Effectiveness of cervical cerclage for a sonographically shortened cervix: a systematic review and meta-analysis

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CRD summary
This review assessed the effectiveness of cervical cerclage for a sonographically shortened cervix. The authors concluded that there is insufficient evidence to support the use of cervical cerclage. The authors' conclusions are appropriate based on the evidence presented.

Authors' objectives
To determine the effectiveness of cervical cerclage for a sonographically shortened cervix on prolongation of pregnancy, perinatal outcome and maternal side-effects.

Searching
PREMEDLINE and MEDLINE (1966 to 2002), EMBASE (1980 to 2002) and the Cochrane Library were searched; the search terms were reported. The reference lists of included studies and review articles were also checked. No attempt was made to identify unpublished studies.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) and non-randomised comparative studies were eligible for inclusion. Case series were excluded.

Specific interventions included in the review
Studies that compared cerclage with no cerclage were eligible for inclusion. The majority of the included studies used McDonald cerclage, while one used Shirodkar cerclage. Some of the studies also used tocolytics and antibiotics. Further details were given in the report.

Participants included in the review
Studies of women who had a documented short cervix (less than or equal to 2.5 cm), dilation of the internal os (less than 2 cm), or funnelling (more than 25% but not beyond the external os) on transvaginal ultrasound, were eligible for inclusion. The participants in the included studies were those at high-risk of pre-term delivery, unselected antenatal patients, or only women with twin pregnancies.

Outcomes assessed in the review
The primary outcomes included in the review were pre-term delivery (less than 34 weeks) and neonatal death. The secondary outcomes were pre-term delivery (less than 37 weeks' gestation, less than 32 weeks' gestation, less than 28 weeks' gestation), neonatal morbidity, pre-term labour, birth weight, gestational age at delivery, and time from the intervention or initial assessment to delivery. Adverse maternal outcomes were also assessed: placental abruption, chorioamnionitis and pre-term premature rupture of the membrane.

How were decisions on the relevance of primary studies made?
Two reviewers independently selected studies for inclusion. Any disagreements were resolved by discussion with a third reviewer.

Assessment of study quality
The authors appear to have assessed aspects of study quality such as methods of randomisation and allocation concealment and blinding of the outcome assessors (for RCTs), completeness of follow-up and baseline characteristics.
The authors did not state how the papers were assessed for quality, or how many reviewers performed the quality assessment.

**Data extraction**
Two reviewers independently extracted the data from the included studies. Data on the occurrence of each outcome was extracted from the individual studies and used to calculate a relative risk (RR).

**Methods of synthesis**
How were the studies combined?
The results from the individual studies were combined using a random-effects meta-analysis (DerSimonian and Laird). A pooled RR with 95% confidence intervals (CIs) was calculated for each dichotomous outcome of interest. A pooled weighted mean difference (WMD) with 95% CIs was calculated for continuous outcomes.

How were differences between studies investigated?
Statistical heterogeneity was assessed using the chi-squared test. Subgroup analyses were planned on studies that were randomised, women with twin versus singleton pregnancies, cervical length (less than or equal to 1.5 cm versus less than or equal to 2.5 cm), and women having a cerclage on the basis of ultrasound findings alone versus ultrasound and other clinical risk factors. Potential reasons for differences in the results of the RCTs were discussed narratively.

**Results of the review**
Six studies (n=359) were included in the review: two RCTs (n=149), three prospective observational studies (n=140) and one retrospective cohort study (n=70).

Both RCTs used adequate methods of randomisation and treatment concealment. Neither reported blinding and both reported losses to follow-up. In some studies there were some baseline differences between the treatment groups.

Primary and secondary outcomes. No statistically significant difference was found between cerclage and no cerclage in the risk of delivery at less than 28 weeks' gestation (RR 1.06, 95% CI: 0.58, 1.95, P=0.9), at less than 32 weeks' gestation (RR 0.38, 95% CI: 0.02, 8.72, P=0.5), at less than 34 weeks' gestation (RR 0.95, 95% CI: 0.57, 1.59, P=0.9), or at less than 37 weeks' gestation (RR 1.14, 95% CI: 0.84, 1.54, P=0.4).

No statistically significant difference was found between cerclage and no cerclage in the risk of neonatal mortality (RR 0.66, 95% CI: 0.20, 2.17, P=0.5), pre-term labour (RR 0.46, 95% CI: 0.13, 1.65, P=0.2), or neonatal morbidity (RR 0.41, 95% CI: 0.04, 4.58, P=0.5).

Cerclage was associated with a significant increase in birth weight when compared with no cerclage (WMD 0.74 kg, 95% CI: 0.23, 1.25, P=0.004). No significant difference was found between cerclage and no cerclage in gestational age of delivery (WMD 0.81 weeks, 95% CI: -1.62, 3.24, P=0.5), or time to delivery (WMD 1.85 weeks, 95% CI: -0.66, 4.36, P=0.15).

Statistical heterogeneity was found in the analyses of delivery less than 32 weeks' gestation (P=0.002), pre-term labour (P=0.02), neonatal morbidity (P=0.02) and gestational age at delivery (P=0.02).

Adverse maternal outcomes.
No statistically significant difference was found between cerclage and no cerclage in the risk of pre-term premature rupture of the membranes (RR 1.23, 95% CI: 0.67, 2.27, P=0.5), chorioamnionitis (RR 1.93, 95% CI: 0.77, 4.87, P=0.16), or placental abruption (RR 0.79, 95% CI: 0.29, 2.13, P=0.6).

Subgroup analyses.
The analysis of RCTs only or singleton pregnancies did not change the results obtained. However, there was evidence of statistical heterogeneity between the RCTs for delivery at less than 34 weeks' gestation (P=0.03), neonatal morbidity
(P=0.02) and gestational age at delivery (P=0.01).

Insufficient data were available to perform an analysis of cervical length or women having a cerclage on the basis of ultrasound findings alone.

**Authors' conclusions**
There was insufficient evidence to recommend cerclage for a sonographically detected short cervix.

**CRD commentary**
The review addressed a clear research question and used inclusion criteria that appeared appropriate. Several sources were searched for published studies only, therefore publication bias was possible. No details were given of the languages eligible for inclusion, thus the potential for language bias could not be assessed. Methods were used to minimise bias and error in the study selection and data extraction processes. It was unclear whether the authors systematically assessed the validity of the included studies as aspects of study quality appear to have been selectively reported.

The details presented on each included study were adequate, but suggested clinical and methodological differences across the included studies. Therefore, the decision to statistically combine the studies was inappropriate. The authors considered the RCTs in a subgroup analysis but evidence of statistical heterogeneity was found; this highlights that a meta-analysis was not appropriate. The authors considered some of the limitations of the included studies. Their subsequent conclusions and recommendations for future research are appropriate based on the evidence presented.

**Implications of the review for practice and research**
Practice: The authors stated that cerclage could not be recommended for the treatment of short cervix on the basis of transvaginal ultrasound scanning.

Research: The authors stated that a large, well-conducted RCT was needed to determine the most appropriate use of cerclage for a shortened cervix detected by transvaginal ultrasound. The primary outcome evaluated should be perinatal or neonatal mortality, or serious neonatal morbidity.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.