Economic impact of drug-eluting stents on hospital systems: a disease-state model

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
The use of drug-eluting stents (DES) in patients with coronary disease was examined.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of patients presenting with coronary disease shown on angiography.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and resource use data were derived from studies published between 1996 and 2002 and from a database covering the period January to December 2000. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a synthesis of completed studies and from expert opinion.

Modelling
A state-transition computer model was constructed to simulate the clinical and economic outcomes in an initial sample of 3,112 patients with coronary disease, who were undergoing catheterisation at the authors’ institution (the Duke University Medical Center). The time horizon of the model was 5 years and each cycle lasted one year. At year 0, there were 623 patients in the MED group, 138 patients in the BA group, 1,287 patients in the USI group, and 1,064 patients in the CABG group. DES were available at the start of year 1. The model considered the proportion of patients in each of the four initial groups who were treated with DES, and the changes in clinical and economic outcomes associated with the use of DES. A simplified structure of the model was reported.

Outcomes assessed in the review
The outcomes estimated from the literature were the revascularisation and restenosis rates, and the number of stents for diseased vessels.
Study designs and other criteria for inclusion in the review
A systematic review of the literature does not appear to have been undertaken to identify relevant studies. Primary sources were the Duke Databank for Cardiovascular Disease (DDCD) and clinical trials. However, the design of some studies was not reported.

Sources searched to identify primary studies
Not stated.

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

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

Number of primary studies included
Six primary sources were used to identify relevant studies.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
The risk of percutaneous intervention was 5% in MED patients. BA patients had a 36% risk of restenosis requiring repeat revascularisation.

USI patients had a 26% risk for repeat revascularisation. CABG patients had a 2% risk for percutaneous intervention for graft failure.

The initial restenosis rate for DES was 4% per patient.

Patients who required revascularisation were assigned to DES in a similar fashion to patients with de novo disease.

Patients who had restenosis within a DES would require BA in 10% of cases, CABG in 5% of cases, and additional DES in 85% of cases.

Patients who returned for repeat revascularisation had a higher risk for recurrent restenosis and later percutaneous procedures.

the risks for repeat revascularisation increased to 40% for BA, 30% for USI, 10% for DES, and 10% for repeat graft interventions.

USI patients had a mean of 1.3 diseased vessels and required a mean of 1.477 stents during their procedures (1.14 stents per diseased vessel treated). CABG patients had an average of 2.7 diseased vessels. These patients required comparable revascularisation (3.1 stents) if percutaneous methods were to be substituted for bypass grafting. MED patients had an average of 2.3 diseased vessels and required 2.6 stents if converted to percutaneous intervention.
Methods used to derive estimates of effectiveness
The percentage of patients shifting from the current interventions to DES was evaluated using expert opinion. A questionnaire was administered to cardiologists at the Duke Hospital.

Estimates of effectiveness and key assumptions
The cardiologists predicted that DES would be used for 12% of patients previously receiving MED, 38% of patients with restenosis after BA, 85% of patients with restenosis of a bare stent, and 33% of patients with recurrent symptoms after CABG.

Measure of benefits used in the economic analysis
The main model output was the reduction in the number of patients requiring repeat revascularisation procedures due to the use of DES, compared with a scenario where DES were not available. However, such a benefit measure was not combined with the costs. In effect, a cost-consequences analysis was performed.

Direct costs
Discounting could have been relevant since a time horizon of 5 years was used in the simulation model. However, no discounting appears to have been applied. The unit costs were not presented separately from the quantities of resources used. The costs were presented as macro-categories. The health services included in the economic evaluation were all hospital resources associated with the interventions under examination, MED, BA, USI, CABG, and DES. The cost/resource boundary of the study was that of the hospital. The costs and resource use were derived from the DDCD, but some assumptions were also made. The fixed costs were assumed to remain constant and be independent of coated stents. The variable costs for coated and uncoated stents were assumed to be identical. The conversion from current interventions to DES was evaluated using a questionnaire administered to cardiologists at the Duke Hospital. The price year was not explicitly reported.

Statistical analysis of costs
Statistical analyses were performed. These assessed the 95% confidence interval (CI) of patient flows and cash flows.

Indirect Costs
The indirect costs were not considered in the economic evaluation.

Currency
US dollars ($).

Sensitivity analysis
Univariate sensitivity analyses were carried out to deal with three uncertain aspects of the model. More specifically, diversion rates from current therapy to coated stents, the risk of repeat revascularisation for patients receiving DES, and the hypothesis that patients diverted from CABG or MED would be fully revascularised. The minimum and maximum probability values of diversion from current therapy to coated stents were derived from the physician survey. The ranges of other model inputs were presumably derived from the literature.

Estimated benefits used in the economic analysis
In the absence of DES, over the 5-year time horizon, 520.5 patients (95% CI: 519.2 - 521.8) required repeat revascularisation procedures. However, in the scenario where DES were available, the average number of repeat revascularisation procedures was 206.4 (95% CI: 204.4 - 207.2), thus resulting in a 60.4% reduction.
**Cost results**
The annual fixed costs were $25.1 million. These were constant for all years of simulation.

The impact of DES led to an increase in variable costs, which at year 5 were $32.8 million in the model without DES and $34.6 million in the model where DES were available.

Without any change in reimbursement policy, first-year revenue declined from $59 million in the model without DES to $53.7 million in the DES model.

The simulated hospital converted from an annual profit of $2.01 million to a loss of $8.10 million in the first year (95% CI: 8.09 million - 8.12 million) and an $8.7 million annual loss in later years.

The overall change in cash flow was $55.71 million (95% CI: 55.66 million - 55.76 million) over 5 years.

The sensitivity analysis showed that the diversion of bypass-surgery patients to DES was the largest driver of hospital profits, followed by diversion from USI to DES. Annual losses in year 5 ranged from $3 million to $17.8 million, depending on the magnitude of diversions from existing therapies to DES.

If the increase in the reimbursement for DES were $2,090 for diagnosis-related groups, as proposed by the US Department of Health and Human Services, then losses would be reduced to $4.75 million in the first year and $5.6 million annually thereafter. The net cash flow away from the hospital remained greater than $25 million over 5 years.

To make DES margin-neutral, the reimbursement increase would need to exceed $4,400 per patients in settings with minimal diversion from bypass surgery (15%). At the study institution, where 33% of bypass surgery patients were shifted to DES, an increase in reimbursement of greater than $5,700 per patient was required for profits to remain neutral.

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was not relevant since a cost-consequences analysis was performed.

**Authors' conclusions**
Typical reimbursement policy adjustments did not accommodate the diversion of patients with coronary disease from conventional treatment to coated stents.

**CRD COMMENTARY - Selection of comparators**
The selection of the comparators was appropriate as it reflected standard patterns of care at the authors’ institution before DES were available. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness evidence came from published sources and a hospital database. The primary studies appear to have been identified selectively and a systematic review of the literature was presumably not undertaken. Limited information on the design and characteristics of the primary studies was provided. The methods used to extract and combine the primary estimates were not reported. Some of the sources used were clinical trials, which ensure a high internal validity of the model estimates. Only some model inputs were varied in the sensitivity analysis.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments reported in the "Validity of estimate of measure of effectiveness" field (above).

**Validity of estimate of costs**
The authors reported explicitly the perspective of the study. The costs were derived from the hospital database, while some key resource use data (i.e. the shift from conventional treatments to DES) were derived from a survey of cardiologists. As this estimate could vary across centres, wide variations of the model input were investigated in the sensitivity analysis. All relevant hospital costs were included in the economic evaluation. However, the costs were presented as macro-categories and a breakdown of the cost items was not provided. This limits the possibility of replicating the study. The price year was unclear, which makes reflation exercises in other settings difficult. Discounting could have been relevant, owing to the long time horizon of the study, but it was not applied.

Other issues
The authors did not report the results of economic analyses evaluating the impact of coated stents. The issue of the generalisability of the study results to other settings was, in part, addressed by carrying out sensitivity analyses where alternative model inputs were considered. However, the sensitivity analysis focused primarily on economic estimates. The authors noted some limitations to the validity of their study. First, most of the evidence came from a single institution and referral patterns could not be representative of other centres. Second, the survey sampled the opinions of interventional cardiologists, but the attitudes of cardiac surgeons, internists, or other specialties were not examined. Third, the impact of changes in the use of brachytherapy was not considered in the model. Fourth, referral patterns from small to larger hospitals were not evaluated. Finally, a long-term time horizon was not considered.

Implications of the study
The study results suggested that, although Medicare had proposed incremental reimbursement for coated stents, this increase would not totally offset the impact of using coated stents on the hospital costs. Hospitals could approach cost neutrality only if bypass surgery patients were not diverted to stents, or if patients were willing to be treated with uncoated stents when the effectiveness difference was small. Alternatively, cost neutrality could be achieved only with the introduction of less expensive coated stents.

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Other publications of related interest


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