

Rapid testing for group B streptococcus during labour: a test accuracy study with evaluation of acceptability and cost-effectiveness

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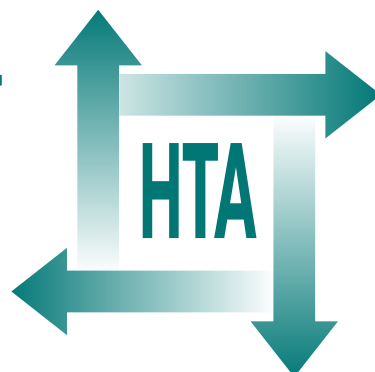


Executive summary

Health Technology Assessment 2009; Vol. 13: No. 42

DOI: 10.3310/hta13420

Health Technology Assessment
NIHR HTA programme
www.hta.ac.uk





Executive summary

Background

Early-onset group B streptococcus (EOGBS) disease is the leading cause of serious neonatal sepsis in developed countries. It is transmitted to neonates during birth from colonised mothers, in whom it is an opportunistic pathogen harboured in the vagina or rectum. Intrapartum antibiotic prophylaxis (IAP) given to the mother reduces the risk of EOGBS disease in the newborn by reduction of maternal transmission and protection of the neonate, providing it is administered sufficiently early before delivery. There is disagreement about the best screening strategies, with the UK currently recommending IAP on the basis of risk factors present at the time of labour. In some countries, screening of women for GBS colonisation is undertaken at 35–37 weeks' gestation with culture of vaginal and/or rectal swabs. This report assesses the accuracy and acceptability of an alternative approach, based on intrapartum rapid testing for maternal GBS colonisation, to determine which women should receive IAP, and models its cost-effectiveness against alternative strategies.

Objectives

This health technology assessment completed three distinct pieces of work:

- to determine the accuracy (sensitivity, specificity, predictive values) of polymerase chain reaction (PCR) and optical immunoassay (OIA) technologies as rapid tests for maternal vaginal and rectal GBS colonisation at the onset of labour using selective enrichment culture as the reference standard
- to determine the acceptability of rapid testing for GBS colonisation among pregnant women of different age and ethnic groups
- to determine the cost and cost-effectiveness of rapid intrapartum testing for maternal GBS colonisation to prevent EOGBS disease, and compare this with other strategies for screening and prevention.

Methods

A primary test accuracy study obtained swabs at the onset of labour from 1400 women from two large maternity units to compare the results of vaginal and rectal PCR and OIA (index tests) with the reference standard of enriched culture of combined vaginal and rectal swabs. The study compared the accuracy of index tests, determined the relative accuracies of tests on vaginal and rectal swabs, evaluated whether test accuracy varied according to the presence or absence of maternal risk factors, and explored the determinants of neonatal colonisation.

Acceptability of testing to participants was evaluated through a structured questionnaire administered as soon as possible after delivery. The characteristics of those who declined to take part in the study when first approached were also analysed. Acceptability of rapid testing to staff was evaluated through two focus groups with midwives who had taken part in the study.

For the economic evaluation resource usage data were collected alongside the test accuracy study to establish the cost of rapid testing. A decision-analytic model was constructed to assess the cost-effectiveness of various screening and prevention strategies, using a perspective of the NHS and an outcome of cost per case of EOGBS disease or death avoided.

Results

Main findings of test accuracy study

PCR was significantly more accurate than OIA for the detection of maternal GBS colonisation, for all combinations of index and reference test. Combined vaginal or rectal swab index tests were more sensitive than either test considered individually [combined swab sensitivity for PCR 84% (95% CI 79–88%); vaginal swab 58% (52–64%); rectal swab 71% (66–76%)]. The highest

sensitivity for PCR came at the cost of lower specificity [combined specificity 87% (95% CI 85–89%); vaginal swab 92% (90–94%); rectal swab 92% (90–93%)]. The sensitivity and specificity of rapid tests varied according to the presence or absence of maternal risk factors but not consistently. PCR results were determinants of neonatal GBS colonisation, but maternal risk factors were not.

Overall levels of acceptability for rapid testing amongst participants were high and there was no evidence that screening had raised anxiety. They did not find the process of swabbing unpleasant, although vaginal swabs were more acceptable than rectal swabs. Compared with white British women, South Asian women were less likely to have participated in the study and were less happy with the sampling procedure and with the prospect of rapid testing as part of routine care; they were also more likely to prefer professional judgement as the basis for treatment. Midwives were generally positive towards rapid testing if practical problems could be overcome but had concerns that it might lead to overtreatment and unnecessary interference in births.

The rapid tests were both relatively expensive compared with the other strategies (PCR test £29.95; OIA test £16.09). Modelling analysis revealed that the most cost-effective strategy was to provide routine IAP to all women without screening. As this was deemed unlikely to be acceptable to the majority of women and midwives, the analysis was repeated with the removal of this strategy. Here, screening based on a culture test at 35–37 weeks' gestation, with the provision of antibiotics to all women who screened positive, was most cost-effective, assuming that all women in premature labour would receive IAP. The results were sensitive to very small increases in costs and changes in other assumptions. Screening using a rapid test, whether PCR or OIA, and based on

rectal or vaginal swabs combined, was not cost-effective, based on its current sensitivity, specificity and cost.

Conclusions

Implications for health care

Although PCR performed better than OIA, neither rapid test evaluated was sufficiently accurate to recommend it for routine use in clinical practice. Rectal swabbing was less acceptable and the technologies need to be further refined for point-of-care use. The most cost-effective approach to reducing EOGBS disease is likely to be the provision of IAP to all women without testing. If this strategy is discarded on grounds of acceptability, IAP directed by screening with enriched culture at 35–37 weeks' gestation, with IAP to all women in premature labour, becomes cost-effective. However, it is premature to suggest the implementation of either strategy at present.

Recommendations for research

The relative effectiveness, feasibility and acceptability to women of screening by enriched culture and provision of routine IAP should be explored. Further refinements of rapid tests would be required to improve accuracy to make point-of-care testing practicable at reduced cost. Any new development would require further evaluation and comparison with existing strategies.

Publication

Daniels J, Gray J, Pattison H, Roberts T, Edwards E, Milner P, *et al.* Rapid testing for group B streptococcus during labour: a test accuracy study with evaluation of acceptability and cost-effectiveness. *Health Technol Assess* 2009;**13**(42).

NIHR Health Technology Assessment programme

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ISSN 1366-5278

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Published by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk), on behalf of NETSCC, HTA.

Printed on acid-free paper in the UK by the Charlesworth Group.