Rapid fetal fibronectin testing to predict preterm birth in women with symptoms of premature labour: a systematic review and cost analysis


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
The objective was to assess the clinical effectiveness and cost-effectiveness of rapid foetal fibronectin testing to predict preterm birth in pregnant women with threatened preterm labour. The authors concluded that the test was moderately accurate and could reduce health care costs, but there was significant uncertainty in the results. The study was well reported and valid methods were used. The authors' conclusions were appropriately cautious.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to assess the clinical effectiveness and cost-effectiveness of rapid foetal fibronectin testing to predict preterm birth for pregnant women with threatened preterm labour before 37 weeks of gestation.

Interventions
The intervention was rapid foetal fibronectin testing in addition to usual care. The test aimed to detect increased levels of foetal fibronectin in cervicovaginal secretions between 22 and 37 weeks of gestation, which could indicate preterm birth. Rapid test results were available within 30 minutes. Treatment decisions were made by the patient's clinician. The comparator was usual care, with no testing. This included hospitalisation; medications, such as antenatal steroids and tocolytic agents; occasional in utero transfer; and preterm delivery.

Location/setting
UK/secondary care.

Methods
Analytical approach:
A decision tree was used to assess the impact of the test on costs; effectiveness was not modelled as no significant differences in effectiveness were identified by a systematic review. The time horizon was from hospital admission to the time of delivery. The authors stated that they took a UK NHS perspective.

Effectiveness data:
A systematic review was conducted for clinical effectiveness and test accuracy. Clinical effectiveness was measured by the impact of the test on the incidence of preterm births over different gestation periods, hospital admissions, administration of treatment, and newborn and maternal health outcomes. These outcomes were from five randomised controlled trials; test accuracy was from 54 diagnostic accuracy studies. Where three or more studies reported the same outcome, a random-effects model was used to pool their data. Based on the trials, it was assumed that testing did not lead to more adverse events or worse pregnancy outcomes than usual care.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
No benefit measure was used, as there was no evidence of a significant difference in effectiveness with the addition of the test.
Cost data:
The cost categories included the foetal fibronectin test, hospital admissions, and interventions. The cost of the test was from a Health Technology Assessment report, for an alternative form of the test. Admission and treatment rates were from the only identified UK study. Treatment costs were from the British National Formulary, and hospital costs were NHS reference costs. Emergency hospital transfer costs were from the Personal Social Services Research Unit. All costs were reported in 2011 UK £.

Analysis of uncertainty:
One-way sensitivity analyses were performed for all parameters. Probabilistic sensitivity analysis was undertaken to estimate the impact of joint parameter uncertainty on the results. Exploratory analysis assessed different prices for the foetal fibronectin test, varying from zero to £300. Scenario analyses tested various alternative assumptions.

Results
The foetal fibronectin test was estimated to have an overall sensitivity of 60.8% and specificity of 85.3%; it was most sensitive at predicting preterm births within seven to 10 days of testing. There were no significant differences between the two groups in the incidence of preterm birth, incidence of hospital admissions, and administration of treatment. One trial estimated that the foetal fibronectin test reduced hospital stay by 40%.

The main cost analysis estimated £599.53 for usual care and £575.65 with testing, indicating that the test could save £23.88 compared with usual care alone.

The results were most sensitive to changes in the admission rates in the one-way sensitivity analysis. The probabilistic sensitivity analysis estimated that testing could save £25.58 (95% CI -304.96 to 240.06). Testing was estimated to be cost neutral at a test price of around £45.

Authors' conclusions
The authors concluded that the foetal fibronectin test was moderately accurate and could reduce health care costs by reducing hospital admissions, but the results were highly uncertain.

CRD commentary
Interventions:
Both the intervention and usual care were clearly described. The authors stated that two forms of the foetal fibronectin test were available; they focused on rapid testing as they considered it to be more practical than the enzyme-linked immunosorbent assay, which delivered results after four to 48 hours. For a full assessment, data on the accuracy and cost of this other test are needed.

Effectiveness/benefits:
The systematic review was well reported and used appropriate methods. It is likely that the best available evidence was identified, but the authors noted that these trials were of unknown or poor quality, so there was a risk of bias in the results. The authors also stated that the trials were generally underpowered, which reduces the ability to identify any differences between the two groups.

Costs:
The perspective was clearly stated and all the relevant costs appear to have been included. The resource use estimates seem appropriate and the data sources were relevant and appropriate for a UK setting. The results indicated that foetal fibronectin testing could save costs if it reduced the hospital admissions. The authors highlighted the considerable uncertainty around the impact of the test on admission rates, as well as the cost of the test, making the results very uncertain. They stated that the impact of the test on admissions and treatment depended on the weight placed on the its results by clinicians in conjunction with other information such as signs, symptoms and physical examination.

Analysis and results:
The analytic approach was clearly described, with clear reasoning for not undertaking a full cost-effectiveness analysis; no indication of an impact on effectiveness. The model was clearly described and a diagram was presented. The results were clearly presented and uncertainty was adequately assessed using appropriate techniques.
Concluding remarks:
The study was well reported and used valid methods. The authors highlighted the significant uncertainty in the results.

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