Evidence on the benefits and harms of screening and treating pregnant women who are asymptomatic for bacterial vaginosis: an update review for the U.S. Preventive Services Task Force

Nygren P, Fu R, Freeman M, Bougatsos C, Klebanoff M, Guise J M

CRD summary
This updated review of the impact of screening and treating bacterial vaginosis in asymptomatic pregnant women found no benefit for low- or medium-risk women, and inconsistent results for women at a high level of risk. Overall, this was a well-conducted review and the results are likely to be reliable.

Authors' objectives
To provide an updated review of the impact of screening and treating bacterial vaginosis in asymptomatic pregnant women.

Searching
The original report searched MEDLINE (1966 to 1999) and the Cochrane Library; the search terms were reported. The updated review also searched the Cochrane CENTRAL Register, the Cochrane Database of Systematic Reviews and DARE from inception to September 2007. MEDLINE was searched from 1996 to September 2007. The search strategies and terms were reported in an appendix. Reference lists from systematic reviews, included studies, editorials and websites were used to locate further citations, and experts were consulted.

Study selection
Eligible study designs comprised systematic reviews and randomised controlled trials (RCTs). Studies were required to have evaluated the screening, treatment, pregnancy outcomes or adverse effects of treating asymptomatic pregnant women with bacterial vaginosis. Eligible participants were women who presented for routine prenatal care who were not aware of their status. The included studies in this review were all RCTs, comprising a mixture of low-, medium- and high-risk pregnant women who were screened or diagnosed with bacterial vaginosis using Gram stain or other method.

Two independent reviewers selected the studies in the updated review, and any discrepancies were resolved through discussion and consensus. It was unclear how the studies were selected in the original review.

Assessment of study quality
Two independent reviewers assessed the validity of the included studies using quality criteria specified by the U.S. Preventive Services Task Force and the Jadad scale. Any discrepancies in the quality assessment were referred to a third reviewer and discussed to reach consensus. The original review used only the Jadad scale and it was unclear how many reviewers performed this assessment.

Data extraction
Data were extracted on the adverse effects of screening and of antibiotic treatment for bacterial vaginosis, and reductions in adverse pregnancy outcomes (endometritis/neonatal sepsis, low birth weight, perinatal mortality, pre-term delivery, pre-term and premature rupture of membranes, spontaneous abortion). The study populations were categorised as being at low, average or high risk for pre-term delivery. The primary measure of effect was calculated as an absolute risk reduction (ARR) and standard error for each study. This represented the effects of antibiotic treatment on pre-term delivery, low birth weight, and pre-term and premature rupture of membranes.

Two independent reviewers extracted the data in both the original and updated reviews.

Methods of synthesis
The primary studies were pooled in a meta-analysis using a random-effects model to produce combined estimates of ARR with 95% confidence intervals (CIs). Analyses were stratified according to risk group (low, average or high) and
pooled accordingly. Heterogeneity was tested for using $\chi^2$ tests, and $I^2$ was calculated to indicate the degree of unexplained variance between primary studies. Sensitivity analyses were used to assess the impact of study quality on the results; trials with a Jadad score of ≤2 were excluded from these analyses. Publication bias was assessed using funnel plots and the Egger linear regression method.

The results of the meta-analyses were used to construct a projected outcomes table, which summarised estimates of benefit and harm for screening and treatment in women at a high risk for pre-term delivery.

**Results of the review**

This updated review included 7 new RCTs (number of participants unclear as one trial did not report them) and the 7 RCTs (n=3,860) identified and included in the initial review.

Based on the Jadad scale, one trial scored 2 out of 5, three scored 3, eight scored 4 and two scored 5. No publication bias was detected.

The main results are reported below; further analyses are detailed in the original publication. Sensitivity analyses were carried out, excluding those studies with low internal validity, but this did not alter any of the overall estimates of treatment effect.

**Low-risk women:** 3 trials reported the results of treatment in low-risk women. No significant effect of treatment on delivery before 37 weeks was found (ARR -0.019, 95% CI: -0.056, 0.018). No significant heterogeneity was noted in these studies.

**Average-risk women (general population):** 8 trials reported the effect of treatment on delivery before 37 weeks and found no significant benefit (ARR 0.006, 95% CI: -0.009, 0.022). Three trials assessed the impact of treatment on delivery before 32 weeks and found no significant benefit (ARR 0.001, 95% CI: -0.008, 0.010). Seven trials found no benefit of treatment for low birth weight (ARR 0.000, 95%CI: -0.018, 0.018). No significant heterogeneity was noted in any of these analyses.

**High-risk women:** studies reporting the results of treatment in high-risk women were more heterogeneous overall and less statistical pooling was carried out. Studies reporting on the impact of treatment on delivery before 37 weeks were inconsistent: three showed some benefit, one indicated harm and the fifth found no benefit. Pooled data for 5 RCTs on the outcome of delivery before 34 weeks indicated no significant benefit of treatment (ARR 0.006, 95% CI: -0.067, 0.079).

An outcomes table, which summarised the clinical effects of screening and treating asymptomatic women for bacterial vaginosis, was presented in the main publication. Overall, some high-risk women may benefit from such an intervention, but many would experience either no benefit or may potentially be harmed.

**Authors’ conclusions**

This updated review found no benefit of screening and treating women who are asymptomatic for bacterial vaginosis when they are at low or medium risk for the following events: delivery before 37, 34 or 32 weeks, pre-term and premature rupture of membranes, or low birth weight. The results were mixed and inconsistent for women at a high level of risk.

**CRD commentary**

This review addressed a clear research question with appropriate inclusion criteria. Some literature may have been omitted as a restricted number of databases were searched. The review procedures were described in detail and are likely to have minimised bias and error. The validity of the primary studies was considered in some detail and sensitivity analyses were used to assess the impact of lower quality studies on the results. Statistical meta-analyses were carried out for the majority of the outcomes of interest, but where heterogeneity was noted a narrative approach was adopted. The authors’ conclusions follow clearly from the primary data presented, and the results of this review are likely to be reliable.
Implications of the review for practice and research

Practice: The authors stated that clinicians should remain aware of the potentially harmful effects of treatment for bacterial vaginosis.

Research: The authors stated that more research is needed to clarify which groups of women may benefit or be harmed by screening and treatment for bacterial vaginosis.

Funding
Agency for Healthcare Research and Quality, contract number: 290-02-0024.

Bibliographic details

PubMedID
18252684

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Female; Humans; Mass Screening /adverse effects; Pregnancy; Pregnancy Complications, Infectious /diagnosis /drug therapy; Premature Birth /prevention & control; Risk Factors; Vaginosis, Bacterial /diagnosis /drug therapy

AccessionNumber
12008008088

Date bibliographic record published
09/08/2008

Date abstract record published
03/11/2008

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.