Effectiveness and infectious morbidity of outpatient cervical ripening with a Foley catheter

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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
Pregnant women in an outpatient setting who were going to have their labour induced in the morning were given a Foley catheter the preceding evening in order to ripen the cervix. After a nonstress test, and confirmation of cephalic presentation, a 16-French Foley catheter was placed in the endocervical canal with 30 mL sterile normal saline. The comparator group of women had the same procedure performed in an inpatient setting and underwent continuous foetal monitoring until the initiation of labour the following morning.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised pregnant women whose labour was going to be induced the following day.

Setting
The setting was secondary care, inpatient and outpatient settings. The economic study was carried out in Ohio, USA.

Dates to which data relate
The effectiveness evidence related to 1994 to 1999. The dates for the resource evidence were not reported. The price year was also not reported.

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

Link between effectiveness and cost data
The costing was carried out retrospectively. It was unclear whether actual patient data were used to derive the cost estimates, or whether they were obtained from the standard hospital charges for the two kinds of procedures.

Study sample
The authors reported power calculations that were apparently carried out after the study. The power to detect a significant difference with an alpha value of 0.05 and a beta value of 0.2 was 30% for successful cervical ripening, 6% for combined infectious morbidity, 46% for maternal infectious morbidity and 54% for neonatal infectious morbidity. In order to attain significance (alpha = 0.05, beta = 0.20), the number of patients required in each group would be 1,500 (successful cervical ripening), 16,433 (combined infectious morbidity), 711 (maternal infectious morbidity) and...
566 (neonatal infectious morbidity), respectively. There were 315 women in the inpatient group and 300 women in the outpatient group.

**Study design**
This was a retrospective, case-control study that was carried out in a single centre. The patients were followed up until hospital discharge and until readmission when it occurred.

**Analysis of effectiveness**
The basis of the analysis was intention to treat. The primary health outcomes used were:

- the percentage of women achieving a vaginal delivery,
- the percentage of women attempting and achieving a vaginal birth having had a Caesarean delivery (VBAC),
- the neonatal and maternal infectious morbidity, and
- the number of readmissions.

The women in the two groups were not comparable in terms of the reason for their induction. The most common reasons were post-term and diabetes in the outpatient group, and preeclampsia and oligohydramnios in the inpatient group. There was a significantly greater number of parous women in the inpatient group (58.4% versus 48.5%; p=0.02), while the weight of women in the outpatient group was significantly higher (93.5 +/- 23.4 kg versus 89.5 +/- 23.1 kg; p=0.03). The groups were comparable in terms of age, race and gestational age. Logistic regression was used to account for differences between the two patient groups.

**Effectiveness results**
A total of 28.3% of the inpatient group and 33.2% of the outpatient group had Caesarean deliveries, (p=0.2).

For attempts at VBAC, the rate was 13.7% in the inpatient group and 17.6% in the outpatient group, (p=0.2).

The success rate of VBAC was 70% in the inpatient group and 38% in the outpatient group, (p= 0.002).

Maternal febrile morbidity was 6.4% in the inpatient group and 10.3% in the outpatient group, (p=0.08).

There were 7 readmissions, all in the inpatient group.

The rate of neonatal infectious morbidity was 4.8% in the inpatient group and 2.3% in the outpatient group, (p=0.13).

When maternal and neonatal infectious morbidity were combined, the rate was 10.5% for the inpatient group and 12.0% for the outpatient group, (p=0.61).

The logistic regression did not show any significant difference between the two patient groups in terms of vaginal delivery and infectious morbidity.

**Clinical conclusions**
There were no statistically significant differences between the two patient groups in terms of the success rate in achieving a vaginal delivery and infectious morbidity for both mothers and infants.

**Modelling**
Logistic regression, to allow for confounding variables, was used to assess the effect of the location of cervical ripening on whether a vaginal delivery occurred and on the level of maternal morbidity.
Measure of benefits used in the economic analysis
No summary measure of benefits was produced. As such, the authors carried out a cost-consequences analysis.

Direct costs
No discounting was carried out as the costs were incurred during less than one year. The costs and the quantities were not reported separately. The estimated costs were derived from the hospital charge rates for different components of delivering a baby, rather than the actual charges faced by individual patients. The costs of a nonstress test, an hour of outpatient triage and 1 day's hospital charges for labour and delivery were given. Thus, the difference in costs between the two kinds of cervical ripening was defined as 1 day's hospital charges for labour and delivery admission. No price year was given.

Statistical analysis of costs
No sensitivity analysis of the costs was carried out.

Indirect Costs
No indirect costs were included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The cost per labour and delivery was $750 with outpatient cervical ripening with a Foley catheter versus $1,300 with inpatient cervical ripening. The incremental cost of inpatient cervical ripening was $550.

Synthesis of costs and benefits
The costs and benefits were not combined as the study was, in effect, a cost-consequences analysis.

Authors' conclusions
Outpatient cervical ripening with a Foley catheter was just as successful as inpatient cervical ripening at obtaining vaginal deliveries, and it did not result in worse health outcomes for the mothers or infants. Outpatient cervical ripening also reduced the costs.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was justified by it being commonly used. You should decide if it is widely used in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a single study. The study design is associated with a number of limitations in relation to testing the stated hypothesis, as it was not a randomised controlled trial and there was no way of determining how women had been selected for the two kinds of cervical ripening. The study sample was representative of the study population for that hospital, described as "primarily indigent", as there was no sample selection described. It should also be noted that the patient groups were not comparable at baseline in several respects. However, to address this issue, the authors carried out a logistic regression to account for differences between the patient groups, and calculated odds ratios for the key effectiveness variables.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The health benefits are therefore those associated with the effectiveness outcomes.

**Validity of estimate of costs**
From the cost perspective adopted (i.e. the hospital), not all of the relevant categories of costs were included, as the authors calculated theoretical costs for cases where there were no complications and the mothers did not stay more than a day after delivery. Omissions are likely to have affected the authors' conclusions. The costs were not reported separately from the quantities, although the unit costs for three cost components were included. The resource use quantities were theoretical, and no analysis of any kind was carried out on them. The unit costs were taken from the authors' setting. No statistical analysis, sensitivity analysis, or any other kind of analysis was carried out of the prices. Charges were used to proxy unit costs (the reader should note that charges do not reflect true opportunity costs) and no date for the prices was reported. Thus, the cost results need to be treated with some caution.

**Other issues**
The authors compared their results with the findings from other studies. The issue of generalisability was not addressed. The authors did not present their results selectively, but their conclusions did not reflect the scope of the analysis. The authors seem to have been unaware of the defects of their cost analysis, as described above. They were aware of the drawbacks of the noncomparability of the patient groups, but argued that their logistic regression dealt with the problem. They were also aware that the number of patients was insufficient to exclude Type II error, so there might be important differences between the two patient groups.

**Implications of the study**
The authors concluded that outpatient cervical ripening does not harm mothers or newborns, and it reduces the costs. This conclusion seems stronger than the data would justify, given the lack of comparability of the patient groups, the insufficient cost data and the inadequate study sample size.

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