Clinical impact of in-stent late loss after drug-eluting coronary stent implantation


CRD summary
The authors concluded that there was a significant relationship between "the difference in in-stent late loss after drug-eluting stent implantation compared with bare-metal stent implantation" and the number-need-to-treat for new revascularisations. Given the methodological limitations of this paper as a systematic review, the reliability of these conclusions are unknown.

Authors' objectives
To assess the clinical impact of in-stent late loss after drug-eluting stent implantation.

Searching
MEDLINE and abstract supplements from four scientific meetings (European Society of Cardiology, American College of Cardiology, American Heart Association and Transcatheter Cardiovascular Therapeutics) were searched until January 2006. No search terms were reported.

Study selection
Randomised controlled trials (RCTs) that included patients undergoing stent implantation were eligible for inclusion in the review. Included trials had to compare drug-eluting stent implantation with bare-metal stent implantation. Eligible trials had to provide follow-up angiographic data of in-stent late loss and the rate of target lesion revascularisation. In-stent late loss was defined as the difference between minimum lumen diameter immediately after implantation and that obtained at angiographic follow-up. Included trials were required to evaluate coronary stents commercially available in Europe by 2006.

In included trials, the mean age of patients ranged from 59 to 67 years, with the majority of participants being male. The proportion of diabetic patients ranged from 2 to 100%.

The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
Blinding and intention-to-treat were reported. No other criteria were used to assess quality.

The authors did not state how many reviewers performed the validity assessment.

Data extraction
The authors used mean in-stent late loss values from each trial in their statistical analyses. Δin-stent late loss was calculated as the difference in mean in-stent late loss in patients allocated to drug-eluting stent and those allocated to bare-metal stent. The authors also calculated number-needed-to-treat for new target lesion revascularisation procedures as a measure of the clinical benefit of using drug-eluting stent instead of bare-metal stent in each trial.

The authors did not state how many reviewers performed the data extraction.

Methods of synthesis
The authors stated that data were pooled using the Peto fixed-effect method, weighted by the number of patients in each trial. Heterogeneity was assessed using Cochran's Q statistic. Publication bias was assessed using the Begg and Mazumdar correlation test and Egger's regression method. Linear regression analyses were conducted to assess associations between angiographic data (mean in-stent late loss and Δin-stent late loss), the incidence of target lesion revascularisation, and number-needed-to-treat for new revascularisations (number-needed-to-treat for target lesion revascularisation).
Results of the review
Twenty-one RCTs (n=8,641 patients) were included in the review; 4,320 patients allocated to bare-metal stents and 4,321 patients allocated to drug-eluting stents. The sample sizes ranged from 42 to 1,197.

Mean in-stent late loss ranged from -0.01 to 0.63 mm in drug-eluting stent patients, and 0.63 to 1.09 mm in bare-metal stent patients. Δin-stent late loss ranged from 0.00 to 1.04 mm. Number-needed-to-treat for new target lesion revascularisation procedures ranged from four to 22 patients. No publication bias was reported. Heterogeneity was not reported.

There was a significant relationship between mean in-stent late loss in patients randomised to drug-eluting stent and number-needed-to-treat for target lesion revascularisation (0.62 mm, 95% confidence interval (CI) for β: 5.8 to 31.0; p=0.007), such that a 0.1 mm increase in mean in-stent late loss-drug-eluting stent was associated with a 1.8 increase in number-needed-to-treat for target lesion revascularisation.

There was also a significant association between Δin-stent late loss with the number-needed-to-treat for target lesion revascularisation (0.61 mm, 95% CI for β: -20.1 to -3.6; p=0.008), such that a 0.1 mm reduction in Δin-stent late loss was associated with a 1.2 decrease in mean number-needed-to-treat for target lesion revascularisation.

Additional outcomes were also reported.

Authors' conclusions
There was a significant association between the degree of inhibition of in-stent restenosis (due to neointimal formation) with the use of drug-eluting stent and the clinical impact of using drug-eluting stent instead of bare-metal stent.

CRD commentary
The inclusion criteria were clearly reported for interventions, outcomes and study designs, but less clear for participants. Although the authors did not search for unpublished studies, they assessed publication bias. The authors did not state how many authors were involved in the review process, thus potentially introducing reviewer bias. Assessment of the quality of the trials was not undertaken or considered in the analyses. The objective of the paper was to assess the clinical impact of in-stent late loss after drug-eluting stent. As such, the paper explored relationships using linear regression rather than effectiveness per se. Pooled data were not provided. Given the methodological limitations of this paper as a systematic review, the reliability of the conclusions are unknown.

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

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