acute myocardial infarction. In addition subjects with B2/C lesions, which are known to have a higher risk for cardiac complications or restenosis have been evaluated.

RESULTS Nine hundred seventy one men (72%) and three hundred eighty five women were enrolled at 43 sites in 14 countries. The mean age was 66.1 ± 10.7, ranging from 29 - 91 years. The majority of subjects presented with hypertension 76%, hypercholesteremia 60%, smoker 55%, and diabetes 30%. 48% of all stented vessels had a diameter ≤2.75mm, 4% presented with chronic total occlusion. Eleven percent of the subjects experienced unstable angina, 47% stable angina. Acute MI was seen in 33% of the subjects (NSTEMI 22%, STEMI 11%). The portion of elderly subjects (≥75 years) is represented by 25%. An unbiased patient population was seen in the registry with more than 52% type B2/C lesions. Moderate and severe calcification was observed in 31%. The Orsiro hybrid stent system demonstrated excellent device (98.7%) and procedure success (98.2%). In this all-comers setting a TLF rate of 5.1% was observed within the first 12 months. The low TLF rate was also confirmed for the subgroups: diabetics (7.7%), acute MI (7.2%), small vessel (5.8%), CTO (1.8%) and complex B2/C lesions (5.1%).

CONCLUSION The results observed in this "real world" population demonstrate a low TLF rate comparable to other state of the art DES at 6- and 12-months.

CRT-156

Two Year Safety And Clinical Performance Of The Drug Eluting Orsiro Stent In The Treatment Of Subjects With Single De Novo Coronary Artery Lesions (BIOFLOW-II)

Michael Haude,[1] Thierry Lefévre,[2] Bernhard Witzenbichler,[3] Karl Stangl,[4] Franz-Josef Neumann,[5] Ton Slagboom,[6] Rafael Ruiz-Salmeron,[7] Manel Sabaté,[8] Gert Richardt,[9] Béla Merkely,[10] Javier Goicolea,[11] Johannes Bilger,[12] Paul Barragan,[13] Ron Waksman,[14] Stephan Windecker[15]
[1]Städtische Kliniken Neuss, Lukaskrankenhaus GmbH, Neuss, Germany; [2]Hospital Prive Jacques Cartier, Massy, France; [3]Charité- Campus Benjamin Franklin, Berlin, Germany; [4]Charité - Campus Mitte, Berlin, Germany; [5]Universitäts-Herzzentrum Freiburg-Bad Krozingen, Bad Krozingen, Germany; [6]OLVG Amsterdam, Amsterdam, Netherlands; [7]Hospital Virgen de la Macarena, Sevilla, Spain; [8]Hospital Clínico y Provincial de Barcelona, Barcelona, Spain; [9]Segeberger Kliniken, Bad Segeberg, Germany; [10]Semmelweis University, Budapest, Hungary; [11]Hospital Puerta de Hierro, Madrid, Spain; [12]Klinikum Nürnberg Süd, Nürnberg, Germany; [13]Polyclinique Les Fleurs, Ollioules, France; [14]MedStar Health Research Institute, Washington, DC; [15]Inselspital Bern, Bern, Switzerland

OBJECTIVES BIOFLOW-II is a randomized controlled study, comparing the clinical efficacy of the Orsiro Hybrid Drug Eluting Stent (Orsiro) with the Xience Prime™ Everolimus Eluting Stent (Xience Prime) at 2 Years in the complete study population as well as in the diabetic and small vessel subgroups, which are known to have a higher risk for cardiac complications. Here we present the outcome through the clinical endpoints Target Lesion Failure (TLF) and Stent Thrombosis (ST).

METHODS A total of N=452 subjects (62.7±10.4, 38-80 yrs) were enrolled in the Intention to Treat population in the BIOFLOW-II study, registered at clinicaltrials.gov (NCT01356888). All subjects were stratified for diabetes and then randomly assigned (2:1) to receive the Orsiro or the Xience Prime stent. The diabetic subgroup accounted for 28.3% N=128 (Orsiro N=84, Xience Prime N=44) of all subjects. The small vessel cohort included all subjects with a reference vessel diameter ≤2.75mm, accounting for 57.3% N=259 (Orsiro N=168, Xience Prime N=91) of all subjects. Clinical follow up visits are performed at 1, 6, 12 months and annually up to 5 years after the procedure. All angiographic images were analyzed by an independent Corelab. All clinical events were adjudicated by an independent clinical events committee.

RESULTS All three study groups showed comparable populations in both randomization arms in terms of demographics, current risk factors, clinical history and lesion/vessel characteristics. The TLF rate at 24 months was 8.4% for the Orsiro vs. 10.0% for the Xience Prime in the full cohort, 9.7%vs. 9.1% in the diabetic subgroup and 9.4% vs. 13.3% for subjects with small vessel lesions. There was no statistical significance between the two study arms in any of the three analyzed populations. No ST (definitive, probable or possible) occurred through 24 months in the Orsiro arm. Conclusion In this RCT the clinical event rates of the Orsiro SES with a biodegradable polymer were low and comparable to the Xience Prime up to 24 month in all three analyzed populations.

CRT-157

Does the Drug Eluting Stent Implantation Decrease with Age Increase in Elderly Population?

Wenjie Tian, Rebecca Torguson, Hideaki Ota, Thibault Lhermusier, Smita Negi, Ron Waksman
MedStar Washington Hospital Center, Washington, DC

BACKGROUND The aim of this study is to investigate whether age increase affects the decision to use drug-eluting stents (DES) in elderly patients undergoing percutaneous coronary intervention (PCI).

METHODS This is a single center registry including elderly patients (≥ 65 year-old) undergoing PCI. We defined first DES era as the period between April 2003 and July 2008, and second DES era the period of July 2008 to March 2014. Multivariable model was created for both eras to assess the independent factors associated with DES implantation and the impact of age (per 10 year increase).

RESULTS A total of 8,598 elderly patients were included, of whom 4,528 (52.7%) and 4,070 (47.3%) underwent PCI in the first and second generation DES eras, respectively. Multivariable logistic regression showed that age increase of per 10 years was associated with less likelihood to receive DES implantation. Similarly, patients with acute myocardial infarction, chronic renal insufficiency, chronic heart failure, cardiac shock and current smoking were less likely to receive DES in the two DES eras.

CONCLUSION Among elderly patients undergoing PCI, age is independently associated with a lower likelihood of DES implantation in the second generation era. This finding may highlight the clinical difficulty in assessing the risk/benefit balance of DES in the elderly population.

Table I. Adjusted Multivariate Logistic Outcome

Variable	First-generation era		Second-generation era	
	OR [95% CI]	p value	OR [95% CI]	p value
Age (10 years)	0.78(0.69-0.89)	<0.001	0.53(0.47-0.58)	<0.001
African American	0.9(0.75-1.10)	0.303	0.87(0.74-1.02)	0.079
Male	0.82 (0.69-0.98)	0.026	0.93 (0.79-1.08)	0.331
Diabetes	0.96 (0.81-1.15)	0.662	1.27 (1.08-1.48)	0.003
Hypertension	0.63 (0.46-0.85)	0.003	0.86(0.67-1.12)	0.266
AMI	0.36 (0.28-0.46)	< 0.001	0.33(0.26-0.41)	<0.001
Cardiac shock	0.32(0.21-0.49)	<0.001	0.30 (0.19-0.48)	<0.001
CHF	0.75 (0.61-0.91)	0.005	0.78 (0.65-0.94)	0.011
CRI	0.89 (0.72-1.11)	0.301	0.77 (0.65-0.92)	0.004
PVD	1.02 (0.82-1.25)	0.887	1.09 (0.90-1.31)	0.377
PTCA history	1.33 (1.09-1.61)	0.004	1.61(1.35-1.91)	<0.001
CABG history	1.05(0.85-1.29)	0.678	1.01 (0.84-1.21)	0.929

CABG: Coronary artery bypass grafting; CRI: Chronic renal insufficiency; PTCA: Percutaneous transluminal coronary angioplasty; PVD: Peripheral vessel disease; CHF: Congestive heart failure; AMI: Acute myocardial infarction

CRT-158

Comparison Of Everolimus- And Paclitaxel-eluting Stents in Dialysis Patients

Masaya Otsuka
Division of Cardiology, Cardiovascular Center, Akane Foundation Tsuchiya General Hospital, Hiroshima, Japan

BACKGROUND We previously reported that the incidence of 1-year major adverse cardiac events (MACE) in patients treated with paclitaxel-eluting stents (PES) was lower than that in the sirolimus-eluting stents, mainly due to reduction of target lesion revascularization (TLR) in dialysis patients. However, it is unclear whether there are differences in clinical outcomes between everolimus-eluting stents (EES) and PES in dialysis patients.

METHODS Between February 2010 and September 2013, 248 maintenance dialysis patients were treated with coronary stents. In this study, 102 maintenance dialysis patients with 135 lesions treated with EES were compared to 107 maintenance dialysis patients with 147 lesions treated with PES. Of these, 60 patients were prospectively randomized to either EES (32 patients) or PES (28 patients) between March 2011 and September 2013. Angiographic and 1-year clinical outcomes were investigated.

RESULTS Diabetes mellitus (DM) was present in 64.7% in the EES group and 71.0% in the PES group (p=0.33). Dialysis period was 6.4 ± 6.3 years vs 6.2 ± 5.9 years respectively (p=0.77). Heavy calcification was in 27.4% vs 34.0% (p=0.23). In-stent restenosis lesion was in 14.1% vs 10.9% (p=0.42). There were no significant differences in reference diameter (2.62 ± 0.64mm vs 2.66 ± 0.60mm, p=0.52) and lesion length (15.0 ± 12.2mm vs 16.5 ± 11.4mm, p=0.29). Rotational atherectomy was undergone in 11.1% vs 23.1% (p<0.01). Total stented length was not significantly different (23.5 ± 14.6mm vs 24.4 ± 13.2mm, p=0.60). One patient in the EES group was lost to follow up. Angiographic follow-up was obtained in 73.3% vs 74.8% (p=0.77). Restenosis rate was not significantly different (18.2% vs 13.6%, p=0.37). At 12 months, MACE occurred in 13.2% in the EES group and 17.4% in the PES group (p=0.25). TLR was observed in 9.5% vs 10.4% respectively (p=0.77). Mortality was 11.8% vs 13.1% (p=0.35). Cardiac death was 5.0% vs 7.7% (p=0.09). Definite stent thrombosis was observed in 2.0% vs 0% (p=0.14). Subgroup analysis in patients with DM revealed no significant differences in MACE (12.7% vs 14.9%, p=0.36), TLR (8.3%

vs 7.4%, p=0.42), mortality (13.7% vs 13.2%, p=0.28), and cardiac death (6.3% vs 8.0%, p=0.15) between the two groups. Subgroup analysis in randomized patients showed no significant differences in MACE (9.4% vs 18.4%, p=0.39), TLR (3.3% vs 12.0%, p=0.17), mortality (6.3% vs 14.3%, p=0.20), and cardiac death (6.3% vs 7.3%, p=0.90).

CONCLUSIONS One-year clinical outcomes following EES and PES implantations are similar in dialysis patients.

CORONARY

CRT-159

Vasomotor Function among Coronary Arteries in Healthy Miniswine

Xinhua Yin,[1] Arihiro Sumida,[2] Yawei Xu,[3] Jimmy Li,[2] Jack P. Chen,[1] Nicolas Chronos,[1] Spencer King,[1] Dongming Hou[4]
[1]SJTRI, Atlanta, GA; [2]SJTRI, Atlanta, GA; [3]Cardiology department, at 10th hospital, Shanghai, China; [4]BSC, Plymouth, MN

BACKGROUND Swine model plays an instrumental role in the assessment of vascular healing response to implantable device. Restoration of vasomotion has been reported as a key feature of following DES with biodegradable polymer and fully bioabsorbable scaffold. So far, evaluation of invasive vasomotion response to acetylcholine (Ach) in naïve health miniswine coronary is lacking. Therefore, we aimed to study the vasomotion response in cath lab setting.

METHODS Seventy coronary arteries (LAD=24, LCX=23 and RCA=23) from 30 healthy adult animals underwent vasomotor function evaluation. Endothelium-dependent function was assessed by infusion of incremental Ach at doses of 10^{-6} and 10^{-5} mol/L. Followed by baseline angiography, Ach was administrated via a coronary infusion catheter (Ultra-Fuse, Boston Scientific) in proximal of artery with 1 ml/min for 2min. Coronary angiography was performed 30s after each dose with 5min intervals. Endothelium-independent function was evaluated by NTG (200μg). The mean luminal diameter of mid-artery in a length of 20mm was measured by QCA. Responses to infusions of Ach and NTG were expressed as percentages of diameter changes from baseline.

RESULTS Animals were tolerated well without hemodynamic and other complications during test. There were no differences of lumen diameter among groups from baseline angiograph (LAD, 2.75±0.29mm; LCX, 2.67±0.31mm; and RCA, 2.67±0.21mm; p>0.05 respectively). However, dilation of right coronary artery (RCA,3.3±4.3%) was significant more than both LAD (0.5±4.6%, p=0.02) and LCX (-1.2±4.2%, P=0.002) in response to low-dose of Ach. All of the three epicardial arteries had a mild vessel constriction instead of dilation to response the high-dose of Ach. No difference was detected regard the percentage of diameter changes (LAD, -3.9±7.9%; LCX, -4.5±7.9%; and RCA, -5.7±13.8%; p>0.05 correspondingly). NTG-induced endothelium-independent vasorelaxation was comparable between LAD and RCA (6.75±5.9% and 6.6±5.4%; p>0.05). LCX (3.3±5.2%) relaxation was significantly less in response to NTG when compared to LAD and RCA (p=0.04, individually).

CONCLUSIONS Healthy adult miniswine is FDA accepted model to evaluate novel coronary device in preclinical study because their size and anatomy are comparable to human. The data demonstrated that dilation of epicardial vessels in response to endothelium-dependent Ach challenge is only occurred at lower dose. The preclinical implications of these findings are potentially useful for design pf preclinical vasomotion study.

CRT-160

Influence of Stent Length on Stent Deliverability between First and Second Generation Drug-Eluting Stent Platform Using Bench Test Model

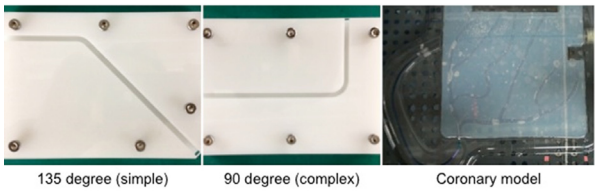
Katsuhisa Waseda, Hiroaki Takashima, Masanobu Fujimoto, Yasuo Kuroda, Takashi Kosaka, Akiyoshi Kurita, Hirohiko Ando, Kazuyuki Maeda, Shinichiro Sakurai, Akihiro Suzuki, Tetsuya Amano
Aichi Medical University, Nagakute, Japan

BACKGROUND While drug-eluting stents (DES) have recently improved their efficacy and safety profiles, differences in stent deliverability among various coronary stents have not been systematically evaluated. The aim of this bench test study was to evaluate the impact of stent length on stent deliverability between first and second generation DES systems.

METHODS Three coronary stent systems (Bx Velocity, Integrity and Multi-link 8), using 6 of each, were assessed with 3 bench test models: 135 degree (simple model), 90 degree (complex model) and coronary model (coronary). Stent delivery systems were inserted into each model using a dedicated machine and the delivery force was computed, measured, and compared.

RESULTS For first generation DES, long stent systems showed deliverability with significantly greater force compared with short stent systems regardless of bench test model. For second generation DES, complex and coronary model showed similar force for both short and long stent, however, simple model revealed greater force in long stent systems compared with short stent systems.

CONCLUSION Our results suggest that second generation DES platforms overall are more deliverable, requiring less force, than first generation DES platforms.



Average Force (gf)

	First generation			Second generation		
Model type	Short	Long	p	Short	Long	p
Simple	16.0±0.8	20.9±2.3	<0.001	11.2±0.6	12.5±0.5	<0.001
Complex	25.4±0.6	40.6±0.8	<0.001	19.9±1.0	20.6±1.3	0.106
Coronary	50.8±3.0	60.3±3.3	<0.001	33.0±4.7	34.0±4.3	0.597

CRT-161

The Impact of Precise Robotic Lesion Length Measurement on Stent Length Selection: Ramifications For Stent Savings

Paul T. Campbell, Kevin R. Kruse, Christopher R. Kroll, Janet Y. Patterson, Michele J. Esposito
Carolinas Medical Center - NorthEast, Concord, NC

BACKGROUND Coronary stent deployment outcomes can be negatively impacted by inaccurate lesion measurement and inappropriate stent length selection (SLS). We compared the manual measurement of these parameters to those provided by the CorPath 200® Robotic PCI System.

METHODS Sixty consecutive patients who underwent coronary stent placement utilizing the CorPath System were evaluated. The treating physician assessed orthogonal images and provided visual estimates of lesion length and SLS. The robotic system was then used for the same measures. SLS was considered to be accurate when manual and robotic measures were in agreement. Manual SLSs were considered to be "short" or "long" if they were below or above the robotic-selected stents, respectively.

RESULTS Only 35% (21/60) of visually estimated lesions resulted in accurate SLS. Whereas, 33% (20/60) and 32% (19/60) of the manually-determined SLSs were long and short, respectively. In 5 cases (8.3%), 1 less stent was placed based on the robotic lesion measurement being shorter than the visual estimate (TABLE 1).

CONCLUSIONS Manual assessment of lesion length and SLS is highly variable with 65% of the cases being inaccurately measured when compared to objective measures obtained from the robotic system. The 32% of the cases where lesions were visually estimated to be short represents cases that often require the use of extra stents after the full lesion is not covered by 1 stent [Longitudinal Geographic Miss (LGM)]. Further, these data showed that the use of the robotic system prevented the use of extra stents in 8.3% of the cases. Measurement of lesions with robotic PCI may reduce measurement errors, need for extra stents, and LGM.

Table 1. Cases with Definite Stent Savings

Case	Visual Measurement (mm)	Visual Stent Length Selection (mm)	CorPath Measurement (mm)	Final Stent Length Chosen (mm)
1	38	23+18	34.9	38
2	46	24+24	38.0	38
3	52	24+28	37.7	38
4	44	24+20	28.0	32
5	40	18+23	35.1	38

CRT-162

Hybrid Approach of Percutaneous Coronary Intervention Followed by Minimally Invasive Valve Surgery for Patients with Concomitant Coronary Artery and Valvular Heart Disease and Severely Reduced Left Ventricular Systolic Function

Andres M. Pineda, Juan Pablo Rodriguez-Escudero, Christos G. Mihos, Rama Krishna, Orlando Santana, Nirat Beohar
Mount Sinai Medical Center, Miami Beach, FL

BACKGROUND The subset of patients with severely reduced left ventricular systolic function requiring coronary revascularization and valve surgery are at increased risk for adverse post-operative outcomes. They may benefit from a hybrid approach of percutaneous coronary intervention (PCI) followed by minimally invasive valve surgery (MIVS), rather than a combined median sternotomy coronary artery bypass graft and valve surgery.