Cost-effectiveness of paclitaxel-coated balloon angioplasty in patients with drug-eluting stent restenosis


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 evaluated the cost-effectiveness of drug-coated balloon angioplasty for patients who had drug-eluting stents that required restenosis. The authors concluded that drug-coated balloon angioplasty was cost-effective; its higher costs were offset by later savings. It is unclear if all the relevant effectiveness data and interventions were considered, which could have distorted the conclusions. It is unclear if the cost-effectiveness results and authors’ conclusions are valid.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study evaluated the cost-effectiveness of drug-coated balloon angioplasty for patients who had drug-eluting stents that required restenosis.

Interventions
Drug-coated balloon angioplasty was compared with plain balloon angioplasty and drug-eluting stent replacement. It was assumed that after the initial revascularisation, two more revascularisations could be performed using drug-coated balloon angioplasty or plain balloon angioplasty (a maximum of one drug-eluting stent and three balloon angioplasties per lesion), and one revascularisation could be performed using another drug-eluting stent (a total of three drug-eluting stents per lesion).

Location/setting
Germany/secondary care.

Methods
Analytical approach:
A Markov model was developed for the ongoing risk of death, bleeding, target lesion revascularisation and myocardial infarction, after drug-eluting stent restenosis, target lesion revascularisation, and coronary artery bypass graft surgery. The time horizon was six months. The authors stated that the perspective was that of a health care payer (German statutory insurance).

Effectiveness data:
The clinical data were identified by a systematic review of the literature. The key data were the rates of procedural success, complications, and deaths. Target lesion revascularisation rates for each intervention came from one or two studies of specific brands of drug-eluting stent or angioplasty balloon. The event rates for complications and deaths were from large clinical trials, registries and meta-analyses.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The measure of benefit was life-years gained.

Cost data:
The unit costs for surgery were from the German diagnosis-related group system. Pharmaceutical costs were from the Rote Liste (Red List). Drug-coated balloon angioplasty included extra-budgetary payments for new diagnostic and treatment methods. The costs were reported in 2012 Euros (EUR).

Analysis of uncertainty:
Probabilistic sensitivity analysis was performed by varying each model parameter simultaneously. One-way deterministic sensitivity analyses were conducted, by varying all parameters individually by ±25%. The number of target lesion revascularisations allowed for each treatment arm was also varied.

Results
The mean cost per patient was EUR 4,028 for drug-coated balloon angioplasty, EUR 4,101 for drug-eluting stent implantation, and EUR 4,169 for plain balloon angioplasty. The mean life-years per patient were 0.497 for drug-coated balloon angioplasty, 0.494 for drug-eluting stent, and 0.489 for plain balloon angioplasty.

Drug-coated balloon angioplasty was the dominant treatment as it was more effective and less costly.

The cost-effectiveness of drug-coated balloon angioplasty was sensitive to varying several parameters, particularly the initial procedure costs, the target lesion revascularisation rates, and the costs of dual antiplatelet therapy; drug-coated balloon angioplasty remained cost-effective.

In the probabilistic sensitivity analysis, drug-coated balloon angioplasty was dominant over plain balloon angioplasty 88.9% of the time at a threshold of EUR 25,000 per life-year gained, and was dominant 95% of the time against drug-eluting stents at the same threshold.

Authors’ conclusions
The authors concluded that drug-coated balloon angioplasty was cost-effective for drug-eluting stent in-stent restenosis; its initial higher costs were offset by later savings.

CRD commentary
Interventions:
The interventions were described. Current practice was included which is useful for local decision-makers. Two interventions were mentioned in the introduction, but were not analysed and no reason was given for this. The authors stated that the natural comparison for the paclitaxel-eluting balloon was a paclitaxel-eluting stent, but this is not necessarily true. The inclusion of other stents might have changed the cost-effectiveness conclusions.

Effectiveness/benefits:
The authors stated that they conducted a systematic review of the literature to identify the data, but they gave no details; it is not clear if the best available evidence was used. Two small (50 and 110 patients) six-month trials were chosen for the primary effectiveness comparisons between drug-coated balloon angioplasty and plain balloon angioplasty. It was unclear how the results of these trials were synthesised and neither reported a myocardial infarction in drug-coated balloon angioplasty patients. The authors stated that restenosis occurred in 10% to 15% of patients – it is surprising that more trials of drug-eluting stents were not identified. Trials of other stents could have been included in a mixed-treatment comparison. A 402-patient trial comparing drug-coated balloon angioplasty, drug-eluting stents, and plain balloon angioplasty was referenced (ISAR-DESIRE 3; now fully published see Other Publications of Related Interest). This trial found no differences in myocardial infarction and death rates between paclitaxel drug-eluting stents and paclitaxel drug-coated balloon angioplasty, which could significantly change the conclusions of the model.

Costs:
The extra-budgetary payments for drug-coated balloon angioplasty were not explained. They could be additional costs to the health care payer for innovation. The costs and their sources for the interventions and treatment of complications were all reported. The costs were applicable to the German study setting.

Analysis and results:
The modelling appears to have been appropriate and beta distributions were appropriately used for the probabilistic sensitivity analysis. For the sensitivity analyses, it was not clear what the authors meant by parameter variations only.
affected the costs, but not the effectiveness. Given the small samples in the trials of drug-coated balloon angioplasty, it would have been appropriate to vary the estimates by more than ±25% of the mean. The threshold used to judge cost-effectiveness appears to have been EUR 25,000 per life-year gained; it has to be assumed that this was used for all analyses.

Concluding remarks:
It is unclear if all the relevant effectiveness data and interventions were considered, which could have distorted the conclusions. It is unclear if the cost-effectiveness results and authors’ conclusions are valid.

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