Contemporary PCI Practices Across Three Continents: A Glimpse Into the Preliminary Results of e-NObori Study

Jawed Polad1, Kristof Graf2, Sanhae Askhat Kotsyubaevich3, Shih-Hung Chan4, Martine Gilard5, Sacha Gruner6, Andres Hijuez7, Stefan James8, M. Meanwissen9, Luiz Alberto Piva Mattos10

1Division of interventional cardiology, Department of Cardiology, Jeroen Bosch Ziekenhuis, s’Hertogenbosch, Netherlands, 2Jüdisches Krankenhaus, Berlin, Germany, 3Saratov Research Institute of science for cardiology, Saratov, Russian Federation, 4Division of Cardiology, Department of Internal Medicine, National Cheng Kung University Hospital, Tainan, Taiwan, Republic of China, 5La Cavale Blanche Hospital, Brez, France, 6Ev. BETHESDA-JOHANNISTER- Klinikum Duisburg GmbH, Duisburg, Germany, 7Hospital of Vigo, Vigo, Spain, 8Uppsala Clinical Research Center, Uppsala, Sweden, 9Anphia Hospital, Breda, Netherlands, 10Irmandade da Santa Casa de Misericórdia de Marília, Marília, Brazil

Background: Besides the established guidelines, different region-specific recommendations for the use of DES exist worldwide, most are restricted to high-risk patients groups. Our aim was to evaluate the current PCI practice in a large population of patients in a real world clinical setting focusing on three main regions: Europe, Asia and Latin-America.

Methods: e-NOBORI is a prospective, multinational, single-arm, multi-centre, observational study. A total of 6087 patients have been enrolled in Europe, 887 in Asia and 776 in Latin-America. The primary endpoint of the study is target lesion failure (TLF) a composite of cardiac death (CD), target vessel myocardial infarction (MI) and target lesion revascularization (TLR).

Results: Patients: In Europe were oldest (63±12), with highest history of PCI (31%), and frequency of occluded and calcified lesions; In Asia were the youngest (57±11), more often diabetic (41%) with highest prevalence of multivessel disease (21%) and centrally occluded lesions (6%); and in Latin-America were more often female (25%), with the lowest number of lesions treated. Treatment of AMI was highest in Europe (30%) and lowest in Asia (9%), while distribution of left main (~2%) and true bifurcation (~5.5%) was similar. Pre- and post-dilatation were more often performed in Asia while Europe presented the highest rate of radial access (57%) and direct stenting (40%) with the lowest rate of post-dilatation (28%). At 1-month the rate of CD was 0.2%, 0.3% and 0.9%, MI 0.6%, 0.0% and 0.8% and TLR 0.8%, 0.0% and 0.0% for Europe, Asia and Latin-America, respectively. The TLF was 0.7%, 0.3% and 1.8%. Stent thrombosis frequency will be added at the time of the presentation along with fully adjudicated adverse events at 1-month and 1-year.

Conclusions: Interesting findings were observed related to regional differences in procedure characteristics and complexity of the patients and lesions. Despite these differences the procedural success was over 99% for all three regions and the preliminary clinical outcomes showed similarly low TLF rate in this complex, all-comer’s population, treated with Nobori DES, in three continents.

TCT-633

Impact of Ad Hoc Percutaneous Coronary Intervention with Drug-Eluting Stent in Angina Patients

Young-Hak Kim1, Duk-Woo Park2, Jung-Min Ahn2, Jung-Min Park2, Martin Gilard5, Sacha Gruner6, Andres Hijuez7, Stefan James8, M. Meanwissen9, Luiz Alberto Piva Mattos10

1Asan Medical Center, Seoul, South Korea, 2Asan Medical Center, Seoul, South Korea, Republic of, 3Asan Medical Center, Seoul, South Korea

Background: Besides the established guidelines, different region-specific recommendations for the use of DES exist worldwide, most are restricted to high-risk patients groups. Our aim was to evaluate the current PCI practice in a large population of patients in a real world clinical setting focusing on three main regions: Europe, Asia and Latin-America.

Methods: e-NOBORI is a prospective, multinational, single-arm, multi-centre, observational study. A total of 6087 patients have been enrolled in Europe, 887 in Asia and 776 in Latin-America. The primary endpoint of the study is target lesion failure (TLF) a composite of cardiac death (CD), target vessel myocardial infarction (MI) and target lesion revascularization (TLR).

Results: Patients: In Europe were oldest (63±12), with highest history of PCI (31%), and frequency of occluded and calcified lesions; In Asia were the youngest (57±11), more often diabetic (41%) with highest prevalence of multivessel disease (21%) and centrally occluded lesions (6%); and in Latin-America were more often female (25%), with the lowest number of lesions treated. Treatment of AMI was highest in Europe (30%) and lowest in Asia (9%), while distribution of left main (~2%) and true bifurcation (~5.5%) was similar. Pre- and post-dilatation were more often performed in Asia while Europe presented the highest rate of radial access (57%) and direct stenting (40%) with the lowest rate of post-dilatation (28%). At 1-month the rate of CD was 0.2%, 0.3% and 0.9%, MI 0.6%, 0.0% and 0.8% and TLR 0.8%, 0.0% and 0.0% for Europe, Asia and Latin-America, respectively. The TLF was 0.7%, 0.3% and 1.8%. Stent thrombosis frequency will be added at the time of the presentation along with fully adjudicated adverse events at 1-month and 1-year.

Conclusions: Interesting findings were observed related to regional differences in procedure characteristics and complexity of the patients and lesions. Despite these differences the procedural success was over 99% for all three regions and the preliminary clinical outcomes showed similarly low TLF rate in this complex, all-comer’s population, treated with Nobori DES, in three continents.

TCT-634

Randomized Comparison of Direct Stenting with Conventional and Provisional Stent Implantation in Elective PCI Patients Using Bare Metal and Drug Eluting Stents

Samer Somi1, Wouter Remkes2, Jan-Henk Dambrik3, Marcel Gosselin1, Hoornije4, Harry Saruppananal5, Jan Paul Ottervanger2, Arnon van ’t Hof1, Isala Klinieken, Zwolle, Netherlands

Background: Although direct stenting has become a daily practice and been proposed as an alternative for conventional stenting with predilation, there have been no randomized evaluations using bare metal and drug eluting stents in elective PCI patients. The aim of this study was to assess clinical outcome of a strategy of direct stenting without pre-dilation compared to conventional stenting with or without provisional stenting.

Methods: A total of 1360 patients with stable or unstable angina pectoris or a recent (<30 days) myocardial infarction with objective evidence of myocardial ischemia were randomized to direct stenting, stenting after predilation or a provisional stenting strategy. The primary endpoint was the mean minimal lumen diameter (MLD) at follow-up angiography. The secondary endpoint was the clinical procedural success defined as angiographic success without major adverse cardiac events (MACE) at 9 months follow-up.

Results: Follow-up angiography was performed in 367/736 pts in the BMS and in 524/532 pts in the DES cohort. Stents were used in 57.8% (BMS) and 77.5% (DES) of patients in the provisional arm.

Conclusions: Ad hoc PCI using DES appears to be feasible for angina patients at a relatively low-risk of procedure. This approach may be reasonably performed with evaluation of objective ischemia using noninvasive or invasive tests.

TCT-635

Provisional Stenting vs. Direct Stenting in elective PCI: Impact on the Hard Outcomes

Saverio Iorio1, Domenico Iorio2, Giovanni Bellavite3, Arnon van ’t Hof1, Isala Klinieken, Zwolle, Netherlands

Background: The clinical importance of ad hoc percutaneous coronary intervention (PCI), which combines coronary angioplasty and PCI in the same procedure, in the era of drug-eluting stents (DES) has not been fully evaluated.

Methods: From the IRIS-DES registry, 4738 angina patients treated using PCI with DES were enrolled. The 18-month outcomes were compared between ad hoc and non-ad hoc patients in the provisional arm.

Results: Ad hoc PCI was performed in 3562 (75.2%) patients. The ad hoc PCI group had more extensive coronary disease and received fewer stents. The incidence of major adverse cardiac or cerebrovascular events (MACCE) consisting of death, myocardial infarction (MI), stroke, or repeat revascularization did not differ between the ad hoc and non-ad hoc groups (8.3% vs. 7.6%; adjusted hazard ratio [aHR] of ad hoc PCI, 1.22; 95% confidence interval [CI], 0.91 to 1.63; P = 0.18). The individual end points of death (2.0% vs. 1.9%; aHR, 1.05; 95% CI, 0.76 to 1.44; P = 0.65), MI (0.8% vs. 1.0%; aHR, 0.79; 95% CI, 0.49 to 1.32; P = 0.42), stroke (1.0% vs. 0.9%; aHR, 1.25; 95% CI, 0.58 to 2.69; P = 0.57), and repeat revascularization (4.4% vs. 4.0%; aHR, 1.23; 95% CI, 0.86 to 1.77; P = 0.25) also did not differ between the groups.

Conclusions: Ad hoc PCI using DES appears to be feasible for angina patients at a relatively low-risk of procedure. This approach may be reasonably performed with evaluation of objective ischemia using noninvasive or invasive tests.