Markov model for selection of aortic valve replacement versus transcatheter aortic valve implantation (without replacement) 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
This study examined the cost-effectiveness of transcatheter aortic valve implantation, without replacement, versus tissue aortic valve replacement, for the treatment of high-risk patients with severe aortic stenosis. The authors concluded that implantation was a cost-effective alternative to replacement for high-risk patients. The methods were valid and transparent and key areas of uncertainty were addressed, supporting the validity of the authors’ conclusions.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the cost-effectiveness of transcatheter aortic valve implantation, without replacement, versus tissue aortic valve replacement, for the treatment of high-risk patients with severe aortic stenosis.

Interventions
Transcatheter aortic valve implantation and aortic valve replacement were compared with medical management.

Location/setting
USA/tertiary care.

Methods
Analytical approach:
The analysis was based on a Markov model, with a lifetime horizon. The authors stated that the analysis took the perspective of the health care provider.

Effectiveness data:
The clinical inputs were from various sources, including published reports, and the data were combined using weighted averages and standard deviations. Most of the evidence was from prospective registries, which provided estimates of operative and postoperative events, such as strokes, heart failure, and death, for the two surgical procedures, over the long term. The rates of death and complications were the key inputs. Some adjustments were made to account for differences between the study groups in the registries.

Monetary benefit and utility valuations:
The utility values were from published sources, which included two studies that used the European Quality of life (EQ-5D) instrument, and a comprehensive systematic review that used the time trade-off technique and the standard gamble method.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure and were discounted at an annual rate of 5%.

Cost data:
The economic analysis included the costs of implantation or replacement (procedure, follow-up, and complications), heart failure, stroke, and medical management. Reimbursement rates were used as proxies for the costs and were from published reports, including diagnosis-related group data and Medicare payments for Current Procedural Terminology
codes. The relevant costs were from the Healthcare Cost and Utilization Project's nationwide in-patient sample. Other data on resource consumption were assumed by the authors. The reimbursements for both surgical procedures were assumed to be equal. The costs were in US $ and a 5% annual discount rate was applied. The price year was 2011.

Analysis of uncertainty:
A Monte Carlo simulation was performed to investigate the uncertainty in the model inputs, with beta distributions assigned for probabilities and utility weights, and gamma distributions for costs. Confidence intervals around the health and economic outcomes were generated. A cost-effectiveness threshold of $100,000 per QALY gained was considered for cost-effectiveness acceptability curves. One-way sensitivity analyses were carried out to identify the most influential inputs and a two-way sensitivity analysis was performed for selected parameters.

Results
Both implantation and replacement were cost-effective, compared with medical management. The incremental cost per QALY gained was $39,964 for transcatheter aortic valve implantation and $39,280 for aortic valve replacement.

The lifetime costs were $56,339 with replacement and $59,503 with implantation. The QALYs were 1.72 with replacement and 1.78 with implantation. The incremental cost per QALY gained with implantation over replacement was $52,733.

The sensitivity analysis showed that the probabilities of perioperative death and death each year after replacement or after implantation were key determinants of the model outcomes. When the resource use and costs from a clinical trial were used instead of being assumed to be equal for implantation and replacement, the incremental cost per QALY gained for implantation over replacement was reduced to $32,000.

Threshold analysis suggested that the net monetary benefit was most influenced by the initial cost of implantation.

Authors' conclusions
The authors concluded that implantation was a cost-effective alternative to replacement for high-risk patients.

CRD commentary
Interventions:
The authors justified their selection of the comparators. The two surgical procedures were the available interventions for high-risk patients with severe aortic stenosis. Medical management was not an option, but was considered to define the cost-effectiveness of the two surgical procedures.

Effectiveness/benefits:
Most of the clinical inputs were from registries that included long-term data on many patients. This authors stated they used data from registries, rather than from clinical trials, so as to be more representative of clinical practice. Also the trials only provided data for one year, but the authors analysed a lifetime horizon. There were differences between the study groups in these registries and selection bias cannot be ruled out, but the authors made adjustments for these issues. In the sensitivity analysis, data from a clinical trial were used. QALYs were a valid benefit measure and allow comparisons with other diseases. The utility values were from published sources, and the instruments used were clearly reported. The authors pointed out that utilities were age adjusted.

Costs:
The costs and their sources were consistent with the viewpoint of the health care payer. Typical US sources were used. A key assumption was that reimbursements were equal for implantation and replacement, but this was tested in the sensitivity analysis. The authors stated that the costs of the hospital stay were not considered. The costs were not broken down to individual items and were presented as category totals. This reduces the transparency of the analysis, but was due to using the accounting system of the third-party payer. The price year was explicitly stated, allowing reflation exercises. Variations in the cost inputs were assessed in the sensitivity analyses.

Analysis and results:
The results were clearly reported for both procedures, but the expected costs and benefits of medical management were not stated. An incremental approach was appropriately used to synthesise the costs and benefits of the alternative
strategies. Deterministic and probabilistic approaches were used to assess uncertainty, and the methods and results were clearly illustrated and discussed. The authors acknowledged some limitations to their analysis mainly due to the need for simplifications and assumptions. The findings appear to be specific to the authors' setting and are unlikely to be transferable to other settings without changes to the costs and some clinical data.

Concluding remarks:
The methods were valid and transparent and key areas of uncertainty were addressed, supporting the validity of the authors' conclusions.

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