Effects of intentional delivery on maternal and neonatal outcomes in pregnancies with preterm prelabour rupture of membranes between 28 and 34 weeks of gestation: a systematic review and meta-analysis

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CRD summary
The authors concluded that intentional delivery for pre-labour rupture of membranes at between 28 and 34 weeks of gestation had no maternal and neonatal benefits, compared with expectant management, but it had higher risks of neonatal death and caesarean section. The conclusions of this generally well-conducted review reflect the limitations of the evidence presented.

Authors' objectives
To assess the effects of intentional delivery for pregnancies with pre-labour rupture of membranes, at between 28 and 34 weeks of gestation, on maternal and neonatal outcomes.

Searching
MEDLINE, EMBASE, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL) and Science Citation Index were searched in July 2011, and PubMed was searched in December 2011. Trial registries, abstracts from meetings of the Society of Maternal-Fetal Medicine, and reference lists of identified studies and reviews were checked. Search terms were available from the authors, and no language restrictions were applied.

Study selection
Randomised controlled trials (RCTs) of intentional delivery or induction of labour, compared with expectant management, for women with pre-labour rupture of membranes, at between 28 and 34 weeks of gestation, were eligible for inclusion. Abstracts, trials that included multiple pregnancies, and those that scored less than 2 on the Jadad quality scale, were excluded. The primary outcomes of interest were maternal infection, neonatal sepsis, and respiratory distress syndrome.

In the included trials, intentional delivery was defined as planned early birth, soon after pre-term pre-labour rupture of membranes, by induction of labour or caesarean section. This was compared with expectant management until spontaneous delivery or the presence of a contraindication to continuing the pregnancy. In some trials, corticosteroids were given to the women in the intentional delivery group only. One trial had two intentional delivery groups; one received corticosteroids and the other did not. Tocolysis was used in all but one trial; prophylactic antibiotics were not used in any of the trials. The mean maternal age ranged from 22.4 to 24.9 years; and the mean gestational age at trial entry ranged from 31 to 32 weeks and at birth ranged from 31.3 to 33.5 weeks. The mean time from rupture of membranes to delivery ranged from less than 24 hours to 89.9 days, for the intentional delivery groups, and one day to 125 days, for the expectant management groups. The trials were published between 1981 and 1997.

Two reviewers independently selected studies for inclusion, with any disagreements resolved by discussion with a third reviewer.

Assessment of study quality
The Jadad 5-point scale was used to assess trial quality on three domains – randomisation, blinding, and withdrawals and drop-outs.

It was unclear how many reviewers assessed trial quality.

Data extraction
The data were extracted to calculate risk ratios, with 95% confidence intervals, for all outcomes; and incidence data were extracted for all outcomes.

Two reviewers independently extracted the data, with any disagreements resolved by discussion with a third reviewer.
Methods of synthesis
A random-effects model was used to calculate pooled risk ratios for all outcomes. Statistical heterogeneity was assessed using X² and I²; a probability of less than 0.1 indicated significant heterogeneity. Publication bias was assessed using funnel plots. A sensitivity analysis was performed for trials that did not use corticosteroids.

Results of the review
Five RCTs (488 women; range 34 to 160) were included. Two trials scored 3 on the Jadad scale, and the other three scored 2.

There was no statistically significant difference in the risks of maternal infection (RR 1.22, 95% CI 0.69 to 2.25; five RCTs), neonatal respiratory distress syndrome (RR 1.13, 95% CI 0.78 to 1.63; five RCTs), and neonatal sepsis (RR 1.49, 95% CI 0.57 to 3.88; five RCTs), between intentional delivery and expectant management. There was significant statistical heterogeneity for the risk of maternal infection analysis.

The sensitivity analysis, excluding trials that had antenatal corticosteroids for the intentional delivery group, found a similar result for neonatal respiratory distress syndrome. The risks of maternal infection and neonatal sepsis were lower in the intentional delivery group, but these were not statistically significant. There was significant statistical heterogeneity for the neonatal respiratory distress syndrome analysis.

The risk of caesarean section was statistically significantly higher with intentional delivery (RR 1.35, 95% CI 1.02 to 1.80; five RCTs). There was no statistically significant difference in the risk of neonatal death (RR 1.87; 95% CI 0.63 to 5.52; five RCTs), except when excluding trials that used corticosteroids, where the risk of neonatal death was statistically significantly higher with intentional delivery (RR 5.81, 95% CI 1.35 to 25.08; three RCTs).

Publication bias was detected for the primary outcomes.

Authors’ conclusions
Intentional delivery for pre-labour rupture of membranes, at between 28 and 34 weeks of gestation, had no maternal and neonatal benefits, compared with expectant management, but it had higher risks of neonatal death and caesarean section.

CRD commentary
The review question and inclusion criteria were clearly stated. Various databases were searched and no language restrictions were applied. Appropriate steps were taken to prevent error and bias in the review process. There was a risk of bias in some of the included trials. There was no significant statistical variation for most outcomes, but the incidence of the primary outcomes varied between trials, so a random-effects model was appropriate. As the authors noted, the analysis was based on a few relatively old trials that were underpowered to detect an effect, and the results might have been affected by publication bias.

The conclusions of this generally well-conducted review reflect the limitations of the evidence presented.

Implications of the review for practice and research
Practice: The authors stated that until more robust trials were published, intentional delivery should not be considered for women with pre-labour rupture of membranes before 34 weeks of gestation, in the absence of other indications for early delivery.

Research: The authors stated that well-designed and powered RCTs, with long-term follow-up, were needed to confirm these findings and to guide best clinical practice.

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