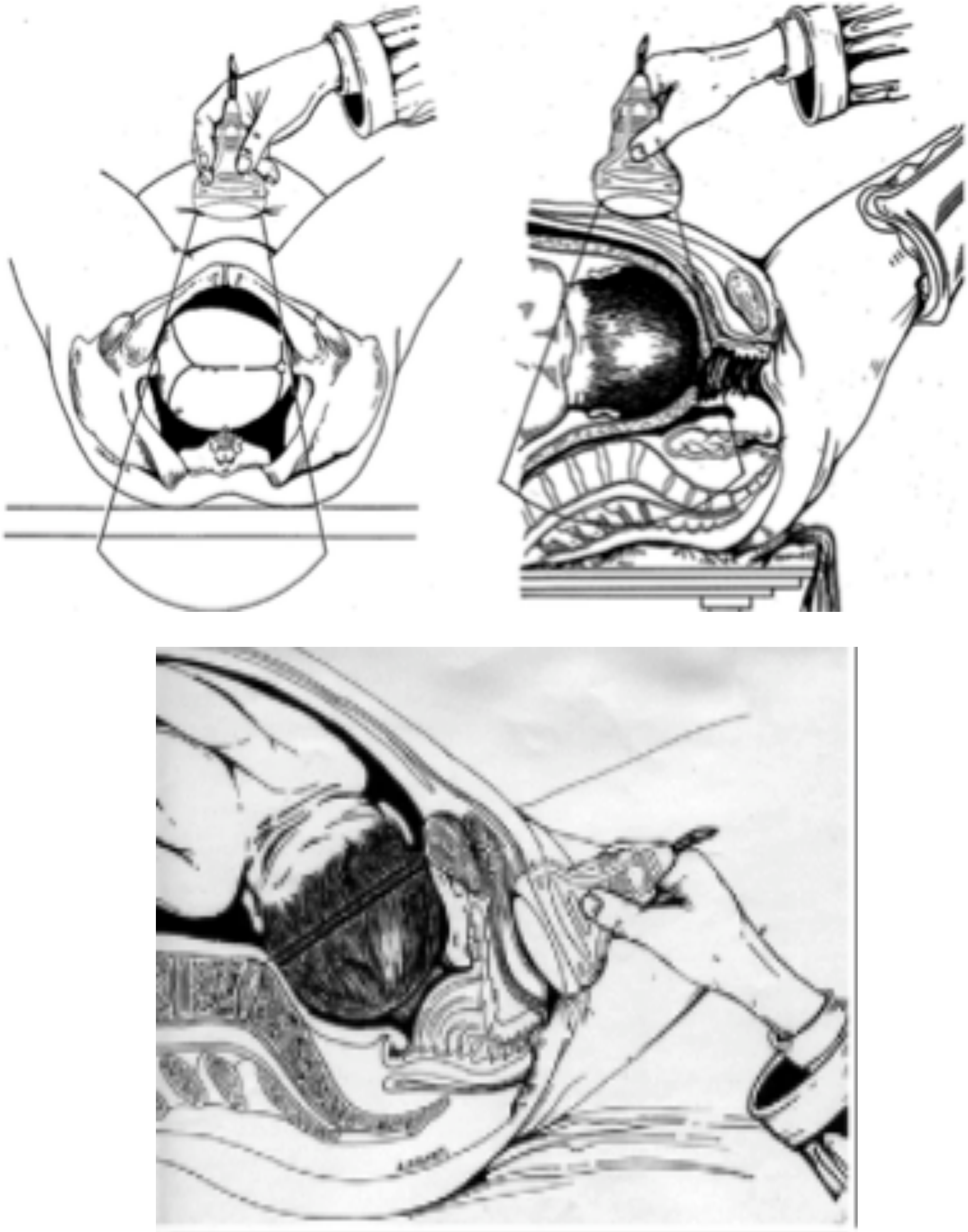


Figure 9: Illustration of transabdominal, transperineal or translabial ultrasound (adopted from RadiologyKey.com: The Use of Two-Dimensional (2D) and Three-Dimensional (3D) Ultrasound in the First stage of Labor).

Intrapartum ultrasound methods

1. Assessment of fetal head position or rotation:

The mechanism of human labor includes cardinal movements of the fetus that comprises of engagement, descent, flexion, internal rotation, extension, external rotation and expulsion. Research has shown that ultrasound is more useful and accurate tool in assessing fetal position than digital examination.

Intrapartum ultrasound was researched in determining the fetal head position and comparing to digital vaginal examinations. Akmal et al. studied the accuracy of fetal head position by digital vaginal examination during labor and compared to ultrasound assessment of fetal head position. Fetal head position was determined by ultrasound in all 496 women included in the study (Akmal et al. 2002). Souka et al. examined the feasibility of transabdominal ultrasound for determining fetal head position during labor and compared to digital vaginal examinations. The group also studied by ultrasound, the rotation of fetal head in normal and obstructed labor. Ultrasound assessments were performed longitudinally in first and second stage of labor. Digital vaginal examination was found less accurate than ultrasound and particularly in cases of obstructed labor when medical intervention is ore likely to be needed. The study proved the usefulness of ultrasound in prediction and diagnosis of difficult and prolonged labor (Souka et al. 2003). Both studies showed a large discordance between digital vaginal examinations and ultrasound assessments.

It is widely recognized that persistent occiput posterior position is a well-known cause of abnormal labor and associated with increased rate of operative vaginal and caesarean deliveries (Akmal et al. 2004; Cheng, Shaffer and Caughey 2001). Therefore, arguably, the identification of fetal head position or rotation during labor could play an important role in managing patients with persistent occiput posterior positions. Persistent occiput posterior positions occur in approximately 5% of deliveries and 20% at labor onset (Ahn and Oh 2014). Occiput posterior positions during labor mostly change to anterior positions at full dilatation. It has been suggested that occiput posterior positions at delivery are initial posterior positions rather than mal-rotation from anterior positions (Akmal et al. 2004; Cheng, Shaffer and Caughey 2001). Blasi et al. (Blasi et al. 2010) investigated whether fetal head and spine positions in second stage of labor could be practical indicators for predicting occiput posterior position at delivery. In a prospective cohort study, 100 singleton pregnant women underwent intrapartum ultrasound during first and second stage of labor. Positions of fetal head and spine were defined. 51% of cases showed occiput posterior positions during first stage of labor, however majority of these cases rotated to an anterior position before delivery. 23 cases with occiput posterior position in second stage were recorded and only 6 cases were occiput posterior at delivery. Fetuses with spine anterior were all born in occiput anterior position. Conversely, fetuses with occiput posterior position at delivery all had posterior spine during second stage of labor (Blasi et al. 2010). Albeit, this was a small number of cases in a pilot study and further large sample sizes could provide more useful information on the management of occiput posterior positions.

Mostly, the assessment of fetal head position and rotation is done by transabdominal ultrasound in first stage of labor, whereas in second stage of labor a combination of transperineal ultrasound and transabdominal approach is frequently being used (Blasi et al. 2010; Akmal et al. 2003; Akmal et al. 2002; Akmal et al. 2004; Ghi et al. 2009a).

Ariel Zimerman showed useful depiction of transabdominal and transperineal ultrasound imaging of different fetal head positions illustrations in a chapter book: “The Use of two-Dimensional (2D) and Three- Dimensional (3D) Ultrasound in the First Stage of Labor” (Malvasi 2012).

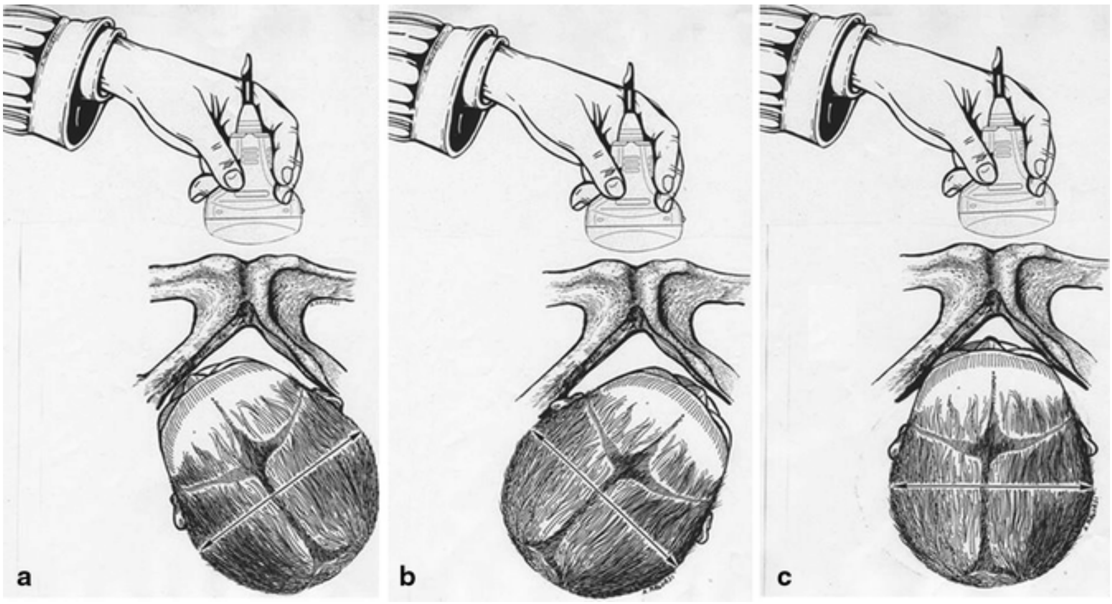


Figure 10: This image demonstrates the posterior occiput position of the fetal head: a) left posterior occiput position, b) right posterior occiput position, c) median posterior occiput position. Adopted from (Malvasi 2012).

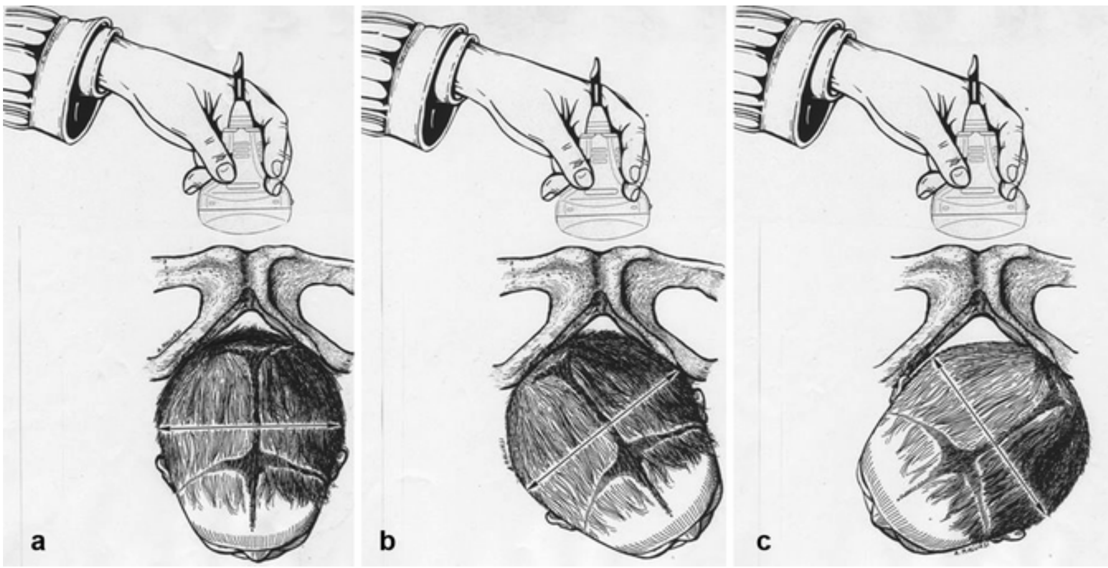


Figure 11: This image demonstrates the anterior occiput position of the fetal head: a) median anterior occiput position, b) right anterior occiput position, c) left anterior occiput position. Adopted from (Malvasi 2012).

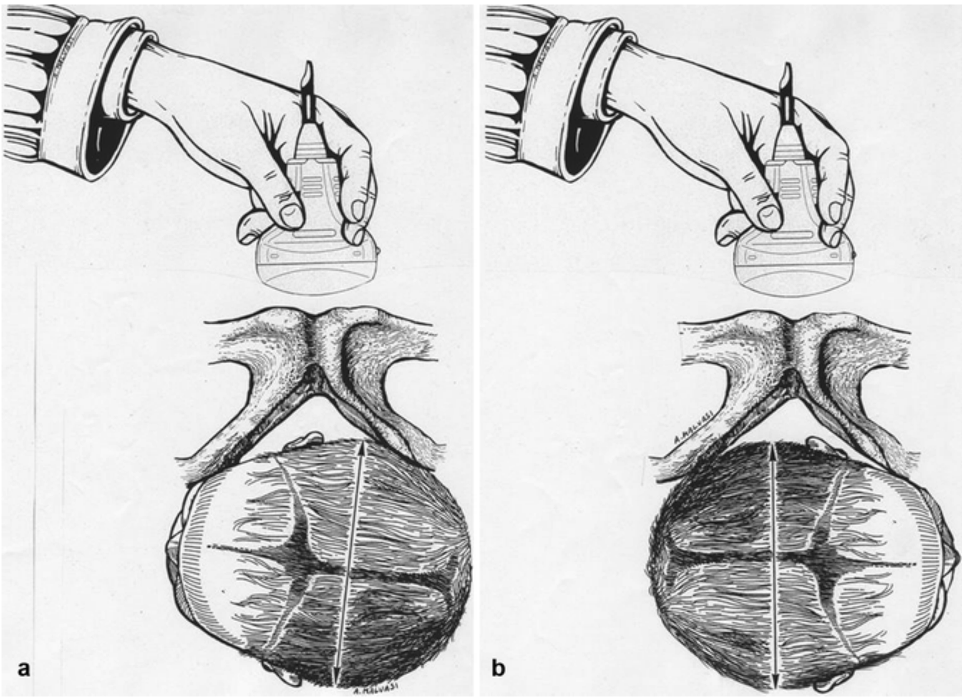


Figure 12: This image demonstrates the transverse occiput position of the fetal head: a) left transverse occiput position and b) right transverse occiput position. Adopted from (Malvasi 2012).

Figure 13: This image illustrates intrapartum translabial 2D ultrasound imaging maternal and fetal head and anatomical landmarks. Adopted from (Malvasi 2012).

2. Fetal head station or descent:

Conventionally fetal head station or descent has been assessed against the maternal ischial spines where station zero is considered that the lower most fetal presenting part is at the level of ischial spines. This is performed widely by digital vaginal examinations. However these are inaccurate and unreliable. We will explore the most researched ultrasound markers or parameters for fetal head station or descent.

Head-perineum distance HPD

Eggebo et al. in 2006 was first to describe head-perineum distance by ultrasound (Eggebø et al. 2006). This is measured by calculating the shortest distance from the perineal skin surface to the utmost bony limit of the fetal skull in a transverse view measured by an ultrasound transducer placed at the perineum (Figure 14). The authors described the method as quick, easy to learn, and well tolerated to predict time to delivery in pregnancies with prolonged rupture of membranes. Variation in measurements may be noted depending on the degree of compression of the soft tissue of the perineum. Furthermore, this method is unreliable when the fetal head is not engaged (Eggebø et al. 2006).

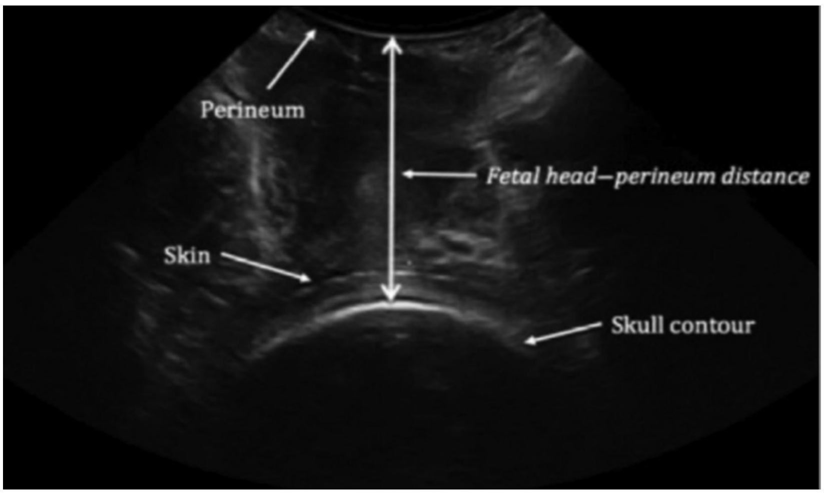


Figure 14: Head-perineum distance measured as the outer bony limit of the fetal skull and the perineum (Eggebo et al).

The same group evaluated fetal head-perineum distance by transperineal ultrasound before induction of labor and compared this distance to maternal factors such as Bishop score, cervical length and occiput position (Eggebø et al. 2008). 275 women admitted for induction of labor. Cervical length was measured by transvaginal ultrasound examination and fetal head position assessed by transabdominal ultrasound. Receiver-operating characteristics (ROC) curves were used for evaluating successful vaginal delivery. Areas under the ROC curve for prediction of vaginal delivery were 62% (95% CI, 52-71%) for fetal head-perineum distance ($P = 0.03$), 61% (95% CI, 51-71%) for cervical length ($P = 0.03$), 63% (95% CI, 52-74%) for cervical angle ($P = 0.02$), 61% (95% CI, 52-70%) for Bishop score ($P = 0.03$) and 60% (95% CI, 51-69%) for BMI ($P = 0.05$). The study concluded that fetal head-perineum distance measured by transperineal ultrasound can predict vaginal delivery after induction of labor with a predictive value similar to that of ultrasound measured cervical length and to the Bishop score (Eggebø et al. 2008).

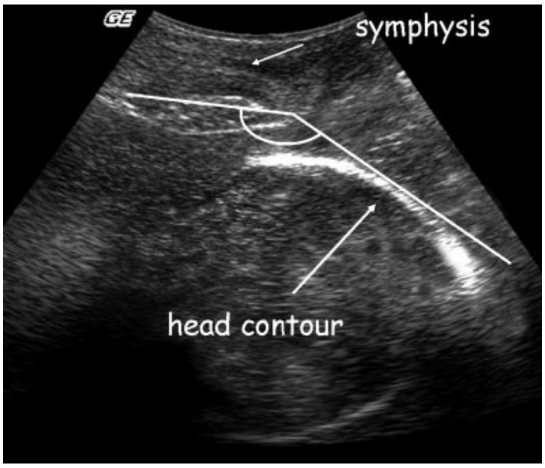
Torkildsen EA et al. in 2011 (Torkildsen, Salvesen and Eggebø 2011) investigated the fetal head-perineum distance and angle of progression with 2D and 3D transperineal ultrasound in prediction of outcome of labor in first stage of labor. 110 primiparous women with singleton pregnancies were included and vaginal delivery vs. caesarean section was the primary outcome. Cesarean section was performed in 25% of the women. Areas under the ROC curves for prediction of vaginal delivery were 81% (95% confidence interval (CI), 71-91%) ($P < 0.01$) and 76% (95% CI, 66-87%) ($P < 0.01$) for fetal head-perineum distance and angle of progression, respectively, as measured by 2D ultrasound and 66% (95% CI, 54-79%) for digital assessment of fetal station (P = 0.01). In 50% of women fetal head-perineum distance was ≤ 40 mm and 93% (95% CI, 83-97%) of them delivered vaginally vs. 18% (95% CI, 5-48%) with distance > 50 mm. In 48% of women the angle of progression was ≥ 110° and 87% (95% CI, 75-93%) of them delivered vaginally vs. 38% (95% CI, 21-57%) with angle < 100°. Results from 2D and 3D acquisitions were similar (Torkildsen, Salvesen and Eggebø 2011).

These studies have evaluated head-perineum distance in first stage of labor in normal and prolonged labor. However the assessment of head-perineum distance in second stage of labor is not well researched.

Angle of progression:

The angle of progression (AOP) is defined as the angle between a line drawn through the midline of the pubic symphysis and a line running from the inferior apex tangentially to the fetal skull (Figure 15). Barbera AF was the first to describe the angel of progression and went to develop a geometric model from computed tomographic (CT) images in non-pregnant women that clinically would reflect an objective assessment of the fetal head station during labor (Barbera et al. 2009a). CT images and transperineal ultrasound images Figure 15 (a, b) were correlated to obtain an angle between the long axis of the symphysis and the midpoint of the imaginary line connecting the two ischial spines conventionally defined at zero station was found to be 99 degree. From this angle, geometric model was built by assigning mean angle each different station, for example (station -2 corresponds to a mean angle of 85 degree, station 0 corresponds to 99 degree and station +2 corresponds to 113 degree angle) Table 1. The group reported very poor correlation between the digital vaginal examinations and the transperineal ultrasound assessments. An agreement of 89% and

100% was only observed with ±2 cm variation, denoting that every time clinical assessment of station at zero (0), the real station may vary between -2 and +2 (Barbera et al. 2009a).



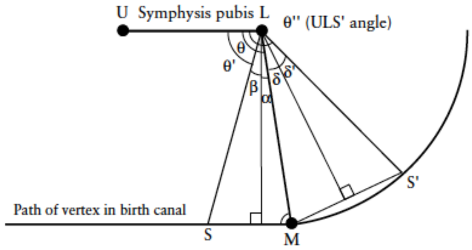


Figure 15 (a): transperineal ultrasound image sagittal view showing long axis of the pubic symphysis. Fetal head contour and line extending from the most inferior point of the symphysis tangentially to the fetal skull contour. (b): Geometric model for assessing a specific angle to each computed tomographic section in both upper and lower segments of the birth canal.

Station	*Angle (°) (mean (SD))*
−5	65 (5)
−4	71 (6)
−3	78 (6)
−2	85 (6)
−1	92 (6)
0	99 (6)
1	106 (7)
2	113 (7)
3	120 (7)
4	127 (7)
5	135 (8)

Table 1: Mean and SD of the calculated pelvic angle for each theoretical clinical station

Barbera et al. also performed reproducibility analysis of transperineal ultrasound in measuring angle of progression in 75 women during labor (Barbera et al. 2009b). They have used the term “angle of head descent” instead of angle of progression in their study. There was a significant linear correlation between the angle of descent measured by transperineal ultrasound and the clinical station assessed by digital vaginal examination ($p<0.001$). It was found that an angle of at least 120 degrees measured during second stage of labor was always associated with subsequent spontaneous vaginal delivery. The authors concluded that the angle of fetal head descent measured by transperineal ultrasound is an objective, reproducible and non-invasive technique that uses precise landmarks to assess fetal head descent (Barbera et al. 2009b).

Kalache et al. investigated the ‘angle of progression’ measured by transperineal ultrasound in prolonged second stage of labor in occipitoanterior positions (Kalache et al. 2009). The ‘angle of progression’ is the same angle used by Barbera et al. (Barbera et al. 2009b) as the ‘angle of descent’. 41 women with prolonged second stage of labor were included. When the angle of progression was 120 degrees, the probability of either an easy and successful vacuum extraction or spontaneous vaginal delivery was 90% ($p=0.0001$).

Magnetic Resonance Imaging (MRI) was used in the context of establishing a relationship between the fetal head station and the angle of progression assessed by transperineal ultrasound *Bamberg et al.* in 2012 (Bamberg et al. 2012). A significant correlation was established between the angle of progression and the distance between the presenting fetal part and the level of the maternal ischial spines. The group reported that station zero would correspond to an angle of progression at 120 degree, however the validity of this technique is questionable because of the lack of sonographic depiction of the ischial spines, furthermore the statistical description in this study is only valid for occipitoanterior position.

Head direction and angle of descent:

Intrapartum sonography can objectively assess the mechanisms of fetal head descent in maternal pelvis by analyzing fetal head station sonographically against landmarks in the maternal pelvis. Mechanisms of fetal head descent were first described and researched by *Henrich W* (Henrich et al. 2006) who used intrapartum translabial ultrasound in second stage of labor. The same group studied the assessment of fetal head station, head direction and angle of descent (angle of progression) in a prospective observational study of 50 laboring women with singleton pregnancies (Tutschek et al. 2011). They used the term “translabial ultrasound” instead of transperineal ultrasound and the probe was placed sagittal to include the whole length of pubic symphysis that serves as a reference axis for head direction. An example of the images produced is shown in Figure 16. In each image, the ‘infrapubic line’ was placed perpendicular to the long axis of the symphysis. The plane of the infrapubic line is 3 cm cranial to a parallel plane passing through the ischial spines. The direction of the longest visible axis of the fetal head was measured with regard to the long axis of the symphysis and defined as head direction, where positive angles correspond to upward directions and negative angles correspond to downward directions. The head station was measured 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 3 cm for the level of the ischial spines. The angle of descent or angle of progression was measured between the symphysis and the tangent of the fetal skull as previously described by other authors.

The group reported operative or spontaneous vaginal delivery in 97% for a head station greater than +2, 94% when the head direction was >22 degree and 94% when the angle of descent was greater than 135 degree. It was concluded that intrapartum translabial ultrasound is a simple technique that improves the understanding of normal and abnormal labor, enables objective measurement of birth progress (Tutschek et al. 2011).

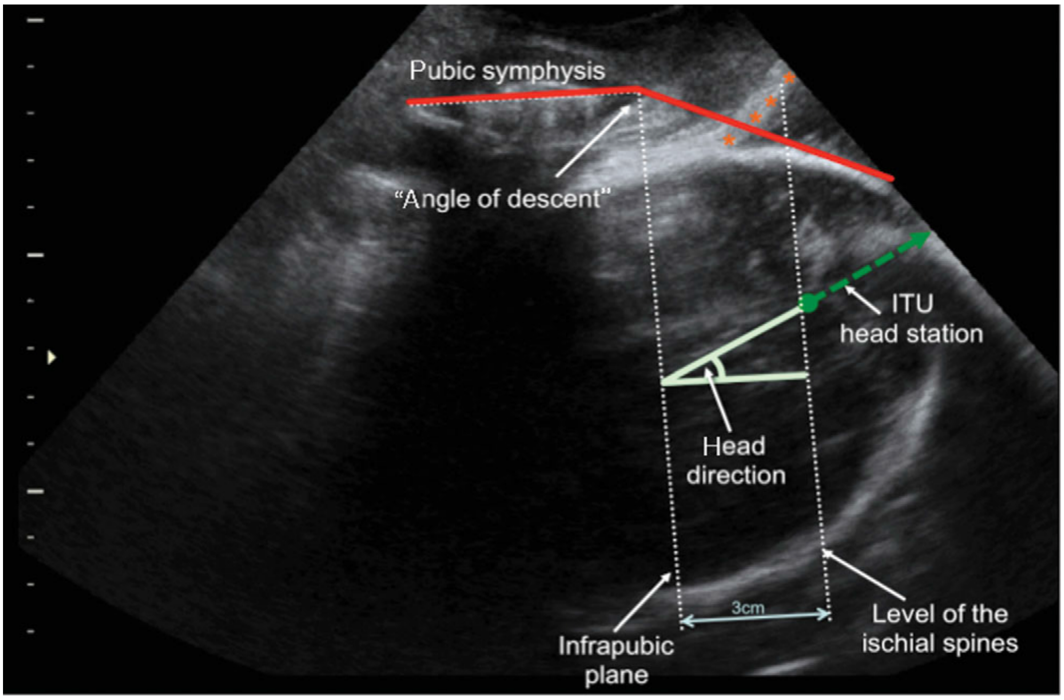


Figure 16: Intrapartum translabial ultrasound (ITU). Typical image with annotated ITU parameters. Mid-sagittal translabial ultrasound shows the fetal head in relation to the long axis of the pubic symphysis. The parallel plane through the ischial spines is 3cm below the infrapubic line, and is used to measure true head station (ITU station). Head direction (degrees upwards or downwards with regard to the long axis of the symphysis) and the angel of descent (tangent to the fetal head from lower margin of

the pubic symphysis) are the two other parameters. Adopted from Tutschek et al. (Tutschek et al. 2011)

Henrich also described head direction with respect to the long axis of the pubic bone. This concept is reasonable taking in consideration the cardinal movements of the fetal head. Horizontal or downward head direction is associated with low success rate for operative vaginal delivery. Ghi et al. did another study that assessed head direction (Ghi et al. 2009b); 60 patients in second stage of labor were included. Serial transperineal ultrasound in a sagittal section was performed using digital examination for assessing station. The downward, horizontal, and upward directions of the fetal head were ≤+1, ≤+2, and ≥+3 cm from the ischial spine, respectively. The probability of a station ≥+3 cm was especially high with an upward direction of the head, combined with a rotation <45°.

Dietz et al. in 2005 described intrapartum assessment of fetal head engagement by translabial ultrasound in a prospective study of 139 nulliparous women and compared to vaginal examinations and abdominal palpation. The method used in this study was difficult to reproduce, however this ultrasound technique has helped significantly future researchers in identifying more reproducible methods of assessment of fetal head engagement. Moreover, the study found a significant correlation with abdominal palpation. Bishop scores were compared with translabial assessment of head engagement in 112 women who agreed to vaginal assessment. Bishop scores were strongly correlated with translabial ultrasound measurements ($p<0.001$). Translabial ultrasound assessment of fetal head engagement seemed to be straightforward with no significant technical difficulties. They concluded that translabial ultrasound assessment of fetal head engagement could play a significant role in prediction of mode of delivery either when assessed on its own or in combination with other known predictors of mode of delivery such as maternal age (Ecker et al. 2001), body mass index (Murphy et al. 2001) and cervical length (Rozenberg, Goffinet and Hessabi 2000).

Head-symphysis distance:

Another ultrasound parameter for assessing fetal head descent was introduced by Youssef et al. (Youssef et al. 2013a) Head-symphysis distance is the distance between the lower margin of the symphysis pubis and the nearest part of the fetal skull along a line crossing perpendicular to the long axis of the symphysis pubis. In their study, 3D ultrasound was used and measurements were correlated with digital vaginal examinations of fetal head station and with angle of progression. Measurements of HSD showed high intraobserver (ICC 0.995; 95% CI, 0.991-0.997) and interobserver (ICC 0.991; 95% CI, 0.984-0.995) reliability. HSD showed significant negative correlation with both fetal head station and AOP (Youssef et al. 2013a). This method has significant limitations that could make it difficult to reproduce; when fetal head station is considered at -3 and above, this method is not reliable, as the fetal head has not passed the pubic bone. Furthermore, the study was not tested in occiput posterior positions particularly where occiput posterior positions are acknowledged to have abnormal labor progress.

3. Assessment of cervical dilatation:

Cervical dilatation is considered an essential indicator of the progress of labor (Letic 2003). Accurate assessment of cervical dilatation is crucial for the management of labor. However the assessment of cervical dilatation by digital vaginal examination can be inaccurate, inconsistent and insensitive (Dupuis et al. 2005; Molina et al. 2010; Phelps et al. 1995).

The first evaluation of intrapartum cervical dilatation by electromechanical devices was trialed by Nizard et al. in 2009 (Nizard et al. 2009). They conducted a study in France, US, Israel and included 188 women with singleton pregnancies during active stage of labor. In total, 333 measurements were obtained, however 90 were excluded as women were fully dilated. They used a magnetic position tracking system including a software and ultrasound technology. The method has proven unsuccessful in tracking cervical changes during labor, due to the complexity of the device and its applicability.

Zimmerman et al. used 3D ultrasound to assess cervical dilatation during labor. Three-dimensional volumes from 52 patients were collected and reviewed by different examiners who were blinded from clinical findings (Zimerman et al. 2009). Twenty-four patients were examined during the latent phase of labor (0-4cm) and 28 patients during active phase of labor (5-10cm cervical dilatation). Positive correlation was noted with digital examination findings (r^2=0.609, 0.587, and 0.469 respectively; all $P<.001$). Although the authors concluded it is feasible to assess cervical dilatation by 3D ultrasound, it was not sufficiently reproducible to replace digital vaginal examination in labor. Furthermore, training healthcare professionals on delivery units in this technology is not feasible and providing 3D ultrasound machines on the labor ward remain an impractical option. However, this study has a positive contribution in introducing intrapartum ultrasound for the assessment of cervical dilatation.

The first method to describe the assessment of cervical dilatation during labor by 2D ultrasound was published by Hassan et al. in 2013 (Hassan et al. 2013). Cervical measurements were obtained by transperineal 2D ultrasound and compared to conventional digital vaginal examinations. This study will be covered in detail in this thesis.

OBJECTIVE

The overall concept of this thesis is to describe the use of ultrasound methods for the assessment of labor progress and namely fetal head rotation, fetal head descent, cervical dilatation, and caput succedaneum; and to describe a new tool for monitoring the progress of labor (sonopartogram). Furthermore, will seek evidence for the use of intrapartum ultrasound in predicting the outcome of delivery in normal and abnormal labor. We applied innovative technology such as transperineal ultrasound during labor to assess cervical dilatation, head perineum distance, angle of progression and caput succedaneum.

More specifically for the purpose of monitoring the progress of labor by ultrasound we studied the following:

- Intrapartum cervical dilatation by 2D transperineal ultrasound
- Novel method for recording the progress of labor by ultrasound
- Intrapartum assessment of caput succedaneum by transperineal ultrasound

And for prediction of mode of delivery by ultrasound we studied the following:

- Prediction of vaginal delivery by ultrasound in prolonged labor
- Fetal head position in prediction of mode of delivery in prolonged first stage of labor.

The selected five papers decided herein are examples of comprehensive discrete studies undertaken whilst employed at Cambridge University Hospital NHS Foundation Trust, investigating the use of intrapartum ultrasound as part of multicenter project.

Ethical aspects and consent:

Ethical committees approved the study (REK 2011/731 in Norway and 11/EE/064 in the UK). The study was registered in Clinical Trials.gov with identifier NCT01610453. Women recruited into the study signed written consent. Researchers who performed ultrasound assessments were blinded from digital vaginal examinations findings by the birth attendant and also from the outcome of delivery. The women continued to receive care from their assigned midwife or doctor and the management of labor was based only on the digital examinations and routinely collected clinical data. The professionals attending to the patient's clinical care were blinded to all ultrasound findings.

A simple 2D ultrasound technique to assess intrapartum cervical dilatation: A pilot study.

Hassan WA, Eggebo TM, Ferguson M and Lees CC

Ultrasound Obstet Gynecol. 2013; 41: 413-418.

Aims

The aims of the study are to investigate the use of ultrasound during labor and determine if this can be helpful in the assessment of labor parameters and more specifically cervical dilatation.

Objectives

Using two-dimensional (2D) ultrasound during labor to describe an ultrasound technique for measurement of cervical dilatation. Furthermore, we compared ultrasound assessments of cervical dilatation to those of digital vaginal examinations. Primiparous women in labor with a live singleton fetus in cephalic presentation and gestational age > 37 weeks were eligible for the study. The women were lying in supine positionin bed with flexed hips and knees. All women had ruptured membranes and an empty bladder.

The women continued to receive care by their assigned midwife or doctor and the management of labor was based only on the digital examinations and routinely collected clinical data. The professionals attending to the patient's clinical care were blinded to all ultrasound findings. Ultrasound images were obtained from both centres from consecutively recruited women and were saved on each system's hard disc drive. The authors, blinded from the patient's identity, the digital cervical examination and the outcome of delivery reviewed the stored ultrasound images and measured the cervical dilatation in the anterio-posterior diameter.

Vaginal digital examinations were performed prior to or immediately after the ultrasound examination by the responsible birth attendant. Ultrasound examinations were performed using a Samsung Medison Accuvix XG and a GE Voluson i with a 4-6MHz convex transabdominal transducer. The transducer was covered with a glove and ultrasound gel as described by Barbera et al. (Barbera et al. 2009b).

The technique for assessment of cervical dilatation is described as follows: The transducer was placed transperineally at the level of the posterior fourchette in a sagittal position[19] as shown in Figure 1.1(a). Fine lateral movements were performed in order to obtain views of the maternal pubic symphysis and fetal skull landmarks (Figure 1.1b). The anterior part of the cervix was identified on top of the upper part of the fetal skull in a sagittal view. The transducer was then rotated by 90 degrees (Figure 1.1c) without losing from the image the upper part of the cervix or the upper part of the fetal skull. Angling and dipping movements of the transducer were performed to obtain clear views of the cervix. The circular aspect of the cervix was obtained (Figure 1.1d).

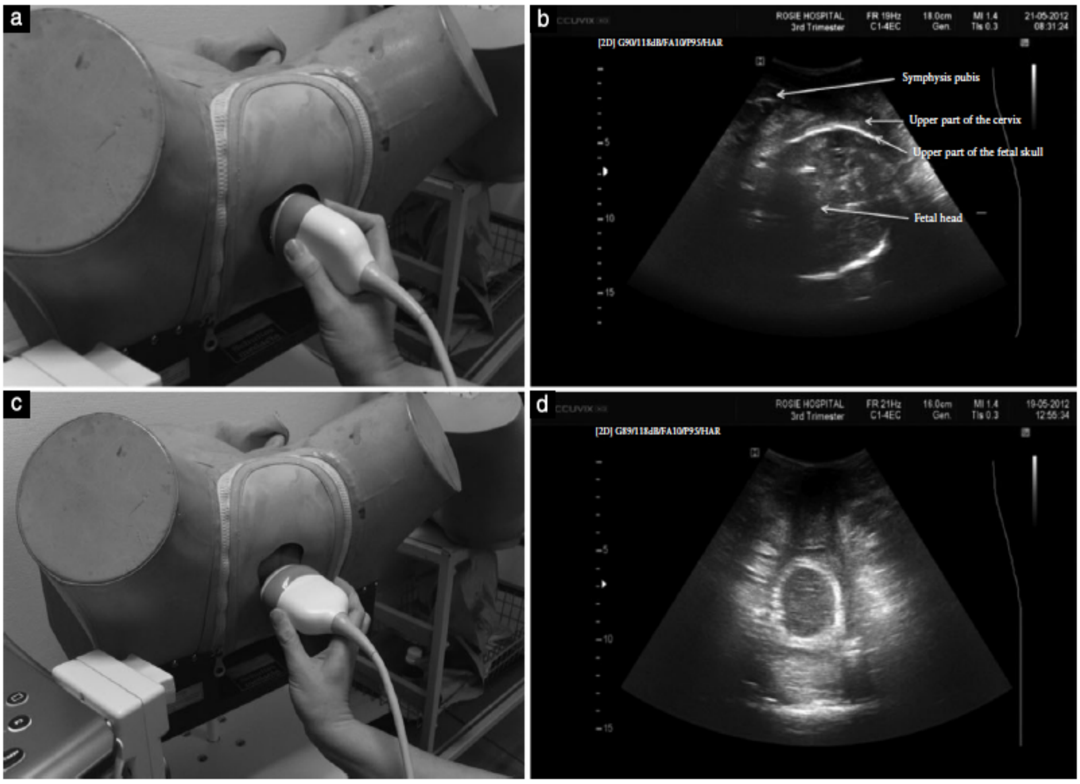


Figure 1.1:(a) Transperineal sagittal application of 2D transducer in order to obtain views of the maternal symphysis pubis, the upper part of the cervix lying just above the upper part of the fetal skull (b). Rotation of the 2D transducer by 90 degrees (c) obtains a view of the cervix (d). Taken from (Hassan et al. 2013).

The measurement of the ultrasound cervical dilatation was obtained in the anterio-posterior plane with the cursors placed on the inner part of the cervical tissue anteriorly and the inner part of the cervical tissue posteriorly (inner-inner) as shown in Figure 1.2.

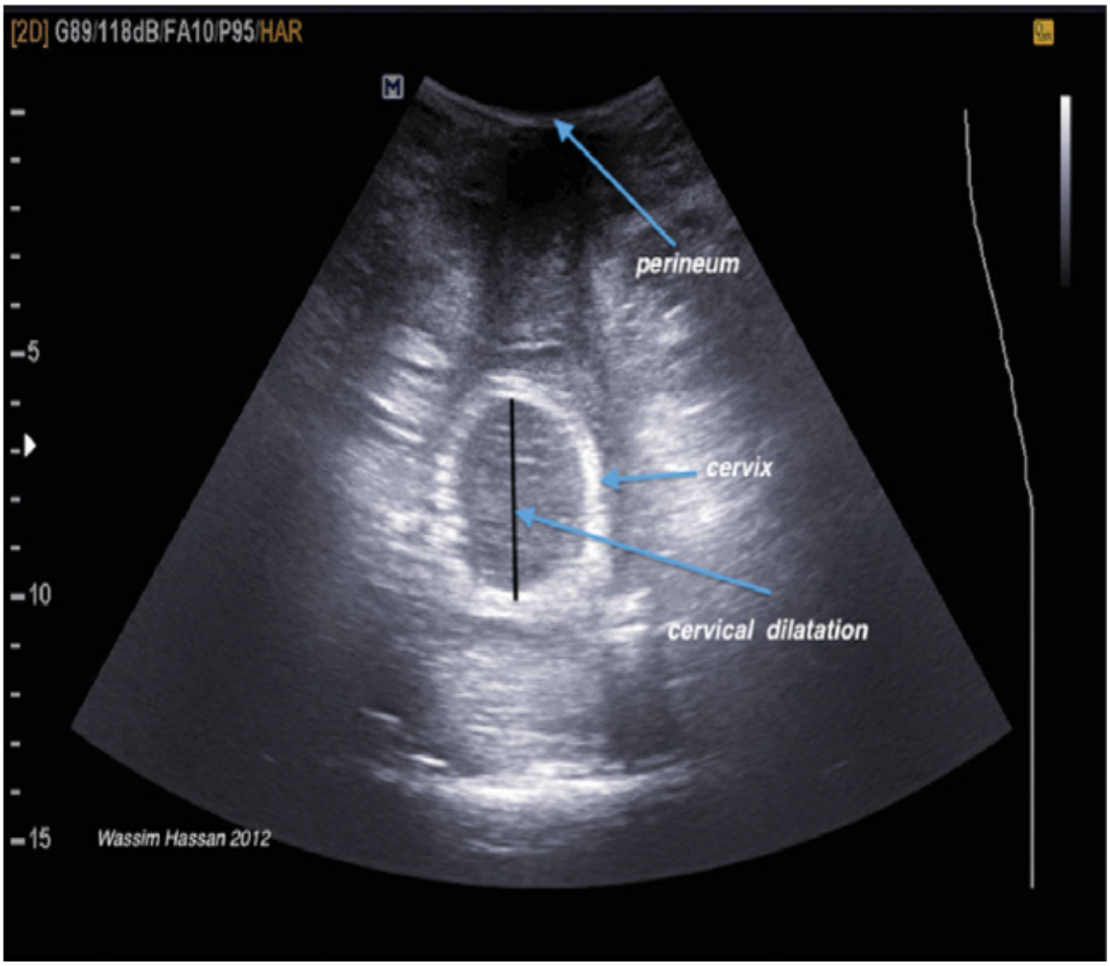


Figure 1.2: Cervical dilatation measured by 2D ultrasound during labor. The cervical dilatation is clearly visible at the center with vaginal wall hyperechogenic laterally to the cervix. At the top of the picture is the perineum where transperineal probe is placed. Taken from (Hassan and Tutschek 2013).

The quality of cervical visualization by ultrasound was assessed on a scale from 0 to 3 (Ultrasound Cervical Visualization Score- Figure 1.3); (3) where cervical dilatation was visible in more than 75% of cervical circumference, (2) where cervical dilatation was visible in 50-75% of cervical circumference, (1) where cervical dilatation was visible in 25-50% of cervical circumference, and (0) where cervical dilatation was visible in less than 25% of cervical circumference.

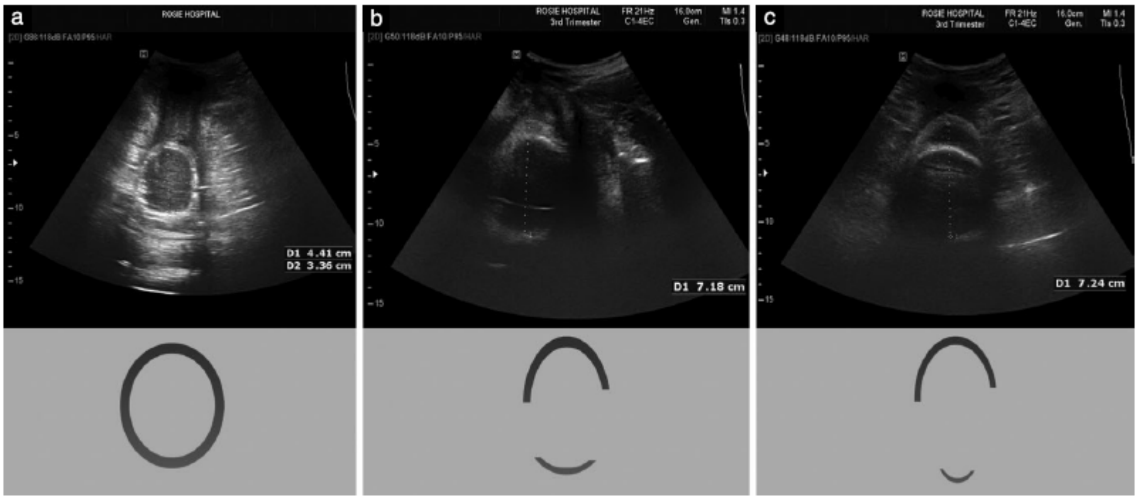


Figure 1.3: Images obtained by ultrasound examination from three nulliparous women in labor, representing ultrasound cervical visualization score of: (a) 3 (more than 75% of the cervical circumference visible), (b) 2 (50-75% of the cervical circumference visible) and (c) 1 (25-50% of the cervical circumference visible). Taken from (Hassan et al. 2013).

Results

By using the technique presented in this study we were able to measure cervical dilatation by 2D transperineal ultrasound. Twenty-one consecutively recruited women had cervical dilatation measured by 2D ultrasound at different stages of labor. In nineteen cases satisfactory cervical dilatation measurement by 2D ultrasound was obtained; in 2 cases the cervix was poorly or not visualized and these cases are not presented.

Demographic and baseline characteristics of the women are shown in Table 1.1. Six cases were in the latent phase of labor (2-4cm), thirteen cases in the active phase of labor (5-10cm). All women reported the technique to be non painful.

Patient Characteristic		**n=21**
Nulliparous		21
Gestation:		37-41weeks
Cervical dilatation:	(2-4cm)	6
	(5-7cm)	10
	(8-10cm)	3
Cervical measurement not obtained		2

Table 1.1: characteristics and distribution by vaginal examination. Taken from (Hassan et al. 2013)

The correlations and comparisons were performed in those 19 women where cervical imaging was possible. The Pearson correlation coefficient between digital and ultrasound measurements showed strong positive correlation (r=0.821, n=19, p<0.01). The mean difference between digital and ultrasound measurements was 0.08cm (with limits of agreement -1.83 to + 2.00) and the absolute difference was 1.24cm. Bland Altman plot illustrates the agreement between digital vaginal examination and ultrasound examination (Figure 1.4). The Intraclass correlation coefficient between the two methods showed a high association with ICC 0.81 (95%CI, 0.578 to 0.924).

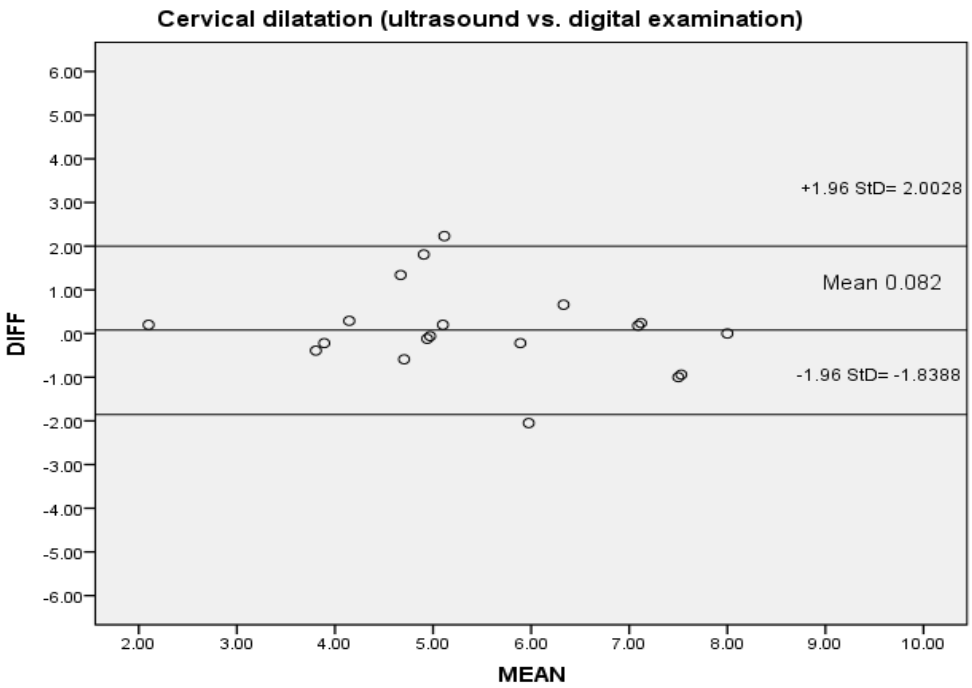


Figure 1.4: Bland Altman plot of differences between digital and ultrasound examinations. Taken from (Hassan et al. 2013).

Ten women had an ultrasound visualization score of 3, six women had a score of 2 and three had a score or 1. Ultrasound images of cervical dilatation at different stages of labor are represented in Figure 1.5.

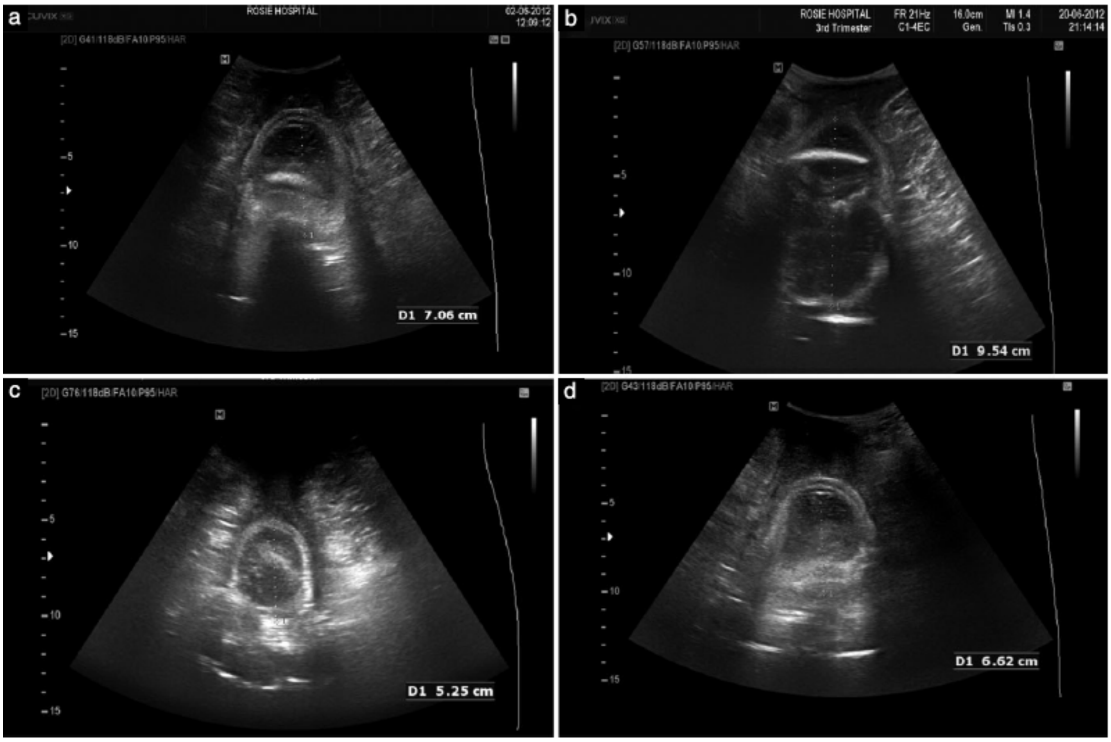


Figure 1.5: Representative images obtained by 2D ultrasound at different cervical dilatations of (a) 7.1cm, (b) 9.5cm, (c 5.3cm and (d) 6.6cm.

Discussion

Intrapartum assessment of cervical dilatation was feasible by using a simple 2D transperineal ultrasound method. Using the above technique, we were able to assess cervical dilatation during labor in most women and could provide satisfactory imaging and visualization of the cervix from 1cm to almost full dilatation of the cervix. We have shown that the ultrasound measurements obtained were concordant with digital vaginal examinations. We have chosen the anterio-posterior diameter for the measurement of cervical dilatation, as this appeared clearer than the transverse diameter. This might be explained by the fact that axial ultrasound resolution being greater than lateral (Lenore 2006).

Assessment of cervical dilatation is an essential prerequisite in determining the progress of labor (WHO 1994) though the technique is acknowledged to be highly observer dependent (Phelps et al. 1995; Huhn and Brost 2004). Women during labor undergo several digital vaginal examinations for the assessment of cervical dilatation and other labor parameters; Borders et al., in an audit of 205 women admitted in spontaneous labor an average of four vaginal examinations were performed (Borders, Lawton and Martin 2012). Internal digital examination can be uncomfortable and intrusive for the mother (Ying Lai and Levy 2002; Murphy et al. 1986; Clement 1994) and there is a risk of introducing infection associated with frequent vaginal examinations (Westover and Knuppel 1995; Seaward et al. 1997b).

Prior to the publication of this novel technique, ultrasound assessment of cervical dilatation in labor has been largely unsuccessful in its application to clinical practice. Intrapartum 3D ultrasound has been reported but it was not sufficiently reproducible to replace digital vaginal examination in labor (Zimerman et al. 2009). It is important to highlight that 3D ultrasound assessment is complicated and operator dependent; moreover it is not suitable for the acute assessment of women on the delivery unit (Dietz 2004).

The transperineal 2D technique that we describe is easy to perform using standard equipment available on most delivery units, requires a short learning curve, and is not unduly intrusive to the women. Nevertheless, there are potential technical difficulties with the technique; we describe visualization of the cervix in women at term with ruptured as opposed to intact membranes. Further, an initial concern was that the fetal skull might look like the anterior echogenic rim of the cervix, however this has proven unfounded as both the skull and the anterior rim of the cervix can be seen separately as is demonstrated in some of the images. Another concern is the level where the measurement of the cervical dilatation should be measured, however all the measurements we report bar one were at cervical dilatation of > 3cm where effacement has occurred. Thus the difference between the internal and external surfaces of a thin, effaced cervix would be likely to be very small. We report one case with cervical dilatation at 2 cm to illustrate that ultrasound measurement of cervical dilatation is possible at early stages of labor.

Undoubtedly the technique of 2D transperineal assessment of cervical dilatation described has formed the basis in conjunction with an assessment of head descent and rotation for the development of the "Sonopartogram". In addition, it is not an overstatement to suggest such a 'Sonopartogram' has the potential to allow the progress of labor to be tracked entirely with ultrasound, potentially dispensing with the variability and discomfort of conventional examination.

Since the publication of this novel technique, some studies have researched the use of 2D ultrasound in the assessment of cervical dilatation and its reproducibility.

Benediktsdottir et al. performed an observational prospective study in 86 women with singleton cephalic presentation during labor (Benediktsdottir, Eggebø and Salvesen 2015). Ultrasound assessment of cervical dilatation was measured in transverse view following the same technique as described in Hassan et al. 2013. The authors calculated the mean value of the anterio-posterior diameter with the cursors placed on the inside of the cervix (inner-inner) as described in my paper. Two doctors and two midwives performed the ultrasound examinations; these were not involved in the clinical management of the cases and were blinded to each other's assessments. In all, 86 women were in active labor and included in the study with cervical dilatation above or 4cm. Cervical dilatation was successfully assessed by ultrasound in 61/86 (71%) of women. When cervical dilatation was palpated >=8cm, ultrasound was not able to measure dilatation in 65% of cases. Therefore, in 59 cases, ultrasound cervical dilatation was compared to clinical assessments. Bland-Altman plots showed a mean difference between cervical dilatation by ultrasound and digital examination of 0.9cm (95%CI 0.47-1.34). ICC was 0.83 (95% CI 0.72-0.9). Limits of agreement were -2.34 to 4.16 (Benediktsdottir, Eggebø and Salvesen 2015).

These results are in concordance with our study that showed a mean absolute difference of 1.24cm between ultrasound and digital examinations. Benediktsdottir et al. though suggested the use of both diameters in assessing the cervical dilatation, the anterior-posterior and the transverse diameter, in their argument highlighted that digital vaginal examinations are typically measured in transverse diameter. Furthermore, cervical dilatation was not visible by ultrasound at 8cm and above, this most likely is due to the shadowing from the fetal skull and lower head positions. It is also plausible that at nearly fully dilated cervix, the cervix is fully effaced and thin as opposed to earlier stages in labor where cervical thickness still measurable.

Another observational prospective study performed in 2014 by Yuce et al. studied transperineal ultrasound for the assessment of cervical dilatation, fetal head station and fetal head position (Yuce, Kalafat and Koc 2015). They recruited 43 women in labor with singleton cephalic term pregnancies. Different operators blinded from each other's findings performed ultrasound and digital assessments. Cervical dilatation was measured according to our technique as described in Hassan et al. and used anterio-posterior diameters. In all, 79 paired examinations were recorded for all women with a median of two examinations per woman. Cervical dilatation by ultrasound was possible in all cases. Good ICC agreement was found between digital and ultrasound assessments ICC 0.88 (95% IC 0.73-0.88). Ultrasound measured cervical dilatation showed lower values as compared to digital assessments by a mean value of 10mm (limits of agreement: -36 to 16mm) (Yuce, Kalafat and Koc 2015).

A recent study suggested the use of a wireless ultrasound device to track the changes in cervical dilatation, effacement, position and consistency during labor; this showed strong correlation with digital vaginal examinations for cervical dilatation and thickness however poor correlation for cervical length. This is promising, however further research is needed to define the role of wireless ultrasound devices during labor (Kim et al. 2017).

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A novel method for recording the progress of labor by ultrasound: The Sonopartogram

Hassan WA, Eggebo TM, Ferguson M, Gillett A, Studd J, Pasupathy D, Lees CC

Ultrasound Obstet Gynecol. 2014; 43:189-94

Objectives

In this paper we introduce the concept of a non-intrusive non-invasive ultrasound based assessment tool of labor progress (the "sonopartogram"). Progress of labor has hitherto been assessed by digital vaginal examinations; by introducing this novel ultrasound concept, we investigate if ultrasound has the potential of providing the necessary clinical measurements required for monitoring the progress of labor whilst comparing to digital vaginal examinations.

And we investigate the feasibility of sonopartogram for assessment of cervical dilatation, fetal head descent and fetal head rotation. These are considered the basic requirements for a "partogram" digital vaginal monitoring tool.

Methods

Women with singleton pregnancy and gestational age >37 weeks in first stage of labor were included. Twenty women were recruited after signing a written consent. The women continued to receive care by their assigned midwife or doctor and the management of labor was based only on the digital examinations and routinely collected clinical data. The professionals attending to the patient's clinical care were blinded to all ultrasound findings.

Where possible, cervical dilatation, fetal head decent and fetal head position were recorded according to normal clinical practice with women in a supine position with flexed hips and knees.

Fetal head descent was described according to WHO classification as the relationship of the vertex in centimetres above or below the ischial spines (– to +) (WHO. 1994). Fetal head rotation was determined based on the position of the posterior fontanelle, according to a 12-hour clock face, with the measurement rounded up or down to the nearest hour (with 12.00 h representing occiput anterior position and 03.00 h representing left occiput transverse position).

Cervical dilatation was assessed by 2D transperineal US in the anterio-posterior plane as described by Hassan et al (Hassan et al. 2013) with the cursors placed on the inner part of the cervical tissue anteriorly and the inner part of the cervical tissue posteriorly (inner–inner). Measurements were rounded up or down to the nearest whole cm, with a measurement at .5 precisely being rounded up.

Fetal head descent was assessed by 2D transperineal US in transverse view by measuring the fetal HPD (in cm) as the shortest distance between the outer bony limit of the fetal skull and the perineum (Kalache et al. 2009; Torkildsen, Salvesen and Eggebø 2012; Rivaux et al. 2012; Maticot-Baptista et al. 2009). Fetal head rotation was assessed by 2D transabdominal US, using the fetal spine or orbits to define the occiput, this being defined as the denominator (Maticot-Baptista et al. 2009), and was expressed according to a 12-hour clock as for the digital VE.

The sonopartogram is based on the conventional partogram, but adapted for recording of ultrasound parameters (Figure 2.1). Key attributes to note for the purposes of this study are as follows: The quality of the US image for cervical dilatation is expressed by a cervical visualization score, a subjective grading system described previously (Hassan et al. 2013). Fetal head rotation is plotted on a 12-hour clock face. Fetal head descent is expressed in centimeters as the shortest distance between the outer bony limit of the fetal skull and the perineum with the transducer placed to obtain a transverse view.

Also displayed in Figure 2.1, though not commented on in this manuscript, are caput and moulding (shown in the explanatory photographs). Caput can be measured transperineally in a sagittal view as the maximum distance between the fetal skin and bone of the leading arc of the skull (proximal skull to outer skin) and moulding is seen when the skull bones of the vertex overlap unequivocally in the sagittal or transverse view). Fetal heart rate and contraction strength and frequency were also recorded.

SONOPARTOGRAM

HOSP. NO: ....
SURNAME ....
FORENAMES ....

AGE ....
CONSULTANT ....

DATE ....

EDD ....

PARITY ....

SPECIAL INSTRUCTIONS

DURATION OF LABOUR IN HOURS

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23

FETAL
HEART
RATE

190 180 170 160 150 140 130 120 110 100 90 80 70 60

CAPUT

CAPUT: SAGITTAL VIEW OF THE HEAD
TRANSPERINEAL ULTRASOUND

0 No caput

1 0-1cm Skull-Skin distance

2 1-2cm Skull-Skin distance

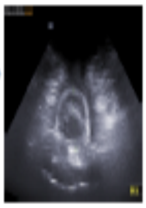
3 2-3cm Skull-Skin distance

MOULDING

MOULDING: OVERLAPPING OF SUTURE
TRANSPERINEAL ULTRASOUND
Yes

No

CERVICAL DILATATION
SCORE (3,2,1,0)



>75% 50-75% 25-50% <25%

Cervix Cervix Cervix Cervix

CERVIX DESCENT

10 9 8 7 6 5 4 3 2 1 0

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24

FETAL HEAD DESCENT
TRANSPERINEAL ULTRASOUND

Fetal head perineum
distance (cm)

HEAD POSITION
(LOA,LOA,LOT,LOP)
(ROP,ROP,ROT,ROA)

FETAL HEAD POSITION
TRANSABDOMINAL ULTRASOUND

>09:00 - <03:00 OA
03:00 - 03:50 LOT
08:00 - 09:50 ROT
>03:00 - <08:00 OP

AMNIOTIC FLUID
OXYTOCIN
ml/hr

CONTRACTIONS
PER 10 MIN

5 4 3 2 1

INITIALS

Figure 2.1: A sample sonopartogram showing fetal head descent, cervical dilatation and head rotation with explanatory ultrasound images and depiction of the cervical dilatation score. Upper sonogram represents an image with caput succedaneum; second sonogram below represents moulding/overlapping of head sutures; third sonogram represents cervical dilatation and the fourth sonogram represent head perineum distance.

Results

Twenty women in the first stage of labor were recruited from both centers between November 2012 and February 2013. The median maternal age was 34 (range, 21–41) years, parity was 0 (range, 0–2) and body mass index was 29 (range, 22–47) kg/m^2. The median gestational age at study inclusion was 40 (range, 37–41) weeks.

The total number of paired digital VEs and US assessments was 52, with a median of three (range, 2–5) per woman. Given that at each assessment three parameters were measured, the total number of individual parameters measured by either US or digital VE was therefore 156. In all cases the US assessment took place within 30 min of the digital VE. Cervical dilatation could be assessed in all cases with digital VE, while in seven (14%) assessments could not be measured by US (P = 0.019). In these seven cases, the cervix was at a dilatation of > 9 cm based on digital VE. In all cases, head descent could be measured by both techniques. Fetal head rotation could not be assessed with sufficient confidence for it to be recorded in 29 (56%) cases by digital VE, while it was recorded in all except one (98%) case using US. Overall, for all possible data obtainable on cervical dilatation, head descent and rotation, there were complete observations for 95% of sonopartogram data and 82% of conventional partogram data (P < 0.001).

We therefore restricted the cervical dilatation analysis to paired measurements with a maximum time difference of 10 min. Twenty-three paired measurements satisfied this condition. Using the Bland–Altman method on this subset, the average difference between digital VE and US (VE – US) was 1.16 (95% limits of agreement, -0.76, 3.08 cm.). A scatter plot of US and digital VE assessments was produced; the r^2 coefficient of determination was 0.68 (P<0.001).

With respect to fetal head descent, the HPD measured by US was not directly comparable with that as measured by digital VE. There was a very large overlap between US-derived HPD for a given station in relation to the ischial spines derived from digital VE. The coefficient of determination between US and digital VE head descent was $r^2 = 0.33$ (P<0.001).

With respect to head rotation, there was complete agreement (agreement to within one clock face hour) between that derived from digital VE compared and that based on US in 39.1% of cases. The Bland–Altman analysis of fetal head rotation compared between the two techniques showed a mean difference of –3.9° (95% limits of agreement, –144.1°, 136.3°), based on data from 15 patients and 23 paired measurements. On average, digital VE gave estimates of head rotation that were 3.9° anti-clockwise of the US estimates. Head rotation was recorded following digital VE in 5/14 (35%) assessments at cervical dilatation ≤ 5 cm and in 17/38 (44%) assessed with digital VE at cervical dilatation ≥ 6 cm (P not significant).

Discussion

Sonographic analysis of the progress of labor is a conceptually simple way of monitoring the key parameters of labor: cervical dilatation, fetal head descent and fetal head rotation. Data completeness, taking into account all three parameters measured under normal clinical conditions, was higher for the sonopartogram than for the conventional partogram. There was moderately good agreement between US and digital VE for measuring cervical dilatation; however, digital VE consistently gave slightly larger measurements than did US. In the cases where cervical dilatation increases as labor progresses, the time difference between digital VE and US assessment is likely to have been responsible for some of the difference in estimation between the two techniques. When US measurements were taken prior to digital VE, they tended to be smaller, for two reasons: first, because they were taken beforehand and were thus smaller because of the effect of advancing dilatation with time, and second, because digital VEs tend to give larger estimates.

Head descent was easy to measure, and complete data were obtained using both methods, though it is clear that head descent as defined by digital VE is not directly equivalent to that based on the US measurement of HPD. There was close agreement between US and digital VE for fetal head rotation; this was assessed easily by transabdominal US but could only be determined in half of the cases by digital VE. Though the agreement between the two techniques to within 1 clock-face hour was 39%, the overall mean difference in measurement corresponded to roughly 1/90th of the clock face.

Neither the digital VE nor the US technique is perfect, however. The cervix was difficult to image on US when dilatation was determined by digital VE to be > 9 cm. A diagnosis of full dilatation of the cervix on digital VE is based on the absence of a positive finding, in other words on the inability to feel the cervix, rather than it being possible to measure the cervix at a dilatation of 10 cm. Interestingly, digital VE consistently over-estimated cervical dilatation compared with US. The very clear appearance of the cervix on US makes it unlikely that the US measurement was inaccurate or that the caput was being measured inadvertently (Fuchs, Tutschek and Henrich 2008). It is possible that when measuring cervical dilatation digitally, the process of examination itself could lead to inadvertent stretching. Another explanation is involuntary systematic bias by caregivers in reporting labor as being more advanced than it actually was.

The comparison between fetal head descent based on US and that obtained from digital VE is problematic. Several studies have assessed the fetal HPD and reported it as a simple and easy method with which to assess head engagement (Kalache et al. 2009; Torkildsen, Salvesen and Eggebø 2012; Maticot-Baptista et al. 2009; Rivaux et al. 2012). Alternative methods of defining head descent include the angle of progression (Barbera et al. 2009b; Kalache et al. 2009), though studies describing this have not reached a consensus as to the appropriate 'cut-off' angle in labor that makes vaginal delivery likely, nor is there good agreement between this technique and head station in relation to the ischial spines. Sonographic HPD measures the shortest distance between the fetal head and the US transducer; digital VE relies on denoting the position of the vertex in relation to an imaginary line between the ischial spines. This is not a comparable measurement plane, though recently a method of converting the US measurement to that obtained from digital VE has been proposed, using three-dimensional stored volumes (Tutschek, Torkildsen and Eggebø 2013).

Importantly, and unlike for digital VE, individual US measurements of cervical dilatation, head descent and head rotation are recordable on a stored US image and can be reviewed at a later date.

Though not tested in this study, as we restricted our patient recruitment to women in term labor, US assessment alone might be desirable in cases in which digital VE is best avoided, particularly in cases of threatened preterm labor, prelabor rupture of membranes or placenta praevia. Furthermore, digital VE may be uncomfortable: the US technique described here was quick (taking no more than 5 min) and well tolerated by patients. Most delivery units in Europe, North America and the developing world have ready access to the simple US equipment that is required for the sonopartogram.

Sonographic assessment of labor requires knowledge of both basic US skills and the conventional techniques for monitoring the progress of labor. We caution against introducing intrapartum US without training for doctors and midwives, though in practice the techniques are relatively simple compared to other areas of obstetric ultrasound.

For the purposes of describing the sonopartogram, we have selected the simplest of the US techniques described, namely transabdominal US to assess fetal head rotation, HPD for head descent and 2D-US of the cervix. That is not to say that other US methods might not be useful as adjuncts to these measurements or even replace them; our aim was to describe the concept and test its feasibility rather than to be categorical about the individual parameters. A sonopartogram, whatever its precise configuration, would allow an objective record of the progress of labor to be documented prospectively at the woman's bedside, something that hitherto has not been possible. Such an advance in obstetric and midwifery practice could fundamentally affect the nature of assessment of labor, changing it from being a largely subjective skill to being a recordable science.

An observational prospective study performed in 2014 by Yuce et al. studied transperineal ultrasound for the assessment of cervical dilatation, fetal head station and fetal head position (Yuce, Kalafat and Koc 2015). They recruited 43 women in labor with singleton cephalic term pregnancies. Different operators blinded from each other's findings performed ultrasound and digital assessments. Cervical dilatation was measured according to our technique as described in Hassan et al. and used anterio-posterior diameters. Head position was evaluated via transperineal or transabdominal approach. Fetal eyes, thalamic nuclei, and the cerebellum were used as major landmarks for determining fetal head position. Occiput positions were determined according to Akmal et al. (Akmal et al. 2002). Head positions were recorded similarly to the "Sonopartogram" paper (Hassan et al. 2014). Fetal head station as head-perineum distance and angle of progression were measured according as previously described (Barbera et al. 2009b; Eggebø et al. 2008; Kalache et al. 2009). Overall, 79 paired examinations were recorded for all women with a median of two examinations per woman. Cervical dilatation by ultrasound was possible in all cases. Good ICC agreement was found between digital and ultrasound assessments ICC 0.88 (95% IC 0.73-0.88). Ultrasound measured cervical dilatation showed lower values as compared to digital assessments by a mean value of 10mm (limits of agreement: -36 to 16mm) (Yuce, Kalafat and Koc 2015). Angle of progression and head-perineum distance were measured in all cases where only 59 of 79 examinations head station was possible. Interestingly, a strong inverse correlation was detected between angle of progression and head perineum distance (PCC = -0.82; $p<0.001$). On the other hand, neither angle of progression (PCC = 0.55, $p<0.001$) nor head-perineum distance (PCC

= -0.42; $p<0.001$) correlated strongly with palpated head station. Ultrasound was able to assess head position in all cases. Digital examination could possibly assess fetal head position in 40 out of 79 observations (51%). Overall this study, as similarly to previous work, highlighted the poor performance of digital vaginal examinations as compared to ultrasound assessments. Although, ultrasound evaluation of the cervix is considered a relatively new method, it is acceptable to think that the use of ultrasound during labor can reduce the number of digital examinations and transperineal ultrasound will come to be more widely used as an adjunct tool in the near future (Yuce, Kalafat and Koc 2015).

Copy of original paper 2

Intrapartum assessment of caput succedaneum by transperineal ultrasound: a two-center pilot study

Hassan WA, Eggebo TM, Salvesen KA, Lindtjorn E, Lees CC

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2015; 55: 401–403.

Objectives

In this paper we aim to describe caput succedaneum by ultrasound and to measure by ultrasound skin-skull distance (SSD). Also we aim to compare clinical and ultrasound assessment of caput succedaneum (caput) in nulliparous women in first stage of labor. Furthermore, we aim to investigate repeatability of ultrasound measurements.

Methods

We conducted a prospective observational study to assess the progress of labor sonographically in nulliparous women after 37 weeks gestation with cephalic presentation in the first stage of labor. This study was part of a larger study conducted in two maternity units in the UK and Norway. Other results from the same women have been reported and published (Eggebø et al. 2014); and this paper will be discussed in this thesis in detail. Women admitted to the labor ward in first stage of labor were recruited and gave written consent that was obtained by a member of the clinical or research team. Ethics committees approved the study in the UK (REC Ref 11/EE/064) and Norway (REK 2011/731). For the assessments, women were lying in supine position in bed with flexed hips and knees. The birth attendant looking after the woman in labor performed digital vaginal examinations and caput was recorded as present or absent. A member of the research team (nine doctors and three midwives) performed the ultrasound examinations in the first stage of labor. The transducer was placed transperineally in a sagittal position with symphysis pubis and fetal skull both visualized as landmarks (Barbera et al. 2009b).

The skin-skull distance (SSD) was measured with ultrasound as the maximum distance between the outer border of the fetal skin and the outer border of the bone of the leading arc of the skull. Blinded SSD measurements by 3 operators (WAH, CCL & TE) were obtained from electronically stored 2-dimensional images. SSD derived from transperineal ultrasound was compared to the vaginal examination assessment of caput where this caput was noted to be present or absent. Measurements of interobserver repeatability for SSD were performed by two operators (WAH & CCL) on 48 electronically ultrasound images.

Statistical analysis

Categorical variables were compared using Chi-square test and Kappa correlation coefficient. Continuous variables were expressed as median (range and interquartile range (IQR)) and compared with Mann-Whitney test. Interobserver repeatability was analyzed using intra class correlation coefficient (ICC) and limits of agreement. P <0.05 was considered significant. Data were analysed with the statistical software package PASW statistics version 21 (IBM, SPSS, Armonk, NY, USA).

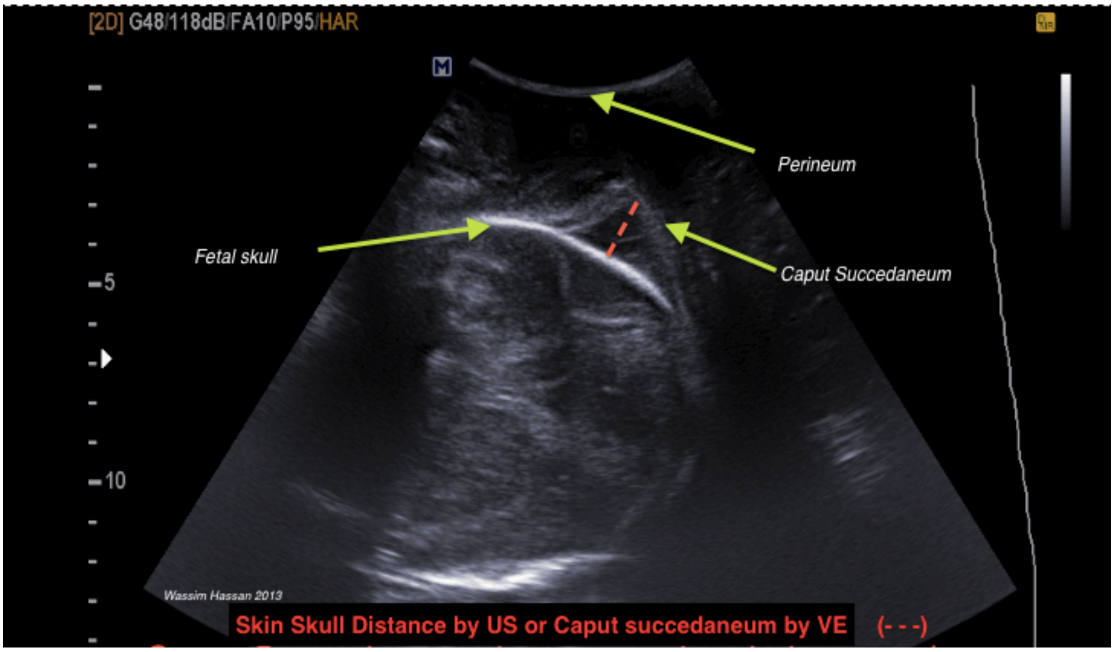

Figure 3.1: illustration of an image captured by 2D transperineal ultrasound from the population data. Note the fetal landmarks such as fetal skull (hyperechogenic line) and the skin (less echogenic) covering it. The dotted line between fetal skull and fetal head skin is considered Skin- Skull Distance (SSD) or as conventionally known caput succedaneum by digital vaginal examinations.

Results

We included 135 women in the study. Ultrasound measurements of caput were not possible in 13 women and therefore excluded. Maternal characteristics and labor outcomes are presented in Table 3.1. The median SSD value for the study population was 10 mm (IQR 8 mm); therefore, we chose 10 mm to define caput being absent (<10 mm) or present (≥10 mm) with the use of ultrasound.

Where caput was judged to be absent on digital VE, the median SSD value was 9 mm (IQR 8 mm; range 2– 20 mm) and where it was present the median SSD was 12.5 mm (IQR 6.5 mm; range 3–19 mm) $P < 0.01$ (Figure 3.1). The Kappa value comparing clinical assessment of caput (+ or -) and ultrasound measured caput (≥10 mm or <10 mm) was 0.29, $P < 0.01$. Twenty-nine (24%) of 122 women were delivered by caesarean section (CS). The median SSD in women delivered by CS was 12mm (IQR 6mm) vs. 9mm (IQR 8mm) in women delivered vaginally ($P < 0.01$). Twenty-four (38%) of 63 women with SSD ≥10mm were delivered by CS compared to 5/59 (8%) of women with SSD <10 mm ($P < 0.01$).

Interobserver repeatability for SSD showed an intraclass correlation coefficient of 0.96 (95% CI, 0.93–0.98). The mean difference for the caput measurements was 0.4 mm (95% CI, 0.85 to 0.05), and limits of were 3.44 to 2.64 mm (Bland–Altman agreement analysis) Figure 3.2.

	$n = 122$ median (IQR) or n (%)
Maternal characteristics	
Maternal age (years)	30 (7)
Prepregnant weight (kg)	66 (13.5)
Gestational age (weeks)	40 (1)
Clinical examinations	
Caput succedaneum present	37 (30)
Cervical dilatation (cm)	6 (2)
Station (−5 to +5)	−1 (2)
Ultrasound examinations	
Caput succedaneum (mm)	10 (8)
Head–perineum distance (mm)	39 (10)
Occiput posterior position ($n = 116$)	37 (32)
Labour characteristics	
Caesarean section	29 (24)
Operative vaginal delivery	37 (30)
Augmentation with oxytocin	97 (80)
Epidural analgesia	108 (89)
Birthweight (g)	3588 (626)

IQR = interquartile range.

Table 3.1: Maternal and labor characteristics of the study population.

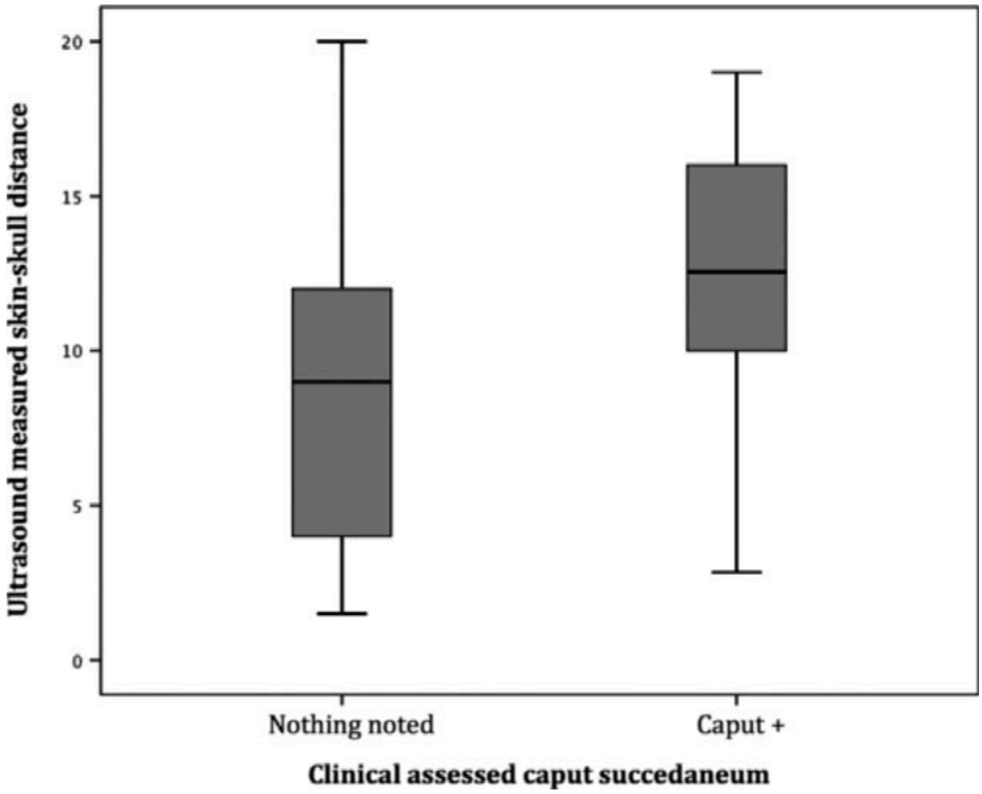

Figure 3.2: Box plot illustrating association between clinical assessed caput succedaneum and ultrasound measured skin–skull distance.

Discussion

Caput succedaneum is conventionally assessed during labor by digital vaginal examination (VE) and is usually recorded as either present or absent or being quantified by a number of + values (Smith 2008). Various definitions of caput exist and the key components of which are a diffuse and palpable swelling of the fetal scalp in labor (Fraser and Cooper 2009).

Recent interest in the use of ultrasound in the context of assessing the progress of labor and likelihood of vaginal delivery has led to the adoption of the technique of transperineal ultrasound in a research setting (Hassan and Tutschek 2013; Maticot-

Baptista et al. 2009; Eggebø et al. 2014). Using this technique, the identification of caput has been demonstrated by obtaining a sagittal view of the fetal skull (Barbera et al. 2009b). In this study we aimed to compare clinical and ultrasound assessment of caput in nulliparous women in the first stage of labor. Furthermore we aimed to investigate the repeatability of ultrasound measurements.

We report that it is possible to measure caput succedaneum with ultrasound in most cases in the first stage of labor. Ultrasound measurements correlated significantly with digital assessments, and the repeatability of ultrasound measurements was good. Adverse sequalae and associations of a diagnosis of caput from vaginal examination include prolonged labor, fetal macrosomia, contracted maternal pelvis and prolonged maternal expulsive pushing (Smith 2008). In one study, caput thickness was measured by ultrasound in prolonged second stage of labor, and no relationship was found between this and mode of delivery, fetal head position or duration of second stage (Gilboa et al. 2013). Our study only included nulliparous women in the first stage of labor. We found an association between ultrasound measured caput succedaneum and delivery mode. The study was not powered to investigate such a hypothesis; however, the results can be used for the basis of a power calculation for a definitive study.

A weakness of our study is that the population was not truly unselected as women with both prolonged (74%) and normal (26%) labor were included. This could have led to a greater number of observations where caput was present, but does not invalidate the comparison between digital VE and ultrasound assessment of caput. In this study, the clinicians were not asked to focus on caput succedaneum in their clinical examinations, and this might explain the relative low correlation between ultrasound measurements and clinical assessments. Further limitations are that SSD could not be measured in 13 of 135 cases due to ultrasound ‘dropout’ where the contour of the fetal skull was parallel to the ultrasound beam.

For the purpose of better understanding of labor and mode of delivery in the presence of caput succedaneum, we performed an audit of 233 consecutive case notes of women during labor. The data in this audit has not been published.

The audit was registered as clinical audit (Ref 2141-10-2012) at he Rosie Maternity Hospital (Addenbrooke’s Hospital, Cambridge). Women diagnosed as being in labor with a singleton cephalic pregnancy were included. Data about digital vaginal examinations (VE), caput, labor and mode of delivery were recorded. We included 233 consecutive case notes which we analysed; caput was recorded as being either present or absent in 222 women, and missing in 11. Caput was present in 74 of these (33.8%) and 80% (59 cases) of women had operative delivery. 148 (66.2%) did not have caput and 92% (136 cases) of these delivered spontaneously (p 0.000). Mean duration of labor when caput was present is 9.4hrs (95%CI, 2-21) compared to 4.7hrs (95%CI, 2-17) where no caput was found (p 0.000). No significant correlation was found between the presence or absence of caput and position at delivery. The number of digital VEs was greater for women diagnosed with caput median 6 (range 1-15) compared to 3 (range 0-9) for those without caput (p 0.000). Nulliparous women are more likely to be diagnosed with caput (p=0.000) when compared to multiparous women. This audit highlights the increased rate of operative delivery and women are exposed to more digital vaginal examinations.

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Sonographic prediction of vaginal delivery in prolonged labor: a two-center study.

Eggebo TM, Hassan WA, Salvesen KA, Lindtjorn E, Lees CC

Ultrasound Obstet Gynecol 2014; 43: 195-201

Objectives

To investigate whether head-perineum distance (HPD) measured by transperineal ultrasound is predictive of vaginal delivery and time remaining in labor in nulliparous women with prolonged first stage of labor. Furthermore we aim to compare the predictive value of HPD with that of angle of progression.

Methods

We conducted a prospective observational study in nulliparous women with prolonged first stage of labor. Women with a live singleton fetus in cephalic presentation and gestational age more than 37 completed pregnancy weeks were eligible. It was originally planned to include six centres, however three centres had recruited no patients and one centre five patients by the time that full recruitment had been reached at the other two centres. Hence women recruited at Stavanger University Hospital, Norway and Addenbrooke's Hospital, Cambridge, UK from January 2012 to April 2013 were included when they gave informed written consent and when a member of the research team was available. The Ethics Committees approved the study (REK 2011/731 in Norway and 11/EE/064 in the UK). The study was registered in Clinical Trials.gov with identifier NCT01610453.

Prolonged first stage was defined according to existing departmental guidelines. In Stavanger this definition was in accordance with the WHO recommendations; when cervical dilatation crossed the 'action line' (4 hours from the 'alert line')(Philpott 1972; World Health Organization 2003). In Cambridge prolonged first stage labor was defined according to NICE guidelines (dilatation of < 2 cm in 4 hours) (NICE 2007). A delivery was considered vaginal if this was spontaneous or successful operative by vacuum extraction or forceps.

The birth attendant (midwife or doctor) looking after the woman in labor evaluated fetal head descent and cervical dilatation by digital vaginal examination (VE). The fetal head station was defined according to the WHO classification with the ischial spines as the reference point 0, and -5 at the pelvic inlet and +5 at the pelvic outlet (World Health Organization 2003). Digital VEs were performed prior to or immediately after ultrasound examinations. Birth attendants were blinded to ultrasound findings from the research team and the parents were not informed about the findings. Transperineal ultrasound measurements of HPD were performed by one of the research team using Voluson *i* ultrasound equipment (GE, Zipf, Austria) with a 3.5-7.5 MHz three-dimensional (3D) curved multi-frequency transabdominal transducer in Stavanger and Samsung Medison Accuvix XG (Samsung Medison, Medical Imaging Systems Ltd, London, UK) equipment with a 4-6 MHz convex transabdominal transducer in Cambridge. Nine doctors and midwives in Stavanger and three doctors and midwives in Cambridge performed ultrasound examinations. All operators performed at least five transperineal ultrasound examinations together with an experienced operator before contributing examinations to the study. The ultrasound operator was not involved in clinical decisions or management of labor. One ultrasound examination was performed per woman between contractions.

Women were lying in a supine position with flexed hips and knees. They had ruptured membranes and an empty bladder, and fetuses in all positions were included.

HPD was measured as the shortest distance between the outer bony limit of the fetal skull and the perineum with the transducer placed in a transverse view in the posterior fourchette as previously described (Eggebø et al. 2006; Hassan et al. 2013; Torkildsen, Salvesen and Eggebø 2011). The soft tissue between the labia majora was compressed with a firm pressure without creating discomfort for the women. AoP was assessed as the angle between a line through the symphysis and the tangent to the fetal head (Barbera et al. 2009b). The mean of three measurements from separate acquisitions was used. Fetal head position was assessed with transabdominal ultrasound and recorded as per a clock face with half hourly divisions. Positions >03.30 and <08.30 were recorded as occiput posterior (Akmal et al. 2002); all other positions were categorized as non-occiput posterior. All acquisitions were analysed immediately in the labor room.

A sample size calculation before the study with alpha 0.05, power 0.8, ratio 1:1 and a cut-off level of HPD at 40 mm, determined that 146 women should be included. The calculation was based on the results from a previous study (Torkildsen, Salvesen and Eggebø 2011), in which 93% of women with HPD ≤40 mm and 57% of women with HPD >40 mm delivered vaginally. Anticipating that the results would be less predictive in a multicentre study with several ultrasound operators, we estimated 85% vs. 65% vaginal births with HPD of 40 mm as cut-off.

Statistical analyses

Normal distribution of variables was tested with Q-Q plots and Kolmogorov-Smirnov's test. The predictive values for vaginal delivery were evaluated with cross-table analyses and with receiver–operating characteristics (ROC) curves. The area under the curve AUC was used as discriminator and considered to have discriminatory potential if the lower limit of the 95% CI interval exceeded 0.5. HPD ≤40 mm, AoP ≥110^{o}, non-occiput posterior position, digital VE assessment of station ≥0, cervical dilatation, spontaneous onset of labor, epidural analgesia, maternal age and body mass index (BMI) were included in a multivariable logistic regression analysis with vaginal delivery as dependent variable. Cases with missing values (n = 12) were excluded and only variables known at the time of ultrasound examinations were included in the model. The time from ultrasound examinations to delivery was evaluated using Kaplan–Meier survival analyses and compared with log rank test. Women experiencing a Caesarean section were censored. Continuous variables were compared using linear regression and correlations were assessed using Pearson correlation coefficient. P <0.05 was considered significant. Data were analysed with the statistical software package PASW statistics version 21.0 (Chicago, IL, USA).

Results

One hundred and fifty women were included in the study: 87 in Stavanger and 63 in Cambridge. HPD measurement was obtained successfully in all women, AoP was not obtained in five (four in Cambridge and one in Stavanger) and fetal head position could not be determined with ultrasound in eight (four in each center), including two women in whom neither AoP nor head position was obtained. In one woman, information about spontaneous or induced start of labor was missing. Thus, there were 12 exclusions from the multivariable logistic regression analysis. Fetal station and cervical dilatation information from digital VE was available for all women. Analyses stratified by center showed no differences for maternal characteristics.

One hundred and eleven (74%) women delivered vaginally. The predictive values of HPD and AoP for vaginal delivery are presented as ROC curves. The AUC for HPD was 81% (95% CI, 73–89%), and results were similar for the two hospitals: 80% (95% CI, 67–92%) in Stavanger and 83% (95% CI, 73–93%) in Cambridge. The AUC for AoP was 72% (95% CI, 63 – 82%): 77% (95% CI, 66 – 88%) in Stavanger and 66% (95% CI, 49 – 83%) in Cambridge. Thirty-one (80%) of 39 Cesarean sections were performed due to slow progress in labor and eight were due to fetal distress. Using Cesarean section due to dystocia as the dependent variable gave AUCs of 75% (95% CI, 65–84%) with HPD as the test variable and 75% (95% CI, 66–84%) with AoP as the test variable.

Both HPD and AoP were normally distributed. The mean value of HPD was 39.7 (median, 39.3; range, 13–67) mm, and HPD was ≤40 mm in 84/150 (56%) women, of whom 77 (92%; 95% CI, 84–96%) delivered vaginally. Among the other 66 (44%) women, in whom HPD was >40 mm, 34 (52%; 95% CI, 40–63%) delivered vaginally. The mean value of AoP was 113° (median, 112° ; range, 87 – 150°) and AoP was ≥ 110° in 84/145 (58%) women, of whom 74 (88%; 95% CI, 79 – 93%) delivered vaginally. Among the other 61 (42%) women, in whom AoP was < 110° , 35 (57%; 95% CI, 45 – 69%) delivered vaginally. Analyses stratified by centres showed similar predictive values (91% of women with HPD ≤40 mm delivered vaginally in Stavanger vs. 93% in Cambridge and 89% of women with AoP ≥110° delivered vaginally in Stavanger vs. 87% in Cambridge).

The frequency distribution for deliveries in relation to subgroups of HPD were as follows: deliveries were vaginal in the one woman included with HPD <20 mm; 15/16 (94%) with HPD 21-30 mm; 61/67 (91%) with HPD 31-40 mm; 29/49 (59%)

with HPD 41-50 mm; 4/15 (27%) with HPD 51-60 mm; 1/2 (50%) with HPD >61mm. The frequency distribution for deliveries in relation to subgroups of AoP were vaginal in 0/2 (0%) women with AoP <90 ^{o}; 4/10 (40%) with AoP 90-99 ^{o}; 31/49 (63%) with AoP 100-109 ^{o}; 38/43 (88%) with AoP 110-119 ^{o}; 31/36 (86%) with AoP 120-129 ^{o}; 5/5 (100%) with AoP ≥130 ^{o}.

Multivariable logistic regression analysis showed that HPD ≤40 mm (odds ratio (OR), 4.92; 95% CI, 1.54 – 15.80), AoP ≥ 110° (OR, 3.11; 95% CI, 1.01–9.56), non-occiput posterior position (OR, 3.36; 95% CI, 1.24–9.12) and spontaneous onset of labor (OR, 4.44; 95% CI, 1.42–13.89) were independent predictors for vaginal delivery. There was no significant interaction between HPD and AoP. We noted that the test characteristics of the variables found to be predictive by multivariable regression analysis.

Kaplan–Meier curves were used to illustrate the association between time remaining in labor using HPD ≤ 40 mm as cut-off level ($P < 0.01$, log rank test) and AoP ≥ 110° as cut-off level ($P < 0.01$, log rank test). The association between HPD and BMI was demonstrated. The regression equation was $y = 30 + 0.4x$ and the correlation coefficient (R) was 0.20, p=0.01.

Discussion

We found that transperineal ultrasound can provide clinically important information that is not available from conventional digital VE in nulliparous women with prolonged first stage labor. When HPD ≤40 mm or AoP ≥110°, the great majority of women underwent vaginal delivery and when HPD > 40 mm or AoP < 110°, approximately half did. Spontaneous onset of labor and non-occiput posterior position were also independently predictive for vaginal delivery. Not surprisingly, we also found that a low fetal head station in prolonged labor was associated with short remaining duration of labor.

AoP >120° has been recommended as a 'safe' cut- off for performing a successful operative vaginal delivery among women in the second stage of labor(Barbera et al. 2009b; Ghi et al. 2009a; Kalache et al. 2009). In this study we found that AoP > 110° and HPD < 40 mm were both good predictors of vaginal delivery in prolonged first stage of labor. The clinical value of HPD in prolonged second stage of labor has not been investigated.

Clinicians sometimes use a combination of dystocia and fetal asphyxia as an indication for operative delivery. This is why we used all Cesarean sections (including failed vaginal operative deliveries) as one of the main outcome measures. Even when a sub-analysis using only Cesarean sections due to labor dystocia was performed, HPD was still related to successful vaginal delivery, albeit with a slightly lower predictive value.

In the multivariable regression analysis we did not include variables such as birth weight, head circumference or oxytocin augmentation because these were not known prospectively at the time of diagnosis of prolonged labor. We did include epidural analgesia in the analysis; however, this showed very wide confidence intervals in the multivariable regression analysis and no significant predictive value, probably because it was offered to most (91%) women in the study.

Similar predictive values of HPD and AoP were found in a previous study (Torkildsen, Salvesen and Eggebø 2011). That study was criticized because one operator obtained all the ultrasound measurements and because it was performed in a single delivery unit with low Cesarean section rates (Mongelli and Benzie 2011). In the present two-center study, in which the Cesarean section rates were different (Stavanger around 14% and Cambridge around 27%), the predictive value of HPD and AoP have been confirmed. In our single-center stratified analysis, AoP did not significantly predict vaginal birth in Cambridge, probably due to the wide confidence intervals. This should be viewed as an exploratory analysis, since the power calculation estimate of 146 women was reached only when the two centers were combined.

The strength of our study is that we report on the use of transperineal ultrasound in the hands of 12 doctors and midwives working in two delivery units with different definitions of prolonged first stage of labor and different Cesarean section rates. A limitation is that women could only be included when a member of the research team was available; hence, we do not know the exact number of eligible women. However, the characteristics of the study women were similar to those of all nulliparous women in Stavanger and Cambridge. These results are therefore likely to be valid for nulliparous women with prolonged first stage of labor. Another limitation is that AoP could not be obtained in five cases. When assessing AoP, the fetal head contour can be difficult to visualize at high stations due to shadowing from the symphysis, and in four of the five cases HPD indicated that the station was high. Head position can also be difficult to define with transabdominal ultrasound, especially in cases with transverse position at low levels and in cases with asynclitism. New ultrasound methods have recently been suggested to overcome this problem(Ghi et al. 2012; Malvasi et al. 2012). Finally, birth attendants were blinded to ultrasound results from the research team, they were not restricted from performing an ultrasound examination themselves later during labor, and this might have influenced their clinical decisions.

We found digital VE for assessment of fetal head station to be predictive in unadjusted regression analyses, but not in the adjusted analysis. Digital VE is inconsistent and, unlike ultrasound measurements, cannot be documented objectively or recorded (Dupuis et al. 2005). The reproducibility of AoP has been documented (Ghi et al. 2010; Molina et al. 2010) and HPD measurements have also shown acceptable intra- and interobserver variation (Eggebø et al. 2006; Torkildsen, Salvesen and Eggebø 2012), similar to the accuracy described for transvaginal ultrasound assessment of cervical length (Valentin and Bergelin 2002). As the transducer is placed in the posterior fourchette and pressed firmly against the pubic bone there might be variation of HPD with BMI. However, the soft tissue in the posterior fourchette is easy to compress even in obese women, and while our analysis suggested a significant effect of BMI on HPD measurements, the correlation was low ($R = 0.2$; $R^2 = 0.04$), indicating that the effect was weak.

We observed a clear relationship of HPD and AoP with vaginal delivery; the shorter the distance or the wider the angle, the higher the likelihood of vaginal delivery and the larger the distance or the smaller the angle, the higher the likelihood of Cesarean section. The question that arises is whether we are ready to apply in clinical setting information derived from intrapartum ultrasound studies. As our study was not interventional, our findings should not change practice, but they might help doctors towards better decision-making. In prolonged labor, women with HPD $\leq$ 40 mm or AoP $\geq 110^{\circ}$ can be reassured, and this information might maintain confidence in achieving vaginal delivery. A finding of HPD >40 mm or AoP < 110° does not necessitate Cesarean delivery, but may help doctors to provide more precise information to the patient when the chance of successful vaginal delivery is slim. Repeat measurements after 1 or 2 hours might be helpful, but their clinical value was not investigated in this study.

Prediction of mode of delivery has attracted more research over the last couple of years. A study in second stage of labor of 68 women at term (36 primiparous, 32 multiparous) were included and had transperineal ultrasound for the assessment of angle of progression, head progression distance, head-symphysis distance and head-perineum distance. Women were divided into two groups after delivery upon the mode of birth; caesarean and vaginal birth groups. 60 delivered naturally and 8 had caesarean section. All patients whose value for head-symphysis distance was below 1.78cm delivered naturally and 21 patients (35%) who delivered naturally had this value above 1.78cm at fully dilatation. All patients whose value for the head progression distance was above 3.43 cm delivered naturally and 12 patients (20%) who delivered naturally had this value below 3.43 cm at the time of complete dilatation. All patients with an angle of progression above 126 degrees delivered naturally and for 9 patients (15%) of those who delivered naturally this value was less than 126 degrees at the time of complete dilatation. All patients whose value for the head-perineum distance was below 3.16 cm delivered naturally and 27 patients (45%) who delivered naturally had this value above 3.16 cm at the time of complete dilatation. All the ultrasound parameters measured correlate strongly with each other, where the highest correlation coefficient of 0.906 is observed for the parameters: head progression distance and angle of progression and the second highest correlation coefficient is observed for head-symphysis distance and angle of progression at an absolute value of 0.76. All multiparas delivered naturally, caesarean sections were performed only in the group of primiparous. In this study angle of progression of 126 degrees resulted with all women having natural delivery. Whereas the angle of progression averaged at 113 degrees for women who had a caesarean section delivery. (Ciaciura-Jarno et al. 2016).

Another study by Kahrs et al. in a multicenter prospective cohort study evaluated the prediction of outcome of vacuum deliveries in second stage of labor. The group included 222 women and assessed head-perineum distance using a cut-off value of 25mm. The main outcome was duration of vacuum extraction in relation to ultrasound measured head-perineum distance. Women with head-perineum distance ≤ 25mm had shorter duration of vacuum extraction with estimated median of 6minutes (95% CI, 5.2-6.8) compared to 8.0 minutes duration (95% CI 7.1-8.9) in women with head-perineum distance >25mm. 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). The study has the potential to predict labor outcome in second stage before attempting vacuum delivery and whether a caesarean delivery should be attempted. Furthermore, it could help in deciding the place of delivery whether in the delivery room or obstetric theatre. (Kahrs et al. 2017).

Youssef et al. analysed fetal head-symphysis distance and prediction mode of delivery in the second stage of labor. The study used 3D transperineal ultrasound by undertaking a series of sonographic volumes at the beginning of second stage (T1) and thereafter (T2, T3, T4, T5, T6) every 20 minutes until delivery. Volumes were retrospectively analysed and head-symphysis distance was measured for each acquisition. Comparison was done between women with spontaneous vaginal delivery and those with operative delivery. Women with spontaneous vaginal delivery had shorter head-symphysis distance than women in the operative group. Receiver operator characteristic curves revealed accuracy values of 81.0%, 87.9% and 77.6% in the prediction of operative delivery at T1, T2 and T3. Therefore, in this study the measurement of head-symphysis distance in the second stage of labor can be used to predict operative delivery (Youssef et al. 2014).

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Prediction of delivery mode with ultrasound assessed fetal position in nulliparous women with prolonged first stage of labor.

Eggebo TM, Hassan WA, Salvesen KA, Torkildsen EA, Ostborg TB, Lees CC

Ultrasound Obstet Gynecol; 2014. 46: 606–610

Objectives

To ascertain if fetal head position on transabdominal ultrasound is associated with delivery by caesarean section in nulliparous women with a prolonged first stage of labor.

Methods

A prospective observational study in nulliparous women with prolonged first stage of labor was performed at Stavanger University Hospital, Norway and Addenbrooke's Hospital, Cambridge, UK between January 2012 and April 2013. The Ethics Committees approved the study (REK 2011/731 in Norway and 11/EE/064 in the UK). The study was registered in Clinical Trials.gov with identifier NCT01610453.

Women with a live singleton fetus, cephalic presentation and gestational age ≥37 weeks according to a second trimester scan were eligible and 87 women in Stavanger and 63 women in Cambridge were included. The main outcome was CS vs. vaginal delivery, and secondary outcomes were operative vaginal delivery, time from ultrasound examination to delivery and agreement between ultrasound examinations and clinical examinations. Nine doctors and three midwives participated in the research team. Women were recruited when a member of the research team was

available, and they gave written informed consent.

In Stavanger prolonged active first stage of labor was diagnosed in accordance with the WHO recommendations (when cervical dilatation crossed the action line four hours delayed from the alert line) and in Cambridge prolonged labor was defined according to NICE guidelines (dilatation of < 2 cm in 4 hours).

The birth attendant responsible for the labor evaluated fetal head position by digital vaginal examination (VE) just before or immediately after the ultrasound examinations. The research team and birth attendants were blinded to the other assessment. Transabdominal ultrasound measurements were performed using Voluson *i* ultrasound equipment (GE, Zipf, Austria) with a 3.5-7.5 MHz three-dimensional (3D) curved multi-frequency transabdominal transducer in Stavanger, and Samsung Medison Accuvix XG (Samsung Medison, Medical Imaging Systems Ltd, London, UK) equipment with a 4-6 MHz convex transabdominal transducer in Cambridge. The ultrasound operator was not involved in clinical decisions or management of the labor.

The ultrasound examination was performed as described by Youssef et al. (Youssef, Ghi and Pilu 2013). Fetal head position was recorded as a clock divided into half hourly divisions. Positions ≥02.30 and ≤03.30 hours were recorded as left occiput transverse and positions ≥08.30 and ≤09.30 as right occiput transverse. Positions ≥04.00 and ≤08.00 were recorded as occiput posterior and positions ≥10.00 and ≤02.00 as occiput anterior position (Rane et al. 2004; Akmal et al. 2002; Eggebø and Salvesen 2010).

Results

In total, 87 women at Stavanger University Hospital and 63 women at Addenbrooke's Hospital were included in the study. Fetal head position was assessed successfully using ultrasound in 142/150 (95%) women. Maternal characteristics, labor and fetal outcome, differentiated into OP or non-OP position as assessed by ultrasound, are presented in the manuscript. In all, 19/50 (38%) women with a fetus in the OP position were delivered by Cesarean section *vs.* 16/92 (17%) women with a fetus in a non-OP positions (P=0.01). In the OP group, 10/19 (53%) deliveries by Cesarean section were carried out because of prolonged first stage of labor, 5/19 (26%) because of prolonged second stage and 4/19 (21%) because of fetal distress. The corresponding numbers in the non-OP group were 6/16 (38%) because of prolonged first stage of labor, 6/16 (38%) because of prolonged second stage and 4/16 (25%) because of fetal distress.

The overall sensitivity of predicting Cesarean section using the ultrasound-assessed OP position as the test variable was 54% (95%CI, 38–70%), the false-positive rate was 29% (95%CI, 21–38%), the positive predictive value was 38% (95% CI, 26 – 52%), the negative predictive value was 83% (95% CI, 74 – 89%), the positive likelihood ratio (LR+) was 1.9 and the negative LR (LR–) was 0.65.

On multivariable logistic regression analysis, the OP position predicted delivery by Cesarean section with an odds ratio (OR) of 2.9 (95%CI, 1.3–6.7; P=0.01) and induction of labor with an OR of 2.4 (95%CI, 1.0 – 5.6; P = 0.05). Maternal age, gestational age and BMI had no confounding effects. The time from ultrasound examination to delivery was not significantly longer for women with a fetus in the OP position (P = 0.37; log rank test). In the manuscript Figure1 shows the time from ultrasound examination to vaginal delivery, with data censored in the event of a Cesarean section.

We observed a tendency to more operative vaginal deliveries associated with a non-OP position, but this was not statistically significant. In total, 13/50 (26%) fetuses in the OP position were delivered by operative vaginal delivery compared with 35/92 (38%) fetuses in a non-OP position (P = 0.15). Information on mode of delivery related to ultrasound-assessed fetal position when prolonged labor was diagnosed is presented in Table 2.

Fetal head position was evaluated successfully by digital assessment in only 48/150 (32%) women. Digitally-assessed OP position did not significantly predict delivery by Cesarean section (P = 0.47). We observed low agreement between digital and ultrasound assessment of OP position (Cohen's kappa = 0.19; P = 0.18).

We lacked information on the position at delivery in five of the 107 vaginal deliveries. All vaginal deliveries among women with non-OP positions according to ultrasound assessment were in the OA position at delivery. Fifty fetuses were found to be in the OP position when the ultrasound examination was performed; 19 were delivered by Cesarean section, 26 rotated spontaneously and were delivered vaginally in the OA position, four remained in the OP position at vaginal delivery, and in one case information on position at delivery was missing.

Discussion

Ultrasound-assessed OP position was associated with delivery by Cesarean section in nulliparous women with a prolonged first stage of labor. In this study we assessed the use of transabdominal ultrasound for evaluating fetal head position. We have reported previously the predictive value of transperineal ultrasound in the same study population and found that both fetal level and head position showed good predictive value in a multivariable analysis (Eggebø et al. 2014). Since many clinicians have been reluctant to adopt the transperineal approach, and use only transabdominal ultrasound to assess fetal position (Youssef et al. 2013b), we felt that it was important to report the clinical value of the transabdominal ultrasound-assessed fetal position alone. However, we recommend the use of both approaches during labor.

Somewhat surprisingly, we found a high rate (38%) of operative vaginal delivery in cases with a non-OP position on ultrasound assessment. A possible explanation is that prolonged labor in cases with the OP position is due to malposition, and prolonged labor in cases with a non-OP position is due to too few contractions. Thus, oxytocin augmentation in the OA group may successfully progress labor into the second stage and make an operative vaginal delivery possible. A recently published study documented an association between operative vaginal delivery and transverse position in the second stage of labor (Phipps et al. 2014).

An association between OP position and delivery by Cesarean section is reported inconsistently in the literature. Results depend on the study population and on the timing of the ultrasound examination. Although it is well known that the OP position is often found in women who deliver by Cesarean section (GARDBERG, LEONOVA and LAAKKONEN 2011), this does not mean that the OP position diagnosed during labor can predict Cesarean section. A systematic review concluded that ultrasound assessment of fetal head position before the start of labor should be avoided because of uncertain predictive value (Verhoeven et al. 2012). Ultrasound results might influence birth attendants' perception of the possibility of a successful vaginal delivery and increase the rate of Cesarean section (Verhoeven et al. 2012; Popowski et al. 2015). The present study differs from previous studies because we selected a subgroup of nulliparous women in a prolonged first stage of labor, in which ultrasound assessment of fetal head position could predict mode of delivery.

Other subgroups may also benefit from ultrasound assessment during labor. Exact knowledge of fetal position and level is required by the obstetrician when performing operative vaginal delivery (Souka et al. 2003; Youssef, Ghi and Pilu 2013; Kalache et al. 2009; Rayburn et al. 1989; Wong, Mok and Wong 2007; Cuerva et al. 2014). In a randomized controlled trial (RCT), ultrasound assessment reduced the incidence of incorrect diagnosis of fetal head position, but did not prevent morbidity (Ramphul et al. 2014). Digital examination could be replaced by ultrasound in women with prelabor rupture of membranes, but studies are needed to document possible benefits. Manual correction of malposition is possible during the second stage of labor when the precise position is known (Le Ray et al. 2007). Maternal position may influence fetal rotation during labor, and an ongoing RCT is evaluating the influence of maternal position in the management of OP position during the first stage of labor (Guittier et al. 2016). Asynclitism can also be diagnosed by ultrasound (Ghi et al. 2012; Malvasi et al. 2012) and is associated with second-stage arrest, but it is a normal finding during the first stage of labor (Malvasi 2012).

In a previous study, we found no clinical value in diagnosing the OP position in nulliparous women with prolonged labor (TORKILDSEN et al. 2012). We believe that the results of the present study are more reliable because it was a two-center study with a larger population than that of the previous one. A good prognostic test should have an LR+ > 10 and an LR – < 0.1 (Jaeschke, Guyatt and Sackett 1994). In the present study, we found statistically significant differences, but clinically less impressive test characteristics (LR+, 1.9; LR –, 0.65). We think that anamnestic information; clinical examination and transabdominal and transperineal ultrasound assessment should be combined and prospectively tested in predictive models (Dietz, Lanzarone and Simpson 2006; Cheung et al. 2010). In this study we tested only variables known at the time of the ultrasound examination in the multivariable analysis, and we did not include oxytocin augmentation and epidural analgesia because around 90% of the women had epidural analgesia and oxytocin augmentation. Longitudinal studies are important in investigating changes during labor (Ghi et al. 2014), and a recently published longitudinal study did not find any influence of epidural analgesia on fetal rotation during labor (Maroni et al. 2014) The use of a sonopartogram including fetal position and level and cervical dilatation might change the method of surveillance of labor in the future (Hassan et al. 2013; Hassan et al. 2014).

Ultrasound assessment of fetal head position is usually easy, however it can be difficult to assess at low fetal head stations, and a transperineal approach can be helpful (Ghi et al. 2009a). Digital assessment of the fetal head position is difficult in early labor and in obstructed labor. In the present study, precise determination of position was achieved by digital examination in only 32% of women, and agreement with ultrasound assessment was poor.

Strengths of the study include a prospective design, two centers in different countries, 12 ultrasound examiners and a blinded study design including only a subgroup of clearly defined nulliparous women with prolonged labor. However, the study does have some limitations. The primary aim was to investigate fetal level in the birth canal, and the size of the study population was calculated based on this primary aim.

We performed a retrospective power analysis using alpha of 0.05, power 80, assuming sizes of groups are in the ratio 2:1. Expecting a 40% rate of delivery by Cesarean section in the OP group *vs.* 15% in the non-OP group, the total study population would be 115 women. Fetal position was not recorded consistently in women who delivered by Cesarean section, and we lacked information on position at delivery in five cases. It has been noted that an oblique position of the fetal spine will increase the probability of spontaneous rotation (Blasi et al. 2010), but this variable was not included in our protocol. One limitation of the study is that the definition of prolonged labor was different in the two centers, however, the results were similar. The Cesarean section rate in the OP group was 37% in Stavanger University Hospital compared with 40% in Addenbrooke's Hospital, and in the non-OP group it was 14% and 21%, respectively. Another limitation is that only one ultrasound examination was performed in each woman, and the precise position of the fetal head immediately before intervention was not known. This explains why position at delivery in some cases differed from the ultrasound-assessed position. Repeat ultrasound examinations may be necessary to ascertain whether the position persists or is part of the second cardinal rotational movement. However, in accordance with the protocol, our aim was to investigate the predictive value of ultrasound when a prolonged first stage of labor is diagnosed.

In conclusion, transabdominal ultrasound assessment of fetal head position was associated significantly with delivery by Cesarean section in nulliparous women with a prolonged first stage of labor. This information could be useful for planning delivery and timing interventions.

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Summary & Prospective

In summary, there is a need for objective and repeatable measurements of cervical dilatation, and the most obvious imaging technology for this is ultrasound. Undoubtedly, the technique of 2D transperineal assessment of cervical dilatation that we describe must be assessed for reproducibility and acceptability in blinded prospective observational studies, which we now plan. However, we do not believe that we overstate its importance in conjunction with an assessment of head descent and rotation, as the logical next step from the partogram of 30 years ago. Such a 'sonopartogram' has the potential to allow the progress of labor to be tracked entirely with ultrasound, potentially dispensing with the variability and discomfort of conventional examination. Such an advance in obstetric and midwifery practice could fundamentally affect the nature of assessment of labor, changing it from being a largely subjective skill to being a recordable science. We showed that Caput could be objectively assessed using transperineal ultrasound and thereby deriving the skin–skull distance (SSD). The importance of this assessment was also showed to be useful in a predictive model for vaginal birth. We observed a clear relationship of HPD and AoP in relation to mode of delivery in prolonged first stage of labor; the shorter the distance or the wider the angle, the higher the likelihood of vaginal delivery and the larger the distance or the smaller the angle, the higher the likelihood of Cesarean section.

The question that arises is whether we are ready to apply in clinical setting the information derived from intrapartum ultrasound studies. And whether this information can help obstetricians how to choose the safest mode of delivery more precisely and objectively. Since the publication of the presented papers, other groups have taken forward the findings of this work, which represent an initial step to highlight the importance of this work. It is obvious that ultrasound represents an objective view of the assessment of labor parameters. The findings of this work and subsequent studies published in this field would have the impact in raising the question on "how to improve the provision of care during labor". We believe without overstating, that the next decade could foresee an essential shift into the use of intrapartum ultrasound in clinical practice.

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23 November 2012

Dr Christoph Lees
Consultant in Obstetrics and Fetal-Maternal Medicine
Addenbrooke's Hospital
Rosie Hospital
Addenbrooke's Hospital, Hills Road
Cambridge
CB2 0QQ

Dear Dr Lees

Study title:	**Prediction of mode of delivery with Transperineal ultrasound in women with prolonged first stage of labour. This is a prospective observational study of women with singelton cephalic presentation at term diagnosed with prolonged first stage of labour.**
REC reference:	**11/EE/0464**
Amendment number:	**Amendment #2 Substantial**
Amendment date:	**26 October 2012**
Amendment summary:	**(1)To perform transperineal ultrasound assessment of cervical dilatation in women in labour who have consented to take part in the study (2) To perform longitudinal assessments of the fetal head descent, fetal head position and cervical dilatation on women during labour to enable us better understanding of the progress of labour by ultrasound.**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

NHS

Health Research Authority

NRES Committee East of England - Cambridge Central

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13 February 2013

Dr Christoph Lees
Consultant in Obstetrics and Fetal-Maternal Medicine
Addenbrooke's Hospital
Rosie Hospital
Addenbrooke's Hospital, Hills Road
Cambridge, CB2 0QQ

Dear Dr Lees

Study title:	**Prediction of mode of delivery with Transperineal ultrasound in women with prolonged first stage of labour. This is a prospective observational study of women with singelton cephalic presentation at term diagnosed with prolonged first stage of labour.**
REC reference:	**11/EE/0464**
IRAS project ID:	**84720**

Thank you for sending the progress report for the above study dated 08 February 2013. The report will be reviewed by the Chair of the Research Ethics Committee, and I will let you know if any further information is requested.

The favourable ethical opinion for the study continues to apply for the duration of the research as described in the application and protocol agreed by the REC, taking account of any substantial amendments.

11/EE/0464:	**Please quote this number on all correspondence**

Yours sincerely

NS Storey

Miss Nicky Storey
Committee Co-ordinator

E-mail: Nicky.Storey@eoe.nhs.uk

Copy to: *Mr Stephen Kelleher, Cambridge and Peterborough NHS Foundation Trust*

Addenbrooke's Hospital NHS
Cambridge University Hospitals NHS Foundation Trust

Consent Form

Title of study: Prediction of mode of delivery with transperineal ultrasound in women with prolonged first stage of labour

Patient Identification Number for this trial:

Name of Researcher: Mr Wassim Hassan

1) I confirm that I have read and understand the information sheet dated 22/10/2012 (Version 3.5) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

   ☐ *Please initials*

2) I understand that my participation is voluntary and that I am free to withdraw at anytime without giving any reason, without any medical care or legal rights being affected.

   ☐ *Please initials*

3) I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the research team. The sponsor of the study may need access to the data for monitoring or audit purposes and access may be granted for regulatory purposes. Anonymous data will be stored for a period of approximately 15 years.

   ☐ *Please initials*

4) I understand that my GP will be informed.

   ☐ *Please initials*

5) I agree to take part in the above study.

   ☐ *Please initials*

Name of patient: ________________________ Signature: ______________ Date:__________

Person taking Consent: ____________________ Signature: ______________ Date: __________

When completed, 1for patient, 1for researcher site file; 1 (original) to be kept in medical notes.

members of the Chief Investigator's team, including non-doctoral student researchers.

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A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- (●) NHS or HSC care organisation
- ( ) Academic
- ( ) Pharmaceutical industry
- ( ) Medical device industry
- ( ) Local Authority
- ( ) Other social care provider (including voluntary sector or private organisation)
- ( ) Other

Commercial status:

If Other, please specify:

Contact person

Name of organisation	Cambridge University Hospitals NHS Foundation Trust
Given name	Addnebrookes Hospital- R&D office
Family name	
Address	Hills Road,
Town/city	Cambridge
Post code	CB2 0QQ
Country	UNITED KINGDOM
Telephone	01223 216 022
Fax	
E-mail	christoph.lees@addenbrookes.nhs.uk

A65. Has external funding for the research been secured?

- [ ] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [x] No application for external funding will be made

Patient Information Sheet

Title of study: Prediction of mode of delivery with transperineal ultrasound in women with prolonged first stage of labour: a multicentre study.

[A study of whether doing a scan of the area behind a woman's vaginal opening during labour if her labour is progressing slowly helps to tell whether she will need to have a Caesarean or not]

We would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

This leaflet:

- Outlines the aim of the study and what will happen to you if you take part.
- Provides more detailed information about how the study will be carried out.

Please do ask us if there is anything that is not clear or if you would like more information.

1. What is the purpose of the study?

The purpose of the study is to investigate whether an ultrasound scan in labour when labour is going slowly is helpful in predicting whether a woman will have a normal delivery or a Caesarean. The study is being carried out in the Delivery Unit of the Rosie Hospital at Addenbrooke's, and is part of an international study which will run simultaneously in delivery units in other European countries. The aim of the study is to gain a better understanding of slow progress in labour and to see if an ultrasound scan could help midwives and doctors make better decisions about labour and delivery.

2. Why have I been invited?

We are asking all first-time mothers who have gone into labour after 37 weeks of pregnancy to take part in the study: both women with a normal first stage of labour and women whose labour is progressing slowly. Slow progress in labour is the commonest reason for Caesarean sections being carried out. Slow labour may be caused by contractions not being strong enough, the baby's head being in an awkward position (malposition) or a mismatch between the size of the baby and the pelvis (disproportion).

3. Do I have to take part?

It is up to you whether or not you decide to join the study. You will be given this information sheet to keep together with a consent form. Once you are in labour and you agree to take part in the study, you will be asked to sign the consent form. We will then arrange for the ultrasound examination to take place. You are free to withdraw from the study at any time, without giving any reason. Withdrawing would not affect the standard of care you receive.

4. What will happen if I take part?

It is normal during labour to have internal examinations to assess how labour is progressing and how the baby's head is moving down into the pelvis. If you agree to take part in the study, then a doctor, midwife or sonographer will perform two quick scans – taking only a few minutes. This person will not been involved in your care up to that point, and will have no involvement after the scans have been done. Firstly, an ultrasound scan of your belly, of the sort you are likely to have had during pregnancy, will look at the position of the baby's head. Secondly, a scan of your perineum, the area between your vaginal opening and your anus, will measure the distance to the baby's head. This scan is performed with the scan probe positioned on the skin, and not inside the vagina. You will need to lie on your back, with your knees bent up and your legs apart, for the scan to be done. The scan is painless and done between contractions. The scan findings will not be used in your maternity care; they will only be used for the study purposes. All other necessary information for the study will be collected from your notes and transferred anonymously to the coordinating centre (in Norway) for analysis. Anonymous data will be stored in a secure database for a period of approximately 15 years. The research will last for under 2 years.

5. What do I have to do?

You will be provided with the relevant information about the study and asked if you wish to take part in it. If during labour you are diagnosed with slow progress, and you agree to take part in the study, then at that point you will need to sign the consent form attached to this information sheet.

6. What are the possible benefits of taking part?

We cannot promise the study will help you personally, but the information we get from this study may be useful for other women in the future. Since this is an observational clinical study, any findings from the ultrasound measurements cannot be used in your delivery. Your care will follow the normal procedures in the department.

7. Will my taking part in the study be kept confidential?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. We will follow ethical and legal practice and all information about you will be handled in confidence. Information will be collected by one of the research team members. All necessary information for the study will be collected from your notes and transferred anonymously to a computer. Only the research team will have access to this.

8. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. You can contact Mr Christoph Lees (01223 217972). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure, details of which can be accessed by contacting PALS- Patient Advice and Liaison Service, Box 53, Addenbrooke's Hospital, Hills Road, Cambridge, Tel: 01223216756, email: pals@addenbrookes.nhs.uk. The NHS indemnity scheme will apply in the unlikely event that something goes wrong.

9. What will happen to the results of the study?

We intend to use the result of this study for managing pregnancies in the future. We intend to publish the results in local and international journals. You will not be identified in any report or publication. We will inform your GP that you have taken part in the study.

10. Who will be doing the research?

The UK research group consists of Mr Wassim Hassan (Senior Clinical Fellow in Fetal Medicine), Mr Christoph Lees (Consultant in Obstetrics and Fetal Medicine), and Professor Kjell Salvesen (Consultant in Obstetrics & Fetal Medicine). If you would like to contact us, please email Mr Wassim Hassan: wassim.hassan@addenbrookes.nhs.uk.