MÆDICA - a Journal of Clinical Medicine

JOURNAL CLUB

Meta-analysis of trials for drug eluting stents

Roxana SISU, MD

University Hospital of Bucharest, Cardiology and Internal Medicine Department and „Carol Davila" University of Medicine and Pharmacy, Bucharest, Romania

The goal of this meta-analysis was to confirm the benefit and the global safety of drug eluting stents (DES) compared to bare metal stents (BMS) and to evaluate the outcome of patients stented with different DES. Two of the tested DES proved effective in large randomized trials: the sirolimus eluting stent Cypher and the polymer based paclitaxel eluting stent Taxus. In this respect in the paper reviewed all the randomised trials comparing paclitaxel or sirolimus eluting stents (and analogues of both) with BMS, published between 1996-2005, with 6 to 12 months follow up. The initial selection included 54 trials, from which for the final analysis were selected 19 randomized controlled trials, concerning 8987 patients, 4574 with DES and 4413 with BMS. ❑

The two primary end points of this meta-analysis were angiographic binary restenosis (restenosis >50% of the luminal diameter) at 6-9 months and major adverse cardiovascular events (MACE), as a composite of death, myocardial infarction (MI) and revascularization. The secondary end points were the numbers of death, Q wave and non-Q wave MIs and late stent thrombosis at intervals of 6-12 months of follow up.

The overall occurrence of MACE was significantly reduced by DES vs BMS, from 19.9 % to 10,1% ($p<0.001$). A significant heterogeneity ($p<0.001$) between subgroups was observed, with a larger reduction of MACE in the sirolimus subgroup (7.4% for DES vs 21.9% for BMS, OR 0.28) than in the paclitaxel subgroup (12% for DES vs 18.3% for BMS, OR 0.62).

The overall adjusted rate for angiographic restenosis was also significantly reduced from 31.7% to 10.5% in the DES vs BMS (OR 0.25, $p<0.001$), with a significant heterogeneity between subgroups. In the sirolimus subgroup the restenosis rate was 7.6% with DES vs 36.8% with BMS (OR 0.14, $p<0.01$). In the paclitaxel subgroup the rate was 12.4% with DES vs 28.4% BMS (OR 0.35, $p<0.001$).

The overall rate for angiographic target lesion revascularization was significantly reduced with DES versus BMS (6.2% vs 16.6%, OR 0.36, $p<0.001$). In the sirolimus subgroup, the

revascularization rate was 6.7% with DES versus 16.7% with BMS ($p<0.001$) and in the paclitaxel subgroup was 8.2% vs 14.7% ($p<0.001$). Mortality was not significantly different between groups: 0.8% with DES vs 1.2% with BMS ($p = 0.92$). There was no significant difference in occurrence of Q/nonQ MI and stent thrombosis between DES and BMS. There was a small nonsignificant trend towards a higher incidence of stent thrombosis associated with DES vs. BMS.

This meta-analysis confirms, with a good evidence, the significant reduction of MACE and restenosis by drug eluting stents compared with bare metal stents, with a larger reduction of these two end points with sirolimus in comparison with paclitaxel. It also suggests that patients at high risk for restenosis benefit even more from sirolimus stents. More informations need to be collected to evaluate the safety with regard to thrombotic events. ❑

Drug eluting stents: an updated meta-analysis of randomised controlled trials
C Roiron, P Sanchez, A Bouzamondo, P Lechat, G Montalescot
Heart 2006; 92:641–649