Vaginal chlorhexidine during labour to prevent early-onset neonatal group B streptococcal infection

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Key findings

- Chlorhexidine vagina washing is not associated with any significant reduction in the risk of early-onset GBS illness, but may reduce GBS colonization of neonates
- Chlorhexidene produces mild maternal mild side effects in the form of stinging or local irritation, but no side effects on neonates were reported

Evidence included in this review

Four studies (n= 1125) were reviewed, of which two (n=987) compared chlorhexidine (vaginal wash/gel) versus placebo or no treatment.

Quality assessment

Generally, trial studies are constrained by small sample size and poor randomization. The quality of trials varied, and overall risk of bias was either unclear or high. GRADE quality of evidence for the outcomes was low.

Clinical implications

GBS is rare but produces serious infection, accounting for about 30% of early-onset disease in preterm and term neonates. Vagina chlorhexidine washing has been proposed as a prophylactic strategy. While chlorhexidine reduces vagina bacteria load, there seems to be no demonstrable reduction in GBS illness in neonates, although evidence is poor. Chlorhexidine is inexpensive and does not impact antibiotic resistance.

Further research

Future research should include larger sample sizes and better randomization to provide firmer scientific validation. Research should be conducted in low resource settings, where vaginal chlorhexidine would be a more appropriate recommendation.

Cochrane review
Abstract

Although early-onset group B \( \beta \)-hemolytic streptococcus (GBS) infection is rare, it accounts for approximately 30\% of neonatal infections, has a high mortality rate, and is acquired through vertical transmission from colonized mothers. Several trials have demonstrated the efficacy of intrapartum antibiotic prophylaxis (IAP) for preventing early-onset disease (EOD). Vaginal disinfection with chlorhexidine during labour has been proposed as another strategy for preventing GBS EOD in the preterm and term neonate. Chlorhexidine has been found to have no impact on antibiotic resistance, is inexpensive, and applicable to poorly equipped delivery sites.

To determine the effectiveness of vaginal disinfection with chlorhexidine during labour in women who are colonized with GBS for preventing early-onset GBS infection in preterm and term neonates.

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 October 2014) and reference lists of retrieved studies.

Randomized and quasi-randomized trials comparing vaginal disinfection with chlorhexidine (vaginal wash or gel/cream) versus placebo, or no treatment.

Three review authors independently assessed the trials for inclusion and risk of bias, extracted the data and checked them for accuracy.

We identified no new trials eligible for inclusion in this update. One study was moved from included to excluded studies from the previous version of the review. Four studies, including 1125 preterm and term infants, met the inclusion criteria and reported on at least one of the outcomes of interest. For the comparison chlorhexidine (vaginal wash or gel) versus placebo or no treatment, two studies (\( n = 987 \)) were pooled. There was no statistically significant difference in early-onset GBS disease (sepsis and/or meningitis) comparing chlorhexidine (vaginal wash or gel/cream) versus placebo or no treatment; risk ratio (RR), 2.32 (95\% confidence interval (CI) 0.34 to 15.63); I-squared (\( \text{I}^2 \)) = 0\% or in GBS pneumonia; RR 0.35 (95\% CI 0.01 to 8.6); test for heterogeneity not applicable. The outcome of colonization of the neonate with GBS was reported in three studies (\( n = 328 \)); RR 0.64 (95\% CI 0.40 to 1.01; there was substantial between-study heterogeneity (\( \text{Chi}^2 = 3.19; P = 0.20; \text{I}^2 = 37\% \)). Maternal mild side effects (stinging or local irritation) (three trials, 1066 women) were more commonly seen in women treated with chlorhexidine (RR 8.50 (95\% CI 1.60 to 45.28); there was no heterogeneity (\( \text{Chi}^2 = 0.01, df = 1 (P = 0.91); \text{I}^2 = 0\% \)). No side effects were reported among the neonates.

For the comparison chlorhexidine vaginal wash versus mechanical washing with placebo or no treatment (one study, \( n = 79 \)), there was a significant reduction in neonatal colonization with GBS; RR 0.32 (95\% CI 0.12 to 0.90). Tests for heterogeneity not applicable. There were no other significant results for this comparison.

For the comparison chlorhexidine gel or cream versus placebo or no treatment, there were no statistically significant results for the outcomes reported on.
The quality of the trials varied and the overall risk of bias was rated as unclear or high. The quality of the evidence using GRADE was very low for the outcomes of the comparison chlorhexidine (vaginal wash or gel/cream) versus placebo or no treatment. These outcomes included: early-onset GBS disease (sepsis and/or meningitis), GBS pneumonia, neonatal colonization with GBS, neonatal mortality due to early-onset GBS infection and adverse (mild) effects in the mother and the neonate.

The quality of the four included trials varied as did the risk of bias and the quality of the evidence using GRADE was very low. Vaginal chlorhexidine was not associated with reductions in any of the primary outcomes of early-onset GBS disease (sepsis and/or meningitis) or GBS pneumonia. Vaginal chlorhexidine may reduce GBS colonization of neonates. The intervention was associated with an increased risk of maternal mild adverse effects. The review currently does not support the use of vaginal disinfection with chlorhexidine in labour for preventing early-onset disease. Results should be interpreted with caution as the methodological quality of the studies was poor. As early-onset GBS disease is a rare condition trials with very large sample sizes are needed to assess the effectiveness of vaginal chlorhexidine to reduce its occurrence. In the era of intrapartum antibiotic prophylaxis, such trials may be difficult to justify especially in developed countries.

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