Labor induction with prostaglandin E-1 misoprostol compared with dinoprostone vaginal insert: a randomized trial

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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
The drug misoprostol, a prostaglandin E1 analogue for cervical ripening and labour induction.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Women who satisfied the following criteria were asked to participate:

(1) obstetric indications for labour induction,
(2) medical complications,
(3) absence of active labour or fetal distress,
(4) no previous caesarean delivery,
(5) singleton pregnancy with vertex presentation and no contraindications to vaginal delivery.

Setting
Hospital. The study was carried out at the University Medical Center, Jacksonville, Florida, USA.

Dates to which data relate
Effectiveness and resource data were collected between 1 February and 30 October 1996. The price year was 1996.

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

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

Study sample
Among the 337 women who presented for labour induction, 114 were ineligible. A total of 223 patients met the criteria and were randomly assigned to the misoprostol group (n=108) and the dinoprostone group (n=115). The sample-size calculation was based on a two-sided test of significance with alpha of 0.05 and beta of 0.2. 214 patients (107 per group) provided 80% power to detect a 35% difference between the proportion of patients who delivered vaginally within 12 hours. This was based on estimated success rates of 60% for misoprostol and 40% for dinoprostone.

**Study design**

The study was a prospective randomised controlled trial carried out at a single centre. Subjects were assigned to the two groups by means of a computer-generated randomisation table. Physicians responsible for intrapartum management were not blinded formally to study group allocation.

**Analysis of effectiveness**

The analysis of the clinical study was based on the intention to treat principle. The primary health outcomes included the interval from induction to vaginal delivery, the percentage of vaginal delivery within 12 and 24 hours of ripening, the percentage of uterine tachysystole, intrapartum complication rate, the mode of delivery, and the percentage of neonatal or maternal adverse outcomes. At analysis, groups were shown to be comparable in terms of patient age, parity, gestational age, weight, Bishop score, race and indications for labour induction.

**Effectiveness results**

43 patients in the misoprostol group and 79 patients in the dinoprostone group required oxytocin to reach the active phase of labour (p<0.001). Increased uterine activity prompted the removal of the vaginal insert or misoprostol tablet in 16 and 11 patients, respectively. The interval from start of induction to delivery (overall) and vaginal delivery was significantly (p<0.001) shorter in the misoprostol group (699 minutes (range: 395 - 1053) and 698 minutes (range: 395 - 1053)) than in the dinoprostone group (1053 minutes (range: 780 - 1590) and 1041 minutes (range: 792 - 1531)). The incidence of successful inductions was significantly (p<0.001) higher in the misoprostol group (98%) compared with the dinoprostone group (77%). 44% of patients in the misoprostol group delivered vaginally within 12 hours compared with 22% of patients in the dinoprostone group (p<0.001). Tachysystole occurred more frequently in the misoprostol group (21.3%) than in the dinoprostone group (7%), (p<0.004). 62% of operative vaginal deliveries in the misoprostol group were due to abnormalities in the FHR pattern, compared with 46.7% in the dinoprostone group, (p=0.51). No significant differences between the groups were noted in terms of mode of delivery, frequency of scalp pH sampling, incidence of hyperstimulation, birth weights, cord pH values or abnormal Apgar scores.

**Clinical conclusions**

Intravaginal misoprostol and dinoprostone vaginal insert appear to be safe agents for cervical ripening and labour induction.

**Modelling**

No modelling was undertaken.

**Measure of benefits used in the economic analysis**

No summary benefit measure was put forward by the authors. Therefore, this study can be classified as a cost-consequences analysis.

**Direct costs**

Costs were not discounted given the short time frame of the study (less than 1 year). Quantities and costs were not reported separately. The direct cost estimate included the induction agent costs. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. The price year was 1996.
Statistical analysis of costs
Not reported.

Indirect Costs
Not included.

Currency
US dollars ($)

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
No summary benefit measure was used by the authors. Therefore, the benefits were assumed to be equal to the effectiveness results.

Cost results
Induction agent costs averaged $85 per patient receiving misoprostol and $606 per patient receiving the dinoprostone vaginal insert.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
Intravaginal misoprostol and dinoprostone vaginal insert appear to be safe agents for cervical ripening and labour induction. However, misoprostol is less expensive and more effective than the dinoprostone vaginal insert.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear.

Validity of estimate of measure of effectiveness
Although power calculations were carried out to detect a reduction in the induction to labour period, the study was neither designed nor had the power to compare caesarean delivery rates by type of PG administered. There was no follow-up of the patients. Physicians responsible for intrapartum management were not blinded. Therefore, differential intrapartum management could have biased the results.

Validity of estimate of costs
Only the induction agent costs were included. Other intervention costs were not examined. Resource quantities were regrettably not presented separately from the cost figures, thus limiting the generalisability of the results. No sensitivity analysis was carried out.

Other issues
The robustness and generalisability of the results to other settings were not examined.

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None stated.
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Other publications of related interest


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