Cost-effectiveness of endovascular abdominal aortic aneurysm repair

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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
Endovascular aneurysm repair (EVAR) was compared with open surgical repair and conservative care in the treatment of abdominal aortic aneurysms (AAAs).

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The model analysed data for two hypothetical reference cases which reflected the study populations of randomised controlled trials (RCTs) in progress. Reference case one (RC1) corresponded to a fit 70-year-old patient, suitable for open surgery, with a 5.5-cm diameter AAA. Reference case two (RC2) referred to an 80-year-old patient, unsuitable for open surgery, with a 6.5-cm diameter AAA.

Setting
The setting was tertiary care. The economic study was conducted in the UK (England and Wales).

Dates to which data relate
The effectiveness evidence data were gathered from a review and studies published between 1992 and 2004. The cost data were taken from a published source relating to 2003 to 2004, and estimated from data obtained from one NHS Trust. Prices for 2003/04 were used.

Source of effectiveness data
The estimates for the final outcomes were derived from a synthesis of published studies.

Modelling
A decision analysis model based on a Markov process was used to estimate the costs and benefits for the intervention and the comparators for two reference cases. In the first scenario, EVAR was compared with open surgical repair in patients considered fit for surgery. In the second scenario, EVAR was compared with non-operative treatment in patients considered unsuitable for open surgical repair. The time horizon for the model was 10 years, but alternative scenarios considered time horizons of 5 and 15 years. The cycle length was not specified.

Seven health states were used in the model. These were continued survival, successful open repair, reintervention, excluded, endoleak, aneurysm-related death and death.
Outcomes assessed in the review
The authors used a published systematic review of the literature (Drury et al. 2004, see ‘Other Publications of Related Interest’ below for bibliographic details) to identify many of the values for the model parameters. This was supplemented by several other published studies. The parameters obtained from published studies and used in the model were:

- the mortality associated with open repair;
- the mortality associated with primary EVAR;
- the mortality associated with open surgery;
- general mortality;
- the aneurysm-related mortality for an observed patient;
- the probability of conversion of EVAR to open surgery;
- the probability of converting at the time of reintervention;
- the probability of having an endoleak at 30 days;
- the probability of developing a new endoleak per month;
- the probability of reintervention in a patient with an endoleak;
- the probability of reintervention in a patient without an endoleak;
- the probability of a failed reintervention leading to a continued endoleak;
- the probability of spontaneous closure of an endoleak; and
- the utility for a living patient following treatment.

Study designs and other criteria for inclusion in the review
No specific criteria for inclusion in the review were stated. The review included a published systematic review, two randomised controlled trials, a modelling study and a national health survey.

Sources searched to identify primary studies
Not reported.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Eight primary studies were included in the review.
Methods of combining primary studies
In general, the effectiveness data were not pooled.

Investigation of differences between primary studies
Differences between the primary studies were not investigated.

Results of the review
The following probabilities were derived from the review of the literature:

- The mortality associated with open repair was 5.80% (Beta distribution: r=40, n=690);
- The mortality associated with primary EVAR was 1.85% (Beta distribution: r=13, n=702);
- The mortality associated with open surgery was 24.40% (Beta distribution: r=10, n=41);
- General mortality was derived from standardised mortality tables and was not reported;
- The aneurysm-related mortality for an observed patient was derived from a table of values and was not reported;
- The probability of conversion of EVAR to open surgery was 1.90% (Beta distribution: r=192, n=9,987);
- The probability of converting at the time of reintervention was 12.30% (Beta distribution: alpha = 188.9, beta = 1,347.1);
- The probability of having an endoleak at 30 days was 17.6% (Beta distribution: r=243, n=1,383);
- The probability of developing a new endoleak per month was 4.90% (Beta distribution: alpha = 9.2, beta = 2,251.8);
- The probability of reintervention in a patient with an endoleak was 0.84% (Beta distribution: alpha = 296.6, beta = 9,271.4);
- The probability of reintervention in a patient without an endoleak was 3.1% (Beta distribution: alpha = 80.4, beta = 9,487.6);
- The probability of a failed reintervention leading to a continued endoleak was 19.7% (Beta distribution: r=26, n=132);
- The probability of spontaneous closure of an endoleak was 6% (Beta distribution: alpha = 3.8, beta = 60.4); and
- The utility for a living patient following treatment was 0.8 (Beta distribution: r=2,000, n=2,500).

Measure of benefits used in the economic analysis
The measure of health benefit used was the quality-adjusted life-years (QALYs). These were obtained from the model. The model was also used to calculate the cost per life-year gained but these results were not reported. EuroQol tariff values elicited in the Health Survey for England 1996 (Prescott-Clarke and Primatesta 1996, see ‘Other Publications of Related Interest’ below for bibliographic details) for men aged 65 to 74 years were used to estimate the utility for a living patient following treatment. Based on evidence from the literature, the authors assumed that there was no significant reduction in long-term quality of life after open repair of an aneurysm. A reduction was applied for the 4 weeks after open surgery and for the 2 weeks after EVAR to account for the loss of utility during the postoperative period. The benefits were discounted at a rate of 3.5%.

Direct costs
The direct costs to the health service were considered. The costs included in the analysis were the cost of open AAA.
repair, the incremental cost of EVAR, the monthly follow-up costs after EVAR (assuming two outpatient visits and two computed tomography scans per year) and the cost of reintervention. The incremental cost of EVAR was estimated from additional data obtained from the Sheffield Teaching Hospitals NHS Trust. All other costs came from published NHS reference costs. The cost estimates were reported separately from other model parameters. Discounting was applied to the costs, which was appropriate given the model's time horizon. A discount rate of 3.5% was used in accordance with guidance issued by the UK National Institute for Clinical Excellence. The price year was 2003/04. The incremental costs were estimated by modelling.

**Statistical analysis of costs**
The mean published reference costs were used as point estimates. Uncertainty in the cost data was explored in a sensitivity analysis that assumed a normal distribution and a standard deviation that 50% of observations were within the published interquartile range.

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

**Currency**
UK pounds sterling (GBP).

**Sensitivity analysis**
Sensitivity analyses were conducted to investigate uncertainties in the model structure, and in the patient-related and treatment-related variables, using a series of alternative scenarios. Both one-way and two-way analyses were undertaken. Uncertainty in the parameter estimates was addressed by a probabilistic sensitivity analysis, using a second-order Monte-Carlo simulation with 1,000 iterations for each scenario. This appears to have been undertaken on all parameters. The authors did not report their justification for the assumptions about the distribution.

**Estimated benefits used in the economic analysis**
For RC1, 0.10 incremental discounted QALYs were gained with EVAR compared with open surgery.

For RC2, 1.64 incremental discounted QALYs were gained with EVAR compared with conservative management.

The authors calculated the duration of benefits over 10 years.

**Cost results**
The total cost of the intervention and the comparators was not reported.

For RC1, the incremental discounted cost of EVAR was 11,449 compared with open surgery.

For RC2, the incremental discounted cost of EVAR was 14,077 compared with conservative management.

**Synthesis of costs and benefits**
The costs and benefits were summarised in the form of an incremental cost-effectiveness ratio (ICER) by dividing the incremental costs by the incremental benefits.

For RC1, the ICER of EVAR compared with open surgery was 109,702 per QALY gained.

For RC2, the ICER of EVAR compared with conservative management was 8,579 per QALY gained.

The costs and benefits were both discounted at 3.5%.
The sensitivity analysis showed that for RC1, all simulations demonstrated an ICER of EVAR compared with open repair that consistently exceeded 30,000 per QALY gained. The probabilistic sensitivity analysis suggested a lower ICER would only be possible if the cost of EVAR was equal to that of open surgery (chance = 13.2%) and if the rate of reintervention was halved (chance = 0.3%). The one-way sensitivity analysis on the mortality for open repair showed that for a mortality rate of 11 to 40%, EVAR provided an ICER of less than 30,000. At mortality rates over 40%, EVAR dominated open repair. For RC2, the ICER of EVAR compared with conservative management was consistently less than 30,000 per QALY gained for all alternative analyses.

Authors' conclusions
From the perspective of the UK National Health Service (NHS), performing endovascular aneurysm repair (EVAR) on patients who are suitable for open repair exceeds the commonly accepted cost-effectiveness threshold for a new technology. However, it is likely to be a cost-effective alternative for those patients who are unfit for open repair.

CRD COMMENTARY - Selection of comparators
Although no explicit justification was given for the comparators used, they appear to have represented current practice in the authors' setting. You should decide if the comparators represent current practice in your own setting.

Validity of estimate of measure of effectiveness
It was stated that a systematic review of the literature had been undertaken. The authors used a systematic review they had published earlier (Drury et al. 2004) to provide many of the parameter estimates, and supplemented this with data from recent studies. The methods and conduct of the review were not described and potential differences between the primary studies were not discussed. Despite the lack of reported detail, the estimates of effectiveness are likely to be valid because they were derived from high-quality primary sources. A thorough investigation of uncertainty in all the effectiveness parameters was undertaken by sensitivity analysis.

Validity of estimate of measure of benefit
The summary measure of benefit was the QALYs gained. These were obtained from the model. Based on evidence from the literature, the authors assumed that there was no significant reduction in long-term quality of life after the open repair of an aneurysm. EuroQol tariff values elicited from English males aged 65 to 74 years were applied. The authors did not discuss whether utility values among females, and adults aged over 74 years, were comparable. However, utility values were varied in the sensitivity analysis. The benefits were discounted.

Validity of estimate of costs
The analysis of the costs was performed from the perspective of the UK NHS. The costs were presented in an aggregated form, so it was not possible to determine whether all the relevant costs and categories of costs were included in the analysis. The costs were reported separately to other model parameters. However, they were presented in an aggregated form and this may limit the reproducibility of the study results in other settings. Sensitivity analyses were conducted on all model input parameters, and a probabilistic sensitivity analysis was undertaken for each scenario. The authors used published national reference costs as the source of all cost data. The costs were treated stochastically, and sensitivity analyses were conducted to assess the robustness of the results when the estimated costs were modified. Discounting was correctly applied and at an appropriate rate. Costs, rather than charges, were reported, thus reflecting the true opportunity costs of the intervention. The year to which the prices referred was reported, and this increases the generalisability of the results.

Other issues
The authors reported that no long-term results were available from randomised controlled trials comparing the clinical outcomes of EVAR with open repair or conservative management. Several trials were in progress, but early or incomplete results could lead to an overestimation of the benefits among fit patients and an underestimation of the benefits among unfit patients. The authors did not directly address the issue of the generalisability of their results to
other settings. They do not appear to have presented their results selectively and the conclusions reflected the scope of the analysis.

The authors discussed several further limitations to their findings. First, a lack of data prevented an analysis of differences in the effectiveness related to patient characteristics (such as high or low risk) or aneurysm size. Second, because EVAR is a developing technology, reductions in adverse effects, such as late complication and reintervention rates, are anticipated as expertise and technology improve. In addition, EVAR should reduce use of critical care facilities, and this would also offset its high cost. Finally, published mortality rates for open repair vary considerably and actual rates may be much higher than those in published studies, favouring the introduction of EVAR.

Please note that, since this abstract was written, the authors have informed us that much of the detail referred to above as not having been reported had to be left out due to the journal's space limitations. These details can be obtained, on request, from the corresponding author.

**Implications of the study**
The authors stated that introducing EVAR for AAA would have implications for equity, configuration of services and opportunity costs for other therapies. They noted that the cost-effectiveness of screening for AAA has been estimated as 8,000 per QALY, and would provide greater benefit than the use of EVAR. Their recommendation is that further research should concentrate on determining accurate rates for late complications and reintervention, especially among patients with high operative risks. In particular, further evidence is required on the value of EVAR for patients with an expected mortality risk between 11 and 40%.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
16034841

**DOI**
10.1002/bjs.5119

**Other publications of related interest**

Prescott-Clarke P, Primatesta P. Health Survey for England '96: a survey carried out on behalf of the Department of Health by the Joint Health Surveys Unit of Social and Community Planning Research (SCPR) and the Department of Epidemiology and Public Health, University College London. London: HMSO; 1996. Available from: URL:

**Indexing Status**
Subject indexing assigned by NLM
MeSH
Aged; Aged, 80 and over; Angioplasty /economics /methods; Aortic Aneurysm, Abdominal /economics /surgery; Cost-Benefit Analysis; Humans; Models, Economic; Quality-Adjusted Life Years; Randomized Controlled Trials as Topic

AccessionNumber
22005006471

Date bibliographic record published
30/04/2006

Date abstract record published
30/04/2006