Incidence of pelvic floor injury after a first normal vaginal delivery in women with and without a mediolateral episiotomy (EPILEVA study)

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Primary ObjectiveDifference in incidence of an avulsion injury and morphological changes of the levator ani muscle after a first normal vaginal delivery between participants with and without a mediolateral episiotomy.Secondary ObjectiveChanges in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Observational non invasive

Summary

ID

NL-OMON39466

Source
ToetsingOnline

Brief title
EPILEVA

Condition

- Muscle disorders
- Pregnancy, labour, delivery and postpartum conditions

Synonym
levator avulsion

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Geld verkregen door tutoring van een workshop door A.B. Steensma (1000 euro)

Intervention

Keyword: 3D/4D transperineal ultrasound, Levator avulsion, Mediolateral episiotomy, Vaginal delivery

Outcome measures

Primary outcome

Main study parameter/endpoint

The differences of a levator avulsion and hiatal dimensions between both groups

All analysis of the ultrasound volumes will be performed off line. The investigators will be blinded against the participants* clinical data and therefore unaware of the delivery outcome and if the participant had a mediolateral episiotomy.

Levator avulsion will be scored using a scoring system based on Tomographic Ultrasound Imaging. To assess a levator avulsion ultrasound volumes on maximum pelvic floor contraction (PFMC) are used. A multislice technique comparable with the computed tomography is utilized. Slices has to be obtained in the axial plane at 2.5-mm slice intervals, from 5 mm below the plane of minimal hiatal dimensions (see figure 3) to 12.5 mm above that plane, to encompass the entire puborectalis muscle.(29) Levator avulsion is diagnosed if three central

slices (reference slice and the slices 2.5 and 5 mm cranial) (i.e. slices 3-5 in figure 4) showed a clearly abnormal muscle insertion, a methodology that has been validated against pelvic organ support data.(30) Good repeatability of the sonographic diagnosis of levator avulsion (* >= 0.7) has been demonstrated by the authors and others. (31-32)

Figure 3: Normal anatomy, on the right a midsagittal 2D section and on the left a 3D section. Depicted line is level of minimal hiatal dimension.

Figure 4: Tomographic ultrasound imaging, with a slice interval of 2.5 mm, showing a normal levator ani on the right(A) and a right-sided avulsion (marked by *) on the left (B).

Secondary outcome

Changes in quality of life and pelvic floor symptoms questionnaires between both groups

Hiatal measurements of the levator hiatus in contraction, rest and in valsalva. These measurements will be performed whilst doing the off line blinded analysis for detecting levator avulsion. These measurements are shown in figure 5.

Figure 5: Measurements in 3D volumes of the anatomy of the pelvic floor and levator ani. Measurement 1 shows the AP(anterior-posterior) diameter of the levator hiatus, measurement 2 the LRI(left-right) diameter of the levator and measurement 3 the hiatal area.

Study description

Background summary

The levator ani muscle, also called the pelvic floor, is attached to the internal surface of the true pelvis and is subdivided into three parts according to their attachments and pelvic viscera to which they are related, namely ileococcygeal, pubococcygeal and puborectal muscle. The pelvic floor is funnel shaped, with the puborectal muscle as the most caudal and central component.
MRI and three dimensional (3D) and four dimensional (4D) transperineal ultrasound technique can visualize abnormalities of the levator ani muscle or pelvic floor.(1,4,20)
Whilst MRI is not widely available, invasive and expensive, 3D/4D transperineal ultrasound offers the same advantages, is less expensive and is well tolerated by the patients. With the increasing experience in these dynamic imaging techniques, new insights have been gained on pelvic floor dysfunction and the impact this has on symptoms and anatomical abnormalities. Anatomical abnormalities are prescribed as a detachment of the puborectalis part at its origin on the pubic bone and are also called a levator avulsion (figure 1). These avulsions can occur either unilateral or bilateral. Most authors assume that levator avulsion happen during crowning of the fetal head.(21)
Lien et al(22) showed that a remarkable degree of distension of levator ani has to appear during labour (figure 2). This study showed that the mediococcygeus muscles undergo the greatest stretch of the levator ani muscle during vaginal birth and therefore at that time are at the greatest risk to develop injury. The diameter of the fetal head is around 9 cm, and assuming that the size of a normal *non pregnant female* is around 2.5 cm, means that the tissue of the pelvic floor, i.e the levator ani has to stretch 3.54 in length and fourfold in proportion to the ratio of the diameter of the hiatus of the levator ani. These findings were confirmed in a recent study in which 227 nulliparous pregnant women were examined before and after childbirth. In this study the levator ani muscle dilated between 25% to 245% during parturition.(23)
Using MRI, DeLancey et al(4) were the first to report a relation between levator ani avulsion and vaginal deliveries. Levator ani avulsion was identified in 20% of women after their first vaginal delivery. No pelvic floor abnormalities were found in nulliparous women. Dietz et al(4,20) reported similar findings using 3D transperineal ultrasound. Levator ani avulsion was identified in up to 36 percent of the women after vaginal delivery. They found no pelvic floor abnormalities in women after Caesarean section. These findings indicate that pelvic floor damage is most likely caused by vaginal delivery. Furthermore, it has been proven that these defects are significantly associated with pelvic organ prolapse and the risk of developing recurrence of prolapsed after surgery.(24) Pelvic organ prolapse is a common condition and the

estimated prevalence is around 40%. Childbirth is considered to be a risk factor for developing pelvic organ prolapse by 4 to 11 times and stress urinary incontinence by 2.7 times. One in three women complaining of pelvic organ prolapse symptoms require surgery and 30% of these operations require a re-operation at some stage.(25) Re-operation usually includes a more extensive procedure, such as a laparoscopic sacrocolpopexy or Mesh Implants.
Vaginal delivery may injure the levator ani in a number of different patterns sometimes termed *defects*.(4) For a long time it has been difficult to examine the pelvic floor in young asymptomatic nulliparous women due to the inherent limitations of magnetic resonance imaging and the logistic problems of performing MRI. With the introduction of 3D pelvic floor ultrasound imaging since the 1990s a non invasive and more practical technique for assessment of levator ani morphology became possible.(1,26) Transperineal ultrasound is an easy accessible investigation and an objective non-invasive method to examine levator ani avulsion. Several studies have shown that this investigation is reliable and repeatable. (27-28)
Prevention of levator avulsion is important, because until now it is not possible to repair this damage. Prevention is possible by identifying risk factors for developing levator avulsion.
Previous research showed that a mediolateral episiotomy during operative vaginal delivery and restrictive use during normal vaginal delivery can protect against anal sphincter injuries another type of pelvic floor injury.(6-9)
A mediolateral episiotomy in certain studies showed also to be preventive for levator avulsion, but other studies show no effect or an increase in levator avulsions.(10-14) The potential benefits of mediolateral episiotomy need to be weighed against potential adverse effects resulting from this procedure, including unsatisfactory anatomic results (eg, skin tags, asymmetry, fistula, narrowing of introitus), increased blood loss, increased postpartum pain, higher rates of infection and dehiscence and sexual dysfunction.(15-19)
To examine this hypothesis we aim to investigate differences in incidence of levator avulsion and morphological abnormalities of the levator ani on 3D/4D transperineal ultrasound volumes and urogynaecological complaints, in women after a first, normal vaginal delivery with and without a mediolateral episiotomy.

Study objective

Primary Objective
Difference in incidence of an avulsion injury and morphological changes of the levator ani muscle after a first normal vaginal delivery between participants with and without a mediolateral episiotomy.

Secondary Objective
Changes in quality of life and pelvic floor symptoms questionnaires between both groups.
Differences in angle and length of the mediolateral episiotomy and incidence of

levator avulsion.

Study design

Retrospective observational cohort study

Women who underwent a first normal vaginal delivery between January 2012- May 2013 will be invited to participate and women between May 2013- May 2014 will be asked permission to contact them after their normal vaginal delivery with or without mediolateral episiotomy to invited them to participate in our study. This permission is obtained prior to their delivery around 37 weeks gestation, directly after the delivery or 6 weeks after delivery at their postpartum check-up. A mediolateral episiotomy was performed by the women*s obstetrician or midwife for medical reasons during labour. The investigators have not been involved in the participants* delivery. Women that gave prior permission will be called 6 months after delivery to invited them to participate. 200 participants divided in two groups, women with and without a mediolateral episiotomy, will be invited to participate 6 months after delivery to fill in an anonymized standardized questionnaire on urogynaecological complaints and impact of complaints on quality of life. After this the participants will undergo one additional exam, measurement of angle en length episiotomy and a 3D/4D transperineal ultrasound. This will take about 30 minutes. No further efforts of the participants are required.

Duration of study
18 months

Setting of study
Outpatient clinic Amphia Hospital Breda

Study burden and risks

Participants in both groups will fill out a standardized questionnaire on urogynaecological complaints.
All participants will be asked to visit the outpatient clinic for one additional examination: dynamic 3D/4D transperineal ultrasound. 3D/4D transperineal ultrasound is a non-invasive, safe imaging method without any risks for the participants. The exam will be performed in a supine position after voiding. The participant will be asked to take off their underwear. The angle and the length of the mediolateral episiotomy will be measured with a set triangle. During the examination the transducer will be covered with a glove and some ultrasound gel placed on the outside of the perineum. Imaging volumes will be acquired in rest, contraction and at Valsalva. This examination takes approximately 30 minutes.
As we only use 3D/4D transperineal ultrasound no harmful adverse effects of this study is expected on the maternal health.

There are no benefits for the participants. The results of the study may contribute to prevent injuries in a future population.

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

primiparous
at least 6 months after spontanuous vaginal delivery
with or without mediolateral episiotomy
single birth

Exclusion criteria

Unable to give informed consent
instrumental delivery
cesarean section
predates
multiparity
malpresentation (non cephalic)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	11-04-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	29-05-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL36549.078.12