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Pulling forces involved with forceps delivery and its association with maternal injury during birth

Submission date
16/08/2019

Recruitment status
No longer recruiting

Registration date
22/08/2019

Overall study status
Completed

Last Edited
22/08/2019

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Forceps delivery has been shown to be associated with a higher risk of injury towards the pelvic floor muscle when compared to normal vaginal delivery or vacuum delivery. The tearing of this muscle from its bony attachment is called avulsion. It's consequences has been associated with a higher risk of pelvic organ prolapse which is the bulging of the pelvic organs, bladder and uterus, into or out of the vagina. This condition affects gravely the quality of life of many women. To date, it is not known exactly the mechanisms involved with forceps and maternal birth trauma. The aim of this project is to study the pulling forces involved with forceps delivery and injuries to the pelvic floor muscle. Recently, the traditional forceps has been modified and has incorporated a sensor capable of recording accurately the pulling forces the birth attendant performs when assisting these deliveries. This forceps is the Pro-nata forceps.

Who can participate?
Possible participants are all women with no previous vaginal delivery that are in labour giving birth to one child and to whom an Obstetrician has indicated a forceps delivery.

What does the study involve?
The study involves recording the pulling forces during a forceps delivery in those women where the forceps has already been indicated by an Obstetrician due to possibly prolonged labour, maternal benefit, fetal malposition or possible fetal distress. In those patients that agree to participate, the Pro-nata forceps will be used instead of the traditional forceps without a sensor. After delivery participants will be followed up 3 months after delivery where a medical history will be taken and a gynaecological examination and a transperineal ultrasound performed. The transperineal ultrasound is used to identify the integrity of the pelvic floor muscle. It is carried out with a covered abdominal ultrasound probe placed on the perineum. Ultrasound has no side-effects on the mother.

What are the possible benefits and risks of participating?
Those who decide to participate will be informed whether they have sustained major pelvic floor birth trauma. Those patients that are symptomatic after delivery will be referred to the

appropriate specialist for treatment and follow up if appropriate. Also, the participants will be coached to perform correctly pelvic floor muscle exercises.
Those that decide to participants are those undergoing a forceps delivery. Participating in this study does not add any other risk than those inherent to forceps delivery such as higher rate of perineal tears, urine, gas and stool leakage among others when compared to normal vaginal delivery.

Where is the study run from?
Servicio de Ginecología y Obstetricia. Complejo Hospitalario Insular-Materno Infantil de Canarias (Gynecology and Obstetrics Service. Canary Islands Insular-Maternal and Child Hospital Complex), Gran Canaria

When is the study starting and how long is it expected to run for?
August 2019 to August 2020

Who is funding the study?
Safe Obstetrics Systems Limited (United Kingdom)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019-275-1

Study information

Scientific Title
A prospective observational study of the traction forces required to deliver with forceps and it’s relationship to levator ani injury.

Study objectives
The levator ani muscle injuries associated with forceps deliveries are a result of exceeding certain traction force threshold. Thus, our objective is to study the association between the traction force of the forceps and trauma to the levator ani muscle (avulsion). Secondly, to determine the obstetrical data that are associated with increased traction force

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/07/2019, Ethics committee of University Hospital of Gran Canaria 'Dr Negrin' (Edf. Anexo al Hospital Univ. de Gran Canaria "Dr Negrín", 35019 Las Palmas de G.C., Gran Canaria), ref: 2019-275-1

Study design
Observational prospective study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Levator ani muscle avulsion during forceps delivery

Interventions
This is a prospective study that will be carried out in a tertiary center where all the nulliparous women who undergo a forceps delivery during the study period will be included. The forceps that will be used is a metric forceps (Pro-nata), manufactured by Surgical Dynamics. This forceps device is a single-use forceps made of disposable material and contains a memory card that records the traction force exerted over time and that can be analyzed on a computer. This forceps also contains an indicator that alerts if the maximum traction has been reached. Since this threshold is unknown, it will be deactivated during the study period thus allowing forceps and traction force to continue in the same manner at this center. After forceps delivery, the memory card will be removed and stored in an envelope identified with the patient's data and date of delivery.

All singleton nulliparae with a Pro-nata forceps delivery carried out at the authors institution will be followed up at three months after delivery. All participants will undergo a 4D translabial ultrasound (TLUS) and volumes will be stored anonymously. Offline analysis of the stored 4D TLUS volumes will be analyzed at a later date blinded to all data using the software 4D view (GE Kretz Medical Ultrasound, Zipf, Austria).

TLUS will be performed in a dorsal lithotomy after voiding using Voluson 730 Expert or S10 system. Stored 4D TLUS volumes will be analysed offline blinded to all data using 4D view by one of the authors. Levator trauma will be established following diagnostic criteria published previously.

As well as an assessment of the presence of injury to the levator ani muscle, obstetrical data and its association to traction force will be assessed. The obstetric data will be obtained from the local electronic database (Drago).

Sample size:
An initial sample of 100 forceps deliveries will be considered. However, a first analysis will be performed after reaching 50 forceps deliveries and the sample size will be recalculated.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure

Avulsion of the levator ani muscle. Avulsion will be diagnosed when a defect is observed at the puborectalis insertion using Tomographic Ultrasound Imaging (TUI) at the level of minimal hiatal dimensions and 2.5 and 5mm slices cranially. In doubtful cases, the 'levator urethra gap' will be used to rate individual slices as abnormal when the distance from the urethra to the insertion of the puborectalis muscle is more than 25mm.

Secondary outcome measures

Obstetric data gathered from patient records:

1. Date of the delivery
2. Age
3. Years from Menarche to delivery
4. Race
5. Weight at the beginning of pregnancy
6. Weight at the end of pregnancy
7. Height
8. Body mass index
9. Gestational age at birth: (completed weeks)
10. Epidural analgesia during dilation
11. Number of cesareans performed in the past
12. Induction of labor
13. Time of first stage of labor
14. Time of the passive expulsive period
15. Time of the active expulsive period
16. Anesthesia in expulsive period
17. Fetal position assumed when performing the instrumental delivery
18. Fetal head Asynclitism
19. Degree of fetal head flexion before applying the obstetrical instrument
20. Indication of instrumental delivery
21. Fetal station
22. Rotational forceps
23. Fetal position at birth
24. Failure of rotation attempt
25. Cesarean section after failure of forceps
26. Removal of the forceps before complete extraction of the fetal head
27. Number of pulls performed with the forceps
28. Maximum traction pull
29. Average traction pull
30. Area under the curve Traction/time
31. Episiotomy
32. Cervical tear
33. Vaginal tear
34. Perineal tear
35. Operator training
36. Operator sex
37. Number of forceps performed in the previous year
38. Number of operators that pull on the forceps
39. Subjective forceps difficulty
40. Fetal weight
41. Head circumference
42. Neonatal arterial pH

43. Apgar score 1 minute
44. Apgar score 5 minutes
45. NICU admission
46. Reason for admission
47. Pelvic floor symptoms:
47.1 Urinary stress incontinence
47.2 Urinary urgency incontinence
47.3 Symptoms of overactive bladder (urinary frequency, hesitancy, urge without urinary incontinence)
47.4 Has the patient had sexual intercourse after delivery?
47.5 Dyspareunia
47.6 Fecal incontinence (at least two episodes separated by one week)
47.7 Fecal urgency
47.8 Symptoms of obstructed defecation
47.9 Pain with defecation,
47.10 Symptoms of genital prolapse
47.11 Symptoms of Vaginal laxity
47.12 Incontinence severity index
47.13 Wexner incontinence scale
47.14 Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ12)
48. Physical examination:
48.1 Perineum scar
48.2 POP-Q Score
48.3 Pelvic organ prolapse grading
48.4 Clinical urethral hypermobility
48.5 Modified Oxford score
48.6 Clinical avulsion
49. Ultrasound analysis
49.1 Hiatal area
49.2 Anterior-posterior and transverse diameters at rest, contraction and Valsalva
49.3 Significant anal sphincter defect.

Overall study start date
15/04/2019

Completion date
19/08/2020

Eligibility

Key inclusion criteria
1. Singleton pregnancy
2. Nulliparae
3. Forceps delivery (Pro-nata forceps)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
We aim to collect 100 patients initially however the final number of patients to be recruited will be recalcuted after the first 50 patients.

Key exclusion criteria
1. Twin deliveries
2. Breech deliveries
3. Previous vaginal delivery

Date of first enrolment
22/08/2019

Date of final enrolment
21/08/2020

Locations

Countries of recruitment
Spain

Study participating centre
Servicio de Ginecología y Obstetricia. Complejo Hospitalario Insular-Materno Infantil de Canarias
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Industry

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
Safe Obstetrics Systems Limited (United Kingdom)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/09/2021

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Stored in repository