Risk of late-acquired incomplete stent apposition after drug-eluting stent versus bare-metal stent: a meta-analysis from 12 randomized trials

CRD summary
This review concluded that drug-eluting stents could be associated with an increased risk of late-acquired incomplete stent apposition compared with bare metal stents, but the long-term clinical implications require clarification. The conclusions reflected the results of the review, but a limited search, lack of validity assessment and poor reporting of review methodology made their reliability unclear.

Authors' objectives
To assess whether implantation of a drug-eluting stent is associated with an increased risk of late-acquired incomplete stent apposition (ISA).

Searching
MEDLINE was searched. Abstracts of major meetings of five relevant professional bodies were searched up to May 2007. Search terms were reported. Only studies reported in English were eligible for inclusion.

Study selection
Randomised controlled trials (RCTs) that compared drug-eluting stents with bare metal stents and reported intravascular ultrasound follow-up for either the whole trial population or as a sub-study were eligible for inclusion. Trials that evaluated paclitaxel-, sirolimus-, zotarolimus- or everolimus-eluting stents were eligible. The primary outcome was late-acquired incomplete stent apposition. Post-procedural, resolved, persistent and total incomplete stent apposition were reported, as was stent thrombosis.

Trials of each of the eligible stent types were included. Mean patient age in the included studies ranged from 58 to 66. The proportion of women was 14% to 37%. One trial enrolled only patients with diabetes; in other trials the proportion of patients with diabetes ranged from 11% to 31%.

The authors did not state how the papers were selected for the review.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
Data were extracted on an intention-to-treat basis to enable calculation of odds ratios (OR) with 95% confidence intervals (CI) for the outcome of incomplete stent apposition.

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

Methods of synthesis
Pooled odds ratios with 95% CI were calculated using a DerSimonian and Laird random-effects model. Statistical heterogeneity between studies was assessed using the Q test and $I^2$ statistic. Sensitivity analyses were used to explore the effect of excluding trials that assessed particular drug-eluting stents. Publication bias was assessed using Begg and Egger's tests.

Results of the review
Twelve RCTs (n=1,834) were included in the review. Sample sizes ranged from 60 to 1,314. All trials reported follow-up at six to 12 months.
Incidence of late-acquired incomplete stent apposition was statistically significantly higher in the drug-eluting stent groups compared to the bare metal stent groups (6.5% versus 2.6%; OR 2.48, 95% CI 1.26 to 4.87; 11 RCTs). Exclusion of trials that evaluated everolimus- or zotarolimus-eluting stents (neither of which recorded any cases of late-acquired incomplete stent apposition) gave an incidence of 8.3% versus 3.2% for bare metal stents. The odds ratio for trials of sirolimus-eluting trials was 17.2 (95% CI 2.3 to 130; two RCTs) and for trials of paclitaxel-eluting stents was 2.45 (95% CI 1.08 to 5.56; six RCTs).

There were no statistically significant differences between drug-eluting and bare metal stents in post-procedural or resolved incomplete stent apposition, but the rate of incomplete stent apposition at follow-up was statistically significantly higher in the drug-eluting groups (13.6% versus 6.7%; OR 2.29, 95% CI 1.35 to 3.91).

There was no evidence of publication bias.

**Authors’ conclusions**
Implantation of drug-eluting stents could be associated with an increased risk of late incomplete stent apposition compared with bare metal stents. The long-term clinical implications require clarification.

**CRD commentary**
The review question and the inclusion criteria were clear. Only one database was searched which, despite the additional searching of some conference abstracts, increased the chances that relevant studies were omitted. The limitation of the review to studies published in English may have led to the introduction of language bias. No evidence of publication bias was detected in the analyses. The authors did not report that they used methods designed to reduce reviewer bias and error at any stage of the review process. The authors did not report that they assessed the validity of the included studies, which made it difficult to assess the strength of the evidence they contributed to the review. The use of meta-analysis and exploration of clinical heterogeneity were appropriate.

The authors’ cautious conclusions reflected the results of the review, but the limited search, lack of validity assessment and poor reporting of review methodology made their reliability unclear.

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

**Research:** The authors stated that further studies with longer clinical follow-up were needed to clarify the role of late incomplete stent apposition in the pathophysiology of very late stent thrombosis.

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