Patient and hospital benefits of local anaesthesia for carotid endarterectomy

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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

The use of local anaesthesia (LA) and general anaesthesia (GA) during carotid endarterectomy (CEA). The GA patients received intravenous midazolam (2 - 3 mg) at induction, then fentanyl or alfentanil and propofol, and were maintained on a mixture of isofluorane, air and oxygen. The LA patients were premedicated with temazepam (20 - 30 mg) and promethazine (25 mg). The regional block consisted of local infiltration and a superficial cervical block using a combination of 0.5% bupivicaine and 1% xylocaine containing 1:200,000 adrenaline. Some LA patients required additional sedation.

Type of intervention

Anaesthesia.

Economic study type

Cost-effectiveness analysis.

Study population

The study population consisted of patients undergoing standard CEA.

Setting

The setting was secondary care. The economic study was carried out at the Royal United Hospital, Bath, UK.

Dates to which data relate

The effectiveness and resource use data were gathered from 1993 to 1999. The price year was 1999.

Source of effectiveness data

The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data

The costing was performed, probably prospectively, on the same sample of patients as that used in the effectiveness study. However, it was not explicitly stated that the costing was prospective.

Study sample

Power calculations to determine the sample size were not performed. All consecutive patients undergoing CEA under GA from January 1993 to January 1998, and under LA from July 1995 to June 1999, were enrolled. It was not stated whether any of the patients refused to participate or were excluded from the initial study sample for any reason. There were 140 CEAs (130 patients) in the GA group and 100 CEAs (86 patients) in the LA group. The median age of the patients was 70 years in the GA group and 71 years in the LA group.

Study design

This was a prospective cohort study that was carried out in a single centre. The procedure (LA or GA) was selected on the basis of the availability of the technique and the surgeon or anaesthetist's preferences. LA was first introduced in 1995 and since then fewer and fewer CEAs were performed under GA at the authors' institution. After the operation, all the patients were reviewed in the surgical outpatient department at 6 weeks, 6 months and 1 year (maximum follow-up). There was no loss to follow-up.

Analysis of effectiveness

All patients included in the initial study sample were considered in the effectiveness analysis. The health outcomes used were:

episodes of death, stroke, death or stroke, transient ischaemic attack, myocardial infarction, arrhythmia, haematoma and nerve injury;

operative factors such as the type of surgeon (consultant or surgical trainee) performing the intervention, use of shunt, patch, intimal suture, and operation time;

systolic blood pressure data; and

the length of stay.

The study groups were comparable at baseline in terms of their demographics and clinical characteristics. However, there were significantly more asymptomatic patients in the LA group, as these patients were concurrently participating in another trial.

Effectiveness results

There were 0 (0%) deaths in the GA group and 2 (2%)in the LA group.

There were 4 (3%) strokes in the GA group and 2 (2%) in the LA group.

There were 4 (3%) of episodes of death or stroke in the GA group and 3 (3%) in the LA group.

There were 2 (1%) transient ischaemic attacks in the GA group and 1 (1%) in the LA group.

There were 2 (1.4%) myocardial infarctions in the GA group and 0 (0%) in the LA group.

There were 4 (3%) arrhythmias in the GA group and 2 (2%) in the LA group.

There was 1 (<1%) haematoma in the GA group and 1 (1%) in the LA group.

There was 1 (<1%) nerve injury in the GA group and 1 (1%) in the LA group.

None of the differences in these outcomes reached statistical significance.

In terms of operative factors:

80% of the surgeons performing the operation in the GA group were consultants and 20% were surgical trainees, versus 100% consultants and 0% surgical trainees in the LA group, ($p<0.001$);

shunt use was 50% in the GA group versus 13% in the LA group, ($p<0.001$);

patch use was 25% in the GA group versus 41% in the LA group, ($p=0.01$);

intimal suture was 3.6% in the GA group versus 2% in the LA group, (p non significant); and

operation time was 110 minutes (interquartile range: 100 - 130) in the GA group versus 98 minutes (interquartile range: 84 - 112) in the LA group, ($p<0.001$).

The systolic blood pressure data suggested that hypertension (and subsequent treatment) was significantly more likely in the LA group, while hypotension (and subsequent treatment) was significantly more likely in the GA group.

In terms of hospital stay, the median length of stay was 2 days (range: 1 - 2) in the LA group. In the GA group, before 1996, the median total stay was 4 days (range: 1 - 4) and the stay in the high dependency unit (HDU) was 1 day (range: 1 - 2). After 1996, the medial total stay was 3 days (range: 1 - 4) and no patient required HDU stay.

Clinical conclusions
The effectiveness analysis showed that, in comparison with GA, the use of LA led to a shorter hospital stay and it lowered hypotension and decreased shunt use.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic evaluation. The study was therefore classified as a cost-consequences analysis.

Direct costs
Discounting was not relevant since the costs per patient were incurred during one year. The unit costs were reported separately from the quantities of resource use, although a detailed breakdown of the costs was not provided. The health services in the economic evaluation were hospital stay in the HDU and ward, and CEA. Operative costs were not considered, as it was assumed that they did not differ between the two groups. The cost/resource boundary adopted in the study was likely to have been that of the hospital that provided the service. Resource use was estimated using individualised data coming from the sample of patients used in the effectiveness study (1993 - 1999). The unit costs were estimated from the study hospital. The price year was 1999.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not included in the economic analysis.

Currency
UK pounds sterling ().

Sensitivity analysis
Sensitivity analyses were not conducted.

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

Cost results
In the post-1996 period, during which both anaesthetic techniques were used, the surgical ward costs were 225 in both groups and the costs per CEA were 675 in the GA group and 450 in the LA group. Thus, LA was associated with cost-savings of 225.

Synthesis of costs and benefits
The costs and benefits were not synthesised.

Authors' conclusions
Carotid endarterectomy (CEA) could be safely and effectively performed under local anaesthesia (LA), with the advantage of more appropriate monitoring and more accurate shunt use in comparison with general anaesthesia (GA). In addition, LA CEA was associated with substantial cost-savings due to the shorter hospital stay.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. The authors stated that CEA could be performed using both anaesthetic techniques, but that there was no consensus as to the best approach. You should decide whether they represent valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness used a cohort study, although a randomised study may have been more appropriate for the study question. Indeed, due to the lack of random allocation, the two groups were significantly different in terms of the number of asymptomatic patients. However, the authors did not consider this to be a confounding factor and, consequently, did not perform an adjusted analysis. The study sample was not selected on the basis of strict criteria and a group of consecutive patients was enrolled. Thus, the study sample is likely to have been representative of the study population. The authors acknowledged that power calculations were not carried out and there was no evidence that the sample size was appropriate. Therefore, the study may have been underpowered to detect statistically significant differences in the outcome measures used in the analysis. It should also be noted that the study was conducted in a single centre. Caution is therefore required when extrapolating the results, owing to the potential variability in the efficacy rates. These issues tend to limit the internal validity of the analysis.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis since a cost-consequences analysis was conducted.

Validity of estimate of costs
The perspective adopted in the analysis was not explicitly reported, but it was clearly that of the hospital since categories of costs relevant to the institution where the study was conducted were included. The price year was reported, thus simplifying reflation exercises in other settings. The source of the resource use and cost data was reported. However, a detailed breakdown of the costs was not provided and the unit costs were not reported separately from the resources used. This could make replication of the economic analysis difficult. In addition, the costs were treated deterministically and sensitivity analyses were not performed. The cost estimates appear to have been specific to the study setting.

Other issues
The authors compared their findings with those from other studies found in the literature and similar trends toward better outcomes with LA were observed. However, the issue of the generalisability of the study results to other settings was not addressed. Also, the overall external validity of the analysis was low since local estimates were used for the costs, while the effectiveness data were derived from a single centre. The study referred to patients undergoing CEA and this was reflected in the conclusions of the analysis.

Implications of the study
The study results suggested that LA might represent the anaesthetic approach of choice for patients undergoing CEA. This conclusion should be confirmed in future randomised trials.

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None stated.

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