C1 FEASIBILITY AND SAFETY/EFFICACY PROFILE OF PERCUTANEOUS PATENT FORAMEN OVALE CLOSURE: NOBLESTITCH EL VS. OTHER DEVICES
Andrea Pascotto1, Chiara Zanchettin2, Domenico Mangino2, Fabrizio D'Errico2, Alessandro Abbenante1, Ermanna Chiar1, Luca Branca1, Giuliano Chizzola1, Emanuele Visco1, Eustachio Agricola1, Luca Testa, Francesco Bedogni2, Antonella De Santis, Fabiana Piccioni, Maria Iamele1, Alessio Stanzione, Fabiana C2

Introduction. Percutaneous closure of patent foramen ovale (PFO) is a valid treatment for selected patients with paradoxical embolism; it has a major complication rate ranging between 0.2% and 1.5%, such as device embolization and erosion, endocarditis, and thrombosis. The early results of this first Italian Registry indicates that the suture-mediated “deviceless” closure of PFO with NobleStitch EL System (HeartStitch, Fountain Valley, CA) is feasible in the majority of septal anatopias and provides an effective closure of PFO.

Methods. 77 consecutive patients (mean age 47±11 years, 33 females) with clinical indication to PFO closure were randomly chosen to undergo the procedure using the NobleStitch EL (37 patients, 47±10 years - Group A), and the other devices (40 patients, 48±11 years - Group B). Patients with unfavorable interatrial septal anatomy (large aneurysm, multiple defects) were excluded. All patients underwent: 1) pre-procedural evaluation (clinical, imaging); 2) percutaneous procedure in general anesthesia under transesophageal echocardiographic guidance; 3) follow-up evaluation at 1 month, 6 months and 1 year after the procedure (clinical and microbubble ultrasound: transthoracic echocardiography and transcranial Doppler).

Results. The main indications to PFO closure were represented by transient ischemic attack in 44 patients (57.1%), cryptogenic stroke in 13 patients (22.1%), decompression sickness in professional diving in 8 patients (10.4%), and disabling migraine in 2 patients (10%). Successful device deployment was obtained in all patients. No major intraprocedural complications were observed. There was no significant difference between the two groups (Group A vs. Group B) in terms of mean duration of follow-up (164±138 vs. 169±171), and no significant residual right-to-left shunt (RLS grade ≤1): 35 patients (94.6%) in Group A, 40 patients (100%) in Group B, respectively; 2 significant RLS were registered in Group A, and none in Group B. There were no complications related to the suture-mediated closure by Group A, while a latent atrial thrombosis during the device in 60 days of Group B was found.

Conclusions. To our knowledge this is the first study demonstrating that the percutaneous PFO closure with NobleStitch EL in favorable atrial septal anatomy is an effective closure, with excellent safety profile at medium term follow-up when compared to traditional devices.

C2 PERCUTANEOUS TRANSSEPTAL MITRAL VALVE-IN-VALVE AND VALVE-IN-VALVE PROCEDURE IN HIGH-RISK PATIENTS: PROCEDURAL AND EARLY OUTCOMES IN THE VENETO REGION
Federico Ronco1, Francesco Caprioglio1, Marco Barbierato1, Andrea Pascotto2, Chiara Zanchettin1, Domenico Mangino2, Alessandro Del Leo1, Diego Calzolari1, Luca Favaero1, Elena Guerr1, Carlo Cornetti1, Alessandro Danioti1, Giuseppe Minniti1, Emanuela D'Ascoli1, Chiara Zanchettin1, Domenico Mangino2, Antonio Colombo1, Anna Sonia Petronio1, Marco Metra1, Federica Ettori1, Spedali Civili, Brescia, Italy; 3Sanaa Fossalta, Milan, Italy; 4Azienda Ospedaliero Universitaria Pisana, Pisa, Italy

Objectives. To compare the feasibility, safety and efficacy of percutaneous PFO closure using two different techniques, the NobleStitch™ system and Gore® (Amplatzer, and GORE). To our knowledge this is the first study demonstrating that the suture-mediated “deviceless” closure of PFO with NobleStitch EL System (HeartStitch, Fountain Valley, CA) is feasible in the majority of septal anatopias and provides an effective closure of PFO.

Methods. 77 consecutive patients (mean age 47±11 years, 33 females) with clinical indication to PFO closure were randomly chosen to undergo the procedure using the NobleStitch EL (37 patients, 47±10 years - Group A), and the other devices (40 patients, 48±11 years - Group B). Patients with unfavorable interatrial septal anatomy (large aneurysm, multiple defects) were excluded. All patients underwent: 1) pre-procedural evaluation (clinical, imaging); 2) percutaneous procedure in general anesthesia under transesophageal echocardiographic guidance; 3) follow-up evaluation at 1 month, 6 months and 1 year after the procedure (clinical and microbubble ultrasound: transthoracic echocardiography and transcranial Doppler).

Results. The main indications to PFO closure were represented by transient ischemic attack in 44 patients (57.1%), cryptogenic stroke in 13 patients (22.1%), decompression sickness in professional diving in 8 patients (10.4%), and disabling migraine in 2 patients (10%). Successful device deployment was obtained in all patients. No major intraprocedural complications were observed. There was no significant difference between the two groups (Group A vs. Group B) in terms of mean duration of follow-up (164±138 vs. 169±171), and no significant residual right-to-left shunt (RLS grade ≤1): 35 patients (94.6%) in Group A, 40 patients (100%) in Group B, respectively; 2 significant RLS were registered in Group A, and none in Group B. There were no complications related to the suture-mediated closure in Group A, while a symptomatic thrombosis of the device at 60 days in Group B was found.

Conclusions. To our knowledge this is the first study demonstrating that the percutaneous PFO closure with NobleStitch EL in favorable atrial septal anatomy is an effective closure, with excellent safety profile at medium term follow-up when compared to traditional devices.

C3 LEFT VENTRICULAR REVERSE REMODELLING PREDICTS LONG-TERM OUTCOMES IN PATIENTS WITH FUNCTIONAL MITRAL REGURGITATION UNDERGOING MITRAL CLIP THERAPY: RESULTS FROM A MULTICENTRE REGISTRY
Giovanni Arano1, Cosmo Godino1, Cristina Giannini2, Andrea Scotti3, Riccardo Liga1, Salvatore Curello1, Claudia Fiorina1, Alessandro Abbenante1, Ermanna Chiar1, Luca Branca1, Giuliano Chizzola1, Emanuele Visco1, Eustachio Agricola1, Assunta Castiello1, Antonio Colombo1, Anna Sonia Petronio1, Marco Metra1, Federica Ettori1, Spedali Civili, Brescia, Italy; 2San Raffaele Hospital, Milan, Italy; 3Azienda Ospedaliero Universitaria Pisana, Pisa, Italy

Objectives. To explore whether left ventricular reverse remodelling (LRRV) is a predictor of outcomes in patients with functional mitral regurgitation (FMR) undergoing MitraClip.

Methods. We analysed 184 consecutive subjects who underwent MitraClip for FMR. LRRV was defined as a reduction in left ventricular end-systolic volume ≥10% from baseline to 6 months and was observed in 79 (42.9%) patients.

Results. Compared with non-LRRV, LRRV patients were more likely to be females, less likely to have an ischaemic aetiology of MR or a prior (<6 months) HF hospitalization and had smaller LV dimensions. NYHA class improved from baseline up to 1-year follow-up in both groups. Two-year survival free from all-cause and cardiovascular (CV) death, HF hospitalization and combined endpoint (CV mortality or HF hospitalization) was higher in LRRV vs. non-LRRV group (87.3% vs. 72.2%, p=0.033; 92.4% vs. 83.8%, p=0.070; 77.2% vs. 60%, p=0.020; and 74.7% vs. 55.2%, p=0.012, respectively). LRRV was associated with a significant reduction in the adjusted relative risk of mortality, HF hospitalization and combined endpoint (HR 0.44, 95% CI [0.20-0.96], p=0.04; HR 0.55, 95% CI [0.32-0.97], p=0.038; and HR 0.54, 95% CI [0.32-0.92], p=0.023, respectively). Female gender, absence of diabetes, freedom from prior HF hospitalization, non-ischaemic aetiology of MR and LVVEDD <75 mm resulted as independent predictors of LVRR.

Conclusions. LRRV is associated with better long-term outcomes in patients with FMR treated with MitraClip. Female gender, absence of diabetes, freedom from prior HF hospitalizations, non-ischaemic aetiology of MR and LVVEDD <75 mm are predictive of LVRR.

C4 PERCUTANEOUS SUTURE-MEDIATED PATENT FORAMEN OVALE CLOSURE WITH THE NOBLESTITCH EL SYSTEM: CENTER EXPERIENCE EFFECT
Alessio Stanzione1, Antonella De Santis, Fabiana Piccioni, Maria Iamele1, Emanuela D'Ascoli1, Gaetano Goffio1, Fabrizio D'Errico1, Francesco Summa1, Gregory Sgueglia1, Achille Galli1, Maria Iamele1, UOC Cardiologia, Ospedale S. Eugenio, Roma, Italy

Background. Percutaneous transcatheter closure of patent foramen ovale (PFO) with the NobleStitch EL (HeartStitch, Fountain Valley, CA) system has been shown to provide safe and effective closure of PFO. This approach appeared to be more technically demanding than typical occluder implantation. Whether this characteristic is a feature of the

Results. From January 2017 to July 2018, 18 consecutive patients were enrolled, 17 receiving TSMV with Edwards Sapien 3 (S3) 22 mm, and 1 TSMVIR with S3 26 mm. Mean age was 78±12 years, 11 males (61%), mean STS score was 21±15. 17 procedures were performed under general anesthesia, one implant under conscious sedation. Procedural success, defined as successful valve implantation without complications and absence of residual significant valve insufficiency was achieved in 17 patients (95%). One patient died of periendar tamponade. One patient died 3 days after the procedure, during rehabilitation, because of intracranial bleeding. Average procedural time was 144±59 min. Mean ICU stay was 1.4 days. 17 of 18 patients (95%) were discharged without in hospital complications and were evaluated at 30 days reporting improvement of functional class (NYHA) without hospital readmission.
Pharmacology

C5
LONG VS. SHORT DUAL ANTIPLATELET THERAPY IN ACS PATIENTS TREATED WITH PRASUGREL OR TICAGRELOR AND CORONARY REVASCULARIZATION: A PROPENSITY SCORE ANALYSIS FROM THE RENAMI REGISTRY
Fabrizio D’Ascenzo1, Maurizio Bertaina1, Francesco Fioravanti1, Sergio Raposeiras-Roubin2, Emad Abu-Assi3, Tim Kinnaird3, Rafael Cobas Paz2, María Cespón Fernández2, Isabel Muñoz Pousa2, Pierluigi Omedé1, Sebastiano Gill1, Fabrizio D’Ascenzo1
1Department of Cardiology, Department of Medical Sciences, University of Torino, Torino, Italy, 2Department of Cardiology, University Hospital Alfredo Cugusi, Cagliari, Italy, 3Department of Cardiology, University Hospital of Wales, Cardiff, UK, 4Royal Brompton and Harefield Hospitals Trust and Imperial College, London, UK

Introduction. The benefits of short vs. long term dual antiplatelet therapy (DAPT) using the 3rd generation P2Y12 antagonists prasugrel or ticagrelor in patients with acute coronary syndromes (ACS) treated with percutaneous coronary intervention (PCI) remain to be defined, due to evidence currently limited to patients treated with clopidogrel.

Methods. From the RENAMI (Registro di Nuovi Antiplaquetari in Patiėnti con Myocardial Infarction) registry undergoing PCI and treated with aspirin prasugrel or ticagrelor were stratified according to the length of DAPT, i.e. shorter than 12 months (D1), 12 months (D2) and longer than 12 months (D3). The groups were compared before and after propensity score matching. NACE (including all cause death, myocardial infarction and BARC 3-5 bleeding) was the primary end point, while MACE (including all cause death and MI) the secondary one. Simultaneously to NACE and MACE the co-secondary end-points, along with BARC 2-5 bleeding and stent thrombosis.

Results. A total of 4424 patients from the RENAMI registry with data about length of DAPT available were included in the model. 965 received DAPT less than 12 months, 2216 DAPT for 12 months, and 1223 DAPT longer than 12 months. After propensity score matching, 628 patients from each group were selected. At 20 months of follow-up, DAPT for 12 months and DAPT for longer than 12 months significantly reduced the risk of NACE compared to DAPT for less than 12 months (D1 11.8% vs. D2 6.7% vs. D3 7.2%, p<0.003), and of MACE (10% vs. 6.2% vs. 2.4%, p<0.001), mainly driven by a reduced risk of all cause death (7.8% vs. 1.3% vs. 1.6%, p<0.001), CV death (5.1% vs. 1.0% vs. 1.2%, p<0.001) and recurrent MI (8.3% vs. 5.2% vs. 3.5%, p=0.002) despite higher risk of BARC 2-5 bleeding (4.8% vs. 5.7% vs. 6.2%, p=0.04) and a trend towards BARC 3-5 bleedings (2.4% vs. 3.3% vs. 3.9%, p=0.06). In particular, DAPT beyond 12 months reduced the risk of MACE compared to DAPT for 12 months (5.2% vs. 3.5% vs. 2.8%, p<0.001), due mainly to a reduced risk of BARC 2-5 and 2-5 bleedings (3.3% vs. 3.9% and 5.7% vs. 6.2%, all p<0.05) resulting in a non-significant but higher risk of BARC 3-5 (2.1% vs. 1.2% vs. 0.7%, p=0.08).

Conclusion. In unselected real world ACS patients treated with PCI, the benefit of prolonged DAPT with prasugrel or ticagrelor beyond 12 months markedly reduced fatal and non-fatal ischemic events and offset the increased risk derived from bleedings.

C6
PRECISE-DAPT SCORE IN PATIENTS UNDERGOING PCI IN REAL WORLD PRACTICE
Andrea Gratta, Michele Bellamomi, Luca Felice Cerrito, Federico Marin, Luca Martan, Gabriele Pesarin, Flavio Luciano Ribichini
Divisione di Cardiologia, Dipartimento di Medicina, Università di Verona, Verona, Italy

Background. PRECISE-DAPT score has been suggested by recent ESC guidelines on DAPT as a useful tool to tailor DAPT duration in patients undergoing PCI. However, data about this score in real world populations are lacking.

Purpose. To evaluate DAPT duration in a real world population undergoing PCI according to the ESC focus update on DAPT.

Methods. In this single-centre retrospective observational study we calculated PRECISE-DAPT score (using baseline blood tests) in every patient undergoing PCI in our cath-lab from September 1st 2017 to January 31st 2018. Exclusion criteria were failure of PCI and angioplasty without stenting. In addition, we calculated HAS-BLED score in patients with indication to OAC.

Results. A total of 258 patients were enrolled in our centre during the study period. Thirty patients were excluded because of failed PCI (n=10) or because of angioplasty without stenting (n=20). Out of 228 patients included, 143 (62.7%) presented with ACS and 85 (37.3%) with stable angina. Mean age was 68±12 years and 80% were males. The mean PRECISE-DAPT score was 21±13 (including also patients with indication to OAC). 33.1% of patients undergoing PCI resulted at high risk of bleeding. If patients with indication to OAC and high HAS-BLED were included, a total of 86 patients (40.3%) resulted at high risk of bleeding and would have received a shorter period of DAPT. In 39 patients in these patients was 32±19 mm and in 47 (53.4%) cases PCI was performed in a crucial coronary segment (LM/proximal LAD) and/or with placement of 3 or more stents.

Conclusion. A strict application of the PRECISE-DAPT indications in patients undergoing PCI would result in one third of the population to be treated with a shorter duration of DAPT. Combining this data with the HAS-BLED score in patients with indication to OAC, more than 40% of this population would receive a shorter duration of therapy. At present, limited data are available in the literature about this matter. For this reason, a strict application of the ESC recommendations would drastically impact in the management of our patients in a real world setting. In our study more than the one third of the patients would have received a shorter period of DAPT, nevertheless 53.4% of them underwent a delicate PCI.

C7
REGISTRY OF NEW ANTIPLATELET THERAPY IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION (RENAI)
1Department of Cardiology, AOI Citta della Salute e della Scienza, Torino, Italy, 2Department of Cardiology, University Hospital Alvaro Cunqueiro, Vigo, Spain, 3Cardiology Department, University Hospital Virgen Antxoxa, Murcia, Spain, 4Department of Cardiology, University Hospital, Orbassano and Infermi Hospital, Rivoli, Italy, 5Catheterization Laboratory, Maggiore della Carità Hospital, Novara, Italy, 6Department of Cardiology, S.G. Bosco Hospital, Torino, Italy, 7Department of Cardiology, Faculty of Medicine, Assiut University, Assiut, Egypt, 8UO Cardiologia, Ospedale Valduce, Como, Italy, 9PoltBioMed Lab, Department of Mechanical and Aerospace Engineering, Politecnico di Torino, Torino, Italy, 10Department of Cardiology, University Hospital from Canarias, Tenerife, Spain, 11Department of Cardiology, University Hospital, Orbassano and Infermi Hospital, Rivoli, Italy, 12Department of Cardiology, Laboratory, Maggiore della Carità Hospital, Novara, Italy

Introduction. Limited data have been provided about difference between prasugrel and ticagrelor in real-life acute coronary syndrome (ACS) patients treated with PCI.

Methods. 4424 ACS patients undergoing PCI from REXy of New Antiplatelet therapy in patients with acute Myocardial Infarction (RENAI) were enrolled and discharged with dual antiplatelet therapy (DAPT) with prasugrel or ticagrelor. Long term NACE was the primary end-point, while MACEs the secondary ones, along with their single components.
Subgroup analysis for freedom from NACE and MACE were performed according to length of DAPT and to clinical presentation (STEMI-ACS) vs. (NSTEMI-ACS).

**Results.** 1699 were enrolled in the Prasugrel group and 2725 in the Ticagrelor group, resulting after propensity score matching in 1290 for each cohort. At 12 months, the incidence of NACE was lower in prasugrel patients (5.3% vs. 8.5%, p=0.0001), as that of MACE (6.05% vs. 8.1%, p=0.001), mainly driven by a reduction in recurrent MI (2.4% vs. 4.0%, p=0.029) and a lower rate of BARC 3-5 bleeding (1.5% vs. 2.9%, p=0.011). The benefit of prasugrel for NACE and MACE was confirmed for NSTE MI patients and for those discharged with a DAPT regimen of 12 months or less, while only a trend in reduction for of NACE and MACE was noted for STEMI or for those treated with longer DAPT.

**Conclusion.** Head-to-head comparison suggests better efficacy and safety of prasugrel versus ticagrelor used in combination with aspirin after NSTEMI, while not in STEMI patients. No differences were found for events occurring after 12 months.

**C9 PRASUGREL OR TICAGRELOR IN PATIENTS WITH ACUTE CORONARY SYNDROME AND DIABETES: A PROPENSITY-MATCHED SUBSTUDY OF RENAMI**

Maurizio Bertaina1, Federico Conrotto1, Sergio Raposeiras-Roubin2, Tim Kinnaird3, Albert Ariza-Sole4, Sergio Manzano-Fernández5, Maurizio Bertaina1, Federico Conrotto1, Sergio Raposeiras-Roubin2, Christian Templin5, Lazar Velicki1, Ioanna Xanthopoulou1, Enrico Cerrato1, Andrea Rognoni10, Giacomo Boccuzzi11, Pierluigi Omedè1, Nicola Castiglioni1, Michele Autelli1, Alberto Grosso1, Giorgio Quadri9, Fabio Dondero6, Fabrizio Acerbo7, Andrea Maggi9, Gianluca Angelelli9, Marco Ancona1, Francesco Moroni1, Paolo Del Sole1, Alessandra Larichia1, Matteo Pagnesi1, Antonio Mangieri1, Francesco Giannini1, Aldeide Chieffo1, Eustachio Agnoli1, Antonio Esposito1, Anna Palmisano1, Matteo Montorfano1, Antonio Colombo1, Azizem Latib1

1Emomdinamica e Cardiologia Interventistica, Ospedale San Raffaele, Milano, Italy, 2Ecocardiografia, Ospedale San Raffaele, Milano, Italy, 3Radiologia, Ospedale San Raffaele, Milano, Italy

Safety and efficacy of prasugrel and ticagrelor in patients with diabetes mellitus (DM) presenting with acute coronary syndrome (ACS) and treated with PCI remain to be assessed.

**Methods.** All DM patients admitted for ACS and enrolled the REGISTRY of Patients with Diabetes Mellitus (RENAMI) were compared before and after propensity score matching. Net adverse cardiovascular events (NACE; composite of death, myocardial infarction [MI] and BARC 3-5 bleeds), and major adverse cardiovascular events (MACE; composite of death and MI), were the co-primary endpoints. Single components of primary endpoints were secondary ones.

**Results.** Among 4424 patients enrolled in the RENAMI registry, 462 and 862 diabetes treated with prasugrel and ticagrelor respectively, were considered. After propensity score matching, 386 patients from each group were selected. At 12±5 months, MACE were similar in the prasugrel and ticagrelor group (4.9% vs. 2.8%, p=0.14), while a non-significant trend against prasugrel in terms of NACE emerged (6.5% vs. 3.6%, p=0.07). Ticagrelor was associated with lower risk of death compared to prasugrel (2.8% vs. 0.8%, p=0.031), with less BARC 2-5 bleeding (6.0% vs. 2.6%, p=0.02) and only a trend for a reduction of BARC 3-5 bleeding (2.3% vs. 0.8%, p=0.08). There were no significant differences in MI recurrence and stent thrombosis.

**Conclusion.** Diabetic patients admitted for ACS seem to benefit equally in terms of MACE from ticagrelor or prasugrel use. Ticagrelor was associated with a trend for reduced NACE and a significant reduction in all cause death and bleedings, with differences in recurrent ischemic events. Large randomized comparison between these two drugs are needed for solid conclusion.

**Aortic valve disease**

**C9 IMPACT OF ASCENDING AORTA DILATATION ON OUTCOME AFTER TAVI**

Marco Ancona1, Francesco Moroni1, Paolo Del Sole1, Alessandra Larichia1, Matteo Pagnesi1, Antonio Mangieri1, Francesco Giannini1, Aldeide Chieffo1, Eustachio Agnoli1, Antonio Esposito1, Anna Palmisano1, Matteo Montorfano1, Antonio Colombo1, Azizem Latib1

1Emomdinamica e Cardiologia Interventistica, Ospedale San Raffaele, Milano, Italy, 2Ecocardiografia, Ospedale San Raffaele, Milano, Italy, 3Radiologia, Ospedale San Raffaele, Milano, Italy

The incidence of AAD in our population was 10.3%. AAD does not appear to impact on periprocedural outcome (moderate-to-severe paravalvular leak, procedural success, peri-procedural death, permanent pace-maker implantation). According to Kaplan-Meier analysis, there was no difference in freedom from cardiovascular mortality at 2 years between patients with and without AAD (95.0% vs. 91.6%, p=0.42).

**Conclusion.** The incidence of AAD in our population was 10.3%. AAD does not appear to impact on acute and midterm outcome after TAVI. However, caution must be paid: there were few patients presenting moderate (diameter ≥45 mm) or severe (diameter ≥50 mm) AAD; a theoretical increased risk of aortic aneurysm is often performed, in order to reduce the risk of rupture. The aim of this is study is to evaluate the impact of AAD on acute and midterm outcome of patients receiving only aortic stenosis treatment through TAVI procedure.
C10 INTRAVASCULAR LITHOTRIPSY TO FACILITATE TRANSFEMORAL TAVI IN SEVERE OBSTRUCTIVE ILIAC DISEASE. PRELIMINARY MULTICENTER EXPERIENCE
Francesca Ristelli1, Marcello Ravani2, Francesco Meucci1, Miroslava Stolcova1, Gennaro Sardella1, Francesco Bedogni2, Sergio Bertì2, Carlo Di Mario3
1 Structural Interventional Cardiology, Careggi University Hospital, Florence, Italy, 2Fondazione Toscana Gabriele Monasterio, Ospedale del Cuore G. Pascainucri, Massa, Italy, 3Department of Cardiovascular, Respiratory, Nephrology, Anesthesiology and Geriatric Sciences, Sapienza University of Rome, Policlinico Umberto I, Italy, 4 Structural Heart DiseaseInterventions Unit, Department of Cardiology, IRCCS Policlinico San Donato, Milan, Italy

Background. Transfemoral access for TAVI is the preferred route for valve implantation as the results from large trials indicate similar or better outcomes than the surgical AVR in moderate, high risk patients. Unfortunately, elderly TAVI candidates often have severe calcific peripheral vascular disease, precluding the delivery of large transfemoral valves.

Aim. To assess safety and efficacy of Intravascular Lithotripsy (IVL) (Shockwave Medical, Fremont, CA) to dilate calcific iliac stenoses during transfemoral TAVI.

Methods. Baseline demographic data, target lesion (TL) characteristics, inflation and IVL treatment, TAVI device and procedural outcomes were prospectively entered into a registry collecting all patients treated in 4 Italian centers.

Results. Between January 2018 and June 2018, 13 patients were enrolled in the registry (mean age 83.5±3.7 years; 6 males), all undergoing TAVI due to severe aortic stenosis. Femoral access was obtained in all but two cases percutaneously with pre-implantation of two ProGildes or one Prostar. Two patients were elective-instrumented after surgical endarterectomy of a calcific cast in common femoral artery. The TL location was in all cases the common and/or external iliac artery (left in 46% of the cases). Mean reference vessel diameter was 8.9±1.8 mm with the TL minimum diameter of 4.3±1.1 mm inducing a stenosis of 55.6±20.5%. Mean length of 24.7±13.3 mm and an arc of calcium of 281±96 degrees. In 1 case with a subocclusive stenosis the lesion was pre-dilated with a 4.0 mm coronary balloon via a long brachial sheath. In all other cases, 60 mm long peripheral IVL catheters could be easily advanced over a 0.014 in wire. Balloon diameter was 7 mm in the majority of cases; in 2 cases a 6.5 mm balloon and in 3 cases a 6.0 mm was preferred due to a small diameter of the external iliac. Only in one case a second treatment with a 7.0 mm balloon was required for advancing the valve delivery system after initial treatment with a 5.0 mm balloon. After IVL the 14 or 16 Fr delivery system of the Evolut R (81%) or EvolutPRO (15%) self-expanding valves and the 14 stretchable E-sheath of 23 or 26 mm Sapient 3 valve (24%) could cross the TL and the valve was successfully implanted across the aortic anulus. After the procedure no TL perforation or severe dissection or residual stenosis was present, with no need for iliac balloon dilatation or stent. Access puncture site could be easily closed with the transcatheter suturets or elective surgery. Because of residual generalized iliac dilation and reversal of femoropopliteal flow in one case a covered stent was implanted in cross-over to the common femoral.

Conclusions. Iliac artery lithotripsy with a Shockwave Peripheral IVL catheter enabled transfemoral TAVI in patients with several iliac stenoses normally considered as absolute contraindications for transfemoral TAVI.

C11 PREDICTORS AND SAFETY OF NEXT-DAY DISCHARGE AFTER MINIMALIST TRANSFEMORAL AORTIC VALVE IMPLANTATION
Andrea Picci, Giuliano Costa
Cardiologia, Ospedale Policlinico G. Rodolico, CAST, Catania, Italy

Aim. With the exponential increase of transcatheter aortic valve implantation (TAVI) and the simplification of this procedure, currently there is a trend to shorten the hospitalization time after TAVI. The aim of this study is to assess predictors and safety of next-day discharge (NDD) after transfemoral TAVI.

Methods and results. This is a single-center, retrospective analysis obtained from a prospective local TAVI registry. From June 2007 to March 2016, 1212 patients underwent transfemoral TAVI in our institution. Among these procedures (96.9%) were performed using a minimally invasive approach, under local anaesthesia with conscious sedation and using only an angiographic guidance. Among these, 134 patients (11%) with a mean age of 83±6 years and a STS score of 8.3±1.2, were discharged after 24 hours after the procedure. Baseline predictors of next day-discharge were prior PM implantation (odds ratio [OR] 2:18; confidence interval [CI] 1.33-5.33) and NYHA class (OR 0.69; CI 0.50-0.93). After TAVI new onset atrial fibrillation (OR 0.30; CI 0.11-0.85) and major or subclinical bleeding disorders (OR 0.09; CI 0.03-0.28) were negative predictors of NDD. Patients were treated using a balloon-expandable (29.5%) or a self-expandable prosthesis (70.5%). During hospitalization, no major vascular complication, life-threatening or major bleeding, strokes or acute kidney injury were reported. Two patients (1.6%) underwent pacemaker implantation, due to complete atrio-ventricular block immediately after procedure. At 30-day, 1 patient with liver cirrhosis died 13 days after the procedure and 1 patient developed high-degree AV block requiring pacemaker implantation 4 days after discharge. No other patients were re-hospitalized within 30 days and the vast majority (94%) of them were in NYHA class I or II.

Conclusions. Next-day discharge after minimlistic, transfemoral TAVI is safe in patients without procedural complications. Factors predicting NDD include lower NYHA class, prior PM implantation, no major or life-threatening bleedings and absence of new onset of atrial fibrillation after TAVI.

C12 THE COST-EFFECTIVENESS OF TRANSCATHETER AORTIC VALVE IMPLANTATION: THE ITALIAN NATIONAL HEALTH SYSTEM PERSPECTIVE
Valentina Lorenzon2, Giuliana Barbieri2, Giuseppe Turchetti1
1 Institute of Management, Scuola Superiore Sant’Anna, Pisa, Italy, 2 Edwards Lifesience Italia SpA, Milan, Italy

Objectives. To assess the cost-effectiveness (CE) of transcatheter aortic valve implantation (TAVI) considering the perspective of the Italian National Health System (INHS).

Methods. A Markov model with 1-month cycle length and comprising eight different health-states defined by New York Heart Association functional classes (NYHA I-IV) with and without stroke plus death was used to estimate the CE of TAVI versus surgical aortic valve replacement for intermediate- and high-risk patients, and versus medical treatment for inoperable from the INHS perspective, considering both 5- and 15-year time horizons. Patients transitioned between health-states and underwent medical intervention, rehabilitation, economic procedural complications and follow-up events according to published efficacy data (and extrapolation from them). Total direct costs (in Euro) estimated from national tariff and life-years-gained (LYG) were derived in each risk-group to calculate incremental cost-effectiveness ratio (ICER) between treatments. All outcomes and costs were discounted at 3% per annum. One-way (OWSA) and probabilistic (PSA) sensitivity analyses were performed to assess robustness of results.

Results. Over 5-years, TAVI implied incremental costs and also additional LYG with the ICER being about €24 000/LYG, €20 000/LYG and €6000/LYG respectively for intermediate-, high-risk and inoperable patients due to both incremental costs and incremental LYG. When considering a 5-year time-horizon ICERs were about €8000/LYG, €12 000/LYG and €6000/LYG respectively for intermediate-, high-risk and inoperable patients. OWSA and PSA suggested that results were consistent to variation of model parameters in almost all risk groups, with mortality being the most relevant driver in all the analyses.

Conclusions. TAVI would be considered cost-effective at frequently cited willingness to pay thresholds in Europe; further studies may help shading light about CE of TAVI in real-life scenarios.

C13 INCIDENCE, PREDICTORS AND CEREBROVASCULAR CONSEQUENCES OF LEAFLET THROMBOSIS AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION: A SYSTEMATIC REVIEW AND META-ANALYSIS
Andrea Saglietto1, Martina Cordese1, Stefano Salizzoni2, Fabrizio D’Ascenzo3, Maurizio D’Amico1
1Institute of Management, Scuola Superiore Sant’Anna, Pisa, Italy, 2Divisione di Cardiologia, Dipartimento di Scienze Mediche, Città della Salute e della Scienza, Torino, Italy, 3Divisione di Cardiacochirurgia, Dipartimento di Scienze Chirurgiche, Città della Salute e della Scienza, Torino, Italy

Introduction. Incidence, impact of subsequent cerebrovascular events and clinical or procedural predictors of leaflet thrombosis (LT) in patients undergoing transcatheter aortic valve implantation (TAVI) remain to be defined.

Methods. MEDLINE/PubMed was systematically screened for studies reporting data on LT in TAVI patients. LT incidence (both clinical and subclinical, that is detected with computed tomography - CT) was the primary endpoint of the study. Predictors of LT evaluated at multivariate analysis despite lack of impact on stroke were the secondary ones.

Results. Fifteen studies encompassing 9133 patients evaluating incidence of LT were included. Pooled incidence of LT was 0.37 events per 100 person-month (0.17-0.62, I²=97%). Pooled incidence of subclinical LT was 1.99 events per 100 person-months (95% CI 0.69-3.83, I²=95%). Clinical LT less frequent (0.04 events per 100 person-months, 95% CI 0.00-0.19, I²=93%) LT increased risk of stroke (OR 6.99, 2.3-21.29), and was more frequent in patients with valve of 28 mm of

Structural intervention 2
OUTCOME PREDICTION AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI): ANALYSIS AND COMPARISON OF PREDICTIVE ACCURACY OF SURGICAL AND TAVI-TOILED MODELS

Anna Maria Ioppolo1, Federico De Marco2, Francesco Della Rosa2, Nedy Brambilla2, Mauro Agnifili2, Luca Testa2, Francesco Bedogni2
1OUC Cardiologia, AOUC Policlinico Gaetano Martino, Messina, Italy, 2Cardiologia Ospedaliera, UTIC e Cardiointerventi, IRCCS Policlinico San Donato, San Donato Milanese, Italy

Background. Transcatheter aortic valve implantation (TAVI) is now a well-established technique in patients with severe aortic stenosis who are at high or intermediate risk for surgical aortic valve replacement (AVR). Risk score is important tools integrated into the decision-making process of heart team in order to choose the most appropriate strategy for these patients though the usefulness of these scores to predict mortality and adverse events after TAVI is still debated. Indeed, after a successful procedure, prognosis may be determined by comorbidities and conditions not included in these models. Thus, appropriate tools to predict short and long-term outcome following TAVI is currently not available. The aim of this study was to evaluate and compare the performance of the STS (Society of Thoracic Surgeons score), ACEF I (age, creatinine, ejection fraction) and II and OBSERVANT (Observational Study Of Appropriateness, Efficacy And Effectiveness of AVR-TAVR Procedures For The Treatment Of Severe Symptomatic Aortic Stenosis) scores as predictors of 30-day mortality and adverse events in patients undergoing TAVI.

Methods. 504 consecutive patients (54.8% female, mean age 82.2±7.9 years) who underwent TAVI between July 2015 to February 2018 in our department were included in the study. Baseline risk was calculated according to STS, ACEF I, ACEF II and OBSERVANT scores. Thirty-day follow-up was performed and available in each patient. Primary endpoint of the study was 30-day mortality. Secondary endpoint clusters several adverse events (death, Ictus/TIA, bleeding, renal impairment, major vascular complications) defined according to the Valve Academic Research Consortium Consensus on Event Definition, occurred during the first month after procedure. In order to define the quality of discrimination, the area under the receiver operating characteristic (ROC) curve was calculated. Brier score and Hosmer-Lemeshow was used respectively for calibration and global accuracy of models.

Table 1. Baseline characteristics of the study population.

<table>
<thead>
<tr>
<th>Overall</th>
<th>Events (n=63)</th>
<th>No Events (n=441)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>82.2±7.9</td>
<td>82.8±8.6</td>
</tr>
<tr>
<td>(84.0, 79.8-87.1)</td>
<td>(83.0, 79.8-88.0)</td>
<td>(84.0, 79.8-87.0)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>276 (54.8)</td>
<td>38 (60.3)</td>
</tr>
<tr>
<td>Male</td>
<td>228 (45.2)</td>
<td>25 (39.7)</td>
</tr>
<tr>
<td>NYHA class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>3 (0.6)</td>
<td>2 (3.2)</td>
</tr>
<tr>
<td>II</td>
<td>50 (9.9)</td>
<td>6 (9.5)</td>
</tr>
<tr>
<td>III</td>
<td>437 (86.9)</td>
<td>51 (81.0)</td>
</tr>
<tr>
<td>IV</td>
<td>14 (2.8)</td>
<td>4 (6.4)</td>
</tr>
<tr>
<td>DM</td>
<td>142 (28.2)</td>
<td>23 (36.5)</td>
</tr>
<tr>
<td>Prior valve replacement</td>
<td>40 (8.0)</td>
<td>6 (9.5)</td>
</tr>
<tr>
<td>Every event day</td>
<td>63 (12.5)</td>
<td>63 (100)</td>
</tr>
<tr>
<td>after TAVI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke/TIA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>7 (1.4)</td>
<td>7 (11.3)</td>
</tr>
<tr>
<td>Renal impairment</td>
<td>20 (4.0)</td>
<td>20 (31.8)</td>
</tr>
<tr>
<td>Death</td>
<td>19 (3.8)</td>
<td>19 (30.2)</td>
</tr>
<tr>
<td>Major vascular complications</td>
<td>10 (2.0)</td>
<td>10 (15.9)</td>
</tr>
<tr>
<td>HD</td>
<td>12.0±1.9</td>
<td>11.4±1.5</td>
</tr>
<tr>
<td>(12.1, 10.7-13.3)</td>
<td>(11.3, 10.2-12.8)</td>
<td>(12.2, 10.8-13.3)</td>
</tr>
<tr>
<td>HTC</td>
<td>36.5±5.1</td>
<td>35.0±4.2</td>
</tr>
<tr>
<td>(36.6, 31.1-39.9)</td>
<td>(34.9, 31.8-38.3)</td>
<td>(36.8, 35.3-40.6)</td>
</tr>
<tr>
<td>Pt</td>
<td>2056.3±797.0</td>
<td>1906.5±7292.3</td>
</tr>
<tr>
<td>(20000, 15600-25000)</td>
<td>(18500, 150000)</td>
<td>(158000-25000)</td>
</tr>
<tr>
<td>ALT</td>
<td>17.2±16.2</td>
<td>20.4±12.0</td>
</tr>
<tr>
<td>(13.0, 10.1-18.0)</td>
<td>(14.0, 10.0-20.0)</td>
<td>(13.0, 10.0-18.0)</td>
</tr>
<tr>
<td>AST</td>
<td>20.3±13.6</td>
<td>24.1±23.1</td>
</tr>
<tr>
<td>(18.5, 10.0-22.0)</td>
<td>(18.0, 13.5-25.0)</td>
<td>(18.0, 15.0-22.0)</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>0.60±0.48</td>
<td>0.62±0.37</td>
</tr>
<tr>
<td>(0.49, 0.35-0.71)</td>
<td>(0.51, 0.37-0.76)</td>
<td>(0.48, 0.35-0.69)</td>
</tr>
<tr>
<td>Creatinine pre-TAVI</td>
<td>1.36±0.97</td>
<td>1.80±1.55</td>
</tr>
<tr>
<td>(1.15, 0.88-1.46)</td>
<td>(1.37, 0.86-1.73)</td>
<td>(1.13, 0.88-1.42)</td>
</tr>
<tr>
<td>Creatinine clearance pre-TAVI</td>
<td>53.8±20.7</td>
<td>46.2±23.8</td>
</tr>
<tr>
<td>(54.0, 38.0-69.0)</td>
<td>(42.0, 31.0-64.0)</td>
<td>(55.0, 40.0-70.0)</td>
</tr>
<tr>
<td>STS score</td>
<td>5.77±3.97</td>
<td>7.17±4.87</td>
</tr>
<tr>
<td>(4.60, 3.10-7.30)</td>
<td>(6.20, 3.80-9.40)</td>
<td>(4.50, 3.00-7.00)</td>
</tr>
<tr>
<td>ACEF</td>
<td>4.30±7.90</td>
<td>5.0±10.51</td>
</tr>
<tr>
<td>(2.95, 3.44-9.92)</td>
<td>(3.14, 2.37-7.07)</td>
<td>(2.94, 2.24-9.68)</td>
</tr>
<tr>
<td>ACEF II</td>
<td>5.32±6.36</td>
<td>6.80±7.42</td>
</tr>
<tr>
<td>(2.89, 2.48-7.33)</td>
<td>(3.94, 2.56-8.38)</td>
<td>(2.78, 2.20-5.39)</td>
</tr>
<tr>
<td>OBS score</td>
<td>4.51±13.27</td>
<td>3.75±6.13</td>
</tr>
<tr>
<td>(3.23, 1.80-9.47)</td>
<td>(4.31, 3.22-7.59)</td>
<td>(3.23, 1.80-4.31)</td>
</tr>
</tbody>
</table>

Data are presented as: mean ± standard deviation (median, interquartile range), or n (percentage).
Results. Overall, the 30-day mortality rate was 3.8% (n=19), and the cumulative 30-day adverse events rate was 12.5% (n=63). In receiver operating characteristics analysis, neither of the investigated scores could accurately predict the 30-day mortality or adverse events. Area under the receiver-operating curve (AUC) of the scores was as follows: STS AUC 0.70 for 30-day mortality and 0.62 for adverse events; ACEF AUC 0.51 for 30-day mortality and 0.55 for adverse event; ACEF II AUC 0.60 for 30-day mortality and 0.65 for adverse events. The differences between curves were not significant except for STS vs. ACEF for 30-day mortality prediction (ROC Contrast Estimation 0.003). The Hosmer-Lemeshow test and Brier score indicated acceptable calibration and global accuracy for all scores. Furthermore, we estimate that for our population the cut off for reaching the best specificity and sensitivity was different from the standard value proposed as references. Notably our cut off for ACEF, ACEF II, OBSERVANT and STS were respectively 3.5, 6.1, 3.2 and 5.1.

Conclusions. All the investigated risk scales proved to be inaccurate in predicting 30-day mortality and adverse event in patients referred to TAVI. These results underscore the primary role of heart team in decision making process for selection of patients suitable for TAVI. Furthermore, this study highlights the need for a new TAVI tailored risk model that might incorporate comorbidities that affect outcome in percutaneous procedure such as frailty syndrome.

Methods. We performed >200 TAVI procedures with a TF, transapical and trans-subclavian approach. We analyzed 150 consecutive patients undergoing TAVI TF and we compared two vascular closure systems: the Prostar XL vs Proglide system (PGs) (Abbott Vascular, Santa Clara, CA, USA). Both of these closure systems require the ‘pre-closing’ before advancing the larger introducers (16-20F), to then obtain vascular haemostasis once the procedure is completed. Contrary to the recommendations, we applied a different implantation modality of the PGs through the systematic ‘outsourcing’ of the suture threads pre-inserted in the femoral access site.

Results. In the PGs group in comparison to the Prostar group we have documented the reduction of VARG 2 major and minor complications (respectively, 0. vs. 3.2% and 10.3 vs. 14.5%), acute closure device failure (2.3 vs. 3.2%), major bleeding (0 vs. 3.2%) and vascular perforation (1.1 vs. 4.8%) without achieving statistical significance. Femoral pseudoaneurysm were significantly reduced (4.6 vs. 14.5%, p<0.03).

Conclusion. We propose the systematic use of ‘externalizing’ the suture threads of the PG system during TAVI procedures via TF as this procedure has proved to be effective, safe and associated with a reduction of major vascular complications. To our knowledge, this is the first consecutive series of elderly patients via TF who underwent access management via externalized PGs.

C16
ATRIAL SEPTAL DEFECTS CLOSURE IN THE ELDERLY: EXPERIENCE AND LONG-TERM FOLLOW-UP OF A HIGH VOLUME CENTRE
Mario Giordano1, Gianpiero Gaio1, Giuseppe Santoro1, Michele D’Alto1, Berardo Sarubbi1, Maurizio Cappelli Bigazzi2, Paolo Golino3, Maria Giovanna Russo1
1Monaldi Hospital, Naples, Italy, 2Ospedale G. Pasquinucci, Massa, Italy

Objectives. Ostium secundum atrial septal defects (ASDs) are a common congenital heart disease. An early diagnosis allows ASD closure before the development of pulmonary hypertension. In some cases, these defects are not diagnosed in childhood, but only at the time of onset of symptoms and signs when pulmonary artery pressure increases. Elderly patients (>60 years) are a complex subgroup to treat with several complications and hemodynamic limitations.

Methods. From March 2000 to April 2018, 1075 patients underwent ASD closure at our institution. 62 were elderly patients (>60 years). Right heart catheterization was performed to evaluate pulmonary artery pressures and to address the closure. Every patient was followed up through electrocardiographic and echocardiographic evaluation.

Results. Among these elderly patients, 23 (37%) had pulmonary hypertension (mean pulmonary artery pressure >25 mmHg) and 14 (22.5%) had a pulmonary wedge pressure ≥15 mmHg (but wedge pressure did not increase significantly during the occlusion test). 21 patients (33.8%) showed atrial fibrillation on admission. Percutaneous closure was effective in all patients and no major complications were recorded. At a mean follow-up of 8.4 years, no mortality or morbidity related to the procedure were recorded and no patients developed new onset arrhythmias.

Conclusion. ASD closure in elderly patients is challenging for interventional cardiology above all because of the high pulmonary artery pressures. Right heart catheterization (with an occlusion test for patients with high pulmonary wedge pressure) can be helpful to guide decision making of interventional cardiology. No mortality or morbidity related to the procedure occurred during follow-up.

Mitril intervention

C17
THIRTY-DAY AND ONE-YEAR OUTCOME OF PATIENTS WITH ESTIMATED LOW OR INTERMEDIATE SURGICAL RISK WHO UNDERTAKE PERCUTANEOUS EDGE-TO-EDGE MITRAL VALVE REPAIR WITH THE MITRALCLIP SYSTEM
Antonio Popolo Rubbio1, Carmelo Grasso2, Sergio Buccheri2, Maria Elena Di Salvo1, Salvatore Scandura1, Sarah Mangiolo1, Silvia Farruggio1, Giuseppe Castania1, Jessica De Santis1, Giordana Finocchiaro1, Anna Caggelli1, Gessica Motta1, Piera Caprannizzo1, Davide Capodanno1, Corrado Tamburini1, Divisione di Cardiologia, Ospedale Polico litico Vittorio Emanuele, CAST, Catania, Italy, 1Fondazione Mediterranea G.B. Morgagni, Catania, Italy

Background. The MitralClip system has emerged as an established treatment in high-risk patients with moderate-to-severe mitral regurgitation (MR) who are deemed inoperable. Outcomes among patients with estimated low- or intermediate-risk according to the Society of Thoracic Surgeons-Predicted Risk of Mortality (STS-PROM) remain to be determined.

Objective. We sought to evaluate the clinical early (30-day) and mid-term (one-year) outcome among patients with estimated low- or intermediate risk that underwent MitraClip procedure in a single center.
C18
PERCUTANEOUS REPAIR OF FUNCTIONAL MITRAL REGURGITATION IN HEART FAILURE PATIENTS: A META-ANALYSIS OF 23 STUDIES ON MITRALCLIP IMPLANTATION
Luca Esposito1, Cesare Baldi1, Angelo Silverio1, Marco Di Maio2, Michele Roberto Di Muro1, Generoso Mastrogiovanni1, Rodolfo Citro1, Roberta De Rosa1, Costantina Prota1, Ilaria Radano1, Michele Debenedictis1, Federico Piscione1, Gennaro Galasso1
1AOU San Giovanni di Dio e Ruggi d’Aragona, Salerno, Italy, 2Università della Campania Luigi Vanvitelli, Ospedale Monaldi, AORN Ospedali dei Colli, Napoli, Italy

Background: A gap of evidence on the clinical performance of MitraClip (MC) in functional mitral regurgitation (MR) and on the prognostic outcomes after MC implantation is still evident in the current practice.

Purpose: To investigate short- and long-term survival, clinical status and echocardiographic findings of heart failure patients with severe functional MR undergoing MC treatment and to explore the prognostic impact of their baseline characteristics on clinical and functional outcomes.

Methods: Randomized and observational studies including patients with functional MR undergoing MC were collected in a meta-analysis finalized to evaluate the overall survival in-hospital and at 1, 6, 12 and 24 months, the New York Heart Association (NYHA) class and the echocardiographic changes after treatment. The baseline features associated to overall mortality and the to the echocardiographic changes at follow-up were also investigated in order to identify predictors of outcome. Results: After a comprehensive MEDLINE, COCHRANE, ISI Web of Sciences, and SCOPUS search, 23 studies enrolling 3253 patients were included in the analysis. The overall death rate was 2.31% (95% CI 0.14-4.48) in-hospital, 5.37% (95% CI 2.90-7.84) at 1 month, 11.87 at 6 months (95% CI 8.60-15.30), 18.47 (95% CI 15.59-21.33) at 1 year and 31.08% (95% CI 29.04-33.77) at 2 years. MR grade 1+ or 2+ was observed in 92.76% (95% CI 90.46-95.07) at discharge and in 83.36% (95% CI 79.22-87.50) at a mean follow-up of 11.7±3.5 months. The 76.73% (95% CI 71.57-81.69) of patients were in NYHA class I or II at mean follow-up of 11.5±5.0 months. A significant reduction of left ventricular (LV) volumes (end-diastolic: -21.96±9.4 mL, p<0.0001; end-systolic: -1.32±7.4 mL, p=0.0035) and systolic pulmonary arterial pressures (7.85±1.0 mmHg, p=0.0001) associated with a significant increase of LV ejection fraction (2.40±1.12, p=0.0315) were observed at a median follow-up of 12±4.8 months. Meta-regression analysis showed a statistically significant negative effect of atrial fibrillation (AF) on 1-year survival (B=0.18±0.06, p=0.0047) and on the reduction of LV end-diastolic (B=-1.05±0.47, p=0.0248) and end-systolic volumes (B=-2.60±0.53, p=0.0032) was observed.

Conclusions. In patients with heart failure and severe functional MR, MC treatment is safe and results in a durable MR reduction associated with a significant clinical and echocardiographic improvement. Owing to the negative prognostic impact on LV reverse remodeling and on 1-year survival, AF should be carefully considered in the selection of patients candidate to MC and during the follow-up.

C19
PERCUTANEOUS REPAIR OF FUNCTIONAL MITRAL REGURGITATION VS. OMT IN CHRONIC ADVANCED HEART FAILURE PATIENTS: DATA FROM A REAL LIFE EXPERIENCE: INSIGHT FROM THE FAILS-II MULTICENTRE REGISTRY
Francesca Giordana, Alessandra Rabajoli, Simone Freo, Stefano Pidelio, Antonio Montefusco, Claudio Moretti, Mauro Rinaldi, Maurizio D’Amico
SC Cardiologia, AOU Città della Salute e della Scienza, Torino, Italy

Background: The benefit of percutaneous mitral valve repair (PMVR) in patients with advanced heart failure (AHF) and severe symptomatic functional mitral regurgitation (FMR) is unclear.

Methods. Data of patients with AHF and FMR evaluated in our center were collected. Patients that underwent MitraClip implantation (group 1) were compared to those refused for anatomical reasons, and thus lefted in optimal medical therapy (OMT). The primary endpoint was a composite of cardiovascular death, left ventricular assist device implantation and hospitalization at follow-up. The secondary one was the improvement of NYHA class at follow-up.

Results. Sixty-eight (70.8%) patients underwent MitraClip implantation (group 1), while 28 (29.2%) were followed in OMT (group 2). Mean age was 68 years, Seattle Heart Failure Model estimated 1-year mortality 39.4%, 18 (18.8%) patients were in NYHA class IV, the others in class NYHA III. Eleven (11.5%) patients were dependent from inotropes. No between groups difference in baseline characteristics were found, except to left ventricular ejection fraction (LVEF) (27.5 vs. 32.8%, p=0.04) and NT-proBNP (6932 vs. 19986, p<0.01). At 500 days of follow-up, a significant between-group difference in the primary endpoint was found (41.6% vs. 61.6%, p=0.01). If the primary endpoint was corrected by LEVEF and NT-proBNP, group 1 continued to show a lower risk, although not statically significant, CV death, LVAD implantation and/or hospitalization compared to group 2 (41% vs. 63%, p=0.06). Excluding from group 2 patients that underwent surgical repair/replacement of the mitral valve, a significant improvement of the NYHA class was observed in MitraClip patients (64.5% vs. 30.5%, p=0.01).

Conclusions. MitraClip procedure in advance heart failure reduces the cardiovascular death, left ventricular assist device implantation and hospitalization compared to optimal medical therapy. Moreover it is associated with an improvement of clinical profile in this selected, high-risk population.

C20
SYNTAX II SCORE VS. SYNTAX SCORE TO PREDICT LONG-TERM PATIENT OUTCOME AFTER LEFT MAIN STENTING WITH SECOND-GENERATION DES: INSIGHT FROM THE FAILS-II MULTICENTRE REGISTRY
Umberto Barbero1, Enrico Cerrato2, Giorgio Quadri3, Rahim Kanji4, Nicola Ryan5, Mario Iannaccone6, Sebastiano Gilli7, Giuseppe Biondi Zoccai8, Claudio Moretti9, Maurizio D’Amico9, Ferdinando Varbella9, Fabio Piazza9, Michele Debenedictis9, Baldassarre Doronzoro9, Antonio Colombo9, Fabrizio D’Ascenzo9, Javier Escaned9
1Cardiologia, Ospedale “Ss. Annunziata” Hospital, Savigliano, Italy, 2Cardiologia, Ospedale degli Infermi, Rivoli, Italy, 3Interventional Cardiology, Royal Free Hospital, London, UK, 4Hôpital Clinico San Carlos, Cardiologia, Madrid, Spain, 5IRCCS Cardiologico Monzino, Milano, Italy, 6Sapienza University of Rome, Department of AngioCardioNeurology, IRCCS Neuromed, Roma, Italy, 7Cardiologia, Città della Salute e della Scienza, Torino, Italy, 8Ospedale San Raffaele, Milano, Italy

Aims. The aim of this study was to evaluate the capacity of the SYNTAX Score-II (SS-II) to predict long-term mortality in patients undergoing left
main percutaneous coronary intervention (LM-PCI) treated with second-generation drug-eluting stents (DES).

**Methods and results:** SYNTAX score (SS) and SYNTAX score II (SS-II) were calculated in 654 patients with de novo left main coronary artery disease (LM-PCI included in FAILS-2 multicenter registry (in Late Main Study With 2nd Generation Stents-Cardiacgill Group Study, III), followed up to 10 years. Patients were divided into tertiles according to the SS-II: low SS-II (SS-II ≤33, n=288), intermediate SS-II (SS-II between 33 and 100), and high SS-II (SS-II >100, n=275). The survival curves were estimated by the Kaplan-Meier method. Cox proportional hazard regression analyses were performed to evaluate associations between the SS-II and long-term mortality or major adverse cardiovascular events (MACE). Area under the receiver operator curve (AUC) and net reclassification improvement (NRI) were assessed comparing with SS-II. Mean SS-II was 39.2±5.5. At a mean follow-up of 5.2±3.6 years, mortality rates were 4%, 7.4%, and 17.4%, respectively among patients in the tertiles with low, intermediate, and high SS-II score showed a more accurate prediction of mortality than SS score (AUC = 0.73, 95% CI 0.67-0.79 vs. AUC = 0.55, 95% CI 0.48-0.63, p<0.001). For all-cause mortality, the NRI was 71% (p<0.001).

**Conclusion.** In real-world high-risk patients with LM-PCI treated with a second-generation DES, the SS-II demonstrated a superior predictability compared with the SS. Besides, other factors not included in the SS-II like ACS at presentation and T2DM has to be considered as an additive marker of poor outcome.

---

**C21 OUTCOMES OF PERCUTANEOUS CORONARY INTERVENTIONS IN CARDIAC TRANSPLANTATION PATIENTS: A META-ANALYSIS OF 21 STUDIES WITH 1031 PATIENTS**

Paolo Vadaiali1, Fabrizio D’Ascanzo2, Sara Hammad1, Pietruigi Omedè1, Antonio Montefusco1, Cristina Barbero1, Federico Conrotto1, Claudio Moretti1, Walter Grosso Marra1, Stefano Pidello1, Mauro Rinaldi1, Massimo Boffini1, Jonathan Tobias1, Raymond Benza2, Giuseppe Tarantini2, Maurizio D’Amico2

1Division of Cardiology, Department of Internal Medicine, Città della salute e della Scienza, Torino, Italy, 2Division of Cardiology, UCLA Medical Center, Los Angeles, USA.

**Introduction.** Outcomes of patients with orthotopic heart transplantation (OHT) undergoing percutaneous coronary intervention (PCI) remain to be defined, especially according to kind of stent and to use of intracoronary imaging.

**Methods.** All studies evaluating the impact of PCI on OHT patients were included. MACE, a composite and mutually exclusive end point of all cause death, target lesion revascularization (TLR) and stent thrombosis (ST) was the primary end point, while its components along with cardiovascular death were the secondary ones Meta-regression analysis was used to assess the impact of percutaneous coronary stent medications (everolimus and sirolimus), of IVUS, and of anti-reject drugs on TLR.

**Results.** 21 studies with 1031 patients were included, with a median time from OHT to 1.7 years (0.8-6.7). Elective angiographic control was the most frequent indication (68% of patients); multivessel disease was reported in 38.8% (28.9-39.0), IVUS was used in 57% (29-80) and drug eluting stents (DES) were implanted in 62.2% (53-510). After 1.3 years, MACE occurred in 38.4% of patients (20.52-71.98), mainly driven by TLR (11.76% [5.57-17.98] for patients with DES and 34.23% [2.21-46.25] for BMS), while ST occurred in 2.03% (0.57-20.3). At meta-regression, IVUS reduced TLR (-0.035-0.045-0.021), while the type of anti-proliferative drug coating the stent or the adjunctive immunosuppressant therapy did not impact subsequent revascularization.

**Conclusion.** Patients with OHT undergoing PCI are at high risk of recurrent revascularization, which are reduced by use of intracoronary imaging and BMS. Although DES is preferable to BMS in preventing restenosis in OHT lesions, the type of antiproliferative drug in the DES did not impact TLR. Further studies are needed to evaluate the effectiveness of adjuvant immunosuppressant therapy.

---

**C22 A POLYMER-FREE BIOLIMUS-COATED STENT FOR THE MANAGEMENT OF REAL-WORLD PATIENTS WITH CORONARY ARTERY DISEASE: DATA FROM A MULTICENTER REGISTRY**

Alfonso Iela1, Fabrizio D’Ascanzo2, Maurizio Di Biasi2, Paolo Vicentini2, Roberto Adriano Latin1, Enrico Ferrato1, Massimo Tespili1, Mauro Iannaccone1, Erika Ferrara1, Vincenzo Infantino1, Massimo Grammario1, Gaetano Senatori1, Arnaldo Poli1, Giacomo Nocuzzo2, Gennaro Scarello3, Ferdinando Varbella3, Bernardo Cortese4, Maurizio D’Urbano1, Maurizio Viecca1, Maurizio D’Amico1, Maurizio Tespili1

1Centro Cardio-Toracico Sant’Ambrogio, Milano, Italy, 2Cardiology Interventions, AOI Città della Scienza e della Salute, Torino, Italy, 3UO Cardiologia, ASSL Fatebenefratelli/Sacco, Milano, Italy, 4UO Cardiologia, ASST Milanese Ovest, Ospedale Fornamori, Magenta (MI), Italy, 5UO Cardiologia, ASST Fatebenefratelli/Sacco, Milanese Ovest, Ospedale Fatebenefratelli, Milano, Italy, 6UO Cardiologia, Ospedale degli Infermi, Rivoli (TO), Italy, 7Emerodinamica, Dipartimento di Scienze Cardiovascolari, Respiratorie, Geriatriche, Anestesiologie e Nefrologiche, Ospedale Umberto I, Roma, Italy, 8Unità di Emodinamica, Ospedale San Giovanni Bosco, Torino, Italy, 9UO Cardiologia, ASST Milanese Ovest, Ospedale Civile, Legnano (MI), Italy, 10UO Cardiologia, Ospedale di Cirie, Cirie (TO), Italy, 11UO Cardiologia, Ospedale Maria Vittoria, Torino, Italy, 12UO Emodinamica, AOU Città della Salute e della Scienza, Torino, Italy

**Background.** A polymer-free biolimus A9 coated and eluting stent (PF-BCS) followed by 1-month dual antiplatelet therapy has been shown to be safer and more effective than a bare-metal stent in high bleeding risk (HB-R) patients undergoing PCI in a clinical trial setting. However, little is known about the performance of this PF-BCS in patients encountered during everyday, routine clinical practice.

**Purpose.** This study aimed at assessing the performance of a PF-BCS (Biofreedom®) in real-world HBR patients with severe coronary artery disease (CAD).

**Methods.** A retrospective, cohort analysis was performed on all comers patients with severe CAD underwent PCI in 11 Italian centers. Primary safety endpoint was to assess the incidence of a composite of cardiac death, target-vascular myocardial infarction (TV-MI), or definite/probable stent thrombosis (ST). The primary efficacy endpoint was target lesion revascularization (TLR). The incidence of type 3 and 5 bleedings according to the Bleeding Academic Consortium (BARC) were also evaluated.

**Results.** A total of 923 HBR patients (1196 lesions) received a PF-BCS during the study period. Among the patients treated 219 (23.7%) required oral anticoagulation, 77 (8.3%) patients had cancer while 76 (8.2%) experienced a prior major bleeding. More than half of the patients (601, 65%) were admitted because of acute coronary syndrome while 33 (33.9%) were diabetics. Among the 1196 lesions treated, 291 (24.3%) were bifurcations, 211 (17.6%) heavily calcified, 132 (11%) unprotected left main while 75 (6.2%) aorto-ostial. Angiographic success was obtained in 99.2% of the cases while the rate of peri-procedural MI was 10.4%. At a median of 9 months of follow-up (IQ 3-19), the incidence of the composite safety endpoint was 1.9% (cardiac death 1.1%, TV-MI 0.5% and definite/probable ST 0.3%) while the incidence of TLR was 1.1%. BARC defined type 3 and 5 bleedings rate was 3.4%.

**Conclusions.** In our real-world experience, the implantation of a PF-BCS in real-world patients is associated with favorable clinical results, pointing toward the overall mid-term efficacy and safety of this novel device in complex clinical scenarios.
and ischemia-driven target lesion revascularization (ID-TLR) at the longest follow-up actually available. The occurrence of Mg-BRS thrombosis was also evaluated.

Results. A total of 75 patients with acute myocardial infarction (n=27, 35.7%) were treated with at least one Mg-BRS during the study period. Mean patient’s age was 58.0±9.3 years. Diabetes mellitus was present in 7 (9.3%) patients while the vast majority of the patients were males (n=67, 89.4%). All the patients were in Killip class I at presentation. Procedural success was obtained in all the cases with the deployment of the Mg-BRS at the culprit site. Pre- and post-dilatation were performed both, in 74 (98.6%) of the cases while intravascular imaging in 33 (44%). A median of 1.4±0.7 Mg-BRS were implanted per procedure and Mg-BRS overlapping was required in 10 (13.3%) cases. No in-hospital events were reported and the vast majority of the patients (n=70, 93.3%) were discharged with the strongest DAPT actually available (including ticagrelor or prasugrel) for 12 months. At a median of 9-month follow-up of any cardiac death, TV-MI, ID-TLR or Mg-BRS were reported.

Conclusions. Our retrospective analysis assessing the performance of a Mg-BRS in patients with acute MI suitable for BRS implantation showed encouraging results similar to that reported in patients with SCA. Larger studies are necessary to better understand the potential benefits associated with the implantation of this novel biereosorbable coronary device.

PCI: lesion/patient subsets 2

C24 FEASIBILITY OF OVERLAPPED MAGNESIUM-MADE BIORESORABLE SCAFFOLD IMPLANTATION IN LONG LESIONS: RESULTS FROM A MULTICENTER ITALIAN REGISTRY

Giorgio Guadini1, Enrico Cerrato1, Alfonso Ielasi1, Salvatore Geraci1, Francesco Tommasini1, Fabio Ferrini2, Cristina Rolfo3, Fabio Marian4, Nadia Garro5, Massimo Leoncini6, Simone Belluccia7, Giuseppe Caramanno7, Chiara Bemelli8, Paolo Sganzerla9, Francesco Granata4, Umberto Barbero10, Giorgio Sacchetta1, Mario Iannaccone2, Gianluca Campo11, Claudio Rapetto3, Maurizio Tespili12, Diego Milazzo13, Gerardo Pilato14, Giovanni Vaccaro15, Ferdinando Varbellia1

1Unità Funzionale Interaziendale di Emodinamica, Ospedale degli Infermi e AO Luigi Gonzaga, Rivoli-Orbassano, Italy, 2Istituto Clinico S. Ambrogio, Milano, Italy, 3Ospedale San Giovanni di Dio, Agrigento, Italy, 4Ospedale Umberto I, Siracusa, Italy, 5SSD Cardiologia Invasiva Enomologica ed Interventistica Cardiovascolare, Ospedale S. Maria delle Grazie, Milano, Italy, 6Cardiologia, Ospedale Bolognese ASST Nord Milano, Cinisello Balsamo, Italy, 7ASST Bergamo Ovest, Ospedale Treviglio-Caravaggio, Treviglio, Italy, 8Clinica Montevergine, Mercogliano, Italy, 9Ospedale di Savigliano, Savigliano, Italy, 10Azienda Ospedaliero-Universitaria di Ferrara, Ferrara, Italy

Background. Prospective registries on New magnesium-made biereosorbable scaffolds (BrS) Magmaris enrolled patients with simple coronary lesions. The present report was sought to give preliminary findings on feasibility and safety of implantation of overlapped scaffolds in long coronary lesions.

Methods. From July 2016 and May 2018, we collected data encompassing patients treated with at least two overlapped BrS (Magmaris, Biotronik, Switterland) in 11 Italian centres involved in the MAGIC registry (Magnesium alloy scaffold for coronary artery disease). Endpoints of interest were successful overlap implantation according to edge-to-edge technique and 30 days target lesion failure (TLF), including target vessel myocardial infarction and ischemia-driven target lesion revascularization.

Results. A total of 100 Magmaris overlaps were performed in 46 patients, which were mainly males (83.0%) with a mean age of 59.2±10.2 years. The majority of them presented with NSTE-ACS (92.2%). Left anterior descending artery was target for revascularization in 58.7% of cases. Mean lesion length was 44.4±20.9 mm treated with a mean of 2.2±0.8 Magmaris scaffolds. Scaffold predilatation and postdilatation were performed in all the patients (100%). Edge-to-edge implantation technique was attempted in all cases, following current technical recommendation supported by enhancement viewers tools. Almost two-third of cases (63.0%) underwent intravascular imaging guided procedure (OCT 25. IVUS 4); successful overlap was performed in 98.0% of attempts with 2 failures due to geographical missing, resolved with bailout BrS and DES (drug-eluting stent) implantation, respectively. Device acute success was achieved in all cases without any in-hospital event. At a mean follow-up of 9.3±4.4 months (available in 89.1% of patients) no DOCE occurred.

Conclusion. Multiple Magmaris implantation using an edge-to-edge technique is feasible with acceptable risk of geographical miss, probably due to the low radiopacity of tantalum markers. Clinical outcomes need to be confirmed in trials with longer follow-up.

C25 PROGNOSTIC VALUE OF THE HIGH-SENSITIVITY TROPONIN I ASSAY AFTER ELECTIVE CTO PROCEDURE

Andrea Rognoni1, Martina Solli2, Marco Giovanni Mennuni1, Vincenzo Alessandro Gallifia1, Roberto Rossio1, Angelo Santo Bongo1, 1Cardiologia 2, AOU Maggiore della Carità, Novara, Novara, Italy

Background. Chronic total occlusion (CTO) is usually defined as a total obstruction (TIMI 0 flow) of a coronary artery greater than three months duration. They account for around one-third of the coronary lesions. The rationale behind CTO recanalization is the improvement of anginal status, left ventricular ejection fraction and quality of life, the reduction of surgical revascularisation and long-term coronary patency. Procedural success depends upon careful review of the angogram including stump morphology, length of occlusion, calcification and presence and extent of collaterals (U CTO score). Despite the high prevalence, only 8-15% of patients undergo PCI. The prognostic value of postprocedural high-sensitivity troponin T (hsTnT) after CTO procedure is unclear.

Methods. We included 104 patients undergoing elective CTO procedure between January 2015 and January 2018. Clinical, angiographic and procedural characteristics were correlated with any or at least five times the 99th percentile hsTnT elevation, as well as a 1-year confirmed endpoint of major adverse cardiac, cerebrovascular events and mortality.

Results. Post CTO hsTnT elevation was observed in 85% (84/104); in 42% (43/104) of cases. hsTnT elevation was more frequent in more complex patients (postcoronary artery bypass grafting, peripheral vascular disease, chronic kidney disease, heart failure and multivessel disease) as well as in the more complex CTO procedures (JCTO scores ≥3). After a medium follow-up of 210 (±35) days postprocedural hsTnT elevation is not associated with major adverse events (death, myocardial infarction and cerebrovascular events).

Conclusion. In patients undergoing elective CTO procedure, postprocedural hsTnT elevation is frequent, but is not correlated with higher adverse cardiac events and mortality rates after 1-year follow-up of our small study population, suggestive of the limited long-term impact of troponin elevation.
the indications and timing of coronary angiography (CA) and angioplasty (PCI) in this setting are controversial except for ST-elevation on 12-lead electrocardiogram (EKG).

Aims. The aim of our study is to understand etiology and survival of patients admitted to our hospital with return of spontaneous circulation (ROSC) after OCHA and whether a strategy that leads to an urgent CA and PCI, if required, can improve the outcome.

Methods and Results. Observational retrospective study. Between January 2006 and December 2009, 70 patients with ROSC after OCHA were referred to our hospital. Mean age was 69.5±13.9; 63% male; 11% previous coronary artery disease (CAD), first rhythm was ventricular tachycardia/ventricular fibrillation (VT/VF) in 62%; in 41% diagnosis was acute coronary syndrome (ACS) based upon ECG and enzyme. Hospital survival rate was 48.5%. One year survival rate was 76% of dismissed. Postresuscitation neurologic injury (PNI): 32.8%. According to the presence of ACS, patients with ACS are mostly male, without differences in age or previous CAD vs. no ACS patients. VT/VF is the most frequent presentation rhythm in ACS patients (89% vs. 40%; p<0.01). Only in 34% of ACS patients first ECG showed signs of myocardial infarction/ischemia. VT/VF is the first rhythm equally in both STEMI and NSTEMI. Early sign of PNI generally are associated with underuse of CA and PCI and worst prognosis. Successful urgent CA and PCI are associated with improved hospital survival in patients with ACS (equally in STEMI 83% vs. 51%, p=0.003, and NSTEMI 81% vs. 55%, p=0.004); and in VT/VF as first rhythm (86% vs. 80%, p=0.001).

Conclusions. In OCHA survivors successful urgent PCI is associated with improved in-hospital survival in STEMI, NSTEMI and in patients with VT/VF as first recorded rhythm.

Physiology

**C28**

**PHYSIOLOGICAL VERSUS ANGIOGRAPHIC GUIDANCE FOR MYOCARDIAL REVASCULARIZATION IN PATIENTS UNDERGOING TRANSCATHETER AORTIC VALVE IMPLANTATION**

Mattia Lunardi, Roberto Scarsini, Gabriele Venturi, Gabriele Pesarini, Andrea Gratta, Anna Piccoli, Valeria Ferrero, Flavio Ribichini

**Divisione di Cardiologia, Università degli Studi di Verona, Verona, Italy**

**Background.** Management of coronary artery disease (CAD) in patients undergoing transcatheter aortic valve implantation (TAVI) is uncertain. Fractional flow reserve (FFR) has never been validated in aortic stenosis (AS). Safety of deferring negative FFR coronary lesions in AS is not established.

**Objectives.** The study aim was to investigate FFR-guided revascularization in TAVI patients, with focus on clinical outcome of deferred patients (FFR negative: >0.80).

**Methods.** Patients with severe AS (n=413) underwent coronary angiography during workup for TAVI between March 2010 and November 2017. Patients with significant CAD (coronary narrowing >50% in the proximal segment of the main coronary branches) were included in this retrospective analysis and divided into two groups: angiographically-guided (109/192, 56.8%) vs. FFR-guided revascularization (83/192, 43.2%), and followed for 24 months.

**Results.** Most lesions in the FFR group resulted negative (96/125, 77%) and were deferred. Less patients were treated with PCI in the FFR-guided group (23% vs 32%) with a significantly better MACCE-free survival compared with the angi-guided group (94% vs. 83.5%, p=0.024). A similar effect was observed in deferred patients against those who underwent angi-guided treatment (90.9% vs. 71.4%, p=0.001). When the clinical outcome of deferred patients with FFR values between 0.75-0.85 was compared with those with FFR >0.85, no significant difference was observed (MACCE-free 94.1% vs. 95.3%, p=0.83).

**Conclusions.** FFR-guided revascularization in patients undergoing TAVI is safe (94% MACCE-free survival at 24 months). Prospective randomized trials are needed to better investigate the long-term effects of FFR-guided revascularization against angiographic guidance alone in patients with AS.

**C30**

**UTILIZZO DELLA QUANTITATIVA FLOW RATIO NELLA STRATIFICAZIONE DELLE STENOSI NON CULPRIT IN PACIENTI CON STEMI E MALATTIA MULTIVASALE**

Francesco Gallo, Giosafat Spitaleri, Simone Biscaglia, Matteo Tebaldi, Johan Reiber, Alfonso Ielasi, Antonio Maria Leone, Salvatore Brugalla, Manel Sabaté, Giancarla Campo

**I. Colaiori1, S. Fournier2, G. Di Gioia1, B. De Bruyne1, E. Barbato2**

**Cardiology, Campus Biomedico, Roma, Italy, 2Cardiology-OLV, Aalst, Belgium**

**Background.** Patency of coronary artery bypass grafts (CABG) is known to be higher in arterial grafts than in venous grafts. However, CABG long-term natural history based on hemodynamic guidance-strategy (angiography vs. fractional flow reserve [FFR]) remains poorly documented.

**Methods.** All consecutive patients having undergone CABG surgery between 2006 and 2010 with repeated angiograms during follow-up were retrospectively included. All grafts were classified according to their hemodynamic guidance-strategy into two groups: an FFR-guided group and an angiography-guided group.

**Results.** Repeated angiograms were available in 512 grafts from 171 patients. 384 (75.0%) were angiography-guided while 128 (25.0%) were FFR-guided. At 6 years, 76/512 (14.8%) grafts were occluded. The proportion of occluded venous grafts was higher than the proportion of arterial grafts (21.76% vs. 9.78%, respectively; p=0.021). Overall, the proportion of occlusion was higher in the angiography-guided group than in the FFR-guided group (16.9% vs. 8.6%, respectively, p=0.022).

**Conclusions.** FFR-guidance is associated with a higher CABG patency at 6 years. Long-term patency of arterial grafts is higher when implanted on coronary arteries evaluated by FFR.

**C39**

**LONG-TERM NATURAL HISTORY OF >500 CORONARY ARTERY BYPASS GRAFTS DEPENDING ON HAEMODYNAMIC GUIDANCE AT IMPLANTATION**

I. Colaiori1, S. Fournier2, G. Di Gioia1, B. De Bruyne1, E. Barbato2

**Cardiology, Campus Biomedico, Roma, Italy, 2Cardiology-OLV, Aalst, Belgium**

**Background.** Patency of coronary artery bypass grafts (CABG) is known to be higher in arterial grafts than in venous grafts. However, CABG long-term natural history based on hemodynamic guidance-strategy (angiography vs. fractional flow reserve [FFR]) remains poorly documented.

**Methods.** All consecutive patients having undergone CABG surgery
potrebbe essere spiegato da un prolungamento della procedura, dai costi o dai possibili effetti avversi dell'adenosina. La quantitativa flow ratio (QFR) rappresenta una nuova metodica atta a valutare la significatività di una lesione; essa si basa su una ricostruzione anatomicca 3D del vaso e sul contrast frame counting, ottenuta a partire da due proiezioni angioarchitettoniche ortogonal, senza necessità di una guida di pressione o della somministrazione di adenosina (Fig. 1). Come già dimostrato in diversi studi1-3, la QFR ha mostrato un'ottima correlazione con la FFR nei pazienti con malattia coronarica stabile.

Obiettivi. L'obiettivo di questo studio è quello di valutare, per la prima volta, tale metodica nell'ambito dello STEMI. Lo studio ha come finalità principale quello di dimostrare una elevata correlazione con la FFR, nonché una forte capacità di stratificare correttamente le lesioni non culprit nel paziente con STEMl e malattia multivasale.

Metodi. Lo studio è costituito da tre coorti differenti di pazienti: Coorte A - la Coorte A rappresenta la componente retrospettiva. In questa coorte abbiamo selezionato pazienti con STEMl e malattia multivasale, giunti nel nostro laboratorio di Emodinamica da gennaio 2009 a dicembre 2012. Abbiamo selezionato soltanto pazienti in cui almeno una stenosi non culprit sia stata valutata con FFR (in genere circa 3-4 giorni dopo la PCI primaria). Abbiamo eseguito su queste stenosi la valutazione con QFR (quando possibile), sia sulle immagini angiografiche acquisite durante la PCI primaria, sia durante la procedura staged. L'obiettivo della coorte A era quello di dimostrare la riproducibilità della QFR sia nella fase acuta, che in quella subacuta dello STEMI. Coorte B - la Coorte B rappresenta la componente prospettica. Abbiamo ammalato pazienti con STEMl e malattia multivasale che hanno avuto giunti presso il nostro laboratorio di Emodinamica da dicembre 2016 a giugno 2017. Durante la PCI primaria l'operatore identificava la lesione culprit e la trattava con PTCA e impianto di stent; se indentificava una o più lesioni non culprit (>50% DS), acquisiva 2 proiezioni angiografiche per l'analisi con QFR. Successivamente l'operatore eseguiva l'analisi delle suddette lesions con FFR (invasiva). Lo scopo della coorte B era quello di verificare la correlazione tra la QFR e la FFR, calcolate entrambe durante la PCI primaria. Coorte C - la Coorte C rappresenta l'analisi clinica. Abbiamo selezionato pazienti con STEMl dal trial EXAMINATION che è un trial multicentrico, prospettico, randomizzato, che ha ammalato pazienti con STEMl e che sono stati randomizzati a ricevere bare-metal stent o everolimus-eluting stent per il trattamento delle stenosi coronariche. Abbiamo selezionato soltanto pazienti con STEMl e malattia multivasale che hanno ricevuto il trattamento con PTCA della sola lesion culprit. Le lesions non culprit sono state valutate con QFR (quando tecnicamente possibile) in modo tale da ottenere il valore di SYNTAX score funzionale (FSS) residuo. L'obiettivo della coorte C è stato quello di valutare la relazione tra il SYNTAX score funzionale non invasivo (NI-FSS), ottenuto mediante la QFR, e il rate di eventi (morte da tutte le cause, infarto miocardico, rivascolarizzazione coronarica non programmat) durante un follow-up di 5 anni.

Resultati. La Coorte A ha incluso 31 pazienti e 34 lesions non culprit. La QFR ottenuta durante la PCI primaria ha dimostrato una buona correlazione con quella ottenuta sulla procedura staged (r=0.98). L'analisi mediante Bland-Altman ha mostrato una differenza media di solo 0.004 (Fig. 2). La Coorte B ha incluso 45 pazienti w 49 lesions non culprit entrambe valutate con FFR e QFR durante la PCI primaria. La QFR ha dimostrato una elevata correlazione con la FFR invasiva (r=0.90). Alla Bland-Altman la differenza media è stata di -0.011 [-0.106 – 0.084] (Fig. 3). La sensibilità, specificità, valore predittivo positivo e valore predittivo negativo erano rispettivamente 88%, 97%, 94%, e 94%; l'accuratezza diagnostica era 94% per il cut-off di 0.80. La Coorte C ha incluso 110 pazienti. Dopo aver calcolato il NI-FSS, abbiamo ottenuto 54 (50%) pazienti che hanno ricevuto una rivascolarizzazione funzionale completa (NI-FSS=0), e 56 (50%) che hanno ricevuto una rivascolarizzazione funzionale incompleta (NI-FSS>0). Ad un follow-up di 5 anni 39 (35%) pazienti hanno manifestato un event avverso. Il rate di eventi era significativamente più elevato nel gruppo che aveva ricevuto una rivascolarizzazione funzionale incompleta (46% vs. 24%; p=0.01) (Fig. 4). Conclusioni. Il nostro studio è basato su di un piccolo campione di popolazione, ma è stato il primo studio a dimostrare la fattibilità e l'efficacia della QFR nello stratificare correttamente le lesions non culprit riscontrate in corso di STEMl e malattia multivasale. Il nostro studio rappresenta inoltre il primo studio in cui il rate di eventi avversi viene valutato sulla base del NI-FSS, derivato mediante QFR, senza l'utilizzo di guida di pressione e senza l'utilizzo di farmaci per indurre l'iperemia massimale.

Bibliografia
C31 PROGNOSTIC IMPACT OF CONTRAST FFR
Giuseppe Zimbardo1, Pio Cialdella1, Eloisa Basile1, Francesca Lassandro Pepe1, Manfredi Arioti1, Italo Porto1, Francesco Burzotta1, Carlo Trani1, Filippo Crea1, Antonio Maria Leone1,2
1Università Cattolica del Sacro Cuore, Roma, Italy, 2Policlinico Casilino, Roma, Italy

Introduction. FFR is the gold standard for the functional evaluation of intermediate coronary stenoses, however the need of adenosine administration in order to induce maximal hyperaemia is one of the main reasons for underutilization of FFR in clinical practice. Contrast FFR (cFFR) using non-ionic radiographic contrast medium has been demonstrated to have superior diagnostic performance, when compared with other adenosine-free indexes, in predicting FFR, even if online. Thus, online outcome data are still lacking.

Methods and Results. 481 patients undergoing functional evaluation with FFR and cFFR were divided into two groups on the basis of FFR and cFFR (cFFR ≤0.80 with FFR >0.80, n=431, mean follow-up 18 months) or disagreement (n=56, mean follow-up 14 months). We found no differences in major adverse cardiac events (MACE, 14% and 14% respectively, p=0.56), death (3% and 5.3%, p=0.03), myocardial infarction (4.4% and 0%, p=0.16) and myocardial revascularizations (7.8% and 14%, p=0.05).

Conclusions. We demonstrated that cFFR is not only accurate in predicting FFR but it is also safe in guiding coronary revascularization, potentially simplifying invasive coronary physiological assessment and treatment.

Imaging and physiology

C32 FRACTIONAL FLOW RESERVE IN PATIENTS WITH AORTIC STENOSIS AND CORONARY ARTERY DISEASE: CORRELATION WITH MYOCARDIAL PERFUSION IMAGING
Roberto Scarsini1, Rosaria Cantone1, Gabriele Venturi1, Giovanni Luigi De Maria1, Andrea Varjola2, Mattea Iurani2, Gabriele Pesarini1, Marco Ferdeghini1, Maurizio Meola1, Rajesh Kharbanda1, Adrian Banning1, Flavio Ribicchi1
1Division of Cardiology, Department of Medicine, University of Verona, Verona, Italy, 2Division of Cardiology, Oxford University Hospitals, Oxford, UK

Background. The incidence of aortic stenosis (AS) is frequently associated with coronary artery disease (CAD). However, the best tool to functionally assess CAD in AS remains undetermined and fractional flow reserve (FFR) has never been validated in this setting. We sought to investigate the concordance between FFR and stress single photon emission computed tomography (SPECT) in detecting myocardial ischemia in patients with severe AS and bystander CAD.

Methods and Results. FFR and SPECT were performed in a consecutive series of 28 patients with severe AS and 41 borderline coronary lesions during the work-up for valve replacement. Angiographic significant obstructions (diameter stenosis >50%) were observed in 31/41 lesions (76%), and SPECT signs of ischemia were identified in 15/41 (37%) of the territories supplied by these 41 stenotic vessels. FFR detected ischemia in 19/41 (46%) of the cases. Overall, the concordance rate between FFR and SPECT was 85%. The presence of ischemia was independently associated with FFR (OR 0.001, CI 0.00-0.02, p=0.003) but not with the angiographic severity of coronary lesions (OR 1.09, CI 0.98-1.19, p=0.10). At ROC curve analysis, FFR demonstrated an AUC=0.91, negative predictive value of 95% and positive predictive value of 74% in detecting myocardial perfusion defects at SPECT. The optimal FFR cut-point was ≥0.78 (sensitivity 87%, specificity 58%), providing an overall agreement of 88% with stress MPI.

Conclusions. FFR detected myocardial ischemia more frequently than SPECT in patients severe AS, maintaining a high concordance rate with myocardial perfusion SPECT. The high FFR NPV is reassuring about the safety of deferring lesions with FFR >0.80 in patients with severe AS.

C33 CORONARY PHYSIOLOGY PREDICTS THE EXTENT OF MYOCARDIAL INJURY AFTER PRIMARY PCI IN STEMI.
Roberto Scarsini, Giovanni Luigi De Maria, Alessandra Borotti, Raffai Angelos Kounias, Jeremy Langrish, Andrew Lucking, Robin Choudhury, Suzanne Ferreira, Manuel Manzana, Ayesha Kharbanda, Adrian Banning
Oxford Heart Centre, Oxford University Hospitals, Oxford, UK

Background. The aim of this study is to compare the performance of thermodilution-derived indexes, namely coronary flow reserve (CFR), microvascular resistance index (IMR) and resistance reserve ratio (RER) in predicting microvascular injury and the extent of infarction after primary percutaneous coronary intervention (PPCI).

Methods. Thermodilution parameters were measured via intracoronary pressure wire after PPCI in 45 ST-elevation myocardial infarction (STEMI) patients. In 30 (67%) cases of patenting strategy in STEMI were enrolled, 15 (33%) were also measured. Cardiac magnetic resonance was performed at 48 hours and 6 months from the PPCI to assess area-at-risk (AAR), infarct size (IS) and microvascular obstruction (MO).

Results. At ROC curve analysis, CFR, IMR and RER performed similarly in predicting the extent of infarction at 48h from PPCI (p=ns for all comparison). However, RER (AUCRER=0.84, CI 0.69-0.99) was superior compared to both CFR (AUCCFR=0.67, CI 0.46-0.86) and IMR (AUCIMR=0.70, CI 0.52-0.88) in predicting IS >15% at 6 months (p=0.05). More in detail, patients with RER <2 units showed larger 48h-IS=75% (CI [14.5-42.5] vs. 15.4 [8.3-26.0], p=0.018), RVO (5.0 [2.1-8.8] vs. 0 [0.0-5.0], p=0.026), 6-months-IS% (22.7 [10.2-35.9] vs. 8.9 [6.9-12.3], p=0.006), and lower rate of adverse revascularization (22.2% vs. 0%, p=0.014) and angiographic myocardial salvage index (34% [22-8-59.2] vs. 53.2% [37-77.7], p=0.032) compared with other patients. CFR (1.4±0.87 vs. 1.47±0.61, p=0.94) and IMR (58.0±37.7 vs. 55.0±49.6, p=0.72) did not improve after PPCI in patients with RER <2, whereas they improved significantly in patients with RER ≥2 (CFR: 1.37±0.43 vs. 1.93±0.49, p=0.018; IMR: 56.8±31.2 vs. 35.9±26.5, p=0.003).

Conclusions. RER could offer incremental prognostic value compared with other thermodilution-derived indexes, with suboptimal myocardial reperfusion and larger IS at follow up observed more frequently in patients with post-procedure impaired RER.

C34 ADENOSINE-FREE INDEXES VS. FFR FOR FUNCTIONAL EVALUATION: A SYSTEMATIC META-ANAlysis
Eloisa Basile1, Francesco Gallo2, Rita Pavasini3, Carlo Trani1, Gianluca Campo1, Antonio Maria Leone3
1Istituto di Cardiologia, Fondazione Policlinico A. Gemelli, Roma, Italy, 2Cardiology Unit, Azienda Ospedaliero Universitaria di Ferrara, Cona (FE), Italy, 3Background. The achievement of maximal hyperaemia is a fundamental requirement to assess fractional flow reserve (FFR) but also a limiting factor. Adenosine free indexes (AFI), like resting Pd/Pa, instantaneous wave-free ratio (IWR) and contrast-FFR (cFFR) have been proposed to circumvent the use of vasodilators in the functional evaluation of coronary stenoses.

Methods and Results. We conducted a systematic review and meta-analysis of observational studies in which AFI were compared to FFR as a reference. After systematic literature search, 18 studies were included in this meta-analysis. Overall, 2907 patients and 3682 lesions were evaluated by FFR, 2023 patients and 2122 lesions by cFFR, 2606 patient and 2775 lesions by resting Pd/Pa (mean age 66.5 years, diagnosis at the admission: 57% stable coronary artery disease; 26% acute coronary syndromes). The overall Pearson’s correlations were 0.91 (79% for FFR vs. IWR, 0.78 (75% for FFR vs. cFFR, 0.78 (72%) for FFR vs. resting Pd/Pa (p<0.0001). The area under the ROC curve was higher for the cFFR (0.94; 95% CI 0.92-0.97, f 48%) compared to IFR (0.90; 95% CI 0.88-0.92, f 68%) and resting Pd/Pa (0.87, 95% CI 0.82-0.92, f 64%). The diagnostic accuracy was higher for RER (0.89 [85%-93%, f 88%), followed by IFR (82%, 95% CI 80%-84%, f 19%) and resting Pd/Pa (79%, 95% CI 77%-82%, f 39%).

Conclusion. Among AFI, cFFR shows the best correlation with FFR and the higher diagnostic accuracy. Contrast-FFR represents a valuable, simple and safe alternative to FFR, superior to IFR and resting Pd/Pa, when FFR is used as a reference.

C35 CULPRIT PLQUE MORMPHOLOGY IN PATIENTS WITH AND WITHOUT PREINFARCTION ANGINA: INSIGHTS FROM OPTICAL COHERENCE TOMOGRAPHY IMAGING IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION
Rocco Vergallo, Alfredo Ricchuto, Domenico D’Amario, Gianmarco Annibali, Mattia Galli, Stefano Migliaro, Francesco Bendandi, Gianluca Auregemma, Antonio Maria Leone, Giampaolo Niccoli, Francesco Burzotta, Carlo Trani, Italo Porto, Filippo Crea
Department of Cardiovascular and Thoracic Sciences, Fondazione Policlinico Universitario A. Gemelli, Catholic University of the Sacred Heart, Rome, Italy

Background. The relation between culprit plaque morphology and the clinical presentation of an acute myocardial infarction (AMI) has not been examined in detail.

Objectives. To study the culprit plaque morphology in patients with AMI with or without preinfarction angina using optical coherence tomography (OCT) imaging.

Methods. A total of 102 patients with AMI (32 STEMI, 70 NSTEMI) who underwent OCT imaging before percutaneous coronary intervention were enrolled. Patients were classified as: i) having either intermittent chest pain in the six hours preceding the final episode of pain, or unstable
angina (or both) in the week preceding AMI (preinfarction angina group); or ii) having a single episode of chest pain without unstable symptoms in the preceding week (no preinfarction angina group). Culprit plaque was described. Prat thrombus score was calculated, and the prevalence of calcification, neovascularization, and OCT-defined macrophage accumulation was assessed.

Results. Patients with preinfarction angina showed a significantly higher prevalence of PR than PP, while those without preinfarction angina showed a significantly higher prevalence of PR than IF (Figure). PR in patients with preinfarction angina were more frequently associated with macrophage accumulation, while those in patients without preinfarction angina were not (Figure). Prat thrombus score tended to be more frequent in patients with preinfarction angina than in those without (85.7% vs. 63.6%, p=0.097), and Prat thrombus score tended to be lower (22.0 (15.8–30.3) vs. 38.5 (12.8–67.5), p=0.145). Calcifications were significantly less frequent in patients with preinfarction angina than in those without (22.0% vs. 40.4%, p=0.045), while neovascularization tended to be more frequent (58.0% vs. 42.3%, p=0.113).

Conclusions. Patients with preinfarction angina have a distinct culprit plaque phenotype, frequently characterized by IF and a relatively lower thrombotic burden, probably reflecting a prevalence of reparative mechanisms and spontaneous thrombolytic activity in these patients.

**C36**

EFFICACIA E SICUREZZA DELLO SCAFFOLD RIASSORBIBILE IN C36 MAGNESIO, MAGNAMIR, IN UNA POPOLAZIONE REAL WORLD. RISULTATI A 12 MESI DEI PRIMI 200 SOGGETTI DEL REGISTRO MULTICENTRICO INTERNAZIONALE BIOSOLVE-IV

Stefano Galli, Piero Montorsi, Sarah Troiano, on behalf of the BIOSOLVE-IV Investigators

Centro Cardiologico Monzino, Milano, Italy

Obiettivi. Lo scopo del registro è investigare la performance clinica e la sicurezza a lungo termine dello scaffolding riassorbibile in Magnesium (Magmaris) in una popolazione “real world”. Lo studio arruolerà fino a 2065 soggetti in 100 centri in Europa, Asia e paesi dell’Asia-Pacifico. Questa analisi include i dati del follow-up a 6 e 12 mesi dei primi 200 soggetti arruolati.

Metodi. Tra settembre 2016 e aprile 2017, sono stati arruolati fino a 2065 soggetti in 100 centri in Europa, Asia e paesi dell’Asia-Pacifico. Questa analisi include i dati del follow-up a 6 e 12 mesi dei primi 200 soggetti arruolati.

Risultati. Tra i primi 200 pazienti (224 lesioni), arrolati in 28 centri, in 12 differenti paesi, 193 (97%) hanno completato il follow-up a 12 mesi. L’età media era 62.3±11.1 anni; 77% erano maschi, 21% età superiore ai 75 anni, 14% insulino-dipendente. L’indicazione al trattamento era angina stabile in 66.5%; l’angina instabile nel 18% mentre il 14.5% dei pazienti si presentava per NSTEMI. Il vaso target era: IVA 51.4%, CXA 19.6% e CD nel 29%, rispettivamente. Il 64% delle lesioni era B2/B3 mentre il 17.3% B2/C, con 6.5% di lesioni con calcificazioni moderate/severe. La lunghezza della lesione e i diametri del vaso di riferimento medi erano 14.5±4.2 mm e 3.2±0.4 mm, rispettivamente. Il follow-up a 6 mesi mostrava TLF di 9/198 pazienti (4.6%) con 1 (0.5%) trombosi di scaffold subacutamente da sospensione di DAPT, mentre a 12 mesi 9/198 (4.6%) dovuti solo a TLR, senza più trombosi di stent (0.5% a 12 mesi). L’unica trombosi si è verificata per sospensione precoce di DAPT dopo la procedura secondariamente a riavascularizzazione bidimensionale (MIDCAB).

Conclusioni. I risultati preliminari a 12 mesi dello studio Biosolve IV confirmano il profilo di sicurezza ed efficacia dello scaffolding Magnamir già mostrati dagli studi precedenti, mostrando una performance globale paragonabile, in una popolazione selezionata, a quella del DES di nuova generazione. Inoltre il profilo di riassorbimento completo a 12 mesi, la bassa trombogenicità del Mg e la bassa incidenza di trombosi, rendono il Magnamir un’alternativa valida per il trattamento con scaffold, riassorbibili.

**C37**

A PROPENSITY SCORE COMPARISON OF BIORESORBABLE POLYMER VS. DURABLE POLYMER STENTS ON ULUM AND CORONARY BIFURCATION: A SUBGROUP ANALYSIS FROM THE RAIN-CARDIOGROUP VII STUDY (VERY THIN STENTS FOR PATIENTS WITH LEFT MAIN OR BIFURCATION IN REAL LIFE)

Michael Iannaccone,1 Umberto Barbero,1 Michele Debednechi1, Daniela Trabattoni2, Andrea Rogno2, Giorgio Quadri3, Enrico Cerrato3, Ferdinando Varbella4, Antonia Bassignana5, Baldassarre Doronzo1, Fabrizio D’Ascanzo2

1SS. Annunziata, Savigliano, Savigliano, Italy, 2Istituto Cardiologico Monzino, Milano, Italy, 3Coronary Care Unit and Catheterization Laboratory, AOUMaggiore della Carità, Novara, Italy, 4Department of Cardiology, Infermi Hospital, Rovigo, Italy, 5Department of Cardiology, San Luigi Gonzaga Hospital, Orbassano, Rovigo, Italy, 6Division of Cardiology, Department of Internal Medicine, Città della Salute e della Scienza, Turin, Italy

Introduction. There is lack of data regarding the impact of bioresorbable polymer drug eluting stent (BP-DES) vs. durable polymer DES on outcomes in unprotected left main (ULM) or coronary bifurcation lesions.

Methods. All patients with a ULM or bifurcation lesion treated with PCI using ultrathin stents (struts thinner than 81 µm) were enrolled. The primary endpoint was the rate of target lesion revascularization (TLR), with major adverse cardiovascular events (MACE), a composite of all-cause death, myocardial infarction, TLR and stent thrombosis and its components, along with target vessel revascularization (TVR) secondary endpoints. A propensity score with matching analysis to compare patients treated with BP-DES vs. Durable Polymer drug eluting stent (stent) was assessed.

Results. After propensity score, out of 3001 patients 1400 patients (700 in each group) were selected: 352 patients treated on ULM and 1048 on non-LM bifurcation lesions. In the overall population, rates of MACE were similar (12.3% vs. 11.6%, p=0.74) as of secondary endpoint at a median follow-up of 16 (12-22) months. Regarding two stents strategy, patients treated with BP-DES revealed a better outcome in terms of MACE (20.4% vs. 10%, p<0.03) and TVR (12% vs. 4.6%, p=0.05) and a trend towards TLR (10.2% vs. 3.8%, p=0.08). In non-LM bifurcation BP-DES seems to significantly reduce definite ST (1.7% vs. 8.8%, p<0.001).

Conclusion. BP-DES seem to perform similarly to DP-DES in patients with ULM or coronary bifurcation with a trend towards better performance when a two-stent strategy is needed, and a lower risk of ST in non-LM bifurcations.

**C38**

FANTOM II TRIAL: SAFETY & PERFORMANCE STUDY OF THE FANTOM SIROLIMUS-ELUTING BIORESORBABLE CORONARY SCAFFOLD – 24-MONTH FOLLOW-UP CLINICAL OUTCOMES

Bernardo Cortese1, Jeffrey Anderson2

1Clinica San Carlo, San Carlo, Italy, 2REVA Medical, San Diego, USA

Background. Bioresorbable vascular scaffolds (BRS) provide temporary mechanical support and may help restore normal vessel reactivity, positive remodeling, and reduce chronic inflammation. The Fantom sirolimus-eluting (BRS) was manufactured from TyroCore™, a unique radiopaque tyrosine based polymer. Methods. FANTOM II is a prospective, multi-center, safety and performance study of patients with myocardial ischemia or a positive functional study. The study included patients with single or de novo lesions in native coronary vessels ranging in diameter from 2.5 to 3.5 mm and lesion lengths up to 20 mm. The primary objective of the study is to demonstrate safety and performance of the Fantom sirolimus-eluting
C40

SUSTAINABILITY OF NEONATAL INHIBITION OVER TIME BY REDUCING THE DENSITY OF ANTI-RESTENOTIC EFFECT ON LUMEN DIMENSIONS IN YUCATAN MINISWINE

Marco Ferrone1, Giliberto Melnick2, Nicolas Isaza3, Yanping Cheng4, Athanasios Pappas5, Gerard Condit6, Grzegorz Kalusza7, Juan Granada1
1CRF-Skirball Center for Innovation, New York, USA, 2Complexo Hospital de Clinicas, Universidade Federal do Parana, Curitiba, Brazil, 3Pontificia Universidad Javeriana, Bogota, Colombia

Background. Pacitaxel-coated balloons (PCBs) employ different coating technologies to deliver the antirestenotic drug without permanent polymer carrier. The ideal formulation should maximize the neointimal inhibition with the least drug possible, while ensuring adequate healing and containing the particulate release from the coating. We have investigated the impact of lowering the dose density on the durability of the antirestenotic effect using porcine model of iliofemoral in-stent restenosis.

Methods. In-stent restenosis was induced in 20 iliofemoral arteries of 10 Yucatan miniswine by 130% balloon overstretch followed by self-expandable stent placement. Four weeks later (Day 0) all lesion sites were evaluated by optical coherence tomography (OCT) and then treated with regular dose density (3.5 µg/mm²) or lower dose (2 µg/mm²) density PCB. Serial angiographic and OCT follow-up was used at 60 and 90 days after treatment to characterize the neointimal response over time.

Results. Nearly identical in-stent obstruction was present in both groups on Day 0 before PCB treatment, making the head-to-head randomized comparison reliable. A trend toward more robust neointimal inhibition was observed at 60 days with the regular dose density PCB, reaching statistical significance at 90 days for neointimal thickness and % area stenosis.

Conclusions. Attempts to lower the dose density of PCB may have implications for sustainability of antirestenotic effect over time. Further investigations are needed to study these implications for longer follow-up time, as well as long-term clinical head-to-head PCB comparisons are necessary to validate these preliminary experimental findings.

PCI

C41

RUOLO DELLA RIVASCOLARIZZAZIONE CORONARICA URGENTE NEL PAZIENTE CON ARRESTO CARDIOVASCULARE IN STADIO ACUTAMENTE (OHCA) DOPO RIPRESA DI CIRCOLO (ROSC): L’ESPERIENZA DELLA PROVINCIA AUTONOMA DI TRENTO

Francoessa Tedoli1, Simona Muraglia2, Filippo Zilio3, Giuseppe Braito4, Michele Dallago5, Alberto Menotti6, Marco Borghesi7, Roberto Bonmassari8
SC Cardiologia, Ospedale S. Chiara, Trento, Italy

Background. Vi sono evidenze cliniche che una strategia invasiva di esecuzione in emergenza del cateterismo cardiaco (CGF) in pazienti con ROSC dopo OHCA sia fattibile. Le linee guida dell’European Resuscitation Council del 2015 ne raccomandano l’indicazione nei pazienti con ST sopraslivellato o con instabilità emodinamica. Di 3,5% dei pazienti con OHCA vengono centralizzati all’Ospedale S. Chiara di Trento (centro Hub), dotato di servizio di Emergenza 124, mediante un sistema organizzativo di tipo “Hub&Spoke”, implementato sul medesimo rete attiva per lo STEMI. Abbiamo eseguito una analisi retросpettiva del nostro data base provinciale dei pazienti con ROCS ricoverati e sottoposti a CGF dal gennaio 2012 al dicembre 2015. Sono stati valutati i dati coronarografici, la rivascularizzazione, la mortalità e l’outcome neurologico mediante il Cerebral Performance Category score (CPCs) alla dimissione e a 6 mesi.

Results. Nel periodo in esame giunti al centro Hub 277 pazienti dopo ROSC. Di questi, 115/277 (42%) non sono stati sottoposti a CGF: 44/115 (38%) mostravano una evidente causa non cardiaca di arresto e 71/115 (62%) non si erano ritenuti idonei alla CGF per cause diverse: lungo tempo preROSC, età molto avanzata, ecc. 152/239 (59%) pazienti giunti al centro Hub dopo ROSC stati sottoposti a CGF urgente. Il quadro elettrocardiografico post ROSC mostrava: STEMI in 62 pazienti (38%), NSTEMI in 17 pazienti (11%) e alterazioni aspecifiche (AS) in 80 pazienti (46%). Di 3 pazienti la ROSC è risultata mancante. La percentuale di vaso occluso, suboccluso o con patologia critica nei 3 gruppi era rispettivamente: 41/62 (66%), 8/62 (13%) e 6/62 (10%) nel gruppo STEMI, 9/17 (53%), 2/17 (12%) e 0/17 (0%) nel gruppo NSTEMI, 17/80 (21%), 13/80 (16%) e 8/80 (10%) nel gruppo con AA. Gli altri pazienti mostravano patologia coronarica non critica. 26/97 (27%) dei pazienti presentavano un quadro angiografico di occlusione coronarica acuta senza segni ECG di STEMI. In un caso è stata documentata la presenza di una dissezione coronarica a carico di...
CD, with quadro ECG of STEMI, and treated in a manner conservatively, 88/162 (54%) of the patients sottoposti a CGF are not sottoposti to rivascularizzazione coronarica: 81/88 (92%) because PCI urgent and 8% mediante BAC diffuso. The percentage of rivascularizzazione nei tre gruppi 352/62 (6%) nel gruppo STEMI (51/83 – 96% con PCI), 12/17 (71%) nel gruppo NSTEMI (100% con PCI), 22/80 (28%) nel gruppo AA (18/22 – 23% con PCI). L’accesso radiale è stato eseguito con successo in 107/162 patients (66%). L’impiego di IGP libilia è stato del 9%. In 32/162 (20%) è stato posizionato due BPG. Nel 100% dei sottoposti a PCI in urgenza è stata trattata solo la culprit lesion. The sopravvivenza alla dimissione a 6 mesi era 104/162 (64%) e 67/162 (54%). L’outcome neurologico valutato con il CPCs era pari a 1 (11/74). L’outcome neurologico valutato con il CPCs era 1 (20/74) e 15% (87/162) dei pazienti sottoposti a CGF sono stati sottoposti a PCI in urgenza e 66% (107/162) del gruppo AA. Nel 31% dei pazienti sottoposti a PCI in urgenza è stata trattata solo la culprit lesion. The sopravvivenza alla dimissione a 6 mesi era 27% (20/74) e 15% (11/74). L’outcome neurologico valutato con il CPCs era 1 (20/74) e 15% (87/162) dei pazienti sottoposti a CGF sono stati sottoposti a PCI in urgenza. 5) La sopravvivenza dei pazienti sottoposti a CGF alla dimissione. Conclusioni. 1) La nostra strategia invasiva di gestione del paziente con ROSC dopo OHCA ha portato oltre la metà della popolazione in oggetto ad essere sottoposta a studio emodinamico urgente. 2) Oltre il 50% è stato sottoposto a rivascularizzazione coronarica urgente (oltre il 90% con PCI). 3) Il 27% dei pazienti mostrava una oclusione coronarica acuta senza un quadro ECG di STEMI. 4) Una strategia di CGF esate anche ai pazienti senza chiara ischemia all’ECC ha permesso la rivascularizzazione urgente di quasi un quarto di questa popolazione. 5) La sopravvivenza dei pazienti sottoposti a CGF alla dimissione ed ai 6 mesi è superiore al 50% con buon outcome neurologico alla dimissione.

C42
LONG-TERM AND IN-HOSPITAL OUTCOMES OF PATIENTS WITH ACUTE CORONARY SYNDROME AND HISTORY OF CORONARY BY-PASS GRAFTING UNDERGOING PERCUTANEOUS CORONARY INTERVENTION
Andrea Demarchi1, Marco Ferrari2, Gurbehj Singh3, Marcello Marino4, Maurizio Ferrario5, Luigi Olivotto Visconti6, Gaetano Maria De Ferrari7
1SC Cardiologia, Ospedale S. Andrea, Vercelli, Italy, 2SC Cardiologia, Policlinico San Matteo, Pavia, Italy, 3Policlinico di Monza, Monza, Italy, 4Cardiologia Molinette di Crema, Crema, Italy

Background. Patients with acute coronary syndrome (ACS) previously treated with coronary artery by-pass graft (CABG) are underrepresented in randomized clinical trials and their optimal treatment is still not defined. The aim of the present study was to investigate management, in-hospital and long-term outcomes of such population which underwent coronary angiography. A comparison between revascularization strategy adopted was also performed: medically managed (Group 1) vs percutaneous coronary intervention (PCI) of native vessel (Group 2) vs. graft (Group 3).

Methods and Results. From January 2010 to December 2016, 200 patients with history of surgical revascularization admitted at our institution for ACS (78% non-ST elevation) underwent coronary angiography. Culprit lesion was identified on graft in 45.5% of cases.

Table 1. Baseline characteristics, angiographic findings and interventional strategies in sub-groups

<table>
<thead>
<tr>
<th>Sub-group characteristics</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD</td>
<td>67.6 ± 9.9</td>
<td>72.9 ± 8.6</td>
<td>71.4 ± 8.5</td>
<td>0.296</td>
</tr>
<tr>
<td>Male sex, n (%)</td>
<td>10 (7.4)</td>
<td>20 (12.2)</td>
<td>8 (12.2)</td>
<td>0.710</td>
</tr>
<tr>
<td>History of diabetes, n (%)</td>
<td>51 (36.7)</td>
<td>5 (3.6)</td>
<td>1 (1.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Smoker, n (%)</td>
<td>8 (28.6)</td>
<td>47 (48.0)</td>
<td>33 (45.2)</td>
<td>0.864</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>9 (32.1)</td>
<td>33 (33.7)</td>
<td>32 (41.5)</td>
<td>0.249</td>
</tr>
<tr>
<td>CKD (creatinine &gt;2.5 mg/dl)</td>
<td>3 (10.7)</td>
<td>18 (18.4)</td>
<td>10 (13.7)</td>
<td>0.414</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>24 (83.7)</td>
<td>83 (84.7)</td>
<td>83 (84.0)</td>
<td>0.432</td>
</tr>
<tr>
<td>Dyslipidemia, n (%)</td>
<td>79 (59.5)</td>
<td>63 (64.3)</td>
<td>57 (74.6)</td>
<td>0.089</td>
</tr>
<tr>
<td>Family history of CAD, n (%)</td>
<td>11 (39.3)</td>
<td>36 (36.7)</td>
<td>35 (45.2)</td>
<td>0.264</td>
</tr>
<tr>
<td>History of ACS, n (%)</td>
<td>20 (71.4)</td>
<td>65 (66.3)</td>
<td>67 (84.4)</td>
<td>0.076</td>
</tr>
<tr>
<td>History of percutaneous coronary revascularization, n (%)</td>
<td>12 (42.9)</td>
<td>46 (46.9)</td>
<td>33 (45.2)</td>
<td>0.822</td>
</tr>
<tr>
<td>CABG indication, n (%)</td>
<td>12 (44.4)</td>
<td>42 (42.4)</td>
<td>27 (35.5)</td>
<td>0.517</td>
</tr>
<tr>
<td>Stent/Graft</td>
<td>23 (33.3)</td>
<td>57 (33.7)</td>
<td>58 (82.1)</td>
<td>0.031</td>
</tr>
<tr>
<td>Days from CABG median (IGR)</td>
<td>3562</td>
<td>3550</td>
<td>3254</td>
<td>0.003</td>
</tr>
</tbody>
</table>

Table 2. Discharge features, in-hospital and long-term outcomes in sub-groups

<table>
<thead>
<tr>
<th>Discharge parameters</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-hospital outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All-cause mortality, n (%)</td>
<td>3 (10.7)</td>
<td>3 (1.9)</td>
<td>2 (1.4)</td>
<td>0.240</td>
</tr>
<tr>
<td>Non-CAB -CAD, n (%)</td>
<td>1 (2.1)</td>
<td>1 (0.4)</td>
<td>1 (0.7)</td>
<td>0.278</td>
</tr>
<tr>
<td>Post discharge outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All-cause mortality, n (%)</td>
<td>3 (10.0)</td>
<td>10 (15.0)</td>
<td>28 (44.9)</td>
<td>0.217</td>
</tr>
<tr>
<td>MI, n (%)</td>
<td>1 (2.1)</td>
<td>12 (15.0)</td>
<td>4 (6.0)</td>
<td>0.422</td>
</tr>
<tr>
<td>Non-urgent PCI, n (%)</td>
<td>1 (0.2)</td>
<td>2 (2.2)</td>
<td>11 (1.7)</td>
<td>0.031</td>
</tr>
<tr>
<td>All-cause mortality + MI, n (%)</td>
<td>13 (6.0)</td>
<td>30 (37.0)</td>
<td>41 (17.4)</td>
<td>0.037</td>
</tr>
</tbody>
</table>

Figure 1. All-cause mortality in sub-groups (log rank p-value). Group 1: medically treated; Group 2: patients who underwent revascularization on native vessel; Group 3: patients who underwent revascularization on the graft.

Figure 2. Secondary composite end-point in sub-groups (log rank p-value). Group 1: medically treated; Group 2: patients who underwent revascularization on native vessel; Group 3: patients who underwent revascularization on the graft.
C43
LA SCELTA DI PERCORSI DIVERSIFICATI NEL FOLLOW-UP POST-PCTA. UNO STUDIO PROSPETTICO OSSERVAZIONALE
Andrea Celestini, Giorgia Caferrì, Rocco Antonio Montone, Giuseppina Ceccarini, Maria Elisa Cicoria, Luigi Sommariva
UOC Cardiochirurgia, Ospedale S. Giovanni Battista, Padova, Italy
Background. The choice of follow-up pathway after primary PCI remains controversial particularly in patients with chronic total occlusion (CTO) and in those with recurrent acute coronary syndrome (rACS). We aimed to investigate the impact of the follow-up pathway on the outcomes of patients with CTO and rACS.
Methods. We performed a retrospective analysis of patients who underwent primary PCI at Cardiology Unit of Padua University consecutively underwent p-PCI at Cardiology Unit of Padua University and followed-up at Cardiology Unit of Padua University and Cardiology Unit of Padua University, Padova, Italy.
Results. A total of 396 patients were enrolled in the study, with a mean follow-up of 36±21 months. The clinical characteristics of the patients are shown in Table 1. The outcomes of the patients are shown in Table 2. The rate of major adverse cardiovascular events (MACE) was significantly lower in the group of patients who underwent a more complex follow-up pathway (p=0.016). The rate of severe side effects was also lower in the group of patients who underwent a more complex follow-up pathway (p=0.03).
Conclusions. The choice of follow-up pathway after primary PCI is important for the management of patients with CTO and rACS. A more complex follow-up pathway is associated with a lower rate of major adverse cardiovascular events and a lower rate of severe side effects. These results suggest that a more complex follow-up pathway should be considered for patients with CTO and rACS.
single AMI followed by a minimum 3-year period of clinical stability (sAMI) (n=38). Non-culprit segments were analyzed by optical coherence tomography (OCT) for assessment of plaque features. HCP was defined as a plaque with at least one heterogeneous signal-rich layer of different optical signal intensity clearly demarcated from the underlying tissue (Figure). The incidence of major adverse cardiac events (MACE), including cardiac death, non-fatal AMI, and re-hospitalization due to unstable angina, was assessed at follow-up.

Results. Median time of clinical stability was 8 years (4.5-14.5) in the IS-AJP group, and 9 years (5.0-15.0) in the ISM group. Patients in the RACS and ISMI groups showed similar prevalence of thin-cap fibroatheroma (40.0% vs. 34.2%, p=0.623), which was significantly higher than in those with IS-AJP (5.1%, p=0.038). In contrast, OCT-defined macrophage accumulation was significantly more frequent in patients with RACS than in those with IS-AJP or ISMI (53.3% vs. 18.9% vs. 18.4%, p=0.002). HCPs were rarely observed in patients with RACS, whereas their prevalence was significantly higher in patients with IS-AJP and ISMI (3.3% vs. 29.7% vs. 28.9%, p=0.014). After a median follow-up of 36.8 months (18.3-56.2), the incidence of MACE was significantly higher in patients without HCP than in those with HCP (31.2% vs. 3.3%, p=0.012); primarily driven by higher rates of non-fatal AMI (13.0% vs. 0.0%, p=0.041). At multivariate analysis, HCP was an independent predictor of better clinical outcome (HR 0.13, 95% CI 0.03-0.64, p=0.012).

Conclusions. HCPs in non-culprit segments represent a novel marker of long-term clinical stability, probably reflecting the prevalence of reparative mechanisms over destabilizing stimuli.

C47 COMPLETE OR CULPRIT ONLY REVASCULARIZATION IN PATIENTS WITH MULTIVESSEL DISEASE PRESENTING WITH CARDIogenic SHOCK: A META-ANALYSIS OF RCT AND ADJUSTED OBSERVATIONAL RESULTS

Maurizio Bertaina1, Ilaria Ferraro1, Pierluigi Omedè1, Maurizio Bertaina1, Ilenia Ferraro1, Pierluigi Omedè1, Federico Conrotto1, Claudio Moretti1, Fabrizio D’Ascenzo1, José P.S. Henriques3, Simone Frea1, Tullio Usmiani1, Mauro Pennone1, Maurizio D’Amico1

1Division of Cardiology, Department of Internal Medicine, Città della Salute e della Scienza, Turin, Italy; 2Department of Medicine, University of North Carolina, Chapel Hill, NC, USA; 3Department of Cardiology, Academic Medical Center, Amsterdam, Netherlands

Introduction. Best strategy for patients presenting with cardiogenic shock (CS) following myocardial infarction (MI) with multivessel (MV) disease remain to be elucidated.

Methods and Results. A meta-analysis of all randomized controlled trial (RCT) and observational studies with multivariable analysis evaluating the impact of MV-PCI (percutaneous coronary intervention) vs. culprit only (C)-PCI in patients admitted for CS and multivessel disease was performed. Primary endpoint was short-term mortality at multivariable analysis; long-term mortality, MI and acute renal injury (AKI) were the secondary ones. 6886 patients in 12 studies (one randomized and 11 observational ones) were included, 2042 treated with MV-PCI and 5841 with C-PCI. MV-PCI was not associated with an increased risk of short-term death compared with C-PCI both at the procedure, the introduction of the artery radial at the term of the procedure and the registration of the pressure arterial radial at a final procedure, which was significantly higher in patients with MV disease (beta -0.022, 95% CI -0.033 to -0.012; p=0.001). MV-PCI strategy was associated with more frequent need for dialysis or CIN after revascularization (OR 1.36, 95% CI 1.06-1.75, p=0.02).

Conclusion. MV-PCI appears more favorable in patients with MV disease admitted for CS after anterior MI. The increased risk for AKI and its negative prognostic impact should be considered in decision making process.

Coronary intervention

C48 ACCESSO TRANSRADIALE ED EMOSTASIA ULTRARAPIDA SENZA SOMMINISTRAZIONE DI EPARINA

Alessio Stanzione, Francesco Summaria, Gaetano Giorfio, Fabiana Piccioni, Fabrizio D’Errico, Gregory Sguiglia, Achille Gaspardone

1UO Cardiologia, Ospedale S. Eugenio, Roma, Italy

Introduction. L’accesso transradiale offre importanti vantaggi rispetto all’accesso transfemorale sia per il confort del paziente e per la possibilità di una dimissione rapida sia in termini di riduzione delle complicanze emorragiche e vascolari, dei costi e soprattutto degli eventi aversi e della mortalità. Tuttavia l’accesso radiale è associato a possibili complicanze tra cui la più importante è l’occlusione dell’arteria radiale. In virtù della duplice irrorazione arteriosa della mano, l’occlusione dell’arteria radiale è un evento generalmente asintomatico ma purtropo pregiudica la possibilità di un futuro utilizzo dell’arteria radiale oculata per la preparazione di una fistola artero-venosa, per interventi di bypass aorto-coronarico o di chirurgia ricostruttiva e in particolare per ulteriori procedure di cardiologia intervettistica. La somministrazione di eparina ha dimostrato di ridurre il rischio di occlusione dell’arteria radiale che tuttavia aumenta con la durata della compressione emostatica. Non è attualmente noto se il non utilizzo dell’eparina possa favorire una riduzione di durata della compressione emostatica e in secondo luogo del rischio di occlusione dell’arteria radiale.

Metodi. In 40 pazienti successivi (65±11 anni, 27 uomini) con indicazione a coronarografia transradiale con finalità esclusivamente diagnostica, è stato utilizzato un introduttore Slender 4F/5F introduzione diagnostico Tiger 5F. Dopo l’accesso venenosa somministrata un bollo di nitroglicerina e soluzione fisica sotto l’utilizzo di eparina. È stato effettuato il cronometraggio del tempo trascorso tra inserimento del cortocoduto e la rimozione dello stesso a fine procedura, la durata dell’emostasi arteriale radiale al termine della procedura sia prima che dopo somministrazione di un bollo di nitroglicerina. Successivamente è stato attuato un protocollo ultrarapido di emostasi perva che prevedeva sgonfiaggio del bracciale compressivo dopo 5 minuti dalla comparsa di gemizia con immediato arresto e re-insuffisianza di 1 ml di aria e rimozione di 2 ml di aria ogni 5 minuti. I pazienti sono stati infine sottoposti a controllo ecografico dell’arteria radiale con sonda vascolare lineare ad alta frequenza a 24 ore dalla procedura.

Risultati. In tutti i pazienti è stata ottenuta l’emostasi con rimozione del dispositivo di compressione emostatica in un tempo compreso tra 15 e 35 minuti. La durata della compressione emostatica non era in rapporto con l’età, il peso, l’altezza, la durata della procedura, la pressione arteriosa e il processo di cardiologia intervettistica. La somministrazione di eparina associata al non utilizzo dell’arteria radiale alla durata di compressione emostatica era da ritenersi più breve rispetto ad altri protocolli. I pazienti sono stati tamponati alla procedura con soluzione fisiologica senza l’utilizzo di eparina. È stato attuato un protocollo ultrarapido di emostasi sistemica che prevedeva il non utilizzo dell’arteria radiale occlusa per la possibilità di un futuro utilizzo dell’arteria radiale.

Conclusioni. Nel paziente sottoposto a coronarografia con finalità esclusivamente diagnostica, la non somministrazione di eparina favorisce l’emostasi perva ultrarapida associata a un rischio nullo di occlusione dell’arteria radiale. Tale osservazione preliminare richiede conferma in studi appropriatamente disegnati.
Pazienti e metodi. Studio osservazionale, retроспективо, monocentrico. Sono stati arrecati 415 pazienti consecutivi ricoverati presso la struttura complessa di cardiology del Policlinico di Modena nel periodo compreso tra il 01/04/2011 e il 01/04/2016 che, dopo essere stati sottoposti a studio anatomico preoperativo (IVUS), sono stati presentati coronarograficamente in sala TC. Dopo essere stati valutati dall’Heart Team, sono stati sottoposti a PTCA (o il Policlinico di Modena) o a CAGB (e/o Hospia Geriatric). La mortalità è stata valutata alla mediana del follow-up (1108 giorni), così come il reintervento, lo stroke e l’infarto acuto del miocardio (IMA) (mediana 775 giorni).

Risultati. Dei 415 pazienti arrecati nello studio, 262 (63%) sono stati sottoposti a PTCA, 153 (37%) a CAGB. La mortalità globale è risultata riscontrabile nella popolazione esaminata (PTCA = 0.005), in particolare nei pazienti con interessamento del TC, SYNTAX score ≥32, età >75 anni (p<0.05), ma non con età >80 anni (p=0.39). Tuttavia, le curve di mortalità non divergono in modo significativo (p>0.05), quando i pazienti venivano stratificati per i seguenti parametri: BMI ≥30, diabete mellito tipo 2, insufficienza renale cronica (IRC), BPCO, abitudine tabagica attiva, SYNTAX score ≥32, presentazione come STEMI e interessamento di 3 vasi isolati, sebbene per quest’ultimo parametro non si osservasse un trend di prevalenza significativa (p=0.07). L’incidenza di stroke e IMA è risultata simile nei due gruppi (p>0.05), mentre i pazienti sottoposti a PTCA avevano una più alta incidenza di reintervento, indipendentemente dal SYNTAX score (p>0.001). I due gruppi di pazienti erano omogenei per età, BMI, diabete mellito tipo 2, IRC, BPCO, abitudine tabagica attiva e SYNTAX score. Invece, il numero di pazienti con EF <30% (13% vs. 4%), presentazione come STEMI (50% vs. 11%) o shock cardicogeno (8% vs. 1%) e STS score elevato, era nettamente maggiore (p<0.05) nel gruppo PTCA. Pertanto trattasi di pazienti a elevato o molto elevato rischio.

Conclusione. Nella nostra esperienza, l’attitudine dell’Heart Team è stata di assegnare il trattamento con PTCA ai pazienti a più alto rischio di morte e reintervento, essendo l’elevato livello di complessità ricevuto dal CABG. Nell’inclusione dei pazienti nelle casistiche cliniche, abbiamo preferito includere anche i pazienti di inferiori complessità (p<0.05). Nella nostra esperienza, l’incidenza di stroke e IMA è risultata simile nel 7% dei pazienti che non presentavano alte rischio di sanguinamento hanno esteso la DAPT con ASA e clopidogrel ad 18 mesi, il 25% a 24 mesi. L’età media dei pazienti era di 59±10 anni. I maschi rappresentavano il 79% della popolazione esaminata. Il 37% dei pazienti era affetto da diabete mellito, il 69% di ipertensione arteriosa e il 37% era farmaci attivo. Le lesioni complesse (tipo B2/C, secondo la classificazione ACC/AHA) hanno rappresentato il 28% del totale, lesioni tipo B1 il 57%, lesioni tipo A il 14%. Il SYNTAX score medio di 11,5 ± 6, 73 scaffold sono stati implantati in 59 lesioni su 57 pazienti. La lunghezza media degli scaffold implantati per lesione è stata di 29±16 mm con un rapporto BVS/paziente di 1,28 e una percentuale di overlap del 24%. Il ramo descrittore anteriore (LAO) ha rappresentato il vaso target nel 49±5% dei casi. Nel registro, grazie alla

**C50**

FIVE-YEAR CLINICAL FOLLOW-UP AFTER ABSORB BVS IMPLANTATION IN A REAL WORLD POPULATION FROM THE AG-SORB REGISTRY

Salvatore Geraci, Diego Milazzo, Gerlando Pilato, Giovanni Vaccaro, Sibilla Alsi, Giuseppe Caramanno
UO Emodinamica, Ospedale San Giovanni di Dio, Agrigento, Italy

**Introduzione e obiettivi.** Il principio della “vascular reparative therapy”, secondo cui è possibile trattare lesioni coronariche con device che si dissolvono nel tempo portando ad una “restitutio ad integrum” del vaso, ha fallito in fase clinicale perché in questi anni si è diffuso tra i cardiologi intervistenti. Nonostante il “first in men trial ABSORB” abbia mostrato come a due anni la mortalità globale e la frequenza di reintervento siano maggiore nel gruppo PTCA rispetto al gruppo CABG, mentre la frequenza di stroke e IMA è risultata simile tra i due gruppi. Nei pazienti con SYNTAX score ≥32 o affetti da STEMI, interessamento di 3 vasi isolati o importanti comorbidità (diabete mellito tipo 2, IRC, BPCO, abitudine tabagica attiva, BMI ≥30), la PTCA non è risultata inferiore al CABG nel ridurre la mortalità e le complicanze a lungo termine, rappresentando quindi un valido approccio terapeutico.

**Caratteristiche cliniche di base**
- Sesso maschile: 79%
- Età media (anni): 58 ± 10
- Ipertensione arteriosa: 69%
- Diabete: 37%
- Insulino-dipendente: 37%
- Fumatori: 20%
- Ex fumatori: 20%
- Familiarità per coronaropatie: 50%
- Dislipidemia: 47%
- Pregressa CABG: 31%
- Pregressa PCI: 11%
- Creatininemia (mg/dl): 0.95 ± 0.2
- Anticoagulazione
  - Angina stabile: 33%
  - Angina instabile: 31.5%
  - NSTEMI: 24%
  - STEMI: 11.5%

**Caratteristiche delle lesioni**
- MVD: 70%
- SYNTAX score: 11.5 ± 6
- LAD trattata con BVS: 50%
- LCX trattata con BVS: 20%
- RCA trattata con BVS: 25%
- Tipo di lesione (ACC/AHA)
  - B1: 14%
  - B2: 57%
  - C: 24%
- Lunghezza lesione (mm): 24 ± 12
- Lesioni >28 mm: 24%

**Anticoagulazione in dimissione**
- ASA+clopidogrel: 24%
- ASA+prasugrel: 53%
- ASA+ticagrelor: 23%
- Durata minima prescrizione della DAPT: 12 mesi
- Sospensione precoce della DAPT: 3.4%

**Follow-up – endpoints**
- Follow-up medio: 47 ± 5 mesi
- Morte cardica: 0 (0%)
- DOCE per lesione: n=59
  - Clinically-driven target lesion revascularization: 3 (5%)
  - Infarto del vaso target: 1 (1.7%)
  - Tromboschi del scaffold: 1 (1.7%)
  - In scaffold restenosis: 2 (3.4%)
- DOCE per paziente: n=57
  - Clinically-driven target lesion revascularization: 3 (5.2%)
  - Infarto del vaso target: 1 (1.75%)
  - Tromboschi del scaffold: 1 (1.75%)

**Caratteristiche procedurali**
- Accesso arterioso cutaneo: 90%
- Imaging invasive (OCT-IVUS): 11.5%
- Predilatazione: 100%
- % Stenosi residua dopo predilatazione: 18.5 ± 7
- Postdilatazione: 98.6%
- Pressioni di postdilatazione in atm: 13.4 ± 1.9
- Rapporto pallone da postdilatazione/BVS ≥3: 100%
- Pallone da postdilatazione <0.5 mm del BVS: 2%

**Caratteristiche del BVS**
- BVS totali: 73
  - BVS per paziente: 14 ± 0.8
  - Pazienti con 4 BVS: 1
  - Pazienti con 2 BVS: 13
  - Pazienti con 1 BVS: 43
- Lesioni trattate con più di 1 BVS: 14 (24%)
- BVS con overlapping: 14 (24%)
- Lunghezza media BVS in mm: 29 ± 16
- Pressione minima di rilascio dei BVS in atm: 11
tecnica d’impianto standardizzata, il 100% dei pazienti ha eseguito predilatazione e il 98.6% postdilatazione con le caratteristiche sopra citate nel paragrafo sui metodi. L’incidenza dei DOCE, analizzando la popolazione per lesione trattata, è stata del 5%, con 1 trombosi di BVS (1.7%) che ha causato riossidalizzazione per NSTEMI a 698 giorni dalla procedura indice, 2 ristenosì critiche in BVS (3.4%) che hanno portato a riossidalizzazione per angina instabile. Non è accorsa nessuna morte cardiaca. Nello specifico la trombosi del BVS si è verificata a 696 giorni dall’impianto sulla paziente di 62 anni, diabetica, pertosi e dislipidemiaca, la diagnosi di ingresso al ricovero indice era NSTEMI e il paziente aveva impiantato un BVS 3/18 mm su LAD, la paziente aveva sospeso a 18 mesi la DAPT ed aveva assunto solo cardioaspirina 100 mg. Il paziente è stato trattato con PCI ed impianto di DES su LAD. È da ricordare inoltre una singola TLR (non clinically-driven) a 5 anni dall’impianto in paziente ospedalizzato per stress test cardiaco positivo ma con concomitante stenosi subocclusiva di altro vaso coronarico. Da segnalare inoltre il totale riassorbimento dello scaffold a OCT eseguito in caso selezionato a 5 anni dall’impianto.

Conclusioni. La frequenza dell’outcome principale a lungo termine, oltre i 5 anni, dopo impianto di BVS in una popolazione real world, risulta relativamente bassa nel registro AG-SORB, con un solo episodio di trombosi dello scaffold, 2 ID-TLR e nessuna morte cardiaca. I risultati del nostro registro mostrano una buona performance del device in termini di sicurezza ed efficacia nella normale pratica clinica quotidiana con l’utilizzo di una strategia di impianto predeterminata e costante e il prolungamento della DAPT a 18 mesi nella maggioranza dei pazienti. Tuttavia AG-SORB è gravato dai limiti di un registro monocentrico, pertanto ampi studi randomizzati con scrupolosa tecnica di impianto predeterminata, alla luce delle nuove evidenze, sono necessari per chiarire meglio il profilo di durata della DAPT, già estesa nel nostro registro a 18 mesi nei pazienti di una strategia di impianto predeterminata e costante e il prolungamento della DAPT a 18 mesi nella maggioranza dei pazienti. Tuttavia AG-SORB è gravato dai limiti di un registro monocentrico, pertanto ampi studi randomizzati con scrupolosa tecnica di impianto predeterminata, alla luce delle nuove evidenze, sono necessari per chiarire meglio il profilo di durata della DAPT, già estesa nel nostro registro a 18 mesi nei pazienti non ad elevato rischio di sanguinamento (80%) in casi selezionati a 5 anni dall’impianto.

C51

NEOINTIMAL HYPERPLASIA AND NEOATHEROSCLEROSIS IN PATIENTS WITH AND WITHOUT CHRONIC KIDNEY DISEASE: AN OPTICAL COHERENCE TOMOGRAPHY STUDY

Rocco Vergallo, Gianluigi Napoli, Comenico D’Amato, Gianmarco Annibali, Cristina Augieremma, Antonio Maria Leone, Giampaolo Niccoli, Francesco Burzotta, Antonino Buffon, Carlo Trani, Filippo Crea, Italo Porto

Department of Cardiovascular and Thoracic Sciences, Fondazione Policlinico Universitario A. Gemelli, Catholic University of the Sacred Heart, Rome, Italy

Background. The effect of chronic kidney disease (CKD) on coronary stent healing and the development of neoahterosclerosis is largely unknown.

Objectives. To assess the prevalence and characteristics of neointimal hyperplasia (NIH) and neoatherosclerosis (NA) in patients with and without CKD.

Methods. A total of 105 patients who underwent follow-up optical coherence tomography (OCT) imaging of a previously implanted stent were enrolled, and classified into 3 groups: 1) patients without CKD (n=69), defined as an estimated glomerular filtration rate (eGFR) >60 mL/min/1.73 m², 2) patients with mild-to-moderate CKD (n=27), defined as an eGFR between 60 and 30 mL/min/1.73 m², and 2) patients with severe CKD (n=9), defined as an eGFR <30 mL/min/1.73 m².

Results. Median time from stent implantation was 51.8 months (IQR: 16.6–85.1), and was not different among the three groups. Analyzed stents were 58 drug-eluting stents and 47 bare metal stents. NIH volume with sCKD (1.64 ± 0.84 mm³ vs. 2.45 ± 1.30 mm³ vs. 2.61 ± 0.85 mm³), was significantly lower in patients with mCKD than in those without CKD and respectively, p=0.007). Prevalence of neoahterosclerosis was significantly lower in patients with mCKD than in those without CKD and with sCKD (7.4% vs. 33.3% vs. 44.4%, respectively, p=0.019). In addition, the number of frames with neoahterosclerosis was with neoahterosclerosis was significantly lower in patients with mCKD than in those without CKD and with sCKD (3.85 ± 4.55 vs. 7.45 ± 6.88 vs. 7.67 ± 5.32, respectively, p=0.038). Neointimal calcifications tended to be more frequent in patients with sCKD than in those with mCKD and with severe CKD (22.2% vs. 4.3%, respectively, p=0.127). No differences in the prevalence of TCFA-like neointima and neovascularization were observed among the three groups.

Conclusions. Our results suggest that patients with mild-to-moderate CKD may be relatively protected from the development of NIH and NA. These findings are not observed in patients with severe CKD, in whom NA and neointimal calcifications appear significantly more frequent. The molecular mechanisms at the basis of these observations need to be investigated in future studies.
efforts have been done to identify new risk factors and potential preventive strategies, such as statin therapy administration. Kinesis-Like Protein 6 (KIF6) is an omodimeric protein expressed in coronary arteries and other vascular tissues, that is involved in microtubular transport. The impact of KIF6 gene on cardiovascular risk modulation has been investigated since 2007 due to the presence of a single nucleotide polymorphism with the replacement of Trp719 with arginine (Arg). Several studies assessed the association between this genetic variant and a significant increase of cardiovascular risk, while, several other clinical trials showed a significant association between "pleiotropic" effects of statin therapy and a reduction in cardiovascular events in the population with the risk allele, due to the documented modulation of response to statin treatment by KIF6 polymorphism.

Methods. We analysed 1253 consecutive patients undergoing coronary angiography and/or PCI. Patients with creatinine clearance <60ml/min were treated with standard hydration (55 1ml/kg/h 12h before and after the procedure) with sodium bicarbonate (3 ml/kg for 1h before and 1 ml/kg/h for 6h after the procedure). Serum creatinine and creatinine clearance (Cookhs-Gault formula) were collected at baseline, 24 and 48 hours after contrast exposure. A blood sample for the determination of Trp719Arg polymorphism was collected for all patients. We performed DNA extraction by the use of SigmA aldrick Gen Elute system. Amplification of the region of interest with PCR and consequent electrophoretic run on agarose gel and digestion with restriction enzyme Fok I was performed for each sample. Digestion product underwent another electrophoretic run on agarose gel and subsequent analysis with UV scan. We therefore were able to identify the different allelic patterns of our population. Among these patients we assessed the incidence of CIN, defined as an absolute increase of 0.5 mg/dL, or a relative increase >25% in serum creatinine levels at 24h and 48h after the procedure.

Results. KIF6 Arg mutation was found in 669 patients (heterozygotes n = 525, homozygotes n = 144). Patients without polymorphism were more often in therapy with angiotensin receptor blockers, beta blockers, but less with acetylsalicylic acid and clopidogrel and they have higher haemoglobin levels at admission. The total prevalence of CIN in our population was 12.5% and we did not find any significant association between KIF6 polymorphism and the development of CIN (Group 1 11.3%, Group 2 13.7%, Group 3 13.2%, p=0.30) (Figure 1). This result was confirmed by multivariate analysis after correction for baseline confounding factors (adjusted OR [95% CI] 1.12 [0.86-1.46], p=0.38). At subgroups analysis we found a higher prevalence of CIN among homozygous patients treatment “naïve” in comparison to wild-type patients (20.7% vs. 11.3%, p=0.05), while patients with statin therapy at admission showed a lower CIN development without reaching a statistical significant result (6.8% vs. 13.2%, p=0.28) (p interaction =0.03). No other significant difference between homozygous KIF6 polymorphism and CIN development according to main risk factors for CIN such as diabetes, renal failure, gender, older age and PCI (Figure 2).

Conclusion. We found that statin therapy at admission did not influence the development of CIN, while, KIF6 homozygous Arg was associated with a significant increase in the risk of CIN only among statin naïve patients. Future ad hoc studies are certainly needed to confirm our findings and to evaluate the beneficial effects of statin therapy especially in this subset of patients.

C54 UNEXPECTED EVENTS DURING CORONARY ANGIOGRAPHY AND HOW TO SOLVE THEM: KINKED LIKE A STRAW

Marco Ruozzi, Salvatore Arrotti, Fabio Alfredo Sgura, Daniel Monopoli, Rosario Rossi, Giuseppe Bionati
UO Cardiologia, Policlinico Modena, Modena, Italy

New materials and the increasing utilization of radial access have contributed to improve safety and reduce the rate of complications in the cath lab. The use of small-caliber arteries such as radial or ulnar arteries, however, is not completely risk-free. We must be careful of ischemic risk, perforation, spasm, pseudoaneurysms formation and also kinking of the angiographic catheters, in particular with the diagnostic material. We report the case of a 66 years old patient, active smoker, with hypertension and diabetes. He suffered one year before of an inferior myocardial infarction treated with angioplasty and implantation of multiple medicated stent on the right coronary artery and the circumflex branch. He underwent subsequent elective revascularization with stenting of the anterior descending artery and the main diagonal branch. The patient presented to the emergency department with symptoms of unstable angina six months after the last revascularization and an angiographic study was performed. Due to the absence of a right radial pulse, a left radial approach was chosen using a Judkins right 3.5 6F diagnostic catheter. During the cannulation maneuvers of the right coronary artery there was a kinking effect of the catheter body at the left subclavian artery level with impossibility to untie it or cross the tortuosity with a guidewire (Fig. 1). After some ineffective attempts to straighten the JR 3,5 percutaneously with a gooseneck catheter (Fig. 2) from right femoral access, a multipurpose catheter was used, with a balloon over the wire inside, to anchor the distal portion of the kinked catheter from the inner lumen (Fig. 3). While inflating the balloon with high pressure, a clockwise rotation of the proximal part of the JR 3.5 catheter was performed with successful kinking resolution and extraction of the catheter from the radial access (Figs. 4 and 5). The subsequent transfemoral coronary angiography has documented an intraartical critical restenosis both of the right coronary and of the anterior descending artery treated with drug eluting balloon. The patient left the hemodynamic room after 1 hour and 30 min without complications in vascular access. No vascular damage was shown by angiography of the left upper limb at the end of the procedure (Fig. 6). In the hemodynamic room it can happen to face unexpected complications and it is necessary to know all the available materials and device that can help in the specific setting while maintaining the concentration in order to avoid further risks for the patient. It may also be necessary to think out of the box in search of unconventional solutions to avoid or minimize collateral damage. There are standardized solutions and materials dedicated to various type of complications but sometimes it may be necessary to opt for different strategies using the "craftmanship" that is part of the cultural baggage of every interventional cardiologist.
C55 ULTRASOUND-ENHANCED CATHETER-DIRECTED THROMBOLYSIS FOR PATIENTS WITH ACUTE PULMONARY EMBOLISM AT HIGH OR INTERMEDIATE-HIGH RISK AND WITH CONTRAINDICATION TO SYSTEMIC FIBRINOLYSIS

Emanuele Visco, Marianna Adamo, Elisa Locantore, Salvatore Curello, Giuliano Chizzola, Alessandro Abbenante, Luca Branca, Assunta Castiello, Marco Metra, Federica Ettori, Claudia Fiorina Spedali Civili, Brescia, Italy

Objectives. To evaluate safety and efficacy of ultrasound-enhanced, catheter-directed thrombolysis using EkoSonic Endovascular System (EKOS) in patients admitted due to acute pulmonary embolism (APE) deemed at high or intermediate-high risk and with contraindication to systemic fibrinolysis.

Methods. Eighteen consecutive patients (5 males, 13 females; mean age 74±12.7 years), affected by high-risk APE (n=4; 22.2%) or intermediate-high risk APE (n=14; 77.7%), were admitted at our institute between February 2015 and March 2017. They were treated with EKOS due to at least one of the following contraindications to systemic fibrinolysis: active bleeding (3 patients, 16.7%), recent ictus (2 patients, 11.1%), traumatic resuscitation (2 patients, 11.1%), recent major surgery (1 patient, 5.6%), known bleeding risk (presence of active cancer, advanced age, frailty, chronic kidney disease and/or hepatic insufficiency: 10 patients, 55.6%). The primary efficacy endpoints were the change from baseline to 72 hours of the right to left ventricular dimension ratio (RVLVRV ratio); the pulmonary embolic burden assessed using the Qanadli index (Qi) and the systolic pulmonary arterial pressure (SPAP).

Results. Mean RVLVRV ratio (1.38±0.3 vs. 0.97±0.16; p<0.0005); Qi (27.0±2.6 vs. 18.8±7.8; p=0.001) and SPAP (71.1±12 mmHg vs. 45.2±16 mmHg; p=0.001) significantly decreased within 72 hours after the procedure. Also heart rate and percentage of arterial oxygen saturation significantly improved after EKOS. One patient died due to a severe bleeding. Six patients experienced moderate bleeding, 3 of them had active bleeding and low haemoglobin levels at the time of the procedure. Femoral hematoma was observed in 2 subjects. Mean length of stay in hospital and in ICU was 13±6 and 6±2.9 days respectively. An 89-year-old patient (PESI score 139), died from multiple organ failure at 12 days from the procedure. No other patients died after the discharge within 30-day follow-up.

Conclusions. EKOS is an effective tool to treat patients with APE at high or intermediate-high risk and contraindication to systemic fibrinolysis. It is a relatively safety therapy considering the critical conditions and the high bleeding risk of the receiving population.

C56 DRUG COATED-BALLOON WITH OR WITHOUT DIRECTIONAL ATERECTOMY FOR PERCUTANEOUS REVASCULARIZATION OF THE SUPERIOR INFRAPUBIC FEMORAL ARTERY: A SINGLE CENTRE RETROSPECTIVE ANALYSIS

Giovanni Teruzzi, Daniela Trabattoni, Sebastiano Gilli, Giulia Santagostino Baldi, Stefano Gailli, Franco Fabbiocchi, Piero Montorsi, Antonio Bartorelli Centro Cardiologico Monzino, IRCCS, Milano, Italy

Background. Percutaneous revascularization has become a mainstay for the treatment of atherosclerotic disease of superficial femoral artery (SFA). The optimal technical approach for this intervention has however yet to be defined. Drug-coated balloon (DCB) angioplasty is the initial preferred treatment in most centres, whereas stent implantation is generally recommended as a bailout option only, as it might increase the rate of long-term complications. In this scenario, use of directional atherectomy (DA) before DCB has been suggested to improve technical success and reduce the need for bailout stenting compared to DCB alone, but scarce data to date corroborate this hypothesis.

Methods. Patients treated with DCB or DA+DCB for de novo SFA lesions from January 2012 to December 2017 at a single institution were included in the present analysis. Patients undergoing stent implantation were excluded, unless stenting was performed as a bailout strategy. Baseline clinical and procedural data were collected. All patients were followed-up for at least six months with clinical control and colorDoppler ultrasound. Need for bailout stenting represented the main procedural outcome. Presence of symptoms (claustrofobic intermitters) and significant restenosis were assessed six months and at the long-term follow-up.

Results. Overall, 164 patients were included, with a mean age of 69.1±8.4 years; 125 (76.2%) were of male gender, 146 (89.0%) had hypertension, 74 (45.1%) had diabetes. One-hundred thirty-three (81.1%) patients had coronary artery disease, whereas 26 (15.9%) chronic kidney disease (CKD). A total of 75 (45.8%) patients had lesions classified as TASC C or D. In 10 chronic total occlusions procedural failure occurred; therefore, in the analysis were included 154 (93.9%) successful procedures performed with DCB (n=122) and with DA+DCB (n=32). No significant differences were observed between patients treated with DCB and DA+DCB, excepted for CKD (13.1% vs. n=0, 28.1%, p=0.040) and Fontaine classification. Bailout stenting was significantly less frequent among patients treated with DA+DCB (n=34, 27.8% vs. n=3, 9.3%, p=0.035); this result was confirmed at multivariate analysis (OR 0.232, 95% CI 0.062-0.877, p=0.031). Among 108 patients with a mean follow-up of 677±359 days, 23 (21.3%) patients developed a significant restenosis, 17/87 (19.5%) in the DCB group vs. 6/21 (28.6%) in the DA+DCB group (p=0.36). Moreover, 9/31 (29.0%) patients with bailout stenting developed a restenosis vs. 14/77 (18.2%) not requiring bailout stenting (p=0.21). Seven patients died during follow-up without significant differences between the two study groups.

Conclusions. DA is independently associated with a lower bailout stenting when treating SFA lesions and might represent a valuable therapeutic option in this setting. Restenosis rate did not differ between patients treated with or without DA.

C57 L'UTILIZZO CHE NON TI ASPETTI DEL PROGLIDE... IN ARCO AORTICO

Daniela Benedetto1, Enrico Bacchigia2, Riccardo Turni1, Alfredo Fede1, Andrea Pacchioni1, Salvatore Saccò1
1Cardiologia, Ospedale Civile Mirano, Mirano, Italy, 2Cardiologia, Ospedale S. Bortolo, Vicenza, Italy

Background. Bailout stenting is preferred treatment in most centres, whereas stent implantation is generally recommended as a bailout option only, as it might increase the rate of long-term complications. In this scenario, use of directional atherectomy (DA) before DCB has been suggested to improve technical success and reduce the need for bailout stenting compared to DCB alone, but scarce data to date corroborate this hypothesis.

Methods. Eighteen consecutive patients (5 males, 13 females; mean age 74±12.7 years), affected by high-risk APE (n=4; 22.2%) or intermediate-high risk APE (n=14; 77.7%), were admitted at our institute between February 2015 and March 2017. They were treated with EKOS due to at least one of the following contraindications to systemic fibrinolysis: active bleeding (3 patients, 16.7%), recent ictus (2 patients, 11.1%), traumatic resuscitation (2 patients, 11.1%), recent major surgery (1 patient, 5.6%), known bleeding risk (presence of active cancer, advanced age, frailty, chronic kidney disease and/or hepatic insufficiency: 10 patients, 55.6%). The primary efficacy endpoints were the change from baseline to 72 hours of: the right to left ventricular dimension ratio (RVLVRV ratio); the pulmonary embolic burden assessed using the Qanadli index (Qi) and the systolic pulmonary arterial pressure (SPAP). The secondary efficacy endpoints were the changes from baseline to 72 hours in heart rate and in the percentage of arterial oxygen saturation. The primary safety endpoint was the occurrence of severe bleeding (GUSTO classification) within 72 hours. The secondary safety endpoints were the rate of moderate/mild bleeding, the mean length of stay in hospital and in intensive care unit (ICU), the in-hospital mortality and the 30-day mortality.

Results. Mean RVLVRV ratio (1.38±0.3 vs. 0.97±0.16; p<0.0005); Qi (27.0±2.6 vs. 18.8±7.8; p=0.001) and SPAP (71.1±12 mmHg vs. 45.2±16 mmHg; p=0.001) significantly decreased within 72 hours after the procedure. Also heart rate and percentage of arterial oxygen saturation significantly improved after EKOS. One patient died due to a severe bleeding. Six patients experienced moderate bleeding, 3 of them had active bleeding and low haemoglobin levels at the time of the procedure. Femoral hematoma was observed in 2 subjects. Mean length of stay in hospital and in ICU was 13±6 and 6±2.9 days respectively. An 89-year-old patient (PESI score 139), died from multiple organ failure at 12 days from the procedure. No other patients died after the discharge within 30-day follow-up.

Conclusions. EKOS is an effective tool to treat patients with APE at high or intermediate-high risk and contraindication to systemic fibrinolysis. It is a relatively safety therapy considering the critical conditions and the high bleeding risk of the receiving population.
sistema Pro-glide. All’aortografia di controllo non evidenza di spandimento di mezzo di contrasto. Veniva posizionato un PM provvisorio dalla vena femorale destra e si decideva di sottoporre la paziente ad angio-TAC di controllo che documentava presenza di anomalia vascolare dell’arteria succlavia destra che origina dall’arco aortico con decorso retroesofageo (arteria succlavia destra lussoria). Non versamento pericardico. Nelle fasi contrastografiche arteriosa e tardiva eseguite, non evidenti segni di spandimento ematico attivo. Non PNX. Discreta fala di versamento pleurico declive bilaterale, più cospicuo a destra con atletassia del parenchima polmonare contiguo. Enfisema delle parti molli latero toraciche di sinistra. Filo elettrotostimolatore che attraversa la vena cava inferiore raggiunge il ventricolo destro. Successivamente si è proceduto a tentativo di impianto del PM previa venografa con accesso periferico dal braccio sinistro fallita per impossibilità a transitare in vena succlavia per estrema esiguità del vaso con decorso tortuoso. Veniva quindi effettuato impianto senza complicanze da vena succlavia destra.

In letteratura sono descritti 4 casi di posizionamento di elettrocatetere in ventricolo sinistro a seguito di eromma puntura venosa. La reale incidenza di questa complicanza non è nota. In ogni caso il riscontro è stato tardivo ed a seguito della valutazione radiografica del torace, eseguita a distanza. Nel 75% casi si è scelto di mantenere il catetere in sede, anticoagulando ed a seguito della valutazione radiografica del torace, eseguita a distanza.

6.6% (per lesion), any ST 0.2%).

11.0% (cardiac death 1.9%, any MI 3.4%, TLR 8.4% (per patient), TLR 6.6% (per lesion), any ST 0.2%).

Conclusion. The use of Agent™ PCB during PCI appears safe and effective in a large real-world experience.

C59 TREATMENT OF BIFURCATION LESIONS WITH AGENT™ PACLITAXEL-COATED BALLOON: A REAL-WORLD MULTI-CENTRE EXPERIENCE
Gianmarco Iannopollo1, Francesco Giannini1, Francesco Ponticelli1, Beniamino Pagliaro1, Satoru Mitomo1, Ozan Demir1, Marco Ancona1, Antonio Mangieri1, Matteo Montorfano1, Mauro Carlino1, Lorenzo Azzalini1, Alaide Chieffo1, Azeem Latib1, Antonio Colombo1, Alessandro Durante2
1Unità di Cardiologia Interventistica ed Emodinamica, Ospedale San Raffaele, Milano, Italy, 2Dipartimento di Cardiologia, Ospedale Valduce, Como, Italy

Background. The Agent™ paclitaxel-coated balloon (PCB) is a new drug-coated balloon technology, with a limited real-world available data. Our study sought to assess the safety and efficacy of a new PCB during percutaneous coronary intervention (PCI) in bifurcation lesions.

Methods. All comers patients undergoing PCI with use of Agent™ PCB on bifurcation lesions in 3 Italian cites between September 2014 and March 2018 were included in this registry. Major adverse cardiac events (MACE) were defined as the composite of cardiac death, recurrent non-fatal myocardial infarction (MI), target lesion revascularization (TLR), or any stent thrombosis (ST). Procedural success was also evaluated.

Results. Among 354 patients (with 450 lesions treated with 508 PCBs) included in the registry, Agent™ PCBs were used for the treatment of in-stent restenosis, small vessel disease, bifurcation lesions and for other de novo lesions in 33.1%, 32.4%, 30.2% and 4.2%, respectively. The implant of Agent PCBs was safe and with a high final procedural success rate (99.5%). At a mean follow-up of 560 (±312) days the rate of MACE was 11.0% (cardiac death 1.9%, any MI 3.4%, TLR 8.4% (per patient), TLR 6.6% (per lesion), any ST 0.2%).

Conclusion. The use of Agent™ PCB during PCI appears safe and effective in a large real-world experience.