ISRCTN13034177 https://doi.org/10.1186/ISRCTN13034177

Comparing outcomes of vaginal delivery with Paily Forceps against a vacuum device

Submission date
18/05/2022

Recruitment status
No longer recruiting

Registration date
25/05/2022

Overall study status
Completed

Last Edited
07/11/2022

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Ideally, vaginal delivery is conducted via the birth canal without additional surgical equipment. However, occasionally, this process can be delayed due to maternal or fetal causes. Such critical delays that cause the baby (fetus) to be stuck midway in the birth canal during labor pains can lead to compromised fetal blood circulation with severe adverse events such as stillbirth or nerve damage in the neonate.

In such scenarios, the obstetrician must be prepared to intervene quickly. According to the clinical scenario and their expertise with available options, the obstetrician can either opt for a vacuum or a forceps instrument. Usually, these instruments are applied over the head of the fetus, to grasp it tightly, while the obstetrician assists the baby's delivery, along the curvatures of the birth canal, by gentle traction (pull) on the instrument.

Operative delivery by forceps has been in practice since the 17th century. An obstetric forceps is a paired instrument, with two “branches” applied individually over the fetus’s head and locked in position before applying gentle traction. In many countries, the Simpson/Neville-Barnes forceps have been the design of choice of an obstetrician for many decades. Its signature curved design is intended to facilitate an easy application and prevent any slippage while gentle traction.

However, in our experience, the Simpson/Neville-Barnes forceps have a few drawbacks. Its blade length and curved design do not fit the fetus’s head within it appropriately and even cause trauma to the fetus and the mother. Its sturdy design has rendered it a heavy instrument, adding to its application and traction difficulties. Due to these practical issues, obstetric forceps delivery has been slowly falling out of practice in modern obstetrics. However, such forceps are essential to assist both vaginal and caesarean deliveries and prevent maternal and fetal harm.

After a decade of research and development, Prof. V.P Paily, redesigned the classic obstetric forceps into the Paily Obstetric Forceps (POF). The notable design differences in POF compared to the Simpson/Neville-Barnes forceps include a reduced length, a straighter curve, reduced maximum width and thinner blades. This versatile, lightweight design enables easier application and secure locking of the two branches, thus increasing the chances of an uncomplicated delivery.

POF has been widely adopted across hospitals in Kerala state, India; replacing the standard Wrigley/Simpson forceps since 2005, with promising results regarding patient safety and obstetrician satisfaction. In this randomized clinical trial, we aim to systematically analyze the effectiveness and safety of POF, compared to Ventouse – another commonly used instrument in operative vaginal delivery.

Who can participate?
We are only looking to enroll mothers in labor, assessed by the attending obstetrician to need an emergency or planned operative vaginal delivery for either the fetus or mother's benefit.

What does the study involve?
Two interventions are compared – i) the Paily Obstetric Forceps and ii) Ventouse. Participants will be randomly allocated to receive one instrument, when needed during labor. The investigator will measure the time taken during labor, any blood loss incurred, and any maternal or fetal injuries sustained during the application.

What are the possible benefits and risks of participating?
There will be no monetary or non-monetary personal benefits for participating in this trial. This is an academic trial intended to study the benefits of two instruments used for operative vaginal delivery. If found effective, other obstetricians can reduce their dependence on cesarean deliveries for similar conditions – which carries a higher risk to all mothers, both short and long term.

Instrumental delivery carries a higher risk of maternal and fetal injury when compared to normal vaginal delivery. But in specific emergency/high-risk conditions, where imminent delivery is needed, instruments are the safer option when compared to cesarean delivery. Maternal injury can involve injury to the vagina and adjoining reproductive tract, which can often present with considerable bleeding, pain and discomfort – and will need further intervention from the attending obstetrician. Fetal injury can involve skull or other long bone fractures, soft tissue injuries or more severe as a brain bleed or fetal demise in rare circumstances. These are identified by the attending neonatologists and may need additional intensive care.

Where is the study run from?
This study is managed by the Department of Obstetrics and Gynecology, Mother Hospital, Thrissur, Kerala, India.

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

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. V. P Paily, vppaily@gmail.com

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A single-blinded randomised clinical trial to determine the effectiveness and safety of Paily obstetric forceps vs ventouse in operative vaginal delivery.

Study objectives
The use of Paily obstetric forceps leads to a higher success rate of operative vaginal delivery, and lowers the risk of maternal and neonatal injury when compared to ventouse use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/07/2006, Mother Hospital Institutional Ethics Committee (Pullazhi P.O., Olari, Thrissur, Kerala, India - 680 012; +91 487 2434800; motherhospitalthrissur@gmail.com), ref: MOTH/2006/006

Study design
Single-center interventional single-blinded parallel-group randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Effectively conducting operative vaginal delivery and preventing maternal or neonatal injuries in term (≥ 37 weeks) mothers.

Interventions
This randomised clinical trial is conducted in the Department of Obstetrics and Gynecology, Mother Hospital, Thrissur, from August 2006 to November 2007, over 16 months. Mother hospital has an annual delivery rate of around 2000. The instrumental delivery rate is about 6-7%. Informed consent is obtained from all patients admitted to the obstetric unit for elective or emergency operative vaginal delivery.

This operative vaginal delivery trial featured two parallel arms interventions: - i) Paily Obstetric Forceps (POF) and ii) Ventouse extractor. Index cards, marked with the choice of intervention, were randomised using a computer-generated random sequence. They were then placed in envelopes by an independent researcher and stored in opaque boxes in the labour room of the obstetric unit.

When the operator decides to intervene during vaginal delivery, an assistant is asked to pick the next envelope from the storage box, which decides the choice of intervention. The patient is not informed about the choice of instrument, prior to intervention.

To apply an instrument, the patient is placed in the dorsal lithotomy position. Under aseptic precautions, the bladder is catheterised and emptied. The operator then re-assesses the patient. On abdominal examination, no pole of head should be palpable. On vaginal examination, based on the position of the presenting part and pelvic dimensions, the cephalo-pelvic disproportion is ruled out. Then the perineum is cleansed and draped. Perineal block/Local anaesthesia is achieved by infiltrating an appropriate dose of Inj. Xylocaine 1%.

The POF (Manufactured by Babu Surgicals, Palakkad, Kerala, India) is a modified obstetric forceps, with shorter (140 mm), thinner blades (3 mm), shorter shank (35 mm) and reduced inter-blade distance (68 mm), when compared to the classical Neville-Barnes/Simpsons obstetric forceps. Along with an English-type lock, POF is designed to be lighter and smaller, to prevent maternal injuries and to improve ease of application for the operator.

Prior to POF application, digital rotation may be performed to ensure that the sagittal suture is anteroposterior. Then, the operator applies the POF, one branch at a time. First, the left blade is introduced under the guidance of the fingers. The handle of the left blade is grasped between the thumb and fingers of the left hand and the tip of the blades are gently passed into the vagina – between the fetal head and palmar aspect of the fingers of the right hand. Similarly, the right blade is also applied to the fetal head. Both branches are then locked and the handles are brought together.

Correct application of forceps is checked before traction. The lambdoid suture should be equidistant from the anterior edge of the forceps, and the sagittal suture should be in the midline of the forceps blades. From this, the accuracy of forceps application is judged. By vaginal examination, the operator confirms no maternal soft tissue is caught between the blade and the fetal part. The tips of the blades are kept in contact with the head so that the soft parts are not

injured. Episiotomy is given before or after the application of the forceps, according to the operator's preference. Then, gentle, intermittent traction is given along with uterine contractions. The direction of traction is first downwards and backwards till occiput hitches against the pubic symphysis, and then traction is applied upwards and forward. The perineum is supported, at the time of traction. After delivery of the head, the forceps are dis-engaged.

The ventouse extractor used in this study features a 50 mm silastic cup and electrical suction device (S 351 NATAL, ATMOS MedizinTechnik GmbH & Ko. KG, Germany). The suction device can be set on an automatic/semi-automatic mode, or the operator can gradually create the vacuum with manual control.

After randomisation, if a ventouse extractor is selected - the patient is positioned, assessed and prepared as described earlier. Digital rotation may be performed. When applying the ventouse, the operator first spreads the patient's labia, compresses the silastic cup and gently advances the cup inwards, downwards and placed as close to the flexion point as possible. This technique avoids undue stretch on the perineum.
When the cup is in contact with the fetal scalp, initial suction is created, just sufficient to fix the cup. Then, the correct application is checked so that centre of the cup should be over the sagittal suture about 3 cm in front of the posterior fontanelle. Before applying traction, the operator ensures that no maternal tissue is trapped between the cup and the fetal head. An episiotomy may be performed at the operator's discretion.

Vacuum is developed gradually, i.e. increase in 75 mmHg every 20-30 seconds up to 525 mmHg. After complete development of vacuum, gentle intermittent traction coordinated with maternal contractions and her voluntary bearing down efforts, is exerted in the proper direction. A maximum of three pulls is permitted. In case, the cup dislodges two times, the vacuum extraction is abandoned. Sequentially, a POF application will be attempted. If vaginal delivery still fails, the instrumental delivery is considered to have failed, and the patient is rushed to the operation theatre for an emergency caesarean delivery.

Typically, after a successful fetal and placental delivery by POF/Ventouse, the maternal perineum, vagina and cervix are inspected for any lacerations and repaired if present. Next, episiotomy is sutured in layers. A per rectal examination is done to rule out any occult tears. The attending neonatologist examines the neonate for injuries.

Intervention Type
Device

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Paily Obstetric Forceps (POF), Ventouse vacuum extractor with 50 mm silastic cup.

Primary outcome measure
Success rate of instrumental delivery - calculated by the ratio of deliveries not requiring a second-line intervention (another instrument or subsequent caesarean delivery) to the total number of instrumental delivery

Secondary outcome measures
All safety analyses will be conducted on an "As-treated" basis.

1. Incidence of Maternal adverse events:
1.1. During the second and third stages of labour:
1.1.1. Episiotomy extension
1.1.2. Cervix laceration
1.1.3. Vaginal laceration
1.1.4. Perineal laceration
1.1.5. Paraurethral laceration
1.1.6. Third and Fourth-degree perineal lacerations
1.1.7. Post-partum haemorrhage (>500 ml of blood loss)
1.2. Fourth stage and puerperium
1.2.1. Need for blood transfusion
1.2.2. Urinary retention
1.2.3. Urinary tract infection
1.2.4. Episiotomy hematoma
1.2.5. Anemia
1.2.6. Need for antibiotics
1.2.7. Duration of hospitalization
2. Neonatal outcomes and adverse events:
2.1. APGAR score at 1st and 5th minute
2.2. Liquor (Clear/ Grade-1/Grade-2/Grade-3)
2.3. Caput succedaneum
2.4. Scalp, facial bruising or injuries
2.5. Cephalhematoma
2.6. Sub-galeal hematoma
2.7. Neonatal jaundice
2.8. Cerebral edema
2.9. Sub-conjunctival hemorrhage
2.10. 6th and 7th brachial plexus injury
2.11. Clavicle fracture
2.12. Intraventricular hemorrhage
2.13. Neonatal Intensive care unit stay
2.14. Hospital stay
2.15. Neonatal death

Overall study start date
15/06/2006

Completion date
30/11/2007

Eligibility

Key inclusion criteria
1. Pregnant women above 18 years of age.
2. Term pregnancy (≥37 completed weeks of gestational age)
3. Cephalic presentation
4. Fully dilated and fully effaced cervix
5. Ruptured membranes
6. Fetal head at +2 station or lower (Low or Outlet station)
7. Fetal head rotation ≤45^{0}
8. Clinically adequate pelvis

9. Clinically indicated instrumental delivery:
9.1. Maternal indications:
9.1.1. Prolonged second stage of labor
9.1.2. Maternal exhaustion
9.1.3. Elective application to shorten second stage of labor
9.1.3.1. Medical diseases like cardiac diseases (NYHA Grade 3 or 4), severe pre-eclampsia, hypertensive crises, cerebrovascular malformation, myasthenia gravis, and spinal cord injury.
9.1.3.2. Vaginal Birth After Cesarean Delivery (VBAC)
9.2. Fetal Indications
9.2.1. Fetal Distress in second stage as determined by non-reassuring fetal heart rate pattern or Grade 3 meconium passage
9.2.2. Prolapsed umbilical cord
9.2.3. Premature separation of placenta.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. Participant refused to participate in trial/ no informed consent provided
2. Patients with bleeding diathesis

Date of first enrolment
01/08/2006

Date of final enrolment
15/10/2007

Locations

Countries of recruitment
India

Study participating centre

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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/02zfghc79

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The data that support the findings of this study are available on request from the corresponding author.
vppaily@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/11/2022	07/11/2022	Yes	No