TYGERBERG HOSPITAL

Department of Obstetrics and Gynaecology

TRANSVAGINAL CERVICAL CERCLAGE FOR PREVENTING PRETERM BIRTH: PROTOCOL

- ✓ A classical diagnosis of **cervical insufficiency** is made based on historical information in which cervical dilatation occurs without contractions in one or more pregnancies leading to delivery in the mid/second trimester of pregnancy of a normal live fetus (**MTL** – mid trimester loss at GA of 14w0-24w0)
- ✓ *All women who are pregnant or planning pregnancy should be evaluated for risk factors of cervical insufficiency and preterm birth (PTB)*
- ✓ *This management protocol is written against the background of **progesterone** not being routinely available in the public sector.*
- ✓ ***Transabdominal cerclage** should be considered in women with previously failed transvaginal cervical cerclage or in the presence of a severely damaged cervix or a very short portio vaginalis (<10mm) presenting before 14w. These patients should be discussed with Prof Hall/Dr JL van der Merwe asap.*

NB! Background risks for women with a history of a MTL varies:

- If one previous MTL then there is about 9-27% risk for a repeat MTL and 11-39% risk for PTB
- If two MTL then there is a 10-40% risk for a MTL and 15-37% risk for PTB
- If > 2 MTL or PTB there is up to 50% risk for a MTL and up to 45% risk for PTB

**Outcomes are dependant on whether a specific underlying cause is present or not*

1. Risk Factors for cervical insufficiency:

1.1. Past obstetrical history:

- Documented MTL following progressive painless cervical dilatation (i.e. in the absence of labour or placental separation) with or without preterm premature rupture of membranes.
- Documented short labours or progressively earlier deliveries in successive pregnancies

1.2. Congenital risk factors:

- Uterine anomalies (esp. septate and bicornuate uterus)

1.3. Acquired risk factors:

- Evidence/History of cervical trauma (i.e. obstetric cervical tears, to be assessed by speculum examination)
- Treatment of cervical intraepithelial neoplasia by cervical conisation/LLETZ.

1.4. Ultrasound findings consistent with cervical incompetence prior to 28 weeks gestation:

- Cervical shortening (<25mm) with development of funnelling.
- No measurable cervical length with or without dilatation.

***** Caution!!*** **Fetal demise documented with ultrasound with subsequent spontaneous abortion at any time between 12 and 26 weeks gestation should not be considered a risk factor for incompetent cervix.**

2. Indications for cervical cerclage:

2.1. History-indicated cerclage (Type 1)

- Three or more previous consecutive MTL after excluding pregnancy- and medical related causes of MTLs.
- Three or more early preterm births (<26 weeks)
- These women should be discussed with the consultant at the HRC and offered a cervical cerclage to be placed ideally at 12-14 weeks gestation, after an NT scan has ruled out significant fetal anomalies. In case of later presentation, the cerclage needs to be placed a.s.a.p., provided the pregnancy is still less than 24 weeks.
- Proposed benefit: Success rates 70-90% (to reach viability); mean stitch interval time of ± 20 weeks

***NB!** A minority of recurrent MTL are primarily, and perhaps exclusively, caused by congenital or acquired structural weakness of the cervix.*

2.2. Ultrasound-indicated cerclage (Type 2)

- Candidates for ultrasound surveillance are women with risk factors for cervical insufficiency and normal cervix on clinical examination that do not meet the above strict criteria for history indicated cerclage.
- Offer progesterone vaginal to these women, on private script and at own cost (micronized progesterone capsules 200mg at night or natural progesterone gel 90mg at night from 16w to 36w at estimated total treatment cost of R1648)
- In women that choose not to take progesterone: initiate 2 weekly transvaginal ultrasound cervical length screening from 16w to 23w (*Appendix A: How to perform a transvaginal cervical length*)
- If the cervical length is 20-25mm: review the patient's condition and repeat the scan in 1 week
- If cervical length is less than 20mm: offer cervical cerclage after discussion with the consultant at the antenatal clinic
- Ultrasound-indicated cerclage, in the absence of other risk factors, is an "urgent cerclage" and needs to be performed ideally within the next 24 to 72 hours.
- Proposed benefit: Success rates 50-80% (to reach viability); mean stitch interval time 4-10 weeks

***NB!** An incidentally detected short cervical length in the second trimester in the absence of a prior MTL/PTB is not diagnostic of cervical insufficiency, and cerclage is not indicated in this setting. Vaginal progesterone should be offered (when available) in these cases.*

2.3. Clinically indicated cerclage, also called rescue or emergency cerclage (Type 3)

- Women who present with cervical dilation (> 1 to 2 cm internal os diameter) in the absence of labour or abruptio placentae (with or without membranes bulging through the external os)
- Rescue or emergency cerclage should only be considered in these women if they are in the mid trimester (16w – 24w0)
- These women should have a detailed assessment as set out below and be discussed with the MFM/Special Care consultant on for the week as care should be individualised.
- Proposed benefit: Success rates 40-60% (to reach viability); mean stich interval rime of 2-6 weeks

***NB!** In addition, al these women should be monitoring for preterm labour from 26-34w.*

3. Contraindications for cervical cerclage:

3.1. Absolute contraindications:

- Active labour
- Active vaginal bleeding
- Premature, prelabour rupture of membranes
- Fetal compromise or death, lethal fetal anomalies
- Suspected or clinically confirmed abruptio placenta
- Suspected or clinically confirmed chorioamnionitis

3.2. Relative contraindications include the following:

- Prolapsed membranes or dilatation more than 4cm
- Vaginal spotting
- Immunosuppression (i.e. complicated DM, HIV etc.)
- Multifetal gestations

** If there is a valid indication for cerclage in the presence of a relative contraindication, a work up as stipulated below should be done and the case discussed with the consult in the antenatal clinic or ward.*

4. Basic initial investigations/work up for transvaginal cerclage:

4.1. A thorough history including obstetric, medical, family and social:

- All patients' risk profile for MTL and PTB should be assessed at their first presentation to the clinic.
- Underlying medical conditions, such as poorly controlled diabetes, hypertension, thyroid disease and thrombophilia might have caused the poor obstetric outcomes (rather than cervical insufficiency).
- Exclude other causes of MTL and PTB (fetal anomalies, infection, placental abruptio, and multiple gestations) in previous pregnancies.
- Women with a **previous failed transvaginal cervical cerclage must be discussed with the MFM/Special Care team**.

4.2. Clinical examination:

- Detailed obstetric and cervical evaluation
- Vaginal speculum to visually inspect the cervix for previous scarring, deformity and length to ascertain the feasibility of placing a transvaginal cerclage.
- A wet mount smear must be performed on all patients to exclude bacterial vaginosis (if present metronidazole 400 mg orally twice a day for 7 days or clindamycin 300 mg orally twice daily for 7 days), trichomonas vaginalis (if present single dose metronidazole 2g orally) or chronic cervicitis (individualize management on suspected underlying cause).
- Urinary dipstix specifically to evaluate for the presence of proteinuria, glycosuria and haematuria.

4.3. Special investigations:

- Ensure that routine antenatal screening investigation results are noted on the card and managed appropriately (syphilis, HIV, Rhesus). If HIV positive the timing and results of the last CD4 and viral

count and type and duration of current treatment should be documented in the maternity case record.

- A mid-stream urine specimen for urine culture and ideally treat ASB prior to cerclage insertion
- Informal ultrasound should be performed at booking to confirm viability and gestation and to rule out major congenital anomalies. If < 13 weeks, a formal NT and anomaly-screen test (screening for Down syndrome) should be offered to all patients at 12-13 weeks, prior to cerclage. If presenting after 13w then an informal ultrasound to confirm a single intrauterine viable pregnancy and to exclude any major anomalies – a formal anomaly scan can be arranged at a GA dependant on the indication and urgency of the cerclage. In all surgical cases, fetal life should be documented before and after the procedure.

4.4. Counselling: Patients should be thoroughly counselled regarding the following risk groups:

- Disease-related risks: premature rupture of membranes; pregnancy loss; infection (chorioamnionitis); preterm labour requiring hospitalization; extreme prematurity.
- Immediate procedure-related risks: usual anaesthetic risks (minor with spinal anaesthesia which is preferable); minor vaginal bleeding; maternal soft tissue injury (rare); cervical trauma and injury during placement, rupture of membranes.
- Ongoing procedure-related risks: cervical injury from the suture in case of uncontrollable preterm labour; chronic cervical irritation and inflammation with possible intra-amniotic infection, suture displacement/migration, increased incidence of caesarean section (soft tissue dystocia from scar tissue).

4.5. Timing of procedure

- History-indicated cerclage should be inserted around 14 weeks.
- Ultrasound-indicted cerclage, (16-22w) in the absence of other risk factors is an "urgent cerclage" to be inserted within 24 to 72 hours
- Clinically indicated rescue cerclage (less than 24w) will be timed and managed individually by the MFM team.

4.6. Preoperative Management

- Tocolytic drugs are not routinely given to women undergoing placement of a history-indicated cerclage however indomethacin has been reported to improve outcome in the clinically indicated rescue cerclage and ultrasound indicated cerclage where cervical activation has commenced.
- Use of antibiotic prior to or after cerclage is controversial. In history-indicated cases antibiotics are not to be used but the following conditions may warrant antibiotics prior to the cerclage placement:
  - Patients with evidence of chronic cervicitis (on speculum examination and wet mount)
  - Patients with copious and malodorous vaginal discharge.
  - Clinically indicated cerclage with exposure of the membranes to the vaginal environment.
- If antibiotics are indicated then complete treatment prior to cerclage placement, if possible.

5. Placement of a transvaginal cervical cerclage

5.1. The following description is applicable to a history-indicated McDonald's technique with a good vaginal portio (>1.5cm) and no old tears or trauma.

5.2. Anaesthesia: Regional anaesthesia is preferred.

5.3. Equipment needed:

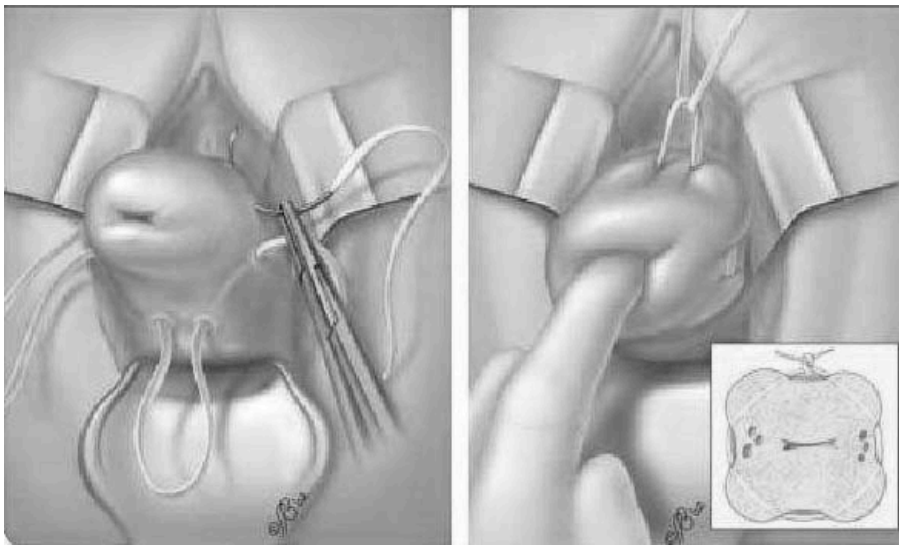
- 5mm Mersilene tape suture on 48mm ½ circle taper-cut or cutting needle (e.g. Clini-Ester Shirodkar®)
- Aseptic syringe for irrigation
- Suction tubing with Yankauer suction tip
- Heaney retractors
- Doyen retractors
- Extra-long blade weighted speculum
- 1" Deaver retractor
- Straight needle holders

5.4. Positioning: Patient in a dorsal lithotomy position. The surgeon must protect vulnerable neurologic, vascular, and bony points of the lower extremities and padding should be used at all potential pressure points. The buttocks should be positioned at the end of the table, with the table level. Hyperflexion of the hips should be avoided, as this can cause femoral neuropathy. Final positioning of the legs should be such to allow for assistants to be able to visualize the operative field.

5.5. The patient is then prepped and draped and the vagina should be gently cleansed with a water-based antiseptic solution.

5.6. Procedure:

- The bladder must be emptied with aseptic technique and the cervix is visualised by placing a long weighted speculum posteriorly, and curved or right angle retractors anteriorly and laterally as needed.
- An Allis clamp is used to grasp the anterior and posterior lips of the cervix as high in the vagina as possible to mobilise the cervix in a gentle downward and lateral direction. The cervix can also be exposed and mobilized by Babcock forceps but care should be taken not to traumatise the tissue.
- Ensure that only cervical stromal tissue is included in the suture and that the cervical canal is not entered.
- The suture is placed above the Allis clamp, curving through the cervical stroma of the right lower quadrant. In order to place the suture as high as possible; the junction of the rugated vaginal epithelium and the smooth cervix just distal to the cervical reflection is used as a landmark.
- This manoeuvre is then repeated in the right upper quadrant in the same fashion and the process is repeated on the left and the knot is placed at 12 o'clock. Care should be taken to avoid the paracervical vessels (at 3 and 9 o'clock), the bladder and the rectum. Additional bites are sometimes necessary when the cervix is damaged/friable or anteriorly in order to ensure that the knot does not slip down.
- The stitch is pulled tight enough to close the internal os, the knot being made anterior to the cervix and the end left long enough to facilitate subsequent removal.



5.7. Post-Operative management

- Despite a lack of evidence, excessive physical activity should be avoided. Routine abstinence for intercourse is unnecessary.
- Paracetamol alone provides adequate analgesia for most women.
- History-indicated cerclage can be done as a day procedure and the patient can be discharged after recovery from the anaesthetic and when ambulant to void.
- For ultrasound- and clinically-indicated cerclage placement:
  - Admit for bed rest until seen by MO in the ward.
  - Patient mobilization may be tailored to each patient's life-style (personal needs and capabilities)
  - Remember that cerclage "failure" may be attributable to preterm labour and more attention should be paid to this as a contributing factor.
- After discharge women are followed up as outpatients on biweekly basis (from 24w onwards) with assessments of cervical length. In the event of PTL after 24w prompt admission with administration of antenatal corticosteroids, magnesium sulphate and tocolyis is indicated as by departmental protocol on spontaneous preterm labour. Removal of the cerclage upon suspected or onset of preterm labour or PPROM before 34w should be discussed with consultant MFM team.
- Patients should be informed that they should present immediately to their health care facility if they experience any of the following symptoms after cerclage insertion: contractions or cramping, lower abdominal or back pain that comes and goes like labour pain, any vaginal bleeding, fever or chills, nausea and vomiting, foul-smelling vaginal discharge, water breaking or leaking (rupture of membranes).

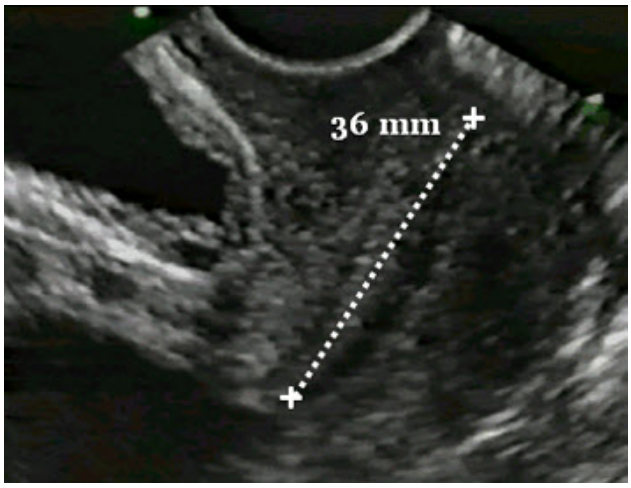
5.8. Cerclage removal:

- Elective cerclage removal is done at 36 - 37w gestation in the antenatal clinic during a routine visit.
- Immediate removal if the women presents in advanced labour at any gestation
- Immediate removal upon onset of preterm labour or PPROM after 34 weeks

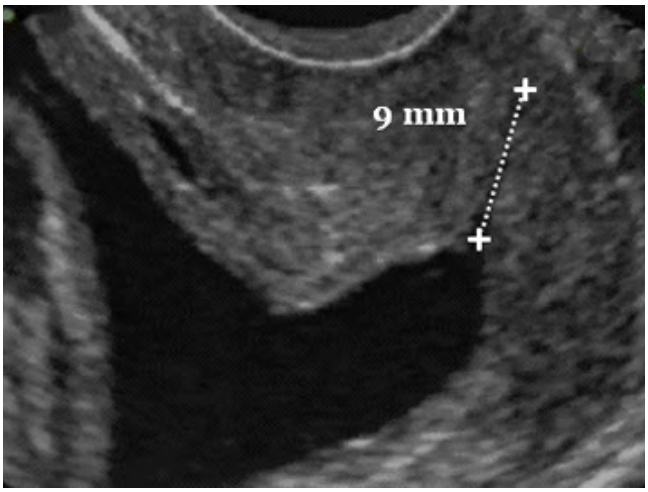
Appendix A: How to perform a transvaginal ultrasound cervical length measurement:

- The woman should have an empty bladder and placed with her legs abducted to allow a full range of movements whilst scanning.
- Ultrasound transducer: 5MHz transvaginal probe. A condom should be used to cover the probe and the lubricating gel should be sterile.
- Gently place the probe in the anterior vaginal fornix to ensure a sagittal view of the cervix is obtained
- Identify the internal os, external os, cervical canal and endocervical mucosa. The endocervical mucosa should be used to define the level of the internal os. Care should be taken to distinguish between cervical canal and a thickened lower uterine segment coming together in the midline, which can give the false impression of a longer canal.
- Do not exert undue pressure on the cervix with the probe because this will falsely elongate the cervix.
- Magnify the picture so that the cervix occupies at least 75% of the image
- Measure the distance between the internal and external os. Take 3 measurements (and pictures) over a period of about 3 minutes. Make sure you visualize the cervix in normal resting position but also with sustained (for at least a minute) and constant pressure being applied to the fundus, and also suprapubically as this may significantly shorten the cervical length.
- Record the shortest measurement of the cervical length in the notes.
- Note the possible presence of funneling at the internal os. The endocervical mucosa will give an accurate definition of the amount of funneling. Occasionally a thickened lower uterine segment can mimic a funnel and this can be identified by the absence of mucosa extending along the walls of the "funnel".
- Note the possible presence of dynamic changes in the cervix, defined by the appearance and disappearance of funneling during the scan.

Vaginal scan: normal cervix



Vaginal scan: short cervix



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