Cost-effectiveness analysis of protected carotid artery stent placement versus endarterectomy in high-risk patients

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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.

CRD summary
The objective was to assess the cost-effectiveness of protected carotid artery stent placement (CAS) versus carotid endarterectomy (CEA) for patients with severe carotid stenosis. The authors' concluded that the marginal benefit of CAS was not enough to overcome its higher cost, so CAS was unlikely to be cost-effective. Overall the methodology and reporting was good. However, given the lack of details regarding the internal validity of the clinical data mean that the conclusions are uncertain.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to assess the cost-effectiveness of protected carotid artery stent placement (CAS) compared with carotid endarterectomy (CEA) for patients with severe carotid stenosis.

Interventions
The intervention was CAS under emboli protection. The comparator was CEA. The study population comprised patients considered to be at high surgical risk for CEA with symptomatic (30%) and asymptomatic (70%) carotid stenosis; mean age was 72 years and there was a high proportion of men.

Location/setting
USA/hospital

Methods
Analytical approach:
Costs and benefits associated with CAS and CEA were estimated over a one-year post procedure period in order to calculate the incremental cost-effectiveness ratio (ICER) for CAS versus CEA. Clinical inputs were obtained from a multicentre non-inferiority randomised trial. Cost data were obtained from a national dataset and published studies. The authors did not state the perspective but appeared to adopt a hospital/health care organisation perspective.

Effectiveness data:
The primary effectiveness inputs were cumulative incidences of death, stroke or myocardial infarction (MI) within 30 days post procedure and death or ipsilateral stroke between 31 days and one year. These were all estimated using the multicentre non-inferiority SAPPHIRE trial (334 participants) which randomised patients equally to CEA or CAS. The trial population was considered to be high risk for CEA. Data were reported to have been analysed using the intention-to-treat principle. Full details of the clinical trial were reported elsewhere (Yadav et al, 2004).

Monetary benefit and utility valuations:
Utility values were derived for three possible health states: good health (no adverse events), myocardial infarction and stroke. Quality of life data were obtained from a published study. Nationally representative quality-of-life weights from self-reported health status in people with health conditions were used and included post stroke survivors and were adjusted for demographic variables. Weights used for each outcome were taken for a person aged 65 to 74. The overall utility for each treatment group were calculated by multiplying the frequency of the measured outcomes in each group by the associated QALY score.
Measure of benefit:
Health benefit was measured in terms of the quality-adjusted life-years (QALYs).

Cost data:
Only direct costs were included in the analysis. Costs were divided into hospital costs (treatment, major/minor myocardial infarction, stroke), disability associated costs (major/minor stroke, myocardial infarction) and death. Frequency of stroke, myocardial infarction and death for each group were taken from the SAPPHIRE trial. Hospital costs were obtained from the Healthcare Cost and Utilization Project (H-CUP), a large Nationwide Inpatient Sample (NIS) dataset. Disability and death costs were taken from two previously published studies. Costs were reported in 2006 US dollars ($). Costs were inflated to 2006 prices using the Medical Care component of the Consumer Price Index.

Analysis of uncertainty:
Probabilistic sensitivity analysis was conducted to assess the impact of effectiveness parameter uncertainty on the results. Results were plotted on a cost-effectiveness plane that showed the distribution of incremental costs and effects. A cost-effectiveness acceptability curve (CEAC) was generated to show the probability that each treatment was the most cost-effective alternative across a range of willingness-to-pay thresholds.

Results
The 30-day incidence of myocardial infarction (Q-wave or non-Q-wave) was 6% for CEA versus 2% for CAS. One-year incidence of ipsilateral stroke (minor or major) was 6% for CEA and 5% for CAS (p=0.37). One-year mortality was 13% for CEA versus 7% for CAS. Average QALYs were 0.753 for CAS and 0.701 for CEA with an incremental difference of 0.052.

Total hospital cost was $12,782 for CAS and $8,916 for CEA with an incremental difference of $3,867. Cost per QALY was $16,223 for CAS and $12,745 for CEA. Incremental cost-effectiveness ratio (ICER) for CAS versus CEA was $67,891 per additional QALY.

The CEAC indicated that at a $67,891 per QALY willingness-to-pay threshold the probability of CAS being cost-effective was less than 40%. At a $100,000 per QALY threshold the probability was between 60% and 70%.

Authors' conclusions
The authors' concluded that the marginal benefit of CAS was not enough to overcome its higher cost so CAS was unlikely to be cost-effective.

CRD commentary
Interventions:
The intervention and comparator appeared appropriate. The authors did not discuss any other relevant alternative treatments.

Effectiveness/benefits:
Effectiveness estimates, utility values and the sources used to derive them were all reported clearly. However, the authors did not report how they identified sources used to derive effectiveness or utility estimates so it was unclear whether the effectiveness and utility estimates represented the best available evidence. Insufficient details were provided to enable a full critique of the clinical trial or assess the appropriateness of the utility estimates.

Costs:
Costs and sources used to derive them were reported clearly. Appropriate sources were used to derive costs and appropriate adjustment methods were applied. The authors highlighted that a limitation of the analysis concerned the exclusion of secondary outcomes (such as cranial nerve palsy or complication incidences) due to uncertainty about assigning a monetary value for these complications. The difference in frequency of cranial nerve palsy was stated to have favoured CAS over CEA; whether or not inclusion of this outcome would have altered the results was unclear.

Analysis and results:
Details and results of the analysis were reported clearly. An incremental cost-effectiveness analysis was conducted (the most appropriate method for assessing cost-effectiveness). Two limitations highlighted by the authors concerned the
sample size and time horizon of the SAPPHIRE trial. The SAPPHIRE trial contained a relatively low number of events and aimed to establish non-inferiority of CAS compared with surgery; a larger sample might have been able to establish superiority of CAS. The trial was conducted over one year. The time horizon may have been insufficient to accurately assess cost-effectiveness if differences in cost or benefits between CAS and CEA could be expected to extend beyond one year.

An appropriate probabilistic sensitivity analysis was conducted and the authors clearly stated the distribution applied to the effectiveness data (to reflect parameter uncertainty), which was appropriate. The analysis was not a comprehensive assessment of the effect of parameter uncertainty on the results (only the effect of uncertainty associated with the effectiveness data was explored).

Concluding remarks:
Methodology and reporting were good but a lack of details on the internal validity of clinical data means that the conclusions are uncertain.

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