Antibiotics for prelabour rupture of membranes at or near term

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Abstract

Background

Prelabour rupture of the membranes (PROM) at or near term (defined in this review as 36 weeks' gestation or beyond) increases the risk of infection for the woman and her baby. The routine use of antibiotics for women at the time of term PROM may reduce this risk. However, due to increasing problems with bacterial resistance and the risk of maternal anaphylaxis with antibiotic use, it is important to assess the evidence addressing risks and benefits in order to ensure judicious use of antibiotics. This review was undertaken to assess the balance of risks and benefits to the mother and infant of antibiotic prophylaxis for PROM at or near term.

Objectives

To assess the effects of antibiotics administered prophylactically to women with PROM at 36 weeks' gestation or beyond, on maternal, fetal and neonatal outcomes.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 July 2014).

Selection criteria

All randomised trials that compared outcomes for women and infants when antibiotics were administered prophylactically for prelabour rupture of the membranes at or near term, with outcomes for controls (placebo or no antibiotic).

Data collection and analysis

Two review authors independently extracted the data and assessed risk of bias in the included studies. Additional data were received from the investigators of included studies.

Main results

This update includes an additional two studies involving 1801 women, giving a total of four included studies of 2639 women. Whereas the previous version of this review showed a statistically significant reduction in endometritis with the use of antibiotics, no such effect was shown in this update (average risk ratio (RR) 0.34, 95% confidence interval (CI) 0.05 to 2.31). No differences were shown on the primary outcome measures of probable early-onset neonatal sepsis (average RR 0.69, 95%; CI 0.21 to 2.33); definite early-onset neonatal sepsis (average RR 0.57, 95% CI 0.08 to 4.26); maternal infectious morbidity (chorioamnionitis and/or endometritis) (average RR 0.48, 95% CI 0.20 to 1.15); stillbirth (RR 3.00, 95% CI 0.61 to 14.82); and perinatal mortality (RR 1.98, 95% CI 0.60 to 6.55), though the number of cases in the control group for these outcomes was low. There were no cases of neonatal mortality or serious maternal outcome in the studies assessed.

Caesarean section was increased with the use of antibiotics (RR 1.33, 95% CI 1.09 to 1.61) as was duration of maternal stay in hospital (mean difference (MD) 0.06 days, 95% CI 0.01 to 0.11), largely owing to one study of 1640 women where repeat caesarean section, increased baseline hypertension and pre-eclampsia were evident in the antibiotic group, despite random allocation and allocation concealment.

Subgroup analyses by timing of induction (early induction versus late induction) showed no difference in either probable or definite early-onset neonatal sepsis in the early induction group (RR 1.47, 95% CI 0.80 to 2.70 and RR 1.29, 95% CI 0.48 to 3.44, respectively) or the late induction group (RR 0.14, 95% CI 0.02 to 1.13 and RR 0.16, 95% CI 0.02 to 1.34, respectively), although there were trends toward reduced probable and definite early-onset neonatal sepsis in the late induction group. A test for subgroup differences confirmed a differential effect of the intervention on probable early-onset neonatal sepsis between the subgroups ($Chi^2 = 4.50$, df = 1 (P = 0.03), $I^2 = 77.8\%$). No difference in maternal infectious morbidity (chorioamnionitis and/or endometritis) was found in either subgroup, though again there was a trend towards reduced maternal infectious morbidly in the late induction group (average RR 0.34, 95% CI 0.08 to 1.47). No differences were shown in stillbirth or perinatal mortality. The quality of the evidence for the primary outcomes using GRADE was judged to be low to very low.

Authors' conclusions

This updated review demonstrates no convincing evidence of benefit for mothers or neonates from the routine use of antibiotics for PROM at or near term. We are unable to adequately assess the risk of short- and long-term harms from the use of antibiotics due to the unavailability of data. Given the unmeasured potential adverse effects of antibiotic use, the potential for the development of resistant organisms, and the low risk of maternal infection in the control group, the routine use of antibiotics for PROM at or near term in the absence of confirmed maternal infection should be avoided.

Plain language summary

Antibiotics for rupture of membranes when a pregnant women is at or near term but not in labour

Background

Sometimes the protective bag of fluid around an unborn baby (the membranes) break when the baby is due without the onset of labour (regular uterine contractions). This is called PROM or prelabour rupture of the membranes. When this happens there is a risk of infection entering the womb (uterus) and affecting the mother and her baby. Newborn infections are rare but have the potential to cause serious harm requiring neonatal intensive care. Giving a pregnant woman antibiotics when she has PROM may reduce the risk of infections for the woman and her baby. Most women spontaneously start labour within 24 hours, so delaying induction of labour and waiting for spontaneous onset of labour (expectant management) may be a possibility. Another treatment for term PROM is to induce labour with oxytocin or prostaglandins. Women are often given antibiotics to prevent infection, but there are concerns about possible side-effects of antibiotics, and that overuse of antibiotics can cause resistance to antibiotics so that they become less effective.

Our review questions

Do antibiotics given to women with PROM when they are at or near term (more than 36 weeks' gestation) but not in labour reduce the risk of infection for the baby and the mother? Are there adverse effects from the antibiotics?

What the studies showed

This review included four randomised controlled studies involving 2639 pregnant women at 36 weeks' gestation or more. The evidence showed that routine antibiotics for term PROM did not reduce the risk of infection for pregnant women or their babies when compared to the control group which received a placebo or no antibiotics. There was not enough strong evidence about other outcomes including death, allergic reactions for the woman or complications for the baby, which rarely occurred in the included studies. The quality of the evidence using GRADE was judged to be low to very low.

Overall

The conclusions from this review are limited by the low number of women who developed an infection across the studies overall. There is not enough information in this review to assess the possible side-effects from the use of antibiotics for women or their infants, particularly for any possible long-term harms. Because we do not know enough about side-effects and because we did not find strong evidence of benefit from antibiotics, they should not be routinely used for pregnant women with ruptured membranes prior to labour at term, unless a woman shows signs of infection.