METHODS Patients receiving two different BVS, Absorb (Abbott Vascular) and DESolve (Elixir Medical) in a single Center, have been followed-up (mean 18 months) with clinical examination, coronary CT-scan and eventually coronary angiography. Quantitative Coronary Angiography (QCA), performed before and after BVS implantation, measured: Minimal Lumen Diameter and Area (MLD; MLA) and % Stenosis. CT images have been post-processed by experienced operators, to get similar measurements.

RESULTS Within 2 years, 50 patients (M/F= 4/1; mean age 54±8 years) have been treated with BVS (26 Absorb; 24 DESolve) for: stable angina (30%), UA/NSTEMI (52%), STEMI (18%). Mean diameter of implanted scaffolds was higher in the Absorb group (3.25±0.4 vs 2.97±0.39; p=0.016), but postdilation diameters were similar (3.44±0.5 vs 3.24±0.54; p=0.2) due to the higher confidence to overdilate the DESolve scaffold. CT highlighted 4 cases of restenosis (Absorb), only 2 confirmed by angiography. Comparison among QCA after-BVS and CT follow-up showed "positive" differences, at 18 months, only in the DESolve group, where significant late Lumen Gain resulted: MLD (2.13±0.5 vs 2.33±0.5; p=0.03); MLA (3.73±1.6 vs 4.45±2; p=0.03). Measures from different techniques (QCA and CT) showed significant correlation. Direct comparison Absorb vs DESolve showed no differences at the follow-up.

CONCLUSION Our experience with two generations BVS showed no acute recoil or mid-term clinical events, with two cases of Absorb failure (TLF). CT resulted a useful tool for qualitative and quantitative BVS assessment, showing good correlation with QCA measures. BVSs kept similar diameters at 18m follow-up. DESolve scaffold showed greater lumen gain compared to the other BVS, due to innovative features.

CRT-600.05

Intravascular Ultrasound Findings of the Fantom Bioresorbable Scaffold at 6 and 9 Months Follow-up: Results from the Multicenter FANTOM II Study

Joost Daemen,[1] Laurens van Zandvoort,[1] Dariusz Dudek,[2] Joachim Weber - Alders,[3] Evald Christiansen,[4] David Muller,[5] Janusz Kochman,[6] Jens Flensted Lassen,[7] Roman Wojdyla,[8] Joanna Wykrzykowska,[9] Alexandre Abizaid[10]
[1]Erasmus MC - Thoraxcenter, Rotterdam, Netherlands; [2]Department of Cardiology, Jagiellonian University Medical College, Krakow, Poland; [3]St.-Johannes-Hospital, Dortmund, Germany; [4]Aarhus University Hospital, Aarhus, Denmark; [5]St. Vincent's Hospital, Syndey, Australia; [6]Medical University of Warsaw, Warsaw, Poland; [7]Rigshospitalet, University, Copenhagen, Denmark; [8]Samodzielny Publiczny Zaklad Opieki Zdrowotnej Szpital Uniwersytecki w Krakow, Krakow, Poland; [9]Department of cardiology, AMC, Amsterdam, Netherlands; [10]Instituto de Cardiologia Dante Pazzanese, São Paolo, Brazil

BACKGROUND FANTOM II is a prospective multicenter study designed to assess the safety and efficacy of the FANTOM Sirolimus-Eluting Bioresorbable Coronary Scaffold (BRS) in patients with stable coronary artery disease. The present substudy focuses on the performance of the device as assessed by IVUS.

METHODS A total of 240 patients with de novo coronary artery lesions presenting with stable or unstable disease were included in 2 cohorts. In cohort A (n=117), angiographic follow-up was performed at 6 months. IVUS data was available in 35 paired cases. In cohort B 23, angiographic follow-up was performed at 9 months, with IVUS available in 26 paired cases. IVUS was performed at 40MHz with a pullback speed of 0.5mm/sec. Analyses were performed by an independent corelab (Cardialysis BV, Rotterdam, the Netherlands). The region of interest beginning 5 mm distal to and extending 5 mm proximal to the treated segment was examined and analyzed.

RESULTS Mean age was 62.7 years, 70.4% were male. Diabetes was present in 23.8% of the patients. Post procedure mean scaffold area was 6.09±1.08mm in cohort A and 6.46±1.11mm in cohort B. diameter was 2.94±0.16 mm. Average scaffold length was 18.59±1.80 mm. Post dilatation was performed in 80.4% of the cases (77.9% in cohort A and 86.1% in cohort B). In cohort A, mean and minimum scaffold area (SA) slightly decreased at 6 months (from 6.09±1.08mm^2 to 5.88±1.07mm^2, p=0.009 and 5.27±0.99mm^2 to 5.05±0.99mm^2, p=0.01 respectively). Neointimal hyperplasia area at 6 months was 0.11±0.12 and in-scaffold obstruction volume was 1.94±2.25%. In cohort B, the struts were still visually recognizable on IVUS as high echogenic structures. No significant change in mean scaffold and minimum scaffold area was observed at 9 months (6.46±1.11mm^2 to 6.38±0.96mm^2; p=0.35 and 5.45±1.00mm^2 to 5.36±0.86mm^2; p=0.32 respectively). Neointimal hyperplasia area at 9 months was 0.20±0.21 and in-scaffold obstruction volume was 3.40±4.11%.

CONCLUSIONS The use of the FANTOM BRS in stable coronary artery disease was safe and effective with low rates of neointimal hyperplasia volume and in-scaffold volume obstruction at both 6 and 9 months.

CRT-600.06

Implantation Technique in Magmaris Second-generation Drug-eluting Absorbable Metal Scaffold in Patients with Denovo Coronary Artery Lesions: Optical Coherence Tomography Analysis

Yuichi Ozaki,[1] Hector M. Garcia-Garcia,[1] Alexandre Hideo Kajita,[1] Kayode O. Kuku,[1] Michael Haude,[2] Hüseyin Ince,[3] Alexandre Abizaid,[4] Ralph Tölg,[5] Pedro Alves Lemos,[6] Clemens von Birgelen,[7] Evald Høj Christiansen,[8] William Wijns,[9] Javier Escaned,[10] Jouke Dijkstra,[11] Ron Waksman[1]
[1]MedStar Washington Hospital Center, Washington, DC; [2]Lukaskrankenhaus GmbH, Neuss, Germany; [3]Vivantes Klinikum im Friedrichschain and Am Urban, Berlin, Germany; [4]Instituto de Cardiologia Dante Pazzanese, Sao Paulo, Brazil; [5]Herzzentrum Segeberger Kliniken GmbH, Bad Segeberg, Germany; [6]University of Sao Paulo, São Paulo, Brazil; [7]Thoraxcentrum Twente, Enschede, Netherlands; [8]Aarhus University Hospital, Aarhus, Denmark; [9]Cardiovascular Research Center Aalst, OLV Hospital, Aalst, Belgium; [10]Hospital Clinico San Carlos, Madrid, Spain; [11]Leiden University, Leiden, Netherlands

BACKGROUND Second-generation drug-eluting absorbable metal scaffold (Magmaris) is an alternative novel device for treating coronary lesions. However, the relationship between in-scaffold geometry after implantation of Magmaris and late lumen loss (LLL) is unknown. The aim of this study is, therefore, to investigate the effect of implantation technique, using optical coherence tomography (OCT), on Magmaris and LLL.

METHODS The present study population comprises of a total 67 patients with 67 lesions who were enrolled in the prospective, multicenter BIOSOLVE-II trial between October 2013 and May 2015. We assessed apposition, dissection, intraluminal mass, side branch relationship, and expansion of Magmaris after implantation evaluating frame by frame using OCT. % device expansion was defined as a ratio of mean device area to mean reference lumen area at post procedure and expansion group was defined as either patients who have in-scaffold MLA > 90% of the average reference lumen area or ≥ 100% of lumen area of the reference segment with the lowest lumen area. In addition, lumen volume loss was also assessed by OCT. Using quantitative coronary angiography (QCA), LLL at 6 months was also assessed.

RESULTS By OCT, a total of 8726 frames were assessed. The total number of incomplete scaffold strut apposition (r = 0.25, p = 0.04) and the sum of maximum distance from strut to lumen surface (r = 0.23, p = 0.06) correlated with in-scaffold LLL (QCA). The other OCT findings including presence of dissection, malapposition, intraluminal mass and presence of a side branch after implantation of Magmaris had no statistically significant correlations with in-scaffold LLL (QCA) at 6 months follow-up. However, in-scaffold lumen volume loss evaluated by OCT was significantly greater in patients with expansion group compared to those without (p = 0.03). Furthermore, % device expansion at post procedure tended to be inversely correlated with in-scaffold lumen volume loss (r = 0.23, p = 0.06).

CONCLUSIONS We found that high expansion indexes are associated with high late luminal loss assessed by OCT. Excessive scaffold expansion (i.e. "the bigger, the better") might not be needed to reduce in-scaffold late luminal loss assessed by OCT in Magmaris implantation. These findings should be considered hypothesis generation and need to be confirmed in future studies.

CRT-600.07

Comparison of Clinical Outcomes Between Magmaris (DREAMS 2G) and Orsiro Drug Eluting Stents: Pooled Patient Level Analysis From Biosolve II-III and Bioflow II Trials

Alexandre Hideo-Kajita,[1] Hector Garcia-Garcia,[1] Viana Azizi,[1] Hüseyin Ince,[2] Stephan Kische,[3] Alexandre Abizaid,[4] Ralph Töelg,[5] Pedro Alves Lemos,[6] Nicolas M. Van Mieghem,[7] Stefan Verheye,[8] Clemens von Birgelen,[9] Evald Høj Christiansen,[10] William Wijns,[11] Thierry Lefèvre,[12] Stephan Windecker,[13] Ron Waksman,[1] Michael Haude[14]
[1]Medstar - MHRI - MCRN - WHC, washington, DC; [2]Lukaskrankenhaus Neuss, Neuss, Germany; [3]Vivantes Hospitals Friedrichshain, Berlin, Germany; [4]Abizaid, sao paulo, Brazil; [5]Herzzentrum Segeberger

TECHNOLOGY

Kliniken, Henstedt-Ulzburg, Germany; [6]Instituto do Coração - HCFMUSP, sao paulo, Brazil; [7]Thoraxcenter, Erasmus Medical Center, Rotterdam, Netherlands; [8]Antwerp Cardiovascular Center ZNA Middleheim, antwerp, Belgium; [9]Department of Cardiology, Medisch Spectrum Twente, Enschede, Netherlands; [10]Aarhus University Hospital, Aarhus, Denmark; [11]The Lambe Institute for Translational Medicine and Curam, Galway, Ireland; [12]Institut Cardiovasculaire Paris Sud, Paris, France; [13]Department of Cardiology, Bern University Hospital, University of Bern, Bern, Switzerland; [14]Städtische Kliniken Neuss, Lukaskrankenhaus GmbH, Neuss, Germany

BACKGROUND Magmaris (DREAMS 2G - Biotronik AG, Bülach, Switzerland), a second generation drug-eluting absorbable metal scaffold, has proved to be safe and effective in the BIOSOLVE-II study up to 2 years follow-up. Recently, biodegradable polymer sirolimus-eluting stent, Orsiro (Biotronik AG, Bülach, Switzerland) has shown good clinical results in Bioflow-V study. This study aims to compare the unadjusted clinical outcomes of patients treated with Orsiro and Magmaris at 12 months.

METHODS The patients included in the Magmaris group (N=184) were taken from the BIOSOLVE-II and BIOSOLVE-III trials. While the Orsiro group (N=298) consist of patients previously enrolled in BIOFLOW-II trial. As exploratory analysis, unadjusted rates were compared at 12-month follow-up. The primary comparison was target lesion failure (TLF, a composite of death, myocardial infarction, or any revascularization).

RESULTS The following baseline and procedure characteristics were different between the two groups: mean age was 62.7±10.4 years in Osiro group vs 65.5±10.8 years in Magmaris group (p=0.004); male gender in Orsiro group was 78.2% and 63.6% in Magmaris group (p=0.005); unstable angina was 19.5% in Orsiro group vs 12.5% in Magmaris group (p=0.04). The lesion distribution according to ACC/AHA lesion characterization, Orsiro and Magmaris groups were 13.8% vs. 47.3% for Type B2 (p<0.001), respectively. The primary comparison showed that TLF in Magmaris group was 6.0% vs. 6.4% in Orsiro group (unadjusted p value 0.8607). The individual components of the TLF also presented similar results between the two groups (Table 1).

CONCLUSION Magmaris and Orsiro groups did not present any statistically significant differences in TLF rate or in the comparison of the individual components of TLF at 12 months. At the meeting, adjusted event rates will be presented.

Table 1. Unadjusted clinical outcomes of the patients treated with Magmaris or Orsiro at 12 months follow-up.

	Orsiro Group (n=298), ITT		Magmaris Group (n=184), ITT		
	N	%	N	%	P value
Events at 12 months					
Death	3	1.0	3	1.6	0.6788
Cardiac death	2	0.7	2	1.1	0.6383
MI*	9	3.0	8	4.3	0.4427
TVMI	8	2.7	6	3.3	0.7143
Clinically driven TLR	10	3.4	3	1.6	0.3869
Any TLR	11	3.7	11	6.0	0.2425
Clinically driven TVR	19	6.4	6	3.3	0.1341
Any TVR	22	7.4	13	7.1	0.8962
Death or MI	12	4.0	11	6.0	0.3289
Cardiac Death or MI	11	3.7	10	5.4	0.3623
Target-lesion failure	19	6.4	11	6.0	0.8607
Target-vessel failure	26	8.7	13	7.1	0.5163
Definite ST	0	0.0	0	0.0	-
Probable ST	0	0.0	0	0.0	-

Legend: ITT = intention to treat; MI = myocardial infarction; ST = stent thrombosis; TLR = target lesion revascularization; TVMI = Target Vessel Myocardial Infarction; TVR = target vessel revascularization.
* Myocardial infarction was reported following the Joint ESC/ACCF/AHA/WHF Task Force universal definition of myocardial infarction.

TECHNOLOGY

EMERGING DEVICES & INNOVATIVE THERAPIES

CRT-600.08

Transeptal Epicardial Puncture Haptic Feedback System

Stuart Schecter,[1] Jacob Koruth,[1] Vivek Reddy,[1] Roger Fan,[2] Wei Lin,[2] Eric Rashba[2]
[1]Mount Sinai Health Network, New York, NY; [2]SUNY Stony Brook, Stony Brook, NY

BACKGROUND Transeptal and Epicardial Puncture (TEP) are necessary for ablation of cardiac arrhythmia, left atrial appendage occlusion, and valve repair. TEP can cause perforation, especially in inexperienced hands. Catheters do not reliably enable palpation of biophysical events. Tactile feedback is advantageous when auditory and visual channels are heavily loaded, providing faster reaction times than visual feedback and alerting operators to unexpected high priority events. Work by our group demonstrated that physicians were able to identify time of contact with and puncture of the septum using digitized pressure waveforms as input into a novel haptic system (HS), and react to palpation of tissue contact in less time than cardiac systole. We also demonstrated the HS enables real-time tactile appreciation of contact force amplitude during ablation in live swine.

METHODS We hypothesized physicians (P) familiar with TEP, as well as, non physicians (NP) blinded to any visual feedback will be able to palpate sensations due to catheter manipulation (M) and transeptal puncture (TP), differentiate a single attempt TP from one that required M, and identify tactile signals indicative of entry into the pericardial space. We prospectively tested the HS by storing and processing real time pressure signals (data) acquired during 13 consecutive TPs performed for atrial fibrillation ablation and a successful attempt at epicardial access (EP) and input the data into the HS. The HS delivered a TP haptic response to 6 P and 4 NP and EP haptic response to 8 P holding a Haptic Handle. Subjects were asked if they could palpate tangible sensations due to signals generated by M and TEP, differentiate a single pass TP from one that required M, and palpate needle localization within the pericardial space during EP. Results during TP were compared between P and NP subgroups to assess if the HS is intuitive.

RESULTS A total of 138 tests were performed. Tangible sensations of M and TP were palpated in 52 of 52 NP and 77 of 78 P tests (p = NS). All 10 subjects were able to differentiate a single attempt TP from one requiring M and all 8 subjects correctly identified time of access within the pericardial space.

CONCLUSION The HS provides P and NP subjects with a means to palpate and identify biophysical signals during M and TEP in the absence of visual cues and can be utilized as a tool to train inexperienced physicians. The HS may reduce complications associated with TEP. More work is required to evaluate the benefits of multi-sensory feedback inclusive of both visual and tactile feedback.

CRT-600.09

CardioHELP Support for High-Risk Percutaneous Coronary Intervention: A Single Center Case Series

Derek Antoku, Wesley Ghasem, Anilkumar Mehra, Ray V. Matthews, Leonardo C. Clavijo, Antreas Hindoyan, David M. Shavelle, Ashwat S. Dhillon
University of Southern California, Los Angeles, CA

BACKGROUND Temporary extracorporeal membrane oxygenation (ECMO) support for high-risk percutaneous coronary intervention (PCI) has been described in select patient groups. Data is limited regarding outcomes using the CardioHELP device (Maquet, Inc.) for patients requiring high-risk PCI. We sought to assess clinical outcomes in consecutive patients undergoing high-risk PCI with CardioHELP support.

METHODS Baseline demographics and outcome were collected for 7 patients undergoing high-risk PCI with CardioHELP support. High-risk PCI was defined as unprotected left main disease (UPLMD), last remaining conduit or multi-vessel coronary artery disease (MV-CAD) and significantly reduced ejection fraction (EF<35%). All patients were deemed non-operative for surgical revascularization by the heart team. Primary outcome was in-hospital mortality. Secondary outcomes included freedom from hemodynamic compromise during PCI (defined as decrease in mean arterial pressure below 60 mm Hg for