COMPARISON OF CHARACTERISTICS AND OUTCOMES OF SAPHENOUS VEIN GRAFT PATIENTS WHO WERE VERSUS THOSE WHO WERE NOT ENROLLED IN THE STENTING OF SAPHENOUS VEIN GRAFTS RANDOMIZED CONTROLLED TRIAL

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Background: Although randomized controlled trials (RCTs) are the best method for determining the safety and efficacy of a treatment, their external validity has often been questioned.

Methods: We identified all patients who underwent Saphenous vein graft (SVG) stenting during the Stenting Of Saphenous vein graft (SOS) trial enrollment period (5/2005 and 10/2007) at our institution. Baseline characteristics and clinical outcomes were compared between SOS trial enrolled versus non-enrolled patients.

Results: Of the 97 patients who underwent SVG stenting during the study period, 62 patients (64%) were enrolled in SOS. In the enrolled group, 62 patients with 91 lesions were randomized to a bare-metal stent (BMS) (n=39) or paclitaxel-eluting stent (PES) (n=41). In the non-enrolled group 35 patients with 44 lesions, received a DES (n=27) or BMS (n=8). During a median follow up period of 2.66 years, non-enrolled patients had higher mortality (31.4% vs. 14.5%, p=0.039), but had lower rates of myocardial infarction (5.7% vs. 32.3%, p=0.005) and target vessel failure (37% vs. 61.3%, p=0.023). Overall, patients who received DES had lower incidence of myocardial infarction, target lesion revascularization, target vessel failure and major adverse cardiac events, and similar mortality compared to the BMS group.

Conclusions: Compared to non-enrolled patients, those who were enrolled in SOS had lower mortality. Patients receiving DES had better outcomes than those receiving BMS in both groups.