Aneurin Bevan University Health Board

Guideline for Cervical Cerclage

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Appendices

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Executive summary:

This document should act as guidelines for the management of women with previous preterm births or mid-trimester losses who are at high risk of recurrence of events and management of women with previous failed cerclage. The opinion expressed in this guideline is evidence-based and reflects professional opinion. They are designed to support safe and effective practice.

Scope of the guidelines:

- The guideline applies to all clinicians working within the maternity services.

Essential implementation criteria:

- Auditable standards are stated.

Aims

- To provide support to clinical decision making
- To provide support for evidence-based management

Responsibilities

- The maternity management team

Training

- Staff are expected to access appropriate training where provided
- Training needs will be identified through appraisal and clinical supervision
Monitoring and Effectiveness:

- Local service improvement plan will guide monitoring and effectiveness. This policy has undergone an equality impact assessment screening process using toolkit designed by NHS centre Equality and Human rights.
- Details of the screening process for this policy are available from the policy owner.

Implementation

- The guidelines will be implemented for the patients with previous history of preterm births or mid trimester losses at high risk of recurrence of events and patients with previous failed cervical cerclage.

Standards for Health Services Wales

Has an equality impact assessment been carried out?
- YES

Has any adverse impact been identified?
- NO

Environmental Impact

- NO

Audit

- Audit tools have been incorporated in the protocol.

Review

- Protocol to be reviewed in 3 years.
CERVICAL CERCLAGE GUIDELINE

Preterm birth (before 37 weeks’ gestation) is the single biggest cause of neonatal mortality and morbidity in the UK. Cervical insufficiency contributes to the burden of preterm deliveries and therefore cervical cerclage has become a part of obstetric practice. Cervical insufficiency is usually defined by painless dilation and shortening of the cervix before 37 weeks in the absence of preterm labour.

Until recently in the UK, only women with a history of preterm birth or midtrimester loss attended the high-risk obstetric prematurity surveillance clinics in order to be considered for cervical suture. In many hospitals, the majority of these referrals now also include women who have had a previous cervical treatment or trauma; a category virtually undetectable in 1999 increasing to more than 40% in 2012.

The incidence of true cervical insufficiency has been estimated to be less than 1% of the obstetric population. There is no diagnostic test for cervical insufficiency, however, transvaginal ultrasound assessment of cervical length has been used for cervical length assessment as cervical shortening correlates with the risk of preterm delivery.

Cerclage should be considered if there is a high risk of cervical insufficiency based in the woman’s obstetric history. Consider these risk factors: prior second trimester loss or previous preterm labour, history of cervical surgery, other forms of cervical trauma (cervical tear, repeated surgical termination of pregnancy or repetitive cervical dilation), mother’s exposure to diethylstilberol when in utero herself, maternal uterine anomaly or connective tissue disease (Ehler’s – Danlos syndrome).

A Cochrane review analysed data from 12 studies of women considered at sufficient risk to justify cerclage who were randomized to cerclage, alternative treatments (e.g., progesterone), or no treatment. This analysis presents conflicting findings in reporting that although cerclage has a statistically significant effect on reducing preterm birth rates, there is no significant impact on perinatal morbidity and mortality. Furthermore, cerclage was associated with increased maternal morbidity and Caesarean section rates. A recent study evaluating the benefits or otherwise of prophylactic cerclage after a history of only a single mid-trimester loss demonstrated higher rates of preterm birth (<37 weeks), preterm pre-labour membrane rupture, and both perinatal morbidity and mortality in those cases treated by cerclage compared to those managed without, in a population of 2175 women (108 treated with cerclage and 2067 without).
Data do not support the placement of a cerclage in women in whom there is an incidental finding by ultrasound of cervical shortening ($\leq 25$ mm) and who are not otherwise considered to be at risk of mid-trimester loss or of preterm delivery.\textsuperscript{8, 9, 10} Women considered to be at risk (e.g., because of a history of mid-trimester loss or early preterm delivery) should be offered cerclage if their cervical length is $\leq 25$ mm before 24 weeks of gestation.\textsuperscript{8,11−15}

**History of treatment to cervix**

Many obstetricians believe that preterm labour following cervical treatment is a result of ‘cervical weakness’, which can be corrected by cerclage. However, cerclage for all women with prior cervical treatment is inappropriate since approximately 85% of them will deliver at term. Serial measurement of cervical length on transvaginal ultrasound to detect cervical shortening has been proven to predict preterm labour in the general population, specifically in women with prior cervical treatment. Poon et al. showed that individual cervical length has the same predictive value in women with cervical cone as in the general population, for whom a cut-off of 25 mm is usually used to target treatment. In the overall obstetric population, cervical cerclage does not reduce the risk of preterm labour where the only risk factor is a short cervix discovered incidentally in the second trimester, but does reduce the risk in women with a short cervix who have a history of mid-trimester losses or preterm births.

Consequently, women with prior local cervical treatment but no other obstetric history fall between these two groups. Since cervical treatment may mechanically damage the cervix, it is plausible that cerclage will be of benefit in some women. However, either CIN itself or the effects of ‘foreign’ material (cervical stitch) may affect the vaginal microenvironment and the immune defence system, such that the risk of preterm labour could plausibly be unaffected or worsened by cervical cerclage. Progesterone may be of value as it has been found to decrease the risk of preterm birth in women with a short cervix.

**Progesterone**

Progesterones have been used in preterm birth prevention and its efficacy data have been extrapolated to be used in cervical insufficiency. This might, however, not be appropriate. A study evaluating the effects
of progesterone on cervical length in women considered at risk of preterm birth suggests that vaginal progesterone helps preserve cervical length and thereby reduces the risk of preterm birth.\textsuperscript{16,17,18} The role of progesterone in mid-trimester loss remains unclear; therefore its routine use is not recommended, and further evaluation is needed.

In Cochrane review, progesterone for women with a past history of spontaneous preterm birth was associated with a statistically significant reduction in the risk of perinatal mortality, preterm birth less than 34 weeks, infant birthweight less than 2500 g, use of assisted ventilation, necrotising enterocolitis, neonatal death, admission to neonatal intensive care unit, preterm birth less than 37 weeks and a statistically significant increase in pregnancy prolongation in weeks. No differential effects in terms of route of administration, time of commencing therapy and dose of progesterone were observed for the majority of outcomes examined.

In the same Cochrane review, progesterone for women with a short cervix identified on ultrasound was associated with a statistically significant reduction in the risk of preterm birth less than 34 weeks and preterm birth at less than 28 weeks. Vaginal but not systemic progesterone reduces the risk of preterm birth in women with a short cervix in general, but it is not known whether this is specific to women with prior cervical treatment. This reflects the limited evidence of the value of these interventions in women after cervical treatment and our inability to stratify women into low or high risk.

In multiple pregnancies, progesterone was associated with no statistically significant differences for the reported outcomes.

In women who presented in threatened preterm labour, progesterone was associated with a statistically significant reduction in the risk of infant birthweight less than 2500 g.

**Based on the findings above there are 4 categories of women considered in this guideline:**

1. Those with a history of 3 or more spontaneous preterm births or mid-trimester losses between 16+0 – 34+0 weeks of pregnancy.
2. Those with 1-2 spontaneous preterm births or mid-trimester losses between 16+0 – 34+0 weeks of pregnancy.
3. Those with a finding of short cervix on ultrasound scan but no history of preterm labour or mid-trimester loss but history of cervical trauma/treatment with depth of excision of more than 10 mm or repeat excisions (LLETZ, cone excision, cervical tear etc).

4. Those who present in threatened preterm labour with painless cervical dilation less than 4 cm.

It is recommended:

1. For women with a history of 3 or more preterm labours or mid-trimester losses offer cervical cerclage. If the patient declined offer ultrasonographic cervical length assessments. If the cervix is less than 25 mm on TVS which has been carried out between 12+0 – 24+0 weeks recommed cerclage.

2. For women with a history of 1 - 2 preterm labours or mid-trimester losses offer transvaginal ultrasonographic assessments of cervical length between 12- 24 weeks every 10 – 14 days. If cervical length measurements before 24 weeks are less then 25 mm offer them cervical cerclage.

3. For women with a cervical length less than 25 mm before 24 weeks on TVS and no history of preterm labour but history of cervical trauma/treatment with depth of excision of more than 10 mm or repeat excisions (LLETZ, cone excision or cervical tear) offer vaginal progestogen.

4. For women with dilated cervix and exposed, unruptured membranes between 16+0 – 27+6 weeks consider ‘rescue’ cervical cerclage.
Below is the flow-chart summary:

**Category 1**
3 or more previous pre term births or 2nd trimester losses

- Offer cervical cerclage between 14 – 16 weeks. If declined offer ultrasonographic cervical length assessments between 12 – 24 weeks. If the cervix is less than 25 mm on TVS recommened cerclage. To be arranged as an elective procedure.

**Category 2**
One or two previous pre-term births or 2nd trimester loss

- Counsel regarding expectant management vs sonographic surveillance.
- If patient opts for sonographic surveillance then cerclage is offered if cervical length <25mm between 12-24 weeks.

(Note: Cervical Cerclage is not recommended for funnelling alone in the absence of cervical shortening)

**Category 3**
Cold knife cone or LLETZ – in depth exision of more than 1 cm of cervix or repeat excisions

- Offer ultrasound surveillance every two weeks between 12 - 24 weeks.
- If cervix shorter than 25 mm before 24 weeks discuss the benefit of progesterone versus cervical cerclage and the lack of robust evidence for strong recommendations regarding cerclage.
- Prescribe Progestogen pessary (Cyclogest) 400 mg nocte. Duration to clinician's discression.

**Category 4**
Rescue cerclage

- Decision needs to be individualised depending on gestation.
- Patient to be couselled regarding the outcome as even with rescue cerclage the risk of severe preterm birth, neonatal morbidity and mortality remain high.
- If cervix >4cm dilated and membranes prolapse beyond external cervical os then cerclage is more likely to fail.
- Cerclage may delay delivery by 5 weeks.

Women with prior history suggestive of cervical insufficiency OR presenting with cervical shortening or dilatation in the absence of contractions
Contraindications
- Active preterm labour
- Clinical evidence of chorioamnionitis
- Continuing p.v. bleed
- PPROM
- Evidence of fetal compromise
- Lethal fetal defect
- Fetal death
- Multiple pregnancy
- Uterine anomalies

Pre-operative considerations
- Offer a first trimester ultrasound scan and screening for aneuploidy before cerclage to ensure viability and the absence of lethal/major fetal abnormality.
- Before rescue cerclage ensure an anomaly scan has been performed.
- If chorioamnionitis is suspected clinically then perform FBC and CRO, if there are no clinical signs then rescue cerclage should not be delayed.
- Routine genital tract screening with swabs is not recommended, however if a recent swab shows positive culture complete course of antibiotics before insertion of cerclage.

Peri-operative considerations
- Routine peri-operative tocolysis is not recommended.
- Administration of antibiotics is left at operating consultant’s discretion.
- Suture material is a choice of operating surgeon (usually Mercilene tape).
- Type of cerclage will depend on examination findings and is left at discretion of the surgeon.

Post-operative considerations
- Non-urgent cerclage should be book as a day case.
- Rescue cerclage can be performed on an emergency basis.
- Patients are advised to stay inpatient for observation for 24 hours post procedure, ultrasound assessment of fetus is advisable for reassurance.
• Following discharge from the hospital: bed rest is not recommended, routine cervical ultrasonographic surveillance after the procedure is not recommended, routine fetal fibronectin testing is not recommended.
• Consider steroids at 26 weeks.

Removal of cerclage
• Suture to be removed at 37+0 weeks.
• Shirodkar’s suture requires anaesthetic before removal.
• If the patient is booked for elective C-section then cerclage removal can be done at the same time.
• In case of PPROM and the patient is not in active labour with no evidence of infection then cerclage removal can be delayed for 24 hours to allow time for steroids administration.
• Delayed suture removal until labour is not recommended in PPROM due to risk of maternal and fetal sepsis.

Transabdominal cerclage
Transabdominal cerclage is indicated if previous failed transvaginal cerclage. It is usually performed preconceptually or in early pregnancy. It can be done laparoscopically or by laparotomy. The suture is placed at the cervicoisthmic junction. If delayed miscarriage or fetal death occurred the suction curettage can be performed up to 18 weeks or suture can be cut via posterior colpotomy. Patients with transabdominal cerclage delivery by C-section and abdominal suture can be left in place. Patients requiring trans-abdominal cerclage should be referred to University Hospital of Wales in Cardiff to Mr Richard Penketh ideally before conception.
References:

1. Preterm labour and birth, NICE guideline, 20 November 2015


5. Scientific Impact Paper No. 21, Reproductive Outcomes after Local treatment for Preinvasive Cervical Disease, RCOG; July 2016


19. Cervical Insufficiency and cervical cerclage No.373, SOGC Clinical practice guideline, February 2019