Cost-effectiveness of a trial of labour after previous Cesarean

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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
Vaginal birth after Caesarean delivery (VBAC) was compared with Caesarean delivery in women who had already had one low transverse Caesarean delivery.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised a hypothetical 30-year-old parturient who had undergone one low transverse Caesarean delivery.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness data were derived from studies published between 1981 and 1999. Several dates for resource use were reported. The price year was 2000.

Source of effectiveness data
The effectiveness evidence came from a review of published studies and the authors' assumptions.

Modelling
A decision tree model was constructed to estimate the clinical outcomes and the costs of the two delivery strategies in a hypothetical 30-year pregnant woman. The time horizon of the model was not reported. The model focused on maternal and neonatal outcomes (equally weighted) and was presented graphically.

Outcomes assessed in the review
Maternal and neonatal outcomes were assessed for a successful trial of labour, a failed trial of labour-Caesarean delivery and an elective repeat Caesarean delivery. The maternal outcomes included infection, haemorrhage, thrombotic events, urinary incontinence, faecal incontinence, uterine rupture, hysterectomy, operative injury, and maternal mortality. The neonatal outcomes were categorised as none/mild morbidity, moderate morbidity, severe morbidity and neonatal mortality.
Study designs and other criteria for inclusion in the review
Not reported. The authors stated that the review included trials regardless of whether they were controlled or randomised.

Sources searched to identify primary studies
MEDLINE was searched systematically from 1976 to 1999. The keywords used were "VBAC", "uterine rupture", "trial of labor", "cesarean delivery", "cesarean section" and "repeat cesarean section". Only English-language studies were included. The references from the retrieved studies were also reviewed.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
The effectiveness evidence was obtained from 24 primary studies.

Methods of combining primary studies
Estimates from the primary studies were combined with adjustments for the sample of patients included in each study, in order to give more weight to the more numerous studies.

Investigation of differences between primary studies
Not stated.

Results of the review
For the maternal outcomes, the mean incidence rates were as follows:

- for infection, 3.4% (range: 3.40 - 3.47) in the successful trial of labour group, 19% (range: 11.3 - 27.1) in the failed trial of labour-Caesarean delivery group, and 7.5% (range: 2.3 - 17.3) in the elective repeat Caesarean delivery group;
- for haemorrhage, 1.2% (range: 0.92 - 5.9) in the successful trial of labour group, 2.1% (range: 1.4 - 14.8) in the failed trial of labour-Caesarean delivery group, and 2.4% (range: 1.4 - 10.4) in the elective repeat Caesarean delivery group;
- for thrombotic events, 0.02% (range: 0.02 - 0.04) in the successful trial of labour group, 0.08% (range: 0.03 - 0.12) in the failed trial of labour-Caesarean delivery group, and 0.07% (range: 0.02 - 0.07) in the elective repeat Caesarean delivery group;
- for urinary incontinence, 2% (range: 1 - 4.4) in the successful trial of labour group, 0.6% (range: 0 - 2) in the failed trial of labour-Caesarean delivery group, and 0% in the elective repeat Caesarean delivery group;
- for faecal incontinence, 1.3% (range: 1 - 2) in the successful trial of labour group, 1.8% (range: 1.3 - 2) in the failed trial of labour-Caesarean delivery group, and 0% in the elective repeat Caesarean delivery group;
- for uterine rupture, 0.047% (range: 0 - 1.22) in the successful trial of labour group, 1.9% (range: 0.6 - 4.4) in the failed trial of labour-Caesarean delivery group, and 0.085% (range: 0 - 0.36) in the elective repeat Caesarean delivery group;
- for hysterectomy, 0.02% (range: 0 - 1.22) in the successful trial of labour group, 0.4% (range: 0 - 0.47) in the failed trial of labour-Caesarean delivery group, and 0.39% (range: 0 - 0.46) in the elective repeat Caesarean delivery group;
for operative injury, 0.102% in the successful trial of labour group, 3.4% (range: 3 - 4.2) in the failed trial of labour-Caesarean delivery group, and 0.39% (range: 0 - 0.62) in the elective repeat Caesarean delivery group; and for maternal mortality, 0.002% (range: 0 - 0.002) in the successful trial of labour group, 0.017% (range: 0 - 0.02) in the failed trial of labour-Caesarean delivery group, and 0.006% (range: 0 - 0.006) in the elective repeat Caesarean delivery group.

The values of the neonatal outcomes evaluated in the analysis were also presented, but are not reported here.

**Methods used to derive estimates of effectiveness**
The authors made some assumptions in the decision model, some of which were based on published data.

**Estimates of effectiveness and key assumptions**
It was assumed that most women suffering a uterine rupture would have a failed trial of labour-Caesarean delivery. Also, protective padding would be required for patients with urinary and faecal incontinence, and some of these patients would go on to have surgery. Finally, it was assumed that the quality of life after the menopause was equivalent whether or not the patient had undergone a hysterectomy.

**Measure of benefits used in the economic analysis**
The summary benefit measure used in the economic analysis was the quality-adjusted life-year (QALY). The utility values associated with the health states considered in the analysis were reported, but the source of these data was not stated. The disutility values associated with the occurrence of specific complications were derived using the Quality of Well-Being classification. Quality of life data were then combined with life table data from the National Center for Health Statistics in 1997. A 3% discount rate was used when calculating the future benefits.

**Direct costs**
Discounting was relevant and a 3% rate was applied, as the costs were incurred over a long time period. The unit costs were not reported separately from the quantities of resources used, but the cost calculations were described. The health services included in the analysis were hospital services, hours of labour, obstetrician's professional service, anaesthesiologist's time and expertise, and the treatment of complications. The cost/resource boundary adopted for the analysis of the direct costs was that of the hospital. The hospital resource use and costs were derived from actual data referring to obstetric patients cared for at the Stanford University Hospital and coming from the hospital's financial managers. Diagnosis-related groups were used to derive the actual costs. Medicare rates were used for professional fees. Finally, the costs of treating complications (including supplies, drugs and personnel) were calculated using the "bottom-up" cost methodology. Assumptions were made in order to estimate resource use. The price year was 2000.

**Statistical analysis of costs**
The costs were treated deterministically in the base-case.

**Indirect Costs**
The indirect costs, such as productivity losses, were included in the analysis indirectly by the benefit measure (QALYs).

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were conducted to test the robustness of the estimated cost-utility ratios to variations in several
variables. The factors investigated were the probability of successful VBAC, the probability of infant morbidities, the cost of moderate morbidity in neonates, the probability of urinary incontinence, the discount rate, the probability of uterine rupture and hysterectomy, and the probability of haemorrhage, infection and operative injury. It seems that the sensitivity analyses were univariate and used ranges derived from the literature.

**Estimated benefits used in the economic analysis**
The estimated number of QALYs obtained with the two strategies under study was not reported.

**Cost results**
The total costs associated with the two procedures were not reported.

**Synthesis of costs and benefits**
An incremental cost-utility analysis was performed to combine the costs and QALYs of the two delivery approaches. The authors used the widely accepted threshold of $50,000, above which the intervention was not considered cost-effective. The incremental cost per QALY of elective repeat Caesarean delivery relative to VBAC was $112,023, which was well above the threshold. Thus, the cost-effective option was VBAC. This conclusion was sensitive to the probability of successful vaginal birth after VBAC. When such a probability was less than 0.65, elective repeat Caesarean delivery was the dominant option. When the probability was between 0.65 and 0.74, the cost-effectiveness ratio of elective Caesarean was below $50,000. When the probability was between 0.74 and 0.76, the cost-effectiveness ratio of elective Caesarean was above $50,000. The results were also sensitive to the costs associated with neonatal outcomes, while the conclusions of the analysis were robust to variations in the remaining factors.

**Authors’ conclusions**
The cost-effectiveness of vaginal birth after Caesarean delivery (VBAC) depended heavily on the probability of a successful trial of labour. Thus, the clinicians’ ability to estimate such a likelihood represents the key variable of the analysis. All of the factors positively associated with successful vaginal births (such as prior vaginal delivery, prior Caesarean due to nonrecurring condition, and so on) should be considered together with the women’s preferences for the delivery method.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. VBAC and repeat Caesarean represented two feasible delivery options for pregnant women who have already had one low transverse Caesarean delivery. You should decide whether they represent two valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of the effectiveness used a review of published studies. The authors gave most of the details relating to the search and the synthesis of the effectiveness data. However, the design of the primary studies was not reported and the authors stated that studies were included in the review regardless of whether they were randomised trials or not. Thus, the internal validity of the studies was unclear. The authors also made some assumptions that were then used in the decision model. Some of these assumptions were investigated in the sensitivity analysis, using the ranges reported in the literature.

**Validity of estimate of measure of benefit**
The benefit measure used in the economic analysis was QALYs, which was appropriate for the detection of the overall benefits of the interventions. Appropriate discounting was carried out. The use of QALYs permits the benefits of the present interventions to be compared with those associated with other health technologies. However, the source of the utility values was not stated clearly and the authors did not report the actual number of QALYs gained with the two treatments.
Validity of estimate of costs
A societal perspective was adopted in the study and all the relevant categories of costs appear to have been included in the economic analysis. The indirect costs were not included directly, as the authors stated that the benefit measure used in the analysis (QALY) already captured them. It is worth bearing in mind that this is still a controversial issue in health economics. The unit costs and the quantities of resources used were not reported separately, but the authors provided numerous details of the cost calculations. The price year was appropriately reported and this allows reflation exercises in other settings. The costs were treated deterministically in the base-case, but some key cost items were varied in the sensitivity analysis. The total estimated costs were not reported.

Other issues
The authors made some comparisons of their findings with those from other studies. They did not address the issue of the generalisability of the study results to other settings. The authors conducted some sensitivity analyses to evaluate the robustness of the estimated cost-effectiveness ratios. However, the external validity of the analysis was low, because most of the estimates were specific to the study setting. The study referred to pregnant women and this was reflected in the conclusions of the study.

Implications of the study
The main implication of the study is that clinicians’ judgment represents the most important factor for VBAC to be cost-effective in pregnant women who have already had one low transverse Caesarean delivery. The authors suggest that risk factor stratification should be used to educate parturients and to make a delivery decision.

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