Non-invasive emergent cerclage using a plastic sling: case series

Humberto Azpurua,1 Otto Paredes,2 Solanye Navas,3 Jose Moros4

ABSTRACT

Cervical incompetence represents a controversial problem for the modern obstetrician. Treatment modalities since its description have changed with time. Shirodkar and McDonald cerclage techniques have remained the mainstay in the treatment of women with incompetent cervices performed either electively or emergently. The most feared complication of an emergency cervical cerclage is the rupture of membranes during the procedure, especially when the cervix is wide open and the membranes are protruding. To decrease that complication, some methods to reduce the prolapsed membranes have been used: filling the bladder with 0.45% saline solution through a Foley catheter, performing an amniocentesis to decrease intra-amniotic pressure and subsequent reduction of the prolapsed membranes as well as the use of balloons to push the membranes back into the uterus before the placement of a suture. Nevertheless, the introduction of such a sharp instrument like a needle in order to place the suture is a very risky step. Lately, a silicone pessary has also been used to perform cerclages but with disparate results. We present the successful use of an innovative method in 3 patients with cervical incompetence who presented with pregnancies <24 weeks and cervical effacement with protruding membranes into the vagina.

INTRODUCTION

Cervical incompetence represents a controversial problem for the modern obstetrician. It was first described by Gream in 1865 in The Lancet.1 Classic cervical incompetence is characterised by a history of recurrent second or early third trimester fetal loss after non-painful dilation of the cervix in the second or the beginning of the third trimester.2 3 It is usually followed by prolapsed membranes into the vagina followed by premature rupture of membranes and loss of an immature fetus. The true incidence is unknown and it is thought that ~10% of preterm deliveries are caused by true cervical incompetence.4 The diagnosis of true cervical incompetence remained retrospective until the introduction of real-time vaginal ultrasonography, which may predict, with some certainty, the risks of preterm labour and cervical incompetence. In the past, the cervix was considered a categorical variable: it was either competent or incompetent. Iams et al5 in 1995 challenged this theory and suggested that the cervix had a variable function along a continuum of competence.5 6

Treatment modalities since its description have changed along time: in 1902, a surgical closure of the cervix with a suture (trachelorrhaphy) was described as the first successful approach to the treatment of cervical incompetence.5 This was followed by the Lash procedure in the early 1950s.7 Shirodkar introduced his cerclage in 1955, and McDonald reported his technique in 1957.8 Shirodkar and McDonald cerclage techniques have remained the mainstay in the treatment of women with incompetent cervices and are performed either electively or emergently.14 6

Emergency cerclage can be offered to women with impending preterm labour and cervical incompetence during their second trimester.6 9 The most feared complication of an emergency cervical cerclage is the rupture of membranes during the procedure, especially when the cervix is wide open and the membranes are protruding. To decrease that complication, some methods to reduce the prolapsed membranes have been used: filling the bladder with 0.45% saline solution through a Foley catheter,10 performing an amniocentesis to decrease intra-amniotic pressure and subsequent reduction of the prolapsed membranes11 as well as the use of balloons to push the membranes back into the uterus before the placement of a McDonalds suture.12–14 In all the previous techniques, the needle is still
used and the introduction of such a sharp instrument is a very risky step. We think piercing the cervical tissue in a potentially contaminated area also is a trigger to inflammation/infection processes that theoretically can be avoided with ‘no needle’ techniques. The use of pessaries has been proposed in the presence of changes in the cervix detected either clinically or by ultrasound but with disparate results.

In 1999, a group of practitioners in Venezuela tested the use of a plastic sling named ty-wrap or cable ties (see description in figure 1) to perform prophylactic cerclages in patients with cervical incompetence; until now, no clinical studies evaluating this technique have been published. We present the use of that needleless innovative method in three patients with cervical incompetence who presented with total cervical effacement and protruding membranes into the vagina (figures 2 and 3).

METHODS

Three patients at gestational ages ≤24 weeks of pregnancy went to the emergency room (ER) reporting increased vaginal discharge and pelvic discomfort. At admission, examination with a sterile speculum noted bulging fetal membranes in the vagina (figure 2). No contractions were detected by tocometry. Two patients were admitted in the obstetric department of the Hospital Universitario de Caracas, and one was admitted in a private hospital in Caracas, Venezuela. Preterm rupture of membranes, preterm labour and chorioamnionitis were ruled out. Patients were admitted receiving indomethacin to prevent contraction and decrease fetal urine output as a theoretically way to decrease intra-amniotic pressure as well as ampicillin/sulbactan 1.5 g twice a day as prophylactic antibiotic therapy.

After signing informed consent and getting approval from the bioethics committee from Hospital Universitario de Caracas, emergency cerclage with a plastic sling was offered as a treatment option. Under epidural anaesthesia, emergency cerclages were done: patients were placed in Trendelenburg position and the bladder was filled with saline in order to decrease membranes bulging. The vulva and distal vagina were cleaned with antiseptic chlorhexidine solution and two valves were carefully introduced into the vagina separating the anterior and posterior walls from the fetal membranes. Cervical edges were pulled out using atraumatic clamps, and

Figure 1 Commercia[...](A) Ensambled, ready to be placed around the cervix. (B) Detail of the sling shows a flexible tape section (T) with teeth that engage with a pawl in the head (H) to form a ratchet so that as the free end of the tape section is pulled, the tie-wrap tightens and does not come undone.

Figure 2 Speculum examination shows a wide dilated cervix (C) with bulging membranes (M) fetal parts were actually seen moving intermittently.
using an embedded in antiseptic ball-shape sterile gauze, the membranes were pushed back into the uterine cavity. Then the clamps were approach joining the cervical lips and the gauze was carefully withdrawn avoiding the membranes to come out.

Keeping the cervical labia together, a gas-sterilised plastic sling (cable ties) was placed around them (figure 4). The cervix was pulled out and the sling was placed as high and close to the inner cervical os as possible. The sling was then closed and tight in the base of the cervix. Pressure applied for tightening of the plastic sling was determined by observation of reduced sliding as well as presence of capillary filling in the cervical tissue (figure 5A).

Continued tocolysis, steroids and bed rest were prescribed during their stay at the hospital. The patients stayed for 48 hours of observation and after discharge had weekly visits to the hospital for cervical surveil-
ance using transvaginal and transperineal ultrasound (figure 5B).

RESULTS

Case 1: A 39-year-old patient with previous history of I instrumental preterm delivery at 33 weeks presents at 24 weeks of gestation, cervix is totally effaced and 4 cm dilated, bulging membranes protrude into the vagina in an hourglass configuration. Fetal ultrasound shows an active male fetus with an estimated fetal weight of 603 g and normal amniotic fluid (C reactive protein (CRP)=2.0 mg/dL and white cell count (WCC) count=9000/m\text{L}). Bacterial cervical culture was negative. After 72 hours of admission, emergency cerclage was performed using the technique described earlier. Cervical height of the cerclage was 25 mm. Pregnancy was prolonged for 6 weeks. At 30 weeks the patient presents uterine contractions. A healthy preterm male fetus weighing 1384 g was delivered by C-section. The neonate stayed for 7 days and was discharged with no complications.

Case 2: A 24-year-old patient with a previous history of two miscarriages between 16 and 19 weeks presents at 22 weeks of gestation with a 3 cm cervical dilation and bulging membranes into the vagina. Fetal ultrasound shows an active female fetus with estimated fetal weight of 588 g and normal amniotic fluid (CRP=3.2 mg/dL and WCC count=11 000/m\text{L}). Bacterial cervical culture was negative. After 48 hours from admission, emergency cerclage was performed using the technique described. Cervical height after the cerclage was 22 mm. Pregnancy was prolonged for 9 weeks. At 31 weeks, the patient had a preterm
rupture of membranes. A preterm female fetus weighing 1520 g was delivered by C-section. The neonate stayed 21 days in the hospital due to neonatal infection and was discharged with no complications after 21 days. Follow-up evaluations showed no neurological impairment.

**Case 3**: A 22-year-old patient with a previous history of one miscarriage at 13 weeks treated with dilation and curettage presents at 23 weeks of gestation with 1.5 cm cervical dilation and bulging membranes into the vagina in an hourglass configuration (figure 3). Fetal ultrasound shows an active female fetus with an estimated fetal weight of 672 g and normal amniotic fluid (CRP=1.6 mg/dL and WCC count=8500/mL). Bacterial cervical culture was negative. An emergency cerclage was performed using the technique previously described. Cervical height after the cerclage was 21 mm. Pregnancy was prolonged for 12 weeks. At 35 weeks, the patient had preterm rupture of membranes. A preterm female fetus weighing 2230 g was delivered by C-section. The neonate did not need admission into the neonatal intensive care unit and was sent home 2 days after birth.

**DISCUSSION**

Cervical insufficiency is a difficult and confusing diagnosis. Its diagnostic criteria, aetiology and treatment are all debated.25 26 Cerclages have been placed because of a patient’s obstetrical history, physical examination, ultrasound or a combination of the above.6 27 Cervical cerclage has been widely used as a surgical method to prevent recurrent mid-trimester pregnancy loss in women at risk. Elective (prophylactic) cerclage placement at 13–15 weeks of gestation may benefit some women with proven cervical insufficiency; ‘proven’ in this setting means a history of painless miscarriages in the past. A number of strategies from expectant management to cerclage have been recommended to treat cervical incompetence.26–29

Ultrasound technology has given us more data about cervical physiopathology allowing an earlier detection of cervical shortening. Screening women at high risk with cervical ultrasound to determine cerclage placement results in more intervention but similar outcome compared with history-indicated placement;30 we think it carries a potential benefit of early intervention, although the data in this regard are limited and additional clinical trials with larger numbers are needed.26 29 31

Controversies arise in the placement of a cerclage in the presence of a short cervix (<2.5 cm) but not shorter than 1.5 cm, a clinical setting where most experts consider that cervical cerclage can be offered.32 33 Several studies compare expectant versus placement of a physical examination-indicated cerclage showing that, in a very specific population (ie, those with cervical dilation in the absence of labour, bleeding, preterm premature ruptura of membranes or any signs of chorioamnionitis clinically or by amniocentesis), cerclage prolongs gestation and improves neonatal outcomes compared with expectant management.34–36 Although emergency cerclage with fetal membranes prolapsed into the vagina is actually a salvage operation, there is increasing evidence that it also prolongs gestation and improves neonatal survival compared with expectant management.36–39 In general emergency, cervical cerclage for cervical incompetence is a very difficult procedure with fatal complications like iatrogenic preterm rupture of membranes and chorioamnionitis.14 33 37 Advanced dilation (>3 to 4 cm) and early gestational age (22–24 weeks) are associated with poorer outcomes.36 Cervical cerclage performed in patients with or without cervical dilation decreases preterm premature rupture of membranes and increases neonatal survival compared with expectant management.38–41 The use of a silicone pessary (a needles method) has shown disparate results.16–18 41

Figure 5  (A) Cartoon showing the final position of the plastic sling in the cervix. (B) Transvaginal ultrasound a week later shows the shadow of the plastic sling (S) and a cervical length of 26 mm.
MEDICAL DEVICES

Our study shows a non-invasive technique of performing cervical cerclage in cases of extreme effacement and membranes protrusion. All procedures lasted <15 min and did not cause bleeding. Accidental piercing of the membranes was not possible since it is a needleless procedure. After the procedure, cerclage height was over 20 mm in all cases, a very important achievement, since cerclage height of 18 mm or greater is associated with a reduction in spontaneous preterm birth for women with an ultrasound-indicated cerclage. Cases were done in non-viable pregnancies as salvage procedures. We do not recommend its use in prophylactic cerclages before safety is evaluated.

The placement of a plastic sling around the cervix, as proposed by Ioannou et al more than 15 years ago, opens a possibility of a safe and standardised method to perform a needleless cervical cerclage. Further investigation using medical compatible materials is needed in order to evaluate safety and efficacy of this innovation.

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