Foley catheter balloon vs locally applied prostaglandins for cervical ripening and labor induction: a systematic review and metaanalysis

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CRD summary
This review found that Foley balloon catheter and locally applied prostaglandins appeared to be comparatively safe and effective methods for cervical ripening in the third trimester of pregnancy. The results should be interpreted with caution due to potential for review bias, presence of heterogeneity and potential issues with the statistical analyses.

Authors' objectives
To evaluate the safety and efficacy of labour induction by cervical ripening with Foley catheter balloon compared to the use of locally applied prostaglandins in the third trimester of pregnancy.

Searching
PubMed, EMBASE and Cochrane Central Register of Controlled Trials (CENTRAL) were searched from January 1966 to April 2008 for relevant fully published studies in English; search terms were reported. References from retrieved articles and reviews were checked for additional studies.

Study selection
Randomised controlled trials (RCTs) that compared Foley catheter balloon to locally applied prostaglandins for cervical ripening and induction of labour in women with singleton pregnancies with an unfavourable cervix (defined as a Bishop score of ≤6 at ≥28 weeks gestation) in the third trimester were eligible for inclusion. Additional criteria for included pregnancies were that the live foetus was in vertex presentation and the membranes were intact.

The included studies were published between 1983 and 2006. Prostaglandin E2 was applied in a gel cervically and vaginally in some trials and as tablets or pessaries in other trials. Inclusion criteria varied across trials for inclusion of women with previous caesarean sections, preterm gestation prior to 37 weeks, parity, body mass index, presentation with gestational diabetes, hypertension, oligohydramnios and polyhydramnios and maximal Bishop score. Various catheter sizes, balloon volumes, prostaglandin types and preparations and dosing regimens were used. The extra-amniotic catheter balloon was applied with or without extra-amniotic saline solution infusion (EASI) and/or intravenous oxytocin. The maximum period of cervical ripening until labour was induced or the attempt was defined as failed ripening ranged from six hours to 48 hours. Definitions of the primary outcomes varied across the included studies.

Primary outcomes were proportion of patients with babies delivered by caesarean section and incidence of excessive uterine activity. Secondary outcomes were proportion of women who delivered vaginally within 24 hours of the beginning of ripening or within 12 hours from the beginning of the induction, proportion of patients with unfavourable or unchanged Bishop score 12 to 24 hours after ripening, interval from ripening to delivery time, need for oxytocin induction and/or augmentation of labour, adverse events and maternal and neonatal morbidity and mortality.

Two reviewers performed the study selection; any disagreements were resolved by consensus.

Assessment of study quality
Methodological quality was assessed using a modified Jadad scale of randomisation, allocation concealment, reporting of drop-outs and withdrawals after randomisation. Use of double-blinding was not assessed because of the nature of the interventions and comparators, so the maximal attainable score was 4. Studies with a score of 3 or more were judged to be of high quality.

It was unclear how many reviewers performed the quality assessment.

Data extraction
Data were extracted by two independent reviewers to calculate relative risks (RR) for dichotomous outcomes and mean differences for continuous variables, each with 95% confidence intervals (CI). Any disagreements were resolved by consensus.

**Methods of synthesis**

Pooled relative risks and weighted mean differences, with 95% CIs, were calculated for each summary estimate using a Mantel-Haenszel fixed-effect model (no statistical heterogeneity observed) or a DerSimonian and Laird random-effects model (statistical heterogeneity observed). Statistical heterogeneity for the pooled estimates across trials was assessed with $\chi^2$ and $I^2$. Analyses were performed on a per protocol basis.

Subgroup analyses were performed a priori to investigate the influence of study quality, term pregnancies, previous caesarean sections, primiparous patients, use of cervical or vaginal prostaglandins, comparison of locally applied prostaglandins with Foley catheter balloon alone and locally applied prostaglandins use combined with intravenous oxytocin and/or extra-amniotic saline solution infusion (EASI). Sensitivity analyses removed individual studies one at a time to determine their influence on the findings and examined effects of study quality.

Publication bias was assessed using Egger's test and by visual inspection of funnel plots.

**Results of the review**

Twenty-seven RCTs (n=3,470 participants) were included in the review. Sample sizes ranged from 44 to 279 women. Sixteen RCTs (n=1,793) compared Foley catheter balloon to locally applied prostaglandins alone, four RCTs (n=376) compared Foley catheter balloon with EASI to locally applied prostaglandins and seven RCTs (n=1,301) evaluated Foley catheter balloon combined with EASI and/or intravenous oxytocin compared to locally applied prostaglandins. Two trials performed intention-to-treat analyses. Seven studies scored 1 or 2 points on the Jadad scale, six studies scored 3 and 14 studies scored 4 points.

There were no statistically significant differences observed between Foley catheter balloon and locally applied prostaglandins in caesarean delivery rates, vaginal delivery, failed ripening at 12 to 24 hours and ripening to delivery time interval. There was a significantly higher risk of excessive uterine activity observed with locally applied prostaglandins ripening compared to Foley catheter balloon ripening (RR 2.35, 95% CI 1.41 to 3.90; 21 RCTs) with significant heterogeneity across the trials ($I^2=79.1\%$). A decrease in oxytocin use was found in the locally applied prostaglandin ripening group compared with the Foley catheter balloon-ripening group (RR 0.73, 95% CI 0.62 to 0.86; 16 RCTs). No differences were observed between the groups for fever, meconium staining, five-minute Apgar scores less than 7 and admission to neonatal intensive care units.

Subgroup analyses showed statistically significant differences in some primary and secondary outcomes on the basis of locally applied prostaglandin type and type of Foley catheter balloon administration. Other adverse events were reported in the review. Sensitivity analyses did not significantly alter the results.

No evidence of publication bias was shown in the Egger test.

**Authors' conclusions**

Foley catheter balloon and locally applied prostaglandins resulted in a similar rate of caesarean deliveries. Use of Foley catheter balloon for cervical ripening was associated with higher use of oxytocin for labour induction and augmentation. Risk of excessive uterine activity was higher with locally applied prostaglandins in patients in the third trimester of their pregnancy. There were no differences in risks of maternal and neonatal complications between the methods of cervical ripening.

**CRD commentary**

The review addressed a clearly defined question. Criteria for inclusion of studies were stipulated. Appropriate electronic databases were searched for studies. The restriction to studies published in English risked language bias. Studies published as abstracts only were excluded and there was a risk that potentially relevant studies were missed. Steps were taken to minimise errors and biases during study selection and data extraction, but the authors did not
specify how many reviewers performed the quality assessment. Substantial clinical heterogeneity made it unclear whether pooling results of the included trials was appropriate, particularly so in light of the statistical heterogeneity observed in the pooled outcomes. The authors did not adjust for the occurrence of zero events in both study arms. The quality of the included studies was variable, with no blinding and no use of intention-to-treat analyses. The authors conducted appropriate subgroup analyses to examine sources of heterogeneity and correctly acknowledged some of the limitations of the review owing to heterogeneity.

The authors’ conclusions should be interpreted with caution given potential for bias in the review, the presence of clinical and statistical heterogeneity and potential issues with the statistical analyses.

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

**Practice:** The authors did not state any implications for practice.

**Research:** The authors did not state any implications for research, but noted that the review lacked sufficient power to determine conclusions on uncommon outcomes such as uterine rupture, meconium aspiration syndrome and maternal and neonatal deaths

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