Do mechanical methods of cervical ripening increase infectious morbidity? A systematic review
Heinemann J, Gillen G, Sanchez-Ramos L, Kaunitz AM

CRD summary
The authors concluded that mechanical agents for cervical ripening were associated with significantly increased maternal and neonatal infections compared with pharmacological agents alone. Despite the inability to fully interpret trial quality, the authors' conclusion reflects the evidence presented and appears to be reliable.

Authors' objectives
To evaluate the safety and efficacy of mechanical methods of cervical ripening in pregnancy.

Searching
Current Contents, MEDLINE, EMBASE, and the Cochrane Library were searched for published or unpublished articles, in any language, from 1966 to 2005. Search terms were reported. Reference lists from reviews, included studies, and textbook chapters were screened to locate additional articles.

Study selection
Randomised controlled trials (RCTs) that compared the transcervical Foley catheter (with or without extra-amniotic saline solution), Laminaria hydrophilic inserts, or hygroscopic dilators with non-mechanical methods or placebo for cervical ripening or induction were eligible for inclusion in the review.

The primary eligible outcome was infectious morbidity. Specific infectious outcomes (chorioamnionitis, endomyometritis, maternal and neonatal infection) were also reported.

Approximately half of the included trials were carried out in the USA. The treatment groups in half of the included trials used the Foley catheter alone, or in conjunction with extra-amniotic saline solution and/or prostaglandin E. Some of these studies used concurrent treatment with oxytocin or other secondary modality. The control groups used prostaglandin E in most trials. A variety of inclusion criteria (including Bishop's score, gestational age, and cervical dilation measurement) for trial participants indicated clinical heterogeneity amongst the trials.

At least two reviewers selected studies for inclusion. Disagreements were resolved by consensus.

Assessment of study quality
Trial quality was assessed and a mean quality score was calculated. The authors did not report any details of the criteria, or interpretation of scoring.

It appeared that two independent reviewers carried out the quality assessment, and disagreements were resolved by consensus.

Data extraction
Data were extracted to enable the calculation of odds ratios (OR) and 95% confidence intervals (CI).

Two independent reviewers extracted the data; disagreements were resolved by consensus.

Methods of synthesis
Odds ratios and 95% confidence intervals were pooled in a fixed-effect (Mantel-Haenszel) or random-effects (DerSimonian and Laird) meta-analysis. The latter was used in the presence of statistical heterogeneity, which was assessed using the Breslow-Day method and L’Abbe plots.
Sensitivity analyses were performed to assess the magnitude of effect change by excluding one trial at a time from the analysis. A meta-regression analysis was carried out to explore the influences of trial location, trial year, Bishop score, duration of labour, and indications for induction and/or cervical ripening, and differences in ripening agents.

Publication bias was examined using the Egger test and funnel plots.

**Results of the review**

Thirty RCTS were included in the review (n=4,335 women). Sample sizes ranged from 44 to 441 women. The mean trial quality score ranged from 4.5 to 7.

Mechanical agents were significantly more likely to cause maternal infection than pharmacologic agents (OR 1.38, 95% CI 1.12 to 1.68; 30 RCTs). Use of the Foley catheter alone was also associated with higher maternal infection (OR 1.50, 95% CI 1.07 to 2.09; 15 RCTs). The results of other mechanical agents (extra-amniotic saline solution, *Laminaria* hydrophilic inserts, and hygroscopic dilators) were not statistically significant. There was no significant heterogeneity, except for the analysis of hygroscopic dilators which required the application of a random-effects model. Meta-regression analysis did not alter the results, and there was no evidence of publication bias.

In terms of specific maternal infections, chorioamnionitis was significantly increased following mechanical methods of cervical ripening (OR 1.35, 95% CI 1.00 to 1.83; 16 RCTs) and Foley catheter alone (OR 2.05, 95% CI 1.22 to 3.44; seven RCTs). Endomyometritis was significantly increased in patients treated with hygroscopic dilators alone (OR 1.53, 95% CI 1.00 to 2.36; three RCTs). Neonatal infections were significantly increased following mechanical methods (OR 2.04, 95% CI 1.19 to 3.51; eight RCTs) and hygroscopic dilators alone (OR 2.04, 95% CI 1.19 to 3.51; three RCTS). There was no evidence of heterogeneity or publication bias in any of the analyses, and results were not altered by the sensitivity testing.

**Authors’ conclusions**

Mechanical agents for cervical ripening were associated with significantly increased maternal and neonatal infections compared with pharmacological agents alone.

**CRD commentary**

The review question was clear and was supported by potentially reproducible inclusion criteria. The search strategy included some relevant data sources. Methods to minimise language and publication biases were evident. The review process was carried out with sufficient attempts to minimise error and bias, although the absence of detail on the applied quality criteria makes these particular results difficult to interpret. Trial details were provided, heterogeneity was assessed, and the chosen methods of synthesis appeared to be appropriate.

Despite the inability to fully interpret trial quality, the authors’ conclusion reflects the evidence presented and appears to be reliable.

**Implications of the review for practice and research**

**Practice:** The authors stated that prophylactic antibiotics might be indicated in patients undergoing cervical ripening with mechanical methods.

**Research:** The authors stated that a randomised controlled trial is warranted to address the administration of prophylactic antibiotics in patients undergoing cervical ripening with mechanical methods.

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