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LECTURE ESSENTIALS

Lecture Notes

American College of Cardiology 60th Annual Scientific Session & i2 Summit

Long-Term Outcomes After Use of DES and BMS for the Treatment of Saphenous Vein Graft Lesions: Results of the Randomized ISAR-CABG Trial

Study Sponsor: Deutsches Herzzentrum Muenchen

Clinical Trial #: NCT00611910

Background

Treatment of saphenous vein graft (SVG) lesions with drug-eluting stents (DES) may decrease the long-term need for repeat target lesion revascularization (TLR) by approximately 50% compared with bare metal stents (BMS)

Objective

- To compare the efficacy of DES against BMS in a randomized trial powered for clinical events

Study Design

- Randomized
- Controlled
- Prospective

Subject Characteristics

- 610 patients with *de novo* SVG lesions and similar baseline characteristics were randomized to receive either DES (sirolimus, paclitaxel, or biodegradable polymer-based sirolimus; n=303) or BMS (n=307)
- Participants had ischemia symptoms or evidence of myocardial ischemia in the presence of ≥50% *de novo* stenosis located in SVGs
- Approximately 40% of patients had moderate to severe SVG degeneration
- Exclusion criteria included cardiogenic shock, target lesions in arterial grafts, malignancies with <1 year of life expectancy, or allergies to study medication
- Clinical follow-up took place at 30 days and 12 months

Primary Endpoint

- A composite of death, MI, or ischemia-related TLR at 1-year post index PCI

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Secondary Endpoints

- All-cause mortality, MI, ischemia-related TLR, or incidence of definite or probable stent thrombosis

Results

- At 30 days, there were no significant differences between the two groups in all-cause mortality or cardiac death
- The incidence rate of MI was 2.0% in the DES group versus 4.6% in the BMS group, which was reflected in respective MACE rates of 2.6% and 5.9% (p=0.05)
- The primary endpoint was 22.1% in the BMS group versus 15.4% in the DES group, a reduction of 35% (RR, 0.65; 95 CI, 0.45 to 0.96; p=0.03)
- TLR in the DES group was 7% in the DES group versus 13% in the BMS group, a reduction of approximately 50% (RR, 0.52; 95 CI, 0.30 to 0.90; p=0.02)
- TVR was 11.5% in DES group versus 17.8% in the BMS group (RR, 0.61; 95% CI, 0.39 to 0.95; p=0.03), about a 40% reduction

Interpretation

- Outcomes show that DES are associated with lower rates of MACE compared with BMS for SVG lesions
- These results are driven largely by a reduced need for revascularization, and there were no significant differences in death or stent thrombosis between groups
- Findings are also supportive of those that are found in the long-term follow-up of the SOS trial, which showed that the use of paclitaxel-eluting stents (PES) was associated with significantly better clinical outcomes than BMS in SVG lesions (NCT00247208) [Emmanouil S et al. *J Am Coll Cardiol Cardiovasc Interv* 2011]

Further Reading

http://clinicaltrials.gov/ct2/show/NCT00611910?term=NCT00611910&rank=1