Infragenicular stent implantation for below-the-knee atherosclerotic disease: clinical evidence from an international collaborative meta-analysis on 640 patients


CRD summary
This review concluded that percutaneous infragenicular stent implantation following unsuccessful balloon angioplasty was associated with favourable results in patients with critical limb ischaemia and sirolimus-eluting stents appeared superior to bare metal and paclitaxel-eluting stents. Given the unexplained variability in the results and the lack of high-quality evidence available, the authors’ conclusions should be interpreted cautiously.

Authors’ objectives
To assess the literature published on the outcomes of stenting for below the knee disease in patients with critical limb ischaemia.

Searching
PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), BioMed Central, ClinicalTrials.gov databases and Google Scholar were independently searched by two reviewers. There were no language restrictions. Search dates were not reported. The search strategy was available online.

Study selection
Studies of percutaneous transluminal angioplasty (PTA) with stent implantation in the infragenicular arteries (tibioperoneal trunk, anterior tibial, peroneal and/or posterior tibial arteries or any of their branches) were eligible. Studies needed at least five participants and at least one month follow-up to be included.

In most of the included studies patients underwent below the knee stenting after having balloon-dilation or flow-limiting dissection that had left significant residual stenosis. A range of different stents were used: balloon-expandable and self-expanding bare metal stents; balloon-expandable drug-eluting stents (sirolimus-eluting stents only, predominantly sirolimus-eluting stents and paclitaxel-eluting stents only); and absorbable metal stents.

Two reviewers independently selected studies. Disagreements were resolved through consensus.

Assessment of study quality
Five aspects of quality were independently assessed by two reviewers: selection, performance, adjudication, attrition and reporting bias. Disagreements were resolved through consensus.

Data extraction
Mean and standard deviation or median and range (where appropriate) were extracted for continuous outcomes or percentages for categorical outcomes.

Two reviewers independently extracted data. Disagreements were resolved through consensus. Principal investigators of included studies were contacted about missing or unclear data.

Methods of synthesis
Single-arm studies were pooled using a random-effects model for computing incidence estimates to derive a pooled estimate with 95% confidence interval (CI). For studies with more than one group that received a stent intervention, each group was entered into the model as single arms. Statistical heterogeneity was assessed using the I² statistic. Differences in the performance of different types of stent were investigated using interaction tests. A sensitivity analysis using a fixed-effect model was also undertaken. The possibility of publication bias was assessed by visual inspection of funnel plots.
Results of the review
Twenty cohorts (n=640 patients, range 10 to 60) from 15 single-arm registries, two non-randomised controlled studies and one RCT were included. Overall study quality was described as moderate. Average length of follow-up was 12 months (range six to 26 months).

At follow-up, binary restenosis in the target lesion occurred in 25.7% of patients (95% CI 11.6% to 40%), primary patency in 78.9% (95% CI 71.8% to 86%), secondary patency in 92.6% (95% CI 87.7% to 97.5%), improvement in Rutherford class in 91.3% (95% CI 85.5% to 97.1%) and limb salvage on 96.4% (95% CI 94.7% to 98.1%). There was a target vessel revascularisation rate of 10.1% (95% CI 6.2% to 13.9%). With the exception of limb salvage, there was moderate or substantial statistical heterogeneity for these outcomes.

Based on subgroup analysis by stent type, studies that exclusively or predominantly used sirolimus-eluting stents reported superior outcomes for binary restenosis and primary patency compared to studies of bare metal stents and superior outcomes for primary patency and repeat revascularisations compared to studies of paclitaxel-eluting stents. Studies of balloon-expandable bare metal stents reported superior outcomes for primary patency and target vessel revascularisation compared to paclitaxel-eluting stents.

Use of a fixed-effect model confirmed the results. Based on inspection of the funnel plot, there was no evidence of publication bias.

Authors’ conclusions
Percutaneous infragenicular stent implantation after failed or unsuccessful balloon angioplasty was associated with favourable results in patients with critical limb ischaemia. Sirolimus-eluting stents appeared superior to bare metal and paclitaxel-eluting stents in terms of angiographic and/or clinical outcomes, notwithstanding limitations in the primary studies.

CRD commentary
There was a clearly stated review question and a number of relevant sources were searched without language restrictions, which reduced the risk of missed relevant studies. Appropriate methods were used to reduce error and bias in all the review processes. Authors of the primary studies were contacted where required data were missing and unclear. Study quality was assessed and classified as overall moderate; it should be borne in mind that the primary studies were all uncontrolled studies or in the case of the small number of controlled studies contributed cohort data only. There was moderate or high statistical heterogeneity in the analyses for most outcomes and this remained unexplained. As the authors pointed out, subgroup analysis that compared the different types of stents should be viewed as exploratory; it was possible that differences between cohorts other than the stent used may have influenced patient outcome. Overall, given the unexplained heterogeneity and the lack of high-quality evidence available the authors’ conclusions may not be reliable.

Implications of the review for practice and research
The authors did not state any implications for practice.

Research: The authors stated that RCTs were required to definitively appraise the role of primary stenting for below the knee disease and that research was required on the most appropriate duration and intensity of antithrombotic therapy following below the knee stenting.

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