Healthcare evaluation of the use of atosiban and fibronectin for the management of pre-term labour

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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
This study investigated the cost-effectiveness of foetal fibronectin testing and an oxytocin-receptor antagonist, atosiban, compared with foetal fibronectin testing then nifedipine or nifedipine alone, to prevent labour in women at risk of pre-term delivery. The authors concluded that foetal fibronectin then atosiban could produce significant cost savings over nifedipine; testing then nifedipine was cheaper, but less safe. There was weak evidence of effectiveness and safety and no consideration of uncertainty, and the authors’ conclusion should be viewed with caution.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The aim was to assess the safety, effectiveness, acceptability, and efficiency of foetal fibronectin testing to triage women at risk of pre-term labour, with atosiban to delay or inhibit labour. The hypothetical cohort contained pregnant women with threatened pre-term labour at 24 to 34 weeks gestation, showing no signs of maternal or foetal compromise, and with intact membranes.

Interventions
Three options were compared; foetal fibronectin testing then atosiban; nifedipine; and foetal fibronectin testing then nifedipine. Nifedipine, a calcium antagonist, was commonly used to prevent contractions in pre-term pregnancy, while atosiban was an oxytocin-receptor antagonist. Foetal fibronectin, a glycoprotein, was successfully used to predict pre-term delivery. Atosiban up to a total of nine vials was compared with five tablets of nifedipine.

Location/setting
UK/out-patient care.

Methods
Analytical approach:
A decision tree was used to synthesise the published data from randomised trials and systematic reviews. The analysis covered one year. The authors did not state the study perspective.

Effectiveness data:
The efficacy of atosiban was measured by the number of patients who had not delivered after seven days. The risk of foetal distress, risk of nausea, risk of in-utero hospital transfer, and risk of caesarean section for foetal distress were key clinical inputs. Nifedipine was assumed to have equal effectiveness to atosiban as there was no reliable evidence comparing nifedipine with either placebo or atosiban. The probabilities of adverse events were from observational data. The clinical event data were from a selection of relevant randomised trials and reviews.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
There was no single measure of benefit. The authors looked for evidence of the number of patients who had not delivered after seven days, and safety outcomes, such as the risk of foetal distress, and the risk of caesarean section.
Cost data:
The direct medical costs were those of foetal fibronectin testing, atosiban, nifedipine, betamethasone given before in-utero transfer, antiemetics, antenatal ward admissions, and caesarean sections. The cost estimates for caesarean section were from a previous study, and personal communication was used to estimate the cost of in-utero transfer. The unit costs were provided and reported in UK pounds sterling (£).

Analysis of uncertainty:
Not reported.

Results
For 188 patients treated, the total cost was £52,083 with foetal fibronectin then atosiban, compared with £272,756 for nifedipine, and £42,923 for foetal fibronectin then nifedipine.

Foetal fibronectin then atosiban produced a cost saving of £220,673 per annum (£1,174 mean per patient) over nifedipine. Foetal fibronectin then nifedipine produced a cost saving of £9,160 per annum (£49 mean per patient) over foetal fibronectin then atosiban.

The authors assumed equal effectiveness between atosiban and nifedipine, but nifedipine had a higher risk of foetal distress than atosiban.

Authors’ conclusions
The authors concluded that foetal fibronectin testing then atosiban could be safer and more acceptable than foetal fibronectin then nifedipine or nifedipine alone, and it generated significant cost savings over nifedipine. Foetal fibronectin then nifedipine could be marginally cheaper, but this might be off-set by the costs of its reduced safety.

CRD commentary
Interventions:
The authors chose specific strategies for the management of pre-term labour and it was unclear why other agents, such as ritodrine, were omitted. The dosages were not provided. These options might be appropriate comparators in other settings.

Effectiveness/benefits:
All the inputs and data sources were clearly documented. The authors assumed that the effectiveness of the two treatments was equal, given a lack of evidence. The safety data were observational and the benefit of atosiban was based on these data.

Costs:
The study perspective was not stated, but the direct medical costs were analysed. There was no description of how the resource types were valued, and the sources for many of the unit costs were not reported. The price year was not stated and there was no evidence that a single cost year was used.

Analysis and results:
The model type and structure were illustrated. The clinical benefits from the economic model were not explicitly stated. The cost and effect outcomes were not synthesised into incremental cost-effectiveness ratios and a cost-consequences analysis was reported. No sensitivity analysis results were given, but the authors stated that there was uncertainty over some variables, especially and most importantly the effectiveness estimates between the three strategies. The model results were very brief, which is most likely to have been because the authors focused on the effectiveness, safety and acceptability results.

Concluding remarks:
Given the weak evidence for the effectiveness and safety of atosiban and nifedipine and the lack of consideration of uncertainty in the results, the conclusion reached by the authors should be viewed with caution.
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