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MATERNAL FETAL MEDICINE

Management of an incompetent mid-second (mid-2nd) trimester absent ecto-cervix: a case series. Cervical amplification pre-cerclage insertion

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Abstract

Background 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-2nd trimester period resulting in a higher risk of late miscarriages, extremely preterm labour with increased neonatal morbidity and mortality.

Methods A retrospective review of 5 consecutive cases managed by a surgical technique—modified high vaginal cerclage insertion at 18-20 weeks—and adjunct protocols which included vaginal progesterone use, serial infection screening and lifestyle advice, over a 12-month period ending in August 2021, is presented. Inclusion criteria included minimal or absent ecto-cervix, singleton pregnancies with an incompetent cervix attending for a vaginal cerclage whilst exclusion criteria were the usual contraindications to a cerclage insertion. Primary outcome was delivery after 34 weeks whilst seconday outcomes included maternal hemorrhage, bowel/bladder injury, chorioamnionitis and neonatal admission.

Results A increased gestational latency of 13 gestational weeks (range 12–18). Mean gestational age at delivery was 36 weeks +1 (253 days) with a range of 241–264 days. Delivery after 34 weeks gestational age was 100% with no maternal surgical complications and corresponding neonatal outcomes.

Conclusion There is a potential therapeutic benefit of this technique and adjunct management, in managing an incompetent mid-2nd trimester absent ecto-cervix.

Keywords Cervical incompetence · Cervical cerclage · Biomedical technologies · Preterm labour

What does this study add to the clinical work

This article provides additional knowledge about vaginal cerclage insertion with success rates for management of cervical incompetence, in a cohort of women presenting with minimal ectocervices.

Introduction

Cervical incompetence 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]. It can be defined as a cervix measuring under 25 mm (< 10th centile) at 24-week gestational age (GA). Aetiology can be congenital including uterine anomalies, Mullerian 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. Efforts to preclude other co-existing preterm labour risks, such as infections, placental and immunological factors, should be made before offering a cerclage.

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Cerclage is the insertion of a suture around the cervix which closes the os upon securing the knot. Due to the clear benefit that has been demonstrated, it is offered as a treatment in a woman with a cervical length < 25 mm 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 < 3 cm [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, complications and difficulty removing suture should be done.

Cerclages which can be performed electively or as an emergency, are routinely categorised by the indication for insertion—*History-indicated*—performed in asymptomatic women with risk factors in the obstetric or gynaecologic history that increase the risk of preterm birth: *Ultrasound-indicated*—performed on asymptomatic women with cervical shortening or: *Rescue cerclage*—where the cervix is already open, and the foetal membranes are exposed [3].

They can also be categorised by level of stitch placement usually done under regional or general anaesthesia.

This can be a McDonald—lower vaginal stitch placement in the cervix with no extensive dissection or colpotomies: Or a Shirodkar—a higher vaginal stitch following anterior and posterior colpotomies for very short cervices with the knot buried under a skin fold to reduce infection risk: Or an Abdominal—performed via a laparoscopic route, sometimes as a robotically assisted procedure or via a laparotomy route, usually pre-conceptually or during the 1st trimester for failed vaginal cerclage, or at the time of a cone biopsy/ trachelectomy. Other 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 foetal delivery by lower segment Caesarean section (LSCS) is indicated, whilst noting the uncommon side effects of stitch erosion or migration or bladder and or bowel injury risk increase with increasing height of stitch placement [7, 8].

Usual sutures include monofilaments, such as Nylon, Prolene, Silk; braided Ethibond or the commonly used material, the braided Mersilene© 5 mm 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 patient cohorts [9, 10].

Background

In this case series, the women were not identified in a timely fashion for a pre-conceptual or 1st trimester cerclage for a variety of reasons which include a perceived infertility, failed contraception or failed progesterone therapy. Once counselled about the new diagnosis of cervical incompetence, all decided for an attempted vaginal cerclage with subsequent expectant management if this was unsuccessful.

All 5 cases in these series had an overall cervical length of < 25 mm with no evidence of infection with very minimal (< 4 mm) or no ectocervices, 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 intra-operative features, it is not unusual for the usual vaginal cerclage procedure to be abandoned as a result of difficult surgical access and associated increased risks of bladder and ureteric injury: and an expectant management with supportive therapy be adopted, pending a high likelihood of late miscarriage or an extremely preterm birth. The use of serial quantitative fibronectin from 22 weeks of gestational age which is under research which may help identify delivery within 7 days, would have been limited in these series.

Methodology

The study was a retrospective review of the management and outcomes of 5 consecutive cases of singleton pregnancies identified at mid-2nd trimester with a sonographic evidence of cervical incompetence with an absent/very minimal (< 4 mm) vaginal cervix (ecto-cervix) on vaginal examination over a 12-month period from August 2020–August 2021, who were managed with this surgical technique and management protocol.

Inclusion criteria included minimal or absent ecto-cervix, singleton pregnancies with a shortening cervix attending for a vaginal cerclage. Presence of infection, multiple gestations, foetal demise or fatal congenital anomalies and other concurrent maternal indications with a possibility of pregnancy interruption, inability to have regional or general anaesthetic in addition to the contraindications stated earlier, were the exclusion criteria.

The primary outcome of this review was to assess gestational latency beyond 34 weeks with secondary outcomes focussed on maternal complications, such as bowel injury,

haemorrhage and neonatal morbidity, such as poor APGARS score, chorio-amnionitis and prolonged NICU admission. Data from a follow-up at 6 months were available in 80% of the women. Permission was obtained from the Ethics and Governance board alongside individuals. Statistics were performed with an Excel spreadsheet application.

Management protocol

Pre-operative preparation

Pre-operative preparation after appropriate consent, is initially with tocolytic use—Indomethacin, after excluding infections— chorio-amnionitis, vaginal and or urinary inflammation— through microbiology assay and a baseline blood test.

Surgical techniques

(1) In the 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 Chlorhexidine, with regard to a slightly higher risk of vaginal soreness and discharge despite proven efficacy, is highlighted to the patient [11, 12]; in our cohort, however, this was not a problem. As the 2% cream product variant is used in many obstetric operative interventions in our unit, patient acceptance was not a 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 and reduced surgical views. 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, identified on digital examination. This mobilised the cervical stump ahead of other surgical incisions. The smaller the suture, the less the trauma and consequent bleeding, obliterating good surgical-site views.
(4) Care is taken to avoid a possible iatrogenic premature rupture of membranes (PROM). This is best done in the deep Trendelenburg position after liaising with the anaesthetist. A full bladder helped elongate the anterior cervical lip. However, this could be counter-productive in women with significant cystoceles giving rise to obstructed views.
(5) Amplification of the cervical tissue is done with 1–2 mls of local anaesthetic ± adrenaline, to a depth of 1–1.5 cm in each cervical lip. This helps with haemostasis, whilst avoiding amniotic cavity infiltration or extra-cervical infiltration with the use of real-time scanning as much as possible. This approach is much shallower than the deep para-cervical block which carries the risk of intra-amniotic infusion with possible foetal compromise. A pudendal needle or long dental needle can be used for women with long vaginas or in the very obese women.
(6) Once amplification is done, gentle anterior and posterior colpotomies are done to gain access to the uterovesical space and pouch of Douglas. However, care is taken to avoid immediate iatrogenic bladder or bowel injury or erosion into the same structures during hydrodissection, depending on anatomical constraints.
(7) Deep dissection depending on initial cervical length which could arrive at or above the cervico-isthmic junction, is avoided. This is primarily done to avoid significant risk of bladder, ureteric and cervical vascular injury: but is in response to the 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, there is no consensus as to determining a minimum adequate post-cerclage cervical length [3, 13]. It is expedient to have a lower stitch with fewer complications than a higher insertion fraught with complications, most especially in the very gravid uterus.

(8) 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 pictures below.

Long ectocervix seen below vaginal cuff with low fetal head

No ectocervix with deep angled bite after dissection, avoiding prarcervical tissue and amniotic membranes

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. Deep angled suture placement as used in this group or superficial circumferential technique is poorly described in literature and its success is yet to be determined and may be related to the variable cervical architecture.

(9) Following bladder catheterization at the end of the procedure, 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 and demonstrated to the mother.

(10) Antibiotic cover intraoperatively consists of broad spectrum antibiotics for up to 24 h post-operatively and the use of vaginal 2% Clindamycin cream up to a week. Rhesus isoimmunisation prophylaxis is considered whilst the short course of tocolytics is completed with a possible discharge 12–24 h later.

(11) This therapy is supported by antenatal clinic visits with serial infection screens—urine and vaginal microbiology assays initially fortnightly then followed by monthly; alongside daily use of vaginal progesterone pessary with usual obstetric care. Post-operative bed rest or a refrain from heavy lifting is advised. The cerclage stitch is removed at or after 36 weeks with delivery plans dependent on obstetric indications. 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 or a significant vaginal prolapse can be managed using large vagina wall retractors such as Vienna and/or self-retaining vaginal retractors with the use of long instruments.

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

(3) Friable tissue is usually granulation tissue or an ectropion. Though uncommon, excluding the unlikely possibility of a pre-invasive or cervical cancer is paramount. In the event of no antecedent concerns, gentle mobilisation after early amplification of tissues with shallow infiltration with adrenaline is advisable.

(4) Previous scarring from multiple vaginal surgeries or pelvic endometriosis results in difficult plane identification. This can be tackled with real-time abdominal or perineal ultrasound scanning. In the absence of a proper plane identification, it might be appropriate to insert deep circumferential cervical stitches with a smaller multi-filament suture as Ethibond or Nylon, in a circumferential manner as these induce more fibrosis whilst minimising injury to surrounding organs.

Results

This case series of 5 patients which met the inclusion criteria are described below:

(1) A 35-year-old primipara with a BMI of 34 who presented at 16-week 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 scan demonstrating a cervical length of 18 mm with a breadth of 12 mm, resulted in a gestational/ pregnancy latency of 14 weeks 3 days. The baby with a birthweight of 2.385 kg, was delivered with APGAR scores of 9 and 9 following a lower segment caesarean section (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-old primipara was seen with a shortened, slightly funnelling cervix despite progesterone use (30 mm at 16-week GA down to 19.8 mm 2 weeks later). A cerclage to a minimal ecto-cervix was able to achieve a 19-week pregnancy latency and a vaginal birth of a well-grown and healthy neonate at 37 weeks 5 days.

(3) A 27-year-old primipara with a history of poly-cystic ovarian syndrome (PCOS) following presentation at the Accident and Emergency department with mild abdominal discomfort, was seen after a dating scan which identified a well-grown foetus, dated at 19 weeks and 3 days, with a short cervix− 16 mm long and a 1 cm dilated open os. The membranes were yet to prolapse into the vagina, through the very short ecto-cervix. Following the cerclage insertion, 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 followed by 2 large loops excision of transformation zone (LLETZ)s for treatment of cervical intraepithelial neoplasia, was given a cervical cerclage at 20 weeks for a 17 mm long cervix with a minimal dimple-like ecto-cervix with no evidence of stenosis. The outcome was a gestational latency of 14 weeks 5 days alongside a vaginal delivery of a healthy neonate, after an 18 h history of spontaneous rupture of membranes.

(5) A 35-year-old G4 Para 1 had a cervical cerclage insertion at 23-week GA due to a shortening cervix and a history of a previous LLETZs followed by two 26 + 3 weeks deliveries—one, a neonatal death and the other, a daughter with significant developmental challenges. A pre-cerclage insertion fibronectin test was declined by the mother given her previous Obstetric history. 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 32 to 25 mm over a 2-week period indicating progesterone failure. 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 in 60% of the series and from 20 weeks onwards in 40%. 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, such as bowel or bladder injury, haemorrhage and no neonatal morbidity, such as poor APGARS score, chorio-amnionitis and prolonged NICU admission. A short period of neonatal surveillance was needed in the two of the three late preterm cases due to feeding problems. Data from a follow-up 6–12 month post-partum were available in 80% of the women, revealing no significant foetal nor maternal morbidity concerns.

Discussion

A cerclage was highly considered in these cases given the current research data and FIGO (2021) consensus. As there is a clear benefit of cerclage insertion in gestations less than 24 weeks in high risk women with cervical length < 25 mm. Use in these women with additional previous second trimester losses resulted in a reduced incidence of birth (RR 0.57; 95% CI 0.33–0.99) before 35 weeks; and in those with an additional previous preterm birth before 36 weeks of gestation (RR 0.61; 95% CI 0.4–0.92) [2]. No insertion method was superior to the other [3]. However caution in expecting similar success rates, was applied during counselling due to clinical heterogeneity.

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 show prolonged gestational latency following TAC insertion was limited to use either pre-conceptually or up on till 14 weeks GA [8]. The invasive nature of the intervention with likelihood of surgical complications, paucity of data at later gestations and implications regarding delivery made this option unacceptable to these women and increased their health anxiety.

Given the gestational age at the time of presentation, middle of the second trimester, the prevailing local consensus was to adopt an expectant management in addition to progesterone use, with robust counselling as to the likelihood of a late miscarriage or an extremely premature birth. 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 20 mm [14, 15]. In addition, progesterone failure has also been reported by the OPPTIMUM trial which could not reproduce the benefits of progesterone as previously seen in smaller studies but identified no long-term effects in developmental domains of children at the age of 2 [16].

An attempt at a modified Shirodkar cerclage after amplifying the cervix was the other option with an adjunct pre-operative and post-insertion protocol. This was arrived at, following assessment of the cervical architecture with

impact on surgical techniques, lack of stenosis, cervical mucus integrity and eliminating possible co-existing subclinical infections. This approach was supported by evidence behind the varying aspects of the surgical protocol, such as skin preparation, anaesthetic infiltration, suture type, antibiotic cover and cerclage technique, which have previously been largely discussed in treatment protocol, alongside the lack of evidence behind the superiority of any stitch insertion and or technique [2, 3, 9, 13].

The benefit of cerclage insertion with additional protocol versus singular progesterone use, was evident due to the success seen in the two cases with progesterone failure. This demonstrates some strong association with delivery after 34 weeks GA. A causal relationship can be best investigated in larger studies.

As a recent systematic review of the data and network meta-analyses (EPPPIC) indicated some benefit of progesterone use in the women with high risk of preterm labour and or short cervix [17, 18]. This in addition to another study by Enakpene et al. with a small cohort of women with very short cervix, demonstrated a clear benefit [19], raised the possible adjunctive benefit of progesterone following a cerclage insertion despite poor results from another study by Lavie et al. [20]. These mixed results were felt to be due to clinical heterogeneity possible related to length of cervix, type of cerclage stitch and a probable presence of an inadequate cervical glue.

Bedrest has been found to be ineffective as a sole agent given the reduced gestational latency results alongside increased risks of thromboembolism identified following a Cochrane review which precludes its routine use [21].

The role of vaginal pessary was questionable here due to the lack of a distinct ecto-cervix and varied results from small studies and RCTs [6, 14, 15, 17].

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, to prevent 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, had also shown increased pathogen movement from the colonised vagina to the relatively sterile uterine cavity, one of the underpinning aetiologies behind preterm labour [22]. Despite studies that show poor benefit from routine infection screening for preterm labour prevention possibly due to poor inclusion criteria-setting, it is prudent to consider screening and treatment in this cohort of women.

Given a lack of strong evidence in this sub-group of women, it was felt expedient to have a management protocol which included the adjuvant therapy of vaginal progesterone, serial infection screening and minimising heavy physical activity, in addition to cerclage insertion. This was further individualised over the course of the pregnancy due to lack of high-quality evidence of benefit as detailed above.

The additional use of fibronectin to identify the likelihood of preterm labour and justify cerclage insertion was not utilised here, as these women were asymptomatic and mostly under 22 weeks GA. Patient choice in addition to lack of preterm labour symptoms played a huge role in the 23-week gestation as she preferred the cerclage insertion over and above serial fibronectin screening following progesterone failure more so as current FIGO guidelines given her previous poor obstetric history indicated a cerclage. It should be noted that research in this cohort of asymptomatic < 24 weeks gestational age is ongoing with equivocal results [23, 24].

Pre-conceptual counselling was reinforced during the pregnancy and in the post-partum period as it was not previously provided in some cases. Advice to have an early transvaginal cerclage or an abdominal cerclage in subsequent pregnancies after early referral for consultant-led care, was reinforced due to their varied risks 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 compares favourably with this large 10-year retrospective study (25). This positive skew could be a reflection of the sample size. However the small sample size, use of a single operator, lack of randomisation and a validated prognostication model alongside cost-effectiveness are recognised limitations of the study.

In summary, this cervical amplification technique alongside other treatment protocol, can potentially increase pregnancy latency to allow for delivery at or after 34-week GA 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 amplification and modified Shirodkar suture placement can be considered. Initial optimistic results which include delivery after 34-week GA with corresponding minimal neonatal morbidity burden have been reported 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 where abdominal cerclage procedures are not readily available. Further research given ethical considerations is needed in this area.

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Declarations

Conflict of interest There are no financial interests to declare.

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

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