Prevention of preterm birth by cervical cerclage compared with expectant management: a systematic review
Odibo A O, Elkousy M, Ural S H, Macones G A

CRD summary
The review compared cervical cerclage with expectant management for the prevention of pre-term delivery (PTD). The authors concluded that there was a trend towards prevention of PTD associated with cervical cerclage, although an increased risk of postpartum fever was found. The authors' suitably cautious conclusion and recommendations for future research appear appropriate based on the evidence presented.

Authors' objectives
To evaluate cervical cerclage in comparison with expectant management for the prevention of pre-term delivery (PTD).

Searching
MEDLINE, the Science Citation Index, and the Cochrane Controlled Trials Register were searched from 1966 to 2002 for published studies; the search terms were reported.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Studies of cervical cerclage compared with expectant management were eligible for inclusion. The type of cerclage in the included studies was McDonalds with silk, nylon, monofilament nylon, polyester or single monofilament suture, or McDonald in 74% and Shirodkar in 26%.

Participants included in the review
Specific inclusion criteria for the participants were not given in the report. It appears that studies of pregnant women at risk of PTD were eligible for inclusion. The mean gestational age at entry ranged from 9 to 29 weeks.

Outcomes assessed in the review
The primary outcomes of interest were delivery at less than 34 weeks, birth weight less than 2,500 g, and neonatal mortality and morbidity (as defined by the trialist). The secondary outcomes of interest were maternal infectious complications, the incidence of pre-term rupture of the membrane, the mode of delivery, use of tocolytics, antepartum haemorrhage and postpartum fever.

How were decisions on the relevance of primary studies made?
Two reviewers independently selected the articles for inclusion. A third reviewer was consulted if there was a discrepancy.

Assessment of study quality
The authors assigned a quality score to each included study (1 being the lowest and 5 the highest) using the Jadad instrument to assess randomisation, blinding and withdrawals. The authors did not state how the papers were assessed for quality, or how many reviewers performed the quality assessment.

Data extraction
One author abstracted the data using a standard data collection instrument. Data were extracted on the occurrence of
each outcome of interest from the individual studies, and were used to calculate an odds ratio (OR) and 95% confidence interval (CI).

Methods of synthesis
How were the studies combined?
The studies were combined in a meta-analysis. A pooled OR and 95% CI were calculated using a random-effects model (DerSimonian and Laird model) and a fixed-effect model (Mantel-Haenszel) for each outcome of interest. Where statistical heterogeneity was found, only the random-effects model was reported.

How were differences between studies investigated?
Heterogeneity was assessed statistically using the Q statistic with a significance threshold of P less than 0.1. Differences in the characteristics of the included studies were discussed in a narrative.

Results of the review
Six RCTs (n=2,190) were included in the review.

In terms of methodological quality, 1 study scored two points, 4 studies scored three and 1 study scored four.

PTD was significantly less common in women undergoing cerclage than in the expectant management group (OR 0.77, 95% CI: 0.59, 0.99, P=0.049), based on 2,190 women in 6 RCTs. There was no evidence of statistical heterogeneity (P=0.14).

No statistically significant difference was found between cerclage and expectant management for the occurrence of perinatal death (OR 0.86, 95% CI: 0.56, 1.33, P=0.5), based on 2,190 patients in 6 RCTs. There was no evidence of statistical heterogeneity (P=0.5).

No statistically significant difference was found between cerclage and expectant management for the occurrence of neonatal morbidity (OR 0.23, 95% CI: 0.02, 2.3), based on 342 patients in 3 RCTs. There was evidence of statistical heterogeneity (P=0.01).

The use of oral tocolytics was significantly higher in women undergoing cerclage than in the expectant management group (OR 1.6, 95% CI: 1.3, 1.9, P=0.001), based on 1,992 patients in 3 RCTs. There was no evidence of statistical heterogeneity (P=0.2).

No significant difference was found between cerclage and expectant management in the use of Caesarean delivery (OR 1.2, 95% CI: 0.95, 1.6, P=0.13), based on 2,042 patients in 4 RCTs.

Maternal postpartum fever was significantly more common in women undergoing cerclage than in the expectant management group (OR 2.5, 95% CI: 1.3, 4.8, P=0.004), based on 1,025 patients in 2 RCTs. There was no evidence of statistical heterogeneity (P=0.53).

No statistically significant difference was found between cerclage and expectant management for delivery before 34 weeks' gestation for women with a cervical length of less than 25 mm (OR 0.23, 95% CI: 0.01, 6.7, P=0.39), based on 148 patients in 2 RCTs. There was evidence of statistical heterogeneity (P=0.03).

No statistically significant difference was found between cerclage and expectant management for the prevention of PTD in women with a history of one or more second trimester miscarriage or pre-term births (OR 0.77, 95% CI: 0.54, 1.08, P-value not given), based on 1,051 patients in 2 RCTs. There was no evidence of statistical heterogeneity (P=0.24).

No statistically significant difference was found between cerclage and expectant management for the prevention of PTD (less than 33 weeks) in women expecting twins (OR 0.72, 95% CI: 0.24, 2.14, P-value not given), based on 78 patients in 2 RCTs. There was no evidence of statistical heterogeneity (P=0.17).
Authors’ conclusions
The results showed a trend towards cerclage preventing pre-term births before 34 weeks. However, the use of cerclage is associated with an increased risk of postpartum fever. Further trials are required to determine the role of cerclage.

CRD commentary
The review question was clear in terms of the interventions, outcome and study design. Information about the eligibility criteria for the participants was limited, which might have contributed to variation in the included studies. Several relevant databases were searched to identify relevant trials. Unpublished studies were not sought explicitly, thus the possibility of publication bias cannot be ruled out. Furthermore, it was unclear whether any language restrictions were applied. Therefore, the potential for language and publication bias cannot be assessed. The authors used methods to minimise bias when selecting the studies for inclusion. However, methods were not used to reduce reviewer error in the abstraction of data from each included study. The quality of each included study was assessed systematically.

Adequate details of the individual studies were given in the report; these suggest that the decision to statistically combine the results might not have been appropriate for all of the outcomes, owing to the apparent clinical heterogeneity. The authors’ suitably cautious conclusions and recommendations for future research have been based on the evidence presented.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that further trials are required to determine the role of cervical cerclage in the prevention of pre-term birth. Future trials need to be designed to allow an assessment of the subgroups of patients who benefit from cerclage, the most effective technique, and the effect on perinatal mortality.

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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.