The cost-effectiveness of outpatient (at home) cervical ripening with isosorbide mononitrate prior to induction of labour

Eddama O, Petrou S, Schroeder L, Bollapragada SS, Mackenzie F, Norrie J, Reid M, Norman JE

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 examined the cost-effectiveness of out-patient (at home) cervical ripening with isosorbide mononitrate, prior to the induction of labour, in comparison with no intervention in nulliparous women with a singleton pregnancy. The authors concluded that isosorbide mononitrate was likely to be cost-effective from the perspective of the National Health Service, but the reduction in the hospital admission to delivery interval was not significant. The methodology was valid and this should ensure the validity of the authors’ conclusions.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to examine the cost-effectiveness of out-patient (at home) cervical ripening with isosorbide mononitrate prior to the induction of labour, in comparison with no intervention, in nulliparous women with a singleton pregnancy and a cephalic presentation at 37 or more weeks of gestation.

Interventions
The intervention was out-patient pre-induction cervical ripening with isosorbide mononitrate 40mg, compared with no intervention. The isosorbide mononitrate was self-administered vaginally at home at 48, 32, and 16 hours prior to the scheduled time of admission for induction.

Location/setting
UK/maternity hospital and community (home).

Methods
Analytical approach:
The analysis was based on a single study with a short time horizon. The authors stated that the analysis was carried out from the perspective of the health system, which was the UK National Health Service (NHS).

Effectiveness data:
The clinical data came from a published randomised controlled trial (RCT), namely the Isosorbide MOnonitrate against Placebo (IMOP) trial, which involved 350 women at a single institution between March 2005 and December 2006. There were 177 women in the isosorbide mononitrate group and 173 women in the placebo group. Women were followed up until delivery or possible neonatal admission to special care. The key clinical outcome was the time interval from hospital admission to delivery.

Monetary benefit and utility valuations:
Not considered.

Measure of benefit:
The benefit measure was the reduction in the time between hospital admission and delivery, expressed in hours.

Cost data:
The economic analysis considered the costs of labour induction, labour procedures, and both maternal and neonatal
complications, including medical and nursing staff, equipment, consumables, revenue and capital overheads, and drugs. The resource use data were collected alongside the RCT, using specific collection forms. The unit costs came from various sources, including the hospital finance department and Department of Health Reference Costs. All costs were in UK pounds sterling (£) and the price year was 2007. Conventional tools were used to test the statistical significance of the cost differences.

Analysis of uncertainty:
Non-parametric bootstrapping was used to generate confidence intervals (CIs) around the mean costs, benefits, and cost-effectiveness ratios. A sensitivity analysis was carried out on the occupancy rates for maternity care and the per day costs for both maternity and neonatal care. Alternative assumptions were based on the hospital database and the ranges of costs were from the Department of Health.

Results
The total NHS costs were £1,254.86 (SD 625.26) in the isosorbide mononitrate group and £1,242.88 (SD 487.56) in the placebo group. This difference was not statistically significant. Isosorbide mononitrate reduced the costs of the prenatal assessment ward, but increased the costs of neonatal care.

Isosorbide mononitrate reduced the hospital admission to delivery interval by an average of 1.6 hours (95% CI -1.9 to 5.1) in comparison with placebo. The differences in most of the other clinical endpoints, such as caesarean sections and epidural usage, were not statistically significant.

The incremental cost per hour reduction in the interval from hospital admission to delivery with isosorbide mononitrate over placebo was £7.53. There was high variability around this cost-effectiveness estimate. The cost-effectiveness acceptability curves showed that, at a willingness-to-pay threshold of £100 per hour, the probability that isosorbide mononitrate was cost-effective was 0.67 and at a threshold of £1,000 per hour it was 0.77.

The sensitivity analysis indicated that the maximum estimate of the incremental cost-effectiveness ratio was £12.68. A net benefit analysis was conducted assuming different willingness-to-pay thresholds for an hour reduction in the time between hospital admission and delivery. A positive net benefit was found for values as low as £40 per hour.

Authors' conclusions
The authors concluded that isosorbide mononitrate was likely to be cost-effective from the perspective of the NHS, but the reduction in the hospital admission to delivery interval was not significant. They recommended further research to confirm these findings.

CRD commentary
Interventions:
The selection of the comparators was appropriate. The choice of no intervention as the comparator allowed the assessment of the additional economic and clinical value of the intervention.

Effectiveness/benefits:
The clinical analysis was based on a RCT, which is usually considered to be a valid source of evidence due to the strengths of its design. Limited information on the methods of the trial was reported as it had been published elsewhere. Two strong points were the baseline comparability of the study groups and the use of intention-to-treat analysis. The authors stated that the sample size was appropriate for their objective. The benefit measure was disease-specific and will not be comparable with the benefits of other health care interventions. It was an intermediate outcome of the intervention.

Costs:
The analysis of costs was consistent with the perspective in terms of the cost categories and the sources of data. Some unit costs and resource quantities were reported separately. On the whole, the reporting of the data was satisfactory, which improves the transparency of the analysis. The use of statistical tests enhances the validity of the cost analysis. The use of non-parametric bootstrapping was appropriate, given that the costs were skewed. The price year was reported.
Analysis and results:
The costs and benefits were clearly presented and were appropriately synthesised, using an incremental approach. The issue of uncertainty was satisfactorily investigated. The impact of variations in the key outcomes was considered in a deterministic analysis. In general, the results were well presented and discussed. A strong feature of the analysis was the use of the intention-to-treat principle for the clinical and economic outcomes. The authors stated that a societal perspective would have been interesting, given the potential costs to families for the different delivery methods.

Concluding remarks:
The methodology was valid and this should ensure the validity of the authors’ conclusions.

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