Protocols in Maternal Foetal-Medicine

INDUCTION OF LABOUR AND CERVICAL RIPENING

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1. INTRODUCTION

1.1. Definitions

- Induction of Labour (IOL) is a procedure aimed at triggering uterine contractions leading to a vaginal delivery.
- Cervical ripening methods aim to ease and stimulate the processes of softening, effacement and early dilation of the cervix in cases where the cervix is considered unfavourable for IOL.

1.2. Information to patients

Induction of labour is generally a very safe medical procedure, although not exempt from potential complications, and should be performed:

1. When there is a clear medical indication.

2. With informed consent and after having informed the mother and her partner and thoroughly discussed with them:

- The indication for IOL and the benefits and risks of this intervention.
- Options for pain management during the process.
- The expected success rate, including the need for caesarean section in certain circumstances.
- Alternative management options.

1.3 Risks associated with induction of labour

- According to several randomised clinical trials, the risk of caesarean section after induction of labour is not increased.
- When compared to spontaneous onset of labour, induction of labour can be associated with a higher rate of uterine hyperstimulation with or without alterations in foetal heart rate, meconium aspiration syndrome, uterine rupture and cord prolapse after amniorrhexis. These risks are reduced or avoided with the use of mechanical methods for cervical ripening and adequate use of oxytocin dosages.
- In women with previous caesarean section and/or uterine overdistension (multiple pregnancies, polyhydramnios, grand multiparity and macrosomia), special caution should be taken due to the risk of uterine rupture, but it is uncertain whether these risks are intrinsic to or associated with the induction.

1.4 Contraindications for induction of labour

Situations that contraindicate vaginal delivery constitute a contraindication for induction of labour. In our setting, the most common situations are the following:

Past history of:

- 2 or more caesarean sections
- 1 or more non-segmental or inverted T-incision caesarean section

- Myomectomy with entry into the uterine cavity
- Uterine rupture

Current pregnancy:

- Transverse lie position of a single foetus
- Complete placenta previa or vasa previa
- Severe placental insufficiency: foetal growth restriction stage II or more.
- Active genital herpes.

1.5. Hamilton manoeuvre

For women after 40 weeks, the Hamilton manoeuvre (i.e. membrane sweep) should be offered, as it can potentially decrease induction rates. The contraindications of this procedure are the same as those for vaginal delivery. Before performing the technique, the patient should be informed of the possible discomfort and/or self-limited bleeding that can happen during or after the procedure.

1.6. Evaluation before cervical ripening or induction with oxytocin

- Review the patient's clinical and obstetric history and rule out contraindications for vaginal delivery.

- The patient should be thoroughly informed about the process and an informed consent should be obtained for the planned method of cervical ripening.

- Assess the pelvis and foetal size for signs suggesting cephalopelvic disproportion.

- Assess and record obstetric presentation and cervical conditions (Bishop Score).

- Check the status of the amniotic membranes (intact or ruptured).

- Baseline CTG for 20-30 minutes to confirm foetal well-being.

1.7. Evaluation of criteria for cervical ripening prior to induction with oxytocin

Most patients undergoing IOL will require cervical ripening prior to induction of labour. The decision is made as per vaginal examination and Bishop score at the time of initiating IOL:

- Bishop = < 6 (see Table 1): the cervix is considered unfavourable or unripe; there is an indication for cervical ripening.
- Bishop is > 6: IOL can be directly initiated.

Table 1: Bishop Score

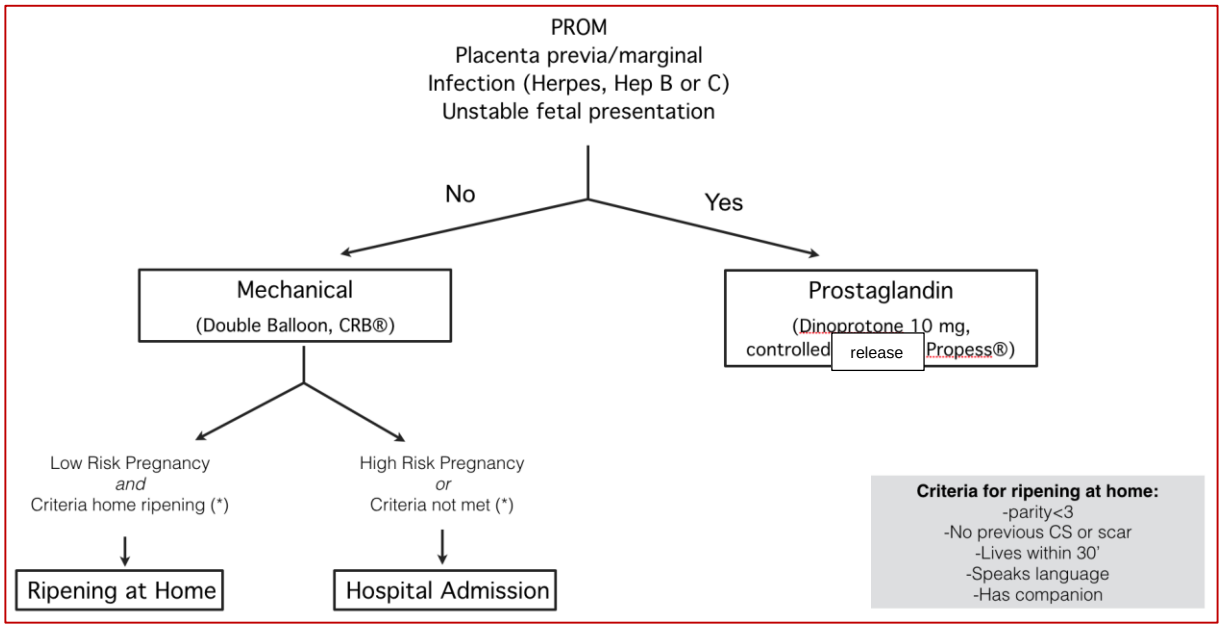
Score	0	1	2	3
Cervical position	Posterior	Midline	Anterior	--
Consistency	Firm	Medium	Soft	--
Length Effacement	3cm 0-30%	2cm 40-50%	1cm 60-70%	Effaced >70%
Dilation	0 cm	1-2 cm	3-4 cm	>4 cm
Hodge plane	free	I-II	III	IV

2.2. Methods of cervical ripening

There are two methods of cervical ripening considered in this protocol:

- **Mechanical cervical ripening**, using a double balloon (CRB®). See **Annex 1** for instructions on insertion and use.
- **Pharmacological cervical ripening**, using a prostaglandin (dinoprostone) controlled-release device. See **Annex 2**.

Cervical ripening can be performed as an outpatient or inpatient procedure, according to the following algorithm:



2.4. Failed cervical ripening

Cervical ripening is considered failed when the cervical conditions remain unfavourable (Bishop= < 6) after 12 hours.

The decision as to whether to continue inducing labour with oxytocin or perform a caesarean section will be discussed with the parents, assisted by the following risk estimations:

Primiparous

- Height < 155cm: risk of CS 75%
- Otherwise: risk of CS 50%

Multiparous:

- Height < 162 and previous CS: risk of CS 90%
- Estimated Foetal Weight (EFW) > 3500 and Bishop= < 2: risk of CS 70%
- Rest of situations: risk of CS 50%

3. INDUCTION OF LABOUR

Labour may be induced after cervical ripening or directly if Bishop score is ≥ 6. The goal is to achieve uterine contractions lasting 60-90 seconds, every 2-3 minutes.

3.1. General considerations

- When technically possible, artificial amniorrhexis will be performed. Exceptions: high foetal presentation or high risk of infection (e.g. GBS, HIV, etc.). FHR should be monitored before and immediately after the procedure.
- Epidural analgesia can be administered at any time on maternal request if this is the preferred option. There is no need to delay the epidural until certain cervical conditions are reached.
- In women without epidural anaesthesia, fasting is not necessary during labour induction.
- An internal pressure catheter is normally not used. It may be used in exceptional situations if there is a very high risk of uterine rupture (previous caesarean section, short interval between pregnancies, intention of vaginal delivery with personal history of 2 caesarean sections).

3.2. Dosage of oxytocin:

- Preparation: 10 IU oxytocin in 1000ml saline solution or Ringer's solution, or 5 IU in 500ml. Final concentration of 10 mU/ml.
- Must be administered with an infusion pump to allow precise dosing.
- Starting dose: 1 mU/min (6 ml/h).
- Uterine response to oxytocin infusion starts 3-5 minutes after initial doses and the oxytocin reaches a stable plasma concentration 20-30 minutes later. After this time, the dose can be increased as required to obtain adequate uterine activity.
- Use the minimum effective dose to achieve uterine contractility and labour progression with reassuring foetal heart rate (FHR) pattern.
- FHR and uterine contractions should be assessed and documented with each dose increase.
- When oxytocin is discontinued, plasma concentration decreases rapidly (half-life 5-12 min).

3.3. Potential complications of oxytocin infusion

3.3.1. *Uterine hyperstimulation:*

Polysystolia or hypertonia can cause uteroplacental hypoperfusion and foetal hypoxia, lead to uterine rupture or placental abruption, precipitous labour and postpartum haemorrhage due to uterine atony.

Therapeutic measures to control hyperstimulation are as follows:

- Stop oxytocin infusion
- Place the patient in left lateral decubitus
- If hyperstimulation persists, Ritodrine should be administered intravenously at a uterine inhibitory dose (60 ml/h=200mcg/min).

3.3.2. Uterine rupture:

The first sign of uterine rupture is usually a marked and abrupt decrease in FHR, uterine atony and loss of foetal presentation height. In patients without epidural, it is accompanied by acute pain (in some cases referred to the shoulder). Bleeding of variable intensity may be present.

3.3.3. Water intoxication and other complications:

- Oxytocin has antidiuretic properties, so when infused in high doses (more than 30 mU/min, 180 ml/h) for prolonged periods of time and when mixed with hypotonic solutions, it can produce symptomatic hyponatremia, and eventually convulsions, coma, heart failure and even death.
- Rapid IV administration of undiluted oxytocin should be avoided as it can produce severe cardiovascular effects (hypotension).
- Given that it contains ethanol as an excipient, it should be administered carefully in patients with liver disease, alcoholism, epilepsy, etc.

3.3.4. Labour dystocia:

Defined as being once the active phase of labour has begun (≥ 4 cm of cervical dilation) and with adequate uterine contractility (3 contractions/10 minutes or 200-225 MU in a 10-minute period), there is NO change in obstetric conditions:

- After 2 hours without epidural analgesia
- After 3 hours with epidural analgesia

3.3.5. Failed induction of labour

Defined as being when, 12+/-hours after the start of the induction process and adequate uterine contractility (3 contractions/10 minutes or 200-225 MU in a 10-minute period), the cervical conditions do not progress to active phase of labour conditions (≥ 4 cm of cervical dilation).

4. SPECIAL SCENARIOS:

4.1 Previous c-section

- Induction of labour in these patients increases the risk of uterine rupture (approximately up to 2%) and emergency caesarean section. However, vaginal delivery after caesarean section can prevent the short and long-term complications associated with iterative caesarean sections.

-The risk of rupture will depend on whether the onset of labour is spontaneous or induced, the method of induction and the use of oxytocin:

- spontaneous onset of labour: 0.4-0.5%
- spontaneous onset of labour + oxytocin: 0.9-1.4%
- oxytocin induction of labour 1.1-2.2%
- cervical ripening with PGE2 +/- oxytocin 0.9-1.4%
- double balloon induction +/- oxytocin 0.9%.

- Failure to progress or prolonged labour is associated with an increased risk of uterine rupture.

- Epidural analgesia does not mask the signs and symptoms of uterine rupture. Suspected uterine rupture is an indication for emergency caesarean section due to its associated maternal and foetal risks.

- In the postpartum, no systematic examination of the uterine scar is necessary. If signs of suspected uterine rupture are present after vaginal delivery, a digital examination of the scar and ultrasound assessment searching for hemoperitoneum should be performed. In the case of suspected uterine scar dehiscence, laparoscopy for the diagnosis and eventual repair can be considered.

- Labour induction time with oxytocin should not exceed 8 hours.

4.2 Multiple pregnancies

- There are no specific guidelines on induction of labour in multiple pregnancies.

- Precautions should be similar to single pregnancies, but taking into account that there is a higher risk of uterine rupture.

-Cervical ripening can be performed with a double balloon or dinoprostone controlled-release device.

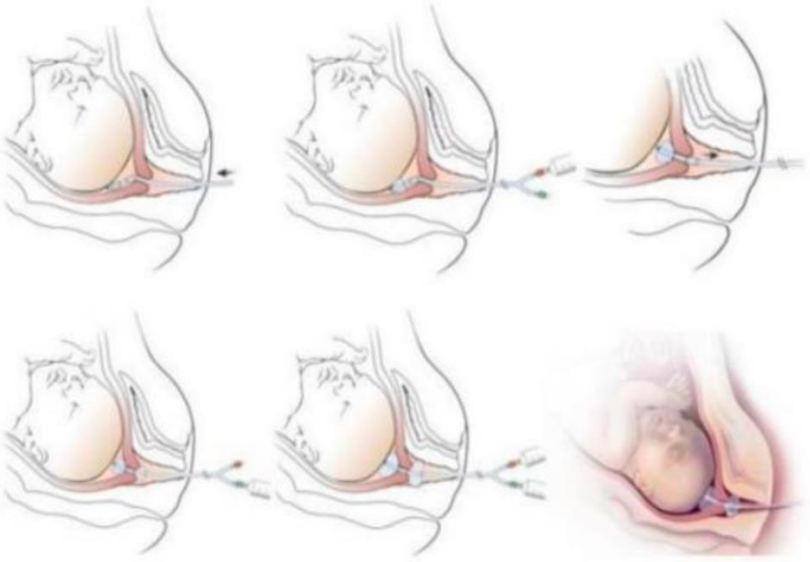
ANNEX 1. MECHANICAL CERVICAL RIPENING WITH DOUBLE BALLOON (CRB®)

The double balloon (CRB®) used for mechanical cervical ripening consists of a silicone catheter with a double balloon at the distal end. It has three lumens that allow the insertion of a malleable guidewire to aid placement in cases with less favourable cervical conditions. See **Annex 1** for insertion instructions.

The main advantage of the mechanical method is the low rate of uterine stimulation, improving the safety profile and therefore allowing the spacing out of foetal monitoring.

Possible complications and adverse effects associated with mechanical cervical ripening
Patient discomfort, with low tolerance to the insertion or presence of the balloon
Exclusion criteria for the use of cervical balloon
- PROM - Marginal insertion of the placenta (less than 20mm from Internal Cervical Os) - Active maternal infections (genital herpes, HVB, HCV) - Unstable foetal presentation *PROM: premature rupture of membranes, HBV: hepatitis B virus, HCV: hepatitis C virus.

INSTRUCTIONS FOR INSERTION AND USE OF THE CRB® DOUBLE BALLON



- Perform an abdominal ultrasound to assess foetal position and presentation.
- Place the patient in lithotomy position and view the cervix with a speculum.
- Sterilize the vagina with aqueous chlorhexidine.
- (If the woman has a poor tolerance to vaginal examination, it is possible to carry out vaginal asepsis without a speculum and then introduce the balloon manually, but it is more difficult).

- Advance the tip of the balloon through the cervical os into the endocervical canal using the guidewire included. If difficult, forester forceps or similar can be used.
- Introduce both balloons through the cervical os just until the vaginal balloon is no longer visible.
- **Step one: inflate the intrauterine balloon** first with 40 mL saline (red connection with a "U") in this order:
    - First inflate 20 ml and check: if the woman complains of pain, the uterine balloon may be in the cervical canal and has not passed the internal os. If so, deflate, advance a little further and inflate again.
    - Remove the guidewire and the speculum.
    - Inflate 20 ml more to complete the total 40 ml.
    - Retrieve the balloon system until resistance is felt and the balloon cannot be further retrieved. This indicates that the uterine balloon is just above the internal cervical os and the vaginal balloon is in the vagina, outside of the canal.
- **Step 2: inflate the vaginal balloon,** initially with 40mL of saline (green connection with a "V") to fix the device.
    - While you are inflating the balloon, make sure that traction is continuously exerted to avoid upward displacement. If the woman complains of pain while the vaginal balloon starts being inflated, this is a sign that the vaginal balloon has moved upwards and is in the canal and not in the vagina. In this case, deflate, and make sure proper traction is maintained in order to fix the internal uterine balloon just next to the internal os.
- **Step 3: complete inflation of both balloons to 80 ml**. The balloons are progressively inflated 20 ml each time up to 80 mL each.
    - If the patient presents poor tolerance or pain, inflation can be lowered to 60 mL and try to reach 80 ml again 1 or 2 hours later. Normally, the balloon causing the pain is the vaginal one: it can be left at 60 ml and in rare cases at 40 ml if this is better tolerated by the patient.
- Foetal monitoring with cardiotocography (CTG) for 30 minutes after balloon insertion.
- If no remarkable findings with CTG, the woman can go home (in case of home ripening protocol) or to her room in the hospital ward, with freedom of movement.
- The balloon is removed 6-12 hours later. It can be removed by the woman herself in case of home ripening protocol.
- Wait 2-3 hours after removal and, if contractions have not started, initiate IOL.

Comments and special situations:

- Most women tolerate the balloon well, but nitrous oxide can be helpful for a better tolerance.
- Optionally, or in case of doubts, the correct positioning of the balloon can be checked by ultrasound.
- **Women with positive Group B Streptococcus**: this does not contraindicate the use of the balloon.
- **Failed insertion:** in the event of 3 failed placement attempts or the onset of moderate/abundant bleeding during the placement, the balloon placement will be withdrawn and the pharmacological method will be offered, ruling out any potential complication.
- **Rupture of membranes**:
    - During the balloon insertion: remove the device and follow the protocol for PROM.
    - Spontaneously during the cervical ripening phase: consider leaving the device a maximum of 12 hours after placement and start prophylactic antibiotic therapy 24 hours after membrane rupture.

ANNEX 2. PHARMACOLOGICAL CERVICAL RIPENING WITH PROSTAGLANDIN CONTROLLED-RELEASE DEVICE

Prostaglandins (PG) are derived from arachidonic acid and produce histological changes in the connective tissue, similar to those seen at the onset of labour in a full-term pregnancy (dissolution of collagen bundles and increased submucosal water content) and may be sufficient to initiate the labour process.

A PG controlled-release device (i.e. *Propess*®) is a polymer containing 10 mg of dinoprostone with a polyester retrieval chain that is placed in the posterior vaginal fornix without the need for a speculum. It releases 0.3 mg/hour in women with intact membranes and 0.4 mg/hour in those with ruptured membranes.

A great advantage of these devices versus other prostaglandin cervical ripening systems is that the release is progressive, and the device can be easily withdrawn in case of uterine hyperactivity or impaired foetal well-being.

Each device contains a **total dose of 10mg** releasing during **12-24h**.

Oxytocin stimulation can be started 12 or more hours after placement of the device if labour has not started. The device should be removed and 30 minutes pass before starting oxytocin.

Complications and adverse effects of PGs

- Frequent (>1/100, <1/10): foetal heart rate alterations, uterine hypertonia, tachysystole, uterine hyperstimulation, hypotension or tachycardia. Most uterine contractility episodes will resolve after removal of the device, but some will require the use of a tocolytic.

- Rare (>1/1000, <1/100): nausea, vomiting, diarrhoea, impairment of foetal well-being secondary to uterine hyperstimulation.

- Very rare (>1/10,000, <1/1000): disseminated intravascular coagulation, uterine rupture.

Contraindications and incompatibilities:

- Initiated labour.
- Simultaneous administration of oxytocin
- Grand multiparity (≥ 6 previous deliveries)
- Previous caesarean section or uterine surgery without entry into the uterine cavity
- Contraindications for vaginal delivery
- History of hypersensitivity to PG or to any of the excipients
- Moderate to severe heart disease (WHO classification III-IV)

Use with special care in the following circumstances:

- Uterine bleeding of unknown cause
- Glaucoma
- Asthma
- Pulmonary, renal or hepatic disease
- Epilepsy

- Uterine overdistention (macrosomia, polyhydramnios, multiparity, multiple pregnancy).

Management of uterine hyperstimulation associated with vaginal prostaglandin release devices

Uterine hyperstimulation may appear as:

- Uterine tachysystole: described by the presence of > 5 contractions in 10 minutes
- Hypertonia: uterine contraction that lasts longer than 2 minutes without objective complete relaxation

The vaginal prostaglandin device should be removed immediately.

In case of altered foetal monitoring, initial measures should be performed as follows:

- Move the patient to left lateral decubitus
- Administration of intravenous tocolysis
- Consider vaginal irrigation.

Most cases resolve spontaneously or with these measures. In case of persistent abnormalities, consider caesarean section.