Comparison of absorbable uterine staples and traditional hysterotomy during Cesarean delivery

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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
Absorbable uterine staples versus traditional hysterotomy during caesarean delivery.

Type of intervention
Treatment; Techniques and equipment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing caesarean delivery.

Setting
University of New Mexico Hospital and the Lovelace Medical Centre. The study was carried out in the USA.

Dates to which data relate
Effectiveness, resource use, and cost data were collected from June 1992 to June 1994. The price year was not reported.

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 analysis. The costing was carried out prospectively alongside the effectiveness analysis.

Study sample
There were 144 patients in the staple group and 144 matched patients in the standard hysterotomy control group. 78 patients were recruited at the private institution and 210 at the university hospital. Patients undergoing elective repeat caesarean deliveries were included as well as those undergoing surgery because of an indication arising during labour. The study had no exclusion criteria other than emergency caesarean delivery for acute severe fetal intolerance of labour. To demonstrate a decrease in the incidence of post-operative infection and anaemia from 15 to 5% with 80% power, at least 134 subjects were required in each study arm.

Study design
Prospective case-control study carried out at two centres. Patients were followed up until discharge. No patients were lost to follow-up.

**Analysis of effectiveness**
The analysis of the clinical study was based on intention to treat. The primary health outcomes studied included operative time, estimated blood loss, change in haematocrit, incidence of post-operative endometritis, and length of stay. Age, parity, ethnicity, gestational age, and number of operations performed electively or in labour did not differ significantly between groups. There were significant differences between groups, however, in the length of labour (5.7 +/- 9.3 versus 8 +/- 13 hours, p=0.01), length of time of ruptured membranes (4.4 +/- 8.6 versus 12.4 +/- 41.8 hours, p=0.02), and number of vaginal examinations in labour (1.6 +/- 2.2 versus 2.5 +/- 5, p=0.01).

**Effectiveness results**
No significant differences were observed in the following:

- infant weight (3,288 +/- 664 versus 3,223 +/- 725 grams);
- Apgar at 5 minutes (8.7 +/- 1.3 versus 8.7 +/- 0.9);
- operative time (64 +/- 23 versus 62 +/- 22 minutes);
- incision to delivery time (10.2 +/- 4 versus 10.5 +/- 6.1 minutes);
- estimated blood loss (822 +/- 338 versus 879 +/- 318 mL);
- pre-operative haematocrit volume (37.5 +/- 33 versus 37 +/- 3.4%);
- post-operative haematocrit volume (31.7 +/- 4.6 versus 31.2 +/- 4);
- endometritis in university patients (18 versus 27);
- endometritis in private plan patients (2 versus 4);
- length of stay for patients with endometritis (5.7 +/- 1.5 versus 5.9 +/- 3.5);
- length of stay for patients without endometritis (3.7 +/- 1 versus 3.4 +/- 1.2).

**Clinical conclusions**
Compared with standard hysterotomy, the uterine stapling device was not associated with a significant decrease in the incidence of post-operative anaemia, infection, or length of hospital stay.

**Modelling**
No modelling was undertaken.

**Measure of benefits used in the economic analysis**
The measures of benefits studied included operative time, estimated blood loss, change in haematocrit, incidence of post-operative endometritis, and length of stay. Thus a cost-consequences analysis was performed.

**Direct costs**
Direct costs were not discounted given the short time frame of the study (less than 1 year). Quantities and costs were not reported separately. Direct costs reflected hospital and patient costs associated with the two procedures. The
quantity/cost boundary adopted was that of the health service. The estimation of quantities and costs was based on actual data. Patient costs were obtained from patients' medical and billing records. The price year was not reported.

Statistical analysis of costs
Not reported.

Indirect Costs
Not included.

Currency
US dollars ($).

Sensitivity analysis
Not reported.

Estimated benefits used in the economic analysis
See Effectiveness Results above.

Cost results
Total costs amounted to $4,490 (+/- 1,544) in the staple group compared to $3,997 (+/- 1,117) in the sutured group, (NS). Costs for infected and non-infected patients were $6,164 and $3,828, respectively, (p=0.001).

Synthesis of costs and benefits
Cost and benefit measures were not combined into a cost-effectiveness ratio.

Authors' conclusions
Compared with the usual suture technique for caesarean delivery, the uterine stapling device was not associated with a significant decrease in the incidence of post-operative anaemia, infection, length of hospital stay, or cost.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used, namely that it represented current practice in the authors' setting. You, as a user of this database, should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
The study design, a prospective case-control study, was appropriate for the study question although a randomised controlled trial would have been preferable. The study sample was representative of the study population. However, although patients were matched, groups were not comparable at analysis in certain respects. Hence, there was an apparent advantage given to the stapled patients with respect to risk factors for post-operative infection. The authors did not derive a summary measure of health benefit and the analysis may therefore be regarded as being a cost-consequences design.

Validity of estimate of costs
A number of limitations were evident with respect to the costing; the authors did not report which cost categories were included in the cost estimate, costs and quantities were not reported separately, no sensitivity analysis was conducted on
quantities or costs, charges (which do not reflect opportunity costs) were used to proxy prices and the price year was not reported. These factors limit the generalisability of the results to other settings.

**Other issues**
The authors did make appropriate comparisons of their findings with those from other studies. However, the issue of generalisability to other settings was not addressed. The study enrolled patients undergoing caesarean delivery and this was reflected in the authors’ conclusions.

**Implications of the study**
The uterine stapling device appears to offer no advantage over traditional hysterotomy and repair.

**Source of funding**
Supported in part by National Center for Research Resources - General Clinical Research Center grant no MO1-RR00997.

**Bibliographic details**

**PubMedID**
8598960

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Case-Control Studies; Cesarean Section /methods; Evaluation Studies as Topic; Female; Humans; Postoperative Complications; Pregnancy; Surgical Staplers; Suture Techniques; Treatment Outcome; Uterus /surgery

**AccessionNumber**
21996000440

**Date bibliographic record published**
31/10/2000

**Date abstract record published**
31/10/2000