P2820

Contemporary indications, dual antiplatelet therapy strategies and clinical outcomes for a polymer-free biolimus A9-coated stent: the all-comers FREEDOM registry

G. Gallone[1], F. D'Ascenzo[1], M.D. Di Biasi[2], R.A. Latini[3], P. Vicinelli[4], A. Poli[5], G. Boccuzzi[6], A. Gagnor[7], L. Gaido[1], E. Cerrato[8], F. Varbella[9], M. Rinaldi[1], A. Ielasi[10]

[1]University Hospital S. Giovanni Battista, Turin, Italy; [2]Luigi Sacco Hospital, Milan, Italy; [3]Fatebenefratelli Hospital, Milan, Italy; [4]Magenta Hospital, Magenta, Italy; [5]Civil Hospital of Legnano, Legnano, Italy; [6]S.Giovanni Bosco Hospital, Turin, Italy; [7]Maria Vittoria Hospital, Turin, Italy; [8]San Luigi Gonzaga Hospital, Turin, Italy; [9]Ospedale Degli Infermi Rivoli, Turin, Italy; [10]San Raffaele Scientific Institute, Milan, Italy

Background: The absence of a polymer-coat along with fast drug absorption represent the benchmark counterpart of the favourable clinical profile of a new polymer-free biolimus A9-eluting stent (PF-BES), also when used with a very short dual antiplatelet therapy (DAPT) strategy. Its current use in the real-world setting has not been thoroughly assessed.

Purpose: We evaluated contemporary patterns of indications, DAPT strategies and outcomes for the PF-BES.

Methods: FREEDOM is a multicenter registry including all patients who underwent percutaneous coronary intervention (PCI) with at least one PF-BES at 10 italian sites. Reasons for PF-BES PCI and planned antithrombotic regimen at discharge were collected. Primary outcomes were the 390-day Kaplan Meier estimates of a patient-oriented composite endpoint (POCE: death, any myocardial infarction [MI] or any target vessel revascularization [TVR]) and of a device-oriented composite endpoint (DOCE: cardiac death, target vessel-MI or ischemia-driven target lesion revascularization [ID-TLR]). The independent outcomes predictors were assessed through multivariate Cox proportional hazards analysis.

Results: Between January 2016 and July 2018, 858 patients (age: 74±10 years, 64.6% males, 58.7% acute coronary syndrome presentation) underwent PF-BES PCI. Main reasons for PF-BES physician's choice were advanced age (26.0%), oral anticoagulation (OAT) to be continued after PCI (25.3%), operator preference for PF-BES (9.9%), planned major surgery (8.6%), cancer (8.6%), anemia (7.9%) and recent bleeding (7.0%). Overall, the operator choice to implant a PF-BES reflected a perceived high bleeding risk in 77.7% of patients. At discharge, 99.2% of patients were on DAPT, 19.5% on triple therapy, and 0.8% on single antiplatelet therapy plus OAT. Planned DAPT duration was 1-month in 40.3% of patients, with 33.8% of these being on triple therapy. At 390-day follow-up (median 340 days, interquartile range: 187–390 days) the incident estimate of POCE was 13.1% (any MI 3.7%, any TVR 3.4%) and of DOCE was 7.1% (TV-MI 3.6%, ID-TLR 1.4%); while 390-day estimate of any bleeding event was 11.1% (BARC 3–5 bleeding 3.0%). Independent predictors of 390-day POCE were eGFR$\leq$60 ml/min (HR 1.81; 95% CI 1.09–3.04, p=0.028), a history of cancer (HR 2.62; 95% CI 1.43–4.81, p=0.002) and severely calcified lesion/s (HR 2.05; 95% CI 1.09–3.85, p=0.025). Independent predictors of DOCE were a previous MI (HR 2.06; 95% CI 1.03–4.15, p=0.041), a history of cancer (HR 2.69; 95% CI 1.18–6.13, p=0.019) and bifurcation lesion/s (HR 2.66; 95% CI 1.38–5.13, p=0.004).

Conclusions: In a large, contemporary all-comers registry, the main reasons for PF-BES use reflected in most cases the operator-perceived high bleeding risk of the patient. Following PF-BES PCI, a very-short DAPT strategy was frequently implemented. The outcomes observed in this registry suggest a favorable safety and efficacy profile for the PF-BES in a real-world clinical setting.