# Transabdominal amnioinfusion for preterm premature rupture of membranes: a systematic review and metaanalysis of randomized and observational studies

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## CRD summary

This review concluded that serial transabdominal amnioinfusion for pregnant women with preterm premature rupture of their membrane, could improve morbidity and mortality. The authors' cautious conclusions reflected the evidence presented, but they were based on small observational studies, and caution is advised when interpreting the results. Their recommendation for further research was appropriate.

## Authors' objectives

To assess the efficacy and safety of transabdominal amnioinfusion for pregnant women with preterm (before 37 weeks gestation) premature rupture of their membranes.

## Searching

Articles in MEDLINE from 1950 to December 2011 and EMBASE from 1980 to December 2011 were searched, with no language restriction. Search terms were reported. ClinicalTrials.gov was searched for ongoing trials. Bibliographies of identified studies was checked for further studies.

## Study selection

Observational studies or randomised controlled trials (RCTs) of transabdominal amnioinfusion plus conventional treatment compared with conventional treatment alone, were eligible for inclusion. Studies that included patients with a confirmed diagnosis of oligohydramnios (low amount of amniotic fluid), associated with preterm premature rupture of membranes, were included. Studies that included patients with oligohydramnios associated with other causes, such as intrauterine growth restriction or renal anomalies, were excluded.

In the included studies, the primary outcomes of interest were the latency period (interval from preterm premature rupture of membrane to birth) and perinatal deaths. Secondary outcomes were pulmonary hypoplasia, neonatal deaths, gestational age at birth, birth weight, chorioamnionitis, early onset (less than 72 hours from delivery) neonatal sepsis, bronchopulmonary dysplasia, and caesarean delivery. Conventional care included bed rest in the hospital and prophylactic antibiotics. Across the studies, the foetal gestational age varied from 16 to 33 weeks. In most studies, the average number of amnioinfusions per patient ranged from 1.23 to four, and the infused volume ranged from 140 to 350mL per infusion.

Two reviewers independently evaluated studies for inclusion; disagreements were resolved through consensus.

## Assessment of study quality

Study quality was assessed using the Newcastle-Ottawa Scale, for observational studies, and the Cochrane Collaboration's risk of bias tool, for RCTs. The Newcastle-Ottawa Scale assessed selection, comparability and outcome biases. The risk of bias tool assessed selection, performance, detection, attrition, reporting, and other biases.

Two reviewers independently assessed quality, and any discrepancies were resolved through discussion, with a third reviewer.

## Data extraction

The data were extracted to calculate the mean difference for continuous data or the odds ratio for dichotomous data, with their 95% confidence intervals. Study authors were not contacted for missing information.

Two reviewers independently extracted the data. Any disagreements were resolved through consensus, with a third reviewer.

## Methods of synthesis

Cohort studies and RCTs were pooled separately. A random-effects model (DerSimonian and Laird) was used to calculate mean differences or odds ratios, with their 95% confidence intervals. Heterogeneity was assessed using Cochran's Q and $I^2$.

## Results of the review

Seven studies (four observational, two RCTs, and one quasi-randomised trial) were included in the review, with 312 patients (range 24 to 71) All observational studies had minimal risks of bias, whereas the RCTs had moderate to high risks of bias.

Observational studies: Compared with conventional treatment, amnioinfusion prolonged the latency period (MD 14.4 days, 95% CI 8.2 to 20.6; $I^2$= 17%; four studies; 147 patients) and reduced perinatal mortality (OR 0.12, 95% CI 0.02 to 0.61; $I^2$ =0; two studies; 60 patients). There were statistically significant decreases in pulmonary hyperplasia (two studies; 45 patients) and the risk of neonatal death (one study; 18 patients) with amnioinfusion. The other secondary outcomes were not statistically significant.

RCTs: There were no statistically significant differences in the latency period (three studies; 165 patients) and perinatal mortality (two studies; 131 patients) between the two groups. For the secondary outcomes, no statistically significant differences were found except for the infectious complications of amnionitis and endometritis, which were fewer in the amnioinfusion group (two studies; 131 patients).

## Authors' conclusions

Serial transabdominal amnioinfusion could improve morbidity and mortality, but adequately powered randomised controlled trials were needed.

## CRD commentary

The review question and inclusion criteria were clear. The search covered relevant sources. No language restrictions were applied, which minimised the risk of language bias. Attempts were made to minimise errors and bias, in the review process. Appropriate quality assessment tools were used and the results were presented. Appropriate methods were used to pool the data and assess heterogeneity.

The authors' cautious conclusions reflected the evidence presented, but they were based on small observational studies, as the RCTs showed no statistically significant difference. Caution is advised when interpreting these results, as acknowledged by the authors, and it was appropriate that they recommended further research.

## Implications of the review for practice and research

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

Research: The authors stated that large multicentre randomised controlled trials, with standardised treatment, were needed. These trials should be adequately powered to detect a significant result.

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