Cost-effectiveness of transcatheter aortic valve implantation (TAVI) for aortic stenosis in patients who are high risk or contraindicated for surgery: a model-based economic evaluation

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Scientific summary

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Background

Calcific aortic stenosis (AS) is a degenerative disease in which narrowing of the aortic valve causes obstruction of left ventricular outflow. AS is the most common valvular heart disease in Western countries, affecting approximately 2% of people over the age of 65 years. In patients with severe symptomatic AS, the risk of death is approximately 2% per month, and typical survival is <2 to 3 years. Intervention in the form of surgical aortic valve replacement (SAVR) in such patients can effectively improve rates of survival, often reaching rates similar to those of an age-matched population without AS. However, in some patients with severe AS, age or comorbidities mean that SAVR is associated with a high risk of operative mortality or morbidity. For these patients, although medical management is considered to be largely ineffective, it has been considered appropriate because the risks associated with SAVR in these patients are too high.

Transcatheter aortic valve implantation (TAVI) is a relatively recent technique (first used in 2002) used for the implantation of replacement aortic valves without the invasiveness of open surgery. TAVI involves catheter-guided transport of a new aortic valve that displaces the old diseased valve and is expanded in place. This procedure has been used for the treatment of patients with severe AS who are unsuitable for SAVR (because the risk is too high and/or for other reasons such as they suffer from porcelain aorta) and, in such patients, TAVI is associated with better outcomes than medical management. TAVI is also increasingly being considered for patients in whom the risk associated with SAVR would be high but not high enough for it to be completely contraindicated.

Guidelines recommend that TAVI may be used in patients in whom SAVR is contraindicated or associated with high risk. Patients are to be assessed by multidisciplinary teams comprising cardiac surgeons, cardiologists and anaesthesiologists, and subsequently referred for SAVR, TAVI or medical management. There are a number of factors that influence the treatment decision, including the assessed patient risk score, pre-existing comorbidities, associated procedures, age, patient preference and the referral process itself. There is no clear distinction of the exact group of patients in whom TAVI is likely to be beneficial, and no fully published cost-effectiveness analysis to evaluate the value of TAVI in practice has been found.

Objective

The objective of this work was to determine the cost-effectiveness of TAVI being available compared with not being available for patients who are high risk or in whom SAVR is contraindicated. The work aimed to conduct a literature review of cost-effectiveness studies and to build a model to analyse the cost-effectiveness of the use of TAVI in practice.

Methods

Comprehensive searches of bibliographic databases [MEDLINE, EMBASE, The Cochrane Library, Health Technology Assessment (HTA), Database of Abstracts of Reviews of Effects (DARE) and NHS Electronic Evaluation Database (EED), Centre for Reviews and Dissemination HTA, DARE and NHS EED], guideline resources, current trials registers, websites/grey literature and manufacturers' websites, and consultation with clinical experts were used to identify studies for the review of cost-effectiveness and studies containing information relevant to the cost-effectiveness model [costs, quality of life (QoL), long-term outcomes and other parameters]. As a recent systematic review (Bazian. *Percutaneous aortic valve replacement for severe aortic stenosis. Part A: Technology assessment and impact model for East Midlands Specialist Commissioning*

Group. Bazian Ltd; 2008) has examined the literature to 2007, searches were conducted to cover the period 2007 to November 2010, and were combined with previous findings. No fully published cost-effectiveness studies were found. Parameters for the cost-effectiveness model were selected on the basis of their applicability to the patient group under consideration and their representativeness in terms of the wider body of evidence.

Cost-effectiveness model

A model was built to assess the cost-effectiveness of TAVI separately in patients suitable and unsuitable for SAVR, together with overall results for the effect of making TAVI available. Substantial deterministic sensitivity analysis was carried out together with probabilistic sensitivity analysis.

Dealing first with the patients not suitable for SAVR, the comparison in this case is simply between TAVI and medical management. The base-case results show that TAVI is more costly but more effective than the comparator, with an incremental cost-effectiveness ratio (ICER) of £12,900 per quality-adjusted life-year (QALY). This result was robust to a number of changes in the model. In the deterministic sensitivity analysis, the only case in which the ICER exceeded £20,000 per QALY was when the QoL scores were taken to an extremely low value. The ICER was below £20,000 per QALY for over 99% of model runs in the probabilistic sensitivity analysis.

On the other hand, for patients suitable for SAVR, the comparator with TAVI is a mixture of SAVR and medical management. In this case, TAVI is both more costly and less effective (in terms of QALYs) than the comparator in the base-case analysis, which assumes that the vast majority of patients in this group would receive SAVR in the absence of TAVI. The base-case result is robust to a number of changes in the assumptions about the effects of treatment, but highly sensitive to assumptions about the proportion of patients receiving SAVR in the comparator arm of the model.

Overall results in the base-case analysis are close to the results for patients not suitable for SAVR, as would be expected given that these patients are assumed to form the majority of the modelled population. When the use of TAVI is extended to include a larger number of patients suitable for SAVR, the overall results from the model become less favourable for TAVI.

Conclusions

The results given here for TAVI compared with medical management in patients unsuitable for surgery are reasonably robust and suggest that TAVI is likely to be cost-effective in these patients. On the other hand, for patients who could have surgery as an alternative, the model results suggest that TAVI could be both more costly and less effective than SAVR. However, these results are not based on randomised data and could easily be upset by the results of trials reporting after this work was carried out.

The overall results suggest that the total effect of introducing TAVI falls within conventional standards of cost-effectiveness. It should be stressed that this depends on the assumption that a very substantial majority of TAVI patients will be those who are unsuitable for surgery. From a decision-theoretic point of view, the overall results should not be used to guide any decision, but the decision to allow TAVI for different patient groups should be taken separately for each group based on the results for that patient group alone. However, in practice a decision to allow TAVI for patients deemed unsuitable for surgery is likely to lead to TAVI being offered to some higher-risk patients who would have received surgery in the absence of TAVI. It is helpful to quantify the importance of this possibility.

Implications for health care

The results in this report suggest that TAVI is a cost-effective treatment when the comparator is medical management. However, the modelling in this report does not suggest that TAVI should be widely used as an alternative to SAVR.

Recommendations for future research

The various initial models, including those produced for manufacturers and the Scottish Health Technologies Group, need to be reconciled with each other and with the model introduced in this report. The sensitivity analysis from each of these models should give an indication of the importance of the various features of an agreed model.

The data being generated while this report was under construction should be included where appropriate in any revised analysis based on an agreed model structure.

Future data collection, including any future trials, should be designed with economic evaluation in mind. In particular, once a set of relevant health states for future modelling is agreed, every effort should be made to obtain realistic and reasonable QoL scores for those health states.

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