First-in-man study of dedicated bifurcation sirolimus eluting stent – interim analysis of BiOSS LIM Registry

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Background

The aim of this first-in-man study is to assess effectiveness and safety of dedicated bifurcation sirolimus-eluting stent BiOSS LIM (Balton, Poland) in patients with stable coronary artery disease (CAD) or NSTE-ACS

Methods

BiOSS LIM is a coronary dedicated bifurcation sirolimus-eluting balloon expandable stent made of 316L stainless steel. The stent consists of two parts with different diameters connected with two struts of 1.5 mm length.

Patients with a final diagnosis of stable CAD or NSTE-ACS who signed informed consent between October 2011 and October 2012 were included into the study. The enrollment was performed in three invasive cardiology centers in Poland, Bulgaria and Spain. Patients with STEMI or Medina type 001 bifurcation lesions were excluded from the registry. Provisional T-stenting was obligatory strategy. An angiographic control is planned at 12 months in all patients. The primary end-point of the study is the rate of death, myocardial infarction, in-stent thrombosis and target lesion revascularization after 12 months. Here are presented complete results of 3-month follow-up. However at the time of ESC Congress 2013 complete clinical 6-month follow-up will be available as well as angiographic controls will be performed in more than 75% of enrolled patients.
Disclosure:
RJG – Balton medical consultant, DV, JB, LAIG – no disclosure

Results
Sixty patients with stable CAD or NST-ACS (78.3% vs 21.7%, respectively) were included into this prospective, feasibility and safety assessment registry. The average age of enrolled patients (71.7% males) was 66.4±11.3 yrs. There were 46 (76.7%) patients with hypertension, 23 (38.3%) with diabetes and 17 (28.3%) with prior MI. Additionally, 28 patients (46.7%) underwent prior PCI, while 6 (10%) patients had previous CABG.

In 46.7% of cases the lesion was localized in LMS, followed by 45% in LAD, 6.7% in LCx and 1.7% in RCA. According to Medina classification true bifurcations were present in 80%. All BiOSS stents were implanted successfully (avg. pressure 14 atm). The mean nominal stent parameters were as followed: 3.67±0.40 mm x 2.98±0.39 mm x 17.13±2.06 mm. In 8 (13.3%) cases the second stent was implanted within the side branch. In 5 cases (8.3%) asymptomatic increase in TnI level was observed. At one and three months all patients were unevenaul (out-of hospital MACE rate 0%). Up to now control angiography was performed at 47 patients (78.3%). TLR from interim analysis was 6.4%.

Conclusions
Dedicated bifurcation sirolimus-eluting stent BiOSS LIM is a feasible device with promising safety profile and short-term clinical effectiveness. Long-term data is pending.