

# Enhancements to angioplasty for peripheral arterial occlusive disease: systematic review, cost-effectiveness assessment and expected value of information analysis

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## Scientific summary

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# Scientific summary

## Background

Peripheral arterial occlusive disease (PAD) is a cause of major morbidity in the UK. There have been rapid technological developments aimed at improving the short- and long-term results of percutaneous transluminal balloon angioplasty (PTA).

## Objectives

This report aimed to assess current evidence on the clinical effectiveness and cost-effectiveness of additional techniques designed to improve the results of standard transluminal balloon angioplasty for PAD, to develop a health economic model to assess cost-effectiveness and to identify areas where further primary research is needed.

## Data sources

The following electronic databases were searched from inception to 2011: MEDLINE; MEDLINE In-Process & Other Non-Indexed Citations (Ovid); EMBASE (Ovid); The Cochrane Library; Cumulative Index to Nursing and Allied Health Literature (CINAHL); Science Citation Index (via ISI Web of Science); Social Science Citation Index (via ISI Web of Science); Conference Proceedings Citation Index – Science (CPCI-S) (via ISI Web of Science); UK Clinical Research Network Portfolio Database; Current Controlled Trials; and ClinicalTrials.gov. Searches were conducted between May and October 2011.

## Methods

Systematic reviews were conducted of clinical effectiveness and cost-effectiveness of enhancement to angioplasty. Additional focused searches were conducted on the natural history and quality of life (QoL) for PAD.

The population was participants with symptomatic PAD undergoing endovascular treatment for disease distal to the inguinal ligament. Interventions were techniques used as an adjunct to, or as a replacement for, balloon angioplasty in the peripheral circulation. Conventional PTA was the main comparator. An expert group of clinicians assisted in the identification of relevant technologies, known trials and important outcome measures. Outcomes included measures of clinical effectiveness, restenosis and the need for reintervention, and costs. Data were extracted from randomised controlled trials (RCTs), which were quality assessed using standard criteria.

A discrete-event simulation model was developed to assess the relative cost-effectiveness of the interventions from a NHS perspective over a lifetime. The patient populations of intermittent claudication (IC) and critical limb ischaemia (CLI) were modelled separately. Univariate and probabilistic sensitivity analyses were undertaken.

## Results

In total, 40 RCTs were included, although many had small sample sizes. Significantly reduced restenosis rates were shown in meta-analyses of self-expanding stents (SES) {relative risk (RR) 0.67 [95% confidence interval (CI) 0.52 to 0.87]}, endovascular brachytherapy (EVBT) [RR 0.63 (95% CI 0.48 to 0.83)] at 12 months and drug-coated balloons (DCBs) at 6 months [RR 0.40 (95% CI 0.23 to 0.69)], and single studies of stent-graft or drug-eluting stent (DES), compared with PTA; a single study showed improvement of DES versus bare-metal stents (BMSs). Compared with PTA, walking capacity was not significantly affected by cutting balloon, balloon-expandable stents or EVBT; in SES, there was evidence of improvement in walking capacity after up to 12 months.

The use of DCBs dominated both the assumed standard practice of PTA with bail-out BMSs and all other interventions because it lowered lifetime costs and improved QoL. These results were seen for both patient populations (IC and CLI). Sensitivity analyses showed that the results were robust to different assumptions about the clinical benefits attributable to the interventions, suggesting that the use of DCBs is cost-saving.

## Discussion

Despite many studies being identified, there remains uncertainty in the results of the report. Clinically, there was evidence of a significant benefit to reducing restenosis rates for SES, stent-graft, EVBT and DCB compared with PTA and for DES compared with BMS. If it is assumed that patency translates into beneficial long-term clinical outcomes, then DCB and bail-out DES are most likely to be the cost-effective enhancements to PTA.

A RCT comparing current recommended practice (PTA with bail-out BMS) with DCB and bail-out DES could assess long-term follow-up and cost-effectiveness. Data relating patency status to the need for reintervention and to the probability of symptoms returning should be collected, as should health-related QoL measures [European Quality of Life-5 Dimensions (EQ-5D) and maximum walking distance].

## Study registration

This study is registered as PROSPERO CRD42012002014.

## Funding

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