

flow velocity, even in stenoses selected on the basis of anatomy. This additive predictive value is retained even in intermediate stenoses when anatomical factors are particularly unhelpful. This supports the use of physiology in a wide range of stenoses when the aim of PCI is improve flow.

TCT-331

Real-World Clinical Experience of Fractional Flow Reserve Assessed With a Rapid Exchange Pressure Sensor on a MicroCatheter

Thierry Lefevre¹, Philippe Guyon², Stephan Fichtlscherer³, Thomas Munzel⁴, Volker Schächinger⁵, Azeem Latib⁶, Ramon Lopez Palop⁷
¹ICPS, Massy, France, ²Centre Cardiologique du Nord, St Denis, France, ³University Hospital Frankfurt, Frankfurt am Main, Germany, ⁴University Medical Center Mainz, Mainz, Germany, ⁵Goethe University, Frankfurt, Germany, ⁶Ospedale San Raffaele, Milan, Italy, ⁷Hospital San Juan de Alicante, Alicante, Alicante

Background: Fractional Flow Reserve (FFR) measurements have been limited by the difficulty of maneuvering 0.014 inch diameter pressure wires. The RXi system (ACIST Medical Systems, Eden Prairie, MN) is a new FFR technology utilizing a monorail ultrathin microcatheter with an optical pressure sensor located close to the distal tip of the catheter. FFR measured with the RXi system has been shown to be correlated closely with the Pressurewire™ (St. Jude Medical, St. Paul, MN). A prospective, observational registry was set up to collect real-world clinical experience of the RXi system.

Methods: The ADVANCE-EU study enrolled 60 subjects at 7 centers in France, Germany, Italy and Spain. Patients 21 years of age or older provided informed consent and were enrolled in the registry following use of the Navvus catheter to guide PCI strategy. Using physician preferred guidewires, FFR measurement and interventional treatment was completed per each center standard care. Procedural success was defined as the ability of the Navvus catheter to acquire FFR measurement without adverse device effect or device malfunction.

Results: Preliminary analysis was obtained in the first 45 patients (57 lesions) already monitored, mean age 69 yrs, diabetes mellitus 31%, stable angina 51%, radial approach 58% of cases. The vessel was moderately or severely tortuous in 36% and 11% of cases respectively and moderately or severely calcified in 54 and 16% of cases respectively. The Navvus Catheter was used without adverse device effect or device malfunction in all cases. The lesions analyzed were successfully crossed with the Navvus catheter in 93% of cases. Jailed side branches and moderate to severely calcified lesions that were not initially crossed by the Navvus catheter were either left untreated or underwent PCI followed by FFR measurement with the Navvus catheter.

Conclusions: The preliminary results of this real world prospective registry show that the RXi system can be used successfully to assess FFR in relatively complex anatomy and lesions. This new device may simplify FFR measurements by allowing the use of standard coronary guidewires to deliver an intracoronary pressure sensor. Final results will be presented at the meeting.

TCT-332

Relation Between Fractional Flow Reserve And Coronary Bifurcation Anatomy: A Novel Quantitative Model To Assess The Stenotic Severity Of Bifurcation Lesions

Shengxian Tu¹, Mauro Echavarría-Pinto², Clemens von Birgelen³, Niels R. Holm⁴, Stylianos A. Pyxaras⁵, Indulis Kumsars⁶, Ming Kai Lam³, Ilona Valkenburg³, Gabor G. Toth⁷, Yingguang Li⁸, Javier Escaned⁹, William C. Wijns⁸, Johan H. Reiber⁸

¹Biomedical Instrument Institute, School of Biomedical Engineering, Shanghai Jiao Tong University, Shanghai, China, ²Cardiovascular Institute, Hospital Clinico San Carlos, Madrid, Spain, ³Department of Cardiology, Thoraxcentrum Twente, Medisch Spectrum Twente, Enschede, the Netherlands, ⁴Department of Cardiology, Aarhus University Hospital, Aarhus, Denmark, ⁵Cardiovascular Center Aalst, OLV-Clinic, Aalst, Belgium, ⁶Department of Cardiology, Paul Stradins Clinical Hospital, Riga, Latvia, ⁷Cardiovascular Centre Aalst, OLV-Clinic, Aalst, Belgium, ⁸Division of Image Processing, Department of Radiology, Leiden University Medical Center, Leiden, Netherlands

Background: Development of advanced quantitative models might aid establishing the relation between bifurcation anatomy and fractional flow reserve (FFR). The aim of this study was to present for the first time a new bifurcation model for quantification of stenotic severity in the entire bifurcation lesion. The diagnostic performance of this model empowered by 3-dimensional quantitative coronary angiography in predicting the functional significance of obstructive bifurcation stenoses was evaluated using FFR as reference standard.

Methods: Patients who had been admitted in five European hospitals for various studies involving FFR measurement in bifurcation lesions were randomly selected and analyzed by a core laboratory. Different diameter models including Murray, Finet, and HK models were implemented in the proposed bifurcation model for optimization of reference diameter functions, resulting in different degrees of stenosis. The conventional straight, i.e., single branch, model was included to compare with the bifurcation model.

Results: Seventy-eight bifurcation lesions in 73 patients were analyzed. In 51 (65%) bifurcations FFR was measured in the main vessel. A total of 34 (43.6%) interrogated vessels had an FFR ≤ 0.80 . Average minimum lumen diameter was 1.27 ± 0.29 mm.

The diameter stenosis optimized by the HK diameter model had the highest correlation with FFR ($r = -0.50$, $p < 0.001$), as compared to the Finet model ($r = -0.49$, $p < 0.001$), the Murray model ($r = -0.41$, $p < 0.001$), and the straight model ($r = -0.23$, $p < 0.001$). The AUC for predicting FFR ≤ 0.80 was significantly higher by the bifurcation model than the straight model, being 0.72 (95% CI: 0.61; 0.82) versus 0.60 (95% CI: 0.49; 0.71), $p = 0.001$. Applying $\geq 50\%$ diameter stenosis assessed by the bifurcation model for predicting FFR ≤ 0.80 resulted in 23 true positives, 27 true negatives, 17 false positives, and 11 false negatives.

Conclusions: The new bifurcation model provides comprehensive assessment of bifurcation anatomy. Compared to the straight model, identification of lesions with preserved FFR values in obstructive bifurcation stenosis was improved. However, Accuracy was limited by use of pure anatomy without integration of coronary flow.

TCT-333

Clinical Relevance of Post-Stent Fractional Flow Reserve after Drug-Eluting Stent Implantation

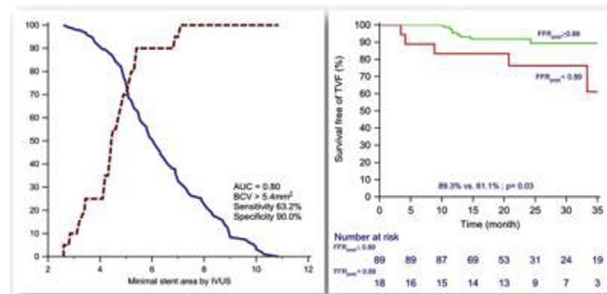
Joon-Hyung Doh¹, Bon-Kwon Koo², Chang-Wook Nam³, Sung Yun Lee⁴, Eun-Seok Shin⁵

¹Inje University Ilsan Paik Hospital, Goyang, Korea, Republic of, ²Samsung Medical Center, Seoul, Korea, Republic of, ³Seoul National University, Seoul, Korea, Republic of, ⁴Keimyung University Dongsan Medical Center, Daegu, Korea, Republic of, ⁵Inje University Ilsan Paik Hospital, Goyang-si, Korea, Republic of, ⁶Ulsan University Hospital, Ulsan, Kyongsangnamdo

Background: The prognostic value of post-stent FFR has not been clearly defined in patients with DES implantation. We sought to evaluate the association between fractional flow reserve (FFR) and clinical outcomes after drug eluting stent (DES) implantation with intravascular ultrasound (IVUS) assistance.

Methods: One-hundred and fifteen lesions (107 patients) with FFR measurement after DES implantation assisted by IVUS were enrolled. Post-stent angiographic and IVUS parameters were compared with FFR values. Clinical outcomes were assessed by target vessel failure (TVF) defined as a composite of target vessel revascularization, death or non-fatal myocardial infarction attributed to the target vessel.

Results: Mean post-stent FFR was 0.92 ± 0.04 . Minimal stent area by IVUS had a positive correlation with post-stent FFR ($r = 0.36$, $p < 0.01$). Post-stent FFR ≥ 0.89 was a physiologic cut-off value for 1-year TVF-free survival. Best cut-off value of minimal stent area to define post-stent FFR ≥ 0.89 was $> 5.4 \text{ mm}^2$, and its sensitivity and specificity were 63.2% and 90.0%, respectively. During a 3 year follow-up, lesions with post-stent FFR ≥ 0.89 had a better TVF-free survival rate than those with post-stent FFR < 0.89 (89.3% vs. 61.1%, $p = 0.03$). By Cox-regression analysis, post-stent FFR ≥ 0.89 was an independent predictor for TVF-free survival (Exp(B) = 7.8, 95% CI = 1.3-46.9, $p = 0.03$).



Conclusions: Post-stent FFR can be a useful predictor for long-term clinical outcomes after DES implantation and relevant to IVUS minimal stent area.

TCT-334

Model-Based Determination of Fractional Flow Reserve Based on Coronary Angiography – Initial Validation by Invasively Measured FFR

Christian Schlundt¹, Thomas Redel², Michael Scheuring², David Groke², Klaus Klingenberg³, Lucian Iu³, Puneet Sharma³, Ali Kamen³, Dorin Comaniciu³, Stephan Achenbach¹

¹University of Erlangen, Department of Internal Medicine 2, Erlangen, Germany, ²Siemens AG, Healthcare Sector, Forchheim, Germany, ³Imaging and Computer Vision, Siemens Corporate Technology, Princeton, NJ

Background: Invasive Fractional Flow Reserve (FFR) is the gold standard to identify hemodynamically relevant coronary stenoses. We developed and evaluated a new approach to determine lesion-specific FFR based on coronary anatomy as visualized by invasive coronary angiography.

Methods: In 52 lesions (48 individuals), Invasive FFR was determined using a pressure wire during adenosine-induced vasodilation. Coronary angiograms from two views were acquired under resting conditions. These were processed offline with syngo IZ3D (SiemensHealthcare Sector) to obtain a 3-dimensional model of the