



**Large Foetal Head Circumference
observed on third-trimester
ultrasound, as a predictor risk
factor for high degree perineal
traumas during a vaginal delivery**

A prospective cohort study

FINAL DEGREE PROJECT

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LARGE FOETAL HEAD CIRCUMFERENCE OBSERVED ON THE THIRD-TRIMESTER ULTRASOUND, AS A PREDICTOR RISK FACTOR FOR HIGH DEGREE PERINEAL TRAUMAS DURING A VAGINAL DELIVERY.

“Daría la mitad de lo que sé por la mitad de lo que ignoro.”

René Descartes

Vull expressar el meu sincer agraïment al Doctor Ferran Montero. Gràcies per tots els teus consells, pel suport continu, per la paciència i sobretot, gràcies per ajudar-me a descobrir i estimar el món de la Ginecologia i la Obstetrícia. Ha sigut un autèntic plaer estar al teu costat i tenir la possibilitat d'impregnar-me d'una petita part del teu gran coneixement.

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1 ABSTRACT

Background: Obstetric anal sphincter injuries (OASIS) are a serious complication that women suffer during vaginal deliveries. Once it has occurred, although obstetricians always suture it at the immediate postpartum, faecal and urinary incontinences, flatulence and pelvic organ prolapse can appear. To prevent it, some protective perineal measures are performed routinely during childbirth. Several researches have confirmed some of the risk factors of perineal traumas, but the majority of them are measured after birth. Hence, foetal head circumference has been proposed as a possible predictive risk factor of these lesions.

Objectives: Assess whether the presence of a large foetal head circumference (FHC) assessed prenatally by ultrasound is associated to an increased risk of suffering a high degree perineal trauma during childbirth and/or an operative delivery among nulliparous and singleton gestation pregnant women. The cut-off point from which women have more risk of suffering a severe perineal lesion will be also determined.

Design: It will be an observational prospective cohort study performed in the Hospital Universitari de Girona Doctor Josep Trueta (HJT) between June 2016 and February 2021.

Participants: Using a non-probabilistic consecutive sampling, 3,080 nulliparous pregnant women older than 18 years and with a singleton gestation of 37 gestation weeks presented cephalically will be recruited.

Methods: Patients will be divided depending on the value of their foetal head circumference observed on the third-trimester ultrasound screening is equal or greater than the 95th percentile (36.4 cm), or lower than it. At the immediate postpartum, we will assess which ones have suffered a high degree laceration.

Main outcomes: Assess if a large foetal head circumference (FHC) assessed prenatally by ultrasound is a predictive factor of suffering a severe perineal tear during a vaginal delivery and if it increases the rates of the assisted births. Moreover, find the cut-off point from which there is more risk to suffer this disease.

Statistical analysis: we will use a Chi-square test to compare the exposed and the non-exposed groups and study whether a large foetal head circumference is a predictive risk of suffering a high degree perineal trauma and also a factor that increases the rates of operative deliveries. To find a cut-off point of FHC from which there is an incremented risk for having a severe perineal tear, we will use a Younden index based on a ROC analysis. Regarding the multivariate analysis, we will adjust the independent variables for covariables by using a multiple logistic regression model. Finally, sensitivity analysis will be performed to assess how the unplanned caesareans due to failure to progress can interfere in our results.

Keywords: foetal head circumference, obstetric anal sphincter injury, OASIS, high degree perineal trauma, severe perineal laceration, assisted deliveries, operative deliveries, instrumental deliveries.

2 ABBREVIATIONS

CRL – Crown-rump length

BPD – Biparietal diameter

HC – Head circumference

FHC – Foetal head circumference

OFD – Occipitofrontal diameter

AC – Abdominal circumference

AD – Abdominal diameter

FL – Femur length

AF – Amniotic fluid

FGR – Foetal growth restriction

HJT: Hospital Universitari de Girona Doctor Josep Trueta

WHO – World Health Organization

OASIS – Obstetric anal sphincter injuries

SEGO – Sociedad Española de Ginecología y Obstetricia

RCOG – Royal College of Obstetricians and Gynaecologists

ACOG – American College of Obstetricians and Gynecologists

EBCOG – European Board and College of Obstetrics and Gynaecologists

EAS – External anal sphincter

IAS – Internal anal sphincter

IUGA – International Urogynaecological Association

3 INTRODUCTION

3.1 PREGNANCY MONITORING BY ULTRASOUND

Prenatal ultrasound screening is performed systematically to pregnant women in order to identify any foetal or placental anomalies. Ultrasound imaging is performed at each trimester of gestation. Hospital Universitari de Girona Doctor Josep Trueta (HJT) employs as a guidance the criteria used in the ultrasound screening protocol of the Hospital Clínic of Barcelona, the published SEGO's protocol (*Sociedad Española de Ginecología y Obstetricia*) and the Catalan protocol "El protocol de seguiment de l'embaràs a Catalunya". On the following **Table 1**, there are summarised the basic sonographic parameters which must be evaluated at each trimester of gestation:

Trimester	Week	Objectives	Content
FIRST TRIMESTER	11 - 13+6 (preferably 12)	<ul style="list-style-type: none"> - Confirmation of an intrauterine and evolutive gestation. - Determination of the date of gestation, number of foetus and, in multiple gestation, the chorionicity. - Determination and measurement of the markers of the aneuploidies and chromosomopathies. - Assessment of early anatomy. - Determination of the pulsatility index of the uterine arteries, in order to calculate the preeclampsia risk. 	<ul style="list-style-type: none"> - Gestational sac and embryo: <ul style="list-style-type: none"> ▪ Number of sacs and embryos. ▪ Presence/absence of the embryo. ▪ Foetal heartbeat. ▪ CRL size and age's estimation. ▪ Nuchal translucence. ▪ Localization and characteristics of trophoblast. - Uterus and annexes observation.
SECOND TRIMESTER	20 - 22 (preferably 21-22)	<ul style="list-style-type: none"> - Evaluation of foetal growth. - Evaluation of foetal anatomy to discard structural pathologies. - Determination of the markers of the chromosomopathies. - Evaluation of placenta and AF. 	<ul style="list-style-type: none"> - Basal biometrics (BPD, HC, AC, HC/AC, FL). - Study of foetal anatomy (head, thorax, heart, abdomen, diaphragm, vertebral column, face, extremities, external genitals). - Characteristics of placenta, cordon (number of vessels) and estimation of quantity of AF.
THIRD TRIMESTER	Low risk	37±1	<ul style="list-style-type: none"> - Foetal growth estimation (BPD, HC, AC, HC/AC, FL). - Study of foetal anatomy (as in the 2nd trimester ultrasound, but especially assessing the nervous, renal, cardiovascular and digestive systems). - Localization and characteristics of placenta and cordon. - Quantification of AF. - Assessment of foetal statics and vitality.
	High risk	Serially at 28±1, 32±1 and 37±1	

BPD: biparietal diameter; HC: head circumference; AC: abdominal circumference; FL: femur length, AL: amniotic fluid.

3.1.1 Foetal biometry

Foetal biometry is the measurement of the foetus and various segments of the foetal anatomy. It is assessed in the systematic second and third trimester ultrasounds of screening (see **Figure 1**). It includes the assessment of the basic ultrasonic biometric parameters (2,4,5):

- **Biparietal diameter** (BPD): it measures the maximum distance between the two parietal bones taken from leading edge of the skull to the leading edge (outer to inner). Image should be oval, with symmetric hemispheres and measured at the thalamic level. Cerebellum must not be seen.
- **Head circumference** (HC): it is measured at the same level at which BPD is taken by using ellipsoid mode of the ultrasound scanner and adjusting the elliptical callipers (which are the cursors electronically superimposed over the scanned cross-sectional image that calculate the size of the structure) to outer margin of the skull. Some authors consider that this parameter is more reliable than BPD because the last one can suffer more variations due to external factors.
- **Abdominal circumference** (AC) **or diameter** (AD): it is taken at the level where the umbilical vein enters the left branch of the portal vein. It is used for monitoring the foetal growth, especially in the third trimester, and for the estimation of foetal weight as well.
- **Femur length** (FL): diaphysis of femur is measured from the greater trochanter above to the lateral condyle below. It should be measured perpendicularly to the axis bone.



Figure 1. Standard foetal biometry: **a)** Biparietal diameter and head circumference; **b)** Abdominal circumference; **c)** Femur length (4).

Measurements must be performed by following **standardized criteria**. Each parameter has its standard values by percentiles depending on the gestational age in the **Hadlock curves** (see **Annex 3.2**) or in **tables of Hospital Clínic de Barcelona** (the most used in Catalan hospitals, see **Annex 3.3**). In combination, biometric values can be used to calculate the gestational age and estimate the foetal weight and growth.

3.1.2 Foetal head circumference as a predictive factor of operative births and unplanned caesareans

A large HC, especially when it measures between 37-41 cm, is associated with a significantly **prolonged labour**, leading to increased rates of operative births and emergency caesarean sections (6).

These types of deliveries cause more maternal and foetal complications and involve higher costs compared with uncomplicated vaginal births. **Foetal HC (FHC)**, as opposite of neonatal HC, could be a

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useful tool to predict the likelihood of pregnant women to suffer these intrapartum interventions, and thus could offer the opportunity to decrease the need for an operative birth by the performance of non-operative measures such as oxytocin use and delayed pushing. Surprisingly, there is only one study, published in 2015, that investigates the FHC as a possible predictive factor of operative delivery (7).

3.1.3 Foetal head circumference as a risk factor of an obstetric anal sphincter injury

Nulliparous women who deliver foetus with a large head circumference have an increased risk for prolonged labour, operative vaginal delivery and maternal and foetal distress, being all risk factors of a severe perineal trauma (6,8–10).

Some studies have shown that head circumference calculated at the third-trimester ultrasound has a good correlation with postnatal values, although there is a tendency to underestimation (11) (see Figure 2).

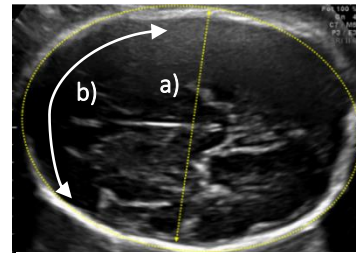


Figure 2. Foetal **a)** Biparietal diameter (BPD) and **b)** Head circumference (HC). Adapted from (73).

3.2 OPERATIVE VAGINAL DELIVERY

Operative vaginal deliveries, also known as assisted or instrumental births, represents 15-20% of total vaginal deliveries and are based on the application of an instrument (forceps, vacuum or spatulas) on the foetal head to extract it, either by traction of it and/or by enlargement of the birth canal (12). The American College of Obstetricians and Gynecologists (ACOG) criteria to classify the instrumental births by station and position are summarized in the Table 2:

Table 2. Classification for operative vaginal delivery. Adapted from (13,14).	
Outlet	Foetal scalp visible without separating the labia and foetal skull that has reached the pelvic floor. Sagittal suture is in the anterior-posterior diameter or right or left occiput anterior or posterior position (rotation does not exceed 45°). Foetal head is at or on the perineum.
Low	Leading point of the skull is at station plus 2 cm or more and not on the pelvic floor. Two subdivisions: <ul style="list-style-type: none"> - Rotation of 45° or less from occipito-anterior position - Rotation of more than 45° including the occipito-posterior position
Mid	Foetal head is no more than 1/5 th palpable per abdomen and the leading point of the skull is above station plus 2 cm but not above the ischial spines.
High	Not included in the classification, as operative vaginal deliveries are not recommended in the situation where the head is 2/5 th or more palpable abdominally and the presenting part is above the level of the ischial spines.

3.2.1 Non-operative measures

As assisted deliveries involve foetal and maternal morbidity, some measures should be performed to reduce the need of these interventions. Continuous support during labour performed by delivery attendants and the use of upright or lateral positions in the second stage of labour reduces the need for assisted births. If possible, the use of epidural analgesia must be avoided and, if it is required, pushing

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should be delayed. When labour is not progressing appropriately, the use of oxytocin can also decrease the need of an operative delivery. Finally, the employment of manual rotation among posterior and transverse foetal positions is also a useful tool to avoid the instrumental procedure (14,15).

3.2.2 Indications and contraindications

Operative intervention is used to accelerate birth when certain maternal and foetal conditions and none of the situations that contraindicate the procedure are present, all of them being included in the following

Table 3. None of the indications is absolute (12,14).

Table 3. Indications and contraindications for instrumental birth. Adapted from (12,14).	
INDICATIONS	CONTRAINDICATIONS
<ul style="list-style-type: none"> - Suspected or anticipated foetal compromise: <ul style="list-style-type: none"> • Foetal descent which can precipitate cord compression • Combination of intense uterine activity and expulsive efforts by the mother, which can reduce placental blood flow. - Maternal effort contraindicated: maternal comorbidities as: <ul style="list-style-type: none"> • Cerebral aneurysm • Proliferative retinopathy • Severe hypertension • Cardiac failure - Delay in the second stage of labour: <ul style="list-style-type: none"> • Nulliparous: lack of continuing progress for 3 hours with regional anaesthesia or for 2 hours without it. • Multiparous: lack of continuing progress for 2 hours with regional anaesthesia or for 1 hour without it. • Maternal exhaustion 	<ul style="list-style-type: none"> - Absolute <ul style="list-style-type: none"> • Non-vertex or brow presentation • Unengaged head • Incomplete cervix dilation • Suspected cephalopelvic disproportion • Foetal coagulopathy • Predisposition to fracture (osteogenesis imperfecta) - Relative <ul style="list-style-type: none"> • Unfavourable attitude of foetal head • Mid-pelvic station • Foetal prematurity • Maternal viral infections (VIH, hepatitis)

3.2.3 Pre-requisites

Before the performance of an instrumental birth, some criteria have to be accomplished. Patients should have a **fully engaged head** and **vertex presentation** of the foetus, **complete cervix dilation** and **membranes ruptured**. A clinical **cephalopelvic disproportion** must be dismissed and the **exact position of the foetal head** needs to be known. Then, once the **informed consent** is obtained, we have to assess if **analgesia** is in place and maternal **bladder** is empty. Finally, the procedure have to be done by an **experienced operator** (13,15).

3.2.4 Types of assisted deliveries

The instruments available for operative births include **forceps**, **vacuum** and **Thierry's spatulas**; the **choice of the most adequate** is determined by the clinical conditions of delivery, experience of the obstetrician, availability of the instrument, degree of maternal anaesthesia and knowledge of both risk and benefits associated to each procedure (14).

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Vacuum is the easiest to use, requires less anaesthesia and has less risk of perineal lesion; however, it involves more risk of foetal injuries and failure of delivery. It is contraindicated in prematurity (gestation less than 34 weeks), and relatively within 34-36 weeks; in these cases, we should use forceps (15).

Forceps has the best exit rates, can be employed in preterm births and allows rotation; even so, it has more risk of perineal trauma to women and, therefore, occurrence of maternal incontinence (12).

Thierry's spatula not only enlarges the canal birth, but also allows the traction of the foetal head. Although having a similar risk of maternal lacerations to forceps (16), is the least used instrument (13,14).

3.2.5 Maternal and foetal complications

The complications of operative births are similar among the use of vacuum, forceps and spatulas (12,13):

- **Maternal perineal lacerations**
- Maternal postpartum haemorrhage
- Shoulder dystocia
- Foetal scalp lacerations
- Foetal skull fractures
- Cephalohematomas (vacuum)
- Facial nerve palsies
- Cervical spine injury
- Subaponeurotic/subgaleal, intracranial and retinal haemorrhages
- Corneal abrasion
- Hyperbilirubinemia (vacuum)

3.3 HIGH DEGREE OBSTETRIC PERINEAL TRAUMA

3.3.1 Female pelvic floor complex

The importance of intact anatomy of the female pelvic floor lies in its function of support of pelvic organs, with a relevant involvement in urinary and anal continence, bladder emptying, defecation, sexual intercourse and childbirth (17). The pelvic floor complex encompasses not only the levator ani group of muscles, but also all the supportive structures included into the pelvic cavity (18,19).

- **Pelvic diaphragm**: is composed by **levator ani** and **coccygeus muscles**, which are attached to the inner surface of the minor pelvis. The union of these muscles with those from the opposite site creates the pelvic diaphragm. Levator ani is compounded of three muscles (17,19):
 - **Pubococcygeus muscle** is the medial portion of the levator ani (19) and is formed by **pubourethralis, pubovaginalis, puboanalis and puborectalis** (19–21).
 - **Iliococcygeus muscle** is the lateral part of the levator ani that emerges from the tendinous arch of the levator ani to the ischial spine and then it attaches to the coccyx. The fibres of each side converge forming a median raphe called **levator plate**, in which pelvic organs rest.
 - **Coccygeus muscle** conforms the posterior part of the pelvis diaphragm (17,19).

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The innervation of the pelvic floor seems to be in charge of two different nerves: **sacral nerves from S2 to S4** which innervate the deeper pelvic floor muscles, and **pudendal nerve** derived from S3 and S4 roots, which innervates more superficial muscles and the caudal part of puborectalis muscle (17,19,22,23).

- **Anal triangle:** this area includes the anal sphincter complex, anal canal and ischioanal fossa.
 - **Anal sphincter complex:** is a multi-layered cylindrical structure that contains the anal canal, with the innermost layer being the canal lining, and then coming consecutively the internal sphincter (IAS), intersphincteric fat layer, longitudinal layer until the striated muscle layer (EAS), being this the outermost sheet (24) (see **Figure 3**).
 - **Internal anal sphincter (IAS):** is a smooth muscle formed by the caudally expansion of the inner circular plane muscle layer of the rectum (20,21). The IAS ends 1 cm above the anal sphincter. Its innervation is in charge of sympathetic fibres from inferior pelvic plexus and parasympathetic fibres from inferior pelvic plexus and splanchnic nerves (S2-S4)(24).
 - **External anal sphincter (EAS):** is a cylindrical and striated muscle which is controlled voluntarily. It is innervated by the inferior rectal branch of the pudendal nerve (S2, S3) and the perineal branch of S4. The regulation of evacuation is partly reflex and partly voluntary by visceral and somatic afferent and somatic efferent nerves. EAS constitutes the final part of the anal sphincter complex (24).

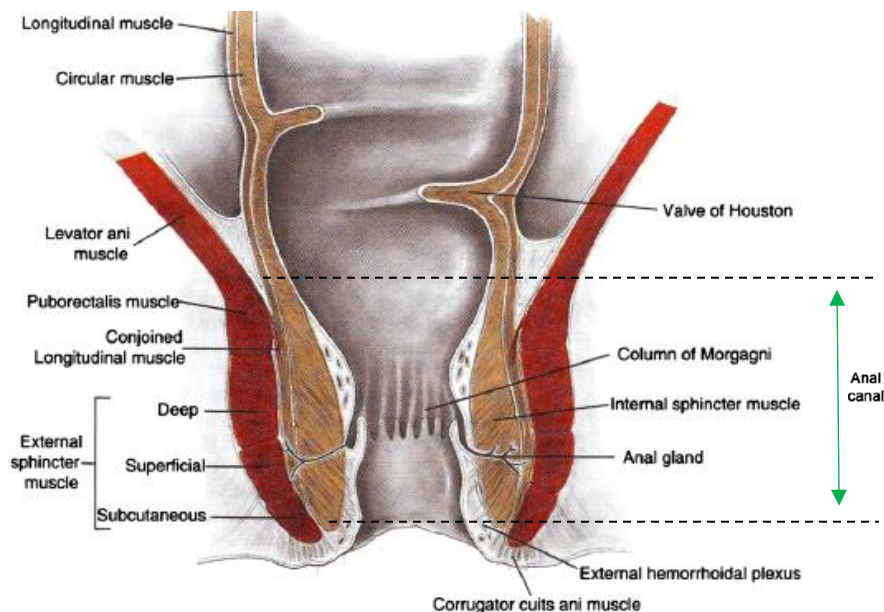


Figure 3. The anal canal, internal and external anal sphincters. Adapted from (20).

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- Anal canal: is 2.5-5 cm long and extends from the anorectal ring (at the level of levator ani muscle) to the anal verge¹ (see Figure 3) (20,25).
- Ischioanal fossa: are spaces located laterally to the anus and below the pelvic diaphragm (19).
- **Perineal membrane:** is a musculofascial structure situated immediately below the pelvic diaphragm. Ischiocavernosus, bulbocavernosus muscles and slim layers of the superficial transverse perinei, form the lower part of the perineal membrane that closes the levator hiatus, providing support to distal vagina and urethra and thus contributing to continence (24) .
- **Perineal body:** is a fibromuscular structure with a pyramidal form, situated in the midline of the anus and the vagina, in which there is attached the rectum, vaginal slips, perineal muscles and the anal sphincter. During childbirth, it distends and after that, backs down(19).

Pelvic floor musculature has been classified according to their position (see Figure 4 and Table 4) (21).

Table 4. Classification of pelvic floor muscles depending on the layer in which they are found. Adapted from (21).	
Muscle layer	Muscles
Superficial	External anal sphincter, perineal body and, possibly the transverse perinei muscles.
Middle	By some authors, puborectalis muscle* should be included into this group.
Deep	Pubococcygeus, ileococcygeus, coccygeus and puborectalis muscles*.

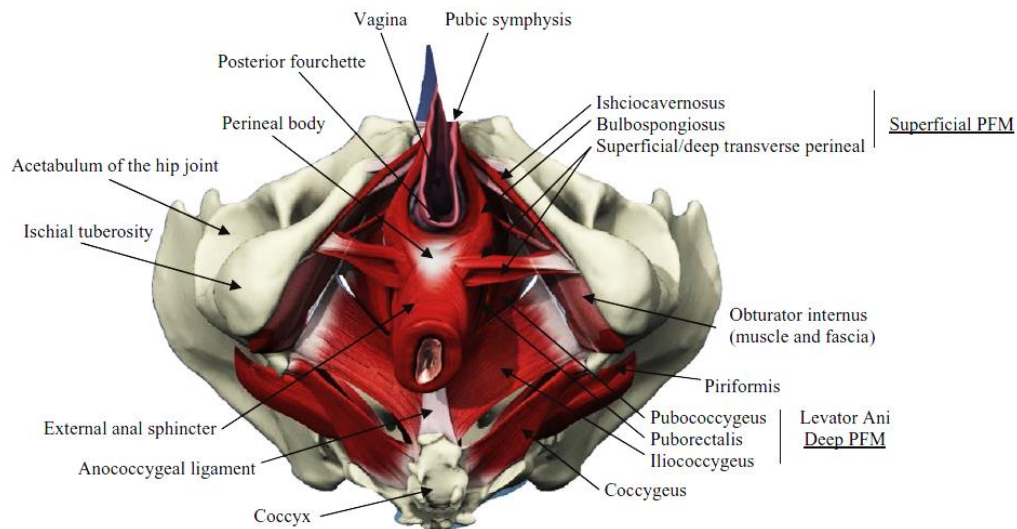


Figure 4. Pelvic floor muscles viewed from an inferior plane (18).

3.3.2 Obstetric perineal trauma and its epidemiology

Perineal trauma is a laceration of one or more structures which conform the pelvic floor complex, mainly due to an injury produced during an operative or spontaneous vaginal delivery (22,26) (see Figure 5). It is

¹ **Anal verge** is a narrow band of tissue that separates anal canal from perianal skin.

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a **serious underreported complication** and a major factor in the development of anal or urinary incontinences and persistent perineal pain which cause emotional and physical effects (16,27).

High degree perineal traumas, which include third and fourth grade tears according to WHO's International Classification of Diseases, are also known together as obstetric anal sphincter (OASIS) lesions and cause significant long-term morbidity with an important social component.

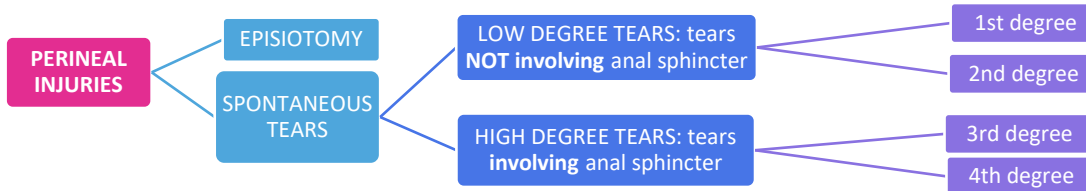


Figure 5. Classification of perineal tears by degrees.

Studies that look at the OASIS incidence based on WHO's International Classification of Diseases, report an incidence of 4-6.6% within vaginal births (22). **OASIS incidence differs between countries, delivery units and presence of risk factors** (eutocic or instrumental delivery, maternal age, birthweight, within others) (28). Recent researches from Scandinavian countries (29), Australia (30), Canada and United Kingdom (see Figure 6) (31), have reported an increment year to year occurrence of high degree perineal tears nationally but internationally as well; from 0.5% in 1967 to 4.1% in 2004 in Norway, from 1.8% in 2000 to 5.9% in 2011 in England, with observed lower rates in Finland (32) (from 0.2% in 2001 to 0.9% in 2007).

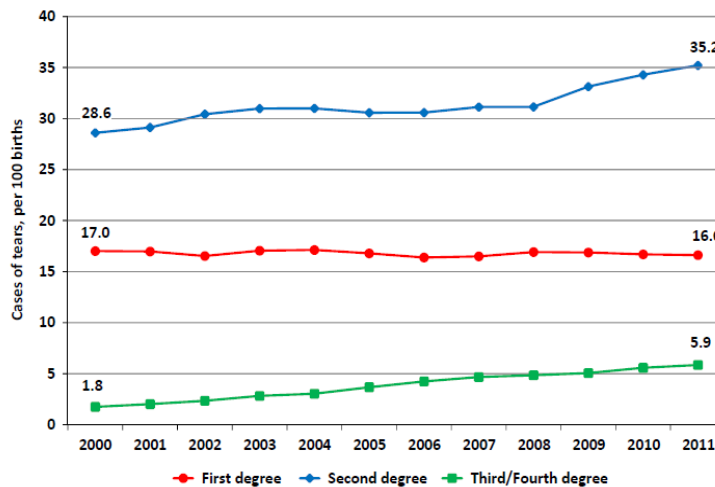


Figure 6. Trends in the rate of perineal tears; rates expressed per 100 singletons, cephalic, term, vaginal first births (31).

The **incidence rates of OASIS in Spain and Catalonia are not well-known**. According to SEGO, 80-85% of women have some degree of perineal trauma, and of these, 70% need reparation (33). Simó et Al. (16) published a recent study in which they registered between 2006 and 2009 a total of 4526 vaginal births within Catalan population, of whom 97 cases suffered OASIS, providing an incidence rate of 2.14%.

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Internationally, **there is not any accurate range of occurrence yet** attributed to considerable variability of its incidence depending on multiple related risk factors such as mode of delivery (1.1% within spontaneous vaginal deliveries versus 2.7%, 4.5% and 4.9% within operative vaginal deliveries using vacuum, forceps and Thierry’s spatulas, respectively), delivery’s assistant (5.7 % obstetricians, 2.3% trainee obstetricians, 1.1% midwives and 0.7% trainee midwives) (16) or type of episiotomy practiced (1.7% in mediolateral episiotomies versus 12% in centres practicing midline episiotomies) (22), within other factors.

Only up to 5% of anal sphincter tears are diagnosed at the time of delivery by the systematic rectal examination; the rest of them, known as **unrecognized or occult perineal injuries**, contributes seriously to underestimate the real OASIS incidence. A transperineal ultrasound performed two months after delivery increases the diagnosis of OASIS by 35-41%, remaining 59-65% of undetected cases (22,26).

3.3.3 Sultan’s classification

In 1999, *Sultan et al.* proposed a grading system for obstetric perineal lacerations that has been adopted by the *Royal College of Obstetricians and Gynaecologists (RCOG)*, WHO and the *International Consultation of Incontinence* (16,33,34). The classification is summarized in the **Table 5** (see **Figure 7** and **Annex 4**).

Table 5. Sultan’s classification of perineal trauma. Adapted from (34).

Grade		Affected anatomical structures
LOW DEGREE	First degree	Laceration of vaginal epithelium or perineal skin, but perineal muscles remain intact.
	Second degree	Laceration to perineum involving the perineal muscles, without affection of anal sphincter.
HIGH DEGREE	Third degree	Injury to the perineum involving the anal sphincter complex (OASIS).
		3a Affection of <50% of the external anal sphincter thickness torn.
		3b Affection of >50% of the external anal sphincter thickness torn.
	3c Affection of both internal and external anal sphincter torn.	
Fourth degree	Third degree tear (affection of the anal sphincter complex, both internal and external anal sphincter) with disruption of the anal epithelium.	

The distinction of perineal injuries involving the external sphincter from those with affection of internal sphincter, **improves diagnosis, reparation of the laceration and also facilitates the outcome research** (22).

Small, skin-deep lacerations (first-degree tears) usually heal naturally, but if there is a perineum muscles affection (second-degree tears), it usually requires stitches. All high degree perineal lacerations (third and fourth degree tears) have to be repaired by suture when identified. The higher the degree of the perineal lesion, the worse the clinical prognosis (22,34). Third-degree lacerations are subclassified into three subgroups (3a, 3b and 3c), because tears 3c involve severe symptoms similar to those of fourth degree lacerations, while **lacerations 3a and 3b have a better prognosis than 3c** (27).

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Sultan's classification does not include a **button-hole injury**, which only affects vaginal and rectal mucosa and that, in case of being an isolated finding, it should not be categorized as a three or fourth degree tear (22).

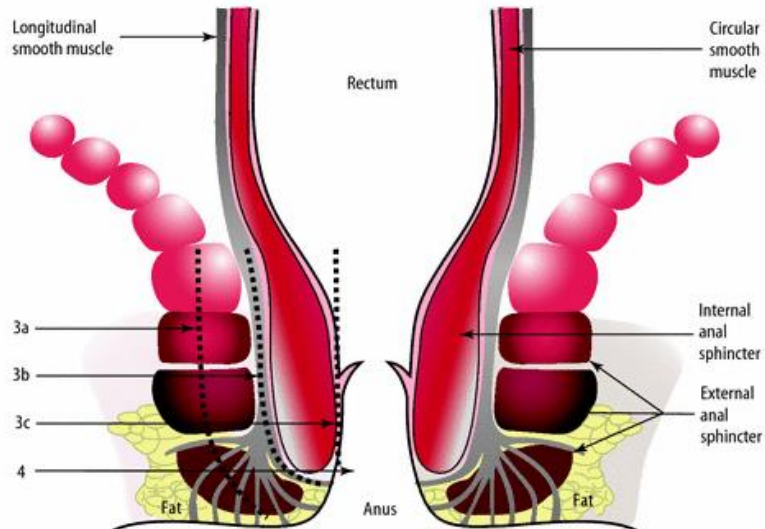


Figure 7. Schematic representation of obstetric anal sphincter injuries (54).

3.3.4 Episiotomy

Episiotomy is a surgical perineal incision done intrapartum to enlarge the vaginal opening and facilitate the baby's birth during a vaginal delivery. Although there are some studies which consider that this intervention prevents women from perineal tears, generally current literature considers that it **increases the risk of suffering a perineal lesion** (35). Incisions can be divided by:

- **Employed criteria:** episiotomy can be **restricted** (only performed when indicated according to selection criteria) or **routine** (performed systematically to all vaginal deliveries) (36). **Restrictive episiotomies** are preferred over routine episiotomies, because they associate less occurrence of perineal trauma (37).
- **Episiotomy site:** midline, mediolateral and lateral incisions are the most commonly performed (see **Figure 8**) (38):
 - **Medial incision** (see number 1 of **Figure 8**): it has its origin in the posterior fourchette and continues through the perineal body, dividing the perineal zone in the middle in direction to the anal canal (36,38).
 - **Mediolateral incision** (see number 4 of **Figure 8**): it begins at the medial incision point, but continues drawing an angle between 40 and 60° to the left/right of the anal

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canal (36). Its performance differs among health professionals due to lack of an accurate definition of the procedure on the current guidelines (22).

- **Lateral incision** (see number 5 of Figure 8): it starts laterally to the posterior fourchette, at 1-2 cm from the midline, and draws a lateral line between 40-60°, as mediolateral incision. In Spain it is obsolete, but in Finland it is the most used (36). Other episiotomy techniques such as **Schuchardt, “J”-shaped and anterior incisions** have fallen into disuse (36,38).

Mediolateral and lateral incisions have less obstetric anal sphincter injuries (OASIS) rates than midline interventions. Mediolateral incision is the most commonly used technique in Europe until now, so it is preferable rather than lateral incision (29,34,39). It must be performed in nulliparous women with an indication of operative delivery (22,34,35,40).

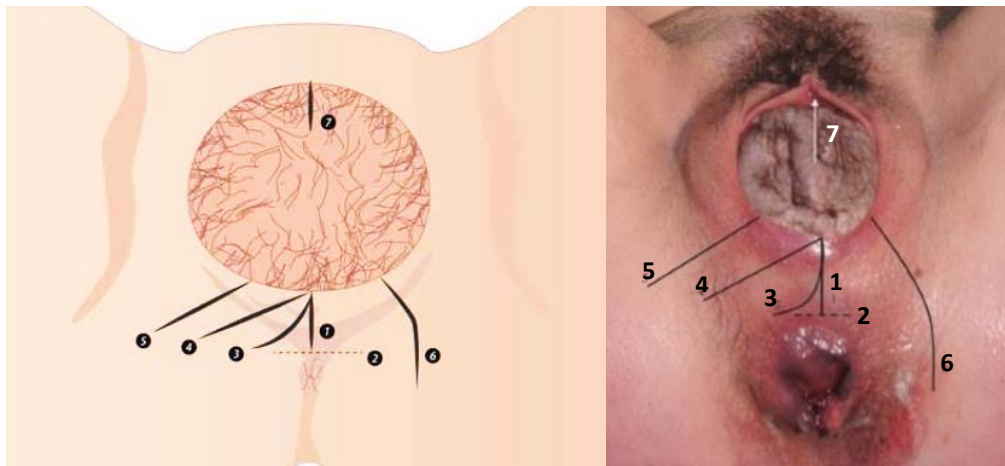


Figure 8. The most common episiotomy sites. **1)** Midline or medial episiotomy, **4)** Mediolateral episiotomy, **5)** Lateral episiotomy. The rest of sites are obsolete nowadays. Adapted from (22,38).

- **Optimal angles of mediolateral episiotomies:** has been discussed. The smaller is the incision angle of mediolateral episiotomy (fewer than 40°), the higher is the incidence of severe perineal trauma. Currently it has been established that the optimal angle is of 45-60° from midline (22,38).
- **Healing episiotomy scars:** factors such as long episiotomies, top of the incision located far away from the vertical line drawn between the vagina and the anus and healed angle between 5 and 60 degrees (considering that there is a difference of 20° between the angle of the incision and the healed angle), decrease OASIS rates (22).

3.3.5 Prevention

The degree to which the perineal trauma risk factors can be prevented during labour have not been identified yet, but until now there are some preventive measures with evidence (22,34):

- **Head control:** it consists to control the speed of foetal head progression by applying some manual assistance and instructing mothers to not push during delivery, so being employed only uterine contractions as expulsion force. This method has evidenced a diminution of OASIS by 50% to 70%, mainly in Norway studies (22,41).
- **Perineal protection:** it is a supportive intervention in which the assistant holds the perineum with a sponge or compress, and applies medial pressure. Perineal protection can be performed either by **hands-on** (active management of the perineum) or **hands-poised techniques** (only supportive management, without perineal manipulation) (42). First method is more effective than the second (41)(28). Among hands-on method, there are two most frequent manoeuvres:
 - **Ritgen's manoeuvre:** delivering foetal head using one hand to pull his chin and the other hand situated on foetal occiput to control head progression through the canal).
 - **Flexion technique:** maintenance of the flexion of foetal head by pressing the occiput (42).

Positive effect of perineal support is unclear because its techniques include both slowing the head progression and supporting the perineum (22). Even though, hands on support is the most recommended measure, with no differences between its both manoeuvres (34).

- **Perineal massage:** when **slow perineal massage** using lubricant is done during the **last month of pregnancy**, there is a reduction of the probability of suffering from anal sphincter injury (42,43). Each patient performs it by themselves and using two fingers, which have to be moved from side to side inside the vagina and then, some pressure have to be applied, mainly towards the rectum, in lateral direction (22).
- **Application of warm compresses:** it lies on putting on a warm compress on the perineum steadily during and between contractions, with positive results in reducing OASIS incidence (22,34,42).
- **Delivery position:** a **standing position** (vertically without support of ischial tuberosities, such as either kneeling and standing) can augment the risk of high perineal injuries rather than a **sitting position** (vertically with support of ischial tuberosities) (22). **Postural changes** every 20 or 30 minutes during the passive period of second stage of labour and, once in the onset of the active pushing period, the adoption of a **lateral Gasquet's position** (each lower leg flexed on the stirrup,

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feet situated higher than the knees and the upper hip internally rotated) reduce the OASIS risk due to the relaxation of the spinal-pelvic curvature proportioned by this position (44).

- **Type of instrumental delivery:** when a shortening of the expulsive period by an operative vaginal delivery is needed, **vacuum** is the most recommended tool to protect the perineal integrity (22,28). **Early withdrawal of the instrument**, once foetal head has reached an enough level of descent, avoids perineal lacerations as well (22).
- **Pelvic floor rehabilitation:** **Kegel exercises** are an intervention aimed at the rehabilitation and strengthening of the pelvic floor complex, and they have to be offered and explained to all pregnant, both antenatally and postpartum during 12 weeks after birth, to prevent urinary and anal incontinence (45). They can be performed both **at home** following the instructions of how to do it given when they attend to the first control citation (see **Annex 5**) or in **health centres**.
- **Others:** there are interventions which have **either divergent results or no enough evidence**:
 - **Perineal hyaluronidase injection:** hyaluronic acid is present in connective tissue of the perineum, providing support and anchorage for cells. So it has been purposed that hyaluronidase injection into perineum during second stage of labour can have a protective effect, with no statistical significant results and **doubtful diminution of OASIS incidence and perineal pain** (46,47), not being a routine intervention.
 - **Water immersion:** as waterbirth increases maternal relaxation, therefore it is thought that it can reduce the likelihood of perineal trauma and maternal pain. Nevertheless, its **results are not reliable** due to heterogenicity of its procedure in controlled trials (48). Some studies consider it a risk factor instead than a protective factor (22).
 - **Effects of pushing:** studies which compare spontaneous pushing versus directed pushing has **contradictory results** in perineal protection; the same occurs when comparing studies between delayed and immediate push (49).
 - **Application of local anaesthetic:** the use of lidocaine in spray during the second stage of delivery **does not protect from neither perineal pain nor OASIS** (40).

We decided to summarize in the **Annex 6** the levels of evidence and recommendation of each protective interventions according to most important clinical practice guidelines.

3.3.6 Risk factors

During the last years, numerous international population based studies have focused on the effect of **foetal, maternal and delivery risk factors** to the occurrence of anal sphincter injuries, but their results usually are heterogeneous, carrying ambiguous conclusions (22). Most demonstrated risk factors in developed countries until now are basically instrumental delivery using forceps, foetal macrosomia, nulliparity and midline episiotomy (22,50).

In the **Table 6** we have included the most agreed risk factors with homogeneous results in the literature and also the uncorroborated ones, which are in study and need more research for its verification.

Table 6. Risk factors of severe perineal trauma injuries. Adapted from (16,22,29,34,37).		
Maternal factors	Delivery interventions	Foetal and infant characteristics
AGREED RISK FACTORS		
<ul style="list-style-type: none"> - Nulliparity - Age ≥ 27 years or ≥30 years - Asian ethnicity - Type 1 and gestational diabetes 	<ul style="list-style-type: none"> - Operative delivery indication. - Type of operative vaginal delivery: Thierry's spatulas, forceps and vacuum. - Double instrumentation in operative vaginal delivery (forceps and vacuum). - Vaginal birth after caesarean - Midline episiotomy - Epidural analgesia - Prolonged second stage of labour (> 1 hour) in primiparas - Shoulder dystocia - Induction of labour, in primiparas 	<ul style="list-style-type: none"> - Foetal macrosomia (birth weight > 4000 grams) - Mal-presentation (non-cephalic presentation) - Post-maturity - Foetal distress - Occiput posterior position in spontaneous and operative vaginal deliveries.
UNCORROBORATED RISK FACTORS		
<ul style="list-style-type: none"> - Previous anal sphincter disruption - Obesity (high IMC) 	<ul style="list-style-type: none"> - Assistant of delivery² - Waterbirth - Great size of maternity unit 	<ul style="list-style-type: none"> - Large new-born head circumference (≥35 cm) - Persistent foetal occiput posterior position

3.3.7 Diagnosis

As Green-top guidelines of RCOG and protocol of SEGO remark (33,34), all women in whom a vaginal delivery is foreseen should be informed prenatally of the OASIS risk that it involves.

OASIS diagnosis is based on the assessment of a **vagina, perineum and rectal examination** by the delivery assistant in immediate postpartum stage (22). To minimize the number of unrecognized perineal defects, some requirements are needed:

² **Physician as the assistant of delivery** compared to midwives has to be considered a factor risk only if both physicians and midwives can perform an operative vaginal delivery; however, in our hospitals, only physicians can do it, so they will have more OASIS rates than midwives.

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- **Woman position:** she should adopt the lithotomy position, in which they can be as comfortable as possible and that offers a clear view of genital structures to physicians.
- **Good lightning:** it is required to ensure detection of minimal defects.
- **Offer analgesia/anesthesia:** if woman want, she can receive it to control his perineal pain produced during the vaginal and rectal assessment.
- **Continued asepsis during the procedure:** it is important in order to avoid immediate severe complications such as the infection of the laceration if it exists, due to manipulation of the zone.

This physical assessment should be done systematically to all women who has already delivered vaginally, dividing it in three different sections (see **Table 7**). We have to verify if analgesia effect is in adequate place and explain them during the examination what we do and why (22).

VISUAL INSPECTION	<ul style="list-style-type: none"> - Assessment of periurethral area, labia and proximal vaginal walls. - Assessment of perineal tear extent to anal sphincter complex or anal margin. - Assessment of anal puckering between 9 and 3 o'clock of anus (if it exists, it can suggest OASIS). 	
VAGINAL EXAM	<ul style="list-style-type: none"> - Establishment of the tearing by inserting the index and third fingers into the vagina, separating the vaginal walls before sweeping downward to reveal the cervix, vaginal vault and walls, floor and posterior perineum. - Identification of the apex of the injury, using vaginal retractors if needed. 	
RECTAL EXAM	Rectal tact	<ul style="list-style-type: none"> - Insertion of index finger into the anus and ask women to squeeze: external anal sphincter (EAS) will retract. - In case of regional analgesia (it affects muscle power), it is better to do a digital palpation.
	Digital palpation	<ul style="list-style-type: none"> - Assessment of the sphincter thickness with the index finger (located in the rectum) and the thumb (it explores the perineum). The displacement of index finger to perineal body lets a better evaluation of the lesioned zone. - Revision of anterior rectal wall for detection of overt or occult tears by palpating and stretching the rectal mucosa with the index finger. - Often is difficult to determine if the internal anal sphincter is injured, requiring accurate inspection by an expert.

Occult obstetric anal sphincter injuries are severe perineal lacerations which escape from being diagnosed by clinical examination in immediate postpartum period and that are detected later when an endoanal sonography is performed. Their prevalence is 35-41% of OASIS (34). Endoanal probe is substituted by transvaginal or transperineal sonography, due to their better practicality and their successful results in identification of anatomical anal defects as well (26). It is not a routine tool of assessment in delivery rooms because **tears have to be clinically apparent to be repaired** (52); even so, it is useful in control citations (6-12 weeks after birth) when an occult OASIS is suspected (26).

The **improvement in clinical diagnostic skills** is the best weapon to combat the underdiagnosis of OASIS in delivery room, instead routine transvaginal or transperineal ultrasound (34,52).

3.3.8 Reparation of the tears

Perineal lacerations require **optimal conditions** when reparation is needed: suture should be performed in the delivery or operating room, by expert clinicians, with patients being under general or regional anesthesia, with good lightning, appropriate instruments and sutures (34,51).

General measures to take into account before initiating the reparation and **material needed for it** are included into the **Table 8**.

Table 8. General measures to do before the suture and material needed for it. Adapted from (22,33,34,51).		
GENERAL MEASURES BEFORE THE SUTURE		
<ul style="list-style-type: none"> - Field preparation and asepsis interventions: sterile gloves of several sizes, physiologic serum or antiseptic (chlorhexidine or povidone iodine) if scrubs are needed. - Adequate analgesia of the zone and relaxation of the anal sphincter. - Adequate illumination of the field. - Antibiotic prophylaxis: single dose of 2nd or 3rd generation cephalosporin iv or im (if penicillin allergy, single dose of gentamycin 240 mg iv plus metronidazole 500 mg iv). The prophylaxis must be continued during 5 days after birth. 		
NECESSARY MATERIAL		
Material of suture	Other material	
1st and 2nd degree tears	<ul style="list-style-type: none"> - Rapid reabsorption type of polyglactin (Vicryl Rapide). 	
3rd and 4th degree tears	<ul style="list-style-type: none"> - Anal sphincter suture: polydioxanone (PDS) 3/0 or conventional Vicryl 2/0; end-to-end or overlapping method. - Rectal mucosa: conventional Vicryl 3/0 or polydioxanone (PDS) 3/0; continual or interrupted suturing of submucosa. 	
	<ul style="list-style-type: none"> - Forceps without teeth - 2 Allis' forceps - Mayo scissors - Matzenbaum scissors - Short needle holder 	

The **technique of suture** depends on the degree of perineal injury (22,51,53):

- **First degree:** unlike other degrees of laceration, it **must only be sutured when the ends of the skin remain separated or active bleeding is observed**. Continual intradermal suture involves less pain in the first 10 days after reparation than interrupted suture, but no long-term differences have been observed between both techniques.
- **Second degree:** all second-degree tears must be repaired, starting in deeper layers and moving towards more superficial ones, to avoid dead spaces. Suture can be performed with a **continual or an interrupted stitch**, without neither functional nor esthetical differences between them. Defects on ani levator muscle should be identified by digital palpation in order to suture them adequately. The segmented ends usually retract, so we have to locate them and join the groups of fibers separated by fat tissue (which is diagnostic of ani levator muscle rupture) by **continual or interrupted suture**, until continuity and overlap of muscle tissue above fat are reached.
- **Third degree:** Anal sphincter must be sutured **without tension**. The reparation of internal anal sphincter (IAS) has to be done completely and independently of the external (EAS) one.

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There are two type of sutures: end-to-end method and overlapping (see Figure 9).

- IAS cannot be sutured secondarily, and it must be done by end-to-end technique without any attempt to overlapping.
- EAS can be repaired by both methods.

We have to distinguish whether it is a full or a partial thickness defect; in the first case, either an overlapping or an end-to-end technique can be used, but in the second case (which involves all 3a and some 3b tears), end-to-end method should be used. Once the laceration has been repaired, it must be verified if anal sphincter has an equal width in all its perimeter in order to avoid long-term consequences as anal incontinence.

- **Fourth degree:** reparation must be initiate by the suture of rectal mucosa. It can be done by interrupted stitch, burying its knots into the intestinal lumen to avoid a further reabsorption of the suture material, or by continual intramucosal suture. Then, it must be performed the anal sphincter reparation as explained previously in the third-degree tears.

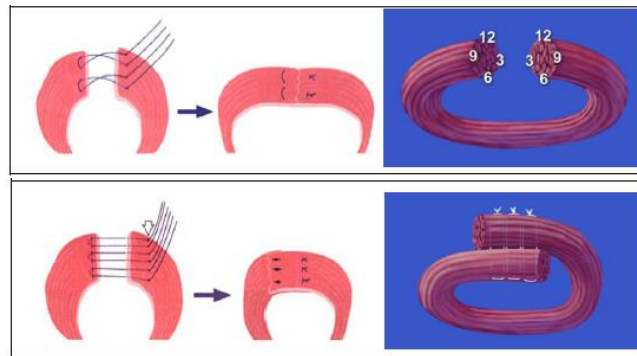


Figure 9. Two commonly used methods of external sphincter repair are **end-to-end**, approximate of the cut ends (top) and **overlapping** the cut ends through the overlapped portions (bottom) (51).

3.3.9 Post-reparation management

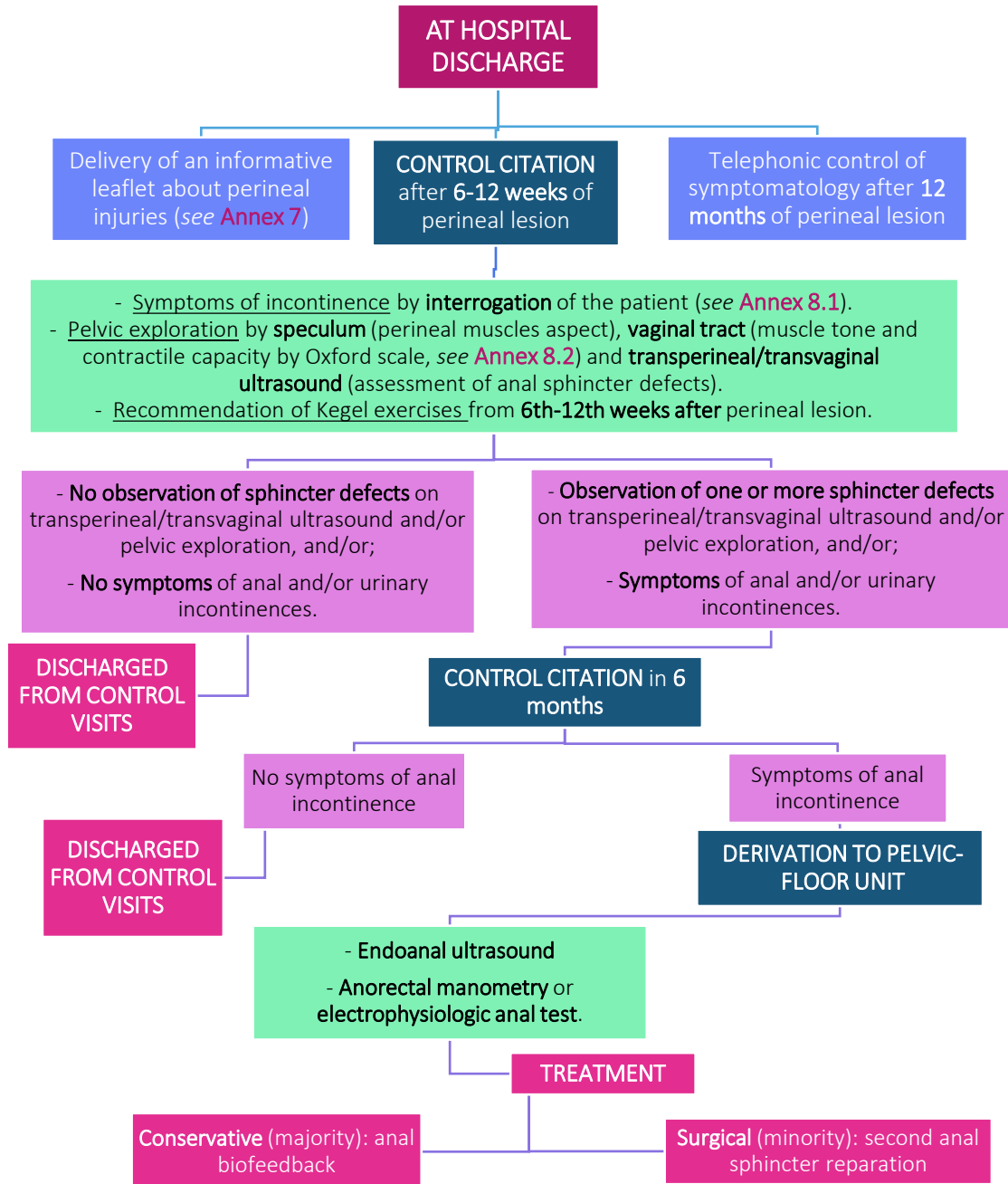
Once suture is completed, some immediate measures are recommended to women (see Table 9).

Table 9. The recommended measures of post-reparation management. Adapted from (22,33,34,51).	
Explanation to patient	Inform women of their lesion, the possible experimented symptoms and the follow-up that they have to do.
Broad spectrum antibiotics	The treatment with cephalosporin used before the suture must be prolonged during at least 5 days after to avoid the wound infection as a complication.
Use of laxatives	Administration of lactulose and a laxative diet, to facilitate defecation and avoid a suture dehiscence. If there is no defecation after 5 days, women should be assessed for suspected faecal impaction.
Kegel exercises	Initiation of them after 2-3 days postpartum or when comfortable, educate women about the correct technique and the importance of long term adherence.
Hygiene and healing	Advice women to support perineal wound when defecating or coughing, wash and dry the perineal zone after toileting and change perineal pad frequently (at least daily).

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3.3.10 Follow-up at discharge

Women with an intrapartum detected and repaired perineal laceration, once are discharged from the hospital, they need to be evaluated at a follow-up appointment (22,33,34,51).



3.3.11 Prognosis and complications

After 12 months of the external anal sphincter suture, 60-80% of women are asymptomatic, while the remaining 20% mostly experience flatus and anal incontinences (53).

Women with low degree tears (1st and 2nd degrees) normally do not suffer any complications after it, on the contrary, 3rd and 4th degree lacerations, almost always entail short or long-term consequences:

- **Short term complications:** perineal pain, bruising and oedema, infection or breakdown of the wound and urinary incontinence (22).
- **Long term complications:** earlier ones are dyspareunia, sexual dysfunction and persistent perineal pain. Later ones are urinary and/or anal incontinence, or even pelvic organ prolapse (54).

3.3.12 Future deliveries

In subsequent pregnancies, physicians must be informed with a detailed description of **perineal laceration antecedent, its reparation and presence or absence of incontinence symptoms** of their current pregnant patient if they still exist as well (22,34).

Regarding the **delivery method**, asymptomatic women, although **vaginal birth** is associated with 17-24% of increased symptomatology, it has to be firstly recommended. However, if they have any incontinence symptoms, residual anatomical or functional anal sphincter abnormalities detected on imaging and manometry tests, the **option of an elective caesarean birth** should be offered. Final decision of delivery method has to be made by women once they are correctly informed. An **elective caesarean** should be recommended to women who have required a surgical anorectal reparation in a second time (33,53).

The possibility of **recurrence of OASIS** in a second vaginal delivery is low (3.6-7.2%), because the majority of the OASIS incidence in vaginal deliveries corresponds to nulliparous (22,51).

4 JUSTIFICATION

Perineal trauma (also called perineal tear) is not an infrequent serious complication following spontaneous or instrumental vaginal delivery among nulliparous women, occurring also secondarily due to an extension of an episiotomy (22). When perineal tears are small (1st degree), they do not require any reparation (suture) because they do not appear to result in significant complications; however, as the tear size increases (2nd, but especially 3rd-4th degree) and involves the anal sphincter complex (Obstetrical Anal Sphincter Injuries – OASIS-), it must be sutured after delivery as it can cause incontinence symptoms which lead to **physical, psychological** (depression and loss of self-esteem) **and social problems** (isolation and reclusion) (16,22) .

In pregnant women, it is important to **prevent high-grade perineal trauma** (3rd-4th degree) during childbirth by controlling all known risk factors, because, once it occurs, even if adequately detected and treated, although it does not cause any vital threat, it can entail severe clinical consequences both short and long term. Even though short-term complications are more common and produce **acute perineal pain, oedema and bruising**, long-term complications, such as **urinary (UI) and anal incontinence (AI) and sexual dysfunction**, are more relevant concerning quality of life (22,28,34).

Several papers have analysed well-known risk factors for OASIS (maternal, foetal and delivery related factors) (55)(56). Except for one study that states that a large neonatal head circumference (HC) has only a modest effect on anal sphincter injuries (57), , other studies consider that a **neonatal HC > 350 mm clearly increases the incidence and severity of perineal trauma** (10,29), mainly due to discrepancy between foetal head size and birth canal width or expansion capacity of perineal connective tissue (9).

Given the high correlation between neonatal cephalic circumference and foetal head circumference (FHC) assessed by ultrasound (11), it would be useful to evaluate the association between a large FHC and the increased incidence of perineal lacerations, in order to **take measures for its prevention**, such as improving the prenatal counselling, Kegel exercises during pregnancy (58), manual techniques of perineal protection and adequate maternal position during the second stage of delivery (41), preference for mediolateral restrictive episiotomy during vaginal delivery over midline and/or routine episiotomies (56,59,60) and the use of vacuum instead forceps or spatulas for instrumental delivery (16).

We decided to analyse **FHC instead of biparietal diameter (BPD)**, because on one hand, infant HC has been associated with perineal trauma as some recent studies have concluded (57), and on the other hand, FHC has demonstrated good correlation with the infant HC (7), which is a well-known parameter to consider as a predictor risk of OASIS. Conversely, it has never been investigated the relationship between the

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biparietal diameter and the rate of OASIS, and it cannot be correlated with the infant HC, so we cannot use it as a good predictor of risk. In addition, values of BPD can overestimate or underestimate the size of the foetal head when it is rounded (brachycephaly) or too oval (dolichocephaly), respectively.

Among all perineal injury risk factors known to date, **vaginal delivery is one of the main factors** and even more if it was operative. Recently it has been proven that an increased FHC is associated with an incremented indication of operative vaginal delivery and unplanned caesarean, due to prolonged second stage labour (9). Moreover, FHC has already been analysed by an intrapartum ultrasound done 24 hours before birth, as a predictor of mode of delivery (7).

One of the reasons by we decided to study the influence of large FHC in to likelihood of suffering severe perineal trauma during vaginal birth, is because this factor observed on routine third trimester ultrasound could become an **early risk predictor of an emergency caesarean section (6) in late stage of labour or of an operative vaginal delivery**, or even a predictive factor of a macrosomic foetus (9). In consequence, it will allow us to take **antenatal preventive measures and planned decisions** about aspects of the delivery such as the method, avoiding risks of emerging decision-making. FHC also would help pregnant women with pre-labour counselling in order to reduce delivery related risks. Some studies conclude that caesarean would prevent OASIS if it were performed early in labour, but not later, since in this case nerve injury can still occur (10,22). However, other authors affirm that caesarean does not prevent nulliparous women from faecal incontinence, so **preservation of perineum should not be used as a criterion to indicate caesarean (61)**.

5 HYPOTHESES

5.1 MAIN HYPOTHESIS

Large infant head circumference is a predictive risk factor of suffering a severe perineal trauma. Derived from this, our main hypothesis is:

- Nulliparous and singleton gestation pregnant women with a large foetal head circumference observed on the systematic third-trimester ultrasound done at the 37th gestation week have an incremented risk of suffering a high degree perineal trauma during a vaginal delivery (eutocic and assisted method).

5.2 SECONDARY HYPOTHESES

On the basis of the obtained values of foetal head circumference at the 37th gestation week, the determination of a certain cut-off point of this parameter would be useful to predict the maternal risk of suffering a high degree perineal trauma after a vaginal delivery and classify pregnant women according to this risk.

Both large infant and foetal head circumferences, the last one measured at the start of labour, have been demonstrated to be predictive factors of having an assisted vaginal delivery. Derived from this, our other secondary hypothesis is:

- Nulliparous and singleton gestation pregnant women with a large foetal head circumference observed on the systematic third-trimester ultrasound done at the 37th gestation week have an incremented risk of indication of instrumental vaginal deliveries.

6 OBJECTIVES

6.1 MAIN OBJECTIVES

- To analyse if a large foetal head circumference observed on the systematic third-trimester ultrasound done at the 37th gestation week, can be a predictor risk factor of suffering a high degree perineal trauma during the vaginal delivery (eutocic or assisted method) among nulliparous and singleton gestation pregnant women.

6.2 SECONDARY OBJECTIVES

- To determine the value of foetal head circumference which has the higher sensitivity and specificity to predict the risk of suffering a high degree perineal trauma and classify nulliparous and singleton gestation pregnant women according to this risk.
- To assess if a large foetal head circumference observed on the systematic third-trimester ultrasound done at the 37th gestation week involves an increment of assisted vaginal deliveries among nulliparous and singleton gestation pregnant women.

7 MATERIAL AND METHODS

7.1 STUDY DESIGN

The study consists in an **observational prospective cohort study** with a follow-up of 3 years (from 2017 to 2020), in Hospital Universitari de Girona Doctor Josep Trueta (HJT).

Patients are going to be evaluated in two times:

In the **first time**, we are going to measure the foetal head circumference (FHC) on the systematic third trimester ultrasound screening of pregnancy done at the 37th gestation week, in order to classify them into large foetal head circumference (FHC) and not-large foetal head circumference (FHC) groups.

In the **second time**, we are going to assess women after their vaginal delivery to determine which ones have suffered a severe perineal trauma. We will also take into account women who have delivered by an unplanned caesarean due to failure to progress. The finality of this procedure is to verify if women who have been classified into large FHC group previously at the third trimester of gestation have more risk to suffer a high degree perineal injury during a vaginal delivery and also find a cut-off point of FHC from which women have this incremented risk.

7.2 STUDY POPULATION

7.2.1 Participants

This research will take place in Hospital Universitari de Girona Doctor Josep Trueta (HJT), a medium-sized centre in the province of Girona.

The target population of the study will be pregnant women of 37 gestation weeks, who come to the external obstetrics consultations of HJT to perform their third trimester ultrasound screening, once they sign the correspondent informed consent of it (see [Annex 1](#)), and in addition accept and sign the informed consent (see [Annex 2](#)) to participate in the study.

7.2.2 Inclusion criteria

- Pregnant women at 37th gestation week
- Nulliparous
- Singleton gestation
- Cephalic presentation
- Age ≥ 18 years

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- Ability to understand English, Spanish or Catalan
- Ability to understand an informed consent

7.2.3 Exclusion criteria

- Gestation not finished in our hospital
- Non-cephalic presentation³
- Multiple gestation
- Preterm delivery⁴
- Post-term delivery⁵
- Elective caesarean section⁶
- Presence of other pelvic floor problems

7.3 SAMPLING PROTOCOL

7.3.1 Sample selection

A **non-probabilistic consecutive sampling method** will be conveniently used. This sampling consists of selecting patients who come to the external obstetrics consultations of the Hospital Universitari de Girona Doctor Josep Trueta (HJT) for the performance of their third trimester ultrasound screening and fulfil the above-mentioned inclusion criteria and none of the exclusion criteria. For further information, *please check Point 7.2 Study population – Sections 7.2.2 Inclusion criteria and 7.2.3 Exclusion criteria*).

The candidate pregnant women, once they have signed the informed consent of the third-trimester screening ultrasound (see **Annex 1**), will be informed about the purpose of the study and invited to participate voluntarily by the signature of the informed consent (see **Annex 2**).

7.3.2 Sample size

To calculate the sample size of the study the **power calculator GRANMO®** will be used. Currently, there is not any research in which the relationship between large foetal head circumference (FHC) and the incidence of perineal trauma is analysed. Furthermore, epidemiological data of the total proportion of

³ **Non-cephalic presentations** refer to breech presentations, which can be Frank, complete and incomplete.

⁴ According to the *World Health Organization (OMS)* and *Sociedad Española de Ginecología y Obstetricia (SEGO)*, **preterm delivery** is defined as childbirth occurring before 37 completed weeks (259 days) of pregnancy since date of last period.

⁵ According to the *World Health Organization (OMS)* and *Sociedad Española de Ginecología y Obstetricia (SEGO)*, it is considered as **post-term delivery** when childbirth occurs after 42 completed weeks (294 days) of pregnancy since date of last period.

⁶ According to *Sociedad Española de Ginecología y Obstetricia (SEGO)*, an **elective caesarean section** is an obstetric intervention for the foetal extraction performed through laparotomy and hysterotomy, planned before the start of the delivery for maternal, foetal or both reasons.

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foetus with large or non-large head circumference at the third-trimester is not available until now, and even less if we look for data of head circumference from foetus of 37 weeks of gestation. Moreover, there are not any literature that contains data of the percentages of neonatal babies with large and non-large head circumference (HC). As a result, we are not able to obtain the proportion of high perineal injuries among pregnant women with large FHC (exposed group) and among those without it (non-exposed group), being all of these values indispensables to calculate our sample size.

For all that reasons, we decided to solve this problem by the use of a **deduction method** according to the trends that neonatal HC values and obstetric anal sphincter injuries (OASIS) incidence have in the studies. Therefore, we have made an **estimation of the expected subjects with and without OASIS among exposed and non-exposed groups**. We assumed that:

- Among women with a large FHC ($\geq 95^{\text{th}}$ percentile), thus belonging to the exposed group, there will be a big number of women with OASIS and a small number of women without it.
- Among women with non-large FHC ($< 95^{\text{th}}$ percentile), thus belonging to the non-exposed group, there will be a small number of women with OASIS and a big number of women without it.

From this, we estimated the number of subjects that belong to each group. With a sample of 100 women, we estimate that 95 of them will be in the non-exposed group, and the remaining 5 will be in the exposed group. Among the 95 non-exposed subjects, 10% will suffer OASIS and 90% of them not; as opposite, among the 5 exposed women, 20% will suffer OASIS and 80% of them not. After that, we obtained this following table:

	SICK (presence of OASIS)	HEALTHY (absence of OASIS)	
EXPOSED GROUP (FHC $\geq p95$)	1	4	5
NON-EXPOSED GROUP (FHC $< p95$)	10	85	95
	11	89	100

In consequence, accepting an alpha risk of 0.05 and a beta risk lower than 0.20 in a bilateral contrast, it is needed **154** women in large FHC group and **2926** women in non-large FHC group to detect a minimum relative risk of 2 if the proportion of OASIS among non-exposed patients is 10%. It has been estimated a follow-up losses tax of 20%.

In 2016, the Hospital Universitari de Girona Doctor Josep Trueta (HJT) assisted a total of **1380 deliveries**, **1100 of whom being vaginal deliveries**. In addition, a recent unpublished research performed in HJT shows that, from 2010 to 2015, the proportion of perineal trauma has been 1.28% in eutocic deliveries and 18.54% among those instrumented. We have therefore concluded that each year, there are approximately **13 severe perineal traumas in eutocic deliveries and 185 among those assisted**, giving a total of **198 OASIS per year**. Hence, we need a 3-year time period of data collection to obtain the desired sample size.

7.4 VARIABLES AND MEASUREMENTS

We will collect all these variables prospectively since the moment at which pregnant women come to the external obstetrics consultations of the Hospital Universitari de Girona Doctor Josep Trueta (HJT) to perform the third trimester ultrasound screening until their childbirth. Collected data will be registered to a sheet created on purpose (see [Annex 9](#)).

7.4.1 Independent variable

The main independent variable will be the large foetal head circumference (FHC). Although FHC is a quantitative continuous variable, we have decided to treat it as **qualitative (categorical) dichotomous** as we will define two categories:

- Large FHC: FHC < 95th percentile.
- Non-large FHC: FHC ≥ 95th percentile.

The value of the 95th percentile is given by the reference table used in the Hospital Clínic de Barcelona of FHC at the 37th week of gestation and corresponds to **34.6 centimetres (cm)** (see [Annex 3.1](#)).

The assessment will be done using the **systematic third trimester ultrasound** performed at the 37th gestation week. It will be calculated by using **ellipse-traced method**, as it is the most accurate one. This technique involves measuring the head circumference (HC) by placing an ellipse around the outer edge of the foetal skull and then, the sonographer automatically identifies the longest and the shortest diameters, which belong to values of occipito-frontal (OFD) and biparietal (BPD) diameters, respectively (see [Figure 10](#)). After that, the measured distances are inserted into the following formula $HC = \pi + \sqrt{[(BPD^2 + OFD^2)/2]}$, and the ultrasound machine gives us directly the HC value (62). Although sonographic scanner correlates each HC value obtained with its pertinent percentile according to the reference values of the Hadlock curves (see [Annex 3.2a](#)), **we will register the total cm of the FHC obtained of each woman** because the value of each percentile of FHC included in the Hadlock curves is different than the one that appear in the reference table of HC of the Hospital Clínic de Barcelona.

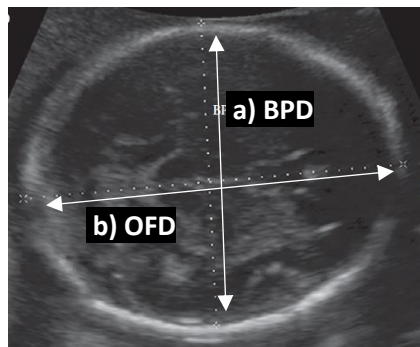


Figure 10. **a)** Biparietal diameter (BPD) and **b)** Occipito-frontal diameter (OFD). Adapted from (74).

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Once we have all the FHC and data needed from the rest of the variables collected, we will give it to the statistician and he/she will analyse it, obtaining then a cut-off value (our secondary independent variable) which allows us to predict the risk of suffering a severe degree perineal tear and classify pregnant women in two groups:

- Pregnant women with low risk of suffering a high degree perineal laceration, who would have FHC values lower than the cut-off point;
- Pregnant women with high risk of suffering a high degree perineal laceration, who would have FHC values equal or higher than the cut-off point.

This variable is **quantitative continuous**.

7.4.2 Dependent variables

Our dependent variables will be:

- High degree perineal trauma: it is defined by the World Health Organization (WHO) as the presence of a perineal laceration that involves the anal sphincter complex, encompassing both **third and fourth-degree perineal tears** according to Sultan's classification adopted by the WHO, *Sociedad Española de Ginecología y Obstetricia* (SEGO) and *Royal College of Obstetricians and Gynaecologists* (RCOG) (33,34,51).

The delivery assistant, who can be an obstetrician or a midwife, will perform a systematic **physical examination** of the perineal, vaginal and rectal areas to the women during the immediate postpartum period, in order to assess whether any high degree perineal laceration have occurred. For more information about how to correctly done this physical assessment, see **Point 3. Introduction – Section 3.3.7 Diagnosis**.

Then, whether the lesion is present or not, it will be registered into the created case report form (CRF) (see **Annex 9**) together with, if the tear exists, the degree of it. Finally, the delivery attendant will proceed to suture it if necessary.

This main variable will be **nominal categorical**, as we will categorize it as presence/absence:

- o Presence: it includes women with a third or fourth degree perineal lesion.
 - o Absence: it includes women without any perineal trauma, first and second degree perineal lesion and an isolated button-hole injury.
- Emergency caesarean for failure to progress: RCOG, SEGO and *The American Congress of Obstetricians and Gynecologists* (ACOG) describe it as a caesarean indicated urgently due to lack of progressive cervical dilation or lack of descent of foetal head, or both (63,64). We will define this variable as **nominal categorical**, treating it as presence/absence.

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- Assisted vaginal delivery: is defined by the Clinical Guideline for the management of an assisted vaginal delivery from the *Sociedad Española de Ginecología y Obstetricia* (SEGO) as the application of an instrument such as forceps, spatulas or vacuum, on the foetal head in order to extract it by traction of it or by an enlargement of the birth canal (14). This secondary variable is **nominal categorical** as we consider the following groups:
 - o Eutocic: is defined as a spontaneous vaginal delivery, without the need of the application of any instrument. The non-operative vaginal deliveries will be included in this category.
 - o Forceps: according to SEGO, is a smooth metal instrument formed by two articulable branches, each one composed by a handle, lock and blade (see **Figure 11a**). The articulation can be fixed or sliding and blades are curved to fit around the baby's head. There are three types of forceps (see **Figure 11b**): outlet, mid-cavity and rotational forceps (12,14).

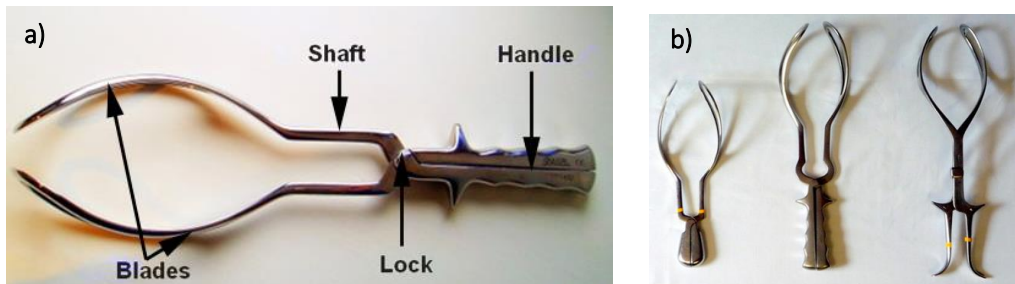


Figure 11. a) Components of the forceps; b) Types of forceps: outlet forceps (left), mid-cavity forceps (centre) and rotational forceps (right). Adapted from (75).

- o Thierry's spatulas: is a tool formed by two independent, slim, non-fenestrated and non-articulable blades. The outer face is slightly convex while the inner one is concave (see **Figure 12**). The pelvic curvature is lightly pronounced, so the application of the spatulas is limited to the lowest parts of excavation (14).
- o Vacuum: is an instrument that uses suction to attach a soft or hard plastic or metal cup to the baby's head by negative pressure. It allows the cephalic flexion and traction, but not the rotation. There are several types of disposable vacuum extractors presently available (see **Figure 13**): Kiwi omnicut, silastic or metal cups (12,14).

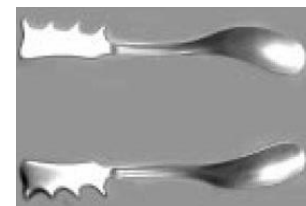


Figure 12. Thierry's spatulas. Adapted from (76).

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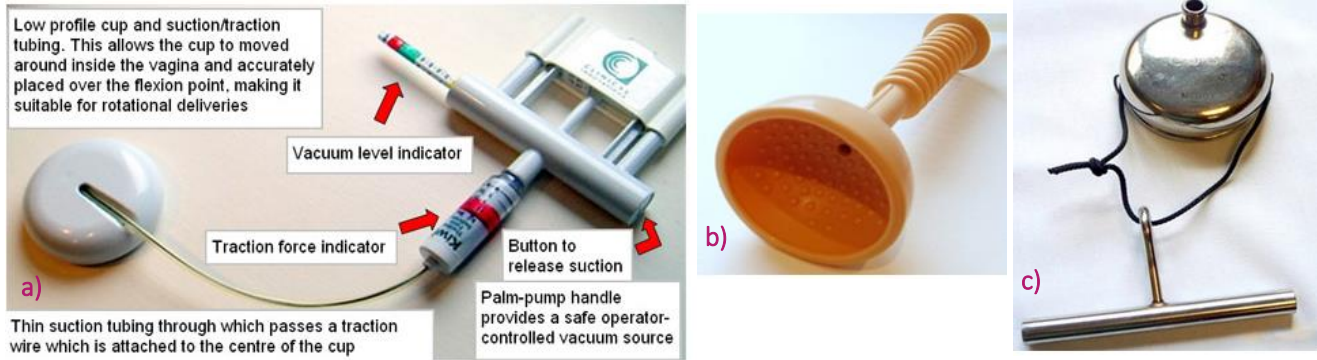


Figure 13. Types of vacuum: **a)** Kiwi omniscup and its components; **b)** Silastic cup; **c)** Metal cup. Adapted from (75).

However, we have decided that we will **dichotomize** this variable into operative/non-operative deliveries to make the statistical analysis easier.

7.4.3 Confounding variables

Regarding the **maternal factors**, the variables that can interfere in our study are:

- **Ethnicity:** is a **nominal categorical** variable that is defined as the human community having racial, religious, linguistic and certain other traits in common. In Hospital Universitari de Girona Doctor Josep Trueta (HJT), ethnicity is always recorded in the first trimester visit and classified in Caucasian, Black African, Asiatic, Maghrebi, South American, or Other.
- **Maternal age:** is a quantitative discrete variable, but we have transformed it to **nominal categorical** by categorizing it in three intervals: 18 – 24 years, 25 – 34 years and ≥35 years.
- **Maternal diabetes:** is a **categorical nominal** variable. The WHO determines that altered laboratory tests of glycaemia, which will be specified below, first detected at any time during pregnancy should be classified as either diabetes mellitus (type 1 or 2) or gestational diabetes. For that reason, we will establish four groups:
 - o **Pre-gestational diabetes:** presence of one or more of the following WHO criteria **before the start of the pregnancy**:
 - Fasting plasma glucose ≥ 126 mg/dl (or 7.0 mmol/l);
 - Two-hour plasma glucose ≥ 200 mg/dl (or 11.1 mmol/l) following a 75g oral glucose load; or
 - Random plasma glucose ≥ 200 mg/dl (or 11.1 mmol/l) in the presence of diabetic symptoms.

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- Gestational diabetes: presence of one or more of the following WHO criteria **for the first time of life at any time in pregnancy**:
 - Fasting plasma glucose ≥ 92 mg/dl (or 5.1 mmol/l);
 - One-hour plasma glucose ≥ 180 mg/dl (or 10.0 mmol/l) following a 75g oral glucose load;
 - Two-hour plasma glucose ≥ 153 mg/dl (or 8.5 mmol/l) in the presence of diabetic symptoms.
- Absence of diabetes: absence of any of the previous WHO criteria for the diagnosis of pre-gestational and gestational diabetes.
- Maternal body mass index (BMI): is a quantitative discrete variable but we will treat it as **nominal categorical**, by establishing four groups according to the pertinent degrees of obesity:
 - Underweight: BMI <18.5 kg/m².
 - Normal weight: BMI comprised between 18.5-24.99 kg/m².
 - Overweight: BMI comprised between 25-29.99 kg/m².
 - Obesity: BMI ≥ 30 kg/m².

The **foetal factors** that we consider as a covariables are the following:

- Foetal weight estimation: is a quantitative continuous variable, but we will treat it as **nominal categorical**. In HJT, the ultrasound scanners calculate it automatically with the **Hadlock's formula**. It needs the abdominal circumference (AC), femur length (FL) and head circumference (HC) values in cm to obtain the foetal weight estimation in grams. We will categorize it in five groups: <2000 grams, 2001 – 2500 grams, 2501– 3000 grams, 3001 – 3500 grams and >3500 grams.
- Foetal malposition: foetal presentation is defined as the part of the foetus which is presenting to the pelvic inlet, while foetal position is defined as the relationship of the denominator (reference point used to determine the position) on the maternal pelvis such as pubic symphysis, iliopectineal eminence, sacroiliac joints and sacrum. **We will only include cephalic presentations** (when the foetus is in a longitudinal lie with the head being closest to the cervix). This presentation is subdivided into vertex, sincipital, brow and face positions. The normal way for a baby to deliver is by the vertex, in which the occiput lies anteriorly. As opposite to it, sincipital, brow and face presentations have the occiput lying posteriorly (see **Figure 14**) (65). We will assess it by a routine vaginal tact performed on the third-trimester screening appointment, when labour has started and periodically during labour. This variable is **nominal categorical** and we will dichotomize it in:

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- Good position: it refers to the vertex presentation.
- Mal-position: it includes sincipital, brow and face presentations.

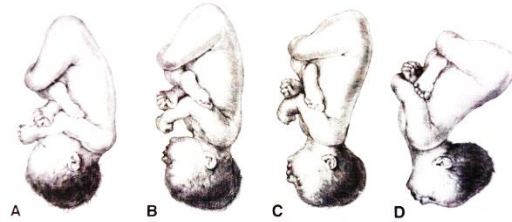


Figure 14. Cephalic presentations: **a)** vertex, **b)** sincipital, **c)** brow and **d)** face presentations. Adapted from (77).

Finally, the **factors related to the delivery period** which can modify our results are:

- Gestational age at birth: is the estimated age or stage of maturity of the foetus. It is a discrete quantitative variable that we will transform to **nominal categorical** by dividing it in the following intervals: week 37-38 (259-266 days), week 38-39 (267-273 days), week 39-40 (274-280 days), week 40-41 (281-287 days), week 41-42 (288-294 days).
It is estimated automatically at the third trimester visit by the software of the echograph, which introduces the values of the BPD, HC, AC and FL in an algorithm. Therefore, we will calculate the subsequent gestational age at birth according to the age obtained in the third-trimester visit.
- Prolonged second stage of labour: the WHO defines it as the onset of regular, rhythmical painful contractions accompanied by cervical dilation of more than 4 cm where progress of labour is slower than expected. The time from which we consider this diagnosis depends on the parity and the administration or not of the epidural anaesthesia. This variable is **nominal categorical** and we will treat it as dichotomous. Hence, we will distinguish this variable in two categories:
 - Presence: it includes nulliparous with >3 hours of labour with epidural anaesthesia or >2 hours without it, and multiparous with >2 hours of labour with epidural anaesthesia or >1 hour without it.
 - Absence: it includes nulliparous with ≤3 hours of labour with epidural anaesthesia or ≤2 hours without it, and multiparous with ≤2 hours of labour with epidural anaesthesia or ≤1 hour without it.
- Induction/maturation of labour: is defined, according to the WHO, as the process of artificially stimulating the uterus to start labour by administering oxytocin or prostaglandins (misoprostol) to the pregnant women or by manually rupturing the amniotic membranes. We treat this **nominal categorical** variable as dichotomous by diving it in presence/absence.

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- Use of epidural anaesthesia: RCOG and ACOG consider it as a commonly-used method of a pain relief performed by an anaesthesiologist to control the pain derived from labour that involves lumbar access (L2-L3, L3-L4, L4-L5) into the epidural space. It is a **nominal categorical** variable that we have decided to dichotomize into presence/absence.
- Delivery assistant: is the person who assists and/or treats the pregnant woman during the delivery period. In the HJT, eutocic deliveries can be attended by either an obstetrician or a midwife, but operative deliveries and caesareans can only be assisted by obstetricians. We consider this variable as **nominal categorical** and we will treat it as dichotomous: obstetrician/midwife.
- Preventive perineal measures: are defined as a group of interventions performed antenatally and/or intrapartum that aim to reduce the risk of suffering a perineal trauma during a vaginal delivery. In HJT, head control and perineal protection by hands-on technique are both performed routinely in all vaginal births, but the rest of the measures explained previously in the **Point 3. Introduction – Section 3.3.5 Prevention** are not always employed. Accordingly, we decided to categorize this **nominal categorical** variable in:
 - o Non-additional measures: includes the performance of the systematic measures (head control and perineal protection by hands-on technique).
 - o Additional measures: includes the performance of one of more of the following measures, in addition to the routine measures: perineal massage, application of warm compresses, delivery position and pelvic floor rehabilitation.
- Episiotomy: is an intrapartum surgical incision performed in the perineum which aims to enlarge the vaginal opening to facilitate the foetal expulsion. In HJT, when its performance is needed, only the restrictive mediolateral technique is used. For this reason, we have decided to simplify its categorization into presence/absence, treating it as a **nominal categorical** variable.
- Shoulder dystocia: is defined by RCOG as a vaginal cephalic delivery that requires additional obstetric manoeuvres to deliver the foetus after the head has delivered and gentle traction has failed. It is a **nominal categorical** variable, so we will dichotomize it as presence/absence.

7.5 PROCEDURE AND DATA COLLECTION

Regarding the process of data collection, all information from participants will be registered in a case report form (see **Annex 9**) and also reported to our study database. All variables will be included.

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The principal investigator Doctor Ferran Montero, during an informative meeting, will explain with detail to the rest of the members of the research team the following points:

- Which information have to be collected;
- How to include the obtained data into the case report form;
- The specific characteristics of the technique which they have to employ for the measurement of the FHC by ultrasound.

All the obstetricians of HJT who take part of the research team will collect the information needed from participants under de supervision of the principal investigator Doctor Ferran Montero.

EXTERNAL OBSTETRICS CONSULTATIONS OF HJT

First of all, once pregnant women at the 37th gestation week come to the external obstetrics consultations of HJT in order to perform the third trimester ultrasound screening, we will facilitate to them an informed consent of the third-trimester ultrasound screening which patients have to sign. After that, we will explain to pregnant women who fulfil the established **inclusion criteria** (adult nulliparous women who are able to understand the informed consent, with a singleton gestation which has a cephalic presentation) in what consists our study and offer them the possibility to participate in it if they accept to **sign an informed consent** created on purpose (see **Annex 2**).

Once they have signed the informed consent, we will proceed to assess if the considered confounding variables, such as **maternal age**, **ethnicity**, **body mass index (IMC)** and **diabetes**, together with data of **previous pelvic floor problems and last menstrual period (LMP)** of the patient, are correctly collected in the clinical history. If any data is lacking, we will have to ask for it to the patient. The **gestational age** will be calculated from the date of the last menstrual period (LMP) and registered in the case report sheet and database. After that, we will perform the routine vaginal tact and the **third-trimester ultrasound screening**, in which we will assess systematically a set of foetal biometrics parameters, among which we highlight the **foetal head circumference (FHC)**, as it is the parameter that we need to collect in our study. We want to emphasize that, despite the ultrasound scanner calculates the **percentile of each obtained value of FHC**, we will register the corresponding percentiles according to the reference table of Hospital Clinic. It is important to clarify that, in order to reduce the intra-observer variability, **FHC will be measured by two different obstetricians and each one will perform it twice, choosing then the most repeated value**. Covariables such as **foetal presentation** (cephalic or non-cephalic) and **weight estimation** will be also measured during this ultrasound assessment. Once we obtain all this values, we will introduce it in the **case report form** and in the **database** as well.

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The obstetrician who attends the patient in that moment will be the responsible of the performance of this third-trimester visit and registration of the needed data in the case report form and the database.

EMERGENCY SERVICE OF OBSTETRICS OF HJT

All pregnant women who perform their follow-up in the HJT and who have no indication of an elective caesarean, when experimenting uterine dynamics or a sensation of hydorrhea⁷, will come to the **Emergency medical services of HJT** as both symptoms could be first signs of labour. From there, patients will be conducted to the **emergency service of obstetrics**, located on the second floor of the hospital building, in where the initial valuation will be done by the following explorations:

- Measurement of the arterial pressure, pulse and maternal temperature;
- Exploration of cervical conditions regarding its dilation;
- Auscultation of the foetal heart rate (FHR) and performance of a cardiotocography⁸ (CTG).

The obstetrician, midwife and nurse who assist the patient are responsible of carrying out this assessment. Only pregnant women that fulfil **criteria of delivery** (regular uterine contractions, shortening of the cervix greater than 50% and dilation equal or greater than 3 cm) will be admitted to the hospital.

It is important to clarify that patients who has an indication of induction of the delivery will come directly to the **emergency service of obstetrics** in order to be adequately explored and then admitted in the hospital. We also have to take into account that only pregnant women visited at the 37th gestation week that deliver at term will be able to participate in our research.

Once the patients have been admitted to the gynaecology and obstetrics service, we will proceed to check their clinical history and **pregnancy report**, in which is gathered all relevant data of each follow-up appointment and the results of the performed tests/proves during them, familiar and personal sociodemographic and medical data, obstetrics data, and a space to register the delivery-related and postpartum data. Moreover, obstetricians of the delivery room, together with the pertinent midwife, will assess the **delivery plan**, fulfil the **partogram**⁹ and inform the patient of the types of analgesia. The obstetrician who is responsible of the patient in that moment will communicate her admission to the **Anesthesiology Service**.

During the stay of the hospital, patients will be classified in **low and risk gestation groups** (see **Annex 10**). Those with a low risk gestation will have overall freedom of movements and positions, and minimal medical

⁷ The **hydorrhea**, in a pregnancy context, is defined as the discharge of a watery fluid from the vagina.

⁸ The **cardiotocography**, also named **electronic foetal monitoring**, is a continuous electronic record of the baby's heart rate obtained via ultrasound transducer placed on the mother's abdomen.

⁹ A **partograph**, according to WHO, is a graphical presentation of a woman's progress of labour that is recommended for routine monitoring of the 1st stage of labour to help the birth attendant identify slow progress of labour and prevent prolonged labour and its complications.

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interventions will be performed in order to control the foetal wellbeing. Otherwise, women being in the high risk group will need a more stricted maternalfoetal control and continual cardiocography tracing.

Patients who have an indication of induced labor, dynamic dystocia, prolonged stage of labour or no progression of the delivery will receive a **dosis of oxytocin**. The administration of this drug and the diagnosis of **prolonged stage of labour** will be registered to the case report form and database by the obstetrician or midwife that assists the patient.

DELIVERY AND OPERATING ROOMS OF HJT

The **delivery room**, in where pregnant women finish their pregnancy vaginally, is located in the emergency service of obstetrics. Patients who are in the first stage of the delivery period (dilation) and are about to reach the expulsion stage, will be brought there in order to complete the third and last stage of delivery.

The midwife or obstetrician that assists the delivery period will collect data of the use of the **epidural anaesthesia**, **delivery assistant** (obstetrician or midwife), **delivery method** and the performance of **episiotomy**, **protective perineal measures** and finally, if existing, the occurrence of a **shoulder dystocia**.

In case of need to perform an **assisted delivery**, an informed consent has to be obtained from the patient. Women with this indication will be addressed to an **operating room** in order to perform it, as we need to have all the material needed for an emergent caesarean closely. The same occurs when an **unplanned caesarean** have to be performed due to maternal or foetal conditions. The obstetrician who assists the patient will be in charge of note these interventions down in the case report form and the database.

After a vaginal delivery, at the immediate postpartum period, the assistant will perform to the woman a physical exploration in order to assess her perineal integrity. If there is any perineal lesion that have to be repaired, the delivery assistant will proceed to suture it. Then, the delivery attendant will register the **absence or presence of a perineal trauma** and, in case of presence, **the degree of it** in the case report form and database as well.

One of the nurses that are in the delivery room will assess the **weight and head circumference of the newborn** and then, she will fulfil the baby-related items of the case reported sheet, and the obstetrician or midwife who assists the delivery will be in charge of supervising it and gathering these data in the database.

8 STATISTICAL ANALYSIS

The statistical analysis will be performed through the use of the IBM SPSS for Windows. We will perform a univariate, bivariate and multivariate analysis of our data collection.

8.1 UNIVARIATE ANALYSIS

In the univariate analysis, variables will be defined as qualitative (categorical) or quantitative variables:

- For qualitative variables, the results will be expressed in **percentages, proportions or frequencies**.
- For quantitative variables, being either continuous or discrete, we will determine whether they follow a normal distribution or not by using the Kolmogorov-Smirnov test. If a normal distribution is assumed, we will use **mean \pm SD**; however, if not, we will estimate the **median**.

8.2 BIVARIATE ANALYSIS

In our project, firstly we will compare the characteristics of our population depending on belonging to large FHC or non-large categories, which are the exposed and non-exposed groups respectively.

- For quantitative continuous variables, we will use a **T-student test**.
- For qualitative variables, we will employ a **Chi-square of Pearson test or the Fisher's exact test**.

Then, we have two independent variables, being the large foetal head circumference (FHC) at the 37th gestation week observed on the third-trimester ultrasound screening the main one and their cut-off point the secondary one; moreover, we have two dependent variables as well, being the presence of a high degree perineal trauma the main one and the indication of an assisted vaginal delivery the secondary one:

- **Large foetal head circumference (FHC)**: we have transformed this quantitative continuous variable into a categorical nominal one by dichotomizing it into large and non-large FHC groups.
- **Cut-off point of FHC**: is a quantitative continuous variable, since FHC can achieve infinite values, normally among 30 and 36 cm at the 37th gestation week.
- **High degree perineal trauma**: is a categorical nominal variable that we decided to divide in presence (3rd and 4th degree perineal tears) and absence (absence of high degree perineal lesions, 1st and 2nd degrees and button-hole injuries) of high degree perineal trauma categories.
- **Assisted vaginal delivery**: is a categorical nominal variable since it is divided in operative/non-operative vaginal deliveries.

For that reason, to compare the main independent (large FHC) and dependent variables (high degree perineal trauma), we will use a **Chi-square of Pearson test or the Fisher's exact test**, as both of them are

categorical variables. Likewise, to compare our main independent variable (large FHC) with the secondary dependent variable (assisted vaginal delivery), we will also employ a **Chi-square of Pearson test or the Fisher's exact test**, since both of them are categorical variables as well.

Finally, the optimal cut-off point of FHC to predict which women are at risk to suffer a severe perineal laceration and classify them according to this risk will be determined based on ROC analysis to maximize sensitivity and specificity by using **Younden index** ($J = \text{sensitivity} + \text{specificity} - 1$).

8.3 MULTIVARIATE ANALYSIS

A multivariate analysis will be accomplished to adjust our independent variables for covariables, thus we will try to avoid potential confounders that could modify our results. Therefore, we will perform a **multivariate regression logistic model** in order to analyze the relationship between our independent variables and the covariates.

8.4 SENSITIVITY ANALYSIS

The incidence of the unplanned caesareans due to failure to progress is incremented among patients with a large FHC and thus we are not able to know if these pregnant women would have suffered a high degree perineal trauma or an operative delivery if their gestation has finalized vaginally. Furthermore, none of the available studies that investigate the association of the large neonatal HC with an increment of perineal trauma rates has taken into account this fact. For these reasons, we have decided to perform a **sensitivity analysis**.

It consists in repeating the above-mentioned statistical analysis, but instead of using the dependent variables of **high degree perineal trauma** and **assisted vaginal deliveries** as in the first analysis, we will use a combined variable of **high degree perineal trauma + unplanned caesareans due to failure to progress** and **assisted vaginal delivery + unplanned caesareans due to failure to progress**. When we use only high degree perineal trauma and assisted vaginal delivery as the dependent variables, we are considering that none of the unplanned caesareans due to failure to progress would have had neither an obstetric anal sphincter injury (OASIS) nor an assisted vaginal birth. However, when we apply the sensitivity analysis and thus employ the combined variables, we are assuming that all the unplanned caesareans due to failure to progress would have had an OASIS and/or an instrumental birth if the delivery has been vaginal.

We will perform also a sensitivity analysis in the estimation of the cut-off point of FHC at which there is more risk of suffering an OASIS, to assess if the first cut-off point is different from the second one obtained.

9 ETHICAL ASPECTS

The research protocol will be presented to the Clinical Research Ethics Committee of the Hospital Universitari de Girona Doctor Josep Trueta (HJT) called *Comitè Ètic d'Investigació Mèdica* (CEIC), in order to be evaluated and approved before the start of the study.

The main investigators and collaborators guarantee that the study will be conducted in accordance to the human rights and the ethical considerations gathered in the World Medical Association Declaration of Helsinki of the *"Ethical Principles for Medical Research Involving Human Subjects revised in 2013"* and the Spanish law concerning medical investigations *"Ley 14/2007, de 3 de julio, de Investigación Biomédica"*.

The patient data will be not used if a previous consent has not been accepted and signed previously. To respect the **principle of autonomy**, at the time of admission, pregnant women will be appropriately informed about most relevant points concerning our study and its purposes and will be invited to voluntarily accept and sign the informed consent (see **Annex 2**).

Names, postcodes, addresses, birth dates or any identifying data will not be collected neither in case report forms nor in database of the research, in order to maintain the **confidentiality and data security** of the subjects. The content of the case report documents and the database will be considered strictly confidential and will not be disclosed to third persons except those already specified. Moreover, data security will be ensured on a locked network that only principal investigators will be able to access.

According to the national and international laws about **patient's privacy and confidentiality**, the study will be governed by *"Ley Orgánica 15/1999, del 13 de Diciembre, de Protección de Datos de Carácter Personal"*, *"Real decreto 1720/2007, del 21 de Diciembre, por el que se aprueba el reglamento de desarrollo de la Ley orgánica 15/1999"* and *"Real decreto 994/1999, del 11 de Junio, de medidas de seguridad para automatizar los registros que contienen datos personales"*. Furthermore, an identification number will be used when elaborating our database instead of the patient's name.

All the members of the research team declare that they have no conflicts of interest.

10 FEASIBILITY

Our research will take place between June 2016 and March 2021 in the Hospital Universitari de Girona Doctor Josep Trueta (HJT), which is the reference hospital of all the territory of the province of Girona. This centre is equipped medically and technologically to accomplish the objectives of our research. Moreover, the memberships of our research team have been working together before in the elaboration of other obstetrics studies.

Regarding the **main researcher** of our study, Doctor Ferran Montero Muñoz is an obstetrician and gynaecologist of the HJT with approximately thirty years of experience. He has obtained a super-specialization in pelvic floor diseases and is the main responsible of the external consultations of it. Moreover, together with some urologists, he conforms the Pelvic Floor Committee of the HJT, which decides how to treat the most difficult cases. Furthermore, he is member of *Societat Catalana d'Obstetrícia i Ginecologia* and *Sociedad Española de Ginecología y Obstetricia (SEGO)*.

Before the starting of the study, two **informative meetings** with all the professionals involved will be organized. In these two appointments, the main investigator will explain the objectives of the study, the data which have to be collected and how to do it, remarking the importance of gathering these data into a case report form and in the created database.

Regarding the **recruitment of the patients**, we have estimated that we will need 3 years to assess the desired simple size of the research. We are conscious that we can lose some of the patients in which we have performed the third-trimester ultrasound screening for having finally their childbirth in another center. Although all the data that we need is gathered systematically in their clinical history, we have decided to not include these subjects in our study because professionals of the other centers do not use the standardized criteria established in our research and thus the results would become imprecise.

About the **budget**, the conduct of it is cheap (10,018 euros in total) as almost all of the activities of our study are routinely done in the clinical practice. In addition, the majority of the budget is due to the publication and diffusion of the results of the research, since additional material is not needed and we will only need to hire a statistician as extra-personnel in order to ensure an adequate statistical analysis of our collected data.

For all the reasons exposed, we do think that the research we proposed can be easily brought out without any barriers of knowledge, logistics, experience and budget.

11 WORKING PLAN

Principal investigators: Ferran Montero Muñoz i Cristina Trullàs Rivero.

Collaborators: obstetricians, midwives and nurses that take part of the Service of Obstetrics of the HJT.

The study will be performed in 4 years and 10 months and it will be composed of 4 stages, which are explained below:

STAGE 1- COORDINATION PHASE. DEVELOPMENT OF OUR THEORETICAL FRAMEWORK (9 months)

- **Activity 1 – First meeting** was in June 2016. I met Doctor Ferran Montero Muñoz, and we decided to start the study.
- **Activity 2 – First informative meeting** was in July 2016. During this first period of time, all the research team, formed by the obstetricians of HJT, establishes the initial idea of the project and start it, define the roles of each participant and agree an execution plan and organization.
- **Activity 3 – Literature review** was performed during a 6-months period and consists on a bibliographic research of the initial idea of our study done by all the team of obstetricians.
- **Activity 4 – Protocol design and elaboration**: the protocol elaboration will be carried by the obstetricians of HJT and will take a time period of 2 months, until January 2016.
- **Activity 5 – Approval from Clinical Research Committee**: the protocol will be brought to the CEIC for its revision and posterior approval.
- **Activity 6 – The second informative meeting** will be organized by the principal investigator once the Ethics Committee give us their approval. Doctor Ferran Montero and Cristina Trullàs will inform the research team, the midwives of HJT and the statistician about the following points:
 - The aim of the study;
 - The specific data which should be collected from each pregnant woman included and how to perform this process;
 - The importance of the signature of the informed consent from each subject.

The session purpose is to homogenize and agree a standardized method of action.

STAGE 2: STUDY CONDUCT (3 years)

- **Activity 7 – Subject's recruitment**: it will start on March 2017 and finishes March 2020. We will recruit pregnant women that fulfill the desired inclusion criteria, until the sample size is achieved.

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During the third-trimester appointment for the ultrasound screening, an informative leaflet and two informed consents (one for their third-trimester ultrasound screening and the other for their inclusion to the study) will be given to the patients.

- **Activity 8 – Data collection**: data from the third-trimester ultrasound screening and delivery period of each pregnant woman will be collected by the obstetrician/midwife who attends or treats the patient, under the supervision of Doctor Ferran Montero. Data collection will finish one month after the last third-trimester appointment in order to include data related to the delivery period from the last participant of the study. All data will be registered in a case report form (see **Annex 9**).
- **Activity 9 – Computer processing of data**: this procedure will start and finish at the same time of data collection, as both are performed simultaneously.

STAGE 3: DATA ANALYSIS (5 months)

- **Activity 10 – Statistical analysis**: a statistician will take the database with the collected data and will proceed to analyze it.
- **Activity 11 – Interpretation and discussion of the results**: all the obstetricians of HJT who participate in the study will meet and discuss the statistical data obtained and also assess whether the expected results coincide with the ones we have obtained.
- **Activity 12** – An adequate interpretation and discussion of the findings will allow obstetricians who take part in the study to draw a meaningful **conclusion**.

STAGE 4: PUBLICATION AND DISSEMINATION OF THE RESULTS (7 months)

- **Activity 13 – Publication of the results**: findings and their derived conclusions of our research will be presented in specific conferences.
- **Activity 14 – Final report dissemination**: the results of our project and the firm drawn conclusions will be sent to scientific journals and to the *Sociedad Española de Ginecología y Obstetricia* to be published.

12 CHRONOGRAM

ACTIVITIES	2016					2017					2018	2019	2020					2021					PERSONNEL NEEDED															
	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D			J		F	M	A	M	J	J	A	S	O	N	D	J	F	M	A
STAGE 1: COORDINATION PHASE. DEVELOPMENT OF OUR THEORETICAL FRAMEWORK																																						
First meeting																																		Dr Montero and Cristina Trullàs				
First informative meeting																																		Dr Montero				
Literature review																																		All research team and midwives				
Protocol design and elaboration																																			Dr Montero and CEIC of HJT			
Approval from Clinical Research Committee																																		Dr Montero				
Second informative meeting																																			Dr Montero			
STAGE 2: STUDY CONDUCT																																						
Subject's recruitment																																		Dr Montero				
Data collection. Consecutive sampling																																			All research team			
Computer processing of data. Data entry																																			Dr Montero			
STAGE 3. DATA ANALYSIS																																						
Statistical analysis																																		Statistician				
Interpretation and discussion of the results																																			All research team			
Conclusion																																						
STAGE 4. PUBLICATION AND DISSEMINATION OF THE RESULTS																																						
Publication of the results																																			All research team			
Final report dissemination - <i>Sociedad Española de Ginecología y Obstetricia</i>																																			All research team			

13 BUDGET

13.1 PERSONNEL

Most of the activities which will be performed according to our working plan take part of the **routine clinical assistance** provided by professionals of our hospital for the adequate management of pregnant women; for that reason, none of them will represent any additional cost.

We will only need to hire a **statistician** in order to carry out the statistical analysis of our data.

13.2 MATERIALS

The quarterly ultrasound assessment forms part of the **systematic control of pregnancy**, so the sonographic scanners and conductive gel needed available in our hospital will be enough to conduct our research and thus they will not suppose an extra-cost.

The **impression of the protocol, informative leaflet of perineal tears, informed consent of the study and case report sheet** are the only material expenses that will be required in our project, since the cost of the photocopies of the informed consent of the third-trimester ultrasound screening are a routine clinical task and thus its expenditure should pass through the budget of routine clinical practices of the Hospital Universitari de Girona Doctor Josep Trueta (HJT).

13.3 REDACTION, DIFFUSION AND PRESENTATION OF THE ARTICLE

The research team will be in charge of the **redaction** of the article in Spanish and of its corresponding translation in English.

Once the article will be finished, it will be sent to the journals of *Sociedad Española de Ginecología y Obstetricia* (SEGO), *European Board and College of Obstetrics and Gynaecologists* (EBCOG) and *International Urogynaecological Association* (IUGA) in order to be published.

Furthermore, our findings will be presented in both **national and international congresses** organized by *Sociedad Española de Ginecología y Obstetricia* (SEGO) and *European Board and College of Obstetrics and Gynaecologists* (EBCOG), respectively.

The costs of the **publication and presentation** of the research have to be stated in our budget.

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ITEMS	Units	Pages/ hours per unit	Price per unit	Total
STAGE 1: COORDINATION PHASE. DEVELOPMENT OF OUR THEORETICAL FRAMEWORK				
Impression of: Protocol	10	80	80 x 0.03 € = 2.40 €	24 €
				TOTAL: 24 €
STAGE 1: STUDY CONDUCT				
Impression of: Informed consent of the research	3300	2	2 x 0.03 € = 0.06 €	198 €
Informative leaflet of OASIS*	3300	2	2 x 0.03 € = 0.06 €	198 €
Case report sheet	3300	2	2 x 0.03 € = 0.06 €	198 €
				TOTAL: 594 €
STAGE 3: DATA ANALYSIS				
Statistician salary	1	100 (h)	1 (h) x 30 € = 30 €	3,000 €
				TOTAL: 3,000 €
STAGE 4: PUBLICATION AND DISSEMINATION OF THE RESULTS				
Publication in journals (SEGO, EBCOG and IUGA)	3	-	1,000 €	3,000 €
Attendance to SEGO and EBCOG congresses	2	-	SEGO: 1.200 € EBCOG: 2.200 €	3,400 €
				TOTAL: 6,400 €
				TOTAL: 10,018 €

*OASIS: obstetric anal sphincter injuries.

14 STUDY LIMITATIONS

In our research, we have detected some potential limitations that can interfere in the results obtained and thus they should be acknowledged:

- Firstly, we consider the foetal head circumference (FHC) measured on the third-trimester ultrasound as a possible limitation, since it has been proven to make an **overestimation of the real head circumference (HC)** in a study that analyses the correlation between the FHC and the neonatal one. However, this overestimation is small, so the authors conclude that, in fact, there is a strong correlation between both parameters (7).
- We have also take into account that there is the possibility of inter- and intra-observer differences in the measurement of the FHC by ultrasound, perineal examination done at the immediate postpartum and collection method of the rest of data, which can interfere in our final results. For that reason, on one hand, we decided that, in order to reduce differences in the estimation of the FHC and the assessment of a possible perineal trauma, both variables will be measured twice by at least two obstetricians, choosing then the most repeated value. On the other hand, to decrease these potential differences in the data collection, in the second informative meeting, the main investigator Doctor Ferran Montero will fix the method that obstetricians and midwives will have to use to collect each variable. Furthermore, he also will supervise all the process of data collection in order to assess if obstetricians follow the framework established in the meeting.
- The design of study, which is a prospective cohort, is one of the limitations that comes to our mind, as it leads to make some **selection bias** causing that the results obtained may be cannot be generalizable to the population. Nevertheless, we tried to reduce this bias by basing our sample selection on the accomplishment of some inclusion an exclusion criteria. In addition, in a prospective study, the selection bias seems rather unlikely because the exposition is determined before the presence of the investigated disease.

Moreover, as this design involves more probability of **losses of the contact with the patient** during the follow-up, we estimated a 20% of possible loss of subjects when we calculated the sample size. Although we could recuperate data through the *Història Compartida de Catalunya* of patients initially included in our study that finally do not deliver in our hospital, we have excluded them because physicians who attend them are not members of the research team and they do not use the standardized criteria established in our study. In cohort studies, they normally involve a **large period of years of follow-up of the patients** but, in our case, we will only need to follow each subject during at least 5 weeks and 3 years to obtain the desired sample size.

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The reviewed studies which analyse the association among the neonatal HC and the incidence of perineal trauma use **case control and cohort designs**. We have decided to conduct a cohort study for having more validity than a case control design, allowing us to calculate the incidence and establish a clear temporal sequence between the exposure and outcome and facilitating the study of the large foetal head circumference (FHC) as we consider it a rare exposure.

- Regarding the limitations due to lack of prior research studies on the topic, despite of existing a lot of studies that investigate the risk factors of obstetric anal sphincter injuries (OASIS), and even the neonatal head circumference (HC) as one of these risk factors, none of them has focused on the FHC observed on the third-trimester ultrasound, which would allow us to prevent women from an OASIS. Due to lack of prior data, as we do not know the attitude of the FHC, our calculation of the **sample size** needed is based on an estimation of the behaviour of it according to the followed trend of neonatal HC (for more information, *please check Point 7.3 Sample protocol – Section 7.3.2 Sample size*).
- As regards the inclusion and exclusion criteria, we decided to discard the mal-presentations of our study because in the HJT there is not any protocol of the performance of a vaginal delivery among breech presentations of the foetus yet, being the majority of them usually finalized as an elective caesarean. Therefore, we would not be able to analyse the associated risk of this variable for perineal trauma. However, soon it will be possible to study it since presently the obstetricians of HJT are elaborating this protocol. Furthermore, it would be an interesting topic of research.
- Finally, we consider our dependent variables, which are the presence of an OASIS and an assisted vaginal delivery, as another limitation of our research, as results obtained of both can be underestimated or overestimated by the variable of unplanned caesareans due to progress failure. Moreover, each of these variables are increased among women with large FHC (9).
In order to avoid this interference of our results, all the research team, together with the statistician, decided to use a **sensitivity analysis**, which consists in repeating all the analysis for a second time by replacing our dependent variables for a combination of each one with unplanned caesareans, considering thus in this second analysis that women with an unplanned caesarean suffered an OASIS and an instrumental delivery, respectively (for further information, *please check Point 8. Statistical analysis – Section 8.4 Sensitivity analysis*).
In this manner, apart from controlling this variable, we can observe if these unplanned caesareans modify the cut-off point of the FHC from which there is more risk of suffering an OASIS and/or the association between the large FHC and increased instrumental deliveries and OASIS rates.

15 IMPACT TO THE NATIONAL HEALTH SYSTEM

Generally, perineal injuries occurred during vaginal deliveries, apart from being common lesions, they are also preventable issues through the performance of antenatal and intrapartum protective perineal measures and the avoidance of the episiotomy and/or operative vaginal delivery unless it is strictly necessary. Moreover, women which have suffered a severe degree perineal trauma are likely to refer urinary and especially faecal incontinences and flatulence, and some of them can even have a pelvic organ prolapse in long term. All these clinical consequences lead to phycological and social problems that cause an important reduction of the quality of life of these patients.

For all the already mentioned reasons, we clearly thought that perineal traumas, mainly the high degree ones, should be a **priority for our national health system**.

Until now, several studies have analysed the main known risk factors of the obstetric anal sphincter injuries (OASIS), but only a few of them have recently investigated the association of the head circumference (HC) with the increased incidence of perineal trauma, and none of them has focused on the foetal head circumference (FHC) instead of the neonatal one. However, **more literature about this relationship is needed**. Therefore, and because FHC can predict the occurrence of an OASIS, we decided to analyse the FHC in relation to the incidence of perineal lesions.

With our research, we will try to demonstrate that the foetal head circumference (FHC) is a relevant risk factor and also a **preventive tool of OASIS**. In addition, we will make an attempt to find a **cut-off point** that allows us to classify patients and thus take consequent planned obstetric decisions according to the OASIS risk before childbirth.

In conclusion, if the results of our study are concluding, it could be created a **predictive risk scale of OASIS** which includes all the defined risk factors until now, taking into account the FHC as a factor, with an adjudicated punctuation to each item and that serves to quantify the associated risk of OASIS of each pregnant woman. Moreover, a cut-off point of the total punctuation from which there is a severe risk of OASIS could be established. Then, as this scale would be used antenatally, women with a punctuation that is equal or greater than the cut-off point obtained, they will be candidates for the performance of antenatal non-systematic preventive measures such as pelvic-floor exercises, perineal massage or application of warm compresses during childbirth.

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ANNEX 1 – INFORMED CONSENT OF THE ULTRASOUND SCREENING OF PREGNANCY

DOCUMENT DE CONSENTIMENT INFORMAT DEL CONTROL ECOGRÀFIC DURANT L'EMBARAS

L'ecografia és una tècnica de diagnòstic per la imatge que pot ser practicada per via vaginal o abdominal (segons l'època de la gestació i condicions) i que permet la visualització del fetus i del seu entorn (placenta, líquid amniòtic, etc.).

Quins resultats té actualment?

Si bé és cert que l'ecografia permet detectar les anomalies morfològiques fetals, cal tenir en compte que la seva precisió depèn de l'època de la gestació (és més fiable al voltant de les 20 setmanes), del tipus d'anomalia (algunes tenen poca o nul·la expressivitat ecogràfica), de les condicions de la gestant que dificulten la visualització ecogràfica (obesitat, poca quantitat de líquid amniòtic o altres) i de la pròpia posició del fetus. La taxa de detecció depèn del tipus d'anomalia i està entre el 18% i el 85% amb una mitjana del 56%, tot i que l'ecografia es realitzi en condicions òptimes.

Quines altres coses cal tenir en compte?

1. L'ecografia només pot informar de l'existència de possibles anomalies físiques i no pas de defectes congènits d'una altra mena (bioquímics, metabòlics, genètics, cromosòmics, etc.). Per tant, una ecografia amb resultat normal no garanteix que el nen neixi sense alteracions o retard mental.
2. En algunes circumstàncies, la detecció d'una anomalia serà per força tardana (infeccions fetals, algunes anomalies digestives, obstruccions urinàries o intestinals, trastorns del desenvolupament d'esquelet, etc.), perquè aquestes patologies es manifesten en una etapa avançada de la gestació.
3. L'ecografia, tot i que orienta sobre l'evolució del fetus, no té per si sola un valor absolut per tal d'assegurar el benestar fetal.

Sra. _____ DNI: _____
manifesto voluntàriament que:

Ha estat informada per l'equip mèdic que l'atèn de la conveniència d'efectuar un **control ecogràfic** periòdic del meu embaràs, del seus resultats i de les seves limitacions. La informació se m'ha proporcionat de forma entenedora i les meves preguntes han estat constestades, i per tant, prene lliurement la decisió d'autoritzar l'esmentat procediment d'acord amb el protocol de l'Institut Clínic de Ginecologia, Obstetrícia i Neonatologia de l'Hospital Clínic, tot acceptant que la freqüència i el tipus de les exploracions dependran de les condicions particulars del meu embaràs. No obstant, podré revocar el meu consentiment en qualsevol moment si aquesta és la meua voluntat.

Girona a _____ de _____ de _____.

Signatura del metge

Signatura de la gestant o representant
(per minoria d'edat o incapacitat)

DOCUMENTO DE CONSENTIMIENTO INFORMADO DEL CONTROL ECOGRÁFICO DURANTE EL EMBARAZO

La ecografía es una técnica del diagnóstico por la imagen que puede ser practicada por vía vaginal o abdominal (según la época de la gestación y condiciones) y que permite la visualización del feto y su entorno (placenta, líquido amniótico, etc.).

¿Qué resultados tiene actualmente?

Si bien la ecografía permite detectar anomalías morfológicas fetales, la precisión de la técnica depende de la época de la gestación (es más fiable alrededor de las 20 semanas), del tipo de anomalías (algunas tienen poca o nula expresividad ecográfica), de las condiciones de la gestante que pueden dificultar la exploración (obesidad, poca cantidad de líquido amniótico u otras) y de la propia posición del feto. La tasa de detección depende del tipo de anomalía y está entre el 18 y el 85%, con una media del 56%, incluso en los casos en que la ecografía es realizada en condiciones óptimas.

¿Qué otras cosas se deben tener en cuenta?

1. La ecografía sólo puede informar de la existencia de posibles anomalías físicas y no de defectos congénitos de otra naturaleza (bioquímicos, metabólicos, genéticos, cromosómicos, etc.). Por tanto, una ecografía con resultado normal no garantiza que el niño nazca sin alteraciones o retraso mental.
2. En algunos casos, la detección de una anomalía será forzosamente tardía (infecciones fetales, algunas anomalías digestivas, obstrucciones urinarias e intestinales, trastornos del desarrollo del esqueleto, etc.), dado que tales patologías se originan o manifiestan en una etapa avanzada de la gestación.
3. La ecografía, aunque orienta sobre la evolución del feto, no tiene por sí sola un valor absoluto para asegurar el bienestar fetal.

Sra. _____ DNI: _____

manifiesto voluntariamente que:

He sido informada por el equipo médico que me atiende de la conveniencia de efectuar un **control ecográfico** periódico de mi embarazo, de sus resultados y sus limitaciones. La información me ha sido facilitada de forma comprensible y mis preguntas han sido contestadas, por lo que tomo libremente la decisión de autorizar dicho procedimiento de acuerdo con el protocolo establecido en el Instituto de Ginecología, Obstetricia y Neonatología del Hospital Clínic, aceptando que la frecuencia y tipo de los exámenes dependerán de las condiciones específicas de mi embarazo. No obstante, podré revocar mi consentimiento en cualquier momento si esa es mi voluntad.

Girona a _____ de _____ de _____.

Firma del médico

Firma de la gestante o representante
(por minoría de edad o incapacidad)

Dr. _____
No. de colegiado _____

Sra. _____
Parentesco _____

Note: this informed consent has been provided indirectly by the HJT through the Hospital Clínic de Barcelona.

ANNEX 2 – INFORMED CONSENT FOR THE STUDY OF THE RISK OF SUFFERING A HIGH DEGREE PERINEAL TEAR AMONG PREGNANT WOMEN WITH A LARGE FOETAL HEAD CIRCUMFERENCE IN HJT

FULL D'INFORMACIÓ A LA PACIENT

EL PERÍMETRE CEFÀLIC FETAL GRAN OBSERVAT A L'ECOGRÀFIA DEL TERCER TRIMESTRE COM A FACTOR PREDICTIU DE RISC PER ESTRIPS PERINEALS D'ALT GRAU EN UN PART VAGINAL

INVESTIGADORS PRINCIPALS: Ferran Montero Muñoz, Cristina Trullàs Rivero.

CODI DEL PROJECTE: _____

- 1) **Generalitats del projecte:** l'estudi que li presentem es durà a terme al Servei de Ginecologia i Obstetrícia de l'Hospital Universitari de Girona Doctor Josep Trueta, de l'any 2017 fins el 2021. El projecte de recerca ha estat valorat i aprovat pel Comitè Ètic d'Investigació Clínica. Els participants de l'estudi col·laboraran en la recollida de dades aportant informació personal i mèdica.
- 2) **Objectius i finalitats de l'estudi:** amb aquest estudi es pretén determinar si un perímetre cefàlic gran observat en l'ecografia del tercer trimestre inclosa en el control sistemàtic de l'embaràs i feta en les Consultes Externes d'Obstetrícia, s'associa a una major incidència d'estrips perineals d'alt grau durant un part vaginal entre les dones nul·líparees i amb una gestació única.
- 3) **Participació:** la seva participació en l'estudi és totalment voluntària. El participant és lliure d'abandonar l'estudi si així ho desitja en qualsevol moment, sense necessitat de justificacions i sense que aquest fet afecti la seva assistència sanitària. La participació en l'estudi és totalment gratuïta i no s'obtindrà compensació econòmica per la participació.
- 4) **Confidencialitat i protecció de dades:** s'adoptaran les mesures per garantir la confidencialitat de les seves dades en compliment de la *Llei Orgànica 15/1999* i les dades seran gestionades de forma anònima i només utilitzades amb fins d'investigació.
- 5) **Tasca del participant en l'estudi:** el participant haurà de cedir informació personal i mèdica sobre la gestació actual, l'ecografia rutinària del tercer trimestre i el moment del part, per tal que el metge obstetra o llevadora que l'ha atès pugui omplir el full de recollida de dades amb la informació facilitada.
- 6) **Resultats i beneficis de la investigació:** el participant està en el seu dret de ser informat dels resultats de la investigació. Els beneficis mèdics derivats de l'estudi seran adequadament utilitzats per millorar la prevenció dels estrips en les gestants i serviran de base per futures investigacions en aquest àmbit.

Gràcies per la seva participació.

FULL DE CONSENTIMENT INFORMAT

EL PERÍMETRE CEFÀLIC FETAL OBSERVAT A L'ECOGRAFIA DEL TERCER TRIMESTRE COM A FACTOR PREDICTIU DE RISC PER ESTRIPS PERINEALS D'ALT GRAU EN UN PART VAGINAL

Jo (Nom i cognoms): _____

- He llegit detingudament i he entès tot el full d'informació que se m'ha entregat.
- He rebut suficient informació sobre l'estudi.
- He parlat amb: (Nom de l'investigador), _____ i m'ha explicat de manera clara tot el procediment.
- He pogut realitzar preguntes sobre l'estudi i tots els meus dubtes han sigut resolts de manera satisfactòria.
- Entenc que totes les meves dades seran tractades de forma estrictament confidencial.
- Entenc quin serà el meu paper com a participant de l'estudi.
- Entenc que la meva participació és voluntària.
- Entenc que puc retirar-me de l'estudi:
 1. En qualsevol moment
 2. Sense haver de donar cap explicació
 3. Sense que això repercuteixi en la meva atenció mèdica i els meus drets legals no es veuran afectats.

Per tant, presto lliurement la meva conformitat per participar en aquest estudi d'investigació i permeto que les meves dades siguin introduïdes en la base de dades per la seva posterior anàlisi.

Firma del pacient



Firma de l'investigador



Girona, _____ de _____ de 20 ____.

Note: the informed consent will be distributed in Catalan to the candidates to participate in the study, but the hospital disposes of a translator that has redacted it in Spanish, French and English.

ANNEX 3 – REFERENCE TABLES OF THE VALUES OF FOETAL BIOMETRIC PARAMETERS

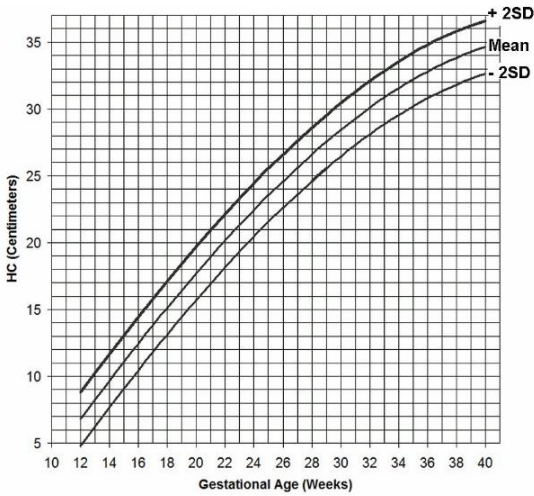
ANNEX 3.1: Foetal head circumference (in mm) for gestational age by percentiles, from the Hospital Clínic of Barcelona (66)

Semanas de gestación	Percentil 5	Percentil 50	Percentil 95	DE
12	59.7	72.1	84.5	7.8
13	73.3	86.1	98.9	7.8
14	86.7	99.9	113.1	8.0
15	99.9	113.5	127.0	8.2
16	112.9	126.8	140.7	8.5
17	125.6	139.9	154.2	8.7
18	138.1	152.7	167.4	8.9
19	150.2	165.2	180.3	9.1
20	162.1	177.5	192.9	9.4
21	173.6	189.4	205.2	9.6
22	184.9	201.0	217.1	9.8
23	195.7	212.2	228.7	10.0
24	206.2	223.1	240.0	10.3
25	216.4	233.6	250.9	10.5
26	226.1	243.7	261.3	10.7
27	235.5	253.4	271.4	10.9
28	244.4	262.7	281.1	11.2
29	252.9	271.6	290.3	11.4
30	260.9	280.0	299.1	11.6
31	268.4	287.9	307.3	11.8
32	275.5	295.3	315.1	12.1
33	282.1	302.2	322.4	12.3
34	288.1	308.7	329.2	12.5
35	293.6	314.5	335.5	12.7
36	298.6	319.9	341.2	13.0
37	303.0	324.6	346.3	13.2
38	306.8	328.8	350.9	13.4
39	310.0	332.4	354.8	13.6
40	312.6	335.4	358.2	13.9
41	314.6	337.7	360.9	14.1
42	315.9	339.4	363.0	14.3

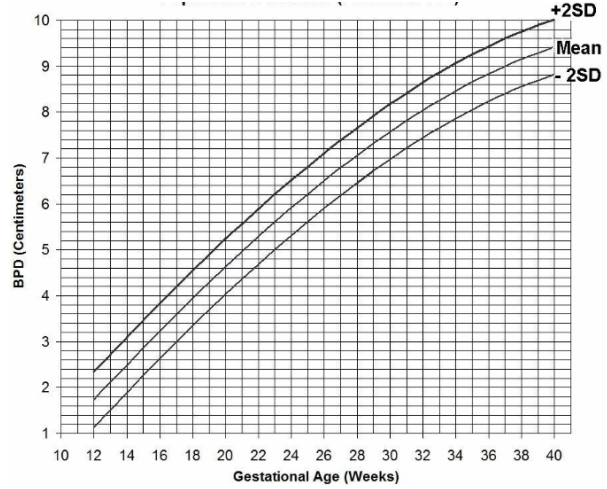
LARGE FOETAL HEAD CIRCUMFERENCE OBSERVED ON THE THIRD-TRIMESTER ULTRASOUND, AS A PREDICTOR RISK FACTOR FOR HIGH DEGREE PERINEAL TRAUMAS DURING A VAGINAL DELIVERY.

ANNEX 3.2: Hadlock graphs for gestational age by percentiles (67).

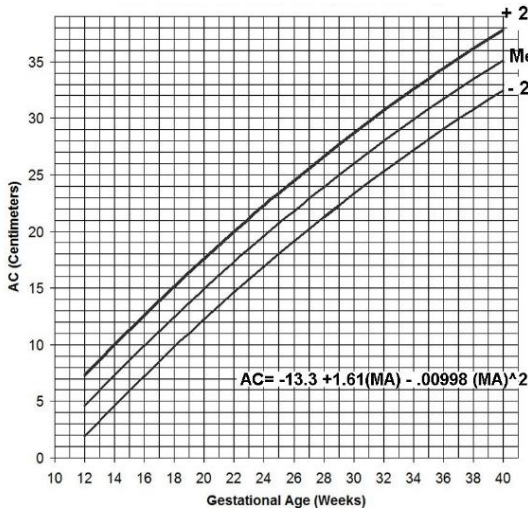
a) HEAD CIRCUMFERENCE



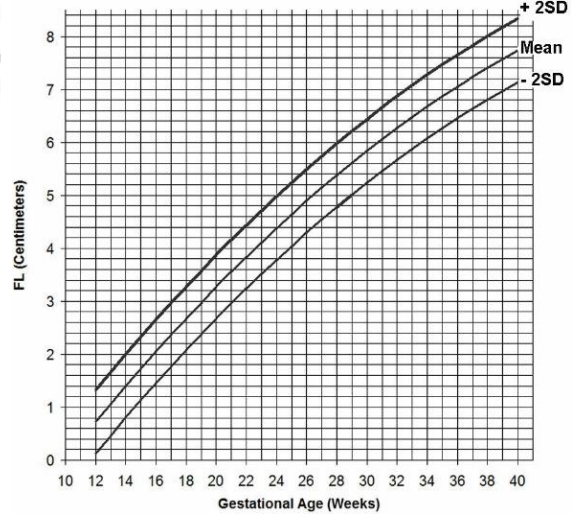
b) BIPARIETAL DIAMETER



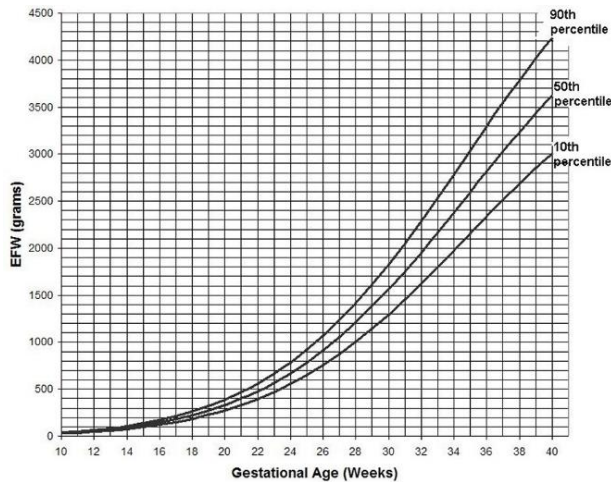
c) ABDOMINAL CIRCUMFERENCE



d) FEMUR LENGHT



e) ESTIMATED FOETAL WEIGHT



LARGE FOETAL HEAD CIRCUMFERENCE OBSERVED ON THE THIRD-TRIMESTER ULTRASOUND, AS A PREDICTOR RISK FACTOR FOR HIGH DEGREE PERINEAL TRAUMAS DURING A VAGINAL DELIVERY.

ANNEX 3.3: Reference tables for gestational age by percentiles, used in the Hospital Clínic de Barcelona (68,69).

ABDOMINAL DIAMETER (in mm)						ABDOMINAL CIRCUMFERENCE (in mm)				
Week of gestation	5th	50th	95th	SD	SE	5th	50th	95th	SD	SE
12	14.5	18.1	21.8	2.23	0.3	45.3	56.6	67.9	6.88	0.9
13	17.9	21.9	25.8	2.38	0.3	56.1	68.2	80.3	7.36	0.9
14	21.4	25.5	29.7	2.53	0.2	66.9	79.8	92.7	7.83	0.8
15	24.8	29.2	33.6	2.68	0.2	77.6	91.3	105.0	8.31	0.7
16	28.2	32.9	37.5	2.83	0.2	88.3	102.7	117.2	8.78	0.7
17	31.6	36.5	41.4	2.98	0.2	98.8	114.0	129.3	9.26	0.7
18	34.9	40.1	45.2	3.13	0.2	109.3	125.3	141.3	9.73	0.7
19	38.2	43.6	49.0	3.28	0.2	119.7	136.4	153.2	10.21	0.7
20	41.5	47.1	52.8	3.43	0.2	129.9	147.5	165.1	10.69	0.7
21	44.7	50.6	56.5	3.58	0.2	140.1	158.5	176.8	11.16	0.7
22	48.0	54.1	60.2	3.73	0.2	150.2	169.3	188.4	11.64	0.7
23	51.1	57.5	63.9	3.88	0.2	160.1	180.0	200.0	12.11	0.7
24	54.3	60.9	67.5	4.03	0.2	169.9	190.6	211.3	12.59	0.7
25	57.4	64.2	71.1	4.18	0.2	179.6	201.1	222.6	13.06	0.7
26	60.4	67.5	74.7	4.33	0.2	189.2	211.5	233.7	13.54	0.8
27	63.4	70.8	78.2	4.48	0.3	198.7	221.7	244.8	14.01	0.8
28	66.4	74.0	81.6	4.62	0.3	208.0	231.8	255.6	14.49	0.8
29	69.3	77.2	85.0	4.77	0.3	217.1	241.7	266.3	14.96	0.8
30	72.2	80.3	88.4	4.92	0.3	226.1	251.5	276.9	15.44	0.8
31	75.0	83.4	91.7	5.07	0.3	235.0	261.1	287.3	15.91	0.8
32	77.8	86.4	95.0	5.22	0.3	243.6	270.6	297.6	16.39	0.8
33	80.5	89.4	98.2	5.37	0.3	252.2	279.9	307.7	16.86	0.9
34	83.2	92.3	101.4	5.52	0.3	260.5	289.0	317.6	17.34	0.9
35	85.8	95.1	104.5	5.67	0.3	268.7	298.0	327.3	17.81	0.9
36	88.4	97.9	107.5	5.82	0.3	276.7	306.8	336.9	18.29	1.0
37	90.9	100.7	110.5	5.97	0.4	284.5	315.4	346.2	18.77	1.1
38	93.3	103.4	113.4	6.12	0.4	292.1	323.8	355.4	19.24	1.2
39	95.7	106.0	116.3	6.27	0.4	299.5	332.0	364.4	19.72	1.3
40	98.0	108.5	119.1	6.42	0.5	306.8	340.0	373.2	20.19	1.5
41	100.2	111.0	121.8	6.57	0.5	313.8	347.8	381.8	20.67	1.6
42	102.4	113.4	124.5	6.72	0.6	320.6	355.3	390.1	21.14	1.8

BIPARIETAL DIAMETER (in mm)										
Week of gestation	5th	50th	95th	SD	SE	5th	50th	95th	SD	SE
12	17.0	21.0	25.0	2.43	0.2	59.7	72.1	84.5	7.6	0.9
13	20.8	24.9	29.0	2.50	0.2	73.3	86.1	98.9	7.8	0.8
14	24.5	28.7	32.9	2.56	0.2	86.7	99.9	113.1	8.0	0.7
15	28.2	32.5	36.8	2.63	0.2	99.9	113.5	127.0	8.2	0.6
16	31.8	36.2	40.6	2.69	0.2	112.9	126.8	140.7	8.5	0.6
17	35.3	39.9	44.4	2.76	0.2	125.6	139.9	154.2	8.7	0.6
18	38.8	43.5	48.1	2.82	0.2	138.1	152.7	167.4	8.9	0.6
19	42.2	47.0	51.7	2.89	0.2	150.2	165.2	180.3	9.1	0.6
20	45.6	50.4	55.3	2.95	0.2	162.1	177.5	192.9	9.4	0.6
21	48.8	53.8	58.8	3.02	0.2	173.6	189.4	205.2	9.6	0.6
22	52.0	57.1	62.2	3.08	0.2	184.9	201.0	217.1	9.8	0.6
23	55.1	60.3	65.5	3.15	0.2	195.7	212.2	228.7	10.0	0.6
24	58.1	63.4	68.7	3.22	0.2	206.2	223.1	240.0	10.3	0.6
25	61.1	66.5	71.9	3.28	0.2	216.4	233.6	250.9	10.5	0.6
26	63.9	69.4	74.9	3.35	0.2	226.1	243.7	261.3	10.7	0.7
27	66.6	72.2	77.8	3.41	0.2	235.5	253.4	271.4	10.9	0.7
28	69.2	74.9	80.7	3.48	0.2	244.4	262.7	281.1	11.2	0.7
29	71.7	77.6	83.4	3.54	0.2	252.9	271.6	290.3	11.4	0.7
30	74.1	80.1	86.0	3.61	0.2	260.9	280.0	299.1	11.6	0.7
31	76.4	82.5	88.5	3.67	0.2	268.4	287.9	307.3	11.8	0.7
32	78.6	84.7	90.9	3.74	0.2	275.5	295.3	315.1	12.1	0.7
33	80.6	86.9	93.1	3.80	0.2	282.1	302.2	322.4	12.3	0.7
34	82.5	88.9	95.3	3.87	0.2	288.1	308.7	329.2	12.5	0.7
35	84.3	90.8	97.3	3.93	0.2	293.6	314.5	335.5	12.7	0.8
36	86.0	92.6	99.1	4.00	0.2	298.6	319.9	341.2	13.0	0.8
37	87.5	94.2	100.9	4.06	0.2	303.0	324.6	346.3	13.2	0.9
38	88.9	95.7	102.5	4.13	0.3	306.8	328.8	350.9	13.4	0.9
39	90.1	97.0	103.9	4.19	0.3	310.0	332.4	354.8	13.6	1.0
40	91.2	98.2	105.2	4.26	0.3	312.6	335.4	358.2	13.9	1.2
41	92.1	99.2	106.3	4.33	0.4	314.6	337.7	360.9	14.1	1.3
42	92.9	100.1	107.3	4.39	0.4	315.9	339.4	363.0	14.3	1.5

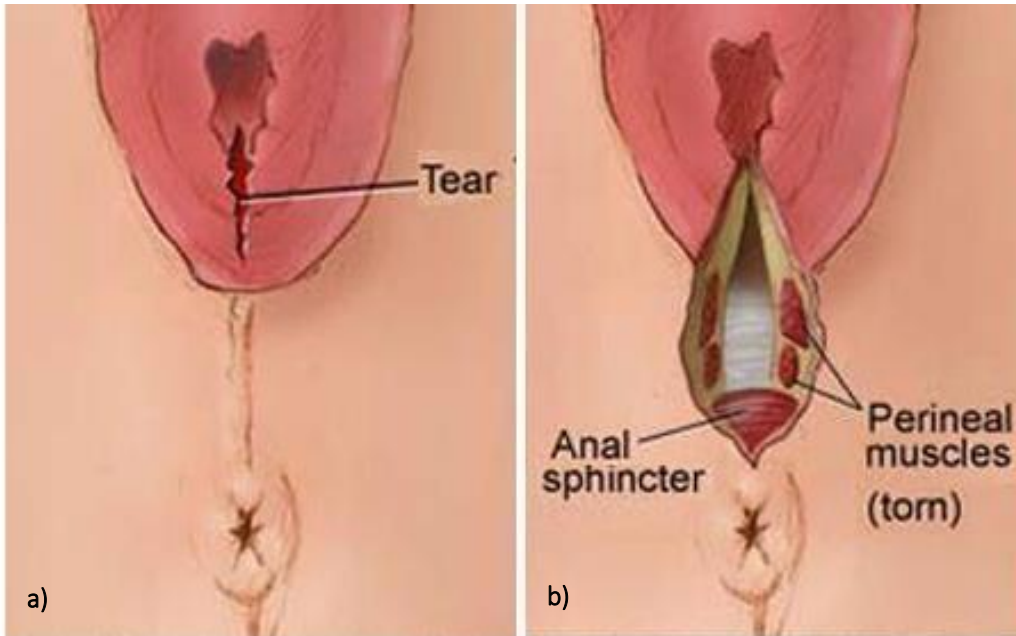
LARGE FOETAL HEAD CIRCUMFERENCE OBSERVED ON THE THIRD-TRIMESTER ULTRASOUND, AS A PREDICTOR
RISK FACTOR FOR HIGH DEGREE PERINEAL TRAUMAS DURING A VAGINAL DELIVERY.

FEMUR LENGTH (in mm)					
Week of gestation					
	5th	50th	95th	SD	SE
12	4.1	7.0	9.8	1.73	0.2
13	7.2	10.3	13.4	1.89	0.2
14	10.3	13.6	16.9	2.03	0.2
15	13.3	16.8	20.4	2.15	0.2
16	16.3	20.0	23.7	2.25	0.1
17	19.2	23.0	26.9	2.35	0.1
18	22.1	26.1	30.0	2.43	0.1
19	24.9	29.0	33.1	2.50	0.1
20	27.6	31.9	36.1	2.57	0.1
21	30.3	34.7	39.0	2.63	0.1
22	33.0	37.4	41.8	2.68	0.1
23	35.6	40.1	44.5	2.73	0.1
24	38.1	42.6	47.2	2.78	0.2
25	40.5	45.2	49.8	2.82	0.2
26	42.9	47.6	52.3	2.86	0.2
27	45.2	50.0	54.8	2.89	0.2
28	47.5	52.3	57.1	2.93	0.2
29	49.7	54.5	59.4	2.96	0.2
30	51.8	56.7	61.6	2.99	0.2
31	53.9	58.8	63.8	3.01	0.2
32	55.9	60.9	65.8	3.04	0.2
33	57.8	62.8	67.9	3.06	0.2
34	59.6	64.7	69.8	3.08	0.2
35	61.4	66.5	71.6	3.11	0.2
36	63.1	68.3	73.4	3.13	0.2
37	64.8	70.0	75.1	3.14	0.2
38	66.4	71.6	76.8	3.16	0.2
39	67.9	73.1	78.4	3.18	0.2
40	69.3	74.6	79.9	3.19	0.2
41	70.7	76.0	81.3	3.21	0.3
42	72.0	77.3	82.6	3.22	0.3

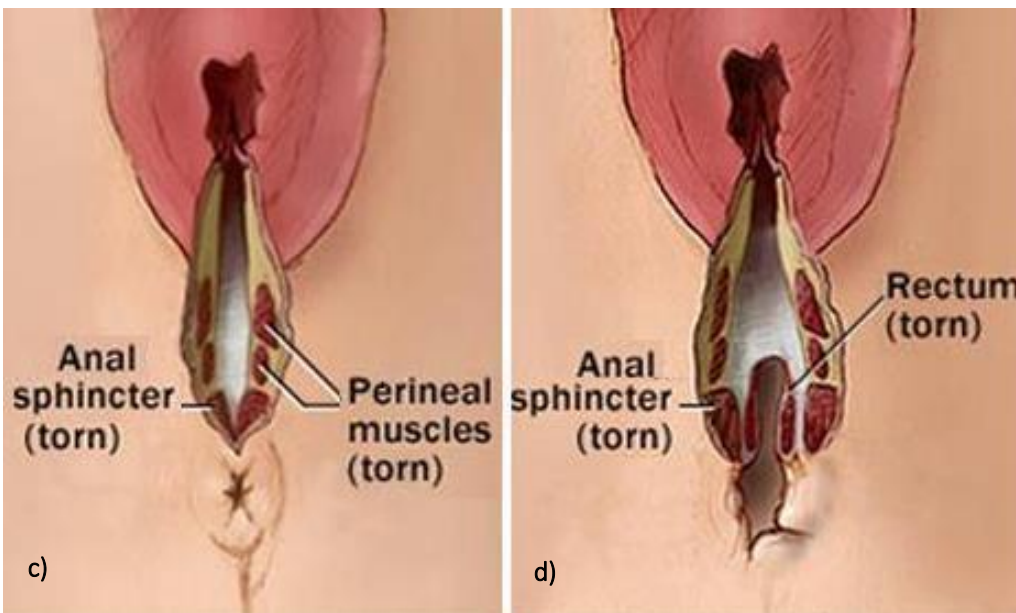
ANNEX 4 – TYPES OF PERINEAL TEARS ACCORDING TO SULTAN’S CLASSIFICATION

Schematic images of low and high degree perineal lacerations. *Adapted from (70).*


LOW DEGREE PERINEAL TEARS: a) first degree and b) second degree perineal tear.



HIGH DEGREE PERINEAL TEARS: a) third degree and b) fourth degree perineal tear.



ANNEX 5 – INFORMATION SHEET ABOUT PELVIC FLOOR REHABILITATION

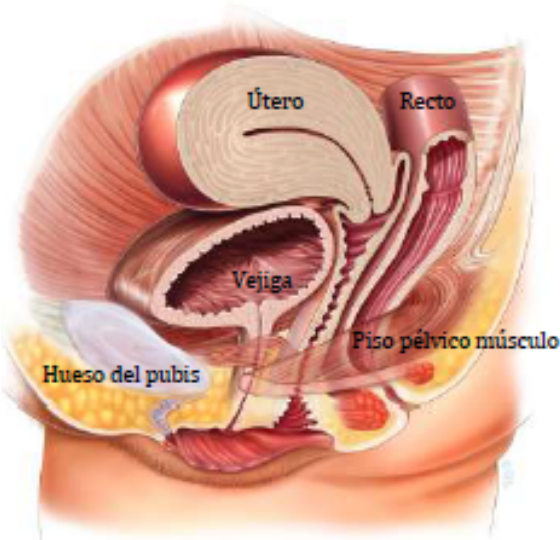
IUGA 
Internacional urogynecological association
Asociación Internacional de Uroginecología

Ejercicios de Piso Pélvico
Una guía para mujeres

1. ¿Qué es el Piso Pélvico?
2. ¿Qué es lo que hacen los músculos del piso pélvico?
3. ¿Qué pasa si mis músculos del piso pélvico están débiles?
4. ¿Qué debilita los músculos del piso pélvico?
5. ¿Cómo ejercitar sus músculos del piso pélvico?

¿Qué es el Piso Pélvico?

El piso pélvico está compuesto por una capa fina de fibras musculares y tejido conectivo asociado, que se extiende en el área por debajo de la pelvis, entre el hueso pubiano en la parte frontal, y el sacro ocoxis en la parte posterior (vea el diagrama más adelante).



¿Qué es lo que hacen los músculos del piso pélvico?

- ♦ Los músculos del piso pélvico se contraen cuando tose, estornuda o puja, ayudando a prevenir la pérdida involuntaria de orina.
- ♦ Ayudan a soportar los órganos intraabdominales, especialmente en posición de pie.
- ♦ Ayudan a proteger los órganos pélvicos de daño

externo.

- ♦ Ayudan a sostener los órganos pélvicos, como la vejiga, en una posición correcta.
- ♦ Ayudan a controlar el paso de la orina, gases y movimiento intestinal.
- ♦ Tienen un papel en la función sexual durante el coito.

A fin de poder cumplir bien su función, necesitan estar bien tonificados, tal como cualquier otro músculo del cuerpo.

¿Qué pasa si mis músculos de piso pélvico están débiles?

La debilidad de los músculos del piso pélvico puede causar o empeorar problemas como:

1. Incontinencia urinaria de esfuerzo. La queja de perder orina en forma involuntaria al esfuerzo físico, incluyendo actividades deportivas, o al estornudar o toser.
2. Incontinencia urinaria de urgencia. La queja de perder orina en forma involuntaria asociada al deseo urgente de orinar.
3. Incontinencia urinaria mixta. La queja de perder orina en forma involuntaria asociada a urgencia y también por esfuerzo o actividades físicas, o al estornudar o toser.
4. Prolapso de Organos Pélvicos. Conduce a un abultamiento hacia la vagina, producido por el descenso de la vejiga, el intestino o el útero, o incluso fuera de la vagina en casos más severos.
5. Pérdida de la sensibilidad sexual, o sensación de ensanchamiento vaginal.

¿Qué puede causar debilidad de los músculos del piso pélvico?

- ♦ Hipoactividad. Como pasa con todos los músculos, los músculos del piso pélvico necesitan ejercitarse para trabajar bien. El ejercicio intenso, regular y adecuado de los músculos del piso pélvico debería mantenerse durante toda la vida (no solo después de haber parido) y por lo tanto es muy importante.
- ♦ El daño a estos músculos durante el embarazo y el parto.
- ♦ El cambio hormonal asociado a la menopausia puede tener un papel en la debilidad de los músculos, pero aun es controversial.
- ♦ Disminución del tono debido a la edad.
- ♦ Daño a los músculos por esfuerzo sostenido en casos de estreñimiento, tos crónica u obesidad.

El papel de los ejercicios de piso pélvico

El ejercicio intenso y regular del piso pélvico ayuda tanto

a fortalecer como a relajar estos músculos pelvianos, de modo que se hacen firmes y de soporte, pero no hiperactivos. Muchas mujeres tendrán mejoría en la recuperación de los síntomas de incontinencia urinaria de esfuerzo al aprender efectivamente estos ejercicios, evitando así o retrasando la necesidad de una cirugía.

¿Cómo ejercitar sus músculos pelvianos?

Es importante aprender a hacer los ejercicios en la forma correcta, y evaluar de tiempo en tiempo que aun los está haciendo en forma correcta. Su terapeuta puede ayudarle a entenderlos utilizando diagramas, dibujos y modelos.

1. Siéntese cómodamente con sus pies y rodillas bien separadas. Reclínesse un poco hacia delante y coloque los codos sobre las rodillas. Recuerde respirar continuamente, y mantenga el estómago, glúteos y muslos relajados.
2. Imagine que está tratando de detener el paso de un gas intestinal y al mismo tiempo tratando de impedir el paso de orina desde la vejiga. Debería sentir que la vagina y el ano se elevan y se estrechan.
3. Observar los músculos puede ser una forma efectiva de verificar si están trabajando apropiadamente. Recuéstese cómodamente en la cama; coloque un pequeño espejo entre sus piernas, con sus rodillas dobladas y separadas. A medida que levanta el piso pélvico debería observar como el ano y la entrada vaginal se elevan y se recogen.

Si observa que la entrada vaginal se ensancha, usted está pujando en vez de elevar, lo cual es opuesto a contraer el músculo del piso pélvico. Igualmente, si pierde orina o deja pasar un gas cuando hace los ejercicios es probable que esté pujando hacia abajo y no halando hacia arriba.

Al principio puede ser que usted no pueda contraer y relajar adecuadamente, no se desanime. La mayoría de los pacientes aprenderán a contraer y relajar si se les da algún tiempo para practicar por sí mismos en casa.

¿Con qué frecuencia debería practicar?

Primero, determine su "punto de partida". Use su diario. Contraiga los músculos del piso pélvico al máximo sin utilizar sus glúteos, muslos o músculos abdominales, según se describió previamente. Mantenga contraído tantos segundos como pueda (hasta un máximo de 10 segundos).

Cuánto tiempo puede mantener la máxima contracción?
_____ segundos.

Deje de contraer y descanse durante el mismo tiempo que dure la contracción. Repita la secuencia de "contraer, mantener y relajar" tantas veces como pueda (hasta un

máximo de 8 - 12 repeticiones).

¿Cuántas veces puede repetir la contracción?
_____ veces (ej: 2 seg 4 veces)

Este se convierte en su "punto de partida". Repita su punto de partida 4 a 6 veces durante el día. Como resultado de este entrenamiento muscular, su piso pélvico se hará más fuerte y su "punto de partida" cambiará. Ej: 4 seg 6 veces.

Este se convierte en su nuevo "punto de partida". Este programa trabaja el fortalecimiento del grupo muscular. En otras palabras, el músculo será capaz de trabajar con más fuerza por más tiempo.

Ahora haga el ejercicio del piso pelviano, pero contraiga y eleve con mayor firmeza, luego suéltelo. Esto se conoce como una contracción rápida y ayudará a sus músculos a reaccionar rápidamente cuando se ría, tosa, se ejercite o levante cosas pesadas.

¿Cuántas contracciones puede hacer?

Trate de incrementar este número a 8-12 contracciones, 3 veces al día durante al menos 6 meses. Esa es la parte fácil. La parte más difícil del programa es recordar hacer los ejercicios!

Aquí hay algunos tips para estimular su memoria:

- Use su reloj en la muñeca contraria.
- Ponga identificadores o calcomanías en lugares que llamarán su atención (ej: el espejo en el baño, el teléfono, refrigerador, cafetera, el volante del auto).
- Ejercítese después de haber vaciado la vejiga.
- Ejercítese en cualquier posición.

¿Con qué rapidez verá los resultados?

Probablemente no sentirá que mejora el control sobre su vejiga sino hasta después de 3 a 6 semanas, incluso, pero tomar hasta 6 meses hasta lograr mejorar. **NO SE DESANIME!!**

Es importante mantener la fuerza de los músculos una vez que haya completado el programa de ejercicio. Practicando sus ejercicios dos veces a la semana, 3 series de 8-12 contracciones 3 veces al día debería ser suficiente. Trate de incorporar estos ejercicios en las actividades cotidianas. Si no está segura de hacer los ejercicios correctamente, pregúntele a su médico familiar, enfermera especializada o fisioterapeuta para que la controle.

¿Qué pasa si no puedo controlar los músculos de mi piso pélvico?

Si no es capaz de contraer sus músculos, el profesional de salud le puede sugerir algunos tratamientos adicionales.

Bioretroacción (Biofeedback)

El objetivo es ayudar a las mujeres a identificar y, contraer y relajar selectivamente los músculos del piso pélvico usando señales de su propio cuerpo. Sentir estos músculos con sus propios dedos es un ejemplo de esto. Otros métodos implican usar pequeños electrodos autoadhesivos colocados en el abdomen y área glútea o un transductor intravaginal o intrarectal conectado a un computador. La fuerza y duración de la contracción que realiza puede verla en la pantalla de su computador.

Terapia de Electroestimulación

Algunas veces no es posible contraer los músculos del piso pélvico debido a daño de los nervios, por ejemplo secundario al parto o después de cirugía. La electroestimulación proporcionará una contracción artificial de los músculos pelvianos, ayudando a fortalecerlos. Este método no es apropiado para las mujeres que pueden contraer los músculos de su piso pélvico aun si estas contracciones son débiles.

Puntos a recordar

1. La debilidad de los músculos del piso pélvico a menudo causa problemas vesicales.
2. Ejercicios diarios intensivos pueden fortalecer estos músculos y mejorar el control sobre la vejiga.
3. Pregúntele a su terapeuta si usted está contrayendo los músculos correctos.
4. Siempre apriete y contraiga sus músculos pelvianos antes de toser, estornudar, saltar o levantarse. Esto puede ayudar a prevenir la pérdida de orina, gases o heces, o el prolapso de órganos pélvicos.
5. Trate de mantener su peso dentro de límites saludables.



La información contenida en este folleto es para uso educativo exclusivamente. No debe utilizarse para el diagnóstico o tratamiento de patología médica alguna. Para estos fines consulte al personal médico calificado.

Traducido por Henrique Arnal B, M.D., Vanda López G, M.D., & Glenda Vervest
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Note: this information sheet has been provided by the Service of Obstetrics of the HJT and it is also available in English.

LARGE FOETAL HEAD CIRCUMFERENCE OBSERVED ON THE THIRD-TRIMESTER ULTRASOUND, AS A PREDICTOR RISK FACTOR FOR HIGH DEGREE PERINEAL TRAUMAS DURING A VAGINAL DELIVERY.

ANNEX 6 – RECOMMENDED MEASURES OF PRIMARY PREVENTION OF OASIS

	Spanish Guidelines (SEGO) (33)	British Guidelines (RCOG) (12,34)	Canadian Guidelines (SOGC) (22)
Head control	RECOMMENDED , performed simultaneously with hands-on technique by flexion method (Evidence 1+, recommendation B).	RECOMMENDED . It is performed simultaneously with hands-on technique , slowing down the head progression and instructing pregnant to not pushing when head is crowning (Evidence 2+, recommendation C).	RECOMMENDED . Tears risk decreases if foetal progression is slowed down (Evidence II, recommendation 2A).
Perineal protection	RECOMMENDED by hands on technique (flexion method) (Evidence 2+), with a reduction of pelvic pain and increment of episiotomies, compared with hands-poised technique. No differences in OASIS rates between both techniques (Evidence 1+, recommendation B).	RECOMMENDED by hands-on technique , with right hand protecting the perineum, left hand slowing down the head expulsion (Evidence 2+, recommendation C). No differences between Ritgen's and flexion manoeuvres (Evidence 1+).	NOT RECOMMENDED
Perineal massage	NOT RECOMMENDED ; it has not shown neither a reduction of OASIS rates nor vaginal pain nor dyspareunia nor the number of episiotomies (Evidence 1+, recommendation A).	NOT RECOMMENDED . It is an optional exercise done during the last month of pregnancy , but not an intrapartum preventive measure (Evidence 1-).	NOT RECOMMENDED
Warm compresses	RECOMMENDED as a possible choice during the second stage of labour. It reduces the OASIS risk, urinary incontinence (during the 3 first postpartum months) and intrapartum pain (evidence 1+), but it is not a preventive measure of perineal trauma (Evidence 2+) (recommendation A).	RECOMMENDED . It is performed during the second stage of labour by holding continuously a warm compress on perineum during and between contractions. It reduces the OASIS rates (Evidence 1++, recommendation A).	NOT RECOMMENDED
Restrictive mediolateral episiotomy	RECOMMENDED . Restrictive episiotomy has higher numbers of intact perineum, and less dyspareunia, need of reparation and pelvic pain. Routine incisions must not be used in women with previous OASIS (Evidence 1+, recommendation A). Mediolateral technique is preferred instead of lateral incision, and directed to the right sight with an angle of 45-60° (Evidence 3, recommendation D).	RECOMMENDED . When episiotomy is indicated, mediolateral incision is recommended, ensuring an angle of 45-60° away from the midline (Evidence 3, recommendation D). Mediolateral episiotomy should be considered in operative deliveries (Evidence 2-, recommendation D).	RECOMMENDED . Restrictive incision is recommended (Evidence I, recommendation A), by mediolateral method and an angle of 45-60° (Evidence II, recommendation 2B).
Pushing position	NOT RECOMMENDED . Vertical and lateral positions have less duration of second stage of labour, assisted deliveries, episiotomies and acute pain. Sitting position protects from OASIS (Evidence 1+). Pregnant should choose the most comfortable position (Recommendation A).	NOT RECOMMENDED	NOT RECOMMENDED because of lack of evidence. Women have to adopt the most comfortable position .
Type of instrumental delivery	RECOMMENDED . When an assisted delivery is indicated, vacuum is preferable rather than forceps, if and when obstetric conditions allow it (Evidence 1+, recommendation A).	NOT RECOMMENDED . When an assisted delivery is indicated, vacuum is preferable rather than forceps if and when obstetric conditions allow it (Evidence 1+). It has no level of recommendation due to all the rest of factors that influence to the decision of using vacuum.	RECOMMENDED . OASIS is more frequently associated with forceps than with vacuum use (Evidence II-2).
Pelvic floor rehab (Kegel exercises)	RECOMMENDED as secondary prevention ; BUT NOT as primary prevention . Pelvic floor rehabilitation by Kegel exercises is an optional measure, performed from 6-12 weeks of the perineal trauma (Evidence 2+, recommendation D).	RECOMMENDED as secondary prevention ; NOT RECOMMENDED as primary prevention . Women with OASIS should be informed of the benefits of physiotherapy activities (Kegel exercises or biofeedback therapy) (Evidence 1+, recommendation v ¹⁰).	NOT RECOMMENDED
Pushing factors	RECOMMENDED . Spontaneous pushing is preferred instead of directed pushing, as it causes less urgent urinary incontinence. Delayed pushing leads to longer duration of second stage of labour but shorter duration of active pushing period and less risk of assisted deliveries. (Evidence 1+, recommendation A).	NOT RECOMMENDED	NOT RECOMMENDED
Local anaesthetic	NOT RECOMMENDED - It does not reduce the perineal pain (Evidence 1+, recommendation A).	NO RECOMMENDED	NO RECOMMENDED

¹⁰ **Recommendation v** is based on clinical experience and consensus of redactor team, but there is not any scientific evidence. It is a good clinical practice recommendation.

ANNEX 7 – INFORMATIVE LEAFLET DELIVERED TO WOMEN

Seguiment i actitud postpart

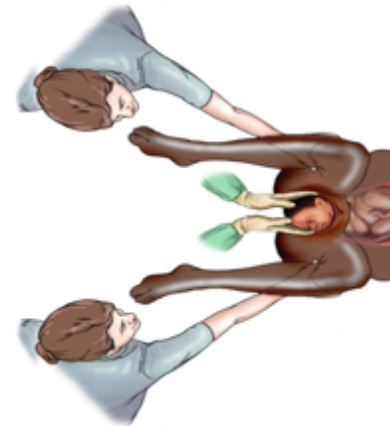
El doctor li explicarà, abans que marxi d'alta hospitalària, en què consistirà el **seguiment que ha de fer** per controlar la curació de la ferida.

Peł que fa la següent vegada que vostè es quedi embarassada, si la ferida està completament curada i no té cap símptoma residual, podrà tenir un **part vaginal sense problemes**. Per contra, si encara té simptomatologia d'incontinència o no té la ferida ben curada, **se li oferirà la cesària electiva**.

Hospital de Girona Doctor Josep Trueta;
Servei de Ginecologia i Obstetrícia
Avinguda de França 5/N, 17007, Girona

Estrip perineal durant el part vaginal

Informació bàsica per dones embarassades.



Servei de Ginecologia i Obstetrícia

Classificació dels estrips:

- **Primer grau:** estrips petits i poc profunds que curen espontàniament.
- **Segon grau:** estrips més profunds que afecten els músculs i la pell perineal.
- **Tercer grau:** estrips que s'estenen cap a l'esfínter anal, que és el múscul que controla l'anús.
- **Quart grau:** estrips que s'estenen cap al canal anal i recte, estructures situades més profundament en l'anús.

Què és un estrip perineal?

Algunes dones pateixen un estrip durant el part vaginal, ja que **la sortida del nen expandeix el teixit de la vagina**. La majoria dels estrips ocorren en la zona del **perineu**, localitzada entre l'obertura vaginal i l'anús.

Els estrips petits, es coneixen com a **baix grau**, i comprenen els estrips **de 1r i de 2n grau**. Els estrips més profunds i grans comprenen els estrips **de 3r i 4t grau** i formen part del grup considerat **d'alt grau**. Els de **1r grau curen sols**, però la resta necessitaran ser suturats.

L'**episiotomia** és una incisió feta durant el part per tal d'eixamplar l'obertura vaginal i facilitar la sortida del nadó, i és causant també d'estrips.

Què són els estrips de 3r i 4t grau?

Els dos tipus impliquen una **afectació de l'esfínter anal**, que és un múscul s'encarrega de controlar l'anús. En el cas d'un estrip de 4t grau, l'estrip s'estén a més cap a l'epiteli de l'anús o recte.

Són comuns els estrips de 3r i 4t grau?

Aproximadament, cada **3 de 100 dones** que tenen un part vaginal, patiran un estrip.

Els estrips perineals **no es poden predir**, però factors com **pes del nadó major de 4 kg, edat materna major de 30 anys, primer part vaginal, episiotomia i necessitat d'un part instrumentat** (utilització d'instruments per eixamplar el canal de part i ajudar la sortida del nen), n'augmenten el risc.

Quines conseqüències té un estrip d'alt grau?

Els estrips de 3r i 4t grau impliquen:

- **Dolor al perineu**
- **Por** alhora de tenir **sexe**
- **Sensació de poca continència** urinària o fecal, o bé sensació **d'haver de córrer cap al lavabo** per evitar que s'escapi l'orina o la femta.

Què passa si pateixo un estrip durant el part?

Immediatament després del part, l'obstetra o bé la comadrona **examinaran la seva zona perineal i l'anús**. Si detecten un estrip, el doctor li explicarà **com ho repararà i utilitzarà un anestèsic i un antibiòtic** per prevenir el dolor i possible infecció de la zona.

I què passa un cop acabada la reparació?

Els següents dies, durant la recuperació, el doctor li prescriurà **analgèsics** (paracetamol, ibuprofeno o diclofenac) per alleujar el dolor de la zona, **antibiòtic** per reduir el risc d'infecció de la ferida i finalment, li recomanarà una **dieta laxant** o, fins i tot, li prescriurà algun **laxant**, per tal de facilitar la defecació.

Un cop el doctor comprovi que vostè ha pogut **defecar sense problemes i que la curació de la ferida evoluciona correctament**, serà donada d'alta i podrà tornar a casa.

I què més haig de fer per accelerar la curació de la ferida?

El més important és **beure 2 o 3 litres d'aigua al dia** i fer una **dieta laxativa**. A més, haurà d'**evitar grans esforços i mantenir l'àrea perineal neta** per mitjà d'almenys una dutxa diària i freqüent rentat de mans. També hauria de començar a fer els **exercicis de sòl pelvià** tan aviat com li sigui possible. 60-80% de les dones, al cap de 12 mesos, estan totalment recuperades.

Podré donar el pit?

Sí, ja que cap dels tractaments que vostè rebrà ho contraindiquen.

Note: we decided to create this leaflet in Catalan, but the hospital disposes of a translator that would redact it in Spanish, French or English if required.

ANNEX 8 – ASSESSMENT IN A CONTROL CITATION

ANNEX 8.1: Questionnaire about symptoms of incontinence. *Adapted from (33).*

- Have you experienced any involuntary loss of solid stools?
- Have you experienced any involuntary loss of liquid stools?
- Have you experienced any involuntary loss of flatus?
- Do you have an incontrollable urge to defecate, with fear of presenting an involuntary loss of stools?
- Have you experienced pain when you defecate?

ANNEX 8.2: Modified Oxford grading scale for the evaluation of pelvic floor strength by vaginal tact. *Adapted from (71).*

DEGREE	MUSCULAR RESPONSE	
0/5	No contraction	Lack of muscle response.
1/5	Flicker	Flicker of non-sustained contraction.
2/5	Weak	Presence of low intensity, but sustained, contraction.
3/5	Moderate (with lift)	Moderate contraction, felt like an increase in intravaginal pressure, which compresses the fingers of the examiner with small cranial elevation of the vaginal wall.
4/5	Good (with lift)	Satisfactory contraction, compressing the fingers of the examiner with elevation of the vaginal wall towards the pubic symphysis.
5/5	Strong (with lift)	Strong contraction, firm compression of the examiner's fingers with positive movement towards the pubic symphysis.

ANNEX 9 – CASE REPORT FORM

Patient identification code: _____		Date: _____
CLINICAL HISTORY DATA		
Type of pregnancy*: singleton <input type="checkbox"/> multiple <input type="checkbox"/> .		
<i>Note: only women with a singleton gestation will be included into the study, so in case of multiple gestation, there is no need to continue filling the case report sheet.</i>		
Maternal age: _____ years.		
Last menstrual period (LMP): ___/___/20___		
Ethnicity: Caucasian <input type="checkbox"/> Black African <input type="checkbox"/> Asiatic <input type="checkbox"/> Maghrebi <input type="checkbox"/> South-American <input type="checkbox"/> Other <input type="checkbox"/>		
Diabetes: yes <input type="checkbox"/> no <input type="checkbox"/> .		
If <u>yes</u> : Pre-gestational <input type="checkbox"/> Gestational <input type="checkbox"/> .		
Body mass index (BMI): <input type="checkbox"/> Underweight (IMC < 18.5 29.9 kg/m ²)		
<input type="checkbox"/> Normal weight (IMC 18.5 – 24.9 kg/m ²)		
<input type="checkbox"/> Overweight (IMC 25 – 29.9 kg/m ²)		
<input type="checkbox"/> Obesity (IMC ≥30 kg/m ²)		
Presence of previous pelvic floor problems*: yes <input type="checkbox"/> no <input type="checkbox"/> .		
<i>Note: if women have had previous pelvic floor problems, they will be excluded of the study, so the case report form does not need to be filled.</i>		
THIRD-TRIMESTER ULTRASOUND DATA		
Gestational age: _____ weeks and _____ days.		
Head circumference: _____ cm, belonging to the _____ th percentile according to the reference table of Hospital Clínic de Barcelona.		
Cephalic presentation*: yes <input type="checkbox"/> no <input type="checkbox"/> . Head position: vertex <input type="checkbox"/> non-vertex <input type="checkbox"/>		
<i>Note: only women with a cephalic presentation of their foetus will be able to participate in our research. In case of non-cephalic presentation, there is no need to continue filling the case report sheet.</i>		
Weight estimation: _____ grams.		
INTRAPARTUM DATA		Date of birth: ___/___/20___
Gestational age*: _____ weeks and _____ days		
<i>Note: women have to deliver between the period comprised in 37 completed weeks and 42 completed weeks of gestation. If they have childbirth before or after this time period, they are not going to be included into our study, so there is no need to continue filling the case report sheet.</i>		
Prolonged second stage of labour: yes <input type="checkbox"/> no <input type="checkbox"/> .		
Induction/maturation of labour: yes <input type="checkbox"/> no <input type="checkbox"/> .		

ASSISTANCE OF CHILDBIRTH

Epidural anaesthesia: yes no .

Delivery assistant: obstetrician midwife

Delivery method:

- Vaginal delivery: eutocic operative .
 - o *If operative, indicate the instrument used:*
Forceps vacuum spatulas .
- Unplanned caesarean section for failure to progress: present absent .

Episiotomy: yes no .

- Protective perineal measures:
- Head control
 - Perineal protection
 - Perineal massage
 - Application of warm compresses
 - Delivery position
 - Pelvic floor rehabilitation

Shoulder dystocia: yes no .

POSTPARTUM DATA

INFANT DATA

Weight at birth: _____ grams. Head circumference at birth: _____ cm.

PERINEAL TRAUMA

Perineal trauma: yes no . If yes, tick the degree of it:

- | | | |
|--|--------------------------|---|
| GROUP: absence of a high degree perineal trauma | <input type="checkbox"/> | Button-hole injury |
| | <input type="checkbox"/> | 1 st degree |
| | <input type="checkbox"/> | 2 nd degree |
| GROUP: presence of a high degree perineal trauma | <input type="checkbox"/> | 3 rd degree; circle the subgroup: 3a / 3b / 3c |
| | <input type="checkbox"/> | 4 th degree |

Obstetrician responsible of fulfilling the case report form: _____

Number of collegiate: _____

Signature:

ANNEX 10 – CLASSIFICATION OF THE OBSTETRIC RISK AT THE DELIVERY PERIOD

Classification of pregnant women at the delivery period according to their obstetric risk (72).	
LOW RISK	
All the gestations in which none of the below-mentioned risk factors can be demonstrated.	
MEDIUM RISK	
<ul style="list-style-type: none"> - Pelvic anomalies - Short height (<1,45 m) - Pregnant woman younger than 17 years - Pregnant woman older than 38 years - Obesity - Rh negative gestation - Habitual smoker - Unfavourable socioeconomic conditions - Previous sterility (> 2 years) - Lower urinary tract infection or asymptomatic bacteriuria - Suspected macrosomia (4000 – 45000 grams) 	<ul style="list-style-type: none"> - Intergenic period lower than 12 months - Occupational risk - Risk of sexually transmitted diseases (STD) - Insufficient control of the gestation (< 5 visits) - Unwanted pregnancy - Metrorrhagias of the first trimester - Grade I of cardiopathy according to NHYA - Excessive increments or insufficient gains of weight - Meconium-stained amniotic fluid - Gestational diabetes without administration of insulin
HIGH RISK	
<ul style="list-style-type: none"> - Severe anaemia (Hb <9 g/dl or HCT <25%) - Twins - Morbid obesity (IMC >40 kg/m²) - Grade II of cardiopathy according to NHYA - Maternal infection (toxoplasmosis, rubella, syphilis and cytomegalovirus when there is evidence of foetal infection; active simple genital herpes, pyelonephritis during childbirth and HIV, hepatitis B/C) - Unfavourable obstetric history (abortions, premature delivery, new-born of <2500 grams, postpartum haemorrhage) 	<ul style="list-style-type: none"> - Suspected foetal malformation - Endocrinopathy (hypophysis, thyroid and suprarenal glands). - Gestational diabetes with administration of insulin - Previous uterine surgery (included caesarean) - Mild preeclampsia / hypertension disorders - Prolonged gestation (>42 weeks) - Suspected macrosomia (>4500 g) - Placenta abruption - Oligohydramnios or polyhydramnios - Preterm rupture of the membranes
VERY HIGH RISK	
<ul style="list-style-type: none"> - Multiple gestation (≥ 3) o monoamniotic twins - Uterine malformation - Recurrent perinatal death - Serious systemic or mental pathology associated - Addiction to drugs or alcohol - Isoimmunization (direct coombs positive) - Pre-gestational diabetes (types 1 and 2) - Hereditarian disease with risk of affectation to the new-born 	<ul style="list-style-type: none"> - Cervical or uterine insufficiency - Confirmed foetal malformation - Intrauterine growth restriction (IGR) - Placenta praevia - Severe preeclampsia - Threatened premature delivery (>32 weeks) - Ruptured membranes in a preterm pregnancy (<32 weeks) - Risk of thromboembolism

NHYA: New York Heart Association; HCT: haematocrit.

ANNEX 11 – SUMMARY OF PERINEAL TRAUMA

PREVENTION MEASURES

ANTENATAL MEASURES:

- Perineal massage
- Pelvic floor exercises

SECOND STAGE IN LABOUR MEASURES:

- Restrictive mediolateral episiotomies with an angle of 45-60 degrees from the midline
- Slow down the progress of foetal head expulsion
- Perineal protection by hands-on technique
- Intrapartum perineal massage
- Application of warm compresses into the perineum
- Vacuum extractor over forceps when instrumental delivery is indicated, if possible

TEAR CLASSIFICATION AND REPARATION

- **FIRST DEGREE TEAR:** involvement of perineal skin only.
Reparation: if wound is not apposed/haemostatic or women's preference to reduce pain.
- **SECOND DEGREE TEAR (AND EPISIOTOMY):** involvement of perineal muscles but not the anal sphincter (AS).
Reparation: use of dissolvable sutures, using a continuous and nonlocking technique for all layers, with a subcuticular suture for skin. Pain relief has to be offered (paracetamol).
- **THIRD DEGREE TEAR:** involvement of <50% of external AS (EAS) thickness torn (**3a**), >50% of EAS thickness torn (**3b**) or both internal (IAS) and external AS thickness torn (**3c**).
- **FOURTH DEGREE TEAR:** involvement of anal sphincter complex (IAS and EAS) and anal epithelium/rectal mucosa.
Reparation (3rd and 4th): done by an expert under anaesthetic, using overlapping or end-to-end techniques and repairing EAS and IAS separately with interrupted sutures. Pain relief has to be offered (paracetamol) and knots have to be buried to avoid its migration.

PERINEAL TRAUMA

POSTPARTUM PERINEAL ASSESSMENT

VAGINAL INSPECTION: periurethral area, labia, vaginal walls, extent of tear, absence of anal puckering.

VAGINAL EXAM: introduce index and third fingers into vagina, separate walls, sweep downwards, check cervix, vaginal vault/walls/floor and posterior perineum.

RECTAL EXAM: place index finger into anus and, while women squeeze, the ends of anal sphincter retract and a gap is felt anteriorly. If unable to squeeze, digital palpation by index placed into anus and thumb into vagina, to check inconsistencies of anal sphincter thickness.

CLINICAL CONSEQUENCES

Short term: perineal pain, bruising, oedema, infection or wound breakdown
Long term: sexual dysfunction, dyspareunia, persistent pelvic pain and anal and urinary incontinences.

POSTNATAL PERINEAL CARE

ALL PERINEAL INJURIES:

- Daily inspection
- Apply cool packs
- Offer regular oral analgesia (AINE)
- Educate women for self-care: perineal hygiene, signs of infection or dehiscence of the wound, positions to reduce oedema, pelvic floor exercises
- Advice if they experience dyspareunia, sexual dysfunction, anal or urinary incontinences or pelvic pain
- Control citation in 6-12 weeks (transperineal/transvaginal ultrasound).

ADD FOR SEVER DEGREE TEARS:

- Administration of prophylactic antibiotics (via intravenous and then oral)
- Laxatives during at least 10 days after birth
- Advice of morbidity risks, benefits of follow-up and options in subsequent deliveries
- Control citation in 6-12 weeks (transperineal/transvaginal ultrasound) and, depending on the incontinence symptomatology, after 6 months of OASIS (endoanal ultrasound and manometry/electrophysiological test).
- Advice if they experience dyspareunia, sexual dysfunction, anal or urinary incontinences or pelvic pain.

**LARGE FOETAL HEAD CIRCUMFERENCE OBSERVED ON THE THIRD-TRIMESTER ULTRASOUND, AS A PREDICTOR
RISK FACTOR FOR HIGH DEGREE PERINEAL TRAUMAS DURING A VAGINAL DELIVERY.**