Summary

Changes in contemporary obstetric and gynaecological practice in relation to ultrasound cervical screening during pregnancy, the treatment of intra-epithelial cervical neoplasia and laparoscopic surgery have resulted in an increased utilization of trans-abdominal cervico-isthmic cerclage in an attempt to reduce the incidence of mid-trimester and early preterm birth in women with repeated pregnancy loss.

Introduction

In the last decade there has been a perceptible revisiting of the use of trans-abdominal cervical cerclage (TAC) as a strategy to reduce mid-trimester miscarriage and preterm birth as a result of presumed cervical incompetence.

Trans-abdominal placement of a cervical suture at the cervico-isthmic junction was first described by Benson and Durfee in 1965 [1].

The potential advantages are a more proximal placement of the suture, a decreased risk of suture migration, absence of a foreign body in the vagina which might increase the risk of ascending infection and the opportunity to leave the suture in place for future pregnancies.

Of the 1-2% of pregnant women with presumed cervical incompetence it has been estimated that approximately 13% of these women may not be able to have the suture placed vaginally and hence the requirement for a trans-abdominal approach [2].

Discussion

Traditionally TAC, with its greater chance of maternal morbidity due to the requirement for a laparotomy to perform the cerclage and the need for a caesarean section to deliver the neonate, has been reserved for those women with

1. An abnormal/scarred cervix where vaginal placement of a cervical cerclage was not possible.
2. A shortened (<2.5 cm) or amputated cervix.
3. Two or more previous vaginally placed cervical sutures which failed to prevent pregnancy loss.

What has changed in our obstetric and gynecological practice in the last decade which may have accounted for this resurgence of TAC utilization?
There would appear to be three main influences in contemporary practice which may have accounted for this change.

1. Ultrasound surveillance of the cervix and the increased utilization of emergent cervical cerclage particularly in women deemed high risk for cervical incompetence.

2. Pre-pregnancy conservative surgical procedures to deal with cervical intra-epithelial neoplasia.

3. Refinement of TAC using a laparoscopic approach with the potential of reduced maternal morbidity and equivalent perinatal outcome.

**Ultrasound surveillance of the cervix**

A recent review of the contemporary use of cerclage suggested that history-indicated cerclage should not be recommended in women with only 1 or 2 prior preterm births or second trimester losses and that they should be monitored with serial ultrasound measurements of cervical length to determine which women might benefit from cerclage [3].

A prospective randomized controlled trial of cervical scanning vs history to determine cerclage in women at high risk of preterm birth (CIRCLE) was carried out by Simcox et al. [4].

This study found that for women fulfilling these criteria ultrasound surveillance of cervical length increased the likelihood of suture insertion, hospital admission, progesterone supplementation and other interventions without increasing the gestational age at delivery (RR 0.97, 95%CI 0.54–1.76).

An earlier study by Incerti et al. [5], demonstrated that cerclage placement did not decrease the rate of preterm delivery at < 35 weeks or prolong gestation in low risk women with cervical length < 2.5 cm in the early second trimester (OR 0.01, 95% CI -2.01–2.00).

However a more recent meta-analysis by Bergella et al. [6], demonstrated that in women with previous spontaneous preterm birth, singleton gestation and cervical length less than 25 mm, cerclage significantly prevents preterm birth (RR 0.70, 95%CI 0.55–0.89) and composite perinatal mortality and morbidity (RR 0.64, 95%CI 0.45–0.91).

Despite these apparently conflicting findings in these well conducted trials along with the presence of subgroups suggesting benefit from intervention, the sheer desperation of these women and the desire for their obstetricians to help their patients will often lead to cerclage which in turn will may fail in a significant number (approximately 30%) which in turn may direct attention to TAC as a possible solution in a subsequent pregnancy.

The above studies excluded women with an open cervix and in a review of the available literature by Namouz et al. [7], on cerclage in women with an open cervix as opposed to a short cervix demonstrated a similar dilemma.

Emergency cerclage can be of benefit to a number of well selected patients with advanced cervical dilatation as it has been associated with a longer latency period and better neonatal outcomes compared with bed rest and conservative measures [8].

Whilst there may be two different populations of “responders” and “non-responders” to cerclage the clinical predictors to differentiate between both groups are imprecise [9] and the current speculation that many of these cases may be associated
with inflammation or infection will in turn often lead to failure of the vaginally placed emergent/emergency cerclage leading to consideration of TAC in subsequent pregnancies by the patient and her obstetrician.

TAC has been evaluated for women with failed trans-vaginal procedures in previous pregnancies.

A systematic review conducted by Zaveri et al. [10], evaluated pregnancy outcome after TAC in women whose prior pregnancy ended in mid-trimester loss or preterm delivery before 34 weeks gestation despite the placement of a trans-vaginal cervical cerclage.

TAC in this setting was associated with a lower likelihood of perinatal death or delivery before 24 weeks gestation (6% vs 12.5% with repeat trans-cervical cerclage) but a higher rate of more serious maternal morbidity such as blood transfusion or bowel injury (3% vs 0%).

Subsequent studies by Lotgering et al. [11], and Debbs et al. [12], reported similar findings.

A subsequent literature review by Debbs et al., identified 276 women who underwent TAC in 306 pregnancies. Fetal survival in pregnancies before TAC was of the order of 2.5% to 55% and after TAC was 60% - 100% respectively but these results must be interpreted in light of the retrospective nature of the study and the possibility of altered clinical status of the women before and after TAC.

Pre-pregnancy conservative surgical treatment of cervical intra-epithelial neoplasia

Early detection and treatment of pre-invasive cervical intra-epithelial neoplasia (CIN) generally occurs in women of reproductive age and this has substantially reduced the incidence and mortality from invasive cervical cancer.

However, the impact on future fertility by conservative surgical measures such as cold knife cervical conisation, large loop excision of the transformation zone (LLETZ), loop electrosurgical excision procedure (LEEP), laser conisation or ablative therapy is of concern to women of reproductive age [13].

More recent well-designed studies with larger sample size, systematic reviews and meta-analyses have demonstrated an almost three-fold increase in the risk of preterm birth and mid-trimester loss particularly with cold knife conisation, LLETZ and LEEP [14].

Interestingly Bergella et al. [15], reported that only 28% of pregnant women who had a pre-pregnancy history of having such a procedure performed had a short cervix (< 2.5 cm) on ultrasound at 16–24 weeks gestation which has led to conjecture as to the possible mechanisms of pregnancy loss in such women.

Decreased mechanical support or increased susceptibility to infection after loss of cervical mucous plug may contribute to pregnancy loss.

Increasing mechanical support of the pregnancy by prophylactic cerclage (elective) including emergent (ultrasound indicated) and emergency (definitive cervical dilatation) did not appear to prevent pregnancy loss.

Kyrgiou et al. [16], suggested that the increased risk of adverse pregnancy outcomes may not be attributed solely to the treatment itself but to common risk factors that also predispose to precancerous cervical conditions ie. HPV infection which is in tune with recent evidence which suggests that a cervical inflammatory milieu in early or mid-trimester pregnancy is associated with preterm birth.
Hence for prevention of preterm birth in this situation the efficacy of progesterone after cervical conisation requires to be evaluated and equally TAC, which may bypass the vaginal milieu, could also be considered.

In the long term, HPV vaccination programs have the potential of a significant reduction in CIN [17], which in turn will reduce the requirement for conservative surgical treatment procedures which should reduce pregnancy loss associated with these procedures irrespective of the purported mechanism.

**Laparoscopic trans-abdominal cervical cerclage**

Advances in minimally invasive surgery have inevitably led to the development of laparoscopic cervical cerclage.

As with other forms of laparoscopic surgery it offers the potential of reduced blood loss, reduced post-operative pain, possibly fewer adhesions as well as a decreased length of hospital stay and shorter post-operative recovery time compared with open trans-abdominal cerclage.

In line with the open operation, laparoscopic cerclage can be performed pre-pregnancy (interval procedure) or during pregnancy (ideally at 11–14 weeks gestation).

Guidance from the National Institute for Health and Clinical Excellence (NICE) in 2007 [18], drew attention to the variation in techniques between centres and the limited evidence of the safety and the efficacy of laparoscopic cerclage and that it should only be carried out as part of a clinical trial with special arrangements for consent and audit.

A nominated Specialist Committee also expressed their uncertainty about the efficacy of all cervical cerclage techniques used in the management of recurrent pregnancy loss due to cervical incompetence.

In order to bring some clarity to laparoscopic TAC, the same NICE Specialist Committee designated certain key efficacy outcomes in their report of the Interventional Procedures Program overview in 2018. [19].

The following outcomes were highlighted:

**Conception rate:** In a systematic review of 41 studies of laparoscopic or open abdominal cerclage done before (interval) or during pregnancy [20], found that conception rates in the interval group was 78% for those having a laparoscopic cerclage (n=511) and 74% for those had open abdominal cerclage (n= 160; p = 0.3567).

**Live birth rate or neonatal survival:** The same systematic review of 41 studies, neonatal survival was 89% in both the laparoscopic cerclage (n=621 pregnancies) and the open abdominal cerclage (n= 937 pregnancies) groups (p = 0.0002) [20].

Neonatal survival excluding first trimester loss was 96% (597/621) with laparoscopic cerclage and 91% (835/937) with open cerclage (p = 0.0002).

In a systematic review of 8 studies Zybek et al. [21], of robot-assisted transabdominal cerclage during pregnancy, the live birth rate was 90%.

**Second or Third Trimester loss:** In the systematic review of 41 studies the proportion that ended with a second trimester loss was 4% (23/621) in the laparoscopic cerclage group and 8% (73/937) in the open abdominal cerclage group (p = 0.001) [20].

**First Trimester loss:** In Moawad et al. [20], systematic review of 41 studies,
the proportion of pregnancies with a first trimester loss was 7% (43/621) in the laparoscopic cerclage group and 2% (15/937) in the open abdominal cerclage group (p< 0.05).

**Gestational Age at Delivery:** In the same systematic review of 41 studies [20], the proportion of pregnancies delivering at more than 34 gestational weeks was 83% (410/494) in the laparoscopic cerclage group and 76% (710/937) in the open abdominal cerclage group (p = 0.0016).

Delivery between 23 and 34 gestational weeks occurred in 7% (34/494) in the laparoscopic cerclage group and in 14% in the open abdominal cerclage group (p = 0.0001).

In the case series of 225 patients (121 pregnancies) Ades et al. 2018 [22], 80% of babies were delivered at 34 weeks or more gestation.

The mean gestational age at delivery was 35.2 weeks after laparoscopic cerclage insertion (n = 121) compared with 23.9 weeks in pregnancies before the procedure (n = 402).

Before laparoscopic cerclage 59% (235/402) of pregnancies ended with delivery at 13–24 weeks compared with 2% (2/121) of pregnancies after laparoscopic cerclage.

Eight (7%) deliveries occurred between 24 and 34 weeks because of preterm labour (PTL) or preterm premature rupture of the membranes (PPROM) and the cerclages in these patients were deemed suboptimal.

In the systematic review of 8 studies of robot assisted transabdominal cerclage during pregnancy, the median gestational age at delivery was 37 weeks (33–39 weeks) [21].

**Safety summary**

**Overall intraoperative complications:** The overall rate of intraoperative complications was 1% (8/728) for patients who had laparoscopic cerclage and 1% for patients who had open abdominal cerclage [20].

Conversion to laparotomy was reported in 1% (10/728) of patients undergoing laparoscopic cerclage, two (2) with interval procedures and 8 performed during pregnancy.

Conversion to laparotomy was reported in 2 out of 7 patients who had robot assisted transabdominal cerclage during pregnancy in a case series of 16 patients [21].

**Uterine perforation:** Uterine perforation was reported in < 1% (3/728) of the patients in the review by Moawad et al. [20].

In review by Ades et al. [22], perforation of the uterus was reported in one patient in case series of 225 laparoscopic assisted cerclage which was repaired laparoscopically.

One patient experienced uterine perforation in robot assisted transabdominal cerclage during pregnancy [20], and one case at open transabdominal cerclage conducted during pregnancy [23].

**Small bowel injury:** In Moawad et al., review of 41 studies [20], small bowel injury was reported in 1 patient who had a laparoscopic cerclage.

**Bladder perforation:** Bladder perforation was reported in the systematic review [20], in one patient who had a laparoscopic cerclage while in Ades et al., case series of 225 patients undergoing laparoscopic cerclage, one patient had a bladder injury which was repaired laparoscopically [22].
Vascular injury: Uterine vein laceration was reported in one patient who had a laparoscopic cerclage [20].

A number of unspecified vascular injuries were noted in patients undergoing abdominal cerclage by either method in the first trimester of pregnancy [20,23].

Broad ligament laceration: Broad ligament laceration was reported in 1 out of 7 patients who had robot-assisted transabdominal cerclage during pregnancy in the systematic review of 16 patients [20].

Infection: Pelvic infection was reported in two patients undergoing laparoscopic cerclage (one robotically assisted) [20], similarly one patient in Ades et al., series of 225 laparoscopic cerclage procedures [22].

Perioperative post conceptual miscarriage rate: A miscarriage rate (up to 2 weeks after the cerclage procedure) was 1% for patients undergoing laparoscopic cerclage and 3% for patients who had open abdominal cerclage [20], whilst sporadic reports confirmed a low first trimester miscarriage rate for women undergoing abdominal cerclage by either method [23].

This apparently low rate of spontaneous miscarriage has been noted by many authors but there is no feasible explanation.

Long term, anecdotal and theoretical adverse events: These include vaginal erosion of a cerclage performed laparoscopically [24], general anaesthetic or laparoscopy complications, damage to the uterine artery causing bleeding and growth restriction of the fetus if performed during the pregnancy and perhaps in future pregnancies [25-27], possible mesh-related/suture material complications, damage to the cervix if labour occurs with the suture in situ [28], need for hysterotomy after a failed first and second trimester pregnancy unable to be evacuated vaginally and chorioamnionitis [23,25].

Conclusion

Trans-abdominal cervical cerclage would appear to have a restricted role in the management of women experiencing pregnancy loss as a result of presumed cervical incompetence.

Whilst intuitively the procedure would appear to be indicated in women where anatomically the cervical suture cannot be placed vaginally the other indications for trans-abdominal cerclage viz previously damaged cervix, two or more failed vaginally placed cervical sutures are scientifically less robust [19].

Most operators would recommend that the procedure be carried out as an interval rather than as an intra-pregnancy procedure due to risk of unacceptable bleeding at the time of insertion of the cerclage [20].

Preliminary studies [18], and now later reviews [19,20], would appear to suggest that laparoscopic placement may be more advantageous to the patient in terms of reduced maternal morbidity with comparable fetal outcomes than open laparotomy placement.

Although the place of trans-abdominal cervical cerclage has yet to be confirmed scientifically by truly randomized controlled trials, the accumulated evidence, coupled with the comparable safety of women having an elective caesarean section compared to women with ‘intention to deliver vaginally’, will make this an increasingly attractive option to offer to these desperate couples experiencing repeated mid-trimester miscarriage or early perinatal loss.
References


19. NICE: Interventional Procedure Overview: Laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth 2018; 1-46.


23. Svigos JM. Personal series of 30 consecutive cases of open transabdominal cerclage (Unpublished data).


