Reduction in hospitalisation rates following simultaneous carotid endarterectomy and coronary artery bypass grafting: experience from a single centre

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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 study compared two options for surgical treatment. One option was the reversed stage procedure, which comprised coronary artery bypass grafting without cardiopulmonary bypass (off-pump CABG) as the first procedure followed by carotid endarterectomy (CEA) as the second procedure. The other option was simultaneous CEA and off-pump CABG. CEA was performed under locoregional anaesthesia using bupivacaine 0.5%, lidocaine 2% with epinephrine 1:200,000, adding lidocaine 1% with epinephrine or fentanyl intravenously if necessary.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients with COD or CAD.

The inclusion criteria for off-pump CABG were: New York Heart Association symptom Class III or IV; ejection fraction at least 30%; coronary syndrome necessitating revascularisation; patients had not previously undergone CABG, pre-operational 6-minute hall walk test was 195 (+/- 114) m; pre-operational echo cardiogram diagnosed and mean left ventricular end diastolic dimension of 6.6 (+/- 0.2) cm; QRS duration greater than 130 milliseconds; mean duration of symptom 4.5 years.

Patients who underwent CEA had to fulfil the following inclusion criteria based on colour Doppler flow imaging characteristics, irrespective of symptoms: stenosis greater than 70%; ulceration or ulcer thrombosis; thrombosis of the stenotic site; echolucency-gray scale median 25 - 32; soft-core or lipoid plaque; plaque haemorrhage; frayed plaque.

The neurological inclusion criteria were: no disturbances according to the four subscales of the Freiburger Personality Inventory; momentary loss of consciousness in the supine position; experiencing an aura followed by confusion or amnesia, diplopia, limb weakness, sensory deficits or speech difficulties.

It was reported that patients with obstructing lesions equally severe in the two vascular territories, and with cardiac and neurological symptoms, underwent simultaneous procedures.

Setting
The setting was secondary care. The economic study was carried out in Croatia.

Dates to which data relate
The effectiveness and resource use data on patients undergoing reverse-staged procedures were collected between
January 2000 and September 2003. The data on patients undergoing simultaneous procedures were collected between 14 September 2003 and 30 September 2004. The patients were followed up for 1 year. Dates for the cost data and the price year were not reported.

**Source of effectiveness data**
The effectiveness data were derived from a single study.

**Link between effectiveness and cost data**
It appears that the costing has been carried out simultaneously on the same sample of patients as that used in the effectiveness study.

**Study sample**
The sample size was not determined in the planning phase of the study. Power calculations were not conducted retrospectively. Consecutive patients from the author's setting were selected and those who fulfilled the inclusion criteria were included in the study. It was reported that, of the total of 53 patients (44 men and 9 women) included in the study, the first 23 refused to undergo simultaneous procedures and underwent reversed-staged procedures. These patients comprised the control group. The remaining 30 patients underwent simultaneous procedures and comprised the study group. The mean age of the patients was 65.4 (+/- 5.9) years.

**Study design**
The analysis was based on a single-centre cohort study. The patients were followed up for a total of 1 year (baseline, 72 hours after surgery, 30 days and every 3 months after surgery).

**Analysis of effectiveness**
It appears that all the patients who entered the study have been included in the analysis. The patient groups were comparable in terms of their baseline characteristics, such as age, previous myocardial infarction (MI), diabetes, hyperlipidaemia, hypertension, history of smoking, obesity, renal insufficiency, pulmonary insufficiency, chronic obstructive pulmonary disease, extent of CAD (double and triple), ejection fraction (moderate or poor) and carotid occlusive disease (left and right).

The following clinical outcomes were assessed during the short postoperative period (up to 30 days):

- the length of hospital stay,
- hospital mortality,
- cardiac-related events,
- pulmonary events,
- cases of acute renal failure, and
- vascular related events.

It was reported that, during the first 72 hours, patients were examined using a Swan-Ganz pulmonary catheter and subjected to continuous electrocardiographic monitoring. MI was assessed using electrocardiographic and biochemical criteria and through increases in levels of the myocardial-specific isoenzyme of creatine kinase. Fever and purulent sputum necessitating antibiotic treatment indicated chest infection. The outcomes assessed at the 1-year follow-up were cardiac-related events (new MI, recurrence of angina, progressive heart failure), vascular events (stroke and transient ischaemic attack) and various pulmonary complications.
Effectiveness results
The statistical analysis was conducted using chi-squared or Fisher's exact tests for categorical variables and the two-sample t-test for continuous data. As the results were reported in considerable detail, only those outcomes that were significantly different between the two groups are reported here.

During hospitalisation, 3 patients died in the control group versus one in the study group (simultaneous procedures). At 30 days, the mortality rate was 15% in the control group and 5% in the study group. However, the difference was not statistically significant, (p=0.25).

There were 11 cases of arrhythmia in the control group and 6 in the study group. The difference was statistically significant, (p=0.07).

There were 10 cases of significant inotropic use in the control group and 2 cases in the study group. The difference was statistically significant, (p=0.003).

The incubation time was longer in the control group (mean 11.6 hours, standard deviation, SD=7.5) than in the study group (6.7 hours, SD=1.6), (p=0.005).

There were 9 cases of chest infection in the control group versus 2 cases in the study group, (p=0.008).

The total blood loss was significantly lower in the study group (650 +/- 250 mL) than in the control group (1,150 +/- 540 mL), (p<0.001). Similarly, the number of transfusions required was lower, 4 (18%) in the study group versus 13 (65%) in the control group, (p<0.005).

Mean hospitalisation was 17.9 days in the control group and 10 days in the study group, whilst the mean lengths of stay in the intensive care unit were 5.08 days (control group) and 0.30 days (study group), respectively, (p<0.05).

At the 1-year follow-up there were no statistically significant differences between the two groups in terms of the primary outcomes.

Clinical conclusions
According to the analysis, the two methods demonstrated similar effectiveness 1 year after surgery. However, in the short postoperative period, simultaneous procedures appear to have been more effective in terms of the primary clinical outcomes.

Measure of benefits used in the economic analysis
The author used quality-adjusted life-years (QALYs) as the measure of benefit in the economic analysis. However, the method used for the evaluation of health states and the health values used were not reported.

Direct costs
The health service costs included in the analysis were for hospitalisation, computed tomography scans and further unspecified tests and procedures, emergency room visits, general practitioner visits, specialist visits and cardiovascular surgeon visits. Data on resource use were collected directly during the study (baseline, during the procedure and every 3 months) using special report forms, and were obtained for the whole sample. The unit cost data appear to have come from the University hospital and the Croatian Health Organisation. The costs and the quantities were reported separately for only limited cost categories (e.g. emergency room and general practitioner visits, and hospital admissions). Discounting was not relevant as the costs were incurred during 1 year. The price year was not reported.

Statistical analysis of costs
The costs were treated deterministically. Cost-differences between the two groups were compared using a two-sample t-test.
Indirect Costs
Productivity costs (i.e. mean paid days off from work and mean hours of care provided by others) were included in the analysis. Resource use was derived directly from patients during the study. However, the source of the costs and the price year were not reported.

Currency
Euros (EUR)

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
The total QALYs gained were 0.843 in the control group and 0.777 in the simultaneous procedures group.

The mean difference in QALYs between the two groups was 0.066.

Cost results
The average total costs were reported per patient.

The total health care costs were EUR 20,518 in the control group and EUR 8,254 in the study group.

Accounting for indirect costs, the reversed stage procedure resulted in an average total cost of EUR 21,028 and the simultaneous procedure in an average cost of EUR 9,160.

The mean annual cost-difference was EUR 11,418. The author appears to have incorrectly reported the cost-difference in the text.

Synthesis of costs and benefits
The author calculated an incremental cost-effectiveness ratio, which was incorrect as the cost-difference was incorrectly calculated. In addition, such a calculation was unnecessary as the simultaneous intervention (CEA plus off-pump CABG) was dominant (i.e. it was cheaper and more effective).

Authors’ conclusions
The author did not draw any conclusions about the cost-effectiveness of the two options.

CRD COMMENTARY - Selection of comparators
A justification for the comparators chosen was provided. The comparator used appears to have been the most common practice.

Validity of estimate of measure of effectiveness
The estimate of measure of effectiveness was determined from a cohort study. The sample selection method was explicitly described and the study sample was representative of the study population. In addition, a statistical analysis demonstrated that the patient groups were comparable in terms of their baseline characteristics. However, as the patients were not randomly allocated to the intervention groups, it is possible that selection bias might have affected the results. Also, since power calculations were not reported, it is difficult to determine whether the study was adequately powered or whether the results obtained were due to chance.
Validity of estimate of measure of benefit
The author used health utility (QALYs) as the measure of benefit in the economic analysis. However, the valuation method and health values assigned were not reported, which introduces uncertainty in the quality of the estimates used.

Validity of estimate of costs
Although the perspective adopted was not explicitly reported, it might have been societal as indirect costs were included in the analysis. The author mainly reported summary costs and, as the costs and quantities were not reported separately for each category, it would be difficult to rework the analysis in other settings. The costs were treated deterministically and no sensitivity analyses of the costs or resource use data were conducted. Also, the price year was not reported, which will hinder any future reflation exercises.

Other issues
Since the author did not compare the results with those from other studies, it is therefore not possible to be certain whether the results agree with previous findings. The author explicitly pointed out the restrictions around the generalisability of the results to other settings. The author appears to have miscalculated the cost-difference and inappropriately calculated an incremental cost-effectiveness ratio since one intervention was dominant. The author acknowledged some limitations to the validity of the study findings. In particular, the study design, the small sample size used, the deterministic analysis of the costs, the lack of sensitivity analyses, and the controversial evidence in the literature concerning the comparability of simultaneous and staged patients.

Implications of the study
The author did not make explicit recommendations for changes in policy or practice, but did recommend a long-term randomised controlled trial comparing staged versus simultaneous patients and accounting for baseline differences between these patient groups.

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