Other (Unclassified)

(TCTAP A-001)

TCTAP A-001

Twelve-month Clinical Outcomes of Transradial Coronary Artery Intervention: Comparison of the Right and Left Radial Artery Approach

<u>Ji Young Park¹</u>, Seung-Woon Rha², Byoung Geol Chol², Dong Joo Oh², Jae Woong Chol¹, Sung Kee Ryu¹, Myung Ho Jeong³, Sang Sik Jung⁴, Moo Hyun Kim⁵, Hyoung-Mo Yang⁶, Junghan Yoon⁷, Keum Soo Park⁸, Kyoo Rok Han⁹, Byung Ryul Cho¹⁰, Kwang Soo Cha¹¹, Byung Ok Kim¹², Min Soo Hyun¹³, Won Yong Shin¹⁴, Hyunmin Choe¹⁵, Jang-Whan Bae¹⁶, Hee Yeol Kim¹⁷

¹Eulji General Hospital, Seoul, Korea (Republic of), ²Korea University Guro Hospital, Seoul, Korea (Republic of), ³Chonnam National university, Gwangju, Korea (Republic of), ⁴Ulsan University GangNeung Asan Hospital, GangNeung, Korea (Republic of), ⁵Dong-A University Medical Center, Pusan, Korea (Republic of), ⁶Ajou University Hospital, Suwon, Korea (Republic of), ⁷Yonsei University Wonju Hospital, Wonju, Korea (Republic of), ⁸Inha University Hospital, Incheon, Korea (Republic of), ⁹Hallym University Kangdong Sacred Heart Hospital, Seoul, Korea (Republic of), ¹⁰Kangwon National University Hospital, Chuncheon, Korea (Republic of), ¹¹Pusan National University Hospital, Busan, Korea (Republic of), ¹²Inje University Sanggye Paik Hospital, Seoul, Korea (Republic of), ¹³SoonChunHyang University Seoul Hospital, Seoul, Korea (Republic of), ¹⁴Soonchunhyang University Seoul Hospital, Seoul, Korea (Republic of), ¹⁵Inje University Ilsan Paik Hospital, Ilsan, Korea (Republic of), ¹⁶Chungbuk National University Hospital, Cheongju, Korea (Republic of), ¹⁷The Catholic University of Kores Bucheon St. Mary's Hospital, Bucheon, Korea (Republic of)

Background: The tranradial intervention (TRI) has several advantages such as reduction of bleeding risk, improvement of patients' convenience, and immediate ambulation as compared with the transfermoral intervention (TFI). In TRI, there are some anatomical and technical differences between right and left radial approach. The aim of this study is to evaluate the impact of the choice of the right or left radial approach on 12 months clinical outcomes in patients undergoing TRI.

Methods: A total of 1,653 consecutive patients underwent TRI were enrolled from Nov 2004 to Oct 2010 in Korean TRI Registry. The patients were divided into two groups; right radial approach group (n=792 pts) and left radial approach group (n=861 pts). To adjust potential confounders, propensity score matched (PSM) analysis was performed using the logistic regression model (C-statistics: 0.726). After PSM, total of 1,100 pts (550 pairs) were enrolled for this analysis.

Results: After PSM, the baseline clinical and angiographic characteristics were balanced between two groups. However, contrast volume during procedure were larger and fluoroscopic time (22.5 ± 28.0 min vs. 17.1 ± 12.6 min) were longer in right radial approach group (259.3 ± 119.6 cc vs. 227.0 ± 90.7 cc, p-value <0.001), whereas procedure time (49.2 ± 30.4 min vs. 55.4 ± 28.7 min, p-value=0.003) were longer in left approach group. After PSM, procedural and in-hospital complications were similar between the two groups. The cumulative clinical outcomes up to 12 months including mortality, recurrent myocardial infarction (MI), repeat revascularization, stent thrombosis and MACE were similar between the two groups (Table). **Conclusion:** In this study, despite the procedural efficacy including procedural time and contrast volume were increased in right artery approach, however, 12 months cumulative clinical outcomes were similar between the two groups.

Variable, N (%)	Right radial (n=550 pts)	Left radial (n=550 pts)	p Value
Mortality	21 (3.8)	26 (4.7)	0.456
Cardiac death	15 (2.7)	16 (2.9)	0.855
Recurrent Myocardial infarction	3 (0.5)	3 (0.5)	ns
Repeat Percutaneous Coronary Intervention (PCI)	25 (4.5)	27 (4.9)	0.776
Target lesion revascularization (TLR)	17 (3.0)	23 (4.1)	0.334
Target vessel revascularization (TVR)	25 (4.5)	27 (4.9)	0.776
Stent Thrombosis	5 (0.9)	0 (0.0)	0.062
MACE (Mortality, repeat PCI, MI)	44 (8.0)	53 (9.6)	0.339
MACCE (Mortality, repeat PCI, MI, CVA)	49 (8.9)	53 (9.6)	0.678

Innovative Devices and Futuristic Therapies (TCTAP A-002)

TCTAP A-002

Paclitaxel-coated Balloon Versus Paclitaxel-eluting Stent for the Treatment of Diffuse DES In-stent Restenotic Lesions: A Substudy of PEPCAD China ISR Trial

<u>Ye-lin Zhao'</u>, Bo Xu¹, Jie Qian¹, Jian-an Wang², Shao-liang Chen³, Yue-jing Yang¹, Jun-bo Ge⁴, Run-lin Gao¹

¹Fu Wai Hospital, National Center for Cardiovascular Diseases, Beijing, China, ²The Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, China, ³Nanjing First Hospital, Nanjing Medical University, Nanjing, China, ⁴Fudan University Zhongshan Hospital, Shanghai, China

Background: Treatment of drug-eluting stent in-stent restenosis (DES-ISR) is still challenging especially in diffuse lesions. The intention of this subgroup analysis is to compare the safety and effectiveness of paclitaxel-coated balloon (PCB) versus paclitaxel-eluting stent (PES) in the treatment of patients with diffuse DES-ISR.

Methods: PEPCAD China ISR was a prospective, multicenter, randomized (1:1), single blind trial conducted in China (n = 220). There were 33 patients in PCB (SeQuent® Please, B.Braun Melsungen AG, Germay) group and 44 patients in PES (Taxus® LibertIJ, Boston Scientific, Natick, MA, USA) group with diffuse in-stent restenotic lesions (Mehran type II-IV). All patients were required to undergo angiographic follow-up at 9 months and clinical follow-up at 1 month, 6 months, 1 year, and 2 years. The primary endpoint was in-segment late lumen loss (LLL) at 9 months. Secondary endpoints included % diameter stenosis (DS), binary restenosis rate, and target lesion failure (TLF), a composite of cardiac death, target vessel myocardial infarction (MI) or ischemia-driven target lesion revascularization. In addition, definite/ probable stent thrombosis (ST) rates were documented.

Results: There were no significant baseline differences between both treatment groups in terms of patient, lesion or procedural characteristics. At 9 months, in-segment LLL in the PCB group was comparable to the PES group ($0.74 \div 0.53$ mm vs. $0.80 \div 0.74$ mm, p = 0.69). The rates of 9-month in-segment binary restenosis, 12-month TLF, composite of all cause death, all MI and any revascularization, and definite/ probable ST were no statistical differences between both treatment groups (27.3% vs. 32.4%, p = 0.65; 21.2% vs. 15.9%, p = 0.55; 27.3% vs. 29.5%, p = 0.83; 3.0% vs. 0.0%, p = 0.43, respectively).

Conclusion: The present substudy offers preliminary evidence that DES-ISR patients with diffuse lesions receiving PCB therapy were non-inferior to PES implantations. However, current treatment options with either PES or PCB are not optimal for diffuse in-stent restenotic lesions after DES failure. Further innovative therapies are needed to address this kind of particularly difficult patients. (ClinicalTrials.gov identifier: NCT 01622075).

Valvular Heart Disease (TCTAP A-003)

TCTAP A-003

Comparison of Multi-detector Row CT Morphology Between CoreValve and Edwards Sapien Valve After Transcatheter Aortic Valve Implantation

Yusuke Watanabe, Thierry Lefevre, Bernard Chevalier, Marie-claude Morice Institut Cardiovasculaire Paris Sud, Massy, France

Background: This study sought to compare the morphological characteristics and underlying mechanism of paravalvular leak (PVL) after transcatheter aortic valve implantation (TAVI) using the CoreValve (Medtronic, Santa Rosa, California) and the Edwards valve (Edwards Lifesciences, Irvine, California).

Methods: A total of 68 TAVI patients (aged 84.2 ± 7.4 years, Logistic EuroSCORE 21.5 ±12.4) who had pre and post-procedural multidetector computed tomography (MDCT) were studied.

Results: In this cohort, 43 (63.2%) patients were treated with the CoreValve and the remaining 25 (36.8%) patients received the Edwards valve. Post-TAVI eccentricity index was significantly higher in patients of the CoreValve group at each level of prosthesis (start bottom 18.4 \pm 9.23 vs 5.2 \pm 4.0, p < 0.01, annulus level, 19.0 \pm 8.9 vs 5.8 \pm 7.8, p<0.01, leaftet level 16.6 \pm 8.3 vs 4.5 \pm 3.5, p < 0.01). By multivariate analysis, only the Valve Calcification Index (aortic valve calcification volume / body surface area) was identified as independent predictor of any post-procedural PVL after CoreValve implantation (odds ratio [OR] 1.002, 95% confidence interval [CI] 1.000-1.004, p=0.03). In patients with Edwards valve, post-TAVI eccentricity index (leaftet level) was identified as an independent predictor of post-procedural PVL (OR 1.31, 95% CI 1.02-1.68, p=0.04).

Conclusion: Post-TAVI valve eccentricity was more frequently observed in CoreValve implantation than after Edwards valve implantation. Valve eccentricity was associated with PVL after Edwards valve implantation but not after CoreValve implantation probably because of the supra-annular design of the CoreValve.