POLICY STATEMENTS

It is the responsibility of the attending physician to ensure the selection of the most appropriate care is ordered and carried out based on the following established criteria.

These guidelines will provide established criteria for care providers as well as a standard of practice related to the initiation and/or continuation of mechanical cervical ripening in patients within the Women’s & Newborn Health Program. The guidelines will also support the safe placement and appropriate monitoring of the effects of the mechanical method of cervical ripening.

In addition, it is anticipated the guidelines will assist with reducing risk to patients, reduce costs, and enhance patient care outcomes for those women pursuing mechanical cervical ripening.

This method of cervical ripening will be used in patients in whom there is a medical or obstetrical indication for the induction of labour (i.e. unripe cervix with Bishop Score less than 6). For Bishop score greater than 6, oxytocin is recommended as the method of choice for induction of labour.

GUIDING PRINCIPLES AND VALUES

A mechanical method of cervical ripening such as the placement of an indwelling catheter can be used in both an inpatient and outpatient setting. Mechanical methods of cervical ripening are the only option that can be offered to woman who have had a prior C/S or
significant uterine surgery after consultation has deemed that a trial of vaginal delivery is appropriate and safe.

Only an obstetrician/delegate may insert mechanical cervical ripening devices.

**GUIDELINE**

An obstetrical consultation is required before the use of a mechanical method of cervical ripening such as an indwelling catheter. The obstetrician/delegate must assess the patient to determine the Bishop score, fetal presentation and fetal wellbeing before recommending placement of a mechanical device. This assessment must be documented on the patient’s permanent health record. Documentation may be either on an interdisciplinary progress note (IWKKINPR) or on a consultation report (IWKCOREA). A procedure note must also be written.

**PROCEDURE**

1. Assess the woman for contraindications/precautions to placement of a mechanical cervical ripening device such as an indwelling catheter. Contraindications to cervical ripening and induction include, but are not limited to, the following:
   - Any contraindication to labour or vaginal birth
   - Fetal malpresentation

2. Confirm the woman gives informed consent, including having been informed by the physician of the potential risks, benefits, and expected outcome of cervical ripening.

3. Complete Maternal Nursing Assessment (including baseline vital signs (TPR and BP) using either Form #IWKMANU or Intellispace Perinatal electronic documentation if this assessment is not already on the patient’s chart.

4. Perform Non Stress Test (NST) according to the Antepartum Fetal Health Surveillance Policy # 7068 assessing for fetal wellbeing (exception – intrauterine fetal death or live nonviable fetus).

5. Obtain routine lab work for CBC and group and screen as ordered.

6. Instruct woman to void prior to insertion of the mechanical device.

7. Ensure placement equipment is available in the procedure room

8. Insert the selected device. The Foley balloon should be inflated with 30 cc of sterile water, if using a double balloon catheter follow the product monograph recommendation for balloon inflation. Only a physician can perform this procedure.
9. Initiate continuous electronic fetal monitoring (EFM) and continue for a minimum of one hour following the device insertion.

10. Assess vital signs (pulse, respiration and BP) one hour post insertion.

11. Ensure the time of the mechanical device (i.e. indwelling catheter) placement is documented on the patient’s health care record.

12. An appointment time in Birth Unit must be provided for the reassessment of outpatients within 12 hours of device placement. If the patient’s management plan is that oxytocin will be initiated immediately following device placement, then an induction appointment for device insertion and oxytocin infusion should be organized with Birth Unit.

13. On arrival in Birth Unit, if cervical assessment reveals the mechanical device to be still in place do not remove the device, initiate oxytocin infusion as per protocol (IWK Health Centre Oxytocin Infusion, Medication Management Policy # 30.11)

OUTPATIENT

Outpatient cervical ripening with a mechanical device may be considered at the discretion of the physician.

1. Outpatients may be discharged (as indicated by the attending physician) after a minimum of one hour after device insertion.

2. Clinical evaluation and patient teaching must be completed prior to discharge. This should include but is not limited to:
   
   i. Normal Fetal Heart Rate (FHR) tracing
   ii. Vaginal examination (as indicated) to rule out active labor
   iii. Patient teaching regarding when to return and/or call the hospital:
       
       • Onset of regular contractions less than or equal to every 5 minutes
       • Bleeding
       • Spontaneous rupture of the membranes
       • Decreased fetal movement
       • Fever
       • Chest pain or shortness of breath
   
   iv. The patient will be provided with instructions on how to remove the mechanical device, if necessary. (See Information Sheet Cervical Ripening: balloon Catheter)

   v. The patient must be provided with hospital contact information and a clear follow-up appointment in Birth Unit within 12 hours of placement of the device. (maximum 24 hours later).
3. Conduct continuous EFM for 30 minutes post removal of the mechanical device. After 30 minutes conduct ongoing fetal health surveillance according to IWK Health Centre Fetal Health Surveillance During Labour Policy #7070 for women in active labour.

4. Documentation on the Interdisciplinary progress note (IWKINPR) should include:
   - Device insertion time
   - Patient tolerance of procedure
   - FHR status prior to insertion and following insertion
   - Maternal assessment
   - Interventions
   - Patient teaching
   - Evaluation and follow-up plan

5. An outpatient telephone tracking record should be completed each time a patient calls or is called. The call must be documented on the patient’s permanent health record by using the Telephone Practice Record A (IWKHEPR) and Telephone Practice Record B (IWKHEPRTE).

**INPATIENT**

Inpatient cervical ripening with a mechanical device may be arranged at the discretion of the physician.

1. Following mechanical device placement, Birth Unit needs to be notified so they can enter the patient’s information in the induction book and assign a time within 12 hours post placement when the patient will be brought to Birth Unit. If the patient’s management plan is that oxytocin will be initiated immediately following device placement then an induction appointment for device insertion and oxytocin infusion should be organized with Birth unit.

2. If the post insertion monitoring is normal, the patient is permitted to ambulate within the Birth Unit or on the Prenatal Special Care Unit (PSCU) as determined by the physician.

3. When regular uterine activity is noted, fetal health surveillance should be instituted as per the IWK Health Centre Fetal Health Surveillance During Labour Policy #7070.

4. If no labour ensues, the woman should be reevaluated every 6 hours including assessment of TPR, BP and FHR auscultation.

5. If no labour has been established at 12 hours post device insertion (unless directed otherwise by the physician) prior to transfer to the Birth Unit the Bishop score is to be reassessed.
6. If the cervix is still unfavorable after 12 hours, it will be the physician’s decision as to how to proceed. (i.e. further cervical ripening time or initiation of IV oxytocin with or without the mechanical device in situ)

7. Conduct continuous EFM for 30 minutes post removal of the mechanical device. After 30 minutes conduct ongoing fetal health surveillance according to IWK Health Centre Fetal Health Surveillance During Labour Policy #7070 for women in active labour.

8. Documentation on the Interdisciplinary progress note (IWKinPR) should include:
   - Device insertion time
   - Patient tolerance of procedure
   - FHR status prior to insertion and following insertion
   - Maternal assessment
   - Interventions
   - Patient teaching
   - Evaluation and follow-up plan including but not limited to date and time of appointment In Birth Unit.

Risks of using a Mechanical Device

Using a mechanical device such as an indwelling catheter for cervical ripening is unlikely to cause excessive uterine activity.

1. The patient is to be assessed for possible removal of the mechanical device if there is:
   - Regular painful contractions lasting 40-50 seconds each for one hour (active labour suspected)
   - 5 or more contractions in a 10 minute period (tachysystole)
   - Contraction lasting greater than 120 seconds (hypertonus)
   - Significant vaginal bleeding
   - Atypical or abnormal FHR tracing
   - Rupture of the membranes

2. If tachysystole (greater than 5 contractions in 10 minutes) or hypertonus (contraction lasting greater than 120 seconds) present without fetal heart rate changes:
   - Remove the mechanical device
   - Place the woman in the left lateral position
   - Obtain equipment to start an intravenous infusion
   - Notify the physician
3. If Hyperstimulation (tachysystole or hypertonus with atypical/abnormal fetal heart rates changes) is present:

- Remove the mechanical device
- Notify the physician
- Place the woman in the left lateral position
- Apply oxygen via face mask at 10 L/min
- Start an IV of Ringer’s Lactate and run at 500 mL/hour
- Obtain nitroglycerin to be administered by the physician
  a. Nitroglycerin 50 micrograms IV push
  b. Nitroglycerin 0.4 milligrams/spray, 1-2 sublingual sprays

REFERENCES


Jazwiak m. Foley catheter versus vaginal prostaglandin E2 gel for induction of labour at term (PROBAAT trial): am p[em-label, randomised controlled trial Lance (2011);378: 2095-2103.


This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against the electronic file version prior to use.
RELATED DOCUMENTS

Policies
IWK Health Centre Consent to Treatment Policy #124.0.
IWK Health Centre Antepartum Fetal Health Surveillance During Labour Policy #7068
IWK Health Centre Intrapartum Fetal Health Surveillance During Labour Policy #7070
IWK Health Centre Interdisciplinary Telephone Practice (TP) Policy #1802
IWK Health Centre Oxytocin Infusion, Medication Management Policy #30.11
IWK Health Centre Quality Practices for Fetal Tracings Policy #7118

Forms
Interdisciplinary Progress Note (IWKINPR)
Maternal Nursing Assessment (IWKMANU)
Telephone Practice Record A (IWKHEPR)
Telephone Practice Record B (IWKHEPRTE)
Consultation report (IWKCOREA)

Brochures
Cervical Ripening: Dinoprostone Vaginal Insert (Cervidil) Information for Patients and Families PL# 0901
Cervical Ripening: Balloon Catheter Information for Patients and Families PL# 0899
Obstetrical Day Unit PL# 0190

Appendices
Appendix A – Procedure for Balloon Catheter Placement
Appendix A - Procedure for Balloon Catheter Placement

Equipment required for balloon catheter placement:

- Disposable catheter tray
- Sterile water
- Bridine
- 30-50cc syringe
- Silastic (latex free) foley catheter with 30cc bulb
- Sponge/ polyp forcep
- Uterine dressing forcep
- Speculum

Procedure

1. The patient should be placed in lithotomy position with the bed broken

2. The balloon catheter will be placed by a physician

3. Placement may be done under direct visualization or digitally after prepping the cervix and vagina with bridine

4. After catheter placement past the internal cervical os the balloon should be inflated with sterile water to and not exceeding 30cc

5. The balloon catheter should be pulled downward against the internal cervical os and then taped to the inner thigh under mild tension
District Health Authority/IWK Policies Being Replaced

This is a new clinical guideline and does not replace an existing IWK Health Centre guideline.

Version History

(To Be Completed by the Policy Office)

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<th>Minor Revisions (e.g. spelling correction, wording changes, etc.)</th>
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