TCT-46
Long-term Survival in Patients Undergoing Sirolimus-eluting Stent PCI of the Unprotected Left Main Coronary Artery According to EuroSCORE, SYNTAX score and GRC: the Milan and New-Tokyo Registry

Kensuke Takagi,1 Alfonso Ielasi, Jeanne Shannon,1 Azem Latib,1 Cosmo Godino,2 Giedrius Davidavicius,3 Marco Messa4, Mauro Carline,1 Matteo Montorfano,1 Adaide Cheiffi,1 Sanas Nakamura,1 Antonio Colombo1

1Cardiovascular unit, San Raffaele Hospital, Milan, Italy; 2Emo GVM Centro Cuore Columbus, Milan, Italy; 3New-Tokyo Hospital, Tsutsumo, Japan

Background: There is little available data regarding the long term follow-up of patients treated with Sirolimus-eluting stent (SES) on the Unprotected Left Main (ULM) according to EuroScore, SYNTAX score and GRC.

Methods: All consecutive patients treated with SES implantation for ULM stenosis between March 2002 and December 2008 were retrospectively assessed for clinical and angiographic risk. The primary end-point of the study was a composite of major adverse cardiovascular events (MACE) at 3 years defined as all-cause death, myocardial infarction (MI) and target lesion revasculatization (TLR) according to EuroScore, SYNTAX score and GRC. Secondary end-points were the individual components of MACE.

Results: Data on 404 patients treated with SES on the ULM were available for outcome analysis. The median follow-up period was 1373 days (IQR 205-2209 days). The patients were classified into low (<22), intermediate (23-34) and high SYNTAX (35+) groups (118, 142 and 143 patients respectively), low (0-2), intermediate (3-5) and high EuroScore (6-) groups (128, 172, 103 patients) and low, intermediate and high GRS groups (204, 152 and 47 patients). MACE at 3 years were as follows: SYNTAX low 15.3%, SYNTAX inter 29.6% and SYNTAX high 23.1%, EuroScore low 22.7%, EuroScore inter 20.9% and EuroScore high 27.2% and GRC low 22.7%, GRC inter 20.9% and GRC high 27.2%. Cardiac-death at 3 years was as follows: SYNTAX low 3.4%, SYNTAX inter 5.6% and SYNTAX high 4.9%, EuroScore low 1.6%, EuroScore inter 3.5% and EuroScore high 10.7% and GRC low 2.9%, GRC inter 5.3% and GRC high 10.6%. Non cardiac-death at 3 years was as follows: SYNTAX low 5.1%, SYNTAX inter 4.2% and SYNTAX high 7.7%, EuroScore low 3.9%, EuroScore inter 3.5% and EuroScore high 11.7% and GRC low 3.9%, GRC inter 4.6% and GRC high 17.0%

Conclusion: The EuroScore and GRC seem to better predict the outcome compared to the SYNTAX score in patients undergoing PCI with SES for ULM disease.

TCT-47
Assessment of the Left Main (LM) with Fractional Flow Reserve (FFR): The Influence Of Concomitant Proximal Epicardial Coronary Disease

David Daniels1, Marcel van’t Veer2, Arjen van der Horst2, Nico H Pijls2, William F Fearon2

1Stanford University Hospitals and Clinics, Stanford, CA; 2Catharina Hospital and Emo GVM Centro Cuore Columbus, Milan, Italy

Background: In the setting of moderate LM disease, a severe stenosis of the proximal Left Anterior Descending (LAD) or Circumflex (CTX) could elevate the measured LM FFR, and hence increase the probability of a false negative test. In the current study, we modeled these stenoses and proposed a resistance-based equation to predict the true LM FFR irrespective of a concomitant epicardial obstruction.

Methods: In a previously validated in vitro model of the coronary circulation, pressure and flow were measured in the setting of a moderate LM stenosis. FFR LM TRUE was defined as pd/pa in the absence of an epicardial stenosis. With increasing concomitant stenoses in the LAD or CTX, FFR LM-MEASURED was calculated from pd/pa in the unobstructed vessel. The equation for FFR LM-PREDICTED = RLM/(RLM+ RMICRO), where RLM = 1/(1/RMICRO+1/ RMICROCTX). The Axxess Plus trial enrolled 139 patients with single de novo coronary bifurcation lesions treated with the Biolimus A9 Coated Dedicated Axxess Stent: Results from the Prospective, Multicenter AXXESS Plus Trial (Final Report of the Study)

Eberhard Grube1, Franz-Josef Neumann2, Stefan Verheyen1, Alexandre Abizaid3, Dougal McClean4, Karl E Heitgopman5, Iain Simpson6, Philip MacCarthy7, Christophode Daboss8, Ralf Mueller9

1University Bonn, Bonn, Germany; 2Herz-Zentrum Bad Krozingen, Bad Krozingen, Germany; 4AZ Middelheim, Antwerp, Belgium; 7Christchurch Hospital, Christchurch, New Zealand; 3Institute Dante Pazzanese of Cardiology, Sao Paulo, Brazil; 9University Hospital Southampton, Southampton, United Kingdom; 8King’s College Hospital, London, United Kingdom; 2UZ Gasthuisberg, Leuven, Belgium; HELIOS Heart Center, Siegburg, Germany

Background: Coronary bifurcation lesions remain a challenge in interventional cardiology, and have been associated with increased adverse event rates and inability to preserve the side branch (SB) ostium. The Axxess stent is a self-expanding bifurcation stent which releases Biolimus A9™ (BA9) from an abluminal biodegradable polymer coating, is conically shaped to conform to the bifurcation anatomy, and supports the carina while preserving the side branch. Overall, the Axxess dedicated device demonstrated safety and efficacy for the treatment of complex bifurcation lesions in the mid-term follow-up (FU); however, the very late outcomes are still unknown.

Methods: The Axxess Plus trial enrolled 139 patients with single de novo coronary bifurcation lesions including 78% “true” bifurcation lesions. Of that, 136 patients received the Axxess stent, and depending on the extent of disease, additional stents were placed in one or both distal branches – 40% of SB were treated with an additional drug-eluting stent (DES). All patients were assigned for anastomotic angiographic FU at 6 months, and clinical FU was scheduled at annually up to 5 years.

Results: Device success was 93.5%, and in-stent late lumen loss at 6 months (primary endpoint) was 0.09 mm in the Axxess DES; regarding restenosis, 7.9% of SB treated with DES presented with recurrence. Overall, target lesion revascularization (TLR) rate was 7.5% at 6 months, and there were 3 cases of stent thrombosis (2.2%). The cumulative incidence of major adverse cardiac events (MACE) at 4 years was 19.7% (23/117) including cumulative incidence of TLR rate of 12.6%. Importantly, there were no cases of very late stent thrombosis

Conclusion: The dedicated Axxess bifurcation stent demonstrated sustained efficacy and safety in patients with complex coronary bifurcation lesions. At 4 year clinical FU, there were 12.6% TLR rate and no occurrence of very late stent thrombosis. The complete 5-year clinical FU will be presented at the meeting.