How cost-effective is it to leave perineal skin unsutured

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 use of two-stage postpartum perineal repair (2SPPR), leaving the skin unsutured, for women who underwent spontaneous vaginal delivery and experienced perineal trauma (PT). The vagina was repaired in the usual way, but the skin edges of the perineal muscles were apposed, instead of sutured.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women requiring surgical repair of episiotomy, or first- or second-degree laceration, following a spontaneous or simple instrumental delivery.

Setting
The setting was the community and secondary care. The economic study was carried out in the UK.

Dates to which data relate
The dates to which the effectiveness and resource use data related were not reported, although the effectiveness study had been published in 1998. The price year was 1997.

Source of effectiveness data
The effectiveness data were derived from a single published study (see Other Publications of Related Interest).

Link between effectiveness and cost data
The costing was performed on the same sample population as that used in the effectiveness analysis. The authors reported that the data were collected prospectively.

Study sample
Power calculations were performed in the planning phase of the study in order to assure a certain power. Women meeting the study requirements (see 'Study Population' section) were randomised to either the 2SPPR or the 3SPPR strategies. In total, 1,780 women were randomly allocated to the alternative strategies, 890 to 2SPPR and 890 to 3SPPR. The authors did not report any evidence that the study sample was representative of the study population. They also did not report whether some women refused to participate in the study.
**Study design**
This was a randomised controlled study. The number of sites involved was not reported, nor was the randomisation method used to allocate the patients to the alternative strategies. The duration of follow-up was 3 months. It was not reported whether there were any losses to follow-up. The authors reported that some outcomes at both 24 to 48 hours and at 10 days were assessed by a research midwife blinded to the woman's allocation group. It does not appear to have been possible to blind the patients.

**Analysis of effectiveness**
The authors reported that the analysis of the clinical study was conducted on an intention to treat basis. The primary health outcomes assessed for both strategies (2SPPR and 3SPPR) were:

- the percentage of patients reporting tight stitches at 10 days and the associated relative risk (RR);
- the differences in the percentages of patients with perineal pain at 24 to 48 hours, at 10 days and at 3 months, between the study groups (and the corresponding RR);
- the percentage of women who had resumed pain-free sexual intercourse by 3 months postpartum (and the RR);
- the percentage of women reporting dyspareunia at 3 months among those who had resumed intercourse; and
- the risk of perineal stitch removal or perineal resuturing.

At both 24 to 48 hours and at 10 days, evaluators assessed the health outcomes. At 3 months postpartum, the women themselves assessed the outcomes using a questionnaire. The authors commented that the study groups were comparable at baseline in terms of maternal age, prior experience of vaginal delivery, prior experience of perineal suturing, mode of delivery, birth weight and cause of perineal injury. However, no data pertaining to these comparisons were reported.

**Effectiveness results**
The percentage of patients reporting tight stitches at 10 days was significantly lower for 2SPPR than for 3SPPR patients (14.2% versus 18.4%; RR 0.77, 95% confidence interval, CI: 0.62 - 0.96; p=0.02).

The percentage of women reporting dyspareunia at 3 months among those who had resumed intercourse was significantly lower for 2SPPR patients than for 3SPPR patients (15% versus 19%; RR 0.80, 95% CI: 0.65 - 0.99; p=0.04).

Although there was a trend for patients in the 2SPPR group to show better results in terms of perineal pain at 24 to 48 hours, at 10 days and at 3 months, and the resumption of pain-free sexual intercourse by 3 months postpartum, the differences between the study groups were not significant.

The 2SPPR strategy was not associated with a higher risk of perineal stitch removal or perineal resuturing.

**Clinical conclusions**
Compared with the 3SPPR strategy, 2SPPR resulted in a significant reduction in the risk of adverse outcomes at 10 days and at 3 months.

**Measure of benefits used in the economic analysis**
The summary measures of health benefit used (for the 2SPPR strategy versus the 3SPPR strategy) were:

- the average number of avoided tight stitches at 10 days,
- the average number of women with avoided pain event at 3 months,
the average additional number of women resuming pain-free intercourse by 3 months, and
the average number of avoided cases of dyspareunia by 3 months.

These measures of health benefit were obtained directly from the effectiveness analysis.

**Direct costs**
The direct costs considered in the economic analysis were those of the health service. These were for both hospital care and community care. Hospital care covered such costs as perineal suturing or apposing costs (including anaesthesia and suture materials), use of pain relief, hospitalisation costs, health professionals, removal of perineal stitches and resuturing of the perineum. Community care covered medication, removal of suture, resuturing and visits. All the resource quantities were identified and reported, although not the unit costs. The quantities were obtained from questionnaires completed by the caregivers at 24 to 48 hours and at 10 days, and by the women at 3 months. The unit costs were obtained from local hospital finance departments, national insurance costs, superannuation costs and other employer on-costs, and the British National Formulary. Therefore, the costs were derived from actual data. The price year was 1997. No discounting was performed, which was appropriate as the time horizon considered for the cost estimation was 3 months. The costs reported were the average net costs per patient.

**Statistical analysis of costs**
The costs were treated stochastically since average and standard deviations (SDs) were reported. Two-sided t-tests were carried out to compare the costs associated with each of the alternatives. The authors did not state whether they considered the specific distributions of the data before applying the statistical analyses, but reported only the type of variable analysed (continuous versus categorical).

**Indirect Costs**
No indirect costs were estimated.

**Currency**
UK pounds sterling (.)

**Sensitivity analysis**
Sensitivity analyses were performed to assess the uncertainty surrounding the values of the key costs and outcome variables, using the upper and lower 95% confidence limits. The area of uncertainty investigated was variability in the data. An analysis of extremes was carried out to identify the ranges within which the incremental cost-effectiveness of 2SPPR was likely to fall.

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

**Cost results**
The estimated total costs per patient were not significantly different between 2SPPR patients (697.73, SD 367.83) and 3SPPR patients (690.81, SD 377.40), (p=0.70).

**Synthesis of costs and benefits**
The estimated health benefits and costs were combined by means of incremental cost-effectiveness ratios (ICERs). These calculated the extra cost incurred to:
avoid one additional tight stitch at 10 days;

prevent one further pain event at 3 months;

achieve one additional resumption of pain-free intercourse at 3 months; and

avoid one further case of dyspareunia by 3 months.

The ICERs (and the corresponding ranges following the results from the sensitivity analyses) for 2SPPR in comparison with 3SPPR were:

166.45 per avoided tight stitch at 10 days (range: -70.69 - 175.97);

267.77 per avoided pain event at 3 months (range: -123.71 - 307.94);

293.28 per women with additional resumption of pain-free intercourse by 3 months (range: -98.97 - 246.35); and

181.14 per avoided case of dyspareunia by 3 months (range: -77.32 - 192.46).

Authors’ conclusions
The two-stage postpartum perineal repair (2SPPR) strategy was likely to represent a cost-effective use of health-care resources. It may offer good value for money as it seems to lead to economic savings under many circumstances in a routine care environment.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator chosen. The 3SPPR strategy was the standard approach for treating PT after a spontaneous vaginal delivery. You must decide whether this strategy is widely used in your own setting.

Validity of estimate of measure of effectiveness
The study was based on a randomised controlled trial, which was appropriate for the study question. However, it is not possible to assess whether there were biases affecting the internal validity of the study, as some relevant information about the design and development of the study was not reported (e.g. randomisation method, evidence of the comparability of the study groups at analysis). Moreover, the authors did not report any evidence that the study sample was representative of the study population. Consequently, the external validity of the effectiveness results could also not be assessed. A positive aspect of the effectiveness analysis was that it used a large study sample, allowing the detection of relatively small differences between the study groups.

Validity of estimate of measure of benefit
Although some of the primary outcomes used in the effectiveness analysis did not show significant differences between the study groups, the authors used them as summary measures of health benefit in order to estimate ICERs, which may not have been appropriate. Alternatively, other summary measures of benefits (e.g. quality-adjusted life-years gained) could have been used, which would have allowed the study findings to be compared with the findings of other studies.

Validity of estimate of costs
All the costs relevant to the perspective adopted appear to have been included in the economic analysis. Although the unit costs used were not reported, there was a detailed description of the resource quantities considered, which should enhance reflation exercises in other settings. Statistical analyses of the costs were performed, as was an analysis of extremes. The latter allowed the identification of the ranges within which the ICERs would fall, consequently reducing the uncertainty surrounding the study results. The price year was reported. Discounting was, appropriately, not performed since the time horizon considered was shorter than 2 years. The time horizon was rather short, as the authors reported that PT may have long-term economic implications, thus affecting the cost-effectiveness results.
Consequently, the cost-effectiveness of 2SPPR might have been underestimated.

Other issues
The authors did not compare their findings with those obtained in other studies because, to their knowledge, there were no other cost-effectiveness analyses of the interventions compared at analysis. The issue of the generalisability of the results was not addressed. The results were not presented selectively and the conclusions drawn accurately reflected both the scope of the analysis and the results presented. Several limitations were discussed. Notably, those focusing on the perspective adopted for the economic analysis (a societal perspective would have been more appropriate for the study question) and the limited time horizon.

Implications of the study
The authors recommend further research to evaluate whether the adoption of a societal perspective would have a significant impact on the study results. They also suggested the use of a longer time horizon in future studies in order to capture the long-term costs and health benefits.

Source of funding
None stated.

Bibliographic details

Other publications of related interest

Indexing Status
Subject indexing assigned by CRD

MeSH
Adult; Comparative Study; Cost-Benefit Analysis; Episiotomy /adverse effects; Female; Obstetric Labor Complications /surgery; Perineum /injuries /surgery; Polylactin 910; Pregnancy; Suture Techniques /adverse effects /economics; Treatment Outcome

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