Dedicated Bifurcation Optimization Stent System BIOSS in Distal Left Main bifurcation stenosis – First-in-Human Results: Data from BIOSS Registry (Poland and Bulgaria)

Dobrin Vassilev1, Alexander Alexandrov2, Robert Gil3, Slawomir Golebiewski4, Tomasz Kaluwski5, Piotr Kwiatkowski5, Hrasto Mateen6, Pavlin Pavlov7, Milena Pehlivanova2

1National Heart Hospital, Sofia, Bulgaria, 2National Heart Hospital, Sofia, Bulgaria, 3Central Clinical Hospital of the Ministry of Internal Affairs and Administration, Warsaw, Poland, 4CSK MSWA, Warsaw, Poland, 5CSK MSWA, Warsaw, Poland, 6North-Eastern Regional Hospital, Tallinn, Estonia, 7Clinical Center of Niš, Niš, Serbia, 8University of Indonesia Medical School, Medistra Hospital, Jakarta, Indonesia

Background: The distal left main coronary artery disease is a particular form of coronary disease, still challenging for intervention. The results with regular drug-eluting stents (DES) are not optimal. The dedicated bifurcation stents are promising solution of this form of coronary disease.

Methods: Dedicated bifurcation paclitaxel-eluting stent BIOSS® Expert and next generation sirolimus eluting stent BIOSS LIM (Balton, Poland) were used. This dedicated bifurcation device consists of two parts with different diameter, connected with two short bridges. BIOSS is mounted on dedicated bifurcation balloon – Bottle – with three markers (at both ends and at the mid part – for easy positioning at the level of the curva). 51 patients (17 from Bulgaria and 34 from Poland) were included and followed for 12 months into prospective, feasibility and safety assessment registry, with exclusions criteria STEMI, contraindication for 12 months DAP and lack of informed consent. The primary end-points of the study are: death, myocardial infarction, in-stent thrombosis and target lesion revascularization (in-hospital and 1, 3, 6, 12 months after the intervention).

The first wave of registry started in Poland in 2009 and was followed in Bulgaria from second half of 2010.

Results: The average age of the enrolled patients (71% males) was 67±15 years. 80% had hypertension, and 44% have diabetes – 62% for the Bulgarian group and 30% for the Polish group. Most of patients enrolled have severe coronary disease – more than 50% had previous AMI, 60% had previous PCI, 13% were after CABG. All BioSS stents were implanted successfully without any periprocedural complication. Side branch stent was implanted more frequently in Polish group – 24% vs. 12% in Bulgarian Group. The TLR rate at 12 months was 11% - 5.9% (1/7 in BG) and 17.6 (6/34) in Poland; TVR rate was equivalent - 17.7% vs. 17.6% respectively. MACE rates differ - 23.5% in Bulgarian group (because of one possible stent thrombosis and MI during follow-up) and 17.6% (because of restenosis) in Polish group.

Conclusions: The BIOSS bifurcation dedicated stent is a feasible device with promising safety and short-term clinical effectiveness/profile in LM bifurcation lesions.

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Drug-Eluting Stents for the Treatment of Left Main Coronary Artery Disease with Bifurcated Lesions: A Comparison with Sirolimus, Paclitaxel, Zotarolimus (Endeavor Resolute), BioHitpa, ECP Capture and Everolimus-Eluting Stent: Multicenter Registry in Asia

Sanas Nakamura1, Hisao Ogawa2, Jun-Ho Baet3, Yeo Calyadi4, Wasan Udachachulerm5, Damnras Treskorn6, Sudaratana Tantruphaswadi7

1New Tokyo Hospital, Chiba, Japan, 2Kumamoto University Hospital, Kumamoto, Japan, 3Konyang University Hospital, Daejeon, Korea, Republic of, 4Husada Hospital, Jakarta, Indonesia, 5King Chulalongkorn Memorial Hospital, Bangkok, Thailand, 6Faculty of Medicine Siriraj Hospital, Bangkok, Bangkok, Thailand, 7Chest Disease Institute, Nonthaburi, Thailand

Background: The aim of this study is to compare the safety, efficacy and durability of Sirolimus (SES), Paclitaxel (PES), Zotarolimus (ZES-R/ Endeavor Resolute), BioHitpa, ECP Capture and Everolimus-eluting stent (EES) on the outcome of patients with left main coronary arteries (LMT) stenosis.

Methods: A prospective analysis of 1127 LMT stenosis (321 SES, 277 PES, 129 ZES-R, 172 BHS, 55 EES) in six high volume Asian centers after successful stenting in LMT stenosis was performed. The study endpoints were 30 days major adverse cardiac events (MACE) and 12, 24, 36 and 48 months target lesion revascularization (TLR) and MACE in those groups.

Results: See table for clinical results.

Conclusions: The use of drug-eluting stents in patients with LMT stenosis was safe with low acute complication. Patients treated with BHS and EES showed lesser rate of restenosis compared with ZES-R and ECS.