External cephalic version with epidural anaesthesia after failure of a first trial with beta-mimetics

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
External cephalic version under epidural anaesthesia and beta-mimetic tocolysis after the failure of an initial attempt with tocolysis alone in women with breech presentation.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Women with breech presentation at around 36 weeks of gestation, who had an initial failed attempt with tocolysis alone and who consented to try a second attempt under epidural anaesthesia. The exclusion criteria were as follows: placenta praevia, premature rupture of the membranes, prior caesarean section or signs of foetal distress.

Setting
Hospital. The economic study was carried out in France.

Dates to which data relate
Effectiveness and resource use data corresponded to women treated between October 1995 and March 1998. The price year appears to be 1998.

Source of effectiveness data
The evidence for the final clinical outcomes was derived from a single study.

Link between effectiveness and cost data
Costing was retrospectively undertaken on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 68 patients (out of 73) with breech presentation and a mean (SD) age of 28.6 (3.8) years who agreed to a second attempt at external cephalic version under epidural anaesthesia. (Initially 169 patients out of 171 (3.1% of 5453 births) with breech presentation agreed to undergo an attempt at external cephalic version under salbutamol).
Study design
This was a pragmatic prospective cohort study, carried out in a single centre. The duration of the follow-up appears to have been until discharge from hospital after delivery. The study appears to have had no loss to follow-up. The initial external version was attempted using intravenous salbutamol (200 miug in 30 minutes) on patients with a breech presentation between weeks 36 and 37.

Analysis of effectiveness
The principle used in the analysis of effectiveness appears to have been intention to treat. The main health outcomes were the global success rate, and complications. The success rates were also reported for subgroups of patients such as multiparas versus nulliparas, women weighing 70 kg or over versus those weighing less than 70 kg, and women with incomplete breech presentations. Obstetric and neonatal outcomes (such as rate of caesarean delivery, 5-minute Apgar score of at least 7 for newborns, pH less than 7.20, birth weight (g), and length of hospitalisation (days)) were also reported according to whether the external cephalic version (ECV) with epidural anaesthesia was successful.

Effectiveness results
The effectiveness results were as follows:

The global success rate under epidural anaesthesia was 39.7% (27/68). There were two cases of complications, one case of inadvertent dural puncture and one case of moderate bleeding occurring the day after the version.

The success rate was 68.4% among multiparas compared with only 28.6% among nulliparas (p=0.002).

The success rate for women 70 kg or over was 36% compared with 64% for women weighing less than 70 kg (p=0.004).

The success rate for women with incomplete breech presentations was 42% versus 15.4% for those with complete breech presentation (p=0.07).

The rate of caesarean section was 7.4% for the ECV success group versus 46.3% for the ECV failure group (p=0.0007).

All newborns in both ECV success and failure groups had a 5-minute Apgar score of at least 7.

The rate of pH less than 7.20 for the ECV success group was 11.1% and for the ECV failure group was 9.7% (p=0.85).

The mean (SD) birthweight was 3,181 (315) g in the ECV success group versus 3,207 (506) in the ECV failure group (p=0.81).

The corresponding values in terms of length of hospitalisation were 4.6 (1.3) for the ECV success group and 5.4 (1.5) for the ECV failure group (p=0.04).

Clinical conclusions
While the efficacy of this procedure is now clear, its safety cannot yet be prudently affirmed. The aggressive manipulation made possible by analgesia may increase the risk of Rhesus iso-immunisation, placenta abruption, prolapsed cord, premature rupture of membranes, and rupture of the uterus. Although the two complications in this study ended well, the marginal placental separation could have had a more dramatic outcome.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Some quantities were reported separately from the costs. Cost items were reported separately. Cost analysis covered the costs of obstetrical procedures (medical and non-medical personnel, medical supplies, drugs, laboratory tests, equipment, and overhead costs) and hospitalisation. The costing was based on accounting sheets provided by the hospital administration and the activity data from the clinical and technical departments. Costs were calculated by using the hospital's accounting system and the diagnosis-related groups (DRG) system. The cost data were based on local and national sources. The perspective adopted in the cost analysis was that of the hospital. The price year appears to have been 1998. It was not reported that any adjustments were made for inflation. The costs of subsequent hospitalisation and complications were not included in the cost analysis.

**Indirect Costs**
Not included.

**Currency**
French francs (Ffr). The exchange rate in 1998 was 1 = Ffr10.

**Sensitivity analysis**
Not conducted.

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
The cost of a successful ECV birth was Ffr 22,308 versus Ffr 25,954 for unsuccessful ECV birth. The mean cost of delivery with no second ECV attempt was estimated to be Ffr 21,187 based on the mean prevalence of caesarean sections for breech presentation of 75% and on the French diagnosis-related groups. Given probabilities of 57% for initial ECV success, 16% for second ECV success and 27% for ECV failure, the average weighted cost for attempted cephalic version was Ffr 13,204 compared with Ffr 23,138 for routine caesarean sections, without any trial of labour.

**Synthesis of costs and benefits**
Not combined.

**Authors’ conclusions**
The efficacy of external cephalic version under epidural reduces the rate of caesarean sections associated with breech presentation, but its relative safety remains in question. Moreover, this study's economic analysis discourages the hope of lowered costs suggested by earlier reports that this technique is more expensive than expectant management, except in institutions with a policy of systematic caesarean sections when version fails.

**CRD COMMENTARY - Selection of comparators**
No explicit justification was provided for the choice of the comparator (expectant management), however it appears to be the routine procedure in the context in question.

**Validity of estimate of measure of effectiveness**
As the authors acknowledge, the internal validity of the effectiveness results can not be guaranteed due to the lack of a control group comprising women who did not undergo ECV with epidural analgesia. The patient sample appears to have been representative of the study population.
Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The economic analysis was therefore of cost-consequences design.

Validity of estimate of costs
Some quantities were reported separately from the costs. Adequate details of methods of cost estimation were given. The exclusion of the cost of subsequent hospitalisation and complications may have adversely affected the internal validity of the cost analysis. Cost results may not be generalisable to other settings or countries. Although the price year was not explicitly stated it appears to have been 1998. No adjustment appears to have been made for inflation. The effects of the alternative strategies on indirect costs (productivity loss) were not analysed. The conversion rate from French currency to pounds sterling was reported. Some statistical analysis was performed on resource use data for subgroups of patients.

Other issues
Given the main limitation of the study design (the lack of a proper control group) and the lack of sensitivity analysis and statistical analysis of costs, some degree of caution may need to be exercised in the interpretation of the study results. The issue of generalisability to other settings or countries was not addressed. Appropriate comparisons were made with other studies. The study sample consisted of women with breech presentation at around 36 weeks of gestation, who had an initial failed attempt with tocolysis alone, and who consented to undergo a second attempt under epidural anaesthesia, and the authors' general comments appears to reflect this. The authors acknowledge that cost-utility analysis may have been a more appropriate framework in which to conduct the economic analysis, given the involvement of the mothers' quality of life due to averted caesarean deliveries.

Implications of the study
It would be premature to introduce this technique into routine practice: it must continue to be tested in large-scale trials in order to clarify the morbidity associated with the new technique. Additional information about quality of life should be collected to document the non-monetary nature of the gain from avoided caesarean sections.

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