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Title **Drug-Eluting Stents: A Systematic Review and Economic Evaluation**

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Aim

To assess the effectiveness and cost effectiveness of using drug-eluting coronary artery stents in percutaneous coronary intervention (PCI) in patients with coronary artery disease (CAD).

Conclusions and results

In the 17 randomized controlled trials (RCTs) of drug-eluting stents (DES) versus bare metal stents (BMS), no statistically significant differences in mortality or myocardial infarction (MI) were identified up to 3 years. Significant reductions in repeat revascularizations were determined for DES compared with BMS. This estimated benefit appears to be stable from 1 to 3 years. Binary restenosis and late luminal loss also favored DES. In the 8 RCTs of DES versus DES, no statistically significant differences in mortality or MI were detected between DES designs. In meta-analyses of target lesion revascularization (TLR), target vessel revascularization (TVR), and composite event rate, a marginal improvement in efficacy of Cypher™ over Taxus™ was observed. These results await confirmation beyond 1 year, and differences in study design may have influenced the reporting of outcomes. The review included 10 full economic evaluations, and the balance of evidence indicated that DES are more cost effective in higher risk patients. The review of submitted models confirmed the view that DES may be cost effective only under very limited circumstances when realistic assumptions and data values were used. In the cost-utility analysis of DES versus BMS, the use of DES appears to reduce the rate of repeat revascularizations; benefit estimates used in the economic assessment are defined as 'broad' (ie, cases involving any TLR/TVR irrespective of any other lesions/vessels undergoing revascularization) and 'narrow' (ie, cases involving TLR/TVR only). The incremental benefit to the patient is described as the loss of quality-adjusted life-years (QALYs) avoided by not having to undergo repeat revascularization. Univariate sensitivity analysis and extreme values analysis indicate that the price premium, numbers of stents used in the index procedure, and absolute risk reduction in repeat interventions most significantly influence the cost-effectiveness ratios. Sensitivity analyses also permit a range of values for efficacy and effectiveness to be considered for individual designs of DES. The cost-effectiveness results reveal that (all patients considered together) the calculated cost per QALY ratios are high (GBP 183 000–562 000) and outside the normal range of acceptability. Cost effectiveness is only achieved for those non-elective patients who have undergone a previous coronary artery bypass graft and have small vessels. 'Real-world' data show that patient numbers in this latter group are small.

Recommendations

DES would be best targeted at subgroups of patients with the highest risks of requiring re-intervention, and could be considered cost effective in only a small percentage of such patents. This is similar to the conclusion of our previous assessment. The annual volume of DES purchased by the NHS in England is estimated to range between 35 000 and 42 000 units, costing an additional GBP 21–25 million. If anecdotal evidence of 70% current DES usage is accepted, the estimated total cost of purchasing DES rises to GBP 30–36 million; if 100% DES usage were assumed, the projected cost would be around GBP 42–51 million.

Methods

A systematic literature review of effectiveness focused primarily on RCTs. Full economic evaluations that compared 2 or more options, and considered both costs and consequences, were eligible for inclusion in the economic review. A critique of manufacturer submissions to NICE and an economic evaluation (cost-utility analysis) were carried out.

Further research/reviews required

Further research would be useful in the following areas: trials of DES compared with new generation BMS, trials of DES compared with DES, and evaluation of newer BMS in combination with drug administration.

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