Defining patients at high risk for gastrointestinal hemorrhage after drug-eluting stent placement: a cost utility analysis
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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, compared with bare metal stents, for patients at risk of gastrointestinal bleeding due to the prolonged use of dual anti-platelet therapy. Drug-eluting stents were cost-effective for average-risk patients, but not for patients with two or more risk factors. The methods were valid, but more detail in the reporting would have allowed an objective assessment of the authors’ conclusions.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the cost-effectiveness of drug-eluting stents compared with bare metal stents in patients who were at a high risk of gastrointestinal bleeding due to the prolonged use of dual anti-platelet therapy to prevent stent thrombosis.

Interventions
Drug-eluting stents were compared with bare metal stents. After surgery, dual anti-platelet therapy was administered for two weeks with bare metal stents or three months with sirolimus-eluting stents.

Location/setting
USA/secondary care.

Methods
Analytical approach:
The analysis was based on a Markov model, with a one-year time horizon and a hypothetical 60-year-old patient who had non-emergent percutaneous coronary interventions (PCIs). The authors stated that the analysis was carried out from the perspective of the third-party payer.

Effectiveness data:
The clinical data were from published literature, identified through a review in PubMed. This included randomised controlled trials (RCTs) that compared bare metal stents versus drug-eluting stents and were published between 1990 and November 2009. The bibliographies of the retrieved trials were reviewed. Averages, weighted by sample size, were calculated where more than one study was found for a model parameter. A published meta-analysis was used for the risk of gastrointestinal bleeding while on aspirin and Plavix (dual anti-platelet therapy), which was the key model input.

Monetary benefit and utility valuations:
The utility values were from a published study.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure.

Cost data:
The economic analysis included the costs of initial stent placement, aspirin, Plavix, coronary artery bypass graft, and gastrointestinal haemorrhage. Procedure-related costs were from the literature and weighted averages were calculated.
where multiple sources were available. The costs of drugs were from average wholesale prices. All costs were in US dollars ($) and the price year was 2009.

Analysis of uncertainty:
A one-way sensitivity analysis was undertaken varying the risk of gastrointestinal bleeding from dual anti-platelet therapy. A two-way analysis was carried out varying the risk of gastrointestinal bleeding while on aspirin alone and the risk of gastrointestinal bleeding while on dual anti-platelet therapy. A tornado analysis was performed to rank the most influential inputs.

Results
In the base case, the mean costs were $15,695.60 with bare metal stents and $15,956.40 with sirolimus-eluting stents and the benefits were 0.94611 with bare metal stents and 0.95174 with sirolimus-eluting stents. The incremental cost per QALY gained with sirolimus-eluting stents over bare metal stents was $46,387.66.

At a threshold of $100,000 per QALY, sirolimus-eluting stents remained cost-effective when the rate of annual gastrointestinal bleeding on dual anti-platelet therapy was as high as 6.52% (1.14% at a threshold of $50,000 per QALY and 9.69% at a threshold of $150,000 per QALY). As the risk of gastrointestinal bleeding while on aspirin alone increased, the threshold incremental risk of bleeding while on dual anti-platelet therapy decreased.

The most influential inputs were the cost of the initial sirolimus-eluting stent placement, the rate of repeat revascularisation for bare metal stents, the cost of the initial bare metal stent placement, the mortality from cardiac causes, and the rate of repeat revascularisation for sirolimus-eluting stents. At a threshold of $100,000 per QALY, in patients with two risk factors for gastrointestinal bleeding, the threshold relative risk of gastrointestinal bleeding from dual anti-platelet therapy could be as low as 1.6, making drug-eluting stents unlikely to be cost-effective.

Authors’ conclusions
The authors concluded that drug-eluting stents were likely to be cost-effective for average-risk patients, even when the risk of gastrointestinal bleeding from dual anti-platelet therapy was high, but for patients with two or more risk factors, they were not cost-effective.

CRD commentary
Interventions:
The selection of comparators was appropriate. Drug-eluting stents were compared against bare metal stents and these were the two technologies available for patients having non-emergent PCIs. There were two types of drug-eluting stent; sirolimus-eluting and paclitaxel-eluting. The paclitaxel stent was not considered because it appeared to be equivalent to the sirolimus one in the medical literature and because US guidelines recommended longer anti-platelet therapy with paclitaxel-eluting stents, which was of no benefit for these patients.

Effectiveness/benefits:
The clinical analysis was appropriately based on a review of the medical literature to identify the relevant sources of data. The authors provided the key details of the methods and conduct of the review. The inclusion criteria were designed to identify high-quality data, as well-conducted RCTs have sound methods. The use of a published meta-analysis for the data on bleeding was appropriate. These points enhance the validity of the clinical inputs. The utility values were from a published study and the tool used to value them was not described. QALYs were an appropriate benefit measure due to the impact of the disease on survival and health-related quality of life.

Costs:
The economic analysis included those costs relevant to the perspective stated. Most of the cost data were from published literature, but the authors did not provide details of these studies. The costs were reported as category totals and the unit costs were not presented separately from the resource quantities. In general, little information was given on the economic inputs. Some cost categories were varied in the sensitivity analysis and they had a strong influence on the findings.

Analysis and results:
The results were clearly reported and the costs and QALYs were appropriately synthesised in an incremental analysis. Threshold analyses were carried out to identify the critical values for the model inputs that changed the cost-effectiveness decision. Other sensitivity analyses were performed on some inputs. The authors did not justify the short (one year) time horizon of the model. The exclusion of the increased risk of stent thrombosis with drug-eluting stents biased the model in favour of drug-eluting stents. Some limitations were acknowledged by the authors, such as the heterogeneity in patient populations and other characteristics of the included trials, the uncertainty around the utility values, and the need for some assumptions, which generally favoured drug-eluting stents.

Concluding remarks:
The methods were valid, but more detail in the reporting would have been useful for an objective assessment of the authors' conclusions.

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