Brachiocephalic reconstruction II: operative and endovascular management of single-vessel disease


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
Two approaches to brachiocephalic (BC) disease were compared, operative bypass (the traditional approach) versus percutaneous transluminal angioplasty (PTA) and stenting.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients treated for symptomatic atherosclerotic single-vessel BC disease of the subclavian artery or common carotid artery. Patients with BC lesions caused by either inflammatory arteritides or radiation exposure were excluded.

Setting
The setting was tertiary care. The economic study was performed in the USA.

Dates to which data relate
The patients were treated from January 1966 to June 2004. Information on the resources used included data from 2002 to 2004. The price year was not stated.

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

Link between effectiveness and cost data
The costing was carried out retrospectively on a sub-sample of the study patients (2002 - 2004).

Study sample
The sample size was not determined in the planning phase of the study. In addition, power calculations were not performed retrospectively. The authors did not comment on whether the study sample was appropriate for the clinical study question. A total of 391 consecutive patients (mean age 61.9 years; 43.7% male) met the inclusion criteria for chart review. Of these, 229 underwent operative bypass (group A) and 162 PTA and stenting (group B). The authors did not state whether any patient refused access to their data.
Study design
This was a single-centre, retrospective cohort study. The mean follow-up was 5.2 (+/- 0.4) years for group A (range: 0.25 - 30.0) and 3.3 (+/- 0.2) years for group B (range: 0.25 - 11.6). There was no indication of blinding.

Analysis of effectiveness
The analysis of effectiveness was conducted on the basis of treatment completers. No primary health outcome was stated. The outcome measures used were immediate and long-term mortality, stroke, myocardial infarction, freedom from graft or intervention failure, and patient satisfaction. Patient satisfaction was evaluated using general and specialty-specific surveys (Press-Ganey Satisfaction Measurement) completed by patients treated for single-vessel BC disease in the past 4 years (n=180). The groups were comparable at baseline in terms of their symptoms and some clinical-demographic variables, but were significantly different in the prevalence of hypertension, tobacco use and hyperlipidaemia. A multivariate regression analysis was used to adjust for these risk factors when the incidence of long-term events was compared.

Operative results were analysed for each group using the Fisher exact test. To evaluate the long-term results, actuarial curves were obtained by means of Kaplan-Meier statistical analysis. A multivariate Cox regression analysis was used to adjust for risk factors when the incidence of long-term events was compared between groups.

Effectiveness results
All patients were asymptomatic after either treatment. Group A and group B had similar rates of operative mortality (0.9% versus 0.6%) and stroke (1.3% versus 0%). One myocardial infarction occurred in group A versus none in group B.

At 5 years, group A had significantly better freedom from graft or intervention failure than group B (mean +/- standard deviation was 92.7% +/- 2.1 versus 83.9% +/- 3.7; multivariate analysis, p=0.001).

Actuarial freedom from other events at 5 years (presented as mean percentage of participants +/- standard deviation for group A versus group B) was:
- for death, 88.6 (+/- 2.8) versus 96.3 (+/- 1.2);
- for myocardial infarction, 89.0 (+/- 2.8) versus 96.3 (+/- 1.8);
- for stroke, 96.9 (+/- 1.4) versus 98.2 (+/- 1.0);
- for BC failure, 93.6 (+/- 2.1) versus 83.6 (+/- 3.7);
- for coronary revascularisation, 92.1 (+/- 2.1) versus 91.4 (+/- 2.6); and
- for other vascular operation, 85.1 (+/- 3.0) versus 87.1 (+/- 3.5).

Additional actuarial data at 10 years were reported for group A only.

In terms of patient satisfaction, 96.5% of patients receiving an endovascular intervention and 95.1% of patients receiving operative bypass for single vessel BC disease rated their treatment as "good" or "very good".

Clinical conclusions
Both treatments for single-vessel BC disease (operative bypass and endovascular intervention) had acceptably low operative morbidity and mortality. Though endovascular treatment was less invasive, operative bypass produced significantly better mid-term freedom from graft or intervention failure than endovascular intervention and also produced excellent long-term freedom from failure.
Measure of benefits used in the economic analysis
No summary measure of benefit was used. The study can thus be categorised as a cost-consequences analysis.

Direct costs
The study included short-term in-hospital costs of the two compared procedures. A sub-set of 23 bypasses and 73 endovascular interventions from 2002 to 2004 were used for the cost calculations. The categories of costs varied according to the different groups and included length of stay, angiographic suite use, equipment (including catheters and stents), operating room use and conduit. The costs excluded surgeons' fees. Hospital charges were used as proxies for the costs. The quantities and the costs were not analysed nor reported separately. Discounting was appropriately not carried out as the cost time horizon was short term. The price year was not reported.

Statistical analysis of costs
No statistical analysis of the costs was reported.

Indirect Costs
No indirect costs were reported.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was reported.

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

Cost results
Mean savings of $8,787 per procedure resulted when the endovascular intervention, rather than operative bypass, was used for single-vessel BC disease.

No other cost data were reported.

Synthesis of costs and benefits
The costs and benefits were not combined as a cost-consequences analysis was carried out.

Authors’ conclusions
Operative bypass and endovascular intervention for single-vessel brachiocephalic (BC) disease were both associated with acceptably low operative morbidity and mortality. Although operative bypass produced significantly better mid-term freedom and excellent long-term freedom from failure, the endovascular intervention offered tangible benefits in cost, level of invasiveness, and subjective patient satisfaction.

CRD COMMENTARY - Selection of comparators
The choice of the comparators was explicitly justified. The authors' justification was that these two strategies were the main approaches to single-vessel BC disease. You should judge whether these strategies are relevant in your setting, or whether other comparators could have been relevant as well.
Validity of estimate of measure of effectiveness
The study was a retrospective single-centre cohort study. The internal validity of the effectiveness results cannot reasonably be guaranteed, given the retrospective nature of the study design and the non-randomisation of patients in each group. Further, the study groups were not comparable in terms of preoperative risk factors such as hypertension, tobacco use and hyperlipidaemia. However, the authors adjusted for baseline differences between the two groups and tried to account for such differences. The outcome assessment was not reported to be blinded, which can potentially introduce bias into the study results. In addition, since no power calculations were reported, the study might have had insufficient power to detect statistical differences in rates of mortality, stroke or myocardial infarction. The study sample seems to have been representative of the study population since all consecutive patients (other than those with lesions caused by either inflammatory arteritides or radiation exposure) who underwent either intervention were reviewed, and no refusal to participate was reported.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. See the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
There was very limited information on the actual costs collected. Therefore, it was unclear whether all the relevant costs were included in the analysis. In addition, the study perspective was not stated, though it appears to have been that of the hospital. The analysis included short-term in-hospital charges that were used as cost proxies without any adjustment. The use of charges to proxy costs may limit the generalisability of the study results. The exclusion of surgeons’ fees might affect the study results. The costs were estimated in a sub-sample of the study patients, but it was unclear if the sub-sample was composed of consecutive patients. The quantities and the costs were not analysed nor reported separately, thus limiting the reproducibility of the study in other settings. No statistical analysis was performed on the cost or quantity data. Discounting was appropriately not carried out as the cost time horizon was short term. The price year was not reported, thus impeding any future refiation exercises.

Other issues
In view of the retrospective nature of the study design, its methodological drawbacks and the lack of a sensitivity analysis, some degree of caution may be required in the interpretation of the study results. The authors compared their findings with those from other studies and found them, in general, to be concordant. The authors did not address the issue of generalisability of the results to other settings. They do not appear to have presented their results selectively. The study involved patients treated for symptomatic atherosclerotic single-vessel BC disease and this was reflected in the authors’ conclusions. The authors’ conclusions reflected the scope of the analysis. The authors did not report any limitations to their study.

Implications of the study
Long-term data about endovascular procedures are still needed to compare both strategies in terms of their long-term durability, patterns of failure, efficacy as an adjunct to coronary artery bypass grafting, need for anticoagulation, efficacy as treatment for complex (multi-vessel) disease, and long-term cost. Until these additional questions are answered, the precise indications for endovascular intervention versus operative reconstruction for the treatment of BC disease remain unsettled.

Source of funding
None stated.

Bibliographic details