Cervical stitch (cerclage) for preventing pregnancy loss: individual patient data meta-analysis

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CRD summary
This review concluded that cerclage may reduce the risk of pregnancy loss or neonatal death before discharge in singleton pregnancies, but that it should be avoided in multiple pregnancies. Given the limitations of the included studies and the lack of a complete data set, the authors' conclusions may be overly strong and should be treated with some caution.

Authors' objectives
To evaluate the effect of cerclage in women with confirmed or suspected cervical insufficiency on neonatal and maternal outcomes.

Searching
The search strategy used in a previous Cochrane review (see Other Publications of Related Interest) was repeated, which included searching the Cochrane Pregnancy and Childbirth Group's Specialised Register, handsearching congress proceedings of the International and European Society meetings of feto-maternal medicine, recurrent miscarriage and reproductive medicine and contacting researchers in the field; update searches were conducted up to December 2005.

Study selection
Randomised controlled trials (RCTs) comparing cervical cerclage with expectant management or no cerclage in pregnant women with confirmed or suspected cervical insufficiency were eligible for inclusion. The primary outcomes were pregnancy loss or neonatal death before discharge from hospital and absence of neonatal morbidity. Secondary outcomes were preterm delivery and maternal morbidity. Where reported, previous cerclage occurred in 0 to 21 per cent of women, previous cervical surgery in 0 to 30 per cent. The mean age ranged from 25 to 35 years. The indication for cerclage were short cervix on ultrasound or obstetric history. The cerclage methods used included McDonald type, Shirodkar suture and multiple types of suture. Two reviewers independently applied the inclusion criteria; differences were resolved by discussion.

Assessment of study quality
Studies were assessed in terms of randomisation, allocation concealment and loss to follow-up. Individual patient data were cross-checked against published reports.

Data extraction
Individual patient data were obtained for each trial. The incidence of pregnancy loss or death before discharge from hospital, a healthy baby at discharge, spontaneous labour, pyrexia, chorioamnionitis, preterm pre-labour rupture of membranes (PPROM) and the need for induction or caesarean section were used to calculate the odds ratios (OR) and 95% confidence intervals (CI) for each study.

Methods of synthesis
Pooled OR and 95% CI were calculated using the Peto method. Women were categorised into one of five categories dependent upon their history of preterm deliveries, miscarriage and cervical surgery. Statistical heterogeneity was assessed using the $\chi^2$ and $I^2$ tests. The impact of the women's obstetric history was investigated using two level logistic regression models stratified by trial. Multiple births were excluded from the main analyses as the risks and outcomes from these births were not considered comparable to single births.

Results of the review
Nine trials met the inclusion criteria. Individual patient data was available for seven trials and these were included in the analysis (n=2,091; range 35 to 1,264). Six trials used adequate randomisation procedures, but none were blinded. For singleton pregnancies, cerclage significantly increased the incidence of maternal pyrexia (OR 2.35, 95% CI: 1.37 to 4.05; p=0.002; three trials), but did not significantly alter the rate of pregnancy loss or death before discharge (OR 0.81,
95% CI: 0.60 to 1.10; seven trials), healthy babies at discharge (all babies four trials; live babies only four trials), spontaneous labour (four trials), chorioamnionitis (two trials), PPROM (five trials) or the need for induced labour or caesarean section (two trials). The analyses of chorioamnionitis and PPROM exhibited statistically significant heterogeneity. For multiple gestations cerclage significantly increased the incidence of pregnancy loss or death before discharge (OR 5.88, 95% CI: 1.14 to 30.19, p=0.03) and significantly decreased the number of healthy babies at discharge (all babies OR 0.12, 95% CI: 0.02 to 0.89, p=0.04; live babies only OR 0.54, 95% CI: 0.07 to 0.48; the test for interaction was not significant p=0.56). There was no significant effect of cerclage on maternal morbidity. There was no relationship between cerclage and the timing of preterm births.

**Authors’ conclusions**
Cerclage may reduce the risk of pregnancy loss or neonatal death before discharge in singleton pregnancies, but should be avoided in multiple pregnancies.

**CRD commentary**
The authors addressed a clear research question. They searched a number of relevant sources, however, the complete individual patient data set for trials that met the inclusion criteria could not be obtained. Two reviewers applied the inclusion criteria. It was unclear whether similar precautions against error during data extraction were used, although this was checked against reports. Validity was assessed using appropriate criteria and details reported for each study. Most of the studies were small and the number of events infrequent, therefore, many may not have been adequately powered. There was no evidence to support the use of cerclage in women with singleton pregnancies in terms of pregnancy loss or neonatal death; the authors conclusions may be overly strong in this respect. Given this and the missing data, the conclusions should be treated with some caution.

**Implications of the review for practice and research**
Practice: The authors stated that women with singleton pregnancies should be advised of the increased risk of maternal pyrexia and treated accordingly. Cerclage should be avoided in multiple pregnancies.

Research: The authors stated that further large trials were needed to investigate the risk-benefit ratio in singleton pregnancies with precision and attempt to identify groups most likely to benefit.

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