Preventing Preterm Birth guideline (GL1032)

Approval

<table>
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<tr>
<th>Approval Group</th>
<th>Job Title, Chair of Committee</th>
<th>Date</th>
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<tbody>
<tr>
<td>Maternity &amp; Children’s Services Clinical Governance Committee</td>
<td>Chair, Maternity Clinical Governance Committee</td>
<td>7th September 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>
<th>Reason</th>
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<tr>
<td>1.0</td>
<td>August 2018</td>
<td>Surabhi Bisht, Consultant Obstetrician</td>
<td>To set up Preterm Birth Clinic</td>
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<tr>
<td>1.1</td>
<td>Oct 2018</td>
<td>Surabhi Bisht, Consultant Obstetrician</td>
<td>Pg 7 – sentence added re: MagSulf bolus to be given to all in utero transfers &lt;27 weeks</td>
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<tr>
<td>1.2</td>
<td>May 2019</td>
<td>Surabhi Bisht, Consultant Obstetrician</td>
<td>To add Preop pathways</td>
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PATHWAY FOR WOMEN AT RISK OF PRE-TERM LABOUR ANTEMATALLY

Aims

• To identify women at high risk of pre-term birth (PTB) or late miscarriage and manage their pregnancies.
• To implement strategies to reduce the severity of PTB and recurrent late miscarriage.
• To provide continuity of care and support for at risk women.

Pre-term Birth (PTB) Clinic Referral Criteria

1. Previous spontaneous pre-term birth <34+0 weeks gestation associated with:
   • Painless cervical dilatation
   • Abdominal pain or uterine contractions
   • Antepartum haemorrhage
   • Pre-term premature rupture of the membranes (PPROM) before 34+0 weeks
2. One or more mid-trimester fetal loss (14 – 24 weeks of gestation).
3. Repeated (>3) late surgical termination of pregnancy (>12 weeks of gestation).
5. Repeated (-2 or more) large loop excision of the transformation zone (LLETZ)
6. Single cone biopsy to cervix.
7. Radical trachelectomy for locally invasive carcinoma of the cervix.
8. Uterine anomaly, e.g. bicornuate uterus and with a previous history of PTB
9. Incidental finding of short cervix on ultrasound (US): ≤ 2.5 cm before 24 weeks
10. Follow-up of women who have a rescue cervical cerclage placed in pregnancy.

This clinic is NOT for women with:

• Previous iatrogenic pre-term delivery for other obstetric causes (e.g. severe pre-eclampsia, stillbirth, placenta praevia).
• Previous single late surgical termination of pregnancy, repeated early surgical terminations of pregnancy (<12 weeks) or medical terminations.
• Recurrent first trimester pregnancy loss.
• Single LLETZ with no other risk factors.
Clinic Protocol

1.0 First visit

The first appointment should be between 14-16 weeks of gestation, after the first trimester screening scan. The Preterm Birth clinic would run fortnightly on Tuesday afternoon (1330 hrs to 1600 hrs) in the Antenatal clinic area on level 2 in Maternity.

At their first appointment:

- **Give**
  - Information leaflet about clinic.

- **Ask about**
  - a detailed history
  - smoking
  - genital tract infection and h/o bacterial vaginosis (BV)
  - recurrent urinary tract infection
  - record BMI

- **Discuss**
  - role of ultrasound cervical length
  - cervical cerclage and if indicated or not
  - progesterone and other preventive methods
  - role of fetal fibronectin
  - risk of recurrence of preterm birth – it is not inevitable
  - modifying risk factors and refer to stop smoking clinic

- **Explain**
  - warning signs of preterm labour and what to do

- **Agree**
  - an individualised plan of care for this pregnancy.
  - any other referrals that may be needed.

- **Check**
  - BP and dip urine
  - booking bloods

- **Perform**
  - High vaginal swabs for bacterial vaginosis
  - transvaginal scan

- **Document**
  - the visit in hand held obstetric notes.
  - complete PTB clinic proforma for audit purposes
  - complete Viewpoint data and print off, one copy for patient, one copy to clinic note

- **Arrange next visit.**
2.0 Second and subsequent visits

See below for individualised schedule of care according to patient needs.

- Ask for any symptoms (pain, pressure, contractions, vaginal discharge)
- Check
  - BP and dip urine
  - low threshold for sending urine for microscopy and culture in patients
  - all blood and swab results.
- Arrange next visit.
  - If this is her last visit (usually by 24 weeks), arrange follow up with Miss Bisht in her Antenatal clinic for around 28-30 weeks.
- Perform
  - transvaginal scan
- Treatment of urinary tract or genital tract infection if confirmed
- Document
  - the visit in hand held obstetric notes.

complete Viewpoint data and print off, one copy for patient, one copy to clinic notes.

3.0 Scan protocol

Cervical length scans are performed transvaginally to obtain the most accurate measurement.

- Informed verbal consent is obtained prior to the scan.
- Exclude latex allergy, and use latex free probe cover if they are allergic to latex.
- The woman must be asked to empty her bladder just prior to the scan (within 30 minutes).
- Give the woman a clean sheet to cover herself and allow her to undress her lower body in privacy.
- All transvaginal scans must be performed with a chaperone present.
  - Follow steps from Fetal Medicine Foundation to perform Cervical Length scan (https://fetalmedicine.org/education/cervical-assessment)

For women with a cervical cerclage, record the total closed length and the closed cervical length cranial to the stitch, as closed length above the stitch is the best predictor of outcome.

3.0 Cervical length measurement interpretation

- > 25mm - reassure the patient
- ≤ 25mm
  - in women with a history of preterm birth or late miscarriage, a cerclage is recommended
  - in women with incidental finding of a short cervix, screen for infection (MSU, cervical/vaginal swabs) and explain that cerclage is probably not of benefit.
Prevention of Spontaneous Severe Preterm Birth – PTB CLINIC ALGORITHM (see Appendix 1)

High risk for severe spont PTL  Incidental finding of short cervix on low risk women

LVS/ MSU/ BV screen (14-16 weeks)  life style advice

Cervical length scan/ TVS from 14-16 weeks
(2-4 weekly) till 24 weeks

Offer Progesterone until 34/40
(200-400 micgm PV or P/R)

If history indicate cerclage

TVS cervix at ≤ 24 wks  Elective cerclage  TVS cervix at ≤ 24+0 wks

≤25mm  0 mm /through os  ≤ 10mm  >10mm, ≤25mm

>25mm (history indicated cerclage)

Do speculum and HVS  Start cyclogest  Start cyclogest

Chorioamnionitis?

Yes  No  ?

Refer to Oxford to consider

Amniocentesis and Rescue cerclage

Offer Cerclage  IVABs and deliver  No action
4.0 Cervical cerclage

This procedure involves a stitch being inserted into the cervix under an anaesthetic. It may be done at any time up to 23+6 weeks of pregnancy. Ideally, the stitch should remain in place until about 37 weeks, but should be removed if the waters break early, or if premature labour is diagnosed. Patients requiring elective cervical cerclage to be booked as third patient on an elective LSCS list (Jill Ablett/ Patrick Bose/ Sunetra Sengupta/ Surabhi Bisht/ Mayura Nisal/ Mustabshera Fayyaz/ Anu Dhanpal)

- Offer cerclage to:
  - women with a previous history of preterm birth or late miscarriage whose cervix measures ≤ 25mm/ >25 mm if suggested by history
  - women with a previously successful cervical cerclage.
  - women with a previous failed cervical cerclage (delivery or PPROM at <28 weeks) should be offered an abdominal cervical cerclage – Refer to JRH, Oxford.

- The cerclage is to be inserted as soon as is feasible after the Combined Test results.

- Swab results should be available prior to placement of cerclage to allow sufficient time for treatment of infection.

- If the membranes are exposed or if the cervix measures 0mm in length, refer to JRH, Oxford

5.0 Types of Cervical Cerclage

6.1 Transvaginal cerclage (McDonald):
A transvaginal purse-string suture placed at the cervicovaginal junction, without bladder mobilisation.

6.2 High transvaginal cerclage (Shirodkar):
A transvaginal purse-string suture placed following bladdermobilisation, to allow insertion above the level of the cardinal ligaments.

See appendix 2 and appendix 3 for pre-op and post-op care pathway for women who need cervical stitch.

Cerclage is contra-indicated if there is PPROM/ Bleeding/ contractions/ cervical dilated and membranes bulging in vagina The suture should be removed after discussion with a consultant if:
• There are signs of systemic infection (local infections without maternal or fetal problems may be treated as appropriate).
• There is bleeding with or without contractions.
• There is unexplained pain, with or without bleeding (i.e. where there is a high probability of concealed abruption).
• 37 week gestation is attained.

6.3 Rescue cerclage
The decision for emergency or ‘rescue’ cerclage insertion is based on the clinical presentation. Emergency cervical cerclage implies cervical dilatation and, therefore, bulging membranes into the vagina seen on speculum examination. Insertion of a rescue cerclage may delay delivery but, even with rescue cerclage, the risks of severe pre-term delivery, neonatal mortality and morbidity remain high.

Decision to consider a rescue cerclage should be individualised on the basis of:
• Cervical dilatation
• Intact membranes
• No uterine activity
• No evidence of infection

Patients requiring Rescue Cerclage - Offer transfer to JRH, Oxford as these women are likely to deliver before 28 weeks of gestation and level 3 Neonatal Unit care required for their babies. It is necessary to do a speculum examination to rule out SROM/ infection before offering Rescue Cerclage/ transferring to Oxford.

6.0 Maternal Steroids
All women at high risk of impending preterm delivery between 23+0 and 34+6 weeks of gestation should receive antenatal corticosteroids.
Take into consideration a number of factors: cervical length, partosure test results, maternal circumstances, gestational age.

7.0 Magnesium Sulphate
Offer intravenous magnesium sulphate for neuro-protection of the baby to women between 24+0 and 32 weeks of pregnancy who are in established preterm labour or having a planned preterm birth within 24 hours.

Magsulf bolus to be given to all in-utero transfers (<27 weeks) even if imminent delivery is not anticipated (PreCept protocol)
8.0 PartoSure® testing

Do PartoSure® test after 23 weeks if there are signs of Preterm labour.

The positive predictive value for delivery within 1 week is 76% for women with symptoms of threatened preterm labour. The negative predictive value is 96%. (appendix 4)

9.0 Growth scans

Growth scan will be offered to patients between 28-30 weeks of gestation to patients attending PTB Clinic to consider discharging under Midwifery care if no complications encountered/anticipated.
Managing cervical length at <24 weeks to prevent spontaneous severe singleton preterm labour

- Low/medium risk for severe spontaneous preterm labour
- Incidently performed TVS cervix at ≤24+0
- High risk for severe spontaneous preterm labour
  - Prev spont birth 16-31+6 wks

  - <16 wks?
    - yes
      - Screen for BV: Rx if positive
    - no
      - Start Cyclogest

  - History indicated cerclage
    - yes
      - TVS cervix at >16+0, ≤24+0
    - no

- ≤ 10mm
- >10mm, ≤25mm
- >25mm
- 0mm/through os
- ≤25mm
- >25mm

- Start cyclogest
- No further action
- Chorioamnionitis
  - yes
  - no/unsure
  - Consider amniocentesis
    - Infection
    - No infection
      - Offer rescue cerclage
      - IVABs + deliver
      - Offer USS indicated cerclage
      - Elective cerclage
Appendix 2 - Cervical stitch insertion (elective/ semi elective)

To be done within 2-3 days of decision for Cervical stitch.

1. Consent patient for elective Cervical cerclage
2. Inform theatre staff/ Consultant doing cerclage by phone or email
3. NBM from midnight
4. Prescribe Ranitidine 150 mg at 10:00 pm previous night and 06:00 hrs on the day of surgery
5. Book patient as the third patient on the elective LSCS list
6. If no slot on Elective LSCS list, patient to go through DAU/ LW
7. Use minor op pathway (for midwives when patient comes in to DAU)
8. Post op recovery- either in theatre recovery or in labour ward for 30 min before transferring to Marsh- team to check with theatre staff and labour ward coordinator

Appendix 3 - Cervical stitch removal

McDonald’s stitch can be removed in labour ward without the need of any anaesthesia- these patients can be booked to come to DAU/ LW. No restrictions required.

For patients who need the Shirodkar’s stitch removal

1. Consent patient for elective Cervical cerclage (Shirodkar’s) removal.
2. NBM from midnight
3. Prescribe Ranitidine 150 mg at 10:00 pm previous night and 06:00 hrs on the day of surgery
4. Book patient as the third patient on the elective LSCS list
5. If no slot on Elective LSCS list, patient to go through DAU/ LW
6. Use minor op pathway (for midwives when patient comes in to DAU)
7. Post op recovery- either in theatre recovery or in labour ward for 30 min before discharging patient home.

N.B - If SB away and patient is seen by SA in FM clinic, SA to refer patient to DAU.
Appendix 4

What is PartoSure®?

The PartoSure® Test is a rapid, non-invasive strip test for the detection of placental alpha microglobulin-1 (PAMG-1) in patients presenting with signs and symptoms of preterm labour.

PAMG-1, a protein found in very high concentrations in amniotic fluid and in very low concentrations in normal vaginal discharge. Recent clinical studies have demonstrated a strong correlation between a positive PAMG-1 test and imminent delivery in patients presenting with threatened preterm labour and intact membranes. Two possible explanations for the presence of PAMG-1 in cases of threatened preterm labour have been postulated: transudation of PAMG-1 through chorio-amniotic pores in fetal membranes during uterine contractions and degradation of extracellular matrix of fetal membranes due to inflammatory process of labour and/or infection.

When should we not do this test?

The PartoSure® test should not be used for "symptomatic women" with one or more of the following conditions:

• advanced cervical dilatation (≥ 3 centimetres)
• rupture of amniotic membranes
• moderate or gross vaginal bleeding

The PartoSure® test should not be used for “asymptomatic women” with one or more of the following conditions:

• placenta praevia (partial or complete)

Test procedure

1. Insert the tip of the sterile swab into the vagina 5-7cm for 30 seconds (speculum optional for testing).

2. Place swab into vial and rotate swab in solvent for 30 seconds. Discard swab.

3. Insert white end of test strip into vial with solvent. Remove after appearance of two lines or at 5 minutes (whichever is sooner).

4. Do not read test strip after 10 minutes from insertion into vial.

5. Extract test strip from vial and record results.

Negative result - one line

Positive result - two lines (Faint or broken lines should always be read as positive where two lines are present)
Auditable Standards

1. Documented involvement of consultant in decision on in-utero transfer of mothers between 24 and 27 weeks admitted in very early preterm labour
2. Number of women transferred to JRH, Oxford for Rescue Cerclages.
3. Number of women who SROMed/ miscarried after an Elective Cervlage.

References

5. Shennan AH. MAVRIC trial abstract. BJOG. 2015;122(Supplement 22).