Universitat de Girona
Facultat de Medicina

CESAREAN DELIVERY RATES BETWEEN FETUS IN CEPHALIC PRESENTATION AFTER A SUCCESSFUL EXTERNAL CEPHALIC VERSION AND THOSE WITH SPONTENOUS CEPHALIC PRESENTATION

Final degree project

Author: **Clàudia Segura Villagrasa**

Clinical tutor: **Dr. Josep Inglada Estruch**

Methodological tutor: **Dr. Rafel Santiago Ramos Blanes**

HOSPITAL UNIVERSITARI SANTA CATERINA
FACULTAT DE MEDICINA, UNIVERSITAT DE GIRONA
Girona, November 2019

ACKNOWLEDGMENTS

Thanks to all the Ginecology and Obstetrics' members of the Hospital Universitari Santa Caterina, who embraced me to their team and transmitted me their passion for this speciality.

Thanks to Dr. Josep Inglada for his availability at all times and especially for his patience.

Thanks to the teacher Marc Saez, for its dedication.

Thanks to Dr. Rafael Santiago Ramos for guiding and helping me through this process.

Thanks to Silvia, my best friend, who helped me whatever and whenever.

Thanks to Mireia, my cousin, for believing in me and always encourage me to go ahead.

Finally, thanks to all my family for their affection and for their unconditionally support.

''Childbirth is the only blind date in which you can be sure that you will meet the love of your life.''

INDEX

1. ABREVATIONS

ECV: External cephalic version

sECV: successful external cephalic version

BP: Breech presentation

WG: Weeks of gestation

CS: Caesarian section

BMI: Body mass index

BW: Birth weight

FHR: Fetal heart rate

FB: Fetal bradycardia

USS: Ultrasound scan

CTG: Cardiotocography

EFM: Electronic fetal monitoring

VB: Vaginal birth

E.V: Endovenous

2. ABSTRACT

Background

Breech presentation complicates 3-4% of all term singleton pregnancies. Morbidity and mortality in breech births is high. The incidence of caesarean section for breech presentation has increased markedly in the last 20 years. There is a consensus between health professionals and the authorities that recognizes the actual indexes of caesarean deliveries as excessive and in no case are they justified by an improvement in perinatal outcomes. Thus, reducing the caesarean section rates has become an objective of the majority of public health services. External cephalic version (ECV) refers to a procedure in which the fetus is rotated from a noncephalic to a cephalic presentation by manipulation through the mother's abdomen. External cephalic version (ECV) has been shown to be safe and effective as a preventive measure for reducing the number of BP at birth, as well as the number of CS because of breech presentation. The purpose of ECV is to decrease the incidence of both vaginal breech delivery and CS, without impacting upon maternal or fetal outcomes.

Objective

The aim of this study is to compare the caesarean delivery rates between foetus in cephalic presentation after a successful external cephalic version and those with spontaneous cephalic presentation in nulliparous, low-risk, pregnant women.

Design

The study will be a multi-centric prospective cohort, with a consecutive method of sampling among patients who attend the Ginecology and Obstetrics Service. Six different hospitals from Catalunya will participate in this trial.

Methods

The sample size will be 384 pregnant women at the 33-35 WG, whose foetuses are placed in cephalic or in breech position, and who meet all other inclusion and not the exclusion criteria. To do so, the patients will be classified in two groups according to their fetal presentation (seen in the ultrasound scan): *Group 1* will include 192 patients whose foetuses are already in

vertex presentation and *Group 2* will include 192 in breech position. Group 2 will undergo an external cephalic version to achieve a cephalic position. Both groups will be followed up until spontaneous labour appears. A vaginal delivery will be attempted.

We will collect the number of caesarean deliveries (which is our main dependent variable) in each group to do a statistical analysis and compare the percentages adjusted for all the co-variables.

Key words

External cephalic version, breech position, cephalic position, caesarean section, vaginal delivery, ultrasound scan, tocolysis.

3. INTRODUCTION

3.1. Breech presentation

Breech presentation complicates 3-4% of all term singleton pregnancies (> 37 WG), and a higher proportion of pre- term fetuses. It is more common when there has been a previous BP.

According to the gestation weeks, BP reaches up to 25-30% before the 28 weeks, decreasing to 7% at 32 weeks. (1)

3.1.1. Types of breech presentation

BP can be classified, according to the fetal attitude *(Fig.1)*, into:

- Frank breech: it is the most frequent variety, as they represent 60% of cases. The fetus is with the thighs flexed on the abdomen and the legs extended in front of the thorax, so that the feet are very close to the face of the fetus.
- Complete breech: the baby is sitting flexing de hip and both knees joints, so that the buttocks and feet occupy the upper strait of the maternal pelvis. They account for 5-10% of cases.
- Incomplete breech: it presents the buttocks and one or both feet prolapsing to the vagina. They represent 25 to 30% of cases and there is a great risk of cord prolapse. (2)

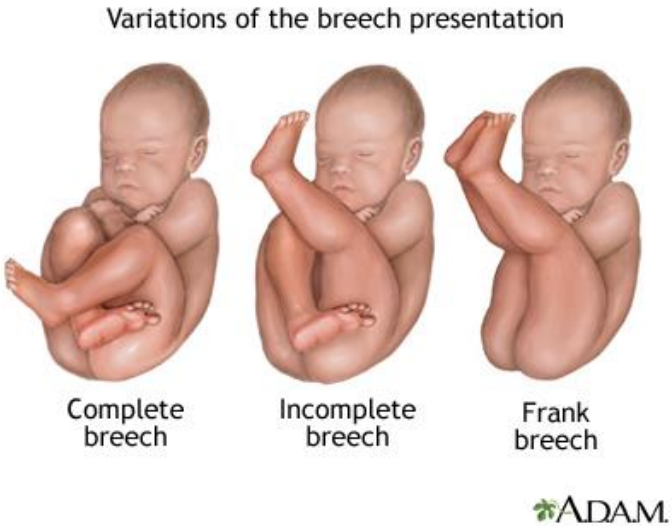

Figure 1. Variations of the breech presentation. (2)

3.1.2. Etiology

The reason why the presentation of certain foetuses does not evolve into cephalic, as it happens in the majority of gestations between 28 and 33 WG, is due to a failure in the spontaneous version that has to occur at this time of pregnancy.

The change in the shape of the uterus in these stages plays an important role in the spontaneous version of the fetus. As the pregnancy progresses, the shape of the uterus evolve from spherical to an ovoid form, whose end of smaller diameters is the lower one. This results in an accommodation of the fetus with its greater and more mobile pole (the breech) to the uterine fundus, and the lesser and less mobile (the cephalic) in the lower area of the uterus.

Moreover, another triggering element of the version is the progressive decrease in amniotic fluid, which becomes evident at 31-32 WG, along with active fetal movements.

3.1.3. Risk factors

Some factors can alter the correct position of the fetus and thus increase the rate of BP; some of them are:

- Preterm delivery: it is the most influential factor (35% of cases are in breech position before 28 WG, versus only <5% are in BP at term).
- Fetal factors: malformations (such as anencephaly, hydrocephaly, polycystic kidney disease, trisomies 13, 18, 21…); multiple gestations.
- Ovular factors: placenta previa, placenta in uterine horn, oligohydramnios, hydramnios, short cord.
- Maternal factors: parity (slightly more common in primiparous than in multiparous women), uterine malformations, myomas.

3.1.4. Complications

Morbidity and mortality in breech births is high, either associated with the birth route or not.

There are some complications due to the birth route itself:

- Cord prolapse *(Fig. 2)*: it is typical of the vaginal delivery route. It occurs in 6% of all breech births and up to 7.4% of women who had a vaginal delivery attempt. Furthermore, the incidence vary with the type of BP, being 0-2% for frank breech and 5-10,5% for complete breech. It was twice as frequent among multiparous women (6%) than among nulliparous women (3%). It is associated with a mortality rate of up to 38,5%.
- Stuck fetal head: it appears in up to 8% of vaginal births with BP. The consequences are fetal asphyxia, neurological lesions and fetal death. It is also more frequent, not only in BP, but in nulliparous women and premature babies.
- Fetal trauma: owing an incidence of 0.3 to 6%, appears to be more common in infants that were born by vaginal delivery. Some of them are spinal lesions (mainly in foetuses with cephalic hyperextension), occipital ostodiastasis (due to suprapubic pressure on the fetal head), Erb and facial nerve paralysis, muscle injuries, genital and anal lesions.

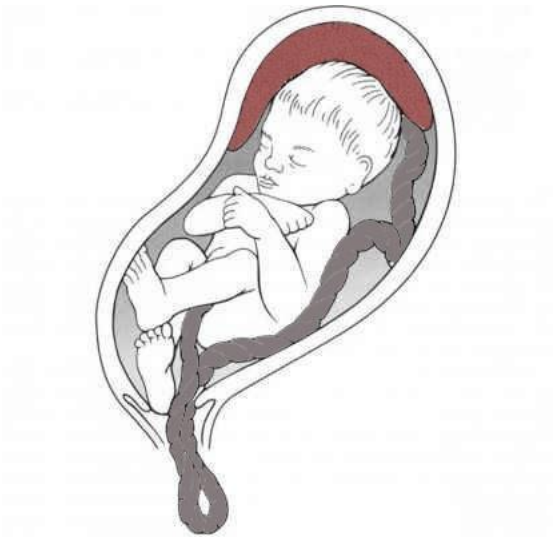

Figure 2. Umbilical cord prolapse. (3)

Women affected by BP may be offered one of these three options: elective caesarean section, vaginal breech delivery or external cephalic version (ECV) (4).

The management of breech presentation at term has undergone substantial changes(5). Historically, vaginal breech birth had always been considered a reasonable and safe option. (6)

However, the incidence of caesarean section for BP has increased markedly in the last 20 years (7) since the publication of the Term Breech Trial at the end of 2000 reported increased perinatal mortality with vaginal breech delivery (4) and also significantly lower perinatal and neonatal mortality and serious neonatal morbidity associated with planned CS (8).

3.2. CESAREA

3.2.1. Definition

Caesarean delivery is considered as the safest mode of delivery and currently the most commonly used method for delivery of the breech fetus. (9)

Caesarean section is an obstetric procedure in which the fetus is removed through the abdominal route and is one of the oldest surgical procedures in history, dating back 800 years B.C. (1)

3.2.2. Epidemiology

It is effective in preventing severe fetal and maternal morbidity and mortality; however, despite the WHO claim in 1985 that 'there is no justification for any region to have a rate higher than 10–15%', CS rates, particularly in middle and high-income countries, are much higher and continue to rise.

A recent study has reported a worldwide increase in CS rates from 6.7 to 19.1% over the period 1990–2014, with country-specific rates ranging from 1.4 to 56.4%. By way of illustration, in 2014, the CS rate in Europe was 25.0% (with a range among countries of 13.9–38.1%), in Asia 19.2% (range 1.7–47.5%), in Latin America and the Caribbean 40.5% (range 5.5–55.6%), in North America 32.3%, and in Australia and New Zealand 32.3%.(8) *(Fig.3)*

There is a consensus between health professionals and the authorities that recognizes these indexes as excessive and in no case are they justified by an improvement in perinatal outcomes. Thus, reducing the caesarean section rate has become an objective of the majority of public health services. (1)

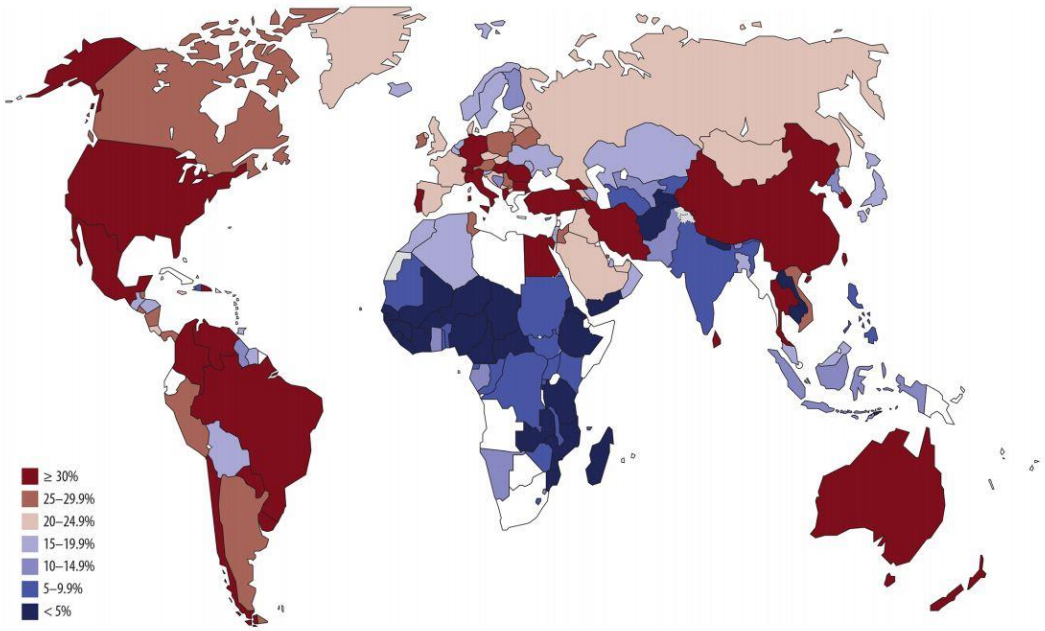

Fig 1. Latest available data on caesarean section rates by country (not earlier than 2005).

doi:10.1371/journal.pone.0148343.g001

Figure 3. Global caesarean section rates. (10)

3.2.3. Types of caesarea according to its indication

The SEGO, in the Consensus on Caesarean section published in 2007, includes a new classification that divides emergency situations into four categories when performing a caesarean section. (1) :

1. Urgent caesarean section to be immediately realized. They are those obstetric situation in which, due to a serious health threat of the mother or the fetus, an immediate surgical intervention is required without delay. For example, when there is a cord prolapse.
2. Urgent caesarean section not to be immediately performed. There is an unavoidable risk, which will be enhanced as time passes by. Thus, the surgical intervention should be performed in a brief time to avoid the progressive deterioration of maternal or fetal health. The '' no progression of labour'' is an example of this category.

3. Non-urgent (scheduled) CS that starts labour before the scheduled date. There is no reason for urgency but it has to be carried out in a matter of hours.

4. Scheduled caesarean section. There is any type of urgency. This category includes all those patients whose delivery is not triggered before the scheduled date. A variant of this category is the CS on demand.

3.2.4. Indications

The most common indications to realize a CS are (1):

- Any failure in the labor process, either by induction failure and by parked delivery. Induction failure is when a patient is not into clear labor in 12 hours. For parked delivery we understand a birth that does not progress in an interval of 3-4 hours with the adequate dynamics (minimum of 200 Montevideo units).
- Non-reassuring fetal pattern: non-reassuring biophysical pattern, abnormal fetal doppler, alterations of the cardiotocographic record, fetal blood microtome with fetal pH< 7,20.
- Previous uterine scar. CS will be scheduled at 39 WG in all patients with:
    - Previous myomectomy (with cavity opening or complications).
    - Iterative caesarean section (≥ 2).
    - In cases of a previous caesarian section if there are one or more of the following: unfavorable gynecological history, prior caesarean section due to pelvic disproportion, uterine malformation, suspected fetal macrosomia, multiple pregnancy,etc.
- Abnormal fetal presentation, mainly by breech presentation in primiparous women.

3.2.5. Surgical technique

Pre-operative measures:

The patient must remain in a supine position with a lateral inclination of 15º to reduce the compression of vena cava and thus, avoid maternal hypotension. (11)

Wall opening:

- *Pfannenstiel* incision *(Fig. 4):* it is transverse suprapubic incision with a superior concavity located two fingers above the pubic symphysis. Then, manual separation of the straight muscles may be required. The opening of the different planes of the abdominal wall may be performed by blunt dissection, as it is associated with shorter operative time and decreased maternal morbidity. On the one hand, this technique is the incision of choice for its excellent aesthetic results, less postoperative pain and lower rate of dehiscence and wall hernias. In the other hand, it carries with more risk of bleeding than the middle laparotomy.

- Middle infraumbilical laparotomy (*Fig.4*): it allows a fast opening, an excellent surgical field and is little bleeding. It is of choice in the following situations:

- Urgent caesarean section with vital risk.
- Massive haemorrhage.
- When there is a need to explore the upper abdomen.
- Pregnant women with bleeding disorders and high risk of bleeding.
- Perimortem caesarean section.
- Pregnant women with previous infraumbilical laparotomy. (11)

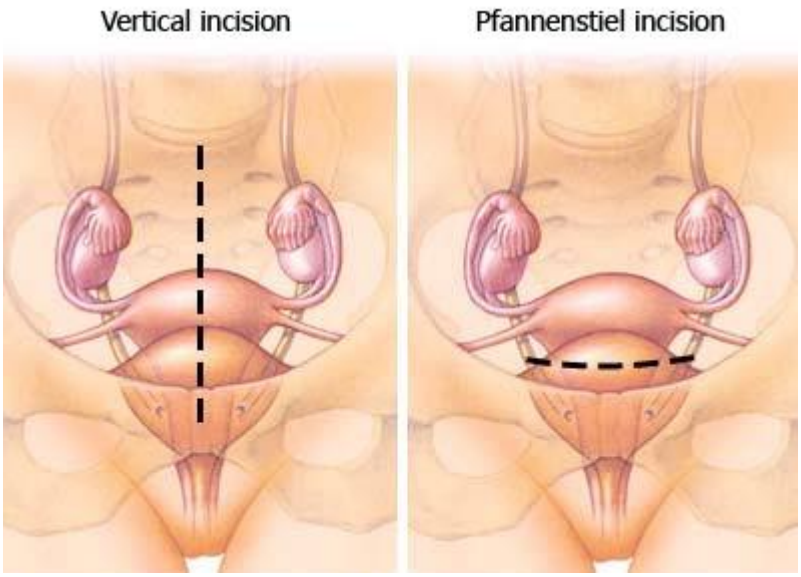

Figure 4. Types of caesarean abdominal incision. (12)

Uterine incision:

- Low transversal segmental incision (*Fig.5*): of choice. It is related with less bleeding, better scarring, lower incidence of both infections and uterine rupture in following gestations. Nonetheless, it could have an in increased risk of injuring the uterine vessels in case of prolongation of the incision angles.
- Vertical or classic body incision (*Fig. 5*): it owns an increased risk of haemorrhage, infection and uterine rupture in subsequent gestations. However, it can be useful in the following cases:
    - Preterm birth (< 26 WG) without the lower uterine segment being formed yet.
    - Transverse situation of the fetus (with lower fetal dorsum) without inferior uterine segment being formed.
    - Large volume cervical myomas.
    - Important adhesions in the lower uterine segment.
    - Postmortem caesarean section.
    - Placenta previa with considerable dilated vessels in the lower uterine segment. (11)

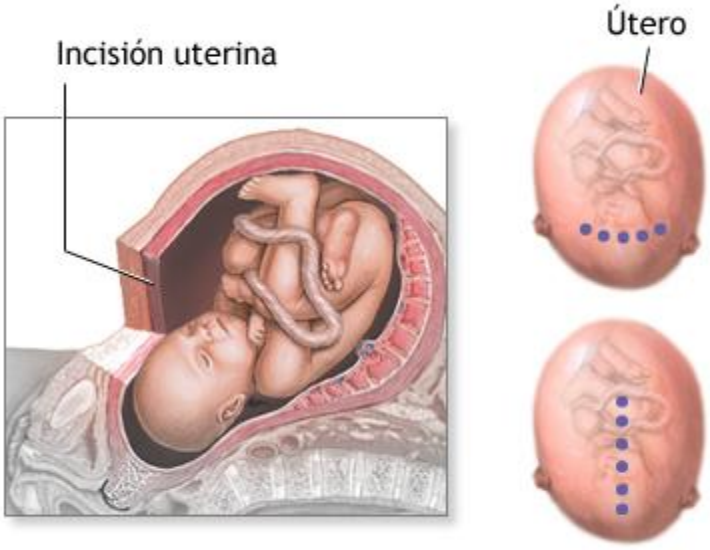

Figure 5. Types of uterine incision in CS. (13)

Extraction of the fetus and placenta

Fetal lesions during the procedure are usually the result of difficult extractions and its incidence is about 2%. In these cases, uterine relaxation with nitroglycerin e.v or any halogenated anesthetic may help. (*Fig. 5*)

The use of forceps or vacuum for fetal head extraction should be reserved only when it is getting hard to achieve.

Systematic collection of umbilical cord blood will be done universally in all pregnant women (except the ones with exclusion criteria) for altruistic donation to the ''Banc de Sang i Teixits''.

The delivery of the placenta should be carried out by sustained traction of the cord and not manually, as this maneuver increases the risk of endometritis. (11)

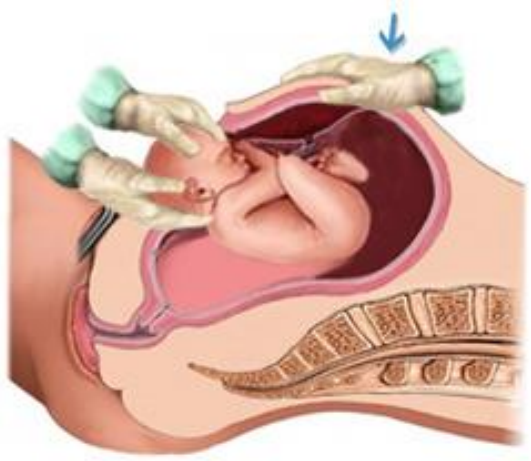

Figure 5. Extraction of the fetus. (14)

Closing of the uterus and abdominal wall:

Closing of the uterus will be performed in monolayer, with vicryl or dexon of number 1. However, in case of a classic incision, the three layers will be closed due to mometrial thicknes and increased risk of uterine rupture.

The externalization of the uterus during the suture is not recommended as it is associated with greater pain, and does not improve the risk of bleeding or the risk of infection.

The visceral or parietal peritoneum may not be sutured. This reduces de operating time, maternal morbidity and the need for postoperative analgesia.

Then, the points in the continuous fascia suture must not the crossed as crossing increases the risk of ischemia of the tissue. Vicryl or dexon of numer 1 should be used with a separation between points of 1 cm. But in case of middle laparotomies, fascia should be closed with continuous suture with absorbable threat. It is recommended to perform two hemicontinues.

Subcutaneous tissue approach should not be performed, except in patients with more than 2cm of subcutaneous tissue.

There is no need to use drains, as they do not reduce the incidence of surgical wound infection nor serohematomas. The use of drains will be justified only in the following situations:

- Subaponeurotic, in case of iterative caesarean section if there is muscle injury.
- In HELLP syndrome if a *Pfannenstiel* incisition has been made.
- Supraponeurotic, in obese patients (pregestational BMI > 30).
- At medical criterion if high risk of bleeding.

Finally, skin can be closed either with intradermal suture, simples stitches or staples; then, place a compressive dressing. (11)

3.2.6. Postoperative medication:

- Serum therapy: alterning both 10% glucose serum and ringer during 24 hours.
- Uterotonics: oxytocin the first 12 hours.
- Thromboembolic prophylaxis: administering low molecular weight heparin 6 hours after the catheter withdrawal or the surgical intervention (if general anesthesia) and will remain until the mobilization of the patient.

  The caesaria section is an independent risk factor for thromboembolic disease. Thus, phrophylaxis with low molecular weight heparin should be done only if the patient has any other risk factor for thromboembolic disease, such as: maternal age > 35 years, obesity (BMI > 25 before pregnancy), severe venous insufficiency, infection with systemic repercussion, preeclampsia, any maternal pathology associated with

thrombotic risk (heart disease, pulmonary pathology, inflammatory bowel disease, nephrotic syndrome or neoplasia).

- Analgesia: There are different analgesic protocols according to the anesthesic technique used during the surgery.

  Patients who have been administered a dose of epidural morphic chloride during CS are prescribed NSAID, as Dexketoprofeno (50 mg e.v) or Metamizol (2g e.v) as a second option, every 8 hours.

  Whereas patients with intradural technique during the surgery, to whom morphic chloride has not been administered, are prescribed Methadone (4-5 mg s.c) every 6-8 hours, alternating with NSAIDs.

  In both groups we can also use: paracetamol (1g e.v every 8h) as a rescue analgesia, ondansetron (4 mg ev) if necessary to treat post-operative nausea or vomiting, gastric protection if indicated with pantoprazole (40 mg e.v). (11)

3.2.7. Intraoperative complications

They oscillate between 1-2% and are more common in urgent and repeated caesarean sections.

- Urinary tract lesions: The bladder is the organ that is most frequently damaged. Cystotomy can be avoided by performing a good bladder detachment.
- Intestinal lesions: although rare, they are usually associated with previous laparotomies. Blind or sigma are typically affected.
- Injury of the uterine vessels: The best prophylaxis is to perform a good surgical technique, avoiding to prolonge the hysterotomy laterally and the careful removal of the fetus.
- Uterine atony: it can be reduced by avoiding manual removal of the placental, cleaning properly the uterine cavity, closing the hysterotomy quickly. But specially, the atony prophylaxis is performed with oxytocine e.v either to facilitate uterine contraction and to decrease blood loss. (11)
- Placental anomalies: such as placenta previa, accreta, increta, percreta and premature detachment of the placenta normoinserta. (1) *(Fig.4)*

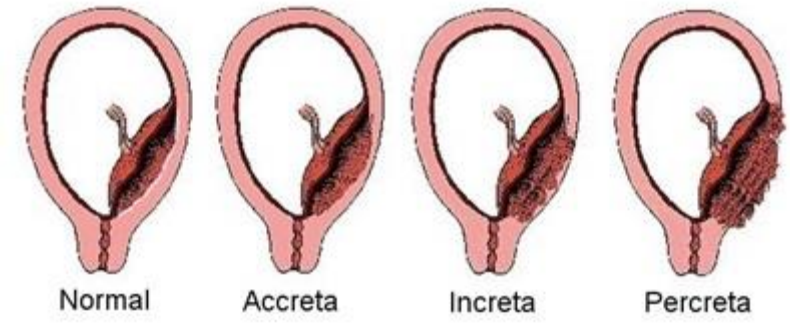

Figure 4. Different types of anomaly insertion of the placenta. (15)

3.2.8. Postoperative complications

- Endometritis: it is the most common complication of caesarean section (about 35-40%), being more likely in long-standing broken pouch, prolonged delivery, multiple vaginal examinations, inadequate surgical technique and in intrauterine manipulations. Using prophylactic antibiotics (usually a single dose of 1st generation cephalosporins) decreases the rate of endometritis after caesarean section down to 5% and also the rate of severe sequels such as abscesses, septic shock and septic pelvis thrombophlebitis to less than 2%.
- Postpartum caesarean fever: All of these patients should be evaluated to determine the origin of the fever, although pelvic and wound infection are the most common causes.
- Urinary infections: their frequency ranges from 2-16% and it is related with bladder catheterization. It could be prevented by performing the technique under the maximum asepsis conditions and keeping the bladder catheter only for the strictly necessary time.
- Abdominal wall infections: obesity, insulin-dependent diabetes and increased wound closure time are considered some of the risk factors. Correct hemostasis and antibiotic prophylaxis will be the best preventive measures. The initial treatment will be the opening of the wound so that it drains, along with serum washes and antiseptics, and debridement if necessary.

- Thrombophlebitis: early mobilization is recommended. If there are varicose veins, an elastic bandage will be placed on lower limbs and prophylactic doses of heparin will be administered.

- Embolism: it is more recurrent in caesarean section than in vaginal delivery. Its prevention is the same as the thrombophlebitis. Moreover, the non-exteriorization of the uterus during the intervention prevents the creation of gas embolism.
- Abdominal scar dehiscence *(Fig.5):* the correct flatness suture minimizes this complication. The fascia suture will be made with synthetic absorbable materials. Moreover, the correct hemostasis of the wound will prevent infection and bruising, thus reducing the risk of dehiscence.
- Post-cesarean ileus: minimized by avoiding unnecessary manipulations of the abdominal cavity and eliminating waste as much as possible (such as blood, meconium and clots) before closing the abdominal wall.
- Abnormal placentation: it is well known that caesarean section increases the risk of abnormal placentation in future pregnancies, such as abruption placentae and placenta previa. (1)

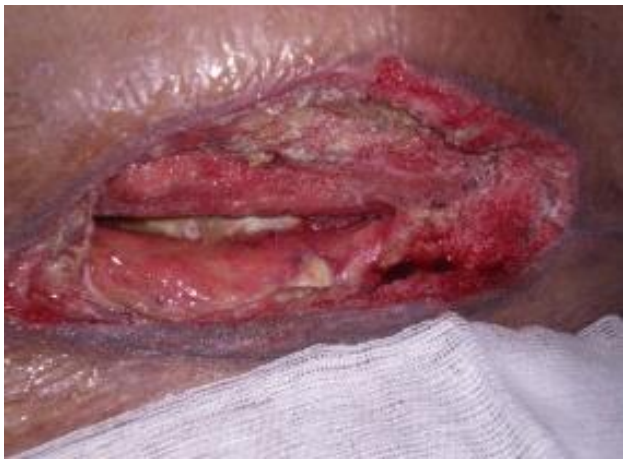

Figure 5. Dehiscence of caesarean suture. (16)

3.2.9. Fetal complications

- Newborn respiratory distress syndrome: it is more frequent in fetuses born by caesarean section, being yatrogenic prematurity one its causes. Therefore, it is not recommended to perform elective caesarean section before 39 WG.

- Obstetric trauma: it can not be always avoided with caesarean section as fetal lesions occur in 0,4% of them. (1)

As we said, BP is associated with a very high likelihood of cesarean delivery, as it remains the preferred option among affected individuals. In turn, it has led to increased rates of this procedure worldwide, specifically about 80 - 95%. (10)

However, caesarean birth itself carries maternal and foetal risks and for this reason, strategies have been developed to lower the malpresentation rate at birth. (17) After 36 WG, ECV is an option to convert the fetus to a vertex presentation. This allows patients to attempt a trial of labor and avoid cesarean or breech delivery. (9)

3.3. External cephalic version (ECV)

The word 'version' comes from the Latin word *vertere* that means flipping. (18)

External cephalic version (ECV) refers to a procedure in which the fetus is rotated from a noncephalic to a cephalic presentation by manipulation through the mother's abdomen. It is typically performed as an elective procedure in nonlaboring women at or near term to improve their chances of having a vaginal cephalic birth (19).

External cephalic version (ECV) has been shown to be safe and effective as a preventive measure for reducing the number of BP at birth, as well as the number of CS because of breech presentation. This procedure was once widely accepted and used in obstetrics and midwifery, but lost its popularity among both obstetricians and midwives around 1970s, primarily because of concerns about the safety of the procedure. (6)

The purpose of ECV is to decrease the incidence of both vaginal breech delivery and CS, without impacting upon maternal or fetal outcomes and is recommended by various national

guidelines (the Royal College of Obstetrics and Gynaecology, the American College of Obstetrics and Gynaecology, and the French National College of Gynaecology and Obstetrics). (4) (20)

In fact, the *American College of Obstetricians and Gynecologists* recommends that "all women who are near term with breech presentations should be offered an ECV attempt if there are no contraindications."(5)

The Royal College of Obstetricians and Gynaecologists recommends that a skilled service for external version should be available and offered for breech presentation at term. (6)

Despite these evidences, ECV is not a widespread practice in our country. (1)

3.3.1. Version procedure

ECV should be performed from 37 WG, when the probability of spontaneous version is smaller, the amount of liquid is still adequate and to avoid iatrogenic prematurity. (1)

ECV should be offered from 36 weeks in nulliparous women and from 37 weeks in multiparous women. ECV before 36 WG is not associated with a significant reduction in noncephalic births or CS.(7)

With a spontaneous version rate of 8% in nulliparous breeches after 36 WG and the very low complication rate, ECV from 36 weeks of gestation in nulliparous women therefore seems a reasonable compromise. (7)

Days before performing the ECV, the doctor should provide anti-D to the patient if she is Rh negative and an ultrasound scan has to be done. She should be given an information sheet and be counselled about the risks and benefits of the procedure.(21)

On day of the ECV, written informant consent should be obtained. It is important that ECV takes places where USS and cardiotocography (CTG) are available to enable the fetal heart rate visualisation. Access to theatres should also be available nearby. The FHR should be monitored on a CTG for at least 15 minutes prior to the ECV. Tocolysis may be offered as subcutaneous terbutaline 250micrograms 10-15 minutes prior to commencing the procedure. (21)

Before the procedure begins, the professional have to:

- Ensure the woman has emptied her bladder.

- Position the woman in a supine recumbent position (better with her buttocks elevated by placing a wedge under them). Also Trendelemburg position works out well.
- Lubricate the maternal abdomen using mineral oil, ultrasonic gel or talcum powder. This decreases friction, which may reduce maternal discomfort. Entonox may also be offered to help reduce maternal discomfort. (21)

The attempt to turn the fetus will take place when the mother's uterus is relaxed. An appropriately trained obstetrician or midwife should perform the technique. The professional has to be placed to one of the sides of the women. It starts with placing both hands on the surface of maternal abdomen: one by the fetus's head and the other between the fetal buttocks and the maternal symphysis pubis (*Fig. 6*).

First, you have to dislodge the fetal part (usually the breech) from the upper strait of the maternal pelvis, rejecting it upwards. When this fetal part has a certain degree of fit in the maternal pelvis, you can push it through the cervical area by placing a hand in the vagina. After that, both hands will act in the opposite direction. The one that grabs the head will attempt its descent toward the maternal pelvis, while the hand located in the pelvic pole will guide the breech towards the fundus. It is necessary to proceed smoothly but also quickly. Obtaining a successful ECV does not mean the immediate fitting of the fetal head. (21) (18).

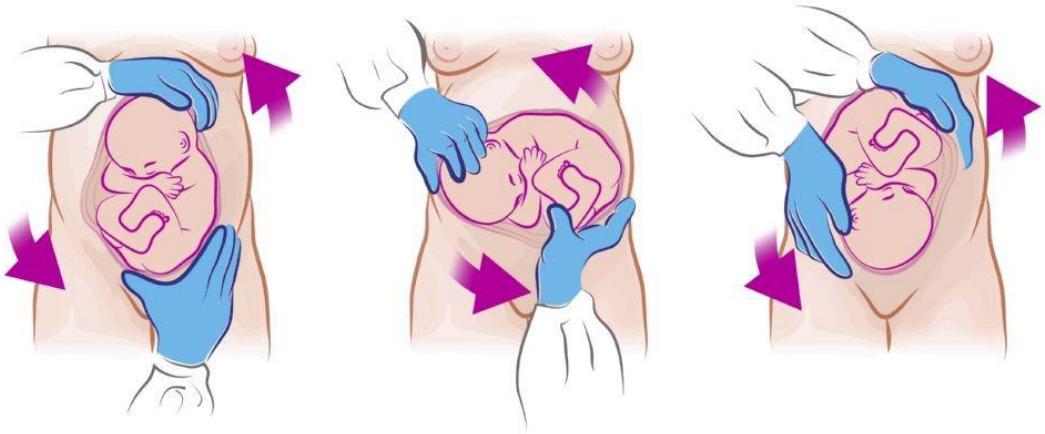

Figure 6. ECV procedure step by step. (2)

The version attempt has to be interrupted if fetal bradycardia, huge maternal discomfort or serious difficulties occur (such as more than 5 minutes of uterine pressure is required). (1), (21)

After performing the version, electronic fetal monitoring (EFM) is convenient for at least 30-45 more minutes (it has to be reactive), and if registration is correct and no pain or blood loss is evident, the patient can return home, keeping a relative rest of 24 hours. (1)

Instruct the woman to phone or return to the hospital if any of the following occur: vaginal bleeding any signs of APH, rupture of membranes, commencement of labour, change in pattern or decreased fetal movements or abnormal abdominal pain.(21)

3.3.2. Tocolysis

Due to ECV it is not always successful, strategies including tocolysis have been implemented to improve success of ECV, its major benefit being a reduction in the amount of force required to turn the fetus. (22)

The use of betamimetics to facilitate ECV is associated with an increase in cephalic presentation in labor and birth. (17)

The success rate of ECV is increased by the use of tocolysis. This has been proven with ritodrine, salbutamol and terbutaline but not with glyceryl trinitrate (GTN) as a patch or

sublingually, or with nifedipine. Intravenous and subcutaneous routes can be used. Tocolysis is also beneficial where an initial attempt without it has failed. (7)

A simple protocol is to offer a slow intravenous or subcutaneous bolus of salbutamol or terbutaline either routinely or if an initial ECV attempt has failed. Women should be advised of the adverse effects of tocolysis with beta-2 agonists. (7)

It has been proved that ritodrine tocolysis (*Annex 1*) significantly improve the success rate of ECV not only in nulliparous but, interestingly, also in multiparous women among whom the success rate is already always higher. This finding suggests that tocolysis should be offered to both nulliparous and multiparous patients. (22)

The ECV in term foetuses and with the use of tocolytics does provide a statistically significant reduction of births in BP and CS rates. Furthermore, no differences were found in Apgar indices (*Annex 2*), cord pH acidosis or perinatal deaths. (1)

On the other hand, it has been proven the effectiveness and safety of ECV when carried out by skilled and experienced practitioners even without tocolysis nor epidural anaesthesia.(6)

When carried out without tocolysis nor epidural anaesthesia, the success rate for ECV was 41% for first attempts and 29% for second attempts. Repeat ECV increases the number of cephalic presentations at birth and should be considered after an unsuccessful ECV. No complications were reported after a second ECV. The prevalence of CP at birth increased with 3% after a second ECV. (6)

3.3.3. Clinical factors

The effectiveness of ECV might be influenced by various factors.

Studies show that maternal and fetal characteristics, such as parity, type of BP, uterine contractility, duration of pregnancy, breech position, ease in palpation of fetal head, liquor volume and placental position may contribute to the success of ECV. The use of tocolysis, epidural anaesthesia and fetal acoustic stimulation may also positively influence the success percentage of ECV. (6)

The highest success rates are seen in multiparous, non-white women with a relaxed uterus, where the breech is not engaged and the head is easily palpable. Success rates are also higher with increasing liquor volume but, in practice, very high liquor volume may be associated with spontaneous reversion too. (7) Moreover, the association between oligohydramnios and decreased ECV success is statistically significant and association between increased fluid and higher success rates is also observed. (23)

On the other hand, maternal weight, placental position, fetal size and position of the legs make less difference and are probably not independent of other factors. (7)

Birth weight only had 11% effect on the success of ECV in women. It suggests that although BW plays a minimal role in success of ECV, it appears to be smaller than the effect of maternal BMI. (9)

ECV success significantly decreased with BMI greater than 40 kg/m2. Women with a normal BMI had a 65.0% success of ECV while women with a BMI >29.9 kg/m2 had a 63.9% success of ECV, which is significantly lower. Most notably, women with a BMI of 40 kg/m2 or greater had a successful ECV 58.5% of the time. So, one of the prognostic parameters associated with a successful ECV is a BMI of 25 or less. (9)

Factors associated with ECV success include increasing parity, posterior placenta, double footling or complete breech, and normal or increased amniotic fluid volume (*Annex 3*). (9)

However, when variables were analysed individually, the only one associated with success was parity. Women in whom ECV was concluded with success had a higher parity than the ones in which the procedure failed. (17). So, it is well-known that parity is strongly associated with ECV success. (23)

As placental location is concerned, no significant differences were shown between successful and failed ECV groups. Though, a trend appeared towards a higher prevalence of anterior

placentas in women in which ECV attempt was not successful. In conclusion, an anterior placental location is slightly associated with a lower likelihood of success in ECV, and therefore an anterior placenta emerges as a negative predictive factor for the outcome of the procedure. (17).

It was found that the overall most important factor in ECV success was parity, followed by fetal presentation and amount of amniotic fluid. (9)

The success of ECV is not only related to physical, obstetric and neonatal factors but may be influenced by other factors such as skill of practitioner, maternal attitude, expectations and stress.(6)

Women who had successful ECV procedures tended to be older than the women with unsuccessful attempts. (23)

Race and ethnicity did not differ significantly between those with successful and unsuccessful procedures, nor did rural versus urban residence. (23)

ECV was successful in 50% women with a prior cesarian section. Labor was attempted in 93.6% of the women for whom ECV was successful and the presentation was cephalic at delivery. In those women who attempted labor, 63.8% gave birth vaginally, with 51.1% of these having a spontaneous vaginal birth and 12.8% an instrumental delivery and 31.9% had an emergency CS following a trial of labor. The overall rate of vaginal delivery in women undergoing ECV after a prior CS was 33%. Comparing to those women who had not had a previous CS, ECV was successful 64.4% and 61.5% were cephalic at delivery. Of these, 94.1% delivered vaginally. Thus, women with a previous CS were less likely to have a successful ECV (although safe) and, where ECV had been successful and the presentation was cephalic, less likely to achieve a VB (4).

3.3.4. Complications and risks

External cephalic version is known to be a safe procedure causing minimal fetal and maternal complications. (22) Therefore, women should be counselled that ECV has a very low complication rate. (21)

Despite the benefits of an ECV, the procedure has physical, emotional, and financial costs, especially when unsuccessful. (23).

Maternal and neonatal complications in women with failed ECV were almost double of women with successful ECV. Additionally, it was found that if ECV was successful the complication rate was similar to women who did not have an ECV. (9)

So, unsuccessful attempts are associated with some adverse health outcomes. (23)

The existence of complications reaches 1-4%, including fetal losses that can reach up to 1.7%. (1)

Although rarely associated with complications, these include uterine rupture, placental abruption, early onset of contractions (though rare), premature rupture of membranes, umbilical cord complications, fetal–maternal transfusion, vaginal blood loss, Rhesus antagonism, fetal heart rate pathology, stillbirth and asphyxia. (6) Despite it can be associated with fetal bradycardia and a non-reactive CTG, they are almost invariably transient and alterations in umbilical artery and middle cerebral artery waveforms.(21)

The most common of these complications is transient fetal bradycardia (in rare cases it is prolonged) not associated with fetal morbidity. (6)

In a retrospective study of women who underwent ECV (performed with tocolysis and combined spinal and epidural anesthesia), 48.5% of cases showed fetal bradycardia during of immediately after the procedure. Of those, bradycardia lasted for <1 minute in 43.4% of the cases and <10 minutes in 98.4% of the cases. Only 1.6% cases showed FB of >10 minutes in duration – with two of the three cases experiencing severe neonatal asphyxia despite the performance of emergent CS. (24)

In conclusion, FB lasting <10 minutes after ECV showed a good prognosis. FB resolved within 5 minutes in 88.9% of cases and resolved within 10 minutes in 98.4% of cases. All of these cases showed Apgar scores (*Annex 2*) at 5 minutes of >7 and none of them experienced any recurrence of bradycardia.(24)

In contrast, cases with bradycardia lasting > 10 minutes had poor neonatal outcomes as two of three of them experienced severe asphyxia. So, FB lasting >10minutes after ECV is a risk factor for asphyxia.(24)

Two factors were found to be significantly associated with FB : women with a lower BMI and an ECV procedure of >5 min in duration. (24)

Delivery should be completed within 10 min when persistent FB occurs after ECV to avoid severe neonatal asphyxia. (24)

A meta-analysis showed no difference in neonatal morbidity (Apgar score under 7 at 5 minutes, low pH in umbilical vein) and mortality between the ECV groups and those not having ECV. (6)

A recent systematic review of version-related risks, showed no increase in fetal mortality or serious morbidity after ECV. However, variable patterns in fetal heart rate as seen in EFM (i.e. transient bradycardia or decelerations in the FHR) frequently occurred, but rarely led to CS. (6)

A composite outcome of maternal and neonatal complications increased as BMI increased. (9)

For women who had a successful ECV, there was a positive trend in the proportion of cesarean deliveries as BMI increased. Women with BMI between 30 and 34.9 kg/m2 were noted to have cesarean delivery rate of 33.8%, whereas they are up to 36% in those with a BMI of 35.0–39.9 kg/m2, and 48.1% in those with BMI greater than 40 kg/m2. Furthermore, obesity also confers a—two to threefold increased risk of cesarean delivery by emergency cesarean. (9)

It has been demonstrated that normal weight women with a successful ECV were almost half as likely to have a cesarean delivery compared to women with BMI greater than 40 kg/m2. Hence, morbidly obese women with a breech fetus may benefit from having a cesarean delivery instead of a failed ECV(9).

Large and consecutive series suggest a 0.5% immediate emergency CS rate. (7)

It is not known from the published literature whether the risk of complications increases after a second ECV attempt. However, several studies have suggested that a large proportion of

severe complications result from the use of tocolysis or anaesthesia leading to a lack of pain signals as a warning that too much force may be applied. (6)

External cephalic version is commonly not performed in women with a previous CS due to fear of uterine rupture. Vaginal birth after cesarean section (VBAC) with a cephalic baby is also supported by *the American College of Obstetricians and Gynecologists and Royal College of Obstetricians and Gynecologists*, as CS is associated with an increase in short-term maternal morbidity, and also increases the risk of abnormal placentation in future pregnancies *(Fig. 4)* . But despite a 60–70% success rate, VBAC is attempted rarely, particularly in the US, due to fear of uterine rupture. So, as both ECV and the presence of a cesarean scar are associated with emergency CS, this procedure in these type of patient must be considered pointless. Previous CS is not currently considered a contraindication for ECV by the relevant RCOG Greentop Guide- lines, however it states that 'there are insufficient numbers to determine the low risk of uterine rupture'. For all these reasons, many women with a breech presenting fetus are simply offered an elective repeat CS.(4)

Therefore, it is recommended that the technique must be performed in an area suitable for the immediate attention of these possible complications.(1)

The procedure can also have emotional consequences for women. Women should be advised that ECV can be painful and the procedure will be stopped if they wish. (7) Thirty-five percent of women who have undergone ECV procedures have reported them to be painful. Many women express anxiety before an ECV. Moreover, some women in whom the ECV was not successful felt guilty about having caused unnecessary stress to their infant. (23)

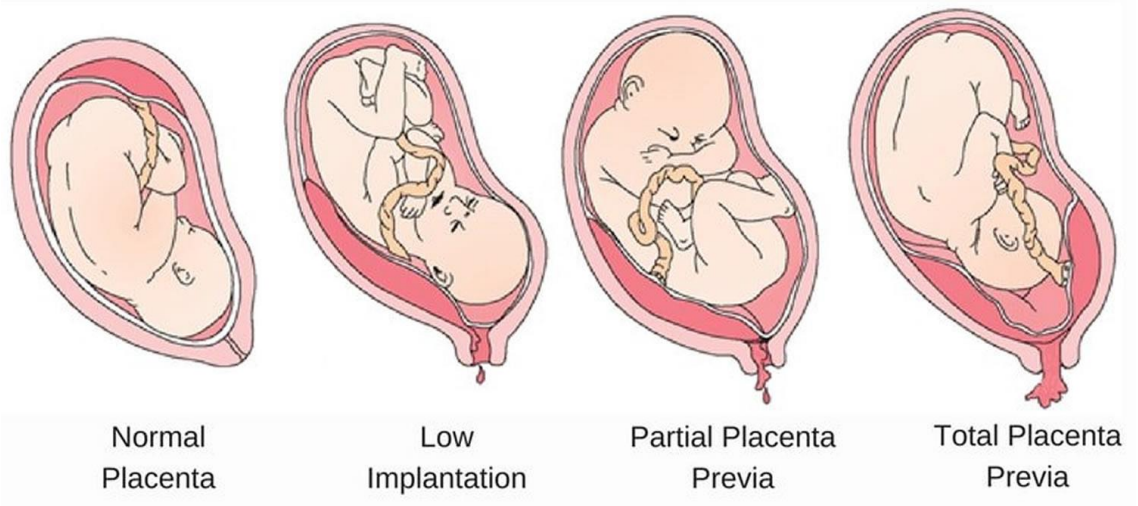

Figure 4. Different types of placenta location. (25)

3.3.5. Contraindications

Absolute Contraindications (21) (1):

- When caesarean delivery is required: such as placenta praevia, DPPNI.
- Antepartum haemorrhage within the last 7 days.
- Abnormal CTG.
- Intrauterus fetal death.
- Major uterine anomaly.
- Ruptured membranes (RPM).
- Severe oligohydramnios (known as amniotic fluid index ≤ 5 cm) (*Annex 3*).
- Rh sensitization.
- Labor.
- Coagulation disorders.

Relative Contraindications (21) (1):

- Multiple pregnancy (except delivery of second twin to be carried out by obstetrician).

- Small-for-gestational-age (SGA) fetus with abnormal Doppler parameters or suspected CIR.
- Proteinuric pre-eclampsia.
- Pregnancy-induced hypertension.
- Uncontrolled hypertension.
- Maternal cardiac disease.
- Maternal BMI >40.
- Major fetal anomalies.
- Scarred uterus.
- Unstable lie.
- Fetal head deflection.
- Fetal weight between 3800-4500 g.
- Anterior placenta.

3.3.6. Success rates

External cephalic version was able to reduce the rate of cesarean section for breech presentation by 33.5% at 37 weeks of pregnancy and beyond. (22)

ECV was successful in 46.9% of cases conducted between 36 and 38 weeks of gestation, before the procedure salbutamol was administered for tocolysis. (17)

Spontaneous version rates (this is, without attempting ECV) for nulliparous women are approximately 8% after 36 weeks but less than 5% after unsuccessful ECV. Whereas spontaneous reversion to BP after successful ECV occurs in less than 5%. (7) This is, spontaneous version to cephalic presentation is more common following an unsuccessful ECV than spontaneously reverting to breech after a successful procedure. (23)

The highest success rates are seen with multiparous, non-white women with a relaxed uterus, where the breech is not engaged and the head is easily palpable. Success rates are also higher with increasing liquor volume but, in practice, very high liquor volume may be associated with spontaneous reversion. Maternal weight, placental position, gestation, fetal size and position of the legs make less difference and are probably not independent of other factors.

An overall success rate of 40% for nulliparous, and 60% for multiparous women can usually be achieved. With every pregnancy, the odds ratio for success of ECV increased almost threefold. (6)

Women with a BMI greater than 40 kg/m2 are less likely than normal weight women to have a successful ECV. (9)

The chance of success of the first ECV attempt increased with every additional parity and with an increase in birth weight of the baby. The chance of success was more than double for multiparous women (64%) compared with nulliparous women (29%). First attempt ECV was also positively influenced by higher age and longer duration of pregnancy.(6)

The success rate of ECV in the USA is approximately 65%. (9)

The investigators found that if the probability of ECV success is less than 32%, the societal and fiscal costs as well as maternal negative quality of life outcomes outweigh the potential benefits of the procedure as compared to a scheduled caesarean birth. The overall success rate of 57.2% in Washington State indicates that attempting an ECV is, on average, financially prudent, and even in subgroups of women with lower success rates (nulliparous women and those with oligohydramnios, for example) success rates remained above the 32% success rate threshold of cost-effectiveness. (23)

3.3.7. Anesthesia

Several interventions, including administration of spinal or epidural analgesia (Fig. 5) as an adjuvant of ECV, have been evaluated in an attempt to increase the success rates of the procedure and so reduce the need for cesarean delivery.(5)

The *American College of Obstetricians and Gynecologists* stated that data are insufficient to conclusively evaluate regional anesthesia without tocolysis or to make a recommendation favoring spinal or epidural anesthesia during ECV attempts. Despite this fact, a meta- analysis

of randomized controlled trials showed that administration of spinal or epidural analgesia substantially increased the success rate of ECV among women with BP at term and decreased the use of caesarean delivery.(5)

Furthermore, it has been tested that repeated ECV with spinal anesthesia after a failed first attempt without spinal anesthesia increased the rate of vertex presentation at birth and decreased the rate of cesarean delivery. These repeat attempts had a 56% success rate. The overall success rate of ECV was 71%, similar to the 72% success rate recorded among the women who requested epidural anesthesia for the initial attempt. Manny different studies confirm these figures. So we can confirm that epidural and spinal anesthesia increased the success rate of previously failed ECV. (5)

By contrast, other studies delayed the ECV attempt with anesthesia until at least week 38 or 39, which has been reported to decrease the success rate of ECV. It is due to the advance in pregnancy length that increases fetal weight which in turn affects the fetal descent in the manternal pelvis, thus leading to a decrease in the success rate of ECV. (5)

In one study, the group of women who refused the repeat ECV with spinal anesthesia were offered planned caesarean delivery at 39 WG or later. As we said, performing a second ECV both increased the rate of vertex presentation and reduced the rate of caesarean delivery. Consequently, these results could pave the way for performing the second attempt with spinal anesthesia before the scheduled caesarean delivery date, because early intervention is associated with high success rates. (5)

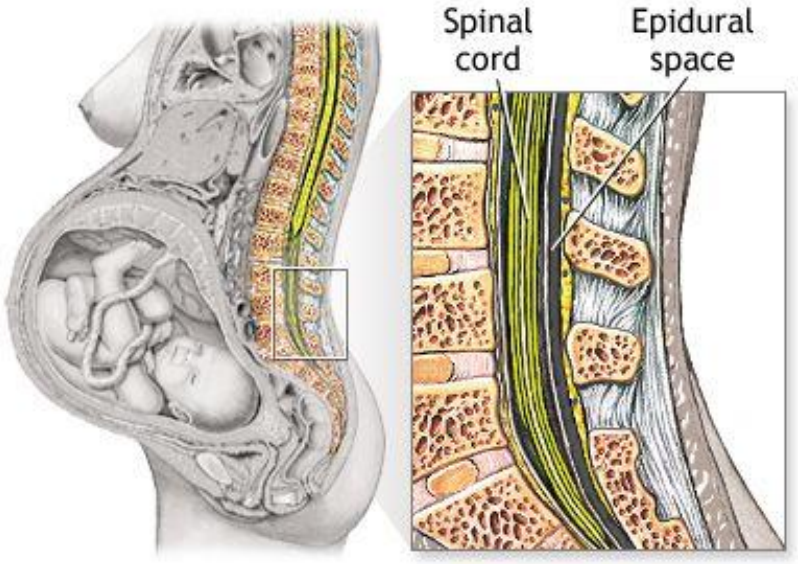

Figure 5. Anatomy of the spinal cord. (26)

4. JUSTIFICATION

Term breech presentation occurs in 3-4% of all pregnancies. The reason why the presentation of certain foetuses does not evolve into cephalic, as it happens in the majority of gestations between 28 and 33 WG, is due to a failure in the spontaneous version that has to occur at this time of pregnancy. Historically, vaginal breech birth was considered a reasonable and safe option. However, nowadays it is well-known that vaginal breech delivery has a moderate risk of severe complications such as cord prolapse (6%), stuck fetal head (8%) and fetal trauma (0,3- 6%).

The publication of the Term Breech Trial, at the end of 2000, reported an increased perinatal mortality with vaginal breech delivery and, in the other hand, a significantly lower perinatal and neonatal mortality and morbidity associated with planned caesarean section.

Since then, despite the WHO claimed, in 1985, that 'there is no justification for any region to have a rate higher than 10-15%', the incidence of caesarean section for breech presentation has increased markedly, currently being the most commonly used method for delivery of the breech fetus. There has been a worldwide increase in CS rates from 6.7 to 19.1% over the period 1990–2014, particularly in middle and high-income countries and it continues to rise. Thus, reducing the caesarean section rate has become an objective of the majority of public health services.

Furthermore, CS, as any other surgical procedure, is not exempt from complications, both for the mother and for the newborn.

The purpose of ECV is to decrease the incidence of both vaginal breech delivery and CS, without impacting upon maternal or fetal outcomes and is recommended by various national guidelines. ECV should be offered to all pregnant women whose foetuses are in breech position in order to be performed at 37 WG, when the probability of spontaneous version is smaller, the amount of liquid is still adequate and to avoid iatrogenic prematurity.

External cephalic version is known to be a safe procedure causing minimal fetal and maternal complications. Despite the benefits of an ECV, the procedure has physical, emotional, and financial costs, especially when unsuccessful. The existence of complications reaches 1-4%, being the most common transient fetal bradycardia not associated with fetal morbidity. The

procedure can also have emotional consequences for women as thirty-five percent of women who have undergone ECV procedures have reported them to be painful. Moreover, some women in whom the ECV was not successful felt guilty about having caused unnecessary stress to their infant.

External cephalic version was able to reduce the rate of cesarean section for breech presentation by 33.5% at 37 weeks of pregnancy and beyond. ECV was successful in 46.9% of cases conducted between 36 and 38 weeks of gestation.

The investigators found that if the probability of ECV success is less than 32%, the societal and fiscal costs as well as maternal negative quality of life outcomes outweigh the potential benefits of the procedure as compared to a scheduled caesarean birth. The overall success rate of 57.2% in Washington State indicates that attempting an ECV is, on average, financially prudent, and even in subgroups of women with lower success rates, it remained above the 32% success rate threshold of cost-effectiveness.

Nevertheless, the problem is that these ECV success rates are only taking into account the achievement of the cephalic position after the manoeuvre. Little evidence is found about the vaginal delivery of these patients that undergone a successful ECV. It would be important to consider if they have more risk of needing a caesarean section during the vaginal delivery attempt, instrumental delivery, maternal morbidity and neonatal outcomes after birth. In other words, if the vaginal birth of women who underwent a successful ECV is comparable to those whose foetuses are spontaneously cephalic. All this should be considered also as a part of the success of the technique, and so, if it really achieves its main goal: to decrease caesarean section rates, not immediately after the technique but also at the moment where vaginal delivery is attempted.

In this context, the intention of this non-randomized intervention study based on a prospective cohort is to prove if women who underwent a successful ECV show higher rates of caesarean section that those whose foetuses were spontaneously cephalic and so did not undergo an ECV. It is true that ECV is quite successful in avoiding breech presentations and so, reducing

caesarean section rates. But, what does have happened with these patients that even undergoing a successful ECV ended up in a caesarean delivery? Thus, if our hypothesis is confirmed, this is that women who underwent an ECV (although successful) have more rates of caesarean section, we can consider if ECV is really worth doing in all women. For this reason, in this trial we will take into account possible individual factors of these patients that can increase the risk of needing a caesarean section although having had undergone an ECV. So, although further studies will be needed, maybe we could avoid performing an ECV, and so avoiding its risks, costs, and discomfort, to some women as they have more risk of caesarean section anyway.

5. REFERENCES

1. Arenas B, Melchor JM, Jc M. Fundamentos de Obstetricia (SEGO). 2007. 401–414 p.

2. VERSIÓN CEFÁLICA EXTERNA: Un giro para evitar la cesárea | Ayúdanos Que Somos Padres [Internet]. [cited 2019 Oct 10]. Available from: http://ayudanosquesomospadres.com/version-cefalica-externa-un-giro-para-evitar-la-cesarea/

3. Umbilical Cord Prolapse - Risk Factors - Management - TeachMeObGynTeachMeObGyn [Internet]. [cited 2019 Oct 20]. Available from: https://teachmeobgyn.com/labour/emergencies/cord-prolapse/

4. Impey ORE, Greenwood CEL, Impey LWM. External cephalic version after previous cesarean section: A cohort study of 100 consecutive attempts. Eur J Obstet Gynecol Reprod Biol [Internet]. 2018 [cited 2019 Oct 3];231:210–3. Available from: https://doi.org/10.1016/j.ejogrb.2018.10.036

5. Massalha M, Garmi G, Zafran N, Carmeli J, Gimburg G, Salim R. Clinical outcomes after external cephalic version with spinal anesthesia after failure of a first attempt without anesthesia. Int J Gynecol Obstet. 2017;139(3):324–8.

6. Rijnders M, Herschderfer K, Prins M, van Baaren R, van Veelen AJ, Schönbeck Y, et al. A retrospective study of the success, safety and effectiveness of external cephalic version without tocolysis in a specialised midwifery centre in the Netherlands. Midwifery. 2008;24(1):38–45.

7. EXTERNAL CEPHALIC VERSION AND REDUCING THE INCIDENCE OF BREECH PRESENTATION A. 2006.

8. Rodgers R. External cephalic version is associated with a low complication rate. BJOG An Int J Obstet Gynaecol. 2019;126(4):500.

9. Chaudhary S, Contag S, Yao R. The Journal of Maternal-Fetal & Neonatal Medicine The impact of maternal body mass index on external cephalic version success The impact of maternal body mass index on external cephalic version success. 2018 [cited 2019 Oct

3]; Available from: https://www.tandfonline.com/action/journalInformation?journalCode=ijmf20

10. Betrán AP, Ye J, Moller AB, Zhang J, Gülmezoglu AM, Torloni MR. The increasing trend in caesarean section rates: Global, regional and national estimates: 1990-2014. PLoS One. 2016 Feb 1;11(2).

11. Materno-fetal SDM. PROTOCOLO : CESÁREA. :1–9.

12. ¿En qué consiste una cesárea? ¿Qué puedo esperar si me la hacen? | [Internet]. [cited 2019 Oct 24]. Available from: https://freedaytripblog.wordpress.com/2013/11/18/en-que-consiste-una-cesarea-que-puedo-esperar-si-me-la-hacen/

13. Cesárea - Serie—Procedimiento (tercera parte): MedlinePlus enciclopedia médica [Internet]. [cited 2019 Oct 24]. Available from: https://medlineplus.gov/spanish/ency/esp_presentations/100191_5.htm

14. El parto por cesárea paso a paso [Internet]. [cited 2019 Oct 24]. Available from: https://www.natalben.com/parto/parto-por-cesarea

15. Complex Obstetric Surgery | University of Maryland Medical Center [Internet]. [cited 2019 Oct 22]. Available from: https://www.umms.org/ummc/health-services/womens-health/maternal-fetal-medicine/services/complex-obstetric-surgery

16. Sánchez-Cabezón C, Montes-Olangua MI, García-Suarez S, García-Carretero R. Dehiscencia de una herida abdominal tras una cesárea tratada con terapia de cierre al vacío en el domicilio. Enferm Clin. 2013 Mar;23(2):73–8.

17. Vaz de Macedo C, Clode N, Mendes da Graça L. Prediction of Success in External Cephalic Version under Tocolysis: Still a Challenge. Acta Med Port. 2015;28(5):554.

18. CARRERA MACIA J. Tratado de Obstetricia Dexeus. 1988.

19. Guerra S, Lopez-Picado A, Muñoz H, Marín JM, Lete I, Echevarria O. Versión cefálica externa en presentación de nalgas: Una técnica ancestral muy actual. Vol. 39, Clinica e Investigacion en Ginecologia y Obstetricia. 2012. p. 113–7.

20. Boujenah J, Fleury C, Bonneau C, Pharisien I, Tigaizin A, Carbillon L. Successful external cephalic version is an independent factor for caesarean section during trial of labor-a matched controlled study. J Gynecol Obs Hum Reprod [Internet]. 2017 [cited 2019 Oct

3];46:737–42. Available from: http://dx.doi.org/10.1016/j.jogoh.2017.09.001

21. External cephalic version protocol. 2015.

22. Nor Azlin MI, Haliza H, Mahdy ZA, Anson I, Fahya MN, Jamil MA. Tocolysis in term breech external cephalic version. Int J Gynecol Obstet. 2005;88(1):5–8.

23. Morgan ER, Hu AE, Brezak AMV, Rowley SS, Littman AJ, Hawes SE. Predictors of a successful external cephalic version: A population-based study of Washington state births. Women and Birth. 2019 Jun 1;32(3):e421–6.

24. Suyama F, Ogawa K, Tazaki Y, Miwa T, Taniguchi K, Nakamura N, et al. The Journal of Maternal-Fetal & Neonatal Medicine The outcomes and risk factors of fetal bradycardia associated with external cephalic version The outcomes and risk factors of fetal bradycardia associated with external cephalic version. 2017 [cited 2019 Oct 3]; Available from: https://www.tandfonline.com/action/journalInformation?journalCode=ijmf20

25. Qué es la placenta previa, síntomas y riesgos [Internet]. [cited 2019 Oct 20]. Available from: https://madreshoy.com/que-es-la-placenta-previa-sintomas-y-riesgos/

26. Anestesia epidural: pros y contras [Internet]. [cited 2019 Oct 20]. Available from: https://www.aboutespanol.com/anestesia-epidural-duele-que-es-como-y-cuando-se-aplica-afecta-a-tu-bebe-1176573

27. FICHA TÉCNICA.

28. Torrent DS, Professora B. Complicacions obstètriques.

29. Ritodrina [Internet]. [cited 2019 Oct 28]. Available from: https://www.vademecum.es/principios-activos-ritodrina-g02ca01

30. Apgar score: MedlinePlus Medical Encyclopedia [Internet]. [cited 2019 Oct 29]. Available from: https://medlineplus.gov/ency/article/003402.htm

31. American Baby and Child Law centers.

6. HYPOTHESIS

6.1. Main hypothesis

Women whose foetus are in cephalic presentation after a successful external cephalic version show higher rates of caesarean delivery compared to those with spontaneous cephalic presentation at term among low risk, nulliparous women.

6.2. Secondary hypothesis

- Greater maternal morbidity is found in patients who underwent a successful ECV rather than those with spontaneous cephalic presentation at term.
- Worse neonatal outcomes are detected in these patients.
- Higher rates of instrumental vaginal deliveries occurred among women who underwent a successful ECV rather than those who did not and were spontaneously cephalic at birth.

7. OBJECTIVES

7.1. Main objective

To compare caesarean delivery rates between foetus in cephalic presentation after a successful external cephalic version and those with spontaneous cephalic presentation in nulliparous, low-risk, pregnant women.

7.2. Secondary objectives

Other objectives of this study would be:

- To analyse if there are differences regarding maternal morbidity (taking into account urinary or gastrointestinal tract injuries, hemoglobin drop > 3 g/dL or blood transfusion, placental abruption, uterine rupture, hysterectomy, birth canal tears or prolonged maternal hospitalization) between women who undergo a successful ECV and those with spontaneous cephalic presentation.
- To determine neonatal morbidity by measuring Apgar score (*Annex 2*) at 1 and 5 minutes, the pH of the umbilical vessels (one from the artery and the other from the vein) in both groups of patients.
- To compare the rates of instrumental vaginal deliveries, either using forceps, spatula or suction cup, in both groups.

8. MATERIAL AND METHODS

8.1. Study design

This study is a multicentre, prospective cohort study to prove if foetus in cephalic presentation after a successful external cephalic version show higher rates of caesarean delivery in comparison with those in spontaneous cephalic presentation in low risk, nulliparous pregnant women.

This study will be performed at the Ginecology and Obstetrics Service of different hospitals from Catalunya as:

- Hospital Universitari Santa Caterina (Girona).
- Hospital Universitari Doctor Josep Trueta (Girona).
- Hospital Materno-Infantil Vall d'Hebron (Barcelona).
- Hospital Universitari Arnau de Vilanova (Lleida).
- Hospital Universitari Joan XXIII (Tarragona).

Hospital Universitari Santa Caterina de Girona will be the reference centre in this trial, and one researcher will be assigned as the representative in each participant hospital to set up a good communication between all of them.

8.2. Study population

The patients of the study should be pregnant women at 33-35 WG, whose fetuses are placed in cephalic or in breech position. These women might have undergone their pregnancy at the selected hospitals in Catalonia and fulfil the inclusion and not the exclusion criteria.

8.2.1. Inclusion criteria

- Nulliparous women.
- Singleton pregnancy.

- Maternal BMI between 18,5 -34,9 kg/m2.
- Gestational age between 33-35 WG, with foetuses in breech or in cephalic position.
- EFW p10- p90.
- Maternal age between 25-39 years-old.
- Caucasian ethnic.
- Women who read and signed the study informed consent.

8.2.2. Exclusion criteria

- Foetuses with known foetal congenital anomalies or aneuploidy incompatible with life or vaginal delivery.
- Macrosomic foetuses.
- Prior caesarean section or other uterine scar (such as a myomectomy scar).
- Uterine abnormality or malformation.
- The present pregnancy complicated by ante-partum haemorrhage, hypertension, diabetes mellitus, intrauterine growth restriction (fetus <10th percentile for gestational age), oligohydramnios (amniotic fluid index of 5 and below), pre-eclamsia, non- reassuring FHR before the ECV attempt, placental abruption, active labour (regular uterine contractions accompanied by cervical dynamics), rupture of the membranes.
- Any contraindication for vaginal delivery.
- Women who delivered before 37 WG.
- Fetuses in a transverse or oblique position.
- Women unable to give the informed consent.

8.2.3. Withdrawal criteria

- Antenatal stillbirth after ECV.
- If spontaneous labour does not appear between 37-41+6 WG, and so it has to be induced.
- Fetuses who revert to breech position after being previously cephalic (either the ones who were spontaneously cephalic and who underwent an ECV).
- If the patients have any contraindication for the administration of ritodrine.

- If any ritodrine's severe adverse effect (*Annex 1*) appears in the ECV group, so that we have to stop its administration and so the manoeuvre cannot be performed.

- Fail to achieve a cephalic position after three attempts in the ECV, in the breech group of patients.
- If any severe complication derived from the ECV appears, so we have to give up the procedure.

8.3. Sampling methods

8.3.1. Sample size

In bilateral contrast, with an alpha risk of 5%, a statistical power of 80%, and assuming a moderate effect size, we will need 350 subjects (175 subjects in each group). Assuming also a 10% of drop-out- rate, we will finally need 384 subjects (192 subjects in each group). These will be divided into two groups: *Group 1* will include patients whose foetuses are already in vertex presentation and *Group 2* will include the ones in breech position.

Computations were carried out with the Prof. Marc Saez' software based on the library pwr of the free statistical environment R (version 3.6.2).

8.3.2. Sample selection

A consecutive non-probabilistic sampling will be applied to pregnant women at the 33-35 WG, whose foetuses are placed in cephalic or in breech position, who fulfil the inclusion criteria and not the exclusion criteria.

The patients will be recruited from Hospital Universitari Santa Caterina (Girona), Hospital Universitari Doctor Josep Trueta (Girona), Hospital Materno-Infantil Vall d'Hebron (Barcelona), Hospital Universitari Arnau de Vilanova (Lleida) and Hospital Universitari Joan XXIII (Tarragona).

All patients will be informed about the purpose of the study. The information document and the informed consent of the study will be given to all participants. They will only be included in the study if they sign and agree with the conditions of the research.

8.3.3. Estimated time of recruitment

According to unpublished data from the Obstetrics and Gynecology department from every hospital taking part in the study, the overall number of births in 2018 are around: 1200 in Hospital Santa Caterina, 1400 in Hospital Universitari Doctor Josep Trueta, 2800 in Hospital Materno-Infantil Vall d'Hebron, 2600 in Hospital Universitari Arnau de Vilanova and 1400 in Hospital Universitari Joan XXIII.

Then, we will take into account the prevalence of foetuses in breech presentation that is around 3-4%, according to national guidelines. We have calculated the 3% of all the newborns of 2018 to have the approximately number of breech foetuses. Furthermore, from this result, we have to calculate the 60% of it in order to have the number of breech foetuses that will undergo a successful ECV. So, the number of births of foetuses that were in breech position and underwent an external cephalic version in 2018 was about: 21 in Hospital Santa Caterina, 42 in Hospital Universitari Doctor Josep Trueta, 84 in Hospital Materno-Infantil Vall d'Hebron, 46 in Hospital Universitari Arnau de Vilanova and 25 in Hospital Universitari Joan XXIII. So, it will be a total of 218 births per year of foetuses who were in breech position and undergo a successful ECV.

Per month will be: 2 women in Hospital Santa Caterina; 4 women in Hospital Universitari Doctor Josep Trueta; 7 women in Hospital Materno-Infantil Vall d'Hebron; 4 women in Hospital Universitari Arnau de Vilanova; and, 2 women in Hospital Universitari Joan XXIII.

Therefore, taking into account that our sample size is 384 subjects (192 subjects in each group), to achieve 192 women whose fetuses are in breech position and will undergo a successful ECV, we will need about 11 months in order to recruit the amount of participants for this study.

If we cannot achieve the whole sample in 11 months, the recruitment time will be prolonged.

8.4. Data collection

To perform the data collection, all the Maternity Unit of Hospital Santa Caterina must be aware about the conduction of the trial to enlist every patient who fit the inclusion and exclusion criteria. The same consideration has to be taken into account for the other hospitals taking part in the study. Moreover, all the participant professionals of all centres will be trained about what they have to enquire and how to collect information. It is important to ensure that everybody participating in this study knows its task and the way to perform it, so data collection could be similar in all participating centres.

Besides, it has to be considered the importance of collaboration with midwifery team, as they will be in charge of most vaginal deliveries and the scheduled visits before the birth.

Patients will be also correctly informed (*Annex 4*) before entering the study and will sign the consent forms (*Annex 5*).

8.4.1. Constitution of the cohort

A non-probabilistic consecutive sample method will be performed in the Obstetrics and Gynecology Service of five hospitals from Catalunya (Hospital Universitari Santa Caterina, Hospital Universitari Doctor Josep Trueta, Hospital Materno-Infantil Vall d'Hebron, Hospital Universitari Arnau de Vilanova, Hospital Universitari Joan XXIII).

According to unpublished data from the Obstetrics and Gynecology department from every hospital taking part in the study, the number of births of foetuses who were in breech presentation and undergo a successful ECV in the five hospitals of the study is around 218 cases per year. Therefore, we will need about 11 months to complete the inclusion of our sample size.

All pregnant women attending the standard scheduled visit at 33-35 WG, who fit in all the inclusion and not the exclusion criteria, will be informed about the possibility of participating in the study. Participants have to be informed both orally and with an information sheet (Anex). If they agree to engage in, they will be given the informant consent (Anex)to enter the study and they may sign it.

Then, according to the fetal presentation seen in the USS in this visit, patients will be grouped in: Group 1) foetuses already in vertex presentation; and Group 2) the ones in breech position. The rest of foetuses, placed in other positions, may be excluded from the study.

The ones in vertex position will attend the follow-up visits according to the standard protocol, which are:

- At 38 WG, by the midwife
- At 40 WG, by the gynaecologist.
- At 41 WG, if the labour has not appeared yet.

The objective of these visits is simply to check that the pregnancy is following its normal course until childbirth. During these visits, a control of the arterial tension, measurement of the uterine height, vaginal touch and Leopold maneuvers will be carried out. In addition, a non-stress test will be performed to ensure the fetus well-being. If any complication, either from the mother or from the fetus, shows up during this period, the patient will be withdrawn from the study.

Whereas breech foetuses will have to undergo another visit at 36 WG in order to check if it is still in breech presentation. If so, we will arrange to perform the ECV at 37 WG; but previously, patients will be given the informant consent for the procedure (*Annex 6*), in which they have to sign if they agree and understand it all. Obviously, if there is any contraindication for the external cephalic version, it will not be performed and this patient must be excluded from the study.

In our study, women will be hospitalised for the day of the ECV. Before the procedure, an ultrasound examination is performed to evaluate the type of breech, fetal weight, amniotic fluid index (*Annex 3*), and localization of the placenta. Ritodrine e.v should be administered 30 minutes before the manoeuvre and making sure the patient has been previously informed about the possible adverse effects of this drug (*Annex 1*), however she will be carefully monitored to avoid any complication. The ECV will be executed with USS assistance. When ECV failed, two more attempts can be performed. A maximum of three attempts can be done. A non-stress test should be performed before and after the procedure.

Only the patients in whom the ECV has been successful (with a maximum of three attempts) can continue taking part in the study. The failed ones, whatever the reason, must be excluded.

Then, the same follow-up as the other group will be made.

If spontaneous labour does not show up from 37 to 41+6 WG, we will program its induction at 42 WG. These patients have to be excluded from the study.

When the spontaneous labour begins, the woman will be hospitalised and vaginal delivery will be attempted (as all foetuses are in cephalic presentation at this moment, whether they have undergone an ECV or not).

Epidural analgesia will be administered, with previous informant consent (Anex), and since then, we should start a rigorous monitoring of both maternal and fetal wellbeing. Thus, a non-stress test is performed intermittently during childbirth.

According to our main objective, we will compare the mode of delivery by the rates of caesarean section and vaginal deliveries between the two groups of patients (the ones that underwent a successful ECV and the ones who were cephalic spontaneously).

If possible, we will also record the rates of instrumental deliveries needed during the vaginal childbirth, either using forceps, spatula or suction cup, in the two groups of patients.

Regarding maternal morbidity, we will take into account any maternal complication that appears during the vaginal delivery in both groups of women.

Finally, we will record the neonatal outcomes by measuring Apgar score at 1 and 5 minutes after birth and the pH of the umbilical vessels (one from the artery and the other from the vein) in both groups of babies' patients.

8.5. Study variables

8.5.1. Independent variable

External cephalic version defined as the manual procedure used by health professionals that reorients, through the maternal abdomen, foetus that are in breech presentation in order to achieve a cephalic position, typically in late gestation (around 37 weeks) in preparation for vaginal birth.

8.5.2. Main dependent variable (primary outcome)

Proportion of caesarean deliveries, this is, the surgical procedure used to deliver the baby that involves one incision in the mother's abdomen and another in the

uterus, in both women that underwent external cephalic version and also those who don't, measured in percentages.

8.5.3. Secondary dependent variables (secondary outcomes):

- Maternal morbidity: taking into account urinary or gastrointestinal tract injuries, hemoglobin drop > 3 g/dL or blood transfusion, placental abruption, uterine rupture, hysterectomy, birth canal tears or prolonged maternal hospitalization.
- Neonatal morbidity by measuring Apgar score (*Annex 2*) at 1 and 5 minutes and the pH of umbilical vessels.
- Rates of instrumental vaginal deliveries, either using forceps, spatula or suction cup.

8.5.4. Co-variables

There are other variables that could affect our dependent and independent variables, but they are not the object of our study. As these variables could act as confounders, we will have to control them in order to increase the internal and external validity of our study.

Among these variables, we find:

- Maternal age: measured in years.
- Pre-pregnancy maternal weight: expressed in kilograms.
- Maternal weight: expressed in kilograms.
- IMC: expressed in kg/m2.
- Socioeconomic factors: defined by education and occupation.
- Prenatal care.
- Maternal smoking during pregnancy.
- Fetal head circumference: measured in centimetres.
- Estimated fetal weight: measured in grams.
- Amniotic fluid volume: measured by amniotic fluid index (ILA) in centimetres (*Annex 3*).

9. STATISTICAL ANALYSIS

9.1. Descriptive analyses

The dependent variable, which is a quantitative discrete variable (number of caesarean deliveries), will be summarized with the median and the interquartile range (IQR), stratifying it by the groups of the independent variable (yes/no ECV).

The analysis will be stratified by the co-variables. The quantitative co-variables will be categorized in quartile; whereas the qualitative ones will be summarized by proportions, always stratifying them by the groups of the independent variable.

9.2. Bivariate inference

We will contrast the difference of medians of the main dependent variable (number of caesarean deliveries) and the quantitative co-variables using the Mann-Whitney'Utest. The means of the continuous co-variables between the groups of the dependent variables will be tested with Student's test.

Difference on proportions of qualitative co-variables variables between intervention groups and control group will be contrasted by χ^2 test (Chi-Square test) and Fisher's exact test when expected frequencies will be less than five.

9.3. Multivariate analysis

The association between the dependent variables and the independent variable will be adjusted in Poisson regressions (because the dependent variable is quantitative discrete), controlling for all the covariates, thus potential confounders that could modify the results will try to be avoided. In all cases, a confidence interval of 95% will be assumed and $p<0.05$ will be considered statistically significant.

10. WORK PLAN

The whole study will last approximately 2 years.

This research team will include different specialists from the Obstetrics and Gynecology Services, such as the obstetricians and gynaecologist, midwifes, nurses and anesthetists. A statistician and a data manager will be hired for statistical analysis and data collection.

All the activities will be organized in five phases detailed below.

10.1. Study stages

1. Protocol design and approbation (4 months, October 2019- January 2020)

   The obstetric unit of *Hospital Santa Caterina,* in Salt (Girona), decided to do this non-randomized prospective cohort study.
   In this first period, the principal investigator and co-workers will perform a draft of the initial idea of the protocol. They will review the bibliography and literature published about this topic mainly in PubMed data base. They will design the protocol and will be shared with the whole Gynecology and Obstetrics Service of their own hospital and it will be sent to the direction of the hospital to get their approbation.
   The protocol will be sent to the *Clinical Research Ethics Committee* (*CEIC)* for its revision and approval. Once we get the approbation, we will share the protocol with the respective services in the proposed participant hospitals. All changes suggested by CEIC will be taken into account.

2. Organization (1 month, February 2020)

   Each Obstetric Service in every participant hospital will have a first informative meeting. In it, it will be presented the protocol draft, with an explanation of the project design (the objectives, methods of data collection, use of patient data sheet, working plan). Collaborators could decide if they agree with the organization of the study. The protocol will be read and understood and somebody will be assigned to be

the coordinator. This person will get in touch with the others to communicate all the research information during the whole duration of it. The chronogram of the study will be done and tasks will be distributed.

The representants of each hospital will have a meeting in *Hospital Universitari Santa Caterina* in Girona to deal with any doubt or problem about the protocol or the organization before starting the interventions of the trial.

Moreover, we will program videoconferences during the study, with the entire research team every 3 months to control the study and answering potential doubts.

Furthermore, all the team will be in contact via e-mail in case there is a need to solve unexpected problems.

The obstetricians of each hospital involved in the trial will meet in *Hospital Universitari Santa Caterina* in Girona to do a practical journal with an expert in external cephalic version that will train them to do the manoeuvre with the same protocol. The last two hours of the journal will be a practical examination where all the obstetricians will have to demonstrate their learned skills.

In addition, with the purpose of homogenizing a standardized method, a second informative meeting will be scheduled after the CEIC approval. All the participant professionals will be trained about what they have to enquire and how to collect information. It is important to ensure that everybody taking part in this study knows its task and the way to perform it.

3. Sample collection, intervention and first data collection (11 months, March 2020-January 2021)

   For 11 months, in the five participating hospitals, the Obstetric Services will be recruiting patients, that meet the inclusion and not the exclusion criteria, as the sample of the study. The information sheet (*Annex 4*) and informant consent (*Annex 5*) will be provided to the patients before including them into the study. The informant consent to perform the ECV will be given to the patients whose foetuses are in breech position.

During this period, performance of ECV will be done to pregnant women with breech foetuses. Finally, all data about birth day will be collected, either if it has been a vaginal or a caesarean delivery.

4. Last data collection (2 months, February 2021- March 2021)

   The last pregnant women included in the trial will be collected in February 2021 so the expected date of birth will be in the same February or March 2021, because when they were enrolled they already were at 33-35 WG, and the pregnancy is maintained until 41+6WG maximum. So, every patient is follow-up about 6-8 weeks.

   While the study is taking place, data collected from each patient will be registered in the database. A data manager will do controls of quality of this data base regularly to make sure there is a good quality of data collection and all information is correctly introduced. This period will finish at the end of the follow-up of the last patient.

5. Statistical analysis (2 months, April 2021- May 2021)

   Once the data collection is finished according to our sampling, the statistician will proceed to recollect all the data from our database and do the statistical analysis.

   A final meeting will be done with all the research team to discuss and interpret the results in order to elaborate definitive conclusions.

6. Results (2 months, June 2021- July 2021)

   The results, whatever they are, will be written in an article and published in an obstetrics journal, in order to properly disseminate the results of the study.

   The scientific evidence obtained from this trial will be presented in national and international congresses of Obstetricians.

WORK PLAN STEPS	DESCRIPTION OF THE ACTIVITY	STAFF	Oct-Nov 2019	Dec-Jan 2020	Feb-Mar 2020	Apr-May 2020	Jun-Jul 2020	Aug-Sep 2020	Oct-Nov 2020	Dec-Jan 2021	Febr-Mar 2021	Apr-May 2021	Jun-Jul 2021
STEP 1	**Scientific research + drafting off the protocol**	Main researcher											
	Protocol approbation	CEIC											
STEP 2	**Organization** - Coordinators meeting - Practical journey	Obstetricians											
STEP 3	**Sample collection**	Obstetricians											
	Intervention	Obstetricians + nurses											
	Follow-up	Obstetricians + nurses											
	Birth day	Obstetricians + nurses											
	First data collection	Obstetricians											
STEP 4	**Last data collection**	Obstetricians											
STEP 5	**Statistical analysis**	Statistician											
STEP 6	**Results** - Publication - Dissemination	Main researcher											

11. ETHICAL AND LEGAL ASPECTS

This research protocol will be presented to the Clinical Research Ethical Committee (CEIC, Comitè d'Ètica d'Investigació Clínica) of *Hospital Universitari Santa Caterina,* where it will be evaluated and will not be applied until its approval. The recommendations given by the committee will be taken into account to carry out and improve the study. It will be also necessary the approval of the direction of each authorized centre.

The project guarantees the respect of human rights and ethical principles established by World Medical Association in the *Helsinki Declaration of Ethical Principles for Medical Research Involving Human Subjects* (last revised in October 2013).

According to the Organic Law *15/1999, of the 13th of December, de Protección de Datos de Carácter Personal*", personal and clinical information of participants will be kept confidential at all times and will only be used just for the purpose of the research. In relation to data collection process, an identification number will be used instead of the patient's name for analysing the information in an anonymous way. Data will only be accessible for the responsible researchers of the project.

Prior inclusion to the study, every patient will be properly informed about the details and procedures of the study. Patients will be invited to read an information sheet where all risks, benefits and alternatives to the procedures will be detailed using the best update data available, at that point to ensure they perfectly understand the study before they sign the informed consents. They will be given time to contemplate their participation in the study. Then, they will sign voluntarily the informed consent to participate in the study. Participants have the right to withdraw the consent without having a negative effect on the relationship with their assigned doctor or treatment received. Thus, the principle of autonomy according to the law *41/2002, Básica reguladora de la autonomía del paciente y de derechos y obligaciones en material de información y documentación clínica*" will be respected.

Being an observational study, in which the procedures that will be carried out are the standard way for the treatment of these patients, there will be no need for extra insurance, with the civil responsibility of the hospitals being enough.

The authors will have to declare that they do not have any conflict of interest.

12. STUDY STRENGTHS AND LIMITATIONS

There are so limitations that should be considered before starting our study in order to limit them:

- This study is planned to be a multicentre study. Therefore, interpretation of endpoints involves some degree of inter-observer variability. For this reason, all the participant professionals of all centres will be trained about what they have to enquire and how to collect information. It is important to ensure that everybody taking part in this study knows its task and the way to perform it, so data collection could be similar in all participating centres.

- As we use a consecutive non-randomized sampling method, we could have a selection bias that we will try to minimize using inclusion and exclusion criteria and adjusting the logistic relation. Nevertheless, it can not be avoided at all because the population of this study may have some concrete characteristics. Only the patients who fulfils the inclusion criteria and do not meet any of the exclusion criteria will be invited to participate in the study. It is also possible that we have not included all the confounder variables. Therefore, results from the study will be adjusted by all potential confounding variables, and a multivariate analysis will be accomplished to adjust variables for these covariates.

- As we are carrying out a study about a manual manoeuvre (ECV) that will be performed by different obstetricians, a procedure bias can be present. Obstetricians' experience is one of the keys to technical success. In order to solve this mishap we are going to have a meeting in *Hospital Universitari Santa Caterina* in Girona to do a practical journal with an expert in external cephalic version that will train them to do the manoeuvre with the same protocol.

-It is an intervention study based on a prospective cohort. Hence, it is defined as observational and these type of studies tend to be of large duration so we can have an information bias due to possible loss of participants during the follow-up. However, we expect these loss to be minimum as little time elapses between a woman entering the study until she leaves it as they are enrolled with 33-35 WG and delivery cannot be extended more than 42+6 WG. Anyway,

we have to take into account that during this pregnancy period, although short, the subjects can move to another place or give birth in other hospitals not involved in the trial. We anticipate this fact by a 10% drop out rate in our sample size. We will solve this possible bias with follow-up calls via telephone for all patients who do not attend to the medical appointments.

- Another limitation is that it has been estimated a period of 11 months to recruit the sample in the five participant hospitals, but in case it was not achieved, we will ask for an extension to complete the sample selection.

On the other hand, this study has also some important strengths that have to be mentioned too:

- The cost of the follow-up in the study is not much higher in itself because, nearly all of the follow-up interventions and materials are included in the usual following of these type of patients.
- As it is a multicentre study, it will have more external validity than if it was only performed in a single centre, as the sample will be more representative because it involves patients of a larger area. To ensure this, it is important that all the participant professionals of all centres are trained so data collection could be similar. Anyway, if significant differences on outcomes are found between the intervention and the control groups, a next study with a larger sample will be necessary, in order to validate this study findings and get definitive conclusions.

13. BUDGET

13.1. Personnel

The research team participating in this study is already employed by the centres where it will be carried, and no extra hours will be needed. For this reason, these services will not be included in the budget. Evaluation of complications is also part of the routine activity related to these patients and will not suppose an extra cost.

However, a statistician and a data manager will be hired in order to create a database, collect the data and perform the statistical analysis. The estimated salary for the statistical specialist will be 35€/hour and approximately 320h will be needed. The estimated cost will be 11.200€. And for the data manager the estimated salary will be 30€/hour and approximately 20 hours/week will be needed, during the 2 years. The estimated cost will be 57.600 €.

13.2. Medical resources

The external cephalic version technique will not be included in the budget because it is part of the normal procedure used in the clinical practice of the centres participating in the study and it is part of the National Health System. The same happens with ultrasonographies and vaginal and caesarean deliveries, so no extra budget will be needed.
After delivery, either vaginal or caesarean section, patients will be hospitalized during few days, which are included in the post-operative plan.
Moreover, we assume 250€ cost for printing information sheets for patients, informed consent forms and participant data sheets.

13.3. Insurance

An insurance policy will be hired covering all participants.

13.4. Meetings

Before starting data collection, we will do one meeting involving each participating hospital in the study. It will take place in *Hospital Universitari Santa Caterina* in Girona. The aim is to do a practical journal with an expert in external cephalic version that will train them to do the manoeuvre with the same protocol.

We will do videoconferences during the study, with the entire research team every 3 months, to control the study and answering potential doubts.

There will be a last meeting that will be done in Hospital Santa Caterina in Girona to discuss the findings, with the research team.

13.5. Publication and diffusion of the results

In order to disseminate the information collected with the outcome of our study we will try to publish our study in scientific journals of Obstetrics. Publication costs will be about 2.500€.

It would be interesting to present this project with its results at national and international congresses, conferences and meetings.

We have estimated at 900€ the costs of the travel, accommodation and food for the national congresses; and 1500€ for the international one.

	Quantity	Cost	Subtotal
PERSONNEL			
Research team	Provided by the National Health System		
Data manager	1920h	30€/h	57.600€
Statistical specialist	320h	35€/h	11.200€
MEDICAL RESOURCES			
Ultrasonography	Provided by the National Health System		
ECV			
Vaginal birth			
Caesarean section			
Printing and paper	11 sheets x 384 patients	0,05€ each sheet	211,2 €
INSURANCE			
Insurance policy			5.000€
MEETINGS			
First meeting (of the representats of different hospitals)	1	500 €	500 €
Last meeting (ECV practical journey)	1	1500€	1500€
PUBLICATION AND DIFUSSION			
Article publication charges	1	2.000€	2.000€
Meetings, conferences and congresses: - **National** - **International**	 1 1	 900€ 1500€	 2.400€
TOTAL COST.....			22.868,8 €

14. FEASIBILITY

Medical team

This non-randomized multicentre study based on a prospective cohort will be developed in five hospitals from Catalunya, in where external cephalic version is commonly performed.

These hospitals are:

- Hospital Universitari Santa Caterina (Girona).
- Hospital Universitari Doctor Josep Trueta (Girona).
- Hospital Materno-Infantil Vall d'Hebron (Barcelona).
- Hospital Universitari Arnau de Vilanova (Lleida).
- Hospital Universitari Joan XXIII (Tarragona).

Our team will be composed of obstetricians and gynecologists, midwifes, nurses, anesthetists, a data manager and a statistical analyst. The whole Obstetrics and Gynaecology services, the midfery team and nursery staff have enough knowledge and experience and are all well trained to achieve the assigned objectives.

Necessary means such as personnel salaries, delivery rooms, operation rooms, surgical material and follow-ups will be provided by the national health system.

We will hire a data manager to help the investigators at coordinating and data quality control and monitoring respectively, because this multi-center study comprises five hospitals. We will need also a statistical specialist in order to do statistical analysis, discussion and publication of the results. Computer devices and programs to elaborate the database and to carry out the statistical analysis will also be provided.

Available Resources

All six centres are totally equipped medically and technologically to accomplish the objectives of the study. The centres participating in the study will provide all the necessary means such as personnel salaries, delivery rooms, operation rooms, cures and follow-up equipment. In case of presenting any complication that requires an emergency caesarea, operating rooms will be available.

The necessary hospitalization for these patients is 2 days in the case of vaginal delivery and 4 days if a caesarean section is performed. No hospitalization is required for ECV. Thus, it is important to have beds for these patients after these interventions.

The material required for this study is the standard material used in a vaginal delivery or a caesarean section.

Patients

Assuming referral of patients from Hospital Santa Caterina, Hospital Universitari Doctor Josep Trueta, Hospital Materno-Infantil Vall d'Hebron, Hospital Universitari Arnau de Vilanova, Hospital Universitari Joan XXIII; we approximate an inclusion in the study of 350 patients. So we believe that in about 11 month of data collection we will reach our sample size.

For all these mentioned above, this protocol is feasible to be brought out in our area, regarding availability of the sample, the professionals and the equipment.

15. IMPACT ON THE NATIONAL HEALTH SYSTEM

As we have already mentioned, term breech presentation occurs in 3-4% of all pregnancies. Nowadays, the normal clinical procedure is to offer to these women an external cephalic version. It is well-know that ECV is quite successful in avoiding breech presentations and so, reducing caesarean section rates. However, although being considered a safe manoeuvre, the existence of complications reaches 1-4% and thirty-five percent of women who have undergone ECV procedures have reported them to be painful.

It is important to point out the health and clinical impact that could produce this trial in the management of pregnancies affected by breech foetuses, that, nowadays are not exempted from medical, social and economic consequences

If our hypothesis is confirmed, this is, that women who underwent an ECV (although successful) have more rates of caesarean section, we can consider if ECV is really worth doing in all women indiscriminately. For this reason, in this study we will take into account possible individual factors of these patients that can increase the risk of needing a caesarean section although having had undergone an ECV

This research would give us scientific evidence about in which women is not worth attempting the external cephalic version because anyway they will have higher rates of needing a caesarean section when vaginal delivery is attempted, even if the ECV has been successful. In this way, we could avoid to these women unnecessarily discomfort and fear due to the technique and the possible maternal or fetal complications derived from it. Moreover, we would avoid an unnecessary expenditure of health resources.

16. ANNEXES

16.1. Annex 1: Ritodrine's relevant information

Relevant information about ritodrine.

Name of the product:

Pre-par 10mg/ml injectable solution. (27)

Qualitative and quantitative composition (27):

Pre-par 50 mg/5ml injectable solution.

- Active ingredient: each ml contains 10 mg of Ritodrina hydrochloride.
- Excipients: each ml contains:
  - 4.4 mg acetic acid.
  - 2.4 mg sodium hydroxide.
  - 1 mg sodium metabisulfite (E-223).
  - 2.9 mg sodium chloride.
  - 1 mg water for injections.

Farmaceutical form: (27)

Injectable solution.

The solution is aqueous and transparent.

Clinical data:

Therapeutic indications: (27)

- *Short-term treatment of uncomplicated premature delivery.*
- *Detention of uterine contractions between 22 to 37 WG in patients without any medical or obstetric contraindications to tocolytic treatment.*
- *Acute fetal distress due to hypermotility of the uterus during childbirth.*
- *Prevention of premature delivery after surgical interventions during pregnancy.*

Contraindications: (27) (28) (29)

- Rupture of membranes or dilation of the cervix above 4 cm.
- Cardiovascular pathology: as cardiac arrhythmias associated with tachycardia or digitalis intoxication, uncontrolled hypertension, previous ischemic heart disease or with significant risk factors, obstructive hyperthrophic cardiomyopathy or any type of obstruction of the left ventricular outflow tract, such as aortic stenosis.
- Pulmonary pathology (such as pulmonary hypertension).
- Thyroid maternal pathology (like hyperthyroidism).
- Pregestational or gestational diabetes (especially if uncontrolled).
- Repeated migraines episodes
- Multiple gestation.
- Hypersensitivity to active ingredient or to any excipient.
- Hypovolemia.
- Pheochromocytoma.
- First 20 weeks of pregnancy.
- Threat of abortion during the first and second trimester of pregnancy.
- Any disorder of the mother or fetus in which the prolongation of pregnancy is dangerous, like: severe toxaemia, intrauterine infection, vaginal bleeding due to placenta previa, eclampsia or severe preeclampsia, placental abruption or umbilical cord compression.
- Intrauterine fetal death, known congenital or fatal chromosomal malformations.

Warnings and precautions:

Ritodrine should be used with caution and during the entire treatment; the cardiorespiratory function and the electrocardiographic state should be monitored. (27)

The following monitoring measures should be applied to the mother and, when possible, also to the fetus : (27)(29)

- Periodic controls of blood pressure, pulse and heart rate.
- ECG.
- Monitor hydration status by evaluating fluids balancing and electrolytes.
- Glucose and lactate levels.

- Potassium levels: its decrease is associated with more risk of arrhythmias.

Parenteral administration should be limited to a maximum of 48 hours. (29)

We must stop the treatment if any sign of myocardial ischemia appears (such as chest pain or electrocardiographic abnormalities). (27)

Interactions : (29) (27)

- Halogenated anesthetics: due to the additional hypotensive effect, there is more risk of haemorrhage. In addition it can cause severe ventricular arrhythmias as a result of an increase in cardiac reactivity. So, the tocolytic treatment should be suspended, if possible, a minimum of 6 hours before if there is any scheduled anesthesia with halogenated anesthesics.
- Corticosteroids: they confer more risk to develop a pulmonary edema, hyperglicemia and hypokalaemia.
- Drugs that decrease potassium levels in serum: such as diuretics, digoxin, methylxanthines and corticosteroids. They can aggravate the hypokalemia and thus, increase the risk of cardiac arrhythmias.
- Moniamine oxidase inhibitors (IMAO): increase the cardiovascular risk.
- Beta adrenergic blockers: it can result in bronchospasm and reduction of the effect of ritodrine. They also increase the risk of pulmonary edema.

Fertility, pregnancy and breastfeeding:

Studies in animals, even in high doses, showed no teratogenicity. Pre-par is not recommended during the first 22 WG. (27)

Ritodrine has been shown to cross the placental barrier. That is why it is advisable to monitor the newborn for possible side effects of ritodrine.

Adverse effects : (27)(29) (1)

The more common are:

- Maternal hypotension, specially the diastolic pressure.
- Maternal tachycardia, palpitations.
- Anxiety, tremor, restlessness.

- Nausea, vomiting.
- Skin redness, heat sensation.
- Erythema, sweating, skin rash.
- Headache.
- Fever and malaise.
- Pulmonary edema.
- Cardiac arrhythmias, pectoral angina.
- Hypokalemia.
- Hyperglycemia.

And, in the fetus and the newborn:

- Cardiac disorders: increase in heart rate from 5 to 30 bpm, without clinical significance.
- Metabolism and nutrition disorders: fetal hyperglycemia and transient hyperinsuliniemia are observed. Hypoglycemia of the newborn can occur when labour starts shortly after an IV tocolysis. (27)

Overdose:

In case of overdose with ritodrine, symptoms of adrenergic stimulation will appear such as nausea, vomiting, tremor, tachycardia, dyspnea. Its antidote is any B-blocking agent. (27)(29)

Pharmacodynamic properties

Ritodrine is a sympathomimetic inhibitor of uterine contractions. Specifically, it is considered an agonist of beta adrenergic receptors. It inhibits spontaneous or induced uterine contraction for oxytocin and prostaglandins, also reducing the frequency and intensity of these contractions. This action has the effect of significantly delaying labour more than 48 hours.

It results in an increase of the number of pregnancies of 37 WG and a weight greater than 2.500 grams, and a decrease in the risk of idiopathic respiratory distress syndrome of the newborn. So, in absence of contraindications, the prolongation of pregnancy due to treatment of premature childbirth is a favourable factor for infant morbidity and mortality. (27)

The treatment should only be carried out in properly equipped centres to perform a continuous monitoring of maternal and fetal state. (27)

Pharmacokinetic properties

Absorption

Ritodrine can be administered by intramuscular route either in the deltoid and in the gluteus, and the difference in plasma levels does not present significant differences between both forms of administration.

Distribution

The half-life of ritodrine in the distribution phase is about 6-9 minutes. It crosses the placental barrier, reaching concentrations in fetal blood approximately equal to one third of the maternal blood.

When the ritodrinemia is 15 micrograms/ ml, obtained after the administration of 100 micrograms/min (i.v), it is expected to achieve tocolytic effect.

Metabolism or Biotransformation

Ritodrine is mainly metabolized in active metabolites in the bowel, liver and the placenta.

Elimination

Both metabolites and ritodrine are eliminated by the urine in 71-93%. The elimination half-life of ritodrine is approximately 60 to 156 minutes. (27)

16.2. Annex 2: Apgar score test

An anesthetist, Virginia Apgar, introduced the Apgar score in 1952. (1)

The Apgar is a quick test performed on a baby at 1 and 5 minutes after birth. The 1-minute score determines how well the baby tolerated the birthing process. The 5-minute score tells how well the baby is doing outside the mother's womb. (30)

The Apgar score alone cannot be considered to be evidence of or a consequence of asphyxia, does not predict individual neonatal mortality or neurologic outcome, and should not be used for that purpose.

The Apgar test should be performed by a doctor, midwife or nurse who examines the baby's: (30)

- Breathing effort.
- Heart rate.
- Muscle tone.
- Reflexes.
- Skin colour.

Each category is scored with 0, 1 or 2, depending on the observed condition. (30)

Apgar Scoring System

Indicator		0 Points	1 Point	2 Points
A	Activity (muscle tone)	Absent	Flexed arms and legs	Active
P	Pulse	Absent	Below 100 bpm	Over 100 bpm
G	Grimace (reflex irritability)	Floppy	Minimal response to stimulation	Prompt response to stimulation
A	Appearance (skin color)	Blue; pale	Pink body, Blue extremities	Pink
R	Respiration	Absent	Slow and irregular	Vigorous cry

According to the total punctuation obtained, Apgar scores of: (31)

- 7 or more: are typically considered normal.
- 4-6: are below normal, which means the baby will likely need medical intervention, such as resuscitation. The lower the score, the more alert the team should be to the possibility of intervention.
- 1-3: are critically low.

16.3. Annex 3: Amniotic fluid measurement

The valuation of the amount of amniotic fluid forms part of the ultrasound evaluation and moreover, for its increasing importance, it has been included as one more test to assess fetal well-being.

The USS assessment of the quantity of amniotic fluid can be made from a subjective-qualitative form, that is, the sonographer informs, based on his experience, of the presence of oligoamnios or hydramnios and of its severity. However, the assessment seems better with semiquantitative criteria. Among them, probably the most widespread is the index of amniotic fluid (ILA) that measures de amount of amniotic fluid in all four quadrants of the maternal abdomen. This technique quantification has shown to reflect properly and repeatable the true volume of amniotic fluid. (1)

According to this, we consider:

- Oligoamnios if ILA <8 cm. At the same time, it can be divided into: slight if 5-8 cm; and severe if < 5 cm.
- Polyhydramnios if ILA > 20-25 cm. (1)

16.4. Annex 4: Information sheet for participants

Project title: Caesarean delivery rates among fetus in cephalic presentation after a successful ECV compared to those who were spontaneously cephalic at term.

INVESTIGATORS: Josep Inglada Estruch and Clàudia Segura Villagrasa.

Centre: Hospital Santa Caterina de Salt, Girona.

Introduction

We are writing to inform you about a research study in which you are invited to participate. The study is conducted by the Obstetric and Ginecology services from different hospitals of Catalunya. It has been approved by the Clinical Research Ethics Committee.

Before deciding whether to participate or not, please take time to read the following information about the study carefully. It is important for you to understand why the research is being done and what it will involve. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

What is the purpose of the study?

The primary aim of the study is to compare caesarean delivery rates between fetus in cephalic presentation after a successful external cephalic version with those in spontaneous cephalic presentation so that we could test which group of foetuses, all in cephalic presentation, have more risk to need a caesarean section at the time of delivery.

This research is directed towards nulliparous, low-risk pregnant women between 33-35 WG.

We also want to assess if patients that underwent an ECV have more maternal morbidity, worse neonatal outcomes and higher rates of instrumental vaginal deliveries.

Description of the study

To carry out this study, we will include 350 women from five hospitals from Catalunya.

All pregnant women undergo a scheduled visit to perform a follow-up ultrasound scan at 33-35 weeks of pregnancy. In this visit, you will be asked to provide us with personal information that

is of interest to conclude if you present the requirements to participate in the study. If so, you will be invited to read the information sheet for the study and if you agree with the process, you will be given the informant consent to enter the study and you may sign it if you decide to participate in it. Then, according to the position of your fetus seen in the USS in this visit, you will belong to one of these two groups of patients: Group 1) foetuses already in vertex presentation; and Group 2) the ones in breech position. The rest of foetuses, placed in other positions, may be excluded from the study.

- If your fetus is already in a vertex presentation, you will attend the follow-up visits according to the standard protocol, which are:
    - At 38 WG, by the midwife.
    - At 40 WG, by the gynaecologist.
    - At 41 WG, if the labour has not appeared yet.

  Meanwhile, we will simply wait until spontaneous labour appears.
- But, if your fetus is in breech position at this moment, we will arrange another visit to repeat the USS at 36 weeks of gestation. If then, it is still in breech presentation, we will arrange to perform the external cephalic version at 37 WG. Previously to the procedure, we will give you an informant consent for the external cephalic version to sign it if you agree and understand the procedure.

  In our study, you will be hospitalised for the day of the ECV. Before the procedure, an ultrasound examination will be performed. You will be administered ritodrine e.v 30 minutes before the manoeuvre but you will be previously informed about the possible adverse effects of this drug (*Annex 1*), however you will be carefully monitored to avoid any complication. The ECV will be executed with USS assistance. When ECV failed, another two attempts can be performed. A maximum of three attempts can be done. A non-stress test will be performed before and after the procedure to ensure the fetal well-being.

  Only the patients in whom the ECV has been successful, this is achieving a cephalic position (with a maximum of three attempts), can continue taking part in the study. The failed ones, whatever the reason, must be excluded.

  Then, the same follow-up as the other group will be made: you have to attend to the following scheduled visits until spontaneous labour birth appears.

When the spontaneous labour begins, you will be hospitalised and vaginal delivery will be attempted.

You will be administered epidural analgesia, with your previous informant consent (*Annex 8*), and since then, we should start a rigorous monitoring of both maternal and fetal wellbeing. Thus, a non- stress test is performed intermittently during childbirth.

If labour does not show up from 37 to 41+6 WG, we will program the induction of labour at 42 WG. These patients may be excluded from the study.

According to the main objective of our study, what we want to prove is if the group of foetuses that have undergone a successful ECV have a higher risk of needing an emergency caesarean section during the attempt of vaginal delivery, in comparison to those who were spontaneously cephalic.

Finally, we will record the neonatal outcomes by measuring Apgar score at 1 and 5 minutes after birth (*Annex 2*) and the pH of the umbilical vessels (one from the artery and the other from the vein) of your baby.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice if you want to participate or not. Whatever your decision, all the services you receive at this clinic will continue and nothing will change.

You may change your mind later and stop participating even if you agreed earlier.

You may also be excluded from the study if the investigators consider it strictly necessary because you may meet the exclusion criteria at one point. In any case, you will receive a proper explanation why have you been withdrawn from the study.

What are my responsibilities if I take part in the study?

• To go to all the study's appointments and other appointments asked by the study team.

• To follow all the study's instructions.

• To inform about any problem or doubt during the study.

What are the possible benefits of taking part?

This study may provide us with more scientific evidence about ECV procedure and its results even when it has been successful.

Although more studies will be needed, it is expected that the knowledge obtained in this trial may benefit other patients in the future by knowing if it is worth attempting the ECV in a specific group of women.

However, it is not guaranteed that you will get any direct benefit from participating in the study.

What are the possible risks of taking part?

No risks or inconveniences are foreseen for participating in this study, since the procedures that will be carried out, as ECV or trying a vaginal birth, are the same as those performed in the standard way for all pregnant women.

Although ECV is known to be a safe procedure, little maternal discomfort during the manoeuvre is common. Therefore, the main risks that arise are those of the ECV itself, which will be explained in the informed consent.

According to the information sheet of ritodrine, it may have some adverse effects about which you will be properly informed. During the administration of this drug you will be carefully and continuously monitored to minimize the possible complications.

Alternatives to the procedure

Although is the conventional procedure to perform an ECV when the fetus is in breech presentation, women who decide not to participate in the study and do not want to undergo an ECV will simply undergo an expectant follow-up. During this time, if the fetus does not revert spontaneously to a cephalic position, when spontaneous labour shows up we can either try a vaginal breech delivery or a caesarean section.

What happens when the research study stops?

Once the study is finished, you will receive the necessary medical attention according to your condition regardless of your participation or not in this study.

Responsibility and insurance

The promoters of the study have contracted an insurance policy in accordance with the current law *Real Decreto 1090/2015* to carry out this study.

Thus, you will be insured for any damage you may suffer as a result of your participation on this trial.

Confidentiality

The treatment, communication and transfer of personal data of all participants will be adjusted according to *Ley Orgánica 15/1999, de 13 de Diciembre, de Protección de Datos de Carácter Personal"* and its last modification *"Real Decreto-ley 5/2018, de 27 de julio, de medidas urgentes para la adaptación del Derecho español a la normativa de la Unión Europea en materia de protección de datos"* that guarantee the confidentiality of all the computerized data.

The data collected in this study will be identified by a code and only the researchers and collaborators will be able to access to this information and data collected during the study. Your personal identification will not be disclosed, except in case of medical emergency or legal requirement.

Sharing the results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

Economic compensation

You will not receive financial compensation for participating but of course it will not cost you anything.

Right to refuse or withdraw

If you decide to withdraw your consent to participate in this study, no new data will be added to your database and may require the destruction of all identifiable data previously collected for this research.

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.

You should also know that you can be excluded from the study if the researcher considers it appropriate, either for security reasons, for any adverse event that occurs due to the intervention in the study or because it is considered that you are not complying with the established procedures. In either case, you will receive an adequate explanation of the reason for the withdrawal from the study.

Who can I contact to for further information, doubts or problems?

If you have any questions about your rights as a research subject, about your participation in the study or any complaints about the study, please contact with your research doctor.

Hospital Santa Caterina de Salt, Girona

Carrer del Dr. Castany, s/n, 17190 Salt, Girona

Thank you for Reading this. Try to keep this information sheet until your participation in the study is finished. If any queries, questions or doubts do not hesitate to contact us.

16.5. Annex 5: Informed consent for the patient

TITLE OF THE STUDY: Caesarean delivery rates among fetus in cephalic presentation after a successful ECV compared to those who were spontaneously cephalic at term.

Me, Mrs. .....

Confirm that:

• I have read and understood the information sheet.

• I have had time to think and consider this information.

• I have had the opportunity to ask any questions about the study and be answered satisfactorily.

• I have received enough information about the study.

• I have been informed by the investigator about the purpose of the study.

• I understand that my participation is entirely voluntary.

• I know that I can withdraw this study any moment I wish, without having to give explanations and without any consequences for the healthcare I receive.

• I give permission to collect my data and analyse it. I have been informed that all my data will be kept confidential.

I have spoken with (name of the investigator / obstetrician or gynaecologist / nurse or midwife):

.....

In accordance with the mentioned, I voluntarily accept participation in the study.

Patient's signature: Researcher's signature:

Name and surname: _____ Name and surname: _____

DNI: _ _ _ _ _ _ _ _ - _ DNI: _ _ _ _ _ _ _ _ - _

Date: __/__/_____ Date: __/__/____

16.6. Annex 6: Informed consent of ECV

Primer cognom.....

Segon cognom.....

Nom.....

Data de naixement: / Sexe:.....

NHC: DNI:.....

CIP: .....

Consentiment informat

Nom del procediment

Versió externa per facilitar l'expulsiu

Descripció del procediment

És una tècnica on, de forma manual, s'aconsegueix que un fetus en presentació de natges canviï la seva posició a una presentació de cap que és la més favorable pel part. Es realitza en complir les 36-37 setmanes perquè a partir d'aquest moment hi ha poques probabilitats que el fetus canviï de posició espontàniament. També s'evita que neixi prematurament. Abans de la seva realització, es descartarà alguna contraindicació que impedeixi el part vaginal i es comprovarà el benestar fetal. Posteriorment es realitzarà un estudi ecogràfic i s'administrarà medicació relaxant uterina per facilitar la tècnica. Mitjançant manipulació externa (pressió mantinguda sobre l'abdomen de la mare), es tracta de desplaçar les natges en la direcció adequada per facilitar la baixada del cap del fetus cap a la pelvis materna. Finalitzat el procés, es controlarà la freqüència cardíaca del fetus. Aquest procediment només es realitzarà en àrees on pugui realitzar-se una cesària urgent en cas de necessitat. Li evitarà una cesària (en el 70% dels casos) i les complicacions, seqüeles i mortalitat materna amb la qual s'associa (de 3 a 7 vegades més que en el part vaginal).

Riscos generals

Qualsevol exploració, tractament o intervenció quirúrgica presenta uns riscs generals. El més greu és la possibilitat d'una parada cardíaca. Altres complicacions són les hemorràgies i les infeccions. En cas d'urgència vital, caldrà actuar sobre aquestes complicacions amb els mitjans oportuns pel bé del pacient, dels quals s'informarà (sempre que les circumstàncies ho permetin) al malalt o a la persona que en sigui responsable.

Riscos específics

ELS MÉS FREQÜENTS: Aparició de bradicàrdies (descens de la freqüència cardíaca) fetals durant la realització de la tècnica, sense repercussió pel fetus i que desapareixen després del cessament de la maniobra. De vegades, aquestes bradicàrdies poden ser indicació d'una cesària urgent (0,5% dels casos) i no s'associa a un increment de les complicacions, seqüeles i mortalitat del fetus.

ELS MÉS GREUS: Encara que resulten ocasionals poden presentar: Hemorràgies. Trencament de membranes. Circulars de cordó (presència d'una o més voltes del cordó umbilical al voltant del coll del fetus). Despreniment de placenta. I altres situacions de risc que motivarien la realització d'una cesària urgent.

Riscos personals i professionals

A més dels riscos ja descrits, per les meves circumstàncies especials, mèdiques o d'altre tipus, es poden esperar els següents riscos: .....

16.7. Annex 7: Authorization sheet for vaginal delivery

FULL D'AUTORITZACIÓ

Núm. Història:

1r Cognom:

2n Cognom:

Nom:

Data Naixement : / / Sexe:

Garant: Núm:

Servei: Hab./Llit: Data:

AUTORITZACIÓ D'EXPLORACIÓ/ TRACTAMENT MÈDIC O QUIRÚRGIC

El/la malalt/a Sr./Sra. ……de …… anys d'edat, amb DNI …… i número d'història clínica ……. dóna lliure i voluntàriament CONSENTIMENT per a la realització de: Assistència al part.

Abans de donar el meu consentiment, signant aquest document, he estat informat/da pel/per la Dr./Dra. …… de forma clara i comprensible de l'actuació que es tracta, de la seva necessitat i de les eventuals complicacions, efectes secundaris i seqüeles.

En cas que sorgeixin situacions imprevistes durant l'actuació, autoritzo per realitzar el que en aquell moment es consideri el més convenient i necessari, sempre i quan no sigui possible un nou full de consentiment.

16.8. Annex 8: Informed consent for anesthesia

CONSENTIMENT INFORMAT PER A PROCEDIMENTS ANESTÈSICS

El/La Dr./Dra…….. informa al pacient la identificació del qual figura a l'adhesiu annex, que per al TREBALL DE PART, valorada la seva historia clínica, proves complementaries efectuades, analítica, procedeix aplicar anestesia ……. (general, locoregional, peridural, intradural, troncular, local,etc).

RISCOS GENERALS

Com en tot procediment quirúrgic sota anestèsia, existeixen riscos i complicacions que poden produir-se tant en el moment de l'inici com durant el manteniment de l'anestèsia o a posteriori en la reanimació postoperatòria.

Aquests riscos i complicacions poden produir alteracions cardíaques, respiratòries, metabòliques, neurològiques o nefrologiques, etc., que poden agreujar-se fins a un estat de coma o àdhuc arribar a la mort, aquesta incidència, la mort, és estadísticament de 0.7/10000 procediments.

Existeixen altres complicacions banals com dolor a la gola que pot durar uns dies, tos, veu ronca, nàusees i/o vòmits, i molt excepcionalment hematoma peridural o meningitis, després d'una anestesia peridural o intradural; en el cas d'anestèsies locals, hematomes com a complicació habitual.

RISCOS PERSONALITZATS

Les circumstàncies personals (edat, malalties, al·lèrgies, complicacions en anestesies anteriors o tractaments previs) així com hàbits tòxics (tabaquisme, ingesta d'alcohol, drogodependències) poden incrementar la incidència d'aparició dels riscos generals esmentats, en el seu cas……

Se m'ha informat de la possibilitat que aparegui una situació inesperada durant l'acte per la que calgui algun procediment diferent o addicional al previst inicialment, en aquest cas autoritzo a l'anestesiòleg/a a realitzar el que cregui convenient o necessari.

Se m'ha informat que, en cas d'ingressar al matí del dia de la intervenció, he d'adoptar les següents mesures de dejuni de ..... hores. Prendre la medicació habitual llevat indicació en contra en la visita preanestèsica, no portar maquillatge, ni pintallavis ni esmalt d'ungles, i advertir a l'ingrés de les pròtesis mòbils que porti (dents, lents de contacte, peercings linguals), i de qualsevulla altra anomalia que s'hagués produït en el temps transcorregut des de la visita preanestèsica.

Atès que la informació se m'ha donat de manera comprensible, he pogut formular les preguntes oportunes i se m'han aclarit els dubtes presentats en llegir o escoltar la informació sobre el procediment específic, **AUTORITZO** a l'equip d'anestèsia del **Parc Hospitalari Martí i Julià** a realitzar el procediment anestèsic esmentat anteriorment.

Sé que puc retirar aquest consentiment, si ho crec oportú, en qualsevol moment previ a la intervenció i que la signatura d'aquest consentiment no suposa cap renúncia a possibles reclamacions futures en l'àmbit que cregui oportú.

Lloc i data:

Signatures:

Pacient Representant legal Familiar Metge/sa informant