Drug-eluting versus bare-metal stents in saphenous vein graft lesions (ISAR-CABG): a randomised controlled superiority trial.

Comparative assessment of clinical outcomes after use of drug-eluting stents versus bare-metal stents for treatment of aortocoronary saphenous vein graft lesions has not been undertaken in large randomised trials. We aimed to undertake a comparison in a randomised trial powered for clinical endpoints. In this randomised superiority trial, patients with de-novo saphenous vein graft lesions were assigned by computer-generated sequence (1:1:1:3) to receive either drug-eluting stents (one of three types: permanent-polymer paclitaxel-eluting stents, permanent-polymer sirolimus-eluting stents, or biodegradable-polymer...
sirolimus-eluting stents) or bare-metal stents. Randomisation took place immediately after crossing of the lesion with a guidewire, and was stratified for each participating centre. Investigators assessing data were masked to treatment allocation; patients were not masked to allocation. The primary endpoint was the combined incidence of death, myocardial infarction, and target lesion revascularisation at 1 year. Analysis was by intention to treat. This trial is registered at ClinicalTrials.gov, number NCT00611910. 610 patients were allocated to treatment groups (303 drug-eluting stent, 307 bare-metal stent). Drug-eluting stents reduced the incidence of the primary endpoint compared with bare-metal stents (44 [15%] vs 66 [22%] patients; hazard ratio [HR] 0.64, 95% CI 0.44-0.94; p=0.02). Target lesion revascularisation rate was reduced by drug-eluting stents (19 [7%] vs 37 [13%] patients; HR 0.49, 95% CI 0.28-0.86; p=0.01). No significant differences were seen between drug-eluting stents and bare-metal stents regarding all-cause mortality (15 [5%] vs 14 [5%] patients; HR 1.08, 95% CI 0.52-2.24; p=0.83), myocardial infarction (12 [4%] vs 18 [6%]; HR 0.66, 95% CI 0.32-1.37; p=0.27), or definite or probable stent thrombosis (2 [1%] in both groups; HR 1.00, 95% CI 0.14-7.10; p=0.99). In patients undergoing percutaneous coronary intervention for de-novo saphenous vein graft lesions, drug-eluting stents are the preferred treatment option because they reduce the risk of adverse events compared with bare-metal stents. Deutsches Herzzentrum.