OUTPATIENT PRE-INDUCTION CERVICAL RIPENING MANAGEMENT GUIDELINES

Discussion: **PAGE:**

Background 2

Candidates for Outpatient Cervical Ripening

- Bishop score 2
- Procedure 3

References 4

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OUTPATIENT PRE-INDUCTION CERVICAL RIPENING MANAGEMENT GUIDELINES

Background

Outpatient cervical ripening with low dose prostaglandins can be a convenient safe, cost- and time-saving procedure for women with a medical need for induction, but without an urgent need to be delivered. Outpatient ripening will be scheduled though OB Triage per Labor and Delivery staffing. Medically indicated ripenings will also be scheduled in Labor and Delivery per Labor and Delivery staffing. At the time of this writing a preliminary PubMed search reveals nearly 100 articles on this topic utilizing different agents in outpatient settings.

ACOG Practice Bulletin No. 107 states ".....outpatient use may be appropriate in carefully selected patients...."

The following guideline is based on that principle.

The Unripe cervix
The following principles / practices especially apply to TOLACs, but actually apply to all cervical ripening

A.) If the pt's cervix is not ripe, then there is no need to start the cervical ripening at the very stroke of midnight on the day the pt just become 37 0/7, 38 0/7, 39 0/7, etc… for the vast majority of indications. If you look at many of the indications for delivery - a range is given e. g., 40-41 wks, etc….

Please don't set up the expectation with the pt that she will get a cervical ripening started at the very millisecond of first day that the guideline says we could start (if she had a favorable cervix) If her cervix is not ripe, then she may not get started until the last day of that week, or later in some cases. If you have a question as to whether you should delay to the end of the 'range' of dates, please consult an OB/GYN or MFM

This may involve a little of the 'art of medicine'
….you clearly state a 'range' of the dates…but the pt hears only the first day of that 'range'….so you then need to tactfully reinforce the 'range' of dates concept so that the pt (and her family) are not fuming* when they show up in OBT and get the bad news that her cervix is completely unripe - and the pt and her family both say she has never heard of such a concept as a 'range' of dates.

B.) Please consider mechanical methods first

-Membrane stripping (Boulvain 2005)
Depending on the situation, one can shorten the length of gestation with outpt membrane 'stripping' without negative infectious outcomes.
This could be done weekly starting at 38 wks in those situations in which you anticipate early cervical ripening will be needed. It also helps establish what the cervical exam is…. well before showing up in OBT, so you can better set the expectations for the pt. (and her family)

-Balloon methods
Randomized trials have reported that use of a balloon catheter is as effective for cervical ripening as prostaglandins.
In many cases this method can lead to a cervical dilation that qualifies the pt for amniotomy.

-Amniotomy
If the fetal calvarium is engaged, cervix is well applied, and there is no funic presentation, then amniotomy can shorten labor and increase the number of pts delivered within the next 24 hrs

In a TOLAC pt, most/all of the above should have taken place before we consider use of Pitocin, if applicable.

Candidates for Outpatient Pre-Induction Cervical Ripening

Women at term with an unripe cervix with a medical indication for delivery, such as:

- Postdates pregnancy
- well controlled diabetes
- mild hypertensive disease
- patients requiring non-emergent ripening/induction with complications of pregnancy warranting delivery

Women who MAY be candidates depending on clinical judgment include:

- intrahepatic cholestasis of pregnancy
- underlying maternal disease—cardiac, pulmonary, coagulopathy, autoimmune disease
- women with a Bishop score >5 but not in labor

Women who are NOT candidates include:

- previous cesarean delivery or other uterine incision
- non-reassuring fetal heart tracing
- unexplained vaginal bleeding, placental abruption, or previa
- unstable hypertensive disease
- uncontrolled diabetes
- women with a history of 5 or more vaginal deliveries
- suspected fetal growth restriction
- multiple gestations
- malpresentation or pelvic structural deformity
- intrauterine fetal demise
- women pregnant with an identified at-risk fetus
- oligohydramnios
- moderate or severe polyhydramnios

	0	1	2	3
Dilatation	Closed	1-2 cm	3-4 cm	>4cm
Effacement	0-25%	25-50%	50-75%	>75%
Station	-3	-2	-1 to 0	+1 to +2
Consistency	Firm	Medium	Soft	
Position	Posterior	Mid	Anterior	

Procedures

Oral Titrated Misoprostol liquid

For more detailed background on pharmacology and references, please see separate guideline:
-Cervical Ripening: Oral Titrated Liquid Misoprostol

Women will be dosed as follows:

1. Misoprostol 200 mcg will be dissolved in 200 mL of tap water, constituting a solution of 20 mcg in 20 mL.
2. An initial dose of 20 mcg (20 mL measured in a syringe) will be given by mouth, and the time of the first dose recorded.
   -the same dose will be repeated ***every hour*** for 2 hours (total of 2 doses).
3. Patients may ambulate and take oral fluids and light foods ad lib during the ripening/induction procedure.
4. The patient will be monitored with the fetal heart tracing and cardiotocogram (CTG) for 20 minutes after receiving the medication. If fetal tolerance has been assured, then the patient can be off the monitor for 20 minutes. The patient is then placed back on the fetal heart tracing and cardiotocogram (CTG) 20 minutes prior to the next dose.
5. Uterine tachysystole, (defined as more than 5 contractions in 10 minutes, averaged over a 30 minute window) ***without*** worrisome fetal heart rate changes, will not be an indication to stop the ripening-induction procedure. If the fetal heart tracing is reassuring, then the medication can be advanced per guideline.
6. Tachysystole ***with*** fetal heart rate abnormalities (Category II or III tracings should result in misoprostol not being given in the subsequent hour, or until the abnormal pattern has resolved. Lateralization, oxygen, and a fluid bolus will be given as per routine.
7. The patient will be monitored with the fetal heart tracing and cardiotocogram (CTG) for 20 minutes after receiving the medication. If fetal tolerance has been assured, then the patient can be off the monitor for 20 minutes. The patient is then placed back on the fetal heart tracing and cardiotocogram (CTG) 20 minutes prior to the next dose.
8. If Oral solution is not available, please see Appendix 2 for Misoprostol tablet

Double balloon device

1. Advance the Cervical Ripening Balloon through the cervix until both balloons have entered the cervical canal.
2. Inflate the uterine balloon with 40 mL of saline. Once the uterine balloon is inflated, the device is pulled back until the balloon abuts the internal cervical os.
3. The vaginal balloon is visible outside the external cervical os and is inflated with 20 L of saline.
4. Once the balloons are situated on either side of the cervix, saline is added to a maximum of 80 mL per balloon.
5. The mother is then monitored at bed rest for an hour after catheter placement. Bedrest is encouraged after placement so that the device is not inadvertently expelled, but the patient may be up to the bathroom as needed, exercising appropriate caution not to pull on the catheter.
6. Approximately 24 hours after placement of the device, it should be re-evaluated. A repeat cervical exam is then performed and the Bishop score reassigned. Oxytocin may be begun and rupture of membranes may be carried out at the discretion of the provider.

Other Inflatable Balloon Devices e. g., foley catheter (Also see Appendix A)

1. Cervical digital examination is carried out and a Bishop score assigned.

2. Sterile prep carried out with use of betadine solution is optional. After testing for integrity of the Foley bulb, the Bozeman or ring clamp is used to insert the catheter high into the endocervical canal. Ideal placement of the bulb of the catheter is at or above the level of the internal cervical os, where it is then inflated with 30 mL of sterile saline. After proper placement, the proximal end of the catheter tubing is taped to the inner aspect of the mother's thigh, allowing sufficient slack for her to extend her leg comfortably
3. The mother is then monitored at bed rest for an hour after catheter placement. Bedrest is encouraged after placement so that the device is not inadvertently expelled, but the patient may be up to the bathroom as needed, exercising appropriate caution not to pull on the catheter.
4. Approximately 24 hours after placement of the device, it should be re-evaluated. A repeat cervical exam is then performed and the Bishop score reassigned. Oxytocin may be begun and rupture of membranes may be carried out at the discretion of the provider.

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Appendix A
Cervical Ripening with Transcervical Balloon Catheter
Inpatient / Outpatient Guidelines, ANMC

Background:
Prior to the development of the current potent uterotonic prostaglandin preparations, extensive experience has accrued with the use of mechanical methods for cervical ripening prior to the induction of labor. Compared to use of oxytocin in women with an unfavorable cervix, pre-induction ripening with use of a transcervical Foley catheter or double balloon catheters reduce the risk of cesarean delivery in induced labor. Compared to use of misoprostol in women with an unfavorable cervix, use of mechanical methods results in a lower rate of vaginal delivery within 24 hours in induced labor, but labors are characterized by a much lower incidence of uterine hyperstimulation. In women with a prior cesarean delivery who require induction of labor, prostaglandin preparations are associated with an excessive risk of uterine rupture. While the success rate for vaginal birth after a prior cesarean in women induced with a transcervical balloon catheter and oxytocin is less than that for such women with spontaneous labor, the rate of uterine rupture is not increased, making this an attractive option in this situation.

Literature Update:
At the time of this writing a preliminary PubMed search reveals nearly 100 articles on this topic utilizing different agents in outpatient settings, including the following mechanical methods.

Randomized trials have generally reported use of a balloon catheter was as effective for cervical ripening as prostaglandins. (Vaknin 2010)

The risk of hyperstimulation with mechanical methods was reduced when compared with prostaglandins (intracervical, intravaginal or misoprostol). Compared to oxytocin in women with unfavourable cervix, mechanical methods reduce the risk of cesarean delivery. (Cochrane 2001)

A meta-analysis (27 randomized trials, 3532 participants) comparing the efficacy and safety of cervical ripening and labor induction in the third trimester by Foley catheter balloon versus locally applied prostaglandins found no significant difference in cesarean delivery rates between the two approaches. (Vaknin 2010)

Advantages of the balloon methods include low cost when compared with prostaglandins, stability at room temperature, and reduced risk of uterine tachysystole with or without fetal heart rate (FHR) changes. (ACOG 2009)

Labor induction using a transcervical Foley catheter is not associated with an increased risk of uterine rupture. (Bujold 2004)

Candidates

1. Women with an indication for induction, in cephalic presentation, reactive NST, single deepest pocket $\geq$2 or amniotic fluid index $\geq$8, and an unfavorable cervix.
2. Women with 2 prior cesarean delivery who are candidates for induction for medical indications are candidates for this method.

Method

1. After informed consent and the patient should empty her urinary bladder in order to facilitate the procedure. Cervical digital examination is carried out and a Bishop score assigned. (Appendix 1)

2. Optional sterile prep is carried out with use of betadine solution. After testing for integrity of the balloon device, the Bozeman or ring clamp is used to insert the catheter high into the endocervical canal. Ideal placement of the bulb of the catheter is at or above the level of the internal cervical os, where it is then inflated with 30-60 mL of sterile saline. After proper placement, the proximal end of the catheter tubing is taped to the inner aspect of the mother's thigh, allowing sufficient slack for her to extend her leg comfortably.

3. An alternative, and equally satisfactory, placement technique for the cervix that is already somewhat dilated, is to simply insert the balloon device over the index and middle fingers, as one would an intrauterine pressure monitor catheter.

4. The mother is monitored at bedrest for fetal heart rate and tocograph for an hour after catheter placement. The patient may be up to the bathroom or to ambulate as needed or desired, exercising appropriate caution not to pull on the catheter. Oral intake may be at the discretion of the provider.

5. With a Category 1 fetal heart rate and the absence of tachysystole, the patient may be triaged to inpatient or outpatient status at the discretion of the provider. Co-morbidities that may pose potential complications should be considered.

6. Outpatients should be given written discharge instructions including a telephone number for 24-hour telephone access to a provider or nurse for any questions or concerns. The patient should be instructed to notify their provider or nurse for heavy vaginal bleeding, rupture of the membranes, painful uterine contractions every 5 minutes or less, severe abdominal discomfort or decreased movement of the fetus. Patients should be informed that extrusion of the balloon device might occur while at home. The patient should record time of extrusion and discard the balloon device. If they were not experiencing any of the aforementioned symptoms, they should dispose of the balloon catheter, remain at home, and call OB Triage 729 4124 to make plans for follow-up.

7. Outpatients should be evaluated in 24 hours regardless of whether the balloon device has not spontaneously been expelled, or not. A Bishop score should be reassigned and oxytocin and/ or AROM initiated, as appropriate.

Appendix 2

Misoprostol Tablet

1. The patient will be scheduled to present to the Ob Triage. She does not need to be fasting the day of the procedure. Patients will be scheduled for ripening by their primary obstetric provider through the Ob Triage nurse (729-4124) and scheduled for formal induction on Labor and Delivery ~48 hours after beginning the ripening procedure (729-3201). If a patient is not ripe for induction after two days of outpatient misoprostol, they can continue outpatient ripening at the discretion of the obstetric provider. (see below)

2. The patient will have a 20 minute pre-ripening non-stress test. If any baseline fetal heart rate abnormality is noted or if the patient is having regular painful contractions every 3-5 minutes, the procedure willbe canceled and the on-call provider notified.
3. An ultrasound to confirm presentation and amniotic fluid evaluation and a cervical check to determine Bishop score will be done prior to the insertion of the misoprostol by the Ob triage nurse or provider.
4. Misoprostol will be administerd as 25 micrograms placed high in the posterior vaginal fornix followed by non-stress test monitoring for 4 hours. This dose may be repeated in 24 hours.
5. The patient should remain recumbent for the first hour following insertion of the tablet. Beginning one half-hour post insertion she should be monitored continuously for one hour. If the fetal tracing remains reassuring, she may then ambulate but should be monitored for at least 20 minutes every hour for the next 3 hours. She may take fluids by mouth ad lib.
6. If the fetal tracing remains reassuring, the patient is not having painful contractions and the cervical dilatation does not indicate active labor, she may then be discharged home after 4 hours.
7. Please document a cervical exam before discharging the patient each day.
8. Uterine tachysystole without any worrisome fetal heart rate changes will not be an indication to stop the procedure or to not send the patient home. If any fetal heart rate decelerations are noted, the patient will be transferred expeditiously to Labor and Delivery for close observation. The on-call Labor and Delivery provider will be notified and assume care.
9. Please carefully explain the temporal vagaries of outpatient ripening to your patient (and her family) to set appropriate expectations for when labor does not commence as quickly as desired, or when staffing/beds are not available.