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INDUCTION CONTROL
AT YOUR FINGERTIPS

Get started ›
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- Successful Induction
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- Uterine Tachysystole
- CERVIDIL Administration
CERVICAL RIPENING PREPARES THE CERVIX FOR LABOUR

CERVICAL RIPENING
(SOFT, PLIABLE CERVIX)

CERVICAL RIPENING PREPARES THE CERVIX FOR LABOUR

CERVICAL RIPENING PREPARES THE CERVIX FOR LABOUR

CERVICAL RIPENING (SOFT, PLIABLE CERVIX)

EFFACEMENT/THINNING

DILATION

CERVIDIL IS APPROVED FOR CERVICAL RIPENING OVER A 12-HOUR PERIOD¹

IN CLINICAL TRIALS, A SINGLE DOSE OF CERVIDIL...

...SUCCESSFULLY RIPENED THE CERVIX IN THE MAJORITY OF WOMEN WITH AN UNFAVOURABLE CERVIX²,³

Cervical ripening⁴
The use of pharmacological or other means to soften, efface, or dilate the cervix to increase the likelihood of a vaginal delivery.

Induction of labour⁴
The initiation of contractions in a pregnant woman who is not in labour to help her achieve a vaginal birth within 24 to 48 hours.

Augmentation of labour⁵
The enhancement of contractions in a pregnant woman already in the active phase of labour.

NOTE: Addition of oxytocin in the latent phase is considered an induction, not an augmentation.

ASSESS, COMMUNICATE AND DISCUSS

Induction of labour and your patient

PRE INDUCTION ASSESSMENT

- Review maternal history
- Confirm gestation
- Perform baseline maternal observations (temperature, pulse, respiratory rate and blood pressure)
- Perform abdominal palpation to confirm (presentation, attitude, lie, position and engagement)
- Assess membrane status (ruptured or intact)
- Vaginal examination to assess the cervix
- Assess fetal wellbeing;
  - Fetal heart rate (FHR)
  - Confirm non-stress test (NST) is normal
  - If NST is abnormal, escalate as per local protocol

Discussion follow-up

- Allow time for decision-making and asking questions
- Obtain informed consent
- Document the entire discussion

Patient communication

- Maternal and/or fetal benefit and risk
- Proposed methods for cervical ripening and/or induction of labour – their pros and cons
- Individual circumstances determining the choice of method
- Options for pain management

PREDICTING SUCCESS OF CERVICAL RIPENING AND INDUCTION OF LABOUR

Understanding the role played by each of the potential predictors of a successful induction of labour (IOL) can aid clinicians in the timing and management of labour.

References:
PREDICTING SUCCESS OF CERVICAL RIPENING AND INDUCTION OF LABOUR

GESTATIONAL AGE

- Gestational age is the common term used during pregnancy to describe how far along the pregnancy is. It is measured in weeks, from the first day of the woman’s last menstrual cycle to the current date. A normal pregnancy can range from 38 to 42 weeks.

FACTORS IMPACTING SUCCESS OF IOL

1-3

GESTATIONAL AGE

- Body mass index (BMI)
- Obstetric history
- Neonatal birth weight

In 1964, Bishop published his seminal work on preinduction assessment of cervical status, which eventually became the most widely used scoring system in predicting the likelihood of successful labour induction.

The Bishop pelvic scoring system plays a crucial role in determining the status of the pelvis when labour induction is indicated. If the Bishop score is more than 8, the chances of vaginal delivery after inducing labour is the same as in spontaneous labour.\(^1-3\)
PREDICTING SUCCESS OF CERVICAL RIPENING AND INDUCTION OF LABOUR

INDICATION FOR INDUCTION

- See Society of Obstetricians and Gynaecologists (SOGC) guidelines

PREDICTING SUCCESS OF CERVICAL RIPENING AND INDUCTION OF LABOUR

Gestational age

BODY MASS INDEX (BMI)

- BMI serves as an important predictor of success of IOL
- Obesity is associated with increased chances of Caesarean section
- Obstetric history of the patient is yet another important parameter
  - Lean = BMI less than 30
  - Obese = BMI 30–39.9
  - Extremely obese = BMI 40 or higher

References:
Predicting success of cervical ripening and induction of labour

Parity

- Parity can be another predictor of success of labour induction with an increase in the success rate associated with multiparity
- Parity refers to the number of previous pregnancies of >20 weeks
  - parity: nulliparity, low multiparity, and grand multiparity

References:
MATERNAL AGE

- The age of the mother at the time of delivery
- Advanced maternal age is defined as age 35 years or more at delivery

ASSESS, COMMUNICATE AND DISCUSS

A Bishop score of <6 may be used to determine the need for cervical ripening and for the clinician to estimate the likelihood of a vaginal delivery.\(^1\)

<table>
<thead>
<tr>
<th>MODIFIED BISHOP SCORING SYSTEM (MBS) (^1)</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Dilation (cm)</td>
<td>0</td>
</tr>
<tr>
<td>Effacement (%)</td>
<td>0-30</td>
</tr>
<tr>
<td>Length (cm)</td>
<td>&gt;3</td>
</tr>
<tr>
<td>Consistency</td>
<td>Firm</td>
</tr>
<tr>
<td>Position</td>
<td>Posterior</td>
</tr>
<tr>
<td>Station</td>
<td>SP-3 or above</td>
</tr>
</tbody>
</table>

Individual scores for each parameter are combined to give a final score.

Contraindications to IOL include, but are not limited to the following:

- Placenta or vasa previa or cord presentation
- Abnormal fetal lie or presentation (e.g. transverse lie or footling breech)
- Prior classical or inverted T uterine incision
- Significant prior uterine surgery (e.g. full thickness myomectomy)
- Active genital herpes
- Pelvic structural deformities
**RECOMMENDED INDICATIONS OF INDUCTION OF LABOUR**

**High Priority**
- Preeclampsia >37 weeks
- Significant maternal disease not responding to treatment
- Significant but stable antepartum haemorrhage
- Chorioamnionitis
- Suspected fetal compromise
- Term pre-labour rupture of membranes with maternal GBS colonization

**Contraindications to IOL include, but are not limited to the following:**
- Placenta or vasa previa or cord presentation
- Abnormal fetal lie or presentation (e.g. transverse lie or footling breech)
- Prior classical or inverted T uterine incision
- Significant prior uterine surgery (e.g. full thickness myomectomy)
- Active genital herpes
- Pelvic structural deformities

RECOMMENDED INDICATIONS OF INDUCTION OF LABOUR

High Priority

Other Indications

- Postdates (>41 + 0 weeks) or post-term (>42 + 0) pregnancy
- Uncomplicated twin pregnancy >38 weeks
- Diabetes mellitus (glucose control may dictate urgency)
- Alloimmune disease at or near term
- Intrauterine growth restriction
- Oligohydramnios
- Gestational hypertension >38 weeks
- Intrauterine fetal death
- Pre Rupture of Membrane (PROM) at or near term, Group B Streptococcus (GBS) negative
- Logistical problems (e.g. history of rapid labour, distance to hospital)
- Intrauterine death in a prior pregnancy

Contraindications to IOL include, but are not limited to the following:

- Placenta or vasa previa or cord presentation
- Abnormal fetal lie or presentation (e.g. transverse lie or footling breech)
- Prior classical or inverted uterine incision
- Significant prior uterine surgery (e.g. full thickness myomectomy)
- Active genital herpes
- Pelvic structural deformities

PROPOSED CONSIDERATIONS FOR PROTOCOL*1-3

- Procedure

- Once approved, procedure with CERVIDIL requires

- Prior to inserting CERVIDIL

- All patients should be instructed to inform the RN when one or more of the following occur

- CERVIDIL insertion

*adapted from current hospital protocols.

## PROPOSED CONSIDERATIONS FOR PROTOCOL*1-3

<table>
<thead>
<tr>
<th>Procedure</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Once approved, procedure with CERVIDIL requires</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Prior to inserting CERVIDIL</strong></td>
<td></td>
</tr>
<tr>
<td><strong>All patients should be instructed to inform the RN when one or more of the following occur</strong></td>
<td></td>
</tr>
<tr>
<td><strong>CERVIDIL insertion</strong></td>
<td></td>
</tr>
</tbody>
</table>

- Review maternal history for indication of induction-related complications in pregnancy
- Obtain informed consent for medical induction of labour (IOL)
- Explain the procedure to the patient
- Provide a written order for IOL, stipulating in or outpatient cervical ripening

*adapted from current hospital protocols.

PROPOSED CONSIDERATIONS FOR PROTOCOL*1-3

**Procedure**

- Chart documentation of obstetrical indication
- Absence of contraindications
- Chart-documented ripening of the cervix (Bishop score)
- Consultation with Ob/Gyn in the presence of an “urgent” indication

**Once approved, procedure with CERVIDIL requires**

**Prior to inserting CERVIDIL**

**All patients should be instructed to inform the RN when one or more of the following occur**

**CERVIDIL insertion**

---

*adapted from current hospital protocols.

References:
PROPOSED CONSIDERATIONS FOR PROTOCOL*1-3

- Ensure qualified nursing staff to provide monitoring
- Normal fetal non-stress test (NST) If NST is atypical/abnormal:
  - Perform intrauterine resuscitation
  - Notify HCP/designate
  - Obtain written order to continue IOL
- Baseline maternal vital signs (BP, P, RR, temperature)

Procedure

Once approved, procedure with CERVIDIL requires

Prior to inserting CERVIDIL

All patients should be instructed to inform the RN when one or more of the following occur

CERVIDIL insertion

*adapted from current hospital protocols.

# Proposed Considerations for Protocol*1-3

| Procedure | • Contractions become regular every 5 minutes or closer  
|           | • Patient becomes uncomfortable with contractions  
|           | • There are signs of bleeding  
|           | • Membranes rupture  
|           | • Insert falls out or drops lower in the vagina  

Once approved, procedure with CERVIDIL requires

Prior to inserting CERVIDIL

All patients should be instructed to inform the RN when one or more of the following occur

CERVIDIL insertion

*adapted from current hospital protocols.

**PROPOSED CONSIDERATIONS FOR PROTOCOL**

*adapted from current hospital protocols.

<table>
<thead>
<tr>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keep CERVIDIL in the freezer until used</td>
</tr>
<tr>
<td>Ask patient to empty her bladder</td>
</tr>
<tr>
<td>Position patient supine with wedge under right hip to maintain left uterine displacement for insertion</td>
</tr>
<tr>
<td>Use water or a small amount of water-soluble gel as a lubricant to assist in the insertion of CERVIDIL</td>
</tr>
<tr>
<td>- Ensure that the lubricant does not come into excessive contact with the vaginal insert and does not cover it. This may prevent optimal swelling of the insert</td>
</tr>
<tr>
<td>Insert CERVIDIL digitally, <em>placing it transversely in the posterior fornix of the vagina</em></td>
</tr>
<tr>
<td>Position the insert string to remain in the vagina with a short length exposed at the introitus, to prevent the insert from accidentally being pulled out</td>
</tr>
<tr>
<td>Inform the physician if signs of uterine hypertonia</td>
</tr>
<tr>
<td>Monitor FHR and contraction continuously with EFM for a minimum of one hour post-insertion; interpret and document tracing per FHS standards</td>
</tr>
<tr>
<td>Maintain patient on bedrest in left lateral or semi-Fowler’s position for optimal fetal oxygenation and monitoring. Patient should not be supine</td>
</tr>
<tr>
<td>Instruct patient to remain lying down for 2 hours following insertion of CERVIDIL. They can move around after this time. HCP should determine inpatient vs outpatient use</td>
</tr>
<tr>
<td>To stop the release of prostaglandin, pull the removal cord. Flushing or cleaning the vagina is not necessary</td>
</tr>
</tbody>
</table>

| Once approved, procedure with CERVIDIL requires |
| All patients should be instructed to inform the RN when one or more of the following occur |
| CERVIDIL insertion |

References:
PROPOSED CONSIDERATIONS FOR PROTOCOL*1-3

Procedure

Once approved, procedure with CERVIDIL requires

Prior to inserting CERVIDIL

All patients should be instructed to inform the RN when one or more of the following occur

CERVIDIL insertion

*adapted from current hospital protocols.

# METHODS FOR INDUCTION OF LABOUR

## CERVIDIL VS OTHER PRODUCTS FOR CERVICAL RIPENING

<table>
<thead>
<tr>
<th></th>
<th>CONTROLLED-RELEASE VAGINAL INSERT¹ (CERVIDIL)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose</strong></td>
<td>10 mg (0.3 mg/hour)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Format</strong></td>
<td>Controlled-release insert</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Administration</strong></td>
<td>Single insert, 0.3 mg/h controlled release over 12 h, removed using retrieval tape</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Site of administration</strong></td>
<td>Posterior vaginal fornix</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Storage conditions</strong></td>
<td>Frozen, -20°C to -10°C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Outpatient procedure</strong></td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Vaginal birth after Caesarean (VBAC)</strong></td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Removable</strong></td>
<td>Yes</td>
<td>• Remove upon the onset of active labour</td>
<td>• Spontaneous rupture of membranes</td>
<td></td>
</tr>
<tr>
<td><strong>Time to oxytocin</strong></td>
<td>30 min</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Use in PROM patients? According to product monographs</strong></td>
<td>Yes</td>
<td>• Listed as warning</td>
<td>• Clinical evidence is up to date</td>
<td></td>
</tr>
</tbody>
</table>

## METHODS FOR INDUCTION OF LABOUR

### CERVIDIL VS OTHER PRODUCTS FOR CERVICAL RIPENING

<table>
<thead>
<tr>
<th></th>
<th>CONTROLLED-RELEASE VAGINAL INSERT¹ (CERVIDIL)</th>
<th>Intravaginal gel²</th>
<th>Intracervical gel³</th>
<th>Intracervical Foley catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose</strong></td>
<td>10 mg (0.3 mg/hour)</td>
<td>1 or 2 mg</td>
<td>0.5 mg /2.5 mL (3 g)</td>
<td>#16 French Foley catheter/urinary catheter with 30 cc balloon</td>
</tr>
<tr>
<td><strong>Format</strong></td>
<td>Controlled-release insert</td>
<td>Pre-filled syringe</td>
<td>Pre-filled syringe</td>
<td></td>
</tr>
<tr>
<td><strong>Administration</strong></td>
<td>Single insert, 0.3 mg/h controlled release over 12 h, removed using retrieval tape</td>
<td>Initial dose: 1 mg; Single repeat dose*: 1 or 2 mg *6 h post initial dose.</td>
<td>Single-dose gel 0.5 mg/2.5 mL syringe</td>
<td>Inflation with sterile water or normal saline 30 – 60 mL. Often requires oxytocin administration</td>
</tr>
<tr>
<td><strong>Site of administration</strong></td>
<td>Posterior vaginal fornix</td>
<td>Posterior vaginal fornix</td>
<td>Cervical canal</td>
<td>Cervical canal</td>
</tr>
<tr>
<td><strong>Storage conditions</strong></td>
<td>Frozen, ~20°C to ~10°C</td>
<td>Refrigeration, 2°C to 8°C</td>
<td>Refrigeration, 4°C</td>
<td>Room temperature</td>
</tr>
<tr>
<td><strong>Outpatient procedure</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Vaginal birth after Caesarean (VBAC)</strong></td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Removable</strong></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes by HCP ONLY</td>
</tr>
<tr>
<td></td>
<td>• Remove upon the onset of active labour</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Spontaneous rupture of membranes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Time to oxytocin</strong></td>
<td>30 min</td>
<td>6 hours</td>
<td>6 hours</td>
<td>No delay ww Use cautiously with prior uterine scar</td>
</tr>
<tr>
<td><strong>Use in PROM patients? According to product monographs</strong></td>
<td>Yes</td>
<td>Contraindicated in patients with ruptured amniotic membranes or suspected chori amnionitis</td>
<td>Contraindicated in patients with ruptured amniotic membranes or suspected chori amnionitis</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>• Listed as warning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Clinical evidence is up to date</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CERVIDIL KEEPS CONTROL AT YOUR FINGERTIPS

Simple insertion to start treatment

- A single insert delivers controlled release of the drug at the cervix for up to 12 hours
- Dinoprostone is released continuously at a mean rate of ~0.3 mg/hour over 12 hours
- The long tape retrieval system allows immediate removal if required
- With a half-life of 1–3 minutes, dinoprostone is quickly cleared from the woman’s system, upon removal of the insert
- Cases of hyperstimulation reversed within 2–13 minutes after removal of CERVIDIL

Notes:
- In addition to proven efficacy and safety, the delivery system for CERVIDIL offers added control and convenience
- The hydrogel polymer matrix releases the drug in a steady and controlled amount over the administration period
- Unlike other formulations (gels or tablets), the unique retrieval system allows immediate removal if circumstances require it
- Following removal of the CERVIDIL insert (in case of an adverse event), the short half-life of dinoprostone (1–3 minutes) means that the drug is quickly cleared from the woman’s system

OUTPATIENT INDUCTION CRITERIA

Careful patient selection\(^1\,^2\)

Low-risk patients may be discharged and advised to return immediately if\(^2\)

Outpatient IOL is not recommended for:
OUTPATIENT INDUCTION CRITERIA

Careful patient selection

- Must be a low risk patient/pregnancy
  - Singleton uneventful pregnancy
  - No fetal or maternal concerns
  - No identified obstetrical risk factors
- Have no contraindication to induction of labour
- Present no logistical issues such as ability of patient to contact the hospital and return quickly should any concerns arise even when she is unable to transport herself
  - Ability to travel to a hospital within 30 minutes
  - Adequate understanding of process and understanding of need to return
- Appropriate indication for induction
- Patients willing to receive outpatient cervical ripening
- Have an EFM tracing classified as normal prior to ripening and following insertion
- Have maternal vital signs within normal limits

Low-risk patients may be discharged and advised to return immediately if

Outpatient IOL is not recommended for:

OUTPATIENT INDUCTION CRITERIA

Careful patient selection

Low-risk patients may be discharged and advised to return immediately if

Outpatient IOL is not recommended for:

- Contractions are every five (5) minutes or less
- Membranes rupture
- Bright red vaginal bleeding occurs
- The insert falls out
- There are any other concerns

References:
OUTPATIENT INDUCTION CRITERIA

Careful patient selection¹,²

Low-risk patients may be discharged and advised to return immediately if²

Outpatient IOL is not recommended for:

• Abnormal fetal wellbeing
• Fetal conditions that require close fetal monitoring (e.g. Intrauterine growth restriction (IUGR)/Small-for-gestational-age (SGA)
• Significant maternal medical condition requiring treatment or close maternal monitoring for more than 12 hours
• Type 1 or 2 diabetes mellitus (DM), unstable DM or gestational diabetes mellitus (GDM)
• Uncontrolled hypertension, preeclampsia
• Seizure disorder
• Active venous thromboembolism (VTE)
• Suspected chorioamnionitis
• Previous Caesarean section
• Breech presentation
• Multipara more than 6 births
• Preterm gestation (less than 37 weeks)
• Preterm and term PROM
• Significant vaginal bleeding
• Uterine over-distension i.e. polyhydramnios or oligohydramnios
• Previously scarred uterus
• Patients living greater than 30 minutes from the hospital or with no means of transportation
• Patients without phone access to communicate with the hospital

CERVIDIL AND PREMATURE RUPTURE OF MEMBRANE (PROM)

Safety and use of CERVIDIL in PROM patients

<table>
<thead>
<tr>
<th></th>
<th>All (n=1179)</th>
<th>Outpatients (n=611)</th>
<th>Inpatients (n=568)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROM</td>
<td>233 (19.8%)</td>
<td>46 (7.5%)</td>
<td>187 (32.9%)</td>
</tr>
<tr>
<td>Postdates</td>
<td>946 (80.2%)</td>
<td>565 (92.5%)</td>
<td>381 (67.1%)</td>
</tr>
</tbody>
</table>

CERVIDIL VS OXYTOCIN IN TERM PROM

- Vaginal delivery within 24 h (primary): 75.8% CERVIDIL vs 63.3% Oxytocin, p=0.001
- Achieved active phase (secondary): 92.4% CERVIDIL vs 83.3% Oxytocin, p=0.004
- Vaginal delivery (secondary): 81.6% CERVIDIL vs 69.7% Oxytocin, p=0.004

*Women with PROM and a Bishop score ≤ 5 were randomly assigned to receive either an intravenous oxytocin infusion (n=223) or a dinoprostone insert followed 6 hours later by an intravenous oxytocin infusion (n=227).

CERVIDIL OUTPATIENTS VS INPATIENTS

Higher level of outpatient satisfaction vs inpatients

- Outpatients reported a higher level of satisfaction 56% vs 39% inpatients during first 12 hours of induction (p<.008)

Pain and anxiety levels were similar to inpatients

- In nulliparous women with a Bishop score ≤4, CERVIDIL limits pain compared with vaginal PGE₂ gel
- CERVIDIL was associated with a lower number of vaginal examinations than PGE₂ gel (p=0.012), suggesting that it may reflect a less invasive treatment option that offers greater patient comfort and satisfaction

Outpatient safety

- An outpatient model of labour induction using dinoprostone inserts is feasible and safe
- CERVIDIL use in outpatient induction priming offers similar neonatal safety and efficacy as inpatient induction model and has the potential advantage of enhanced patient control and satisfaction
- Outpatient induction not only allows for a more familiar and less-threatening environment, but it also increases a patient’s participation in their labour

- No differences in neonatal measures or mode of delivery were seen in CERVIDIL outpatients
- Outpatient induction with CERVIDIL can be a reasonable option for low-risk women

* Unadjusted analysis by location of delivery vs inpatient.

CERVIDIL OUTPATIENTS VS INPATIENTS

Outcome

<table>
<thead>
<tr>
<th>Composite neonatal safety</th>
<th>Outpatients</th>
<th>Inpatients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>84 (14%)</td>
<td>62 (11%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5-minute Apgar &lt;7</th>
<th>Outpatients</th>
<th>Inpatients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10 (1.6%)</td>
<td>6 (1.1%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NICU &gt;12 hours or transfer to level III nursery</th>
<th>Outpatients</th>
<th>Inpatients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>75 (12%)</td>
<td>58 (10%)</td>
</tr>
</tbody>
</table>

* Unadjusted analysis by location of delivery vs inpatient.

### CERVIDIL OUTPATIENTS VS INPATIENTS

<table>
<thead>
<tr>
<th>Mode of delivery</th>
<th>Outpatients (n=611)</th>
<th>Inpatients (n=568)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spontaneous delivery</td>
<td>247 (40%)</td>
<td>248 (44%)</td>
</tr>
<tr>
<td>Assisted vaginal delivery</td>
<td>135 (22%)</td>
<td>110 (19%)</td>
</tr>
<tr>
<td>Failed forceps</td>
<td>11 (2%)</td>
<td>4 (1%)</td>
</tr>
<tr>
<td>Caesarean section</td>
<td>229 (38%)</td>
<td>210 (37%)</td>
</tr>
<tr>
<td>Vaginal delivery in &lt;24 hours</td>
<td>79 (13%) (p&lt;.001)</td>
<td>231 (41%)</td>
</tr>
</tbody>
</table>

* Unadjusted analysis by location of delivery vs inpatient.

References:
CERVIDIL KEEPS CONTROL AT YOUR FINGERTIPS

Simple insertion in the posterior fornix to start treatment

CERVIDIL KEEPS CONTROL AT YOUR FINGERTIPS

Simple insertion in the posterior fornix to start treatment

Single insert delivers controlled release of the drug at the cervix for up to 12 hours

CERVIDIL KEEPS CONTROL AT YOUR FINGERTIPS¹

Simple insertion in the posterior fornix to start treatment

Single insert delivers controlled release of the drug at the cervix for up to 12 hours

Long tape retrieval system allows immediate removal if required

CERVIDIL KEEPS CONTROL AT YOUR FINGERTIPS¹

Simple insertion in the posterior fornix to start treatment

Single insert delivers controlled release of the drug at the cervix for up to 12 hours

Long tape retrieval system allows immediate removal if required

Half-life of 1-3 minutes means quick clearance of the drug from the woman’s system


https://drive.google.com/file/d/1xuxEFwVk4GvXB08mkD7kt_S22keGoj/view?usp=sharing
CERVIDIL KEEPS CONTROL AT YOUR FINGERTIPS

IOL REDUCES CAESAREAN SECTION RATES

Compared with expectant management, IOL was associated with a lower Caesarean section rate.\(^1\)

<table>
<thead>
<tr>
<th>Study/subgroup</th>
<th>Induction n/N</th>
<th>Expectant n/N</th>
<th>Risk ratio M-H, Fixed (95% CI)</th>
<th>Weight</th>
<th>Risk ratio M-H, Fixed (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>37–39 weeks</td>
<td>481</td>
<td>235</td>
<td></td>
<td>2.6%</td>
<td>0.58 (0.30–1.11)</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>39–40 weeks</td>
<td>415</td>
<td>395</td>
<td></td>
<td>2.4%</td>
<td>0.74 (0.38–1.41)</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>41 weeks</td>
<td>501</td>
<td>497</td>
<td></td>
<td>13.6%</td>
<td>0.74 (0.58–0.96)</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;41 weeks</td>
<td>3004</td>
<td>2990</td>
<td></td>
<td>78.9%</td>
<td>0.91 (0.82–1.00)</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>4515</td>
<td>4234</td>
<td></td>
<td>100.0%</td>
<td>0.89 (0.81–0.97)</td>
</tr>
</tbody>
</table>

IRR 0.89, 95% CI (0.81–0.97), \(p=0.0067\).\(^1\)

## CERVIDIL VS FOLEY CATHETER FOR LABOUR INDUCTION

<table>
<thead>
<tr>
<th>Study Details</th>
<th>Key conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled-release dinoprostone insert versus Foley catheter for labor induction: A meta-analysis.¹</td>
<td>• <strong>Time from induction to delivery significantly shorter in CERVIDIL group compared with Foley catheter group</strong> (mean difference=5.73 hours; 95% CI: 1.26–10.20; <em>p</em>=0.01)</td>
</tr>
<tr>
<td>Six randomised controlled trials comparing women who received CERVIDIL ( (n=731) ) with Foley catheter balloon ( (n=722) ).</td>
<td>• No significant differences in vaginal delivery within 24 hours between CERVIDIL group compared with Foley catheter group ( (RR: 0.75; 95% \text{ CI}: 0.43–1.30; p=0.31) )</td>
</tr>
<tr>
<td></td>
<td>• No significant differences for Caesarean section between CERVIDIL group compared with Foley catheter group ( (RR: 0.94; 95% \text{ CI}: 0.80–1.12; p=0.50) )</td>
</tr>
<tr>
<td></td>
<td>• CERVIDIL was associated with increased rate of excessive uterine contraction compared with Foley catheter ( (RR: 0.07; 95% \text{ CI}: 0.03–0.19; p&lt;0.01) )</td>
</tr>
<tr>
<td></td>
<td>• <strong>CERVIDIL was associated with less oxytocin use compared with Foley catheter</strong> ( (RR: 1.86; 95% \text{ CI}: 1.25–2.77; p&lt;0.01) )</td>
</tr>
</tbody>
</table>

CERVIDIL VS FOLEY CATHETER

CERVIDIL has comparable Caesarean section rates to Foley catheter[^1]*

**Tachysystole Rates**

<table>
<thead>
<tr>
<th></th>
<th>CERVIDIL 2%</th>
<th>FOLEY 2%</th>
</tr>
</thead>
</table>

[^1]*RR=1.11 [95% CI: 0.16–7.78]; p=1.00.

**Caesarean Section Rates**

<table>
<thead>
<tr>
<th></th>
<th>CERVIDIL 22%</th>
<th>FOLEY 20%</th>
</tr>
</thead>
</table>

[^1]*RR=0.90 [95% CI: 0.54–1.50]; p=0.68.

**Rate of Oxytocin Augmentation vs Foley catheter[^1]**

<table>
<thead>
<tr>
<th></th>
<th>Foley catheter</th>
<th>CERVIDIL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>78%</td>
<td>66%</td>
</tr>
</tbody>
</table>

[^1]*RR=1.18 [95% CI: 1.00–1.40]; p=0.046.

CERVIDIL VS FOLEY CATHETER

Tachysystole Rates

CERVIDIL 2%

FOLEY 2%

*RR=1.11 (95% CI: 0.16–7.76); p=1.00.
CERVIDIL VS FOLEY CATHETER

Caesarean Section Rates

*RR=0.90 (95% CI: 0.54–1.50); p=0.68.
CERVIDIL VS FOLEY CATHETER

Rate of Oxytocin Augmentation vs Foley catheter

Foley catheter

CERVIDIL

78%

66%

RR=1.18 (95% CI: 1.00–1.40); p=0.046.

### CERVIDIL VS INTRACERVICAL PGE$_2$ GEL

#### FURTHER RECENT DATA

<table>
<thead>
<tr>
<th>Study</th>
<th>Details</th>
<th>Key conclusions</th>
</tr>
</thead>
</table>
| PGE$_2$ GEL compared to dinoprostone vaginal insert for cervical ripening and induction of labor.\(^1\) | • Retrospective, single-centre study of women who required induction of labour with an unfavourable cervix, Bishop score ≤6  
  • Women underwent induction with administration of either intracervical gel (n=100) or vaginal insert (CERVIDIL; n=200) | • Comparable efficacy: 73% of women in the CERVIDIL group delivered within 24 hours, compared with 52% in the gel group (\(p=0.09\))  
  • Greater percentage of women in the CERVIDIL group (86%) delivered after single application compared with the gel group (68%)  
  • No significant difference in Caesarean section rate between the two groups: CERVIDIL (13.5%) and gel (10.0%)  
  • 3 neonates with Apgar <6 at 1 minute in the gel group compared with one in the CERVIDIL group (\(p=NS\))  
  • Hyperstimulation with abnormal fetal heart rate occurred in 11 cases (5.5%), all of them in the CERVIDIL group, requiring device removal in all cases and administration of tocolysis in 3% of cases |
| Efficiency of dinoprostone insert for cervical ripening and induction of labor in women of full-term pregnancy compared with PGE$_2$ Gel: A meta-analysis.\(^2\) | • Meta-analysis of 15 randomised controlled trials involving 1779 women undergoing cervical ripening and induction of labour with CERVIDIL (n=845) or intravaginal gel (n=857), who had a Bishop score of <7  
  • The primary outcomes were the rates of vaginal delivery and Caesarean section | • No significant difference between CERVIDIL and gel in rates of vaginal delivery (OR: 1.12; \(p=0.34\)) or artificial-assisted vaginal delivery (OR: 0.96; 95% CI: 0.59–1.56; \(p=0.87\))  
  • No significant difference between CERVIDIL and gel in the Caesarean section rate (OR: 0.89; 95% CI: 0.71–1.12; \(p=0.34\))  
  • CERVIDIL significantly reduced time to vaginal delivery compared with gel (OR: 2.35; 95% CI: 1.34–4.13; \(p=0.003\))  
  • The rates of hospital stay more than 4 days were 0.41 with CERVIDIL (n=123) vs 0.46 with gel (n=123)  
  • The rate of postpartum haemorrhage was 0.13 for CERVIDIL versus 0.23 for gel |

CERVIDIL VERSUS VAGINAL PGE₂ GEL¹

CERVIDIL 72% spontaneous vaginal delivery

Vaginal PGE₂ GEL 54% spontaneous vaginal delivery

*Difference: 18%; 95% CI: 2–34%; p=0.03.

<table>
<thead>
<tr>
<th>PRIMARY OUTCOMES BASED ON THE INDUCTION METHOD²</th>
<th>CERVIDIL (N=26)</th>
<th>PGE₂ GEL (N=26)</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women initiating labour after vaginal prostaglandin</td>
<td>17 (65.4%)</td>
<td>19 (73.1%)</td>
<td>0.764</td>
</tr>
<tr>
<td>Oxytocin in dilating phase</td>
<td>11 (42.3%)</td>
<td>16 (61.5%)</td>
<td>0.267</td>
</tr>
<tr>
<td>Infusion time, minutes [mean ± SD]</td>
<td>143.6 ± 98.0</td>
<td>157.5 ± 103.8</td>
<td>0.726</td>
</tr>
<tr>
<td>Caesarean section deliveries</td>
<td>9 (34.6%)</td>
<td>10 (38.5%)</td>
<td>0.990</td>
</tr>
</tbody>
</table>

CERVIDIL DEMONSTRATES A RAPID RESOLUTION OF TACHYSYSTOLE FOLLOWING RETRIEVAL

† Uterine tachysystole was defined as uterine activity >5 contractions in a 10-minute window, averaged over 3 consecutive 10-minute periods (i.e. ≥18 contractions in 30 minutes, with each 10-minute period having at least 6 contractions). The contractions must have been of adequate intensity and duration, i.e. moderate intensity and duration ≥45 seconds, in order for the uterine activity to be characterized as tachysystole.

‡ FHR involvement was defined as late decelerations, bradycardia or prolonged decelerations.


<table>
<thead>
<tr>
<th>PRIMARY REASON FOR RETRIEVAL IN WOMEN RECEIVING CERVIDIL FOR IOL</th>
<th>n/N (%)</th>
<th>MEDIAN TIME TO RESOLUTION (MINUTES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intrapartum adverse events (AEs), any</td>
<td>27/680 (4.0)</td>
<td>47</td>
</tr>
<tr>
<td>Uterine tachysystole† with FHR involvement‡</td>
<td>8/680 (1.2)</td>
<td>8.5</td>
</tr>
<tr>
<td>Category II/III FHR pattern AE†</td>
<td>13/680 (1.9)</td>
<td>87</td>
</tr>
<tr>
<td>Uterine tachysystole† or uterine hypertonus</td>
<td>2/680 (0.3)</td>
<td>Not reported</td>
</tr>
<tr>
<td>Meconium in amniotic fluid</td>
<td>2/680 (0.3)</td>
<td>Not reported</td>
</tr>
<tr>
<td>Other AEs</td>
<td>3/680 (0.4)</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

The SOGC Guidelines state that the controlled-release preparation (CERVIDIL) allows for removal in case of uterine tachysystole with FHR changes and requires a 30-minute delay before the initiation of oxytocin upon its removal.†
DEFINING UTERINE TACHYSYSTOLE (HYPERSTIMULATION)

### DEFINITIONS OF UTERINE ACTIVITY IN LABOUR

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>Number of uterine contractions in a 10-minute period</td>
</tr>
<tr>
<td>Duration</td>
<td>Interval [seconds] between contraction beginning to end, measured from the uterine tone baseline, usually with external abdominal tocography</td>
</tr>
<tr>
<td>Intensity</td>
<td>Strength of the peak of uterine contractions minus the resting tone measured: a) Objectively through the use of intrauterine pressure transducer catheter (IUPC). This may range from 25 to 50 mm Hg in the first stage of labor and may rise to &gt;80 mm Hg in the second stage. Contraction can be defined as mild (&lt;50 mm Hg), moderate or strong (&gt;50 mm Hg) b) Subjectively through palpation of the uterus through the maternal abdomen and described as mild, moderate or strong</td>
</tr>
<tr>
<td>Relaxation time</td>
<td>Time [seconds] between the end of one contraction and the onset of the next contraction summed over a 10-minute period</td>
</tr>
<tr>
<td>Montevideo units</td>
<td>Peak Intensity of each contraction calculated in millimetres of mercury (mm Hg) minus resting uterine tone, summed over a 10-minute period</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uterine tachysystole</td>
<td>Greater than 5 contractions in 10 minutes, averaged over 30 minutes; a) Without fetal heart rate changes, previously termed hypertonus b) With fetal heart rate changes, previously termed uterine hyperstimulation</td>
</tr>
</tbody>
</table>

### FACTORS ASSOCIATED WITH AN INCREASED RISK OF UTERINE TACHYSYSTOLE

<table>
<thead>
<tr>
<th>Factor</th>
<th>Characteristics associated with tachysystole</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>- Younger maternal age</td>
</tr>
<tr>
<td></td>
<td>- Nulliparity</td>
</tr>
<tr>
<td></td>
<td>- Chronic hypertension</td>
</tr>
<tr>
<td></td>
<td>- Smoking/alcohol/drug history</td>
</tr>
<tr>
<td>Pregnancy/Delivery</td>
<td>- Preeclampsia</td>
</tr>
<tr>
<td></td>
<td>- Oligohydramnios</td>
</tr>
<tr>
<td></td>
<td>- Induction of labour (not effective)</td>
</tr>
<tr>
<td></td>
<td>- Use of oxytocin</td>
</tr>
<tr>
<td></td>
<td>- Use of misoprostol</td>
</tr>
<tr>
<td></td>
<td>- Longer time in labor</td>
</tr>
<tr>
<td></td>
<td>- Epidural</td>
</tr>
</tbody>
</table>

CERVIDIL IS EASILY ADMINISTERED¹

Insertion of CERVIDIL involves a series of simple steps, which do not require a syringe, a vaginal speculum or stirrups

1. Remove CERVIDIL from freezer and open the aluminum foil at the tear provided

2. Pull out the CERVIDIL vaginal delivery system using the retrieval tape

3. Position CERVIDIL insert securely between the middle and index fingers

4. Introduce CERVIDIL high up into the vagina assisted by a small amount of aqueous gel

5. Position CERVIDIL behind the posterior vaginal fornix transversely to ensure it remains in situ

Proper administration is critical to avoid potential risk and should be performed by trained personnel

CERVIDIL® SAFETY INFORMATION

Indication and clinical use:
CERVIDIL® (dinoprostone) is indicated for: Initiation and/or continuation of cervical ripening in patients at or near term in whom there is a medical or obstetrical indication for the induction of labour. CERVIDIL® is not recommended in the geriatric and pediatric populations.

Contraindications:
- All contraindications to labour induction
- Relative contraindications specific to CERVIDIL
- Hypersensitivity to prostaglandins
- Patients in whom there is clinical suspicion or definite evidence of fetal distress where delivery is not imminent
- Patients in whom oxytocics are contraindicated or when prolonged contraction of the uterus may be detrimental to fetal safety or uterine integrity (previous caesarean section or major uterine surgery)
- Multipara with 6 or more previous term pregnancies
- Patients with a history of difficult labour and/or traumatic delivery
- Patients with overdistension of uterus (multiple pregnancy, polyhydramnios)
- Patients with a history of epilepsy whose seizures are poorly controlled
- History of previous uterine hypertonicity, glaucoma, or childhood asthma
- Caution in patients at risk for developing disseminated intravascular coagulation
- Simultaneously with other oxytocics
- Current pelvic inflammatory disease, unless adequate prior treatment has been instituted

Most serious warnings and precautions:
For Hospital Use Only: CERVIDIL should be administered only by trained obstetrical personnel in a hospital setting with appropriate obstetrical care facilities.

Other relevant warnings and precautions:
- Removal prior to oxytocin administration
- Removal if uterine tachysystole is encountered or if labour commences; prior to amniotomy; if there is fetal distress; if there is evidence of maternal or fetal adverse reactions
- Monitoring: After insertion, the patient should remain supine and monitored for 2 hours for any evidence of uterine tachysystole, change in fetal heart rate or maternal blood pressure or heart rate

For more information:
Please consult product monograph https://www.ferring.ca/en/products/reproductive-health/obstetrics-and-gynecology-products/#obstetrics-and-gynecology-products-expanded-2 for important information relating to adverse reactions, drug interactions and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling 1-866-384-1314.

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