

Cervical cerclage for prevention of preterm birth: a commentary

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Abstract

Cervical cerclage remains a proven method for the prevention of preterm birth caused by a 'weak cervix'. However, there is controversy as regards the precise diagnosis and definition of 'cervical incompetence', the actual surgical technique, choice of suture material and number of sutures and ties to be made during the procedure. There is now emerging evidence that other alternatives to cervical cerclage such as the cervical pessary and progesterone therapy may have a role in the prevention of preterm birth. These could eliminate the exposure of patients to risks associated with surgical interventions. This short commentary presents an update on the role of cervical cerclage in the prevention of preterm birth and explores the available evidence on the alternatives to the procedure.

Introduction

Preterm labour is a major cause of morbidity and mortality accounting for over 28% of neonatal deaths globally (1). Efforts to reduce this rate have been disappointing. Of the various interventions that have been tried, cervical cerclage is the most beneficial in reducing the incidence of preterm birth for women at risk (2). Cervical cerclage is thought to work by providing structural support to the weak cervix, maintaining cervix length of a short cervix or providing a mechanical barrier by keeping the cervical mucus plug in place consequently preventing the ascension of infection and other agents that may induce inflammation in the uterus. Despite conferring these benefits, cervical cerclage does not significantly reduce perinatal mortality and neonatal morbidity associated with preterm labour. Furthermore, this benefit seems restricted to singleton pregnancies and the long term impact of the surgical procedure is still not clear. (3).

The use of cervical cerclage dates back to 1902 when it was inserted in women with recurrent miscarriage due to a presumed 'incompetent' cervix—a very imprecise diagnosis, which has largely been abandoned. However, the technique was first documented in literature by Shrodkar in 1955. He described a transvaginal purse-string suture for women with 'habitual abortion' in the second trimester. The suture was placed following bladder mobilization, to allow insertion above the level of the cardinal ligament (4). McDonald (5), modified this technique and described a transvaginal purse string placed without bladder mobilization, at the cervical-vaginal junction, an approach widely used. There have been variations with regards to the approach used to insert the suture (abdominal versus transvaginal), the type of suture material used (braided versus monofilament), the number of sutures/ties (single versus double sutures), the timing of suture placement and the indication (ultrasound-indicated versus history-indicated, emergency/rescue cerclage). For the abdominal approach there is also debate on laparoscopy versus open approach (6-8). More recently, the cervical pessary has been introduced into the market with the aim of achieving cervical lengthening without exposure to the risks associated with surgery

and the role of progesterone therapy in the prevention of preterm births has also been a subject of interest.

Safety of cervical cerclage

Cervical cerclage is generally a safe procedure. It is associated with a 0.6% (95% confidence interval [CI], -0.26 to 1.66) risk of perioperative complications regardless of the indication or diagnosis. The intraoperative complications include anesthetic-related such as unsuccessful regional anaesthesia. Postoperative complications include contractions and bleeding after cerclage placement (either immediate or remote) and fetal death. Other peripartum complications are chorioamnionitis (6.2%), preterm premature rupture of membranes (11%), preterm labour (20%), and delivery before 32 weeks' gestational age (8%) (9). Cervical cerclage is associated with a higher rate of maternal side effects (vaginal discharge and bleeding, pyrexia) (average RR 2.25; 95% CI 0.89 to 5.69; three trials, 953 women). Caesarean section rates are also significantly higher after cervical cerclage (RR 1.19; 95% CI 1.01 to 1.40; 8 trials, 2817 women) (2). These complications are however small and manageable with an overall survival rate of more than 98% (10).

History indicated versus ultrasound indicated cervical cerclage

Traditionally, cervical cerclage has been inserted in women with three or more mid-trimester pregnancy losses/recurrent miscarriages. However, with the widespread use of transvaginal ultrasound for cervical length estimation, more focus has been on women diagnosed with a short cervix less than 15mm or 25mm for singleton and multiple pregnancies respectively. Both history-indicated and ultrasound-indicated cervical cerclage are comparable in terms of reducing the incidence of preterm birth. Cervical length screening with cerclage for short cervical length is associated with similar incidences of preterm birth before 37 weeks (31% versus 32%, relative risk 0.97, 95% confidence interval [CI] 0.73-1.29), preterm birth before 34 weeks (17% vs 23%, relative risk 0.76, 95% CI 0.48-1.20), and perinatal

mortality (5% vs 3%, relative risk 1.77, 95% CI 0.58-5.35) compared with history-indicated cerclage.

However, monitoring by transvaginal ultrasound has been found to be safer than routine history-indicated cerclage (11,12). The onus remains on the clinician who should individualize cases and decide the patients that will benefit from the procedure. History of painless cervical dilatation, rupture of membranes with cervical dilatation, previous history of cervical surgery or repeated dilatation and curettage do not improve diagnostic accuracy. Preconception cervical tests such as measurement of cervical length, sounding of the cervix with dilators, digital examination for cervical tone are also not predictive of 'cervical incompetence'. Incidental finding of bulging membranes or funneling of the internal os at ultrasound with no other risks of preterm labour is not predictive of preterm labour (13-15). The contraindications for the insertion of cervical cerclage are shown in Table 1.

Table 1: Contraindications for cervical cerclage

Active preterm labour
Clinical evidence of chorioamnionitis
Continuing vaginal bleeding
PPROM
Evidence of fetal compromise
Lethal fetal defect
Fetal death

Sutures material to be used

Several suture materials have been utilized for cervical cerclage. These include human fascia lata (4), Mersilene™ (Ethicon), silk, Prolene™ (Ethicon), Tevdek™ (Teleflex,), metal wire, as well as Mersilene tape™ (Ethicon) and others. Mersilene 5 mm tape™ (Ethicon,) and large non-absorbable monofilament (e.g. Prolene™) are the commonly used sutures (11). The tape has been purported to be better by its ability to spread the tension better in tissue, though this has not been proven.

In their secondary analysis of a multicenter trial data of ultrasound-indicated cerclage for short cervical length (CL), Berghella and Mackeen (12) did not find any superiority of one suture material over the other. However, a similar study by the Global Network for Perinatal & Reproductive Health, Obstetrics and Gynecology, braided suture was associated with decreased preterm labour < 28 weeks (OR 0.20 CI 0.04, 0.89) and improved neonatal survival (OR 15.62 CI 1.81, 135.01) compared to Mersiline tape. There was also a decrease in febrile morbidity, prelabour rupture of membranes, and prevention of preterm births < 32 weeks with the use of braided suture (11). Based on these results alone, it is difficult to recommend one suture over the other in cervical cerclage. Until more convincing evidence is generated, the choice of suture material should be left to the surgeon's preference.

Single versus double suture

Some retrospective cohort studies have shown an increase in the cervical length with a double suture approach compared to a single suture even though there does not appear to be any improvement in perinatal outcomes (20-22). In a small parallel randomized clinical trial in Iran, preterm birth before 33 weeks of gestation was not experienced by any of the patients who received double cerclage. The absolute risk reduction in using double cerclage over traditional method was 18% (95% confidence interval, 4%-32%) (23). Further randomized control studies on the subject are needed.

The cervical (Arabin™) pessary

Randomised control trials have yielded conflicting reports on the efficacy of the cervical pessary. In the Pesario Cervical para Evitar Prematuridad (PECEP) trial, an open label randomized control; 385 pregnant women with a short cervix were assigned to either the pessary or expectant management. Spontaneous delivery before 34 weeks of gestation was significantly less frequent in the pessary group than in the expectant management group, odds ratio 0.18, (95% CI 0.08-0.37; p<0.0001). No serious adverse effects associated with the use of a cervical pessary were reported (24). To the contrary, Ting *et al* (25) reported that the prophylactic use of cerclage pessary did not reduce the rate of preterm delivery before 34 weeks. From the woman perspective, the cervical pessary seems to be well tolerated and acceptable (26). However, this remains a subject for potentially more informative research as the use of the pessary could eliminate the surgical and anesthetic risks associated with cervical cerclage with greater patient satisfaction.

Progesterone compared to cervical cerclage and pessary

Vaginal progesterone is as effective as cerclage in prevention of preterm birth in women with a sonographic short cervix in mid-trimester and previous preterm birth. No direct study comparing these three methods (progesterone, cervical pessary and cerclage) or a combination of either is reported. In the only systematic review comparing the three protocols, Althui Sius *et al* (27) found no statistically significant differences in perinatal losses, neonatal morbidity and preterm births between the three groups, apart from a higher rate of preterm births before 34 weeks' gestation with vaginal progesterone versus cervical pessary (32% vs. 12%; relative risk 2.70, 95% CI 1.10 to 6.67).

Role of rescue stitch/emergency cerclage

The most challenging aspect of cervical incompetence is when a woman with no known risk factors for preterm birth presents with prolapsed membranes at or beyond

the external cervical os. The dilemma is whether or not to insert an emergency /rescue cerclage. This stitch is often recommended in women with an incidental finding of premature cervical dilation and fetal membranes in the vagina, usually during an ultrasound or vaginal examination performed for other purposes. This raises the debate on whether, it is necessary in the first instance, bearing in mind that incidental bulging of membranes beyond the external os alone, is not predictive of preterm birth (12,15). The current practice on rescue cerclage is informed by retrospective cohort studies with only one Randomised Control Trial (RCT) on the subject. The RCT compared the pregnancy outcomes between women treated with emergency cerclage, bed rest, antibiotics and indomethacin and those with bed rest and antibiotics alone. In this study, rescue cerclage prolonged pregnancy by 54 days (95% CI 26-82), which was significantly longer compared to bed rest and antibiotics group 20 days (95% CI 0-41; [p=0.046]). The compound neonatal morbidity was also significantly lower in the cerclage group (RR 1.6 95% CI 1.1-2.3;[p=0.02]) (28). A similar effect has been demonstrated by other prospective non-randomized studies (29-33). Whether cervical cerclage is beneficial at 4cm and beyond is still not clear. However, it is certain from available literature that rescue cerclage is safe and has a role in the prevention of preterm birth. One inherent weakness of the studies that addressed this subject is that considering the rarity of the condition, they were not well powered no detect significant differences in outcomes. Furthermore, there is heterogeneity in the methods used to arrive at the final diagnosis and differences in techniques used at surgery. In most of these studies, indomethacin and prophylactic antibiotics were administered for tocolysis and infection prevention respectively and it is therefore difficult to ascertain whether these agents had a synergistic effect in the prevention of preterm birth (15, 28-33).

Adjuvant management post insertion

Consensus lack on various adjuvant management approaches following insertion of cerclage. These include; bed rest, sexual intercourse, supplemental progesterone, post cerclage sonographic cervical surveillance (3). The indications for removal of cervical cerclage are shown in Table 2.

Table 2: Indications for removal

PPROM
Evidence of infection
Preterm labour
36 weeks gestation
Chorioamnionitis
Antepartum haemorrhage

Conclusion

Despite many uncertainties concerning cervical cerclage, the procedure is still an effective and safe technique for the prevention of preterm birth to those women at risk. The

available evidence is limited and many decisions should therefore be individualized and left to the clinician's discretion. However, national guidelines and consensus statements by the local professional bodies could be useful to in guiding the less experienced clinicians.

References

1. Lawn, J.E., Cousens, S. and Zupan, J. Neonatal Survival Steering Team. 4 million neonatal deaths: when? Where? Why? *Lancet*. 2005; **365** (9462):891-890.
2. Alfirevic, Z., Stampalija, T., Roberts, D. and Jorgensen, A.L. *Cochrane Database Syst Rev*. 2012 Apr 18;4:CD008991. doi: 10.1002/Cervical stitch (cerclage) for preventing preterm birth in singleton pregnancy. 14651858.CD008991.pub2.
3. Royal College of Obstetricians and Gynaecologists. Cervical cerclage green top No. 60. May 2012. London (UK).
4. Shirodkar, V.N. A new method of operative treatment for habitual abortion in the second trimester of pregnancy. *Antiseptic*. 1955; **52**:299-300.
5. McDonald, I.A. Suture of the cervix for inevitable miscarriage. *J. Obstet. Gynaecol. Br Emp*. 1957; **64**:346-350.
6. Zaveri, V., Aghajafari, F., Amankwah, K. and Hannah, M. Abdominal versus vaginal cerclage after a failed transvaginal cerclage: a systematic review. *Am. J. Obstet. Gynecol.* 2002; **187**: 868-872.
7. Davis, G., Berghella, V., Talucci, M. and Wapner, R.J. Patients with a prior failed transvaginal cerclage: a comparison of obstetric outcomes with either transabdominal or transvaginal cerclage. *Am. J. Obstet. Gynecol.* 2000; **183**: 836-839.
8. Carter, J.F., Soper, D.E., Goetzl, L.M. and Van Dorsten, J.P. Abdominal cerclage for the treatment of recurrent cervical insufficiency: laparoscopy or laparotomy? *Am. J. Obstet. Gynecol.* 2009; **201**:111.e1-4.
9. Drassinower, D., Poggi, S.H., Landy, H.J., Gilo, N., Benson, J.E. and Ghidini, A. perioperative complications of history-indicated and ultrasound-indicated cervical cerclage. *Am. J. Obstet. Gynecol.* 2011; **205**(1):53.e1-5.
10. Foster, T.L., Moore, E.S. and Sumners, J.E. Operative complications and fetal morbidity encountered in 300 prophylactic transabdominal cervical cerclage procedures by one obstetric surgeon. *J. Obstet. Gynaecol.* 2011; **31**(8):713-717.
11. Simcox, R., Seed, P.T., Bennett, P., Teoh, T.G., Poston, L. and Shennan, A.H. A randomized controlled trial of cervical scanning vs history to determine cerclage in women at high risk of preterm birth (CIRCLE trial). *Am. J. Obstet. Gynecol.* 2009; **200**(6):623.e1-6.
12. Berghella, V. and Mackeen, A.D. Cervical length screening with ultrasound-indicated cerclage compared with history-indicated cerclage for prevention of preterm birth: a meta-analysis. *Obstet. Gynecol.* 2011; **118**(1):148-155.

13. Lazar, P., Gueguen, S., Dreyfus, J., Renaud, R., Pontonnier, G. and Papiernik, E. Multicentred controlled trial of cervical cerclage in women at moderate risk of preterm delivery. *Br. J. Obstet. Gynaecol.* 1984; **91**: 731–735.
14. Rush, R.W., Isaacs, S., McPherson, K., Jones, L., Chalmers, I. and Grant, A. A randomized controlled trial of cervical cerclage in women at high risk of spontaneous preterm delivery. *Br. J. Obstet. Gynaecol.* 1984; **91**:724–730.
15. Final report of the Medical Research Council/Royal College of Obstetricians and Gynaecologists multicentre randomised trial of cervical cerclage. MRC/RCOG Working Party on Cervical Cerclage. *Br. J. Obstet. Gynaecol.* 1993; **100**: 516–523.
16. Berghella, V., Szychowski, J.M., Owen, J., Hankins, G., Iams, J.D. *et al.* Vaginal Ultrasound Trial Consortium Suture type and ultrasound-indicated cerclage efficacy. *J. Matern. Fetal Neonatal Med.* 2012; **25**(11):2287-2290.
17. Bernard, L., Pereira, L., Berghella, V., Rust, O., Mittal, S. *et al.* Effect of suture material on outcome of cerclage in women with a dilated cervix in the 2nd trimester: results from the expectant management compared to physical exam-indicated cerclage (EM-PEC) international cohort study. *Am. J. Obstet. Gynecol.* 2006; **195**(6):103S.
18. Abdelhak, Y.E., Sheen, J.J., Kuczynski, E. and Bianco, A. Comparison of delayed absorbable suture v nonabsorbable suture for treatment of incompetent cervix. *J. Perinat. Med.* 1999; **27**: 250–252.
19. Park, J.M., Tuuli, M.G., Wong, M., Carbone, J.F., Ismail, M., Macones, G.A. and Odibo, A.O. Cervical cerclage: one stitch or two? *Am. J. Perinatol.* 2012; **29**(6):477-481.
20. Giraldo-Isaza, M.A., Fried, G.P., Hegarty, S.E., Suescum-Diaz, M.A., Cohen, A.W. and Berghella, V. Comparison of 2 stitches vs 1 stitch for transvaginal cervical cerclage for preterm birth prevention. *Am. J. Obstet. Gynecol.* 2012; **28**(12)2178-2183.
21. Woensdregt, K., Norwitz, E.R., Cackovic, M., Paidas, M.J. and Illuzzi, J.L. Effect of 2 stitches vs 1 stitch on the prevention of preterm birth in women with singleton pregnancies who undergo cervical cerclage. *Am. J. Obstet. Gynecol.* 2008; **198**(4):396.e1-7.
22. Broumand, F., Bahadori, F., Behrouzilak, T., Yekta, Z. and Ashrafi, F. Viable extreme preterm birth and some neonatal outcomes in double cerclage versus traditional cerclage: a randomized clinical trial. *Scientific World J.* 2011; **11**: 1660-666.
23. Goya, M., Pratcorona, L., Merced, C., Rodó, C., Valle, L. *et al.* Pesario Cervical para Evitar Prematuridad (PECEP) Trial Group. Cervical pessary in pregnant women with a short cervix (PECEP): an open-label randomised controlled trial. *Lancet.* 2012; **379**(9828):1800-1806.
24. Hui, S.Y., Chor, C.M., Lau, T.K., Lao, T.T. and Leung, T.Y. Cerclage pessary for preventing preterm birth in women with a singleton pregnancy and a short cervix at 20 to 24 weeks: A randomized controlled Trial. *Am. J. Perinatol.* 2012 Aug 8. [Epub ahead of print].
25. Ting, Y.H., Lao, T.T., Wa Law, L., Hui, S.Y., Chor, C.M. *et al.* Arabin cerclage pessary in the management of cervical insufficiency. *J. Matern. Fetal Neonatal Med.* 2012; **25**(12):2693-2695.
26. Alfirevic, Z., Owen, J., Carreras Moratonas, E., Sharp, A.N., Szychowski, J.M. and Goya, M. Vaginal progesterone, cerclage or cervical pessary for preventing preterm birth in asymptomatic singleton pregnant women with history of preterm birth and a sonographic short cervix. *Ultrasound Obstet. Gynecol.* 2012 Sep 18. doi: 10.1002/uog.12300. [Epub ahead of print]
27. Althuisius, S.M., Dekker, G.A., Hummel, P. and va Geijn, H.P. Cervical incompetence prevention randomized cerclage trial: emergency cerclage with bed rest versus bed rest alone; cervical incompetence prevention randomized cerclage trial. *Am. J. Obstet. Gynecol.* 2003; **189**(4):907-910.
28. Daskalakis, G., Papantoniou, N., Mesogitis, S. and Antsaklis, A. Management of cervical insufficiency and bulging fetal membranes. *Obstet. Gynecol.* 2006; **107** (2 Pt 1):221-226.
29. Schorr, S.J. and Morales, W.J. Obstetric management of incompetent cervix and bulging fetal membranes. *J. Reprod. Med.* 1996; **41**: 235–238.
30. Stupin, J.H., David, M., Siedentopf, J.P. and Dudenhausen, J.W. Emergency cerclage versus bed rest for amniotic sac prolapse before 27 gestational weeks. A retrospective, comparative study of 161 women. *Eur. J. Obstet. Gynecol. Reprod. Biol.* 2008; **139**(1):32-37.
31. Ventolini, G., Genrich, T.J., Roth, J. and Neiger, R. Pregnancy outcome after placement of ‘rescue’ Shirodkar cerclage. *J. Perinatol.* 2009; **29**(4):276-279.
32. Novy, M.J., Gupta, A., Wothe, D.D., Gupta, S., Kennedy, K.A. and Gravett, MG. Cervical cerclage in the second trimester of pregnancy: a historical cohort study. *Am. J. Obstet. Gynecol.* 2001; **184**(7):1447-1454.
33. Deb, P., Aftab, N. and Muzaffar, S. Prediction of outcomes for emergency cervical cerclage in the presence of protruding membranes. *ISRN Obstet. Gynecol.* **2012**; 2012: 842841.