High Risk Patients: Diabetes, Heart Failure, Renal Failure, Others

(TCTAP A-075 to TCTAP A-078)

TCTAP A-075

Prognostic Significance of Anemia in Patients Undergoing PCI with First and Second Generation DES (Katowice Registry)

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Background: Anemia present prior to PCI is associated with an increased risk of death, myocardial infarction (MI) and bleeding complications in particular in acute coronary syndromes (ACS). Patients with anemia often do not receive recommended by guidelines antithrombotic treatment and drug-eluting stents (DES) because of the increased bleeding risk. Aim of this all-comer Katowice Registry is to compare 1-year outcomes in patients with coronary artery disease (CAD) and anemia treated with PCI with first and second-generation DES.

Methods: We enrolled 1916 consecutive patients (65% males, mean age 63 y) presenting with unstable angina (78%), NSTEMI (15%) and STEMI/LBBB MI (7%) treated either with first (paclitaxel, sirolimus) or second generation (everolimus, zotarolimus, biolimus A9) DES (o-DES 34%; n-DES 66%). Anemia was defined according to WHO [hemoglobin (Hb) level <13g/dL for men and <12g/dL for women]. Incidence of MACCE (death, MI, stroke, repeat-revascularization) at 1-year was a primary end-point of this study and was evaluated by telephone follow-up or data from national ministry of health.

Results: The study population was stratified according to presence of anemia on admission. Anemia was present in 11% of patients (microcytic 11%, normocytic 53%, macrocytic 35%). Patients with anemia were older (67.1±10 vs. 62.10 years, p<0.001), had diabetes (44% vs. 6%, p<0.02), chronic kidney disease (32% vs. 15%, p<0.001), PAD (17% vs. 10%, p=0.005), carotid disease (10% vs. 5%, p=0.006), history of MI (57% vs. 46%, p=0.002), CABG (31% vs. 19%, p=0.001), impaired LVEF (40.57% vs. 55 (45-60)% vs. 0.001), higher GRACE score [>140 (75% vs. 53%, p=0.010) and more frequently had bleeding requiring transfusion (3.2% vs. 0.5%, p=0.001). Hospitalization was longer (5 (4-7) vs. 4 (3-6) days, p=0.002). Patients with anemia had more 5 vessel disease (36,4% vs. 26,1% p=0.001) and higher SYNTAX [21 (12-27) plt. vs. 14 (8-22) pkt. p=0.001]). Stent thrombosis in culprit vessel was significantly more frequent (1.7% vs. 0.3%, p=0.037). In 1-year FU there was significantly higher mortality (7.4% vs. 2.9%, p=0.001) in pts without anemia. In patients treated with o-DES there was a trend to higher rate of CABG during F-U (41% vs. 0.7%, p=0.083). Univariate regression showed that anemia was a predictor of death, however in multivariate regression model only eGFR, LVEF and anemia was a predictive of death, however in multivariate regression model only eGFR, LVEF and age were independent risk factors for CI-AKI.

Conclusion: Anemia present prior to PCI is associated with an increased risk of death, myocardial infarction (MI) and bleeding complications in particular in acute coronary syndromes (ACS). Patients with anemia often do not receive recommended by guidelines antithrombotic treatment and drug-eluting stents (DES) because of the increased bleeding risk. Aim of this all-comer Katowice Registry is to compare 1-year outcomes in patients with coronary artery disease (CAD) and anemia treated with PCI with first and second-generation DES.

(TCTAP A-076)

Urinary L-FABP Predicts Survival Outcome Before Contrast Agent Administration in Patients with Chronic Kidney Disease

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Background: Preexisting renal insufficiency was independent risk factors for contrast-induced acute kidney injury (CI-AKI). One of the associated predisposing factors for CI-AKI is a propensity for enhanced renal hypoxia. Urinary L-FABP levels correlated well to the level of renal ischemia. Therefore, we believe increased levels of urinary L-FABP relate to the presence of a preexisting renal ischemia in patients undergoing contrast agent administration. The purpose of the present study was to examine the clinical significance of urinary L-FABP levels before contrast agent administration in patients with chronic kidney disease (CKD).

Methods: We performed a retrospective study of 215 patients with CKD who underwent elective catheterization [serum creatinine (Cr) ≥1.1mg/dL]. Serum Cr and L-FABP levels were measured immediately before contrast agent administration. Patients were prospectively followed during a median follow-up period of 755 days with the end points of Cardiac Cerebral death. CI-AKI was defined as an increase of 0.3 mg/dl (26.5micromol/l) within 2 days of contrast media exposure.

Results: CI-AKI developed in 22 patients (10.2%). High L-FABP levels group (defined as more than 24.5 microg/g Cr) was 45 patients and CI-AKI in high L-FABP levels group developed in 11patients. A total of 18 cardiac cerebral deaths occurred during a follow-up period and survival outcome tended to be worse high L-FABP levels group (15.9% vs 6.5% P value: 0.045) Kaplan-Meier analysis clearly demonstrated that patients with high L-FABP levels group were higher rate of cardiac cerebral deaths than those with low L-FABP levels group. (Log rank test:P value: 0.025).

Conclusion: Urinary L-FABP provides an important information for predicting CI-AKI and survival outcome before contrast agent administration. These data indicate that urinary L-FABP level is a novel promising marker to provide useful prognostic information for clinical outcomes in patients with chronic kidney disease.

Innovative Devices and Futuristic Therapies

(TCTAP A-079 to TCTAP A-080)

TCTAP A-079

Clinical Efficacy and Safety of Bioresorbable Vascular Scaffold in an Unselected Patient Population: A Single Centre Real World Experience

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Background: The novel drug-eluting bioresorbable vascular scaffold (BVS) is a revolutionary treatment option for obstructive coronary artery disease in percutaneous
coronary intervention (PCI). There is limited data on the safety and efficacy of BVS in contemporary clinical registries. We evaluated the safety and efficacy of BVS in our unselected South-east Asian patients and report on the clinical outcomes.

**Methods:** Between May 2012 to October 2013, 79 patients (83.5 % male, mean age 52 ± 10 years) with 83 coronary lesions were treated with a total of 116 BVS. The primary endpoint was in-hospital major adverse cardiac events (MACE) i.e. a composite of cardiovascular death, target vessel related myocardial infarction (MI) and target lesion revascularization (TLR). Secondary endpoints included individual components of MACE and scaffold thrombosis at 6 months follow up.

**Results:** The majority of patients presented with acute coronary syndrome (50.6 %). Transradial PCI was performed in 98 % of cases. Intracoronary imaging and cutting balloons were used as adjunctive PCI tool in 46 % and 52 % of cases respectively. The mean number of BVS implanted per patient was 1.4 ± 0.7, mean BVS diameter was 3.1 ± 0.3 mm and total BVS length was 30 ± 19 mm.

BVS was implanted in de novo lesions in 95 % of cases with the left anterior descending artery being the most common target vessel (52 %). 4 BVS were implanted in non de novo lesions (1 saphenous vein graft, 1 left internal mammary artery and 2 implant restenosis).

There was no MACE observed in hospital. However, there were 2 cases of subacute scaffold thrombosis within 30 days of PCI who required re-intervention. There were no further ischaemic events at 6 months follow up.

**Conclusion:** Early experience with BVS in our unselected South-east Asian patients reveals a promising result with a low incidence of ischaemic events. Longitudinal follow-up is necessary to prove its long term efficacy and safety.

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**TCTAP A-080**

Patient-specific Cardiovascular Models for Educational and Training Purposes

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**Background:** Traditional models of the lumen were obtained for educational and communication purposes. Nevertheless, these models are often generic representations of the anatomy and do not account for an array of configurations that congenital cases present.

3D printing offers an adaptable and powerful alternative in creating accurate patient-specific models for educational purposes and pre-surgical planning.

**Methods:** CT and MRi scans of a number of cardiovascular pathologies were obtained. The anatomes were then reconstructed and modified in 3D so that they could be successfully 3D printed. Multiple 3D printing techniques and materials were then utilized to produce physical anatomical representations of the cardiovascular anatomy, according to the specific needs of each case.

**Results:** Rigid models of the lumen were obtained for educational and communication purposes, where each cardiovascular structure is represented in a different color for better understanding of the patient’s pathologies.

Flexible, translucent hollow models of the congenital heart defects were 3D printed for the simulation of the intended procedure, aimed at offering better insight to the surgeons.

**Conclusion:** 3D printed patient-specific models of the cardiovascular anatomy from medical image data hold great promise to improve clinical understanding of congenital heart defects, offering physicians superior training and planning possibilities.

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**Invasive Coronary Imaging: IVUS, OCT, Spectroscopy, and Other**

(TCTAP A-081 to TCTAP A-086)

**TCTAP A-081**

Efficacy of the Comparison Catheter: Intravascular Ultrasound(IVUS) with a Balloon

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**Background:** VIBE RX catheter is the world’s first catheter that combines intravascular ultrasound (IVUS) with a balloon in one device. We evaluated the efficacy of the novel catheter.

**Methods:** 58 patients who underwent percutaneous coronary intervention (PCI) in our hospital between July 2012 and October 2012 were enrolled in this study. They were randomly divided into two groups: using IVUS with a balloon (n=25), and using ordinary IVUS (n=25). Patients with distal lesions, chronic total occlusion (CTO) and acute myocardial infarction (AMI) were excluded. We assessed procedure time, fluoroscopy time, contrast volume, the device crossability.

**Results:** Procedure time were 67.7±24.7 minutes in VIBE group and 79.1±23.3 minutes in EagleEye group (p=0.06). Fluoroscopy time were 20.7±10.5 minutes in VIBE group and 25.5±11.7 minutes in EagleEye group (p=0.10). Contrast volume were 120.2±34.8ml in VIBE group and 119.9±34.1ml in EagleEye group (p=0.81). 3 patients in both groups had difficulties of the device crossability.

**Conclusion:** Our study suggests that using VIBE RX catheter may contribute to reduce procedure time and fluoroscopy time. Further studies about the economic efficacy and the usefulness for more complex situations are needed.

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**TCTAP A-082**

Optical Frequency Domain Imaging Guidance for Coronary Stent Implantation in Comparison with Intravascular Guidance

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**Background:** Intravascular ultrasound (IVUS) has been used as a guidance of stenting. Optical Frequency Domain Imaging (OFDI) has high resolution and super-imposed technology on cineangiography. The aim of this study was to assess the feasibility of OFDI-guided stent implantation.

**Methods:** Total of 25 de novo, consecutive, elective stenting lesions (22 patients) were enrolled in this study. OFDI and IVUS images were recorded before intervention. IVUS images were blinded for operators. Stent implantation was performed under OFDI-guidance alone. IVUS confirmation was performed after the procedure and further treatment was permitted based on IVUS results. One-month after the procedures, strategy of stent deployment was re-built by the same operator with the IVUS results before intervention.

**Results:** Selected stent length and diameter were equal between OFDI-guidance and IVUS-guidance (0.23.8mm vs I;23.3mm;p=0.53, O;3.83mm vs I;3.33mm;p=0.41). The selected landing point difference of OFDI-guidance and IVUS-guidance were 1.8mm at proximal edge and 0.8mm at distal edge. Distal protection device was deployed 4 cases according to OFDI images. Additional inflation was performed after final IVUS in 2 cases. There was no complication (perforation, slow-flow/no-flow, dissection to need additional stenting) during procedure and no in-hospital MACE (death, QMI/nonQMI, subacute thrombosis). 

**Conclusion:** OFDI-guidance is comparable to IVUS-guidance for elective stent implantation.

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**TCTAP A-083**

Impact of Diabetes on Heavily Calcified Plaque in Extremely Late In-stent Restenosis Lesions After Bare-metal Stent Implantation

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**Background:** In-stent neatherosclerosis is a major concern of late in-stent restenosis after either drug-eluting stent or BMS implantation. Patients with DM increase requiring target lesion revascularization (TLR) at long-term follow-up. The characteristics of lesions with extremely late in-stent restenosis after BMS implantation remain unclear.

**Methods:** Median follow-up duration after BMS implantation was 10.0±2.8 years (range 4-16 years). Consecutive 35 late in-stent restenosis lesions required the first TLR beyond 4 years after BMS implantation were estimated with IVUS measuring the calcium arc and length.

**Results:** All patients (67.5±5 y.o.; 28 male) presented ischemic symptoms (18 ACS including 5 STEMI, 17 stable ischemia). All in-stent lesions contained various calcified plaque. The mean calcium arc was 138±100 degree and length 8.2±11.0 mm respectively. In DM patients, calcium arc was significantly greater than those of non-DM (195.8±3 vs 83±79 degree; p<0.01). The rate of severely calcified lesion defined as calcium arc over 180 degree was higher in DM than those in non-DM (63.1% vs 12.5%; p<0.01). There was no difference in the period between the index procedure and TLR (DM 9.8±3.0 years, non DM 10.6±2.1 years).

**Conclusion:** Various calcified plaque are contained in the late in-stent restenosis lesions regardless of DM. However DM is correlated with heavily calcified plaque in lesions with late in-stent restenosis. We showed an association to treatment of late in-stent restenosis with DM patients because of existence of heavily calcified plaque.

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**TCTAP A-084**

Impact of Pre-dilation Strategy on Vessel Response Following Stent Implantation in Patients with De Novo Coronary Artery Lesion

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**Background:** Although follow-up event rates have significantly improved since the introduction of drug-eluting stents, pre-dilation strategy before stenting is still important to achieve better stent expansion. The Lacrosse non-slip element (NSE)