A cost-minimization analysis of intracervical prostaglandin E2 for cervical ripening in an outpatient versus inpatient setting
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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.

Health technology
Prostaglandin E2 (PGE2) gel delivered intracervically on an outpatient basis.

Type of intervention
Treatment; primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Pregnant women with a singleton gestation beyond 37 weeks of gestational age and having a Bishop score less than or equal to 4. The patients eligible for entry into the study had to have access to a telephone and reside within the metropolitan area. Also, an electronic monitoring of fetal heart rate (FHR) and uterine activity had to show evidence of a ‘reassuring FHR pattern (reactive nonstress test)’, and of mild uterine contractions with a frequency of at most every 5 minutes. Historical controls were used as the comparator study population.

Setting
Primary care and hospital. The study was carried out in Oklahoma City, Oklahoma, USA.

Dates to which data relate
The data for the effectiveness analysis and resources used were collected between November 1993 and February 1995 for the intervention. The corresponding data for the control group were collected between September 1992 and November 1993. The prices used were from 1996.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were reported: power of 0.80 for a hypothesised cost difference of 25% between groups and a 0.05 critical p value (the control group having a standard deviation of 40%). 40 patients were included in the intervention group and 36 in the control group.
Study design
A case- (historical) control study design was used. The study was based in a single centre. The duration of follow-up was until hospital discharge. No dropouts occurred.

Analysis of effectiveness
The primary health outcomes used were as follows: oxytocin need (percentages of patients), mean oxytocin requirement in terms of dose (mU per minute) and duration (hours), mean duration of first stage (hours), route of delivery (either vaginal or cesarean section), duration from PGE2 instillation to delivery (hours) and total time of hospitalisation related to delivery. The groups were shown to be comparable in terms of maternal age, race, parity, gestational age, maternal weight, pre-dose Bishop score and reason for induction.

Effectiveness results
The oxytocin need difference had a p value of 0.26; the oxytocin maximum dose received in mU per minute was 13.5 in the intervention and 12.5 in the control, (p=0.45); the duration in hours were 14.8 and 14.7, respectively, (p=0.9); the duration of first stage in hours was 8.0 and 8.8, respectively, (p=0.5); the route of delivery was vaginal in 65% and 69% of the patients, respectively (p value of the difference was 0.6); and the duration of PGE2 instillation to delivery in hours was 35.1 and 35.3, respectively (p=0.9).

Measure of benefits used in the economic analysis
Since the effectiveness analysis showed no difference in clinical benefit between the intervention and the comparator, the economic analysis was based on the difference in costs only.

Direct costs
Only some quantities were reported. The costs measured were operating costs (labour, delivery and drug costs). The cost boundary adopted was the hospital (described by the authors as ‘third party payers’). The costs estimates were based on actual data. The source of data was the institution's files. The quantities were measured between September 1992 and November 1993, for the control group and between November 1993 and February 1995 for the intervention group. The prices used were the fees in the institution in 1996. The costs excluded were those associated with infant charges. Charges were used as a proxy for actual costs.

Statistical analysis of costs
T-tests and ‘p values' were calculated for the length of hospitalisation and total costs.

Indirect Costs
Not done.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Not applicable.
Cost results
The average total hours of hospitalisation was 74.4 in the intervention (outpatient) group and 100.3 in the control (inpatient) group, (p=0.003). The mean total costs in the intervention group were $3,835. The mean total costs in the comparator group were $5,049. The p value of the difference was 0.015.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
The authors concluded that the research "demonstrated in a select group of outpatient-eligible individuals that significant cost savings can be achieved by administering PGE2 gel in the outpatient setting for pre-induction cervical ripening ... The cost savings were highly correlated with the reduction of time spent in the hospital and also seen with lower costs associated with labor in the outpatient group".

CRD COMMENTARY - Selection of comparators
The reason for the choice of comparator is clear. Prostaglandin E2 with one or more doses of 0.5 mg received intracervically by the patient on an outpatient basis was defined as the comparator.

Validity of estimate of measure of benefit
The estimate of measure of benefit is likely to present important biases arising from the retrospective nature of the study and its historical controls. A randomised clinical trial would be desirable in order to avoid potential biases not known ex ante. The power calculations were related with a hypothesised cost difference and not with respect to clinical outcome differences due to previous studies reporting similar clinical benefits arising from both strategies. Therefore, the validity of the clinical benefit results would best be calculated from analyses of those previously published studies (references 3 to 10 and 18 in the paper).

Validity of estimate of costs
Charges were used as a proxy of costs and, consequently, only some quantities were reported separately from the prices. The costs (charges) of infants were excluded because they were common to both strategies.

Other issues
The authors' conclusions were justified only given that the strategies are truly equivalent in terms of clinical benefits. The issue of generalisability was only partially addressed in terms of the entry criteria. No comparisons were made with other studies apart from reporting previously published clinical results as the basis for the choice of study type (cost-minimisation). The results were not presented selectively.

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