Clinical impact of sirolimus-eluting stent in ST-segment elevation myocardial infarction: a meta-analysis of randomized clinical trials

Piscione F, Piccolo R, Cassese S, Galasso G, Chiariello M

CRD summary
This review compared outcomes of patients who underwent sirolimus-eluting stent versus bare-metal stent implantation during primary angiography for ST-segment elevation myocardial infarction. The authors concluded that sirolimus-eluting stent significantly reduced target vessel revascularisation rates without increasing stent thrombosis, recurrent myocardial infarction and death rates up to 12-month follow-up. These conclusions follow from the evidence and are likely to be reliable.

Authors’ objectives
To compare outcomes of patients who underwent sirolimus-eluting stent (SES) versus bare-metal stent (BMS) implantation during primary angiography for ST-segment elevation myocardial infarction (STEMI).

Searching
MEDLINE, EMBASE and Cochrane Central Register of Controlled Trials (CENTRAL) were searched from inception to October 2008 for relevant studies published in any language. Search terms were reported. Reference lists of retrieved articles were screened, as were conference abstracts published in core cardiology journals and on cardiology websites.

Study selection
Randomised controlled trials (RCTs) with over 100 patients and a mean follow-up period of at least six months were eligible for inclusion in the review. RCTs were required to have at least 90% complete follow-up and perform intention-to-treat analyses. The authors appeared to restrict inclusion to studies that directly compared sirolimus-eluting stent to bare-metal stent.

Outcomes evaluated in included studies were target vessel failure, angiographic restenosis, lumen loss and combined death and non-fatal myocardial infarction with recurrent myocardial ischaemia or with stroke and binary restenosis. Length of follow-up ranged from eight to 12 months.

Two reviewers independently selected studies for inclusion. Disagreements were resolved by a third reviewer.

Assessment of study quality
Validity of the included trials was assessed using Jadad criteria, which allocate studies up to 5 points based on randomisation, blinding and patient follow-up. Studies that scored 3 or more points were considered high quality.

Two reviewers independently assessed study quality.

Data extraction
The primary efficacy outcome was target vessel revascularisation. The primary safety outcome was stent thrombosis. Relevant data were extracted to calculate odds ratios (ORs) and 95% confidence intervals (CIs) for these outcomes.

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

Methods of synthesis
Pooled odds ratios were calculated using the Mantel-Haenszel fixed-effect model. Statistical heterogeneity was investigated using $\chi^2$ and $I^2$. The DerSimonian and Laird random-effects model was used in the presence of significant statistical heterogeneity. Publication bias was assessed using a funnel plot with asymmetry measure using Egger test and Begg and Mazumdar test. Analyses were conducted on an intention-to-treat basis.
A meta-regression was undertaken to establish the relationship between number needed to treat for target vessel revascularisation and baseline risk of developing restenosis. A sensitivity analysis was conducted with removal of one study at a time.

**Results of the review**
Six RCTs (n=2,381) were included in the review. One RCT scored 3 Jadad points; the rest scored 4 points.

Target vessel revascularisation rate was significantly lower for sirolimus-eluting stent compared with bare-metal stent up to 12 months (4.5% versus 12.5%, OR 0.33, 95% CI 0.24 to 0.46)

There was no statistically significant differences between sirolimus-eluting stent and bare-metal stent groups in terms of stent thrombosis rate (3.0% versus 3.7%), cardiac death (2.8% versus 3.3%) and recurrent myocardial infarction (2.9% versus 4.0%) up to 12 months. There was no evidence of publication bias or heterogeneity ($I^2=0\%$) for any outcome.

Results of the meta-regression and sensitivity analysis were reported in the paper.

**Authors’ conclusions**
Compared to bare-metal stent, sirolimus-eluting stent significantly reduced target vessel revascularisation rates without increasing stent thrombosis, recurrent myocardial infarction and death rates in STEMI patients up to 12-month follow-up.

**CRD commentary**
The review question was clearly defined in terms of study characteristics of interest and study selection on the basis of participants. Interventions and comparators were clearly implied. Multiple sources were searched to identify relevant evidence, regardless of language or publication status. Attempts were made to prevent and detect publication bias. Study quality was assessed using established criteria. Attempts were made to minimise potential for errors and bias in study selection and assessment. Appropriate methods were used to pool the included studies. Heterogeneity was investigated. Sensitivity analyses were conducted to test the robustness of the analysis. The authors conclusions followed from the evidence and are likely to be reliable.

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

**Research:** The authors stated that further RCTs with longer follow-up were needed to establish subgroups of patients in which sirolimus-eluting stent might be more effective than bare-metal stent.

**Funding**
Not stated.

**Bibliographic details**

**PubMedID**
19360858

**DOI**
10.1002/ccd.22017

**Original Paper URL**
http://onlinelibrary.wiley.com/journal/121675908/abstract
Indexing Status
Subject indexing assigned by NLM

MeSH
Angioplasty, Balloon, Coronary /adverse effects /instrumentation /mortality; Cardiovascular Agents /administration & dosage; Drug-Eluting Stents; Evidence-Based Medicine; Humans; Metals; Myocardial Infarction /mortality /therapy; Odds Ratio; Platelet Aggregation Inhibitors /therapeutic use; Prosthesis Design; Randomized Controlled Trials as Topic; Recurrence; Risk Assessment; Risk Factors; Sirolimus /administration & dosage; Stents; Thrombosis /etiology; Time Factors; Treatment Outcome

AccessionNumber
12009109308

Date bibliographic record published
03/02/2010

Date abstract record published
31/03/2010

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.