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Polymer-free DES in high bleeding risk patients with diabetes mellitus: a pre-specified substudy of the LEADERS FREE trial

RICHARDT G.(1), MAILLARD L.(2), NAZZARO M.(3), CARRI&EACUTE; D.(4), I&NTILDE;IGUEZ A.(5), GAROT P.(6), ABDELLAOUI M.(7), MORICE M-C.(8), FOLEY D.(9), STOLL H-P.(10), ABDEL-WAHAB M.(1), URBAN P.(11)
(1) Heart Center, Segeberger Kliniken, Bad Segeberg GERMANY(2) Service de Cardiologie, Groupement de Coopération Sanitaire Etablissements de Santé, FRANCE(3) San Camillo-Forlanini, Rome ITALY(4) Cardiology Department, Toulouse Rangueil Hospital, Toulouse FRANCE(5) Cardiology Department, Complejo Hospitalario Universitario de Vigo, Hospital Meixoeiro, Meixoeiro SPAIN(6) Hôpital Claude Galien, Institut Cardiovasculaire Paris-sud Ramsay-Générale de Santé, Quincy Sous-SÉnart FRANCE(7) Groupe Hospitalier Mutualiste de Grenoble, Grenoble FRANCE(8) Hôpital Privé Jacques Cartier, Institut Cardiovasculaire Paris-sud Ramsay-Générale de Santé, Massy FRANCE(9) Department of cardiology, Beaumont Hospital, Dublin IRELAND(10) Biosensors Europe, Morges SWITZERLAND(11) Cardiovascular Department, Hôpital de la Tour, Geneva SWITZERLAND

THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

Patients with diabetes mellitus (DM) are at risk of poor outcome after PCI and are particularly sensitive to the type of stent and applied antithrombotic regimen. We report characteristics and outcomes of the DM subgroup of the LEADERS FREE trial.

METHODS AND RESULTS

The randomized, double-blind LEADERS FREE trial compared high-bleeding risk (HBR) recipients of either a polymer-free BA9 coated stent (DCS) or a bare metal stent (BMS) with only one month of dual antiplatelet treatment (DAPT) and showed superior safety and efficacy of the DCS up to two years follow-up. The trial included 2466 patients undergoing PCI who had at least 1 of 13 pre-defined factors for an increased bleeding risk. Out of the 2427 patients with a known DM status at baseline, 805 (33.1%) were diagnosed with DM, 262 (32.5%) of which were insulin dependent. Compared to other HBR patients, DM patients were younger (74.4±9.1 vs. 76.2±9.3 years, p<0.001), with a higher prevalence of hypertension, hypercholesterolemia, previous coronary interventions, renal insufficiency, anaemia and multi-vessel disease. Mean number and total length of implanted coronary stents was higher among diabetic patients.

At 2-years follow-up, compared to non-DM patients, diabetics had higher rates of death (15.6 vs. 12.2%, p=0.01), cardiac death (8.3 vs. 5.9%, p=0.02), myocardial infarction (11.1 vs. 7.8%, p=0.009) and definite or probable stent thrombosis (3.1 vs. 1.7%, p=0.01), though clinically-driven target-vessel and target-lesion revascularization rates were comparable to the non-DM population (10.3 vs. 10.5%, p=0.92 and 9.1 vs. 9.5%, p=0.93, respectively).

In patients with DM, treatment with the DCS was more effective than treatment with BMS at 2 years (clinically driven target-lesion revascularization 6.3 vs. 12.2%, p=0.006). The combined primary safety endpoint (cumulative incidence of cardiac death, myocardial infarction, or definite or probable stent thrombosis) at 2-years occurred less frequently in the DCS group compared to the BMS group (14.9 vs. 19.7%, p=0.10), and was significantly lower with DCS in patients with insulin-dependent DM (13.8 vs. 25.4%, p=0.03). Major bleeding rates were high and not significantly different between DM and non-DM patients (10.2 vs. 8.4%, p= 0.20) or in the DCS and BMS groups (9.9 vs.10.5%, p=0.84).

CONCLUSIONS

Diabetic HBR patients accounted for nearly one third of the LEADERS FREE population, and had worse ischemic outcomes but similar bleeding rates compared to non-DM HBR patients at 2 years. For diabetic HBR patients, DCS use was associated with a significant efficacy benefit and showed a strong trend towards a safety benefit. Given the lack of available data for current-generation DES with shortened DAPT in HBR patients with DM, DCS should currently be considered as the device with the strongest clinical evidence to support its use in this complex group of patients.