Inpatient Induction of Labour with Mysodelle (GL1110)

Approval

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<tr>
<th>Approval Group</th>
<th>Job Title, Chair of Committee</th>
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<tr>
<td>Maternity &amp; Children’s Services Clinical Governance Committee</td>
<td>Chair, Maternity Clinical Governance Committee</td>
<td>4&lt;sup&gt;th&lt;/sup&gt; May 2018</td>
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Change History

<table>
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<tr>
<th>Version</th>
<th>Date</th>
<th>Author, job title</th>
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<tr>
<td>1.0</td>
<td>25/04/2018</td>
<td>C Harding, Consultant MW</td>
<td>Introduction and evaluation of new drug for IOL</td>
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<td>1.1</td>
<td>8/6/18</td>
<td>C Harding, Consultant MW</td>
<td>Live changes following further discussions with the IOL Team</td>
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Author: C Harding
Job Title: Consultant Midwife
Date: June 2018
Location: Policy hub/ Clinical/ Maternity / Intrapartum / GL1110
1. **Introduction**

Mysodelle is a vaginal delivery system containing 200mcg Misoprostol (PGE1) in a thin, flat rectangular pessary. Misoprostol is released in a controlled manner of 7 micrograms/hour over 24 hours. It is licensed for use in the UK for induction of labour in women with an unfavourable cervix (Bishop’s score less than or equal to 4) from 36 weeks.

A Cochrane review in 2010 concluded that vaginal misoprostol is more effective at cervical ripening and labour induction than dinoprostone (Hofmeyr et al 2010). A systematic review of 96 RCTs suggested that vaginal misoprostol is the most effective method for induction of labour to achieve a vaginal birth in 24 hours (Chen et al 2016). Uterine hyperstimulation is, however, associated with vaginal misoprostol use (Wing et al 2013).

The advantages of using Mysodelle are:
- Less vaginal examinations
- Quicker mean time to active labour
- Less oxytocin usage
- No effect on the CS rate when compared to Propess
- No effect on fetal outcomes

The potential disadvantages are
- Increased uterine hyperstimulation
- Increased need for terbutaline

Mysodelle usually results in uterine activity within a few hours with the mean time to labour being 12 hours

2. **Indications**

- Greater than 36 weeks gestation
- Bishops score less than or equal to 4
- No contraindications
- Woman agrees to inpatient induction with Mysodelle

3. **Contraindications**

- At risk of uterine rupture, abruption or neonatal compromise
  - Previous uterine scar (previous CS or myomectomy)
  - Current maternal substance misuse
  - Pre-eclampsia
  - Known small baby (less than 10\textsuperscript{th} centile / 2.5kg estimated weight)
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- Abnormal dopplers
- Oligohydramnios
- Vaginal bleeding in the third trimester

- P3 or more
- Multiple pregnancy
- Stillbirth
- Ruptured membranes
- Less than 36 weeks
- Bishops score greater than or equal to 5
- Mother wishes to have outpatient IOL and fits the criteria for this

4. Booking IOL

IOL should be booked in the usual way and women given the Use of Mysodelle for induction of labour information card

Admission should be to the IOL suite in the morning

5. Initial assessment

Initial assessment should be the same as for any induction of labour method

- History taken and notes reviewed
- Maternal observations
- Abdominal palpation and FH auscultation with pinard or sonic aid
- USS to confirm presentation
- 30 minute CTG

Mysodelle should be prescribed by an obstetrician “Misoprostol 200mcg PV pessary (Mysodelle)”

Terbutaline 0.25mg SC should also be prescribed to be used in case of tachysystole or hyperstimulation and stated on prescription chart

If high risk ensure ranitidine is prescribed during initial assessment for administration once regular contractions commence.

If GBS ensure antibiotics prescribed to be commenced once regular contractions commence or SROM occurs

6. Inserting Mysodelle

Mysodelle is inserted in the same way as Propess in the posterior fornix of the vagina behind the cervix, lying in a horizontal position

Excess tape should be tucked into the vagina and not left hanging out (to reduce the chance of it falling out)
Put a purple wrist band on the woman’s wrist to distinguish those who have had Mysodelle from Propess as the pessaries look identical when taken out of the packaging. This is to be removed when Mysodelle removed

Perform a CTG for 60 minutes and observe for
- Uterine tachysystole/hyperstimulation
- Constant abdominal pain
- Fresh vaginal bleeding
- Diarrhoea
- Vomiting
- Pyrexia

If any adverse reactions occur, ask a senior obstetrician to review and liaise with delivery suite concerning the potential need for transfer

7. **Ongoing observations**
   - Maternal vital signs should be carried out 4 hourly
   - The presence of uterine activity should be recorded
   - CTG should be repeated
     - After 6 hours the CTG should be repeated as this is the time that the drug levels peak
     - If any contractions are experienced
     - Every 6 hours
   - If uterine activity subsides in strength or frequency the CTG may be discontinued until further signs of labour develop, provided it is normal and following a full systematic assessment using the Fresh Eyes approach
   - Encourage mobilisation and light diet
   - Provide analgesia or encourage coping strategies according to the woman’s wishes

8. **Reassessment**

Women should not be reassessed less than 24 hours unless there is
- uterine tachysystole / (Greater than or equal to 5 contractions in every 10 minutes over 20 minutes with a normal CTG)
- uterine hyperstimulation (Greater than or equal to 5 contractions in 10 minutes with an abnormal CTG)
- vaginal bleeding
- ruptured membranes (or leave in situ if CTG is normal and woman is not contracting)
- constant abdominal pain

If not in established labour and CTG is normal after 24 hours
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- Remove Mysodelle pessary
- Perform ARM, after transfer to delivery suite
- If unable to perform ARM seek senior obstetric advice. Consider delaying induction, using Prostin 2mg PV, 4 hours of oxytocin infusion followed by ARM, LSCS. All must be discussed with a consultant

If in established labour or there are maternal or fetal concerns transfer to delivery suite for one to one care, continuous electronic fetal monitoring and care as per management of active labour.

If the pessary falls out
- The same Mysodelle pessary can be reinserted provided it has remained clean, otherwise a new pessary must be inserted
- The pessary time remains 24 hours from insertion of the first pessary

If tachysystole occurs (contractions greater than or equal to 5:10 with normal CTG)
- Remove Mysodelle and put into a universal pot
- Assess cervix
- If the woman is distressed administer terbutaline 0.25mg SC
- If the woman is not distressed observe and if tachysystole persists >30 minutes consider terbutaline 0.25mg SC
- Consider replacing Mysodelle (within 4 hours) if contractions stop completely and the cervix is not favourable

If hyperstimulation occurs (contractions greater than or equal to 5:10 with abnormal CTG)
- Remove Mysodelle
- Assess cervix
- Administer terbutaline 0.25mg SC
- Inform DS coordinator and senior obstetrician and prepare for transfer if CTG does not improve
- If the CTG normalises and the woman is suitable for ARM this should be the next course of action. If unsuitable for ARM consider prostin gel 2mg PV or propess after 4 hours

Terbutaline
single dose of 0.25mg SC to be administered into upper arm
Can be repeated after 20 – 30 minutes to a maximum of 0.5mg in 4 hours

Remove Mysodelle and purple wristband and assess cervix
• Once the woman is contracting 3:10 irrespective of how strong these are or how dilated the cervix is
• If the woman goes into active labour (4cms dilatation with regular contractions)
• If the CTG is abnormal
• If the woman develops constant abdominal pain or fresh bleeding
• 24 hour post insertion

Do not remove Mysodelle if
• The CTG is showing uterine activity greater than or equal to 4:10 but the woman is feeling nothing
• The woman ruptures her membranes but is not contracting and CTG is normal

9. Implementation

Proposed trial period of three months from June – August 2018
Staff administering Mysodelle should have training from the consultant midwife
Staff prescribing Mysodelle should have training from a senior obstetrician

10. Monitoring / audit

This is a new drug which is being used for a trial period. There will therefore be an evaluation after three months and this will inform on going practice and audit

11. References