INAHTA Briefs

Issue 2005/27

Title **Prevention of Restenosis: Drug Eluting Stents**

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Reference Report no 8-2004, ISBN 82-8121-008-7

Aim

Drug eluting stents are rapidly disseminating following positive results from a few pioneer randomized controlled trials (RCTs). The effect of drug eluting stents on restenosis seems well established from a few individual trials. The effect on mortality, myocardial infarction, and thrombosis can only be addressed through a systematic review and meta-analysis of these trials. Thus, we aimed to undertake a systematic review and meta-analysis, and explored the cost and health consequences of replacing bare metal stents (BMS) with drug eluting stents (DES).

Conclusions and results

We included 13 RCTs that compared clinical effectiveness of DES with BMS. In total, 6,000 patients were included in these trials.

Mortality: None of the included studies, or the meta-analysis of these studies, had the statistical power to assess effect on mortality. The relative risk for all-cause mortality was 1.39 (95% CI 0.75-2.58), and the respective rates were 2.9% in the DES group and 2.1% in the BMS group. The incidence of cardiac mortality after 2 years was 1.4% in the DES group and 1.9% in the BMS group, relative risk 0.74 (95% confidence interval 0.37-1.48).

Myocardial infarction: After 2-year followup, the rate of MI was 4.3% in the DES group and 4.7% in the BMS group (RR 0.93, 95% CI 0.68-1.27).

Thrombosis: Late thrombosis was infrequent and similar between the two treatment groups: relative risk (0.98, 95% CI 0.46-2.06).

Reintervention (PCI or CABG): Drug eluting stents reduced the need for repeat interventions. The actual reintervention rates were 4.8% in the DES group and 16.9% in the BMS group (RR 0.34, 95% CI 0.23-0.50).

Cost effectiveness: Replacing BMS with DES implies health benefit to patients, but also additional costs to the healthcare system. The incurred costs for avoiding one revascularization procedure was 39,000 Norwegian kroner (NOK) or around 5,000 €. Sensitivity analyses revealed that the cost effectiveness of DES depends heavily on acquisition price of the device, risk of restenosis, and rate of reintervention in routine practice.

Methods

Eligible studies were identified by searches in MEDLINE from 1966 until March 1, 2004, ongoing and unpublished studies were identified from cardiology web sources and updates of included studies followed until November 2004.

Further research/reviews required

Results from ongoing trials will be important to evaluate the safety of drug eluting stents.

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