Cost-effectiveness analysis of enhancements to angioplasty for infrainguinal arterial disease
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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 assessed the cost-effectiveness of eight endovascular interventions for patients with infrainguinal peripheral arterial disease. The authors concluded that drug-coated balloons were the most cost-effective alternative but acknowledged the need for further research for a definitive conclusion. Methodology was good. Uncertainty around the validity of the effectiveness and cost estimates due to poor reporting and uncertainty around assumptions made in the model mean that we cannot be certain that the authors’ conclusion are appropriate.

Type of economic evaluation
Cost-utility analysis

Study objective
The study objective was to assess the cost-effectiveness of eight endovascular interventions for patients with infrainguinal peripheral arterial disease in the superficial femoral and femoropopliteal arteries.

Interventions
Eight interventions were assessed: percutaneous transluminal balloon angioplasty (PTA) with no bail-out stenting; PTA with bail-out drug-eluting stents; drug-coated balloons; primary bare metal stents; primary drug-eluting stents; endovascular brachytherapy; stent-grafts; and cryoplasty. The comparator was PTA with bail-out bare metal stents (self-expanding or balloon-expandable) which was assumed to reflect standard care. Paclitaxel was the drug considered for interventions involving a drug treatment.

Location/setting
UK/secondary care

Methods
Analytical approach:
A discrete-event simulation model was developed to assess the cost-effectiveness of the interventions over a lifetime horizon. Intermittent claudication (IC) and critical leg ischaemia (CLI) populations were modelled separately. The analysis was conducted from a UK National Health Service perspective.

Effectiveness data:
Key effectiveness estimates were relative risks associated with the time to acute or late failure and symptoms returning following loss of vessel patency. Relative risks were measured at 12 months except for drug-coated balloons which were measured at six months. A systematic review was conducted to identify all evidence for the model. Databases were hosted by Ovid, The Cochrane Library, Web of Science and EBSCO

It was assumed that prolonged patency led to lower re-intervention rates and improved quality of life by stopping the return of symptoms. Patients could also experience contralateral disease progression, amputation, death following an operation or general mortality. These outcomes were assumed to be independent of the interventions.

Monetary benefit and utility valuations:
The model incorporated an IC/CLI specific base-case utility value and utility decrements for asymptomatic cases, amputations and systemic complications. Utility values were measured using the EQ-5D questionnaire.

Measure of benefit:
Health benefit was measured in terms of quality-adjusted life-years (QALYs). Future QALYS were discounted at an annual rate of 3.5%.

Cost data:
The model incorporated a monthly amputation cost, systemic complication costs and an IC/CLI specific monthly cost. Two sources were used: NICE clinical guidelines for Lower Limb Peripheral Arterial Disease (CG147) and a published cost-utility analysis. It was assumed that the costs of PTA and bypass surgery were independent of whether the patient had IC or CLI. Costs were reported in 2009-2010 GBP (£) and discounted at an annual rate of 3.5%.

Analysis of uncertainty:
Univariate and probabilistic sensitivity analysis were conducted to assess the impact of uncertainty on the results. A cost-effectiveness acceptability curve (CEAC) was constructed to show the expected probability that each intervention would be cost-effective for a range of willingness-to-pay thresholds. Scenario analyses were conducted.

Results
Ranking the alternatives in order of increasing cost showed that drug-coated balloons dominated – produced the most QALYs (6.12 for IC and 3.4 for CLI) for the least cost (£12,668 for IC and £49,890 for CLI) – for both IC and CLI populations. The next best alternative was PTA with bail-out drug-eluting stents, which cost £13,032 for IC and £52,335 for CLI and produced 6.081 QALYs for IC and 3.29 QALYs for CLI.

For willingness-to-pay thresholds between £0 and £100,000 per additional QALY, the probability of drug-coated balloons being cost-effective was at least 58.3% for patients with IC and at least 72.2% for patients with CLI. The next best alternative was PTA with bail-out stents, which had a probability of being cost-effective of at least 34% for IC patients and 16.4% for CLI patients. All other alternatives had probabilities of being cost-effective that were less than 4%. The results were robust to all scenario and additional analyses.

Authors’ conclusions
The authors concluded that drug-coated balloons were the most cost-effective alternative but acknowledged the need for further research for a definitive conclusion.

CRD commentary
Interventions:
The interventions were clearly stated. Standard care was an appropriate comparator but the authors assumed this alternative was representative of standard care without providing any justification for assuming so. It appeared that all the relevant comparators were included.

Effectiveness/benefits:
Effectiveness estimates were reported clearly in a table. Sources used to derive estimates were identified appropriately in a systematic review. Inclusion criteria used to select evidence from the systematic review were not reported and there were no details of the specific sources used to derive inputs (other than citations) so it was not possible to assess the appropriateness of the sources and populations used to derive the effectiveness estimates. Utility estimates were clearly reported but there was limited information on the sources used so it was unclear if the estimates were appropriate.

The authors highlighted that a limitation of the analysis concerned the lack of evidence linking patency and clinical outcomes, such as claudication distance, quality of life and re-intervention. Relationships between patency and clinical outcomes may not be constant over time, as assumed. This was accommodated partly by modelling contralateral disease progression.

Costs:
No clear brake-down of costs included in the model was reported so it was unclear what specific resource utilisation items were incorporated into the reported monthly costs. The sources used to derive monthly costs were cited but not discussed. It appeared that the two sources used were UK specific but this was not stated explicitly. It was not clear how costs were inflated. The authors highlighted that the result that use of drug-coated balloons had lower lifetime costs was based on the assumption that prolonged patency led to cost savings as a result of fewer re-interventions. This was stated to be based on relatively little direct evidence.
Analysis and results:
The model was described clearly. A diagram was provided. A full incremental analysis was appropriately conducted. Appropriate and adequate sensitivity analyses were conducted to assess the impact of parameter uncertainty. The distributions applied to parameters in the probabilistic sensitivity analysis were clearly reported and appropriate. The results of the analysis were clearly reported with appropriate diagrams used.

The authors stated that care should be taken in extrapolating the results to other circumstances.

Concluding remarks:
Overall the methodology was good. Uncertainty around the validity of the effectiveness and cost estimates due to poor reporting of the sources and uncertainty around assumptions made in the model mean that we cannot be certain that the authors’ conclusion are appropriate.

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