Winnipeg Regional Health Authority / Office régional de la santé de Winnipeg	**Practice Guideline:** *Cervical Ripening*	
CLINICAL PRACTICE GUIDELINE	**Approval Date:** *April 2024*	**Page:** ***1*** *of* ***13***
		Supersedes: *Induction and Augmentation of Labour and Cervical Ripening (2017)*

The following is a suggested guideline and does not replace ongoing clinical assessment and professional judgment.

1.0 PRACTICE OUTCOME

1.1 To promote the effective and safe use of Prostin®, Cervidil®, misoprostol and balloon catheters for cervical ripening.

2.0 DEFINITIONS

2.1 **Active labour:** Regular uterine contractions approximately every 3-5 minutes of sufficient strength to cause cervical dilatation and/or effacement. Traditionally diagnosed when the cervix is 3-4 cm dilated in nulliparous women/persons or 4-5 cm dilated in parous women/persons (S. Moola, 2018).

2.2 **Cervical Ripening:** The use of pharmacological or mechanical means to soften, efface, and dilate the cervix prior to induction of labour (IOL) to increase the likelihood of a successful vaginal birth (Robinson, d. et al, 2023).

2.3 **Induction of Labour (IOL):** The artificial initiation of labour before its spontaneous onset (Robinson, d. et al, 2023).

2.4 **Most Responsible Provider (MRP):** A regulated healthcare professional, who has overall responsibility for directing and coordinating the care and management of a patient at a specific point in time. For the purpose of this guideline MRP will refer to obstetricians, family physicians and midwives.

2.5 **Tachysystole**: Uterine contraction pattern that is:

- More than 5 contractions in any 10-minute period averaged over 30 minutes, OR
- Contraction lasting greater than 90 seconds, OR
- Resting period between contractions is less than 30 seconds, OR
- The uterus remains firm or is greater than 25 mm Hg between contractions (Dore, S. & Ehman, W., 2020)

2.6 **Unfavorable cervix**: modified Bishop Score less than 7 (Appendix A).

3.0 BACKGROUND

3.1 Prostaglandins (E_1 and E_2) are naturally occurring prostaglandins which stimulate the myometrium of a gravid uterus to contract.

3.2 A balloon catheter is a mechanical method of cervical ripening which results in direct pressure and overstretching of the lower segment, cervix and the local release of prostaglandins. (Leduc, Biringer, Lee, & Dy, 2013).

3.3 Studies show that a balloon catheter is as effective as Prostin or Cervidil and slightly less effective than misoprostol. Use of balloon catheters for cervical ripening have also

demonstrated a greater safety profile compared to medical cervical ripening agents (PGE_2/PGE_1) (de Vaan, MD, Ten Eikelder, MI., Jozwiak, M. et all., 2019)

3.4 Pain scores are significantly lower with the use of a single balloon catheter versus a double balloon catheter. (Pennell, Henderson, O'Neill, McCleery, Doherty & Dickenson, 2009).

3.5 Simultaneous use of balloon catheters and oxytocin may increase the need for additional analgesia and does not decrease the time to commencement of labour (Pettker, Pocock, Smok, Lee & Devine, 2008).

3.6 Misoprostol is a prostaglandin that can cause both cervical ripening and stimulation of uterine contractions. It may be used in a patient who meets the criteria for vaginal prostaglandin use.

4.0 GUIDELINES

4.1 Cervical ripening should be offered when the modified Bishop score (Appendix A) is less than 7, except in term prelabour rupture of membranes (PROM). If the modified Bishop score is greater than or equal to 7 and induction is warranted, IOL is recommended following the Induction and Augmentation of Labour guideline.

4.2 An Induction Booking Form should be completed prior to induction.

4.3 Midwives consult a physician prior to cervical ripening. Midwives may remain as the primary care provider unless transfer of care based on maternal or fetal situations is required.

4.4 The MRP completes an in-person assessment of the patient prior to ordering cervical ripening to assess intervention appropriateness as well as review risks and benefits of the proposed treatment plan to ensure there is informed consent with the patient. This assessment may occur prior to admission and should be documented on the prenatal record/induction booking form.

4.5 A nurse may administer Prostin®, Cervidil® or vaginal misoprostol, with a physician order, if they have received training in prostaglandin insertion.

4.6 Physician order for the chosen intervention is obtained.

4.7 Prior to the administration of Prostin®, Cervidil®, misoprostol or balloon catheter for cervical ripening:

4.7.1 An electronic fetal monitoring (EFM) tracing is reviewed and discussed with the MRP

4.7.2 Patient's vital signs are recorded in the medical record

4.7.3 Physician, resident, midwife or a trained nurse administering the ordered interventions enters the following information in the Progress Note:

- Indication for cervical ripening
- Discussion that took place with the patient for consent to induction of labour (this is documented by the MRP either prior to admission in the prenatal record OR in hospital when consent is obtained)
- Description of the fetal heart rate (FHR) pattern
- Description of the most recent cervical exam with modified Bishop score (Appendix A).

- Description of the fetal lie observed through Leopold's maneuvers and/or point of care ultrasound findings

4.7.4 After the administration of ripening agent document the intervention performed and the time of administration in the medication administration record (MAR) and Birth Summary.

4.7.5 If cervical ripening is progressing slowly, and if fetal and maternal conditions allow, the option of deferring further ripening can be contemplated.

4.7.6 If cervical ripening and/or induction of labour is unsuccessful, health care providers should consider an alternate or combined method of cervical ripening and/or induction of labour before proceeding with cesarean delivery.

4.8 Outpatient cervical ripening should be prioritized for all patients who meet criteria.

5.0 PROCEDURES

5.1 Balloon Catheter

5.1.1 To be inserted by a physician, resident, physician's assistant (PA), clinical assistant (CA) or a midwife (with a physician's order).

5.1.2 Avoid using a balloon catheter for patients with ruptured membranes.

5.1.3 Insert the balloon catheter following the "Instructions for Balloon Catheter Insertion" (Appendix B).

5.1.4 After insertion of the balloon catheter continuous EFM, including assessment of uterine activity, should be carried out for a minimum of 20 minutes.

5.1.5 If the FHR pattern is normal (Fetal Health Surveillance, Intrapartum provincial guideline) after 20 minutes, continuous EFM can be discontinued.

5.1.6 Discharge patient home, with the "Induction of Labour by Balloon Catheter Patient Discharge Information" handout, if they meet the following criteria:

- Normal EFM tracing
- Normal patient vital signs
- MRP order

Exclusion criteria for out-patient use:

- Less than 37 weeks or greater than 42 weeks gestation (relative)
- Atypical/abnormal FHR pattern
- Decreased amniotic fluid volume
- Intrauterine fetal demise (relative)
- Patient lives greater than 30 minutes from hospital or does not have reliable transportation (relative)
- Patient unable to understand instructions
- MRP prefers inpatient care

5.1.7 If the patient remains in hospital following balloon catheter insertion:

- Auscultate FHR every 4 hours
- The patient may ambulate or shower after the initial 20-minute observation
- The patient is instructed to inform nursing staff of the following:
  - Regular contractions
  - Symptoms consistent with spontaneous rupture of membranes
  - Vaginal bleeding

- If the balloon falls out

5.1.8 Once in active labour, assess and document the FHR as per the Fetal Health Surveillance, Intrapartum provincial guideline.

5.1.9 If required for induction of labour, oxytocin or titrated oral misoprostol may be started immediately after balloon insertion.

5.1.10 Balloon catheters may be removed by the physician, resident, PA, CA, midwife or nurse following "Instructions for Balloon Catheter Removal" (Appendix C). Document time of removal in the Progress Note.

5.2 **Cervidil® (Dinoprostone 10mg) Vaginal Insert** (prostaglandin E_2 (PGE_2) mesh)

5.2.1 Prior to insertion by a resident, PA, CA or nurse (See 4.4) discuss intervention with the MRP.

5.2.2 Cervidil® is inserted into the posterior fornix of the vagina. Instruct the patient to dab rather than wipe after voiding.

5.2.3 If the vaginal insert falls out (i.e. protrudes beyond the labia) it may be reinserted. If the product is suspected to be soiled, place a new vaginal insert.

5.2.4 After insertion of Cervidil®, initiate continuous EFM and assess uterine activity for a minimum of 20 minutes. Assess and record FHR and uterine activity every 10 minutes during this time.

5.2.5 Discharge patient home, with the "Patient Instructions for Outpatient Cervidil" handout, if they meet the following criteria:

- Normal EFM tracing
- No signs of acute hyperstimulation reaction
- Normal patient vital signs
- MRP order

Exclusion criteria for out-patient use:

- Less than 37 weeks or greater than 42 weeks gestation (relative)
- Atypical/abnormal FHR pattern
- Decreased amniotic fluid volume
- Intrauterine fetal demise (relative)
- Gestational hypertension severe enough to warrant inpatient monitoring
- Intrauterine growth restriction
- Patient lives greater than 30 minutes from hospital or does not have reliable transportation (relative)
- Patient unable to understand instructions
- MRP prefers inpatient care

5.2.6 If the patient remains in hospital following Cervidil® insertion:

- Assess the FHR every 4 hours with continuous EFM (a minimum of 20-minute assessment strip) while Cervidil® in situ. MRP may order additional fetal monitoring
- Assess contractions every 4 hours while Cervidil® is in situ
- The patient may ambulate or shower after initial 20-minute observation
- The patient is instructed to inform nursing staff of the following:
  - Regular contractions
  - Symptoms consistent with spontaneous rupture of membranes

- Vaginal bleeding
- If the Cervidil® falls out

5.2.7 Once in active labour assess and document the FHR as per the Fetal Health Surveillance, Intrapartum provincial guideline.

5.2.8 Cervidil® should be removed for the following reasons:

- Atypical/abnormal FHR pattern with or without tachysystole
- At the discretion of the MRP when there is tachysystole with a normal fetal heart rate pattern
- Spontaneous rupture of membranes
- Active labour – with cervical dilation greater than 6-7 cm
- 18-24 hours post insertion

5.2.9 If the patient does not go into active labour and a subsequent induction and/or ripening agent is ordered, it may be initiated 30 minutes after Cervidil® is removed.

5.3 **Prostin® (Dinoprostone 2mg/2.5mL) Gel** (PGE_2 gel)

5.3.1 Prior to insertion by a resident, PA, CA or nurse (See 4.4) discuss intervention with the MRP.

5.3.2 Prostin® gel is inserted into the posterior fornix of the vagina.

5.3.3 Prostin® duration of action is 4 – 6 hours.

5.3.4 After insertion of the Prostin®, initiate continuous EFM and assess uterine activity for a minimum of 20 minutes. Assess and record FHR and uterine activity every 10 minutes during this time.

5.3.5 Discharge patient home, with the handout "Going Home After Prostin" handout, if they meet the following criteria:

- Normal EFM tracing
- No signs of acute hyperstimulation reaction
- Normal patient vital signs
- MRP order

Exclusion criteria for out-patient use:

- Less than 37 weeks or greater than 42 weeks gestation (relative)
- Atypical/abnormal FHR pattern
- Decreased amniotic fluid volume
- Intrauterine fetal demise (relative)
- Gestational hypertension severe enough to warrant inpatient monitoring
- Intrauterine growth restriction
- Patient lives greater than 30 minutes from hospital or does not have reliable transportation (relative)
- Patient unable to understand instructions
- MRP prefers inpatient care

5.3.6 If the patient remains in hospital following Prostin® insertion:

- Assess the FHR every 4 hours with continuous EFM (a minimum of 20-minute assessment strip) while Prostin® in situ, MRP may order additional fetal monitoring

- Assess contractions every 4 hours while Prostin® is in situ
- The patient may ambulate or shower after initial 20-minute observation
- The patient is instructed to inform nursing staff of the following:
  - Regular contractions
  - Symptoms consistent with spontaneous rupture of membranes
  - Vaginal bleeding

5.3.7 Once in active labour, assess and document the FHR as per the Fetal Health Surveillance, Intrapartum provincial guideline.

5.3.8 If the patient does not go into active labour and a subsequent induction agent and/or cervical ripening agent is ordered, it may be initiated 6 hours after Prostin® administration.

5.4 **Vaginal misoprostol (PGE_1) tablet for cervical ripening** (prostaglandin E_1 (PGE_1)

5.4.1 Prior to insertion by a resident, PA, CA or nurse (See 4.4) discuss intervention with the MRP.

5.4.2 Administer single 50 mcg dose tablet/suppository into the posterior fornix with minimal lubrication, as medication is absorbed into the lubricant therefore decreasing its bioavailability.

5.4.3 Serum levels peak 75 minutes after administration and clinical activity peaks at 2-3 hours, duration of action is 4-6 hours.

5.4.4 Patient may ambulate for 2 hours after administration

5.4.5 At 2 hours post-insertion, initiate continuous EFM and maintain for a minimum of 1 hour. Assess and record FHR and uterine activity every 15 minutes during this time.

5.4.6 Once in active labour, assess and document the FHR as per the Fetal Health Surveillance, Intrapartum provincial guideline.

5.4.7 May repeat 50 mcg misoprostol vaginal dose once, 6 hours after initial dose, if the following criteria are meet:
- Modified Bishop score less than 7
- No uterine activity present
- Monitor FHR and contractions as in 5.4.5 and 5.4.6.

5.4.8 If the patient does not go into active labour and a subsequent induction and/or cervical ripening agent is ordered, it may be initiated 4 hours after vaginal misoprostol administration.

6.0 REFERENCES:

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7.0 PRIMARY AUTHOR (S)

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APPENDIX A: Modified Bishop Scoring System

Modified Bishop Scoring System			
	Score		
Factor	**0**	**1**	**2**
Dilatation (cm)	0	1-2	3-4
Cervical Length (cm) (previously effacement)	Greater than or equal to 4 (0-30%)	2-3 (31%-50%)	Less than 1-2 (51%-80%)
Consistency	Firm	Medium	Soft
Position	Posterior	Mid	Anterior
Station	-3	-2	-1/0

Burnett JE Jr. Preinduction scoring: an objective approach to induction of labor. Obstet Gynecol 1966;28:479–83.

APPENDIX B – Instructions for Balloon Catheter Insertion

Balloon catheter types

A. 16, 18 or 20 French indwelling urinary catheter with a stated balloon capacity of 30 mL

B. Double balloon catheter

Procedure:

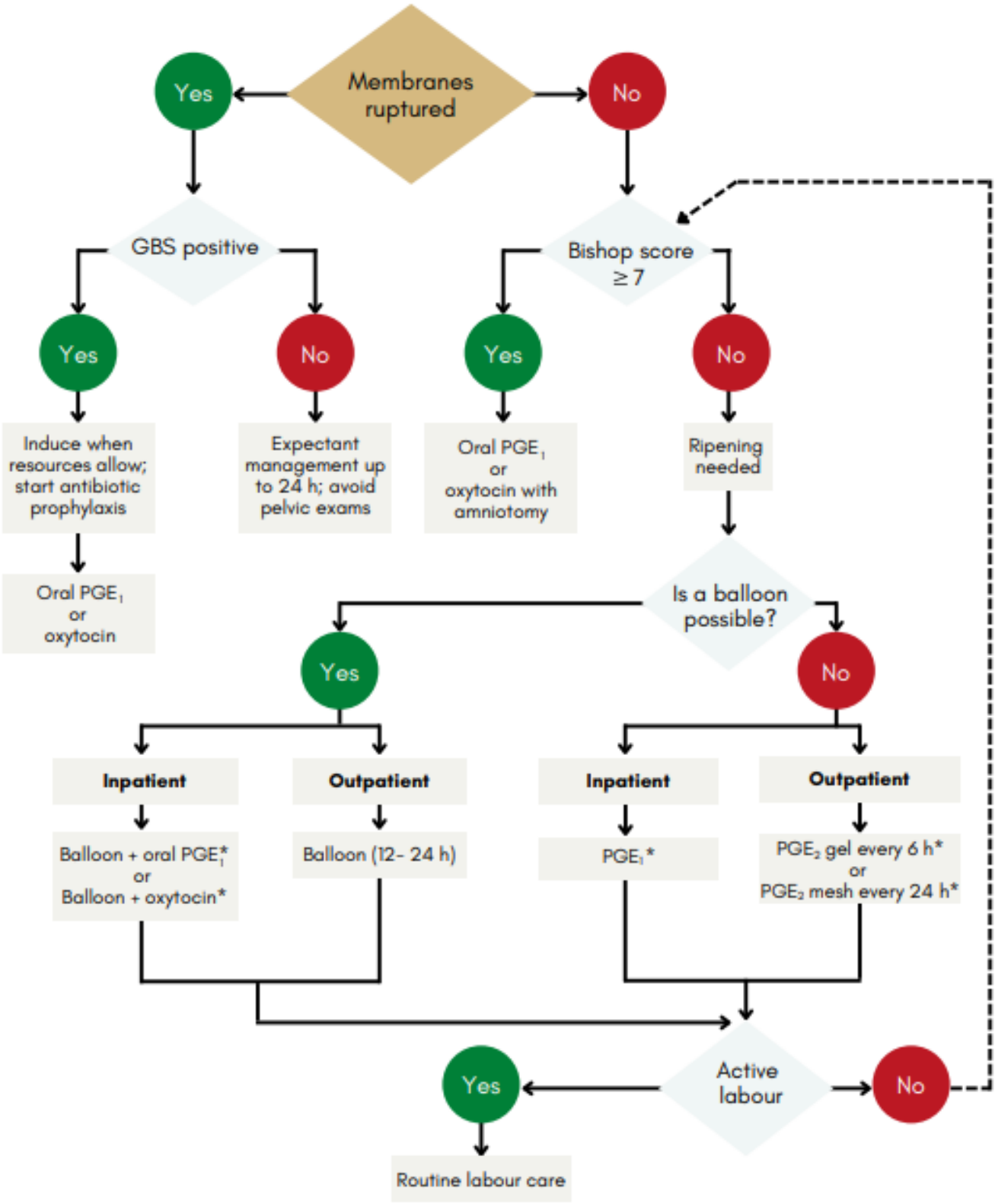
1. Place the patient in a lithotomy position.
2. Introduce balloon catheter under sterile technique into the transvaginal canal ensuring the bulb is above the internal os. This can be done under direct visualization (using a sterile speculum) or digitally.
3. Inflate the balloon with 30 to 60 mL of sterile water. With a double balloon catheter, the lower (vaginal) balloon also may be inflated at the discretion of the MRP.
4. Tape the indwelling catheter hub to the inner thigh. Taping with tension is not required.

Appendix C – Balloon Catheter Removal Instructions

Procedure:

1. Apply gentle traction to the balloon catheter. This often hourglasses the balloon through the cervix leaving it about 3 cm dilated.
2. Deflate the balloon as required to remove.
3. Document time of removal in the Progress Note.

APPENDIX D – Algorithm for Cervical Ripening and Induction of Labour



*A break should be considered when the ripening process is lengthy, as long as the maternal and fetal conditions are stable.
GBS: Group B Streptococcus; PGE: prostaglandin E

Robinson et al. 2023 Guideline 432c

APPENDIX E - Management of Tachysystole with an Abnormal Fetal Heart Rate Pattern

1. Immediately notify the obstetrical care provider on call, and document communication in the IPN or Progress Notes.
2. Call the charge nurse.
3. Perform a vaginal exam to assess progress, and diagnose/manage cord prolapse, if present.
4. Remove Cervidil® vaginal insert if in situ.
5. Stop Oxytocin.
6. Turn the patient to a lateral position.
7. Improve hydration with an IV fluid bolus (if needed).
8. Consider Nitroglycerin (spray or sublingual tabs) when required and ordered by the physician (Appendix F).
9. Prepare the patient for an emergency cesarean section if required

Note: When an abnormal tracing is apparent, attempts at intrauterine resuscitation continue while the attending obstetrical provider/senior resident is called to review the overall clinical situation, consider obtaining scalp pH/lactate (if appropriate), and prepare for delivery.

APPENDIX F - Nitroglycerin Sublingual Spray

Note: When treating intrapartum tachysystole, Leathersich et. al. (2018) found that there was little evidence to recommend one single treatment. One trial compared nitroglycerin to subcutaneous terbutaline and found both had similar effectiveness.

Rho-Nitro Pump Spray 0.4 mg per metered dose

Dosage: At onset of tachysystole with abnormal fetal heart rate pattern or loss of soft resting tone, spray 1 or 2 metered doses onto or under the tongue **WITHOUT INHALING**.

- The optimal dose may be repeated twice at 5 to 10 minute intervals.
- Administer at rest, ideally in the sitting position.
- As per distributor's directions Sandoz Canada, Inc. Laval, Quebec.