Balloon angioplasty compared with stenting for treatment of femoropopliteal occlusive disease: a meta-analysis

CRD summary
This review concluded that stent placement in femoropopliteal occlusive disease does not increase the patency rate when compared with angioplasty alone at one year. Given the methodological shortcomings of this review, the results should be considered with caution.

Authors' objectives
To compare the short and long term results of primary stenting with balloon angioplasty for femoropopliteal occlusive disease.

Searching
MEDLINE and EMBASE were searched between 1980 and January 2007, the Science Citation Index was searched between 1990 and 2007, and the Cochrane Central Register of Controlled Trials was also searched. Search terms were reported. Reference lists of citations were checked and authors contacted. Although no language or date restrictions were applied during the initial searches, only papers published between September 2000 and January 2007 in English, German or French were considered for selection. Unpublished studies were considered if sufficient data were reported.

Study selection
Studies were considered eligible if they compared balloon angioplasty with stent implantation in patients aged over 18 years with femoropopliteal occlusive disease. Study design was not pre-specified but trials were required to include a minimum of 20 patients and report on at least 1-year primary patency or restenosis rate. Any stent was eligible and studies were required to report type of stent and number of initial failures.

Included studies were either randomised controlled trials (RCTs) or retrospective studies. A total of six different stent types were used across the included studies (Dynalink, Hemobahn, Luminexx, Memotherm, Palmaz, Wallstent) of which three studies used balloon expandable stents, and the two most recent trials used self-expandable stents. Follow-up varied across studies from 6 months to 4 years. Overall about 60% of the included patients were male and the average age ranged from 66.1 yrs in the angioplasty group to 67.5 yrs in the stent group.

The authors did not report how study selection was performed, or how many reviewers performed the selection.

Assessment of study quality
Study quality was assessed using the 5-point Jadad scale which assesses RCTs on the basis of randomisation, blinding and withdrawals. The reviewers decided a priori that studies scoring 4-5 points should be described as high quality and low quality if the Jadad score was equal to or less than 3. No quality assessment appears to have been carried out for the non-RCT study.

The authors did not state how the validity assessment was performed.

Data extraction
Patency (<50% stenosis) of femoropopliteal segment rates were extracted for each study to give odds ratios (OR). Outcomes data were also extracted on changes in ankle-brachial index (ABI), improvement of claudication distance, healing of wound, stent fracture (classed as grade 1, 2 or 3), rate of restenosis, cardiovascular and procedural complications. Where standard errors (SE) were not reported, these were estimated using the Greenwood formula.

Data was extracted independently by three reviewers using a standardised form with any discrepancies resolved by discussion.
Methods of synthesis
Pooled ORs and associated 95% confidence intervals (CI) comparing primary patency and postoperative ABI were calculated using a random-effect meta-analysis model (DerSimonian and Laird) where significant statistical heterogeneity was found. Heterogeneity was assessed using the $I^2$ test, and explored through sensitivity analyses, using ANOVA and regression models, on the basis of two key variables; 1-year patency rate and post-operative ABI. A funnel plot was used to evaluate publication bias.

Results of the review
A total of eight studies were included in this review (total n = 1,020), with seven RCTs being included in the meta-analyses (n=934). The mean Jadad score was 2 out of 5, range not reported. No publication bias was noted although the authors report that it could not be excluded.

Primary patency at 1-year (7 trials, n=452) was not significantly different between angioplasty and stenting, OR 0.989 (95% CI: 0.623, 1.570; p=0.962). Postoperative ABI showed no significant difference between treatment groups, OR 0.869 (95% CI: 0.557, 1.357; p=0.561). Balloon angioplasty patency rates at one year ranged from 45% to 84.2%, stent implantation patency rates were reported between 63% to 90% at one year. Stent fractures were reported only with self-expandable stents.

The regression analysis found that poor run-off vessels and pre-operative ABI were associated with patency rates.

Sensitivity analyses: both fixed and random effects models were used when exploring the effects of only including the most recent two trials, excluding poor quality studies and excluding studies with missing data. None of these analyses significantly changed the primary findings of this review.

Authors' conclusions
Stent placement in femoralpopliteal occlusive disease does not increase the patency rate when compared with angioplasty alone at one year.

CRD commentary
This review addressed a clear question with reasonable inclusion criteria, however clarification on eligible study designs would have been useful. The searches covered the major databases, although the apparent exclusion of trials pre-2000 may have resulted in this review giving a less than complete picture of the available evidence. The procedures of the review were poorly reported, therefore we cannot rule out reviewer error or bias. The analysis was complex but appears to have been appropriate. Given the methodological shortcomings of this review, the results should be considered with caution.

Implications of the review for practice and research
Practice: the authors stated that stent placement remains controversial but may be useful as a last resort procedure to save a failed femoropopliteal balloon dilation procedure.

Research: the authors stated that further research is required to identify suitable patients for primary stenting, and assess the impact of stent fracture and thrombosis on long-term patency rate.

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