Cost-effectiveness of drug-eluting stents including the economic impact of late stent thrombosis

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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 drug-eluting stents, considering the impact of late stent thrombosis and the need for extended clopidogrel therapy, in comparison with bare-metal stents. The authors concluded that extended clopidogrel therapy and the adverse events due to late stent thrombosis increased the cost of treatment, which meant that drug-eluting stents were not cost-effective. The study appears to have been well conducted and both the methods and results were clearly presented. The authors’ conclusions appear to be valid.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
The objective was to examine the cost-effectiveness of drug-eluting stents (DES), considering the impact of late stent thrombosis and the need for extended clopidogrel therapy, in comparison with bare-metal stents (BMS).

Interventions
Two types of DES, based on sirolimus and paclitaxel, were compared with conventional BMS.

Location/setting
USA/hospital.

Methods
Analytical approach:
The analysis was based on data from published studies and the authors stated that it took the perspective of the third-party payer.

Effectiveness data:
The clinical data on the baseline characteristics of patients and the treatment efficacy were derived from two published randomised controlled trials (RCTs): the Sirolimus-Eluting Balloon Expandable Stent in the Treatment of Patients With De Novo Native Coronary Artery Lesions (SIRIUS) trial, which included 1,058 patients receiving either BMS or sirolimus-eluting stents, and the TAXUS-IV trial, which included 1,314 patients receiving either BMS or paclitaxel-eluting stents. The follow-up in both trials was one year and two separate analyses were carried out, one for each trial. The incidence of late stent thrombosis, which was the key variable, but was not considered in the two trials, was estimated from a systematic search in the MEDLINE database using explicitly reported inclusion criteria that identified five eligible studies. The average of the incidence of late stent thrombosis in these five studies was used.

Monetary benefit and utility valuations:
The utility estimates appear to have been derived from the two RCTs, but their details were not reported.

Measure of benefit:
Quality-adjusted life-years (QALYs) and revascularisations avoided were the summary benefit measures.

Cost data:
The economic analysis included four main categories: procedure, follow-up, late stent thrombosis, and two-years of
additional clopidogrel therapy. A breakdown of cost items was provided. The resource use data and costs were derived from the two RCTs, with the cost of late stent thrombosis derived from a published article and authors’ opinions. All costs were in US dollars ($).

Analysis of uncertainty:
A sensitivity analysis was carried out considering the best- and worst-case scenarios by varying the late stent thrombosis incidence, the cost per death, and the cost per myocardial infarction. Published ranges of values were used.

Results
The total costs and QALYs for each option were not reported separately. The cost per revascularisation avoided for DES compared with BMS was $15,056, using data from the SIRIUS trial, and $25,210, using data from the TAXUS-IV trial. The cost per QALY gained was $250,935 with SIRIUS data and $257,591 with TAXUS-IV data.

The sensitivity analyses showed that the cost per revascularisation avoided varied from $14,618 to $15,830 for the SIRIUS trial and from $24,540 to $26,396 for the TAXUS-IV trial. The cost per QALY gained varied from $243,638 to $263,840 for the SIRIUS trial and from $250,739 to $269,708 for the TAXUS-IV trial.

Even in the best-case scenario the cost per QALY gained for DES compared with BMS was higher than the standard threshold for cost-effectiveness.

Authors’ conclusions
The authors concluded that the adverse events related to late stent thrombosis and the need for extended clopidogrel therapy increased the costs of treatment, which meant that DES were not cost-effective.

CRD commentary
Interventions:
The selection of the comparators was appropriate as BMS were the standard care before the introduction of DES and two available DES were considered.

Effectiveness/benefits:
The approach used to identify the relevant sources of evidence was appropriate and two pivotal RCTs were used to derive most of the clinical data for the two types of DES. The key details of the systematic search of the literature were provided and this search was appropriate for identifying the most valid available evidence on late stent thrombosis for the model. Alternative ranges of values were tested in the sensitivity analysis due to the need for some assumptions in the base case. The authors justified their selection of the two benefit measures. QALYs are widely accepted and commonly used due not only to their ability to capture the whole impact of the interventions on both quality of life and survival, but also to their comparability with the benefits of other health care interventions. Revascularisations avoided were a more interesting measure given the modest impact of restenosis treatment on survival.

Costs:
The categories of costs were consistent with the perspective adopted. Extensive information on the costs and patterns of resource consumption were reported for both trials, and, although some costs were presented as macro-categories, in general, the economic analysis was transparently presented. The cost of late stent thrombosis was presented as a macro-category and was calculated as the cost of death (for which some assumptions were required) plus the cost of non-fatal myocardial infarction. Given the uncertainty underlying this estimation, a sensitivity analysis was performed on it. The price year was not reported, which limits the possibility of making reflation exercises in other time periods.

Analysis and results:
The results were clearly presented, but the total costs and QALYs were not reported separately; only incremental values were provided. The issue of uncertainty was investigated using a deterministic approach, which focused on the most uncertain inputs of the model. A more comprehensive approach would have been useful. The time horizon of the analysis was not clear. The RCTs that provided the data had one-year time horizons, but this study aimed to assess the costs and benefits over a longer period. The authors acknowledged some limitations of their study and these should have favoured the DES.
Concluding remarks:
The study appears to have been well conducted and both the methods and results were clearly presented. The authors' conclusions appear to be valid.

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