Angle of progression and vaginal delivery

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Primary Objective: To establish a prediction model for the probability of vaginal delivery and successful vacuum extraction at the second stage of labor, using the angle of progression by transperineal ultrasound. Secondary Objective(s): To evaluate...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational invasive

Summary

ID

NL-OMON43662

Source
ToetsingOnline

Brief title
APRO

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
normal birth, vaginal delivery

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Enkel de echoapparatuur wordt beschikbaar gesteld door GE Healthcare;geen verdere financiering.

Intervention

Keyword: Angle of progression, Intrapartum transperineal ultrasonography, labor

Outcome measures

Primary outcome

Main endpoint includes a cut-off for the angle of progression predicting

successful vaginal delivery and successful vacuum delivery.

Secondary outcome

Secondary parameters include the results of the questionnaires evaluating the

experiences of women in labor undergoing ITU.

Study description

Background summary

Uncomplicated vaginal birth is the favourable outcome in most pregnancies. If women fail to progress in the second stage of labor, obstetric intervention is needed. Obstetric interventions include Cesarean section(15.6%)1, instrumental delivery using forceps or vacuum extraction(10%)1 and secondary Cesarean section after failed instrumental delivery or in case of fetal distress.
A study showed that compared to a successful instrumental delivery, the risk of intracranial haemorrhage increases from 1:860 to 1:334 after failed operative vaginal delivery followed by Cesarean section2. In addition, second-stage Cesarean section yields increased maternal risk as well. Since the fetal head is embedded deeply into the maternal pelvis, it is associated with major haemorrhage, increased risk of bladder trauma and broad ligament hematomas3,4.
Predicting the chance of vaginal delivery is commonly based on digital vaginal examination, where progression of cervical dilatation and fetal head descent are assessed by palpation. However, studies showed that this *golden standard* is a subjective evaluation with several limitations, such as a high error rate of determining fetal head position5-10.
Recently, intrapartum transperineal ultrasonography (ITU) has been studied to predict the mode of delivery. Various ultrasound parameters have been described, including angle of progression, head-perineum distance, head-symphysis distance, mid-line angle, pubic arch angle and fetal direction and rotation. However, the angle of progression (AOP) was found to be the most reproducible parameter for predicting the mode of delivery11. The AOP is defined as the angle between a line drawn through the midline of the pubic symphysis and a line drawn from the inferior edge of the symphysis tangentially to the fetal skull12.
Kalache et al. found that when the AOP was 120*, the probability of an easy and

successful vacuum extraction or spontaneous vaginal delivery was 90%13. Furthermore, Sainz et al. showed that if a progression angle is <= 120*, the foetal head direction is horizontal or head-down and a midline angle is >= 35* before the vacuum is placed, there is a 85% probability that the delivery will require more than 4 vacuum pulls14. Ghi et al. found that the AOP was a significant predictor of duration of the active second stage of labor and that it might play an important role in predicting the mode of delivery15,16. Barbera et al. assessed the feasibility and reproducibility of measuring the AOP by transperineal ultrasound. The study showed good levels of intraobserver variability (approximately 2.9 degrees), and interobserver error (1.24 degrees), indicating the accuracy of the technique12. In addition, where digital examination is often misleading by caput succedaneum formation, head oedema and other pelvic landmarks, these elements will not affect the angle measured, since it only depends on two bony structures with clear landmarks (the pubic symphysis and the calvarium) 5,12.
ITU seems to be an objective and reliable tool to predict the mode of delivery. Based on quantative data, it provides more accurate details about the progress of labor than the traditional digital examination5-7, 10, leading to timely and appropriate decision making during the second stage of labor and improved obstetric outcomes. Although these results are promising, little is known about the use of AOP in predicting the mode of delivery and the existing data relies upon a small number of patients included in the studies.
The aim of this study is to establish a predictive model for the probability of vaginal delivery and successful vacuum extraction at the second stage of labor, using the AOP by transperineal ultrasound. Therefore, a cut-off point for predicting successful vaginal delivery and successful vacuum extraction will be generated. Also the use of GE Healthcare SONO L&D software in measuring the angle of progression will be studied, as well as the experiences of women in labor using ITU.

Study objective

Primary Objective:
To establish a prediction model for the probability of vaginal delivery and successful vacuum extraction at the second stage of labor, using the angle of progression by transperineal ultrasound.

Secondary Objective(s):
To evaluate the experiences of women in labor using ITU, using questionnaires.
To evaluate the use of GE Healthcare SONO L&D software in measuring the angle of progression.

Study design

This will be a prospective cohort study of the angle of progression in the second stage of labor. All women with singleton pregnancies and with a

gestational age >37 weeks with spontaneous or induced onset of labor planning to deliver at the Obstetric Department of the UMCG will be included. We plan to include 250 women. Women will be informed about the study during prenatal visits at our outpatient clinic or before an induction is started at the ward and asked for consent. Written informed consent, inclusion & exclusion criteria will be checked for every patient. When the woman reaches the second stage of labor, an ultrasound examination will be performed every 20 minutes until the moment of delivery. Women are considered to be in the second stage of labor when they reach full cervical dilatation and they feel the urge to start pushing at every contraction. Digital examination as routine care will be used to define the start of the second stage. The transperineal ultrasound will be performed by a Voluson P8 ultrasound system (GE Healthcare). The ultrasound probe, wrapped in a sterile plastic bag, will be gently applied to the labia majora of the women with the use of sterile coupling gel between probe and maternal tissues. The angle of progression will be measured automatically by the built-in SONO L&D software by drawing a line through the midline of the pubic symphysis and another line from the inferior edge of the symphysis tangentially to the fetal skull. The angle will be stored blindly in the equipment and it will not influence clinical management, which will be as usual. Intraobserver and interobserver variability will be calculated. Intraobserver variability will be determined by replicating the measurement on 25 patients by the same observer at approximately the same time. To determine interobserver variability, measuring the angle of progression will be repeated by a second observer to a subset of 25 randomly selected women. Data collection will be checked for every 5th patient and stored anonymously. The measured angles will be analysed and a cut-off for spontaneous vaginal delivery will be established. Women will be requested to fill in a short questionnaire containing 5 multiple choice questions regarding their experiences with transperineal ultrasound during the second stage of labor.

Study burden and risks

Transperineal ultrasound is not associated with additional risks for the mother or the fetus or excessive discomfort. The investigation consists of applying a probe against the labia majora of the parturient during the second stage of labor. ITU will last not more than a few minutes since the software measures the angle automatically and it will be repeated every 20 minutes in case of prolonged second stage. After delivery women are requested to fill out a short questionnaire containing 5 multiple choice questions. The questionnaire is given at the moment the child will be checked and weighted, which is usually a moment of peace in the delivery room. In case a cesarean section is performed, the questionnaire is given at the maternity ward. Before the patient is dismissed from the hospital, the questionnaire will be checked.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Nulliparous and multiparous women.
2. Singleton pregnancy.
3. Age >=18 years and good understanding of the Dutch language.
4. At term gestation (37 weeks or more).
5. Fetus in cephalic presentation.
6. Second stage of labor.

Exclusion criteria

1. Cesarean section or instrumental vaginal delivery performed solely because of suspected fetal distress.

2. Delivery elsewhere than the University delivery ward.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2016
Enrollment:	250
Type:	Actual

Medical products/devices used

Generic name:	Voluson P8 Ultrasound system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-02-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-12-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL55075.042.15