Management of an Incompetent Mid-second (Mid-2nd) Trimester Absent Ectocervix: a Case Series. Cervical Amplification Pre-cerclage Insertion

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Research Article

Keywords: Cervical incompetence, cervical cerclage, biomedical technologies, Preterm labour

Posted Date: January 21st, 2022

DOI: https://doi.org/10.21203/rs.3.rs-1269587/v1

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Abstract

Cervical cerclage is a treatment for an incompetent cervix, the latter being a contributor to spontaneous preterm birth. There is significant difficulty with a transvaginal cerclage insertion for the absent vaginal or ecto-cervix in the mid-2\textsuperscript{nd} trimester period resulting in a higher risk of late miscarriages, extremely preterm labour with subsequent neonatal morbidity and mortality.

A retrospective review of cases managed by additional surgical techniques and protocols increased the likelihood of a successful insertion in this cohort of patients. This was supported by adjuvant post-operative management protocol which included vaginal progesterone use, regular infection screening and lifestyle advice.

Cerclage insertion was mostly from 18-20 weeks gestational age (GA) with an increased gestational latency of 13 gestational weeks (range 12-18) with all deliveries after 34 weeks GA. Mean gestational age at delivery was 36 weeks +1 (253 days) with a range of 241-264 days in this small cohort of patients with minimal surgical complications and corresponding good neonatal outcomes.

This technique has the potential to be a beneficial therapeutic option in management of an incompetent mid-2nd trimester absent ecto-cervix.

Introduction

Cervical incompetence - recurrent, painless cervical dilatation with shortening - is a significant cause of spontaneous preterm labour which is defined as vaginal delivery at below 37 completed weeks’ gestation with a 10% incidence rate in pregnancy and is associated with significant neonatal morbidity and mortality. Cervical incompetence has an estimated prevalence of 1% of all pregnancies and 8% of recurrent mid-trimester miscarriages (1).

Cervical incompetence can be defined as a cervix measuring under 25mm (<10th centile) at 24 weeks gestational age (GA). Aetiology can be congenital, which may include uterine anomalies, Mullerian disorders and collagen disorders, or acquired as found in cervical lacerations following Caesarean sections or cervical surgeries such as a large loop excision of the transformation zone (LLETZ), Cone biopsy or trachelectomies.

Cerclage – the insertion of a suture around the cervix which closes the os upon securing the knot - is a treatment for an incompetent cervix as indicated by previous history of a mid-trimester pregnancy loss, ultrasound findings of a cervical length <25mm at 24 weeks gestational age, or by physical examination wherein the external os of the cervix is open with bulging membranes within the cervix and or vagina.

Clear benefit has been demonstrated in the use of a cerclage in a woman with a cervical length < 25mm with 2 or more mid-trimester losses, and could be considered in a twin pregnancy with a cervical length < 15 mm (2, 3). There is also a role for an emergency cerclage placement in a dilated cervix <3cm (4, 5).
Other treatment modalities for management of an incompetent cervix that have been used include: bed rest, vaginal progesterone, tocolytics and vaginal pessary. All have variable results from a growing research evidence base (6).

Before placement of a cervical cerclage, adequate counselling detailing contraindications (such as foetal anomaly, intrauterine infection, active bleeding, active preterm labour, ruptured membranes, foetal demise), alongside complications, which include: anaesthetic risks, pain, bleeding, bladder and bowel injury, ruptured membranes (2-65%), chorio-amnionitis (1-8%), preterm labour, fetal loss, cervical laceration, cervical dystocia and difficulty removing suture (1%), should be done (7, 8).

Cerclages can be performed electively or as an emergency, and are routinely categorized by the indication for insertion as defined below:

1. **History-indicated** - performed in asymptomatic women with risk factors in the obstetric or gynaecologic history that increase the risk of preterm birth.
2. **Ultrasound-indicated** - performed on asymptomatic women with cervical shortening.
3. **Rescue cerclage** - where the cervix is already open, and the foetal membranes are exposed. (3)

In addition, the level of stitch placement along with indications are described below:

- **McDonald’s** – lower vaginal stitch placement in the cervix that does not require extensive dissection or colpotomies.
- **Shirodkar** – a higher stitch following anterior and posterior colpotomies. This can be buried under a skin fold to reduce infection risk. Removal from 36 weeks gestational age usually requires another regional or general anaesthetic.
- **Abdominal** – a high stitch which is performed via a laparoscopic or a robotic-assisted procedure or as a laparotomy route and timed at: pre-pregnancy, during the 1st Trimester for failed vaginal cerclage, or at the time of a cone biopsy/ trachelectomy. Indications include the very short cervix, congenitally deformed cervix, previously failed transvaginal cerclage, deeply lacerated/ scarred cervix or spontaneous preterm birth with vaginal cerclage in-situ. Post-cerclage delivery by lower segment Caesarean section (LSCS) is indicated; whilst noting the uncommon side effects or risks of bladder and or bowel injury increase with increasing height of stitch placement and stitch erosion or migration. (7).

These procedures are usually done under regional or general anaesthesia.

Sutures include monofilaments such as Nylon, Prolene, Silk, braided Ethibond or the commonly used material, the braided Mersilene© 5mm tape.

Despite infection concerns with the use of braided sutures, none of these techniques nor suture types have been shown to be consistently superior to the others, except in specific cohorts (9, 10).
Background

All the cases in these series had very minimal or no ectocervixes, mostly flush or inferior to surrounding vaginal walls, sometimes with a closed pinpoint os with no sonographic evidence of stenosis. The narrow supra-vaginal cervical length contributed to the difficult dissection at the time of cerclage insertion. Given these features, it is not unusual for the usual vaginal cerclage procedure to be abandoned and expectant management with supportive therapy to be adopted in these cases, pending a high likelihood of late miscarriage or an extremely preterm birth.

Methodology

The study was a retrospective review of the management and outcomes of 5 cases of singleton pregnancies identified at mid-2nd trimester with a cervical incompetence and an absent/ very minimal vaginal cervix (ecto-cervix) over a 12 month period from August 2020 – August 2021, managed with this surgical technique and protocol. Permission was obtained from the Ethics and Governance board alongside individuals. Statistics were performed with an Excel spreadsheet application. The primary objective of this review was to assess gestational latency with secondary outcomes focused on maternal and neonatal morbidity.

Management Protocol:

Pre-operative preparation

Pre-operative preparation after appropriate consent with tocolytics – Indomethacin use, after excluding chorio-amnionitis, vaginal and or urinary inflammation-infection through microbiology assay and a baseline blood test. Infections were treated with broad spectrum antibiotics to cover for bacterial vaginosis agents with delayed recourse to surgery, if at all.

Surgical Techniques

1. With the patient in deep Trendelenburg position following a regional anaesthetic, foetal heart activity confirmation with a sonographic demonstration of the supra-vaginal cervical length and width, is done.

2. Vaginal toileting is performed with Betadine/ Iodine solutions or preferably with 0.5% Chlorhexidine solution (the latter being bacteriocidal with antifungal properties, unlike the former which is bacteriostatic). The concern associated with Chlorhexadine, with regard to a 3-6 times increased risk of dysuria, vaginal discharge despite proven efficacy, is highlighted to the patient (11, 12); in our cohort however this was not a significant clinical problem. Chlorhexidine was seen to provide a clearer surgical field than betadine vaginal preparation though this may be an operator-bias.
3. Depending on the friability of the cervix, the use of ‘Rampleys’ /ring forceps or Allis forceps, though non-traumatic, could lead to bleeding. An alternative approach was the use of a J shaped PDS ‘1’ or Vicryl ‘1’ suture to facilitate a deep bite into the cervical tissue, dependant on the length and breadth of the cervix. This mobilised the cervical stump ahead of other surgical incisions. The smaller the suture the less the trauma and consequent bleeding which could obliterate good surgical site views.

4. Care was taken to avoid a possible iatrogenic premature rupture of membranes (PROM). This was best done in deep Trendelenburg position after liaising with the anaesthetist. A full bladder aided with PROM avoidance as it helped elongate the anterior cervical lip. However this was counter-productive in women with significant cystoceles giving rise to obstructed views.

5. Amplification of the cervical tissue was done with 2-5 mls of local anaesthetic +/- adrenaline, to a depth of 1-1.5 cm which helped with haemostasis, whilst avoiding amniotic cavity infiltration or extra-cervical infiltration with the use of real-time scanning as much as possible. A pudendal needle or long dental needle was used for women with long vaginas, for example in very obese women. Prilocaine was avoided due to the risk of neonatal methaemoglobinaemia, with a preference for lidocaine due to no reported foetal teratogenic effects. Maximum dose for infiltration is 200 mg, which could be increased to 500 mg if given in solutions containing adrenaline; the uncommon side effect of foetal bradycardia often settled spontaneously.

6. Once amplification was done, gentle anterior and posterior proximal vaginal wall incisions are made after infiltration of the vesico-vaginal tissue planes with deflection of the bladder whilst access to the pouch of Douglas was gained to access the posterior supra-vaginal cervical tissue. However, care must be taken to avoid immediate iatrogenic bladder or bowel injury or later erosion into the same structures, depending on the anatomical constraints. Though deep dissection depending on initial cervical length could arrive at cervico-isthmic junction, with cautious insertion of cerclage through the avascular areas, in order to avoid significant risk of bladder, ureteric and cervical vascular injury: this is unlikely due to restricted access caused by the very gravid uterus. Removal of the suture under regional anaesthesia should also take these risks into consideration.

Despite several studies, determining an adequate post-cerclage cervical length has been inconclusive, with no current consensus on the minimum length (3, 13). It is expedient to have a lower stitch with fewer complications than a higher insertion fraught with complications, and this may be especially important to consider in the case of a very gravid uterus.

7. After 4 deeply-angled bites of the cervix (avoiding the vascular supply) have been taken, the suture is tied at 2-4 o'clock position. Both high anterior and posterior lips are taken with lateral stitches slightly lower and directed to avoid cervical vessels as depicted in Picture 2.

The stitch is usually buried. But given our local logistical problems, this is left short, double knotted and unburied to allow for easy removal, under local anaesthetic at or after 36 weeks’ gestation. The vaginal incisions are then closed after stitch insertion.
8. Following bladder catheterization, any haematuria is immediately investigated by a cystoscopy to identify and treat any injury with further formal urological interventions if needed. Foetal well-being is re-checked again and demonstrated to the mother.

9. Antibiotic cover intraoperatively consists of broad spectrum antibiotics for up to 24 hours; post-operatively, use of vaginal 2% Clindamycin cream for a week is a response to any probable infection risk assessed at the time. Rhesus isoimmunisation prophylaxis is considered whilst the short course of tocolytics is completed with a possible discharge 12-24 hours later.

10. This therapy is supported by antenatal clinic visits with infection screens - (M.S.U and H.V.S), initially fortnightly followed by monthly alongside daily use of vaginal progesterone pessary with other indicated maternity care, pending removal at 36 weeks with delivery plans dependent on obstetric indications. Bed rest or a refrain from heavy lifting is advised.

As there is little evidence behind adjuvant or concomitant multiple therapy, this is largely reviewed and applied on a case-by-case basis (3).

**Tackling common additional operational difficulties**

1. Poor access due to overhanging walls commonly seen in cases of morbid obesity - significant prolapse can be managed by using large vagina wall retractors such as Vienna and self-retaining vaginal retractors with the use of long instruments.

2. Bleeding from surrounding varicosities, underlying primary bleeding disorder - such as platelet clotting disorders or secondary to antenatal medication such as combined fragmin and aspirin use; respond to surgical dexterity and speed with an attentive assistant who aids in keeping the surgical field dry, pending completion of the stitch which often stops the bleeding.

3. Friable tissue - usually granulation tissue or an ectropion. Though unlikely, excluding pre-invasive or cervical cancer is paramount, following which gentle mobilisation with early augmentation preferably with Lidocaine/ 1:100,000 adrenaline is advisable.

4. Previous scarring from multiple vaginal surgeries or pelvic endometriosis results in difficult plane identification. Real-time abdominal or perineal ultrasound scanning may provide some help here. But in the absence of a proper plane identification, it might be appropriate to insert deep stitches with a smaller suture as Ethibond or Nylon, in a circumferential manner as these induce more fibrosis.

**Results**

This case series of 5 patients with singleton pregnancies are described below:

1. A 35-year-old primipara with a BMI of 34 who presented at 16 weeks gestational age (GA) with an unplanned pregnancy (hence no pre-conception planning) following a previous cone biopsy of stage 1 cervical cancer. The cervix was very short and described as a ‘dimple’ on examination. A stitch post-amplification inserted at 20 weeks following a cervical scan length of 18 mm with a breadth of 12 mm: brought about a gestational/ pregnancy latency of 14 weeks 3 days following the procedure.
The baby with a birthweight of 2.385kg, was delivered with APGAR scores of 9 and 9 following LSCS for foetal distress soon after a spontaneous rupture of membranes with a closed cervix. There was a good neonatal outcome with home discharge within a week.

2. A 28-year primipara was seen with a shortened, slightly-funnelling cervix despite progesterone use (30mm at 16 weeks GA down to 19.8mm at 18 weeks GA). A cerclage to a minimal ectocervix was able to achieve a 19-week pregnancy latency following the procedure and a vaginal birth of a well-grown and healthy neonate at 37 weeks 5 days.

3. 27-year-old primipara with a history of poly-cystic ovarian syndrome (PCOS) who was unaware of pregnancy until 19 weeks after presentation at the Accident and Emergency department with mild abdominal discomfort. A dating scan had identified a well-grown foetus, dated at 19 weeks and 3 days, with a short cervix -16 mm long with a 1cm dilated open os. The membranes were yet to prolapse into the vagina, through the very short ectocervix. Following the procedure, a pregnancy latency of 18 weeks and a vaginal birth at 38 weeks 3 days after elective cerclage removal, was achieved.

4. A 39-year-old para 2, all term vaginal births preceding her history of 2 LLETZs for treatment of cervical intraepithelial neoplasia, was given a cervical cerclage at 20 weeks for a 17mm long cervix with a minimal dimple-like ectocervix with no evidence of stenosis. The outcome was a gestational latency of 14 weeks 5 days alongside a vaginal delivery of a healthy neonate, following a 18 hour history of spontaneous rupture of membranes.

5. A 35-year-old G4 Para 1 had a cervical cerclage at 23 weeks GA despite previous use of vaginal progesterone, due to a history of a previous LLETZs followed by two 26 + 3 week deliveries – one was a neonatal death and the other, a daughter with significant developmental challenges. At the time of cerclage insertion at 23 weeks’ gestational age after careful counselling, a dimple with an overhanging cystocele was seen on vaginal examination whilst sonographically the cervical length had reduced from 32mm to 25mm over a 2-week period despite progesterone use. A gestational latency period of over 12 weeks was achieved with good neonatal outcomes.

In summary, minimum gestational age for cerclage insertion was from 18 weeks + 5 days GA with 60% of the series; from 20 weeks onwards. A gestational latency average of 13 gestational weeks (range 12-18 weeks) was gained: with all deliveries after 34 weeks 3 days (mean of 253 days with a range of 241- 264 days). There were no reported surgical complications. There was no significant maternal morbidity and neonatal significant morbidity nor mortality. A short period of neonatal surveillance was needed in the two of the three late preterm cases due to feeding problems.

**Discussion**

These women were not identified in a timely fashion for an early or pre-conceptual cerclage for a variety of reasons which include: perceived infertility, previously not wanting to have any more children or concurrent vaginal progesterone use. Once counselled about the new diagnosis of cervical incompetence,
all decided for an attempted vaginal cerclage and adopt an expectant management despite poor prognosis if this was unsuccessful.

Though their minimal or absent ectocervices with a narrow endocervical component, made them suitable candidates for abdominal cerclage (TAC). Their gestational age at time of presentation (>18 weeks 5 days) precluded this option as current evidence from most studies and meta-analyses which show prolonged gestational latency following TAC insertion were limited to use, pre-conceptually or up on till 14 weeks GA (8). The invasive nature of the intervention, paucity of data at later gestations, possible side effects and implications regarding delivery increased their health anxiety and their resistance to consider this option.

Given the gestational age at the time of presentation - middle of the second trimester, the prevailing general consensus is to adopt an expectant management with robust counselling as to the likelihood of a late miscarriage or an extremely premature birth. Additional use of vaginal progesterone is individualised due to paucity of data regarding limited success in this sub-group.

Cerclage remains the gold standard and the counselling extrapolated from the strong evidence from four RCTs for ultrasound-indicated cerclage indicated that use for a cervical length <25 mm in women with one or more spontaneous mid-trimester losses or preterm births resulted in a reduced incidence of birth before 35 weeks (RR 0.57; 95% CI 0.33–0.99 in women who had a previous second-trimester loss, and RR 0.61; 95% CI 0.4–0.92 in women with a previous preterm birth before 36 weeks of gestation). They were made aware that no insertion method was superior to the other (2). However caution in expecting similar success rates, was applied due to the clinical heterogeneity and peculiarity of their anatomy.

Evidence behind the varying aspects of the surgical protocol – skin preparation, anaesthetic infiltration, suture type, antibiotic cover and cerclage technique which have previously been largely discussed in treatment protocol, was provided alongside the lack of evidence behind the superiority of any stitch insertion and or technique (2, 9, 13). Deep angled suture placement as used in this group or superficial circumferential technique is poorly described in literature and its success may be related to the variable cervical architecture.

However the role of vaginal pessaries as a singular treatment, would appear unsuitable for this cohort as there is no reported demonstrable success in achieving a significant gestational latency in small, randomised controlled trials which assess efficacy of progestogen use in cervical lengths of less than 15 or 20mm (14, 15).

The benefit of a cerclage despite vaginal progesterone use, consequently became evident as initial progesterone use alone was inadequate given the two cases in this study. These findings are supported by the results of the OPPTIMUM trial which could not reproduce the benefits of progesterone as previously seen in smaller studies, though it showed no long term effects of progestogens in developmental domains of children at the age of 2 (16). However, a recent systematic review of the data
and network meta-analyses as detailed in the EPPPIC study indicates otherwise, with some benefit in the women with high risk of preterm labour and or short cervix (17, 18).

This recent review lent support to the management protocol which considered, in addition to cerclage insertion, the adjuvant therapy of vaginal progesterone.

Bedrest was found to be ineffective given the reduced gestational latency results, with increased risks of thromboembolism identified following a Cochrane review (19).

Regular Infection screening as part of the treatment modality recognises the importance of a longer physical barrier in protecting the cervical glue—mucus hydrogel plug. Where the cervix is short and narrow as seen in these women, the integrity of the plug as a bacterial deterrent, with a view to prevention of subacute inflammation or infection, comes into question. A study demonstrating the increased permeability and elasticity in the cervical mucus of women deemed to be at high risk of preterm labour supports the role of increased pathogen movement from the colonised vagina to the relatively sterile uterine cavity as part of the underpinning aetiology behind preterm labour (20).

Despite studies that show poor benefit from routine infection screening for preterm labour prevention, it is prudent to consider screening and treatment in this cohort of women. Therefore the additional protocols of serial infection screening and minimising heavy physical activity, was used. The consensus on management was individualised with an informal prognostication model due to a lack of high-quality evidence of benefit as detailed above.

The use of fibronectin to identify the likelihood of preterm labour was not utilised here, as it is still undergoing further research in this cohort of < 24 weeks gestational age.

Pre-conceptual counselling was reinforced as it was not previously provided in some cases – Consideration for an early transvaginal cerclage or an abdominal cerclage in subsequent pregnancies after early referral for Consultant-led care, was reinforced due to their varied associations ranging from previous repeated cervical surgeries to multiple preterm births at 26 weeks. Our referral pathways have also been strengthened with availability of transabdominal cerclage at a sister unit.

Though counselled robustly about poor prognosis, the outcomes in this group of patients turned out to be better than expected.

This positive skew could be a reflection of the sample size and or the use of a single operator, a limitation of the study.

In summary this cervical amplification technique alongside other treatment protocol, can potentially increase pregnancy latency to allow for delivery of a late preterm or term infant with corresponding reduced neonatal morbidity-mortality burden rather than a late miscarriage or an extremely preterm baby. The added advantage of no neonatal infection has also been noted.
Conclusion

In a group of pregnant women, with mid-second trimester ultrasound indicated cerclage and where the vaginal cervix is flush to surrounding walls, cervical tissue augmentation and modified Shirodkar suture placement can be considered. Initial results are optimistic having noted the limitations of the study. This procedure can be offered after robust counselling of patients following a cautious prognostication modelling process. Its suitability can be further explored, especially in low resource settings. Further research is needed in this area.

Declarations

The authors declare that no funds, grants, or other support were received during the preparation of this manuscript.

Competing Interests

There are no financial interests to declare.

Ethics Approval

Informed consent was obtained from all individual participants included in the study

Data availability submission

No

Contributions

Adedipe TO- Study design, Data collection and Manuscript writing

Akintunde AA – manuscript writing

Chukwujama UO - manuscript writing

References


**Picture**

Picture 1 and 2 are available in the Supplemental Files section.

**Supplementary Files**

This is a list of supplementary files associated with this preprint. Click to download.

- Picture1.jpg
- Picture2.jpg