Comunicazioni orali

Non-coronary interventions 1

C1

LEFT ATRIAL APPENDAGE CLOSURE WITH A NOVEL DEVICE: INITIAL EXPERIENCE AND SHORT-TERM FOLLOW-UP FROM A SINGLE CENTER

Paolo Pagnotta, Mauro Chiarito, Elton Pllaha, Dennis Zavalloni Parenti, Marco Luciano Rossi, Riccardo Mantovani, Giulio Giuseppe Stefanini, Bernhard Reimers

Humanitas Clinical and Research Center, Rozzano, Milan, Italy

Aims. Left atrial appendage (LAA) closure is considered an effective option in patients with non-valvular atrial fibrillation (NVAF) and contraindications to long-term oral anticoagulant (OAC) therapy. However, there are some concerns about safety of currently available devices. Our aim is to provide an initial assessment on safety and efficacy of the novel LAA closure Ultraseal device in patients with NVAF and contraindications to long-term OAC therapy.

Methods and Results. Twelve consecutive patients with NVAF undergoing Ultraseal device implantation between July 2016 and March 2017 were included. All patients performed transesophageal echocardiography and computed tomography angiography prior to LAA closure. Procedural success was achieved in all patients except one who experienced incorrect device deployment but with complete LAA closure. Procedure duration halved from first to last procedure performed. No adverse events, including pericardial effusion, were observed during index hospitalization. At mean follow-up (168±84 days) all patients were alive and free from major bleedings and ischaemic strokes.

Conclusions. Our results suggest that the Ultraseal device is a safe and feasible option for LAA occlusion. Notably, the learning curve in this single-center experience was fast, paralleled by extremely low complication rates. These results should be considered hypothesis generating and larger studies are mandatory.

C2

PERCUTANEOUS LEFT ATRIAL APPENDAGE OCCLUSION IN PATIENTS WITH ATRIAL FIBRILLATION AND LEFT ATRIAL APPENDAGE THROMBUS: FEASIBILITY, SAFETY AND CLINICAL EFFICACY

Gianpiero D'Amico[1], Tommaso Fabris[1], Xavier Freixa[2], Ignacio Cruz-Gonzalez[3], Federico Ronco[4], Salvatore Sacca[5], Gaetano Fassini[6], Anna Maltagliati[6], Daniela Trabattoni[6], Azeem Latib[7], Matteo Montorfano[7], Patrizio Mazzone[8], Damiano Regazzoli[7], Reda Ibrahim[9], Chiara Fraccaro[1], Massimo Napodano[1], Giuseppe Tarantini[1]

[1]Cardiology Unit, Department of Cardiac, Thoracic and Vascular Sciences, University of Padua Medical School, Padova, Italy, [2]Department of Cardiology, Hospital Clinic of Barcelona, University of Barcelona, Barcellona, Spain, [3]University Hospital of Salamanca, Salamanca, Spain, [4]Cardiovascular Department, Interventional Cardiology, Ospedale dell'Angelo, Mestre-Venezia, Italy, [5]Cardiovascular Department, Mirano Public Hospital, Mirano, Italy, [6]Department of Cardiovascular Sciences, University of Milan, Centro Cardiologico Monzino, IRCCS, Milano, Italy, [7]Interventional Cardiology Unit, San Raffaele Scientific Institute, Milano, Italy, [8]Arrhythmia Unit and Electrophysiology Laboratories, San Raffaele Scientific Institute, Milano, Italy, [9]Montreal Heart Institute, University of Montreal, Montreal, Canada

Background. The presence of left atrial appendage (LAA) thrombus despite appropriate antithrombotic therapy or in patients with contraindication to systemic oral anticoagulants put these patients are at high-risk of embolic complications.

Objective. To investigate the feasibility, safety and efficacy of percutaneous closure for prevention of thromboembolic events in patients with atrial fibrillation (AF) and LAA thrombus.

Methods. The study included consecutive patients with AF and LAA thrombus that underwent transcatheter occlusion in 8 high-volume centers. Collected data from each center were transferred to a dedicated database and analyzed retrospectively. Clinical follow-up was carried as per center protocol. Transesophageal echocardiography (TEE) follow-up was performed according to the protocol of each center or if clinically indicated.

Results. A total of 28 patients were included in the study. Technical and procedural success was achieved in all patients. A cerebral protection device was used in 6 cases. There were no periprocedural adverse events. Follow-up was complete in 26/28 (92.9%) of patients (median 334 days [interquartile range 106-694 days], total 31.5 patient-years). No death at follow-up was reported as device-related. No death or thromboembolic events were reported. There was one major bleeding during follow-up. Among the 23 patients undergoing TEE follow-up (82.1% of cases), device thrombosis was present in one patient (4.3% of evaluated patients). No significant peri-device leaks were observed, while minor leaks were found in 2 patients (8.7%).

Conclusion. In this multicenter study, percutaneous closure in patients with LAA thrombus is feasible and safe, being associated with high procedural success and a favorable outcome for the prevention of AF-related thromboembolism. Special implant techniques avoiding mechanical mobilization of the thrombotic mass or use of cerebral embolic protection device may be advisable.

C3

IL TRAUMA ADDOMINALE COME URGENZA VASCOLARE

Valentina Maria Rossano, Vito Alberotanza, Annarita Milella, Laura Gabrieli, Rocco Virelli, Cristian Dell'Atti

Radiodiagnostica Universitaria, Policlinico, Bari, Italy

Scopo. Gestire in regime d'urgenza un trauma addominale nel caso in cui vi sia controindicazione all'intervento chirurgico.

Materiali e metodi. Lo studio è stato eseguito su un paziente di 15 anni, politrauma della strada, affetto da tromboastenia di Glanzmann, un disordine auotosomico recessivo che determina una ridotta aggregazione piastrinica e pertanto una maggiore facilità al sanguinamento. Alla TC addome, si evidenzia la presenza di un focolaio contusivo-lacerativo in corrispondenza del V-VI segmento epatico, nel cui contesto, in fase portale, pare evidenziarsi un piccolo spandimento di mdc. Il paziente rapidamente va incontro a shock emodinamico e viene dunque riportato in sala rossa, intubato e stabilizzato emodinamicamente. Si richiede consulenza chirurgica, che controindica al trattamento chirurgico a causa della patologia di base del paziente, per l'elevato rischio di morte intraoperatoria. Pertanto si richiede un'angiografia addominale per embolizzazione del sanguinamento. Sotto sedazione e monitoraggio emodinamico, si comincia lo studio angiografico: si effettua accesso femorale destro 5F e mediante un catetere diagnostico tipo pigtail si esegue l'aortografia, che dimostra la presenza di vasi sottili e spasmizzati, ma non si evidenziano chiari spandimenti di mdc. Tuttavia, a livello del circolo arteriolo-capillare si osserva una irregolarità con microspot emorragici in corrispondenza del V-VI segmento epatico. La fase parenchimografica dimostra una dissociazione del profilo epatico dalle coste, con il fegato che appare schiacciato e dislocato medialmente. Si procede pertanto ad una ecografia, eseguita durante la procedura con l'ecografo presente in sala angiografica, che evidenzia la presenza di un ematoma periepatico sottocapsulare in varie fasi di organizzazione, con diffusa disomogeneità strutturale del parenchima epatico.

Risultati. Previo microcateterismo selettivo dell'arteria epatica destra mediante microcatetere Progreat, si procede a bland embolization dei rami epatici afferenti al lobo destro con particelle riassorbibili di Spongostan. Ai controlli finali si documenta un aspetto ad albero potato dei vasi, con ridotto apporto vascolare alla fonte di sanguinamento. Si effettua un controllo TC post-procedurale che evidenzia un parenchima epatico compresso dall'ematoma sottocapsulare con piccole aree ipodense post-infartuali, ma non spandimenti attivi di mdc.

Conclusioni. In questo caso l'angiografia ha rivestito un ruolo importante nella diagnosi, documentando l'evoluzione del quadro clinico del paziente. L'embolizzazione dell'arteria epatica destra è stata cautelativa, con l'obiettivo di ridurre l'afflusso ematico all'interno della raccolta, data anche la patologia di base del paziente, che ha causato una più accentuata sindrome emorragica post-trauma.

C4

MID-TERM EFFICACY AND SAFETY OF LEFT ATRIAL APPENDAGE OCCLUSION VERSUS STANDARD MEDICAL CARE WITH DOACS IN PATIENTS WITH ATRIAL FIBRILLATION

Barbara Bellini[1], Cosmo Godino[1], Michela Cera[1], Francesco Melillo[1], Luca Arrigoni[1], Francesca Rubino[1], Anna Salerno[1], Carlo Andrea Pivato[1], Mattia Mazzucca[1], Damiano Regazzoli[2], Filippo Figini[2], Paolo Mattiello[3], Alberto Cappelletti[1], Matteo Montorfano[2], Patrizio Mazzone[4], Paolo Della Bella[4], Alberto Margonato[1], Antonio Colombo[2]

[1]Cardiology Unit, San Raffaele Scientific Institute, Milano, Italy, [2]Interventional Cardiovascular Unit, San Raffaele Scientific Institute, Milano, Italy, [3]Data Analyst, Database and Data Warehouse Specialist, San Raffaele Scientific Institute, Milano, Italy, [4]Arrhythmia and Electrophysiology Unit, San Raffaele Scientific Institute, Milano, Italy

Background. Direct oral anticoagulants (DOACs) are the mainstay of the stroke prevention in patients with atrial fibrillation (AF). Nonetheless, in

the real-world there is still a relevant amount of patients who cannot benefit of this therapy because ineligible for any oral anticoagulant due to previous major bleeding or because at high bleeding risk. Left atrial appendage occlusion (LAAO) may be an option for these patients. We sought to evaluate at a mid-term follow-up the efficacy and safety of LAAO in prevention of thromboembolism as compared to standard medical therapy with DOACs in this setting.
Methods. All consecutive patients with non-valvular AF who underwent a successful LAAO (between July 2009 and October 2016) or started a DOAC (between June 2011 and December 2015) at San Raffaele Hospital were enrolled. The primary combined efficacy and safety endpoint was a composite endpoint of systemic thromboembolism (including ischemic stroke and transient ischemic attack) and TIMI major bleedings. The efficacy endpoint (ischemic stroke and TIA) and the safety endpoint (TIMI major bleedings) were also analyzed separately as secondary endpoints.
Results. A total of 935 patients were included (LAAO group n=274, DOACs group n=661). Patients in LAAO group had higher prevalence of diabetes (27.7% vs 18.2%; p=0.001), chronic kidney disease (9.7% vs 0.7%; p<0.001), coronary artery disease (33.9% vs 25.3%; p=0.007), previous ischemic stroke (25.5% vs 11.6%; p<0.001) and previous major bleeding (57.7% vs 12.7%; p<0.001) and had significantly higher CHA_2DS_2-VASc (3.8±1.6 vs 3.5±1.8; p=0.006) and HAS-BLED score (3.6±1.4 vs 2.0±1.0; p<0.001). Median follow-up time was 544 days (25%/75% quartile: 342/806 days).
The primary efficacy and safety endpoint occurred in 14 patients (5.4%) in the LAAO group and in 21 patients (3.5%) in the DOACs group and it was not statistically different between the two groups (p=0.189, Mantel-Cox test). Similarly, no significant difference in terms of thromboembolic events (3.8% vs. 1.5%, p=0.107) and TIMI major bleedings (2.3% vs 1.7% p= 0.51) were observed between the two groups.
Conclusion. Although patients in the LAAO group were at higher risk of both thromboembolic and bleeding events, the primary combined efficacy and safety endpoint was comparable to that of DOACs group. The LAAO procedure can be considered a safe and effective alternative indication in this high risk setting of patients with AF.

C5

INCIDENCE OF LONG-TERM STRUCTURAL VALVE DYSFUNCTION AND BIOPROSTHETIC VALVE FAILURE AFTER TRANSCATHETER AORTIC VALVE REPLACEMENT

Marco Barbanti, Giuliano Costa, Paolo Zappulla, Denise Todaro, Andrea Picci, Giulia Rapisarda, Emanuela Di Simone, Rita Sicuso, Sergio Buccheri, Simona Gulino, Gerlando Pilato, Ketty La Spina, Paolo D'Arrigo, Roberto Valvo, Danilo Trovato, Antonino Indelicato, Daniela Giannazzo, Sebastiano Immè, Claudia Tamburino, Martina Patanè, Carmelo Sgroi, Angelo Giuffrida, Wanda Deste, Piera Capranzano, Davide Capodanno, Corrado Tamburino
Divisione di Cardiologia, PO Ferrarotto, Azienda Policlinico Vittorio Emanuele, Catania, Italy

Background. Long-term data on durability of currently available transcatheter heart valves are sparse. We sought to assess the incidence of long-term (8-year) structural valve dysfunction (SVD) and bioprosthetic valve failure (BVF) in a cohort of transcatheter aortic valve replacement (TAVR) patients who reached at least 5-year follow-up.
Methods and Results. Consecutive patients with at least 5-year follow-up available undergoing TAVR from June 2007 to March 2012 were included. SVD and BVF were defined according to newly standardized EAPCI-ESC-EACTS criteria and reported as cumulative incidence function (CIF) to account for the competing risk of death. A total of 288 consecutive patients with a mean age of 80.7±5.3 years and with a mean STS-mortality score of 8.1±5.1% were analyzed. Survival rate at 8 years was 29.8%. Mean pressure gradients decreased from 53.3±15.9 mmHg (pre-TAVR) to 10.5±4.5 mmHg (in-hospital post-TAVR) (P<0.001). There was a small increase in the transaortic gradient at 5 years (13.5±8.6 mmHg, p=0.048 compared with post-TAVR), which remained steady at 8 years (12.4±6.6 mmHg). BVF was observed in a total of 11 patients (8-year CIF: 4.51%, 95%CI 1.95-8.76). Severe and moderate SVD was reported in 7 patients (8-year CIF 2.39%, 95%CI 0.77-5.71) and 13 patients (8-year CIF 5.87%, 95%CI 3.06-9.96) respectively. Aortic valve re-intervention (redo TAVR) was successfully performed in 2 patients (0.7%) presenting with symptomatic severe restenosis and intraprosthetic regurgitation subsequent to endocarditis.
Conclusions. In an aged population of patients with symptomatic severe AS treated with first-generation bioprostheses, TAVR was associated with a survival rate of 30% but very low rates of bioprosthetic valve failure and structural valve dysfunction at 8 years.

C6

SEVEN YEARS (2010-2016) OF TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI) EXPERIENCE: SHORT AND LONG-TERM OUTCOMES

Francesca Giordana[1], Francesco Bruno[1], Claudio Moretti[1], Maurizio D'Amico[1], Fabrizio D'Ascenzo[1], Stefano Salizzoni[2], Pierluigi Omedè[1], Mauro Rinaldi[2], Fiorenzo Gaita[1]
[1]Division of Cardiology, Città della Salute e della Scienza, University of Turin, Turin, Italy, [2]Division of Cardiac Surgery, Città della Salute e della Scienza, University of Turin, Turin, Italy

Background. Nowadays TAVI is a consolidated therapeutic option for high-risk patients with symptomatic aortic stenosis. Thanks to the developments of technology and the increase of operators' expertise, the rate of overall mortality and complications are expected being decreasing over time. We aim to show how short and long-term outcomes are evolved from 2010 to 2016, assessing the learning curve.
Methods. All the patients underwent TAVI between 2010 and 2016 in our Center were enrolled. They were divided into two groups according to the year of procedure (from 2010 to 2012-group 1, from 2013 to 2016-group 2). 30 days and long term mortality, VARC II peri-procedural complications and TAVI clinical efficacy were compared in the two groups.
Results. 288 patients were enrolled. Mean age 82±7, 58% female, mean Log EuroSCORE I 21±13% and STS score 8±5%. At the baseline, the differences between the two groups were: hypertension (p=0.004), severe BPCO (p=0.003), creatinine (p=0.02), syncope (p=0.007), NYHA III class (p=0.003) and functional aortic area (p=0.02). 170 CoreValve, 104 Edwards Sapien, 10 Engager and 4 Lotus were implanted. 30-days VARC mortality was 6.3% (9% group 1 vs 5% group 2, p=0.33), with a device failure of 11.8% (12% vs 11%, p=0.9). Life threatening and major bleeding were 19.5% (23% vs 17%, p=0.34), major vascular complications 14.2% (19% vs 13%, p=0.19), stroke 3.8% (5% vs 3%, p=0.87). Mean follow-up was 776±621 days, median 674 days. One-year overall and cardiovascular survival was 80% and 90%, respectively, 57% and 82% at 3 years, 32% and 74% at 5 years. Between the two groups, a trend of improvement both in overall (1 year: 72% vs 83%; 3-year 50% vs 64%, p=0.01) and cardiovascular (1 year: 87% vs 93%; 3-year 78% vs 86%, p=0.03) survival was registered. At the multivariate analysis, independent predictors of long-term mortality at 1 year and 3 years were VARC device failure (HR 3.2, 95% CI 1.3-7.7; HR 2.6, 95% CI 1.3-5.1), stroke (HR 8.1, 95% CI 3.4-19; HR 6.4, 95% CI 3-13.7), VARC life-threatening and major bleeding (HR 3.5, 95% CI 1.9-6.7; HR 2.6, 95% CI 1.6-4.2), VARC major vascular complications (HR 2.5, 95% CI 1.3-4.9; HR 1.7, 95% CI 1.02-3.1). Post-TAVI aortic insufficiency (HR 2.3, 95% CI 1.1-4.8) and non-transfemoral access site (HR 1.8, 95% CI 1.1-2.9) were predictor factors only at 3 years. VARC clinical efficacy at 30 days, 1 year and 3 years was 74%, 66% and 46%, respectively. A trend of improvement (p for trend <0.001) in clinical efficacy at 30 days was registered from 2010 to 2016 with a difference between group 1 and group 2 (55% vs 85%, p<0.001).
Conclusions. In the landmark analysis of our population, we found a trend of improvement between the first (2010-2012) and the second (2013-2016) group of patients in short-term outcomes, both procedural and clinical, and a significant improvement in long-term overall and cardiovascular survival. Thanks to technology development, operators' expertise and better patient selection, TAVI could also be available for intermediate and maybe low-risk patients.

C7

FEASIBILITY AND SAFETY/EFFICACY PROFILE OF THE PERCUTANEOUS PATENT FORAMEN OVALE CLOSURE WITH THE NOBLESTITCH™ SYSTEM

Anca Irina Corciu, Federico De Marco, Maurizio Tusa, Lucrezia Delli Paoli, Luca Testa, Francesco Bedogni
IRCCS Policlinico San Donato, San Donato Milanese, Italy

Introduction. Percutaneous closure of patent foramen ovale (PFO) is a valid treatment for selected patients with paradoxical embolism; it is relatively safe, with a major complication rate between 0.2% and 1.5%, such as device embolization and erosion, endocarditis, and thrombosis. Newer percutaneous devices and smaller catheters have led to a decrease in reported major and minor complications. Some of these complications could be avoid using the new available percutaneous technique, NobleStitch™, a suture based closure system with no permanent metal implants and no need for the dual antiplatelet therapy.
Aim. To assess the feasibility, safety and very short-term efficacy of percutaneous PFO closure using the NobleStitch™ system.
Methods: 27 consecutive patients (mean age 47±10 years, 10 females) with clinical indication to PFO closure went through the procedure using the NobleStitchTM system. All patients underwent: 1) pre-procedural evaluation (clinical, imaging); 2) percutaneous procedure in general anaesthesia under transesophageal echocardiographic (TEE) guidance; 3) follow up evaluation at 1 month after the procedure (clinical and microbubbles ultrasound: transthoracic echocardiography and transcranial Doppler-TCD).
Results. The main indications to the PFO closure were represented by transient ischemic attack in 15 patients (57.7%), cryptogenic stroke in 8 patients (30.77%), decompression sickness in professional diving in 2

patients (7.7%), and disabling migraine with aura in 1 patient (3.8%). Successful device deployment was obtained in 26 patients (96.3%), with one failure due to interatrial septum anatomy (increased thickness). No major intraprocedural complications were observed. An acute atrial fibrillation onset during the procedure was registered. The end-procedure TEE with microbubbles showed 1 trivial spontaneous shunt and 7 mild provoked shunts (26.9%). At 1 month from the procedure, no clinical events and no spontaneous shunts were registered; a trivial provoked shunt during TCD in 6 patients was observed.
Conclusions. To our knowledge this is the first study demonstrating that the new percutaneous NobleStitch™ system is feasible and safe, with a good short-term efficacy profile. The new system represents a promising tool for the percutaneous PFO closure and could possibly be associated with less long-term complications.

Miscellaneous 1

C8

CLINICAL PERFORMANCE OF A DEDICATED SELF-EXPANDABLE STENT FOR THE TREATMENT OF LEFT MAIN STEM DISEASE. RESULTS OF THE LEFT MAIN ANGIOPLASTY WITH A SELF-APPOSING STENT-THE MATISSE STUDY

Bernardo Cortese[1], Antonio Montefusco[2], Fabrizio D'Ascenzo[2], Alessio La Manna[3], Giuseppe Andò[4], Teodoro Bisceglia[5], Gioel Secco[6], Markus Meyer-Gessner[7], Wanha Wojciech[8], Paolo Sganzerla[9], Massimo Napodano[10], Gaetano di Palma[1], Corrado Tamburino[3], Pedro Silva Orrego[1], Andreas Baumbach[11]
[1]ASST Fatebenefratelli Sacco, Milano, Italy, [2]Dipartimento di Scienze Mediche, Divisione di Cardiologia, Città della Salute e della Scienza, Torino, Italy, [3]Division of Cardiology Ferrarotto Hospital, University of Catania, Catania, Italy, [4]University of Messina, Messina, Italy, [5]Santa Maria della Misericordia Hospital, Udine, Italy, [6]Santi Antonio e Biagio e Cesare Arrigo Hospital, Alessandria, Italy, [7]Department of Cardiology and Intensive Care, Augusta Hospital, Düsseldorf, Germany, [8]Division of Cardiology, Medical University of Silesia, Katowice, Poland, [9]ASST Bergamo Ovest, Ospedale Treviglio Caravaggio, Treviglio, Italy, [10]Department of Cardiac, Thoracic and Vascular Sciences, School of Medicine, University of Padova, Padova, Italy, [11]Department of Cardiology, St Bartholomew's Hospital, William Harvey Research Institute, and Queen Mary University of London, London, UK

Aims. In the recent years percutaneous treatment of the left main (LM) has gained a precise role thanks to consistent scientific evidence vs. coronary artery bypass. A self-expandable stent offers an improved adaptation to the vessel wall, especially in case of tapered vessels; aim of this study was to investigate the role of Stentys (STENTYS, France) for the treatment of LM coronary artery disease.
Methods and Results. MATISSE is a retrospective, spontaneous, multicenter registry, which enrolled 151 patients at 17 international centers, treated with a the self-expanding sirolimus-eluting Stentys at LM. Co-primary endpoints were procedural success and device-oriented adverse cardiac events (DOCE), a composite endpoint of cardiac death, target lesion revascularization (TLR) and target-vessel myocardial infarction, with at least 6-month clinical follow-up. Lesions were located in distal LM bifurcation in 84% of patients. Procedural success was achieved in 150 patients. The average follow-up length was 239±161 days. DOCE occurred in 6.9% of patients with 2 (1.3%) cardiac deaths. TLR occurred in 7 patients (4.6%). In 2 cases occurred definite stent thrombosis, 1 acute and 1 late. The multivariate analysis showed a not significant trend toward an increase in DOCE in patients that did not receive postdilatation.
Conclusions. A self-expandable stent, when used for LM PCI in a real world, high risk population, showed good immediate procedural results with low rates of adverse events at mid-term follow-up.

C9

OPTICAL COHERENCE TOMOGRAPHY IN ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION WITH BIORESORBABLE SCAFFOLD: IS IT SAFE AND USEFUL? A SUBSTUDY FROM THE PRAGUE 19 TRIAL

Marco Loffi[1], Petr Tousek[2], Tomas Budesinsky[2], Libor Lisa[2], Petr Widimsky[2], Viktor Kocka[2]
[1]Cardiology Clinic, UO Malattie Cardiovascolari, Fondazione IRCCS, Ospedale Maggiore Policlinico, University of Milan, Milan, Italy, [2]Cardiocenter, Third Faculty of Medicine, Charles University, Prague and University Hospital Kralovske Vinohrady, Prague, Czech Republic

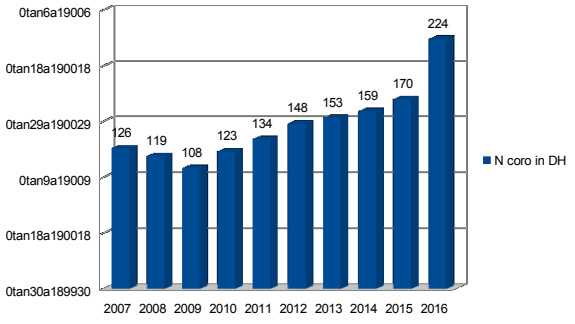
Background. Optical coherence tomography (OCT) is an innovative technique for optimization of coronary stenting and it has been validated in stable and elective patients. Only few data in ST-elevation myocardial infarction (STEMI) are available and coronary flow after OCT is not well studied yet. This study assessed the epicaridal coronary flow before and after OCT, the safety of OCT and its role in STEMI after bioresorbable scaffold implantation.
Methods. Patients enrolled into prospective Prague 19 trial in our hospital were divided into 2 groups: 54 patients with OCT performed at the end of procedure (OCT group) and 22 control patients without OCT (no OCT group). OCT was performed on academic grounds and optimization was left to operator decision. Retrospective analysis of angiographic, in-hospital laboratory and clinical data was performed.
Results. Concerning the flow, small, but significant increase in TIMI frame count was observed (from 9.5 (6.75-12.25) to OCT 11.5 (8-15.25), p=0.001) and, this finding, was supported by higher verapamil administration in the OCT group than in the control group (18.5% vs 0% of the patients; p=0.025). OCT required larger amount of contrast agent (173±32 mL vs 147±37 mL; p=0.004) and procedure time also increased (46.7±11.4 min vs 33±11.7 min, p=0.001). The overall number of procedural complications was not different. In only 9% of patients OCT led to change of strategy.
Conclusion. OCT at the end of primary PCI is a feasible procedure with only small increase in contrast load and procedural time. However, it seems to be associated with transient flow deterioration. The optimization, left to operator decision, was infrequent. We suggest a selective use of this technique in STEMI setting.

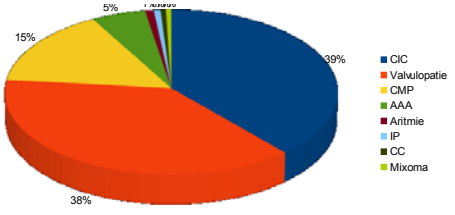
C10

CORONAROGRAFIA IN DAY-HOSPITAL: ESPERIENZA DI 10 ANNI

Mila Menozzi, Andrea Santarelli, Nicoletta Franco, Federica Baldazzi, Caterina Cavazza, Michele Ruffini, Domenico Santoro, Daniele Grosseto, Giancarlo Piovaccari
Cardiologia, Ospedale Infermi, Rimini, AUSL Romagna, Italy

Introduzione. L'accesso radiale nell'esecuzione dell'esame coronarografico ha portato enormi vantaggi in termini di riduzione delle complicanze vascolari, precoce mobilizzazione del paziente, riduzione dei tempi di degenza. Ci sono tuttavia poche esperienze sulle coronarografie in regime di day hospital (DH). Lo scopo del nostro lavoro è stato valutare retrospettivamente la popolazione dei nostri pazienti sottoposti ad esame coronarografico in DH, in particolare riguardo alla sicurezza del percorso in DH.
Materiali e metodi. Nel 2007, anno di inizio delle coronarografie con accesso radiale nel nostro Laboratorio, presso la Cardiologia dell'Ospedale Infermi di Rimini, abbiamo iniziato a studiare i pazienti con coronarografie in regime di DH. Abbiamo raccolto i dati di 10 anni fino al 31/12/2016. Tutti i casi sono stati effettuati tramite accesso radiale. Per incannulare l'arteria radiale abbiamo utilizzato l'introduttore radiale Radifocus (Terumo®) 6 FR 10 cm. È stato somministrato di routine un bolo di 2500 UI di UFH, 2.5 mg di verapamil i.r. e 2.5 mg di isosorbide dinitrato i.r. L'emostasi è stata ottenuta con sistema TR Band (Terumo®). Tutti i pazienti hanno eseguito un prelievo ematico pre-procedura per la valutazione dell'emocromo, la coagulazione e la funzione renale.
Risultati. Dal 2007 al 2016 sono stati sottoposti ad esame coronarografico in DH 1473 pazienti. Di questi 176 (12%) erano follow-up angiografici di angioplastiche del tronco comune (effettuati fino al 2014). L'età media dei pazienti era 70±10 anni. Circa un terzo dei pazienti era di sesso femminile (n=520). Sono stati esaminati 568 pazienti con cardiopatia ischemica cronica (CIC), 561 pazienti con valvulopatie, 224 pazienti con cardiomiopatia di cui 209 con cardiomiopatia dilatativa (CMPD), 81 pazienti con aneurisma dell'aorta ascendente (AAA), 13 pazienti (0.9%) aritmici, 10 pazienti (0.7%) con ipertensione polmonare (IP, sottoposti anche a cateterismo cardiaco dx), 8 pazienti (0.5%) con cardiopatie congenite (CC), 8 pazienti (0.5%) con mixoma. In 182 casi (12.3%) è stata eseguita angioplastica coronarica (PCI) con la sola





Cardioaspirina on board e somministrazione del carico del secondo antiaggregante al termine della procedura. Di questi la maggior parte dei pazienti sono stati sono stati trasferiti in reparto di cardiologia e dimessi il giorno successivo alla procedura. Solo 10 pazienti trattati con PCI (5.5% delle PCI) sono stati dimessi direttamente da DH. Tutti i pazienti sottoposti a coronarografia sono stati dimessi il giorno stesso della procedura. Non si sono registrati casi di complicanze maggiori legate al sito di accesso vascolare né di insufficienza renale acuta.
Conclusioni. La coronarografia in DH oltre ad essere un esame sicuro e ben accettato dal paziente presenta degli enormi vantaggi in termini di ottimizzazione delle risorse, in particolare con un aumento della disponibilità dei posti letto in regime di degenza ordinaria, nell'attuale contesto della loro continua contrazione, e riduzione delle liste di attesa per la coronarografia che non necessita della disponibilità di un posto letto per essere eseguita.

C11

PERCUTANEOUS VERSUS SURGICAL REVASCULARIZATION FOR LEFT MAIN OR MULTIVESSEL CORONARY ARTERY DISEASE: A META-ANALYSIS OF 7 RANDOMIZED TRIALS

Monica Verdoia[1], Lucia Barbieri[2], Harry Suryapranata[3], Giuseppe De Luca[1]
[1]Azienda Ospedaliera-Universitaria "Maggiore della Carità", Università del Piemonte Orientale, Novara, Italy, [2]Ospedale S. Andrea, Vercelli, Italy, [3]UMC St Radboud, Nijemegen, Netherlands

Background. Whether percutaneous or surgical revascularization represent the best treatment options for complex coronary anatomies, as left main (LM) or multivessel coronary disease (MVD), is still a debated matter, and uncertainty still remains after that trials with newer generations of drug eluting stents (DES) have been conducted. Aim of present study was to perform a meta-analysis of randomized trials comparing percutaneous vs surgical revascularization for LM or MVD.
Methods. Literature archives (MEDLINE, Cochrane and EMBASE) and main scientific sessions were scanned. Primary efficacy endpoint was long-term overall mortality. Secondary endpoints were major adverse cardiovascular events, recurrent myocardial infarction, repeated revascularization or stroke at maximum follow-up available.
Results. A total of 8 randomized trials were finally included, involving 8694 patients, 50% undergoing PCI. At a mean follow-up of 39.7 months, mortality rate was 8.2%, with no difference for PCI vs CABG (OR[95%CI]=1.18[0.90;1.55], p=0.24, p_{het}=0.01). However, a significant interaction was observed between revascularization strategy and coronary anatomy, with results slightly favouring CABG for MVD (OR[95%CI] =1.54[1.12;2.13], p=0.008, p_{het}=0.14), while resulting non-inferior in LM disease (OR[95%CI]= 0.88[0.60;1.29], p=0.50, phet=0.10, p interaction =0.03). No impact on mortality was observed according to patients' risk profile, the rate of diabetic patients or the occurrence of cardiovascular or cerebrovascular complications. A similar benefit with bypass surgery was also observed in terms of repeated coronary revascularization. On the contrary, PCI was associated with a significant reduction in the rate of stroke (OR[95%CI]=0.64[0.48;0.85], p=0.002, p_{het}=0.80).
Conclusions. Current meta-analysis shows that surgical coronary revascularization still offers advantages in survival and recurrent ischemic events as compared to PCI with drug-eluting stents in patients with multivessel disease, although being burdened by an increased risk of stroke. However, in trials on left main coronary disease, CABG did not provide benefits in mortality and major adverse cardiac events, but was associated with a higher risk of stroke as compared to percutaneous revascularization. Future additional large randomized trials are certainly needed with new generation DES.

C12

RESULTS AND OUTCOME PREDICTORS OF IMPELLA-PROTECTED PCI IN HIGH-RISK PATIENTS: A TWO-CENTRE EXPERIENCE

Giulio Russo[1], Francesco Burzotta[1], Flavio Luciano Ribichini[2], Anna Piccoli[2], Domenico D'Amario[1], Lazzaro Paraggio[1], Leonardo Previ[1], Gabriele Pesarini[1], Italo Porto[1], Antonio Maria Leone[1], Giampaolo Niccoli[1], Cristina Aurigemma[1], Diana Verdirosi[1], Carlo Trani[1], Filippo Crea[1]
[1]Università Cattolica del Sacro Cuore, Fondazione Policlinico Gemelli, Roma, Italy, [2]Università di Verona, Verona, Italy

Aims. To assess clinical results and outcome predictors in high-risk (HR) patients undergoing percutaneous coronary intervention (PCI) with percutaneous Impella-pump protection (pIMP).
Methods. We retrospectively identified consecutive patients who underwent elective PCI with pIMP in two Italian high-volume tertiary centers. Myocardial revascularization extent achieved was graded using the revascularization index (RI), obtained by comparing the British Cardiovascular Intervention Society jeopardy score (BCIS-JS) before and after PCI. Post-procedural left ventricle ejection fraction (LVEF) at the longest available echocardiographic follow-up examination was recorded and compared with pre-PCI. Clinical outcome at the longest available follow-up was recorded and all-cause mortality constituted the primary study endpoint.
Results. A total of 86 patients, with both stable or unstable coronary artery disease underwent pIMP PCI were identified. Mean EuroSCORE was 9±3, mean Syntax score was 31±10 and mean BCIS-JS score was 10±2. All patients were treated by PCI with full percutaneous (hemostasis attempted using suture-device preclosure technique) IMP support using 2.5 (n=74; 86%) or CP pumps (n=12; 14%). Mean RI was 0.7±0.2. After a mean follow-up time of 14 months, 77 patients were alive (all-cause mortality: 10.5%). Overall, LVEF significantly improved from 31±9% to 39±9% (p<0.001). an higher RI was significantly associated with LVEF improvement (p=0.002) and independently predicted survival (p=0.045).
Conclusions. The results of the present real-world registry support the safety and feasibility of pIMP PCI to manage HR patients. In this cohort, pIMP PCI was associated with significant EF improvement and wider revascularization extent was associated with better survival.

C13

ADHERENCE TO GUIDELINE RECOMMENDATIONS FOR OPTIMAL TIMING OF CORONARY ANGIOGRAPHY IN NSTEMI PATIENTS: FEASIBILITY AND IMPACT ON SURVIVAL

Rita Belfiore[1], Fauzia Vendrametto[2], Eugenio Cervesato[2], Franco Macor[2], Andrea Cocciolo[2], Guglielmo Bernardi[2]
[1]Dipartimento Cardiovascolare, Azienda Ospedaliero-Universitaria "Ospedali Riuniti", Trieste, Italy, [2]SC Cardiologia, AAS 5 "Friuli Occidentale", Pordenone, Italy

Background. Risk profile at presentation in patients (pts) diagnosed with non-ST-segment elevation myocardial infarction (NSTEMI) is the key point to set the proper timing for coronary angiography (CA). Urgent CA (<2h) is to be performed in pts with hemodynamic or arrhythmic instability. An early invasive strategy (<24 h) is recommended in pts with a GRACE score over 140. CA can be delayed (within a 72 h window) in pts considered at intermediate risk (GRACE score >109 and ≤140).
Methods. We carried out an "internal audit" at our Institution to assess actual adherence to current guidelines recommendations for CA in a cohort of 403 pts discharged from the Cardiology Department of our Institution with a diagnosis of type I, II or III NSTEMI. Pts were divided into 3 groups according to their ischemic risk profile at the time of the index event (very high, high and intermediate risk, estimated with GRACE risk score 2.0 calculator). The aim of our study was to evaluate if strict adherence to current guidelines recommendations was a critical element in affecting both short and mid-term outcome.
Results. In a cohort of 403 pts diagnosed with NSTEMI, 367 pts (91.1%) were scheduled for CA. These pts were further divided into 3 groups according to their ischemic risk profile at presentation. Ninety-nine pts (27%) had a GRACE score >109 and ≤140, 178 pts (48.5%) had a GRACE score >140 and just one patient (0.3%) was considered at very high risk and, therefore, addressed to cath lab within 2 h from hospital admission. Among pts at intermediate risk, the vast majority (68.7%) underwent CA within 72 h. On the opposite, only 32 pts (18%) with a GRACE score >140 were studied on time. Pts at high risk, in whom CA was not performed in the recommended temporal window, had a higher rate of major cardiovascular events (MACEs) at the end of follow-up (30.1% vs 6.3%, p=0.01). Similarly, pts with a GRACE score >109 and ≤140 who underwent CA beyond 72 h had a relative increase in MACEs at the end of follow-up, without, though, a statistically significant difference (19.4% vs 7.4%, p=0.1).
Conclusions. Strict adherence to current guidelines recommendations for optimal timing of CA in NSTEMI pts seems to be crucial for survival free from events in this real-life series. This is mostly true for pts considered at high risk at presentation. Nevertheless, pts in whom CA was delayed may had co-morbidities or adjunctive risks not captured by GRACE score (i.e. hemorrhagic risk), thus preventing treatment in the expected times.

C14

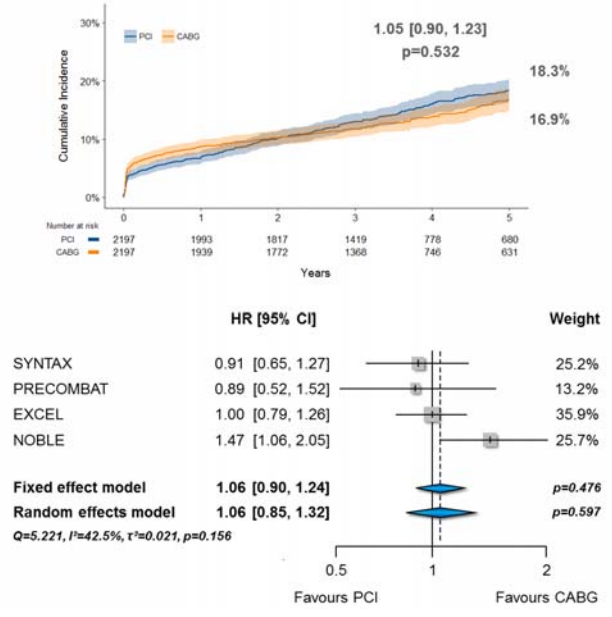
PERCUTANEOUS CORONARY INTERVENTION WITH DRUG-ELUTING STENT VERSUS CORONARY ARTERY BYPASS GRAFTING FOR LEFT MAIN CORONARY ARTERY DISEASE: A META-ANALYSIS OF LONG-TERM SAFETY OUTCOMES COMPLEMENTED WITH INDIVIDUAL PATIENT DATA RECONSTRUCTION

Daniele Giacoppo, Roisin Colleran, Salvatore Cassese, Antonio H. Frangieh, Jens Wiebe, Michael Joner, Heribert Schunkert, Adnan Kastrati, Robert A. Byrne
Deutsches Herzzentrum München, Munich, Germany

Background. As compared with other anatomic sites, left main coronary artery (LMCA) disease is associated with the highest risk of mortality and myocardial injury. Coronary artery bypass grafting (CABG) has been the standard of care for LMCA disease for a long time, but due to significant advances in device technology, increased operators' expertise, and development of a modern adjuvant medical therapy, percutaneous coronary intervention (PCI) has emerged as valid alternative. We aimed to assess safety PCI with drug-eluting stent (DES) and CABG at very long-term follow-up.
Methods. We searched main PubMed, ScienceDirect, Scopus, EMBASE and Web of Knowledge electronic databases from December 18th, 2001 to

December 1st, 2016. No filters or language restrictions were applied. We included trials fulfilling all the following criteria: (i) randomised clinical trial; (ii) PCI versus CABG; (iii) exclusive use of DES; iv. clinical follow-up ≥3 years. The primary endpoint was defined as a composite of all-cause death, myocardial infarction, or stroke. Secondary endpoints were individual components of the primary endpoint. We digitised Kaplan-Meier curves for each trials by using high-quality figures with extreme magnification. Retrieved spatial information of curves was pooled across trials according to the treatment, either PCI or CABG. Combined data, number at risk, and number of events for each time interval (year of follow up) were used to estimate survival function and time-to-first event cumulative incidence by validated algorithm. According to a one-stage individual patient data meta-analysis, risk between PCI and CABG was computed shared frailty model accounting for clustering of patients across trials with semi-parametric penalized likelihood estimation of the hazard function. Cross-validation of results was performed according to standard trial-level fixed- and random-effects meta-analysis of log hazard ratio (HR) and corresponding standard error. Risk measures were expressed as HR and 95% confidence interval (CI). Heterogeneity across trials was assessed with between-trial variance τ^2 and I^2 statistic. Influence of individual trials on pooled estimate and I^2 was inspected by one-leave-out analysis.

Results. After removal of duplicate records and data merging from independent searches, we identified of a total of 6,569 reports. After screening at title and abstract level, 14 potentially eligible trials were identified. After full-text assessment, a total of 4 randomized clinical trials (4394 patients: 2197 PCI vs. 2197 CABG) were included in the primary analysis. With respect to the primary endpoint, PCI and CABG showed comparable safety (HR 1.05, 95% CI 0.90-1.23, p=0.532) at long term follow-up. Kaplan-Meier analysis did not show significant differences between treatments over time, with a cumulative incidence of 18.3% (319 events) in PCI group and 16.9% (292 events) in CABG group at 5-year follow-up; within the first 2 years PCI group exhibited a numerical advantage over CABG group, while from 3 to 5 years CABG group gained a non-significant advantage over PCI. Standard meta-analysis confirmed these findings both by fixed- (HR 1.06, 95% CI 0.90-1.24, p=0.476) and random-effects model (HR 1.06, 95% CI 0.85-1.32, p=597). The EXCEL trial had the highest relative weight (35.9%). A moderate degree of heterogeneity was detected (I^2=42.5%, p=0.154). At one-leave-out analysis this finding resulted to be mainly due to the NOBLE trial (omitting NOBLE: HR 0.96, 95% CI 0.80-1.15, p=0.660; I^2=0%). With respect to all-cause death, PCI was associated with a comparable risk of death (random-effects: HR 1.04, 95% CI 0.81-1.33, p=0.772) as compared with CABG. A numerical excess in myocardial infarction was observed in patients assigned to PCI as compared with those assigned to CABG (random-effects: HR 1.48, 95% CI 0.85-2.58, p=0.170); moreover, a high degree of heterogeneity was detected (I^2=67.4%, p=0.027) as a result of the significant risk increase in the PCI arm of the NOBLE trial (omitting NOBLE: HR 1.13, 95% CI 0.76-1.67. p=0.543, p=0.543; I^2=27.3%) and the comparable incidence between treatments observed in the EXCEL trial (omitting EXCEL: HR 1.95, 95% CI 1.26-3.02, p=0.003; I^2=0.6%). Risk of stroke was comparable between treatments (random-effects: HR 0.87, 95% CI 0.39-1.92, p=0.722) but a high degree of heterogeneity was observed (I^2=62.7%, p=0.045) mainly as a consequence of the increased incidence observed after PCI in the NOBLE trial (omitting NOBLE: HR 0.63, 95% CI 0.37-1.09, p=0.097; I^2=9.1%).



Conclusions. PCI and CABG are associated with a quite comparable risk of a composite of all-cause death, myocardial infarction, or stroke at long-term follow-up. Differences between treatments in individual components of the composite endpoints were not significant. However, a numerical excess in the risk of myocardial infarction after PCI at long-term follow-up and high between-trial heterogeneity were observed, mainly as a result of the diverging effect of the NOBLE trial.

C15

BAILOUT PERCUTANEOUS CORONARY INTERVENTION VERSUS CONSERVATIVE MANAGEMENT OF PERIOPERATIVE MYOCARDIAL ISCHEMIA AFTER EARLY CORONARY ARTERY BYPASS GRAFT FAILURE

Roberto Scarsini, Michele Bellamoli, Gabriele Pesarini, Elena Giulia Milano, Mattia Lunardi, Federico Marin, Andrea Gratta, Claudia Zanetti, Flavio Luciano Ribichini
Divisione di Cardiologia, Università di Verona, Verona, Italy

Background. Postoperative myocardial ischemia (PMI) is a major complication of coronary artery bypass graft (CABG) surgery with relevant prognostic implications.

Purpose. The aim of the study was to review the angiographic findings of patients who underwent urgent coronary angiography for suspected acute PMI at our institution. In particular we sought to assess the diagnostic findings and procedural and mid-term clinical outcome of bailout percutaneous coronary interventions (PCI) after early graft failure.

Methods. Between January 2009 and December 2016 40 patients underwent urgent coronary angiography for suspected PMI within 72 hours from CABG surgery. The angiographic, procedural and clinical outcome were collected and examined retrospectively.

Results. Early graft failure was detected in 26 out of 40 (65%) patients and 31 out of 73 (42.5%) examined grafts. In cases where early graft failure was not detected, coronary angiography revealed incomplete surgical revascularization (5 out of 14 patients, 36%), diffuse spasm that reverted with high intracoronary doses of nitrates (1/14 patients, 7%), or patent grafts without any detectable culprit lesion (8/14, 57%). PCI was performed in 21 out of 40 (52.5%) patients who underwent urgent coronary angiography, 1 patient (2.5%) was candidate to redo-CABG, and 18 (45%) patients were treated conservatively. PCI patients presented higher event-free survival rate compared with patients treated conservatively (log-rank=4.2, p=0.04). Hemodynamic instability at presentation, conservative treatment and PCI failure were associated with poor outcome, but only PCI failure remained a significant prognostic determinant at multivariate analysis (HR 21.5; CI: 1.58-291;p=0.02).

Conclusion. Bailout PCI after early CABG failure provides better MACCE-Free survival rate at 1 year compared with conservative treatment. Nevertheless, bailout PCI remains a high-risk procedure and the PCI failure is associated with poor mid-term clinical outcome.

C16

IMPACT OF PCI ON RENAL FUNCTION IN THE ELDERLY POPULATION OLDER THAN 85 YEARS HOSPITALISED FOR ACS

Simone Muraglia, Filippo Zilio, Giuseppe Braito, Michele Dallago, Alberto Menotti, Marco Borghesi, Roberto Bonmassari
UO Cardiologia, Ospedale S. Chiara, Trento, Italy

Aims. The very elderly population in patients (pts) admitted for ACS is progressively increased. The age and the renal function are predictors of adverse outcomes. Contrast-induced acute kidney injury (AKI) is a potentially adverse complication of PCI.

Methods and Results. Retrospective analysis of consecutive pts older than 85 years admitted to our hospital for ACS between January 2012 and December 2016 who underwent PCI. Baseline characteristics of the pts, ACS data, procedural information, need of access shift, vascular complications were recorded. No pre-PCI prophylactic treatment such as hydration, use of sodium bicarbonate or N-acetylcysteine was performed because of urgent PCI in the STEMI group. 107 pts >85 years with ACS underwent PCI in this period (5% of the ACS population admitted at the intensive coronary care unit). 60% were female. The mean age was 88.0 years (range 85-96 years); 21/107 (20%) were nonagenarian pts. The radial access was performed in 81% of the pts, with a percentage increase from year to year (2016: 90%). 70% of the pts (75/107) were admitted for STEMI, 30% for NSTEMI. No radial access site complications occurred. The success rate of the procedure was 93%. The arterial shift from radial to femoral occurred in 8% of the pts. The percentage of multivessel revascularization was 8.6%. The treated vessel was: 2.8% unprotected left main, 48.6% left anterior descending, 18.7% circumflex, 28.0% right coronary artery, 1.9% SVG. The number of stent per patient was 1.3. The number of DES: 60 (45%). The use of glycoprotein IIb/IIIa inhibitors was 2%. Mean time of procedure duration: 12 min; mean dose of contrast agent: 163 mL; dose area product (DAP): 6210 Gycm^2. The percentage of AKI, defined as an increase in serum creatinine by at least ≥25% from baseline to peak measured within 72h post-PCI, was 16.3%;1 pt was already in dialytic treatment before the PCI. Major bleeding, major stroke, and need for dialysis were respectively <2%, <1%, 0%. The

overall in-hospital mortality rate was 15% (5 pts died during the PCI); the cumulative mortality at 12 months was 48%.
Conclusions. In our experience the percutaneous coronary revascularization strategy in very elderly pts is feasible. The transradial artery approach in this elderly ACS population is safe with high success rate. The percentage of AKI was significant but acceptable without the need for dialysis.

C17

AG-READY (AGRIGENTO-REAL WORLD DRUG-ELUTING BALLOON REGISTRY). 2-YEAR FOLLOW-UP

Salvatore Geraci, Diego Milazzo, Giovanni Vaccaro, Dario Buccheri, Giuseppe Caramanno
UOC Cardiologia, Ospedale S. Giovanni di Dio, Agrigento, Italy

Aims. In the last years there was a growing interest in vascular reparative therapy philosophy and an increased number of interventional cardiologists have started using drug-eluting balloons and bioresorbable vascular scaffolds to coronary artery treatment, in order to overcome limits of permanent metal stents. Our group strongly believes in vascular reparative therapy and is widely engaged in this field. This real-world observational registry aims to highlight our experience since 2011 with drug-eluting balloons (DEB) in the treatment of drug-eluting stent (DES) restenosis (ISR) and de novo lesions in vessel smaller than 3 mm. We enrolled unselected and consecutive patients referred to our center for coronary angiography with indication to coronary revascularization and coronary subsets suitable for DEB use, according to the German Consensus Group recommendations.
Methods and Results. Our study was conducted in a single center. All patients presenting to our institution from October 2011 to July 2015 with significant DES-ISR and/or de novo lesion in vessel smaller than 3 mm, who were eligible to receive paclitaxel-eluting balloon (PEB) treatment, were included in the registry. Clinical and angiographic characteristics were obtained. Clinical follow-up with clinical examination or phone call was scheduled for all patients after discharge, at 1, 6, 12 and 24 months. Complete 24 months follow-up was performed in 96% of patients. Post-procedural and follow-up endpoints included in the analysis were: cardiac death, myocardial infarction and target lesion revascularization (TLR). A total of 288 patients received treatment with PEB in the study period; significant number having major risk factors for coronary artery disease, 42% diabetics; 81% hypertensive; 62% hyperlipemic). 59% of the patients had multivessel disease. Target vessel was most commonly first obtuse marginal branch (30%). 36% was treated for ISR, 64% for de novo lesions. Only 6% of the procedures was switched on stenting. "SeQuent® Please" PEB (B. Braun Melsungen AG), Pantera Lux PEB (Biotronik SE & Co. KG, Berlin) and Zonda PEB (Hexacath, Rueil-Malmaison, France) was used for revascularization. PEB use was always preceded by predilatation with semicompliant or non-compliant balloon with maximum balloon:PEB ratio of 1:1. PEB were all dilated and maintained at nominal pressure for 60 s. Patients were clinically followed up to 24 months. No patients died, 12.5% received TLR and successfully performed a re-PCI with DES (60%), BMS (20%) or DEB (20%); re-admission diagnosis were unstable angina in 40% of the cases and stable angina in 30%, 30% of TLR was performed after angiographic evidence of significant ISR at follow-up; In TLR group, 60% of the patients had performed re-PCI for re-ISR, 20% after small vessel treatment and after bifurcation treatment (1 of these was admitted for NSTEMI). The worst results for ISR treatment with DEB were observed in coronary venous graft (12 patients treated), with 75% of restenosis after DEB treatment.
Conclusions. Our experience highlight the safety and efficacy of PEB in the treatment of drug-eluting ISR and de novo lesion in vessel smaller than 3.0 mm, for patients having significant risk factors for coronary artery disease. DEB treatment represents an effective tool for a variety of clinical settings and it seems to be affected by a low rate of complications and adequate results at long-term follow-up without any permanent device after interventions. Nevertheless, poor results were observed in the treatment of ISR on venous graft, although our data were derived from a relatively small number of patients. This registry is continuing to enroll patients currently, hoping to make more meaningful our experience. It is clear that further studies are needed to define the real DEB indications and limitations in coronary artery disease treatment.

Top-ranked oral presentations 1

C18

RIPARAZIONE PERCUTANEA DI INSUFFICIENZA MITRALICA SEVERA MEDIANTE IMPIANTO MITRACLIP: SURVEY MULTICENTRICA DEI LABORATORI DI EMODINAMICA DELLA REGIONE CAMPANIA

Cesare Baldi[1], Marco Di Maio[2], Arturo Giordano[3], Paolo Golino[4], Vittorio Monda[5], Maurizio Cappelli Bigazzi[2], Emilio Di Lorenzo[6], Giovanni Esposito[7], Luigi Salemme[8], Michele Roberto Di Muro[1], Giuseppe Verolino[1], Rodolfo Citro[1], Gennaro Galasso[1], Pietro Giudice[1]
[1]UOC Cardiologia Interventistica, AOU S. Giovanni di Dio e Ruggi d'Aragona, Salerno, Italy, [2]Cardiologia SUN, Ospedale dei Colli, Napoli, Italy, [3]UOC Interventistica Cardiovascolare, PO Pineta Grande, Castel Volturno (CE), Italy, [4]Cardiologia Universitaria, AORN S. Anna e S. Sebastiano, Caserta, Italy, [5]UOC Cardiologia Interventistica, Ospedale dei Colli, Napoli, Italy, [6]UOC Cardiologia-UTIC, AORN S. Giuseppe Moscati, Avellino, Italy, [7]Dipartimento di Scienze Biomediche, Università di Napoli "Federico II", Napoli, Italy, [8]Cardiologia Interventistica, Casa di Cura Montevergine, Avellino, Italy

Introduzione. La riparazione mitralica percutanea mediante impianto MitraClip ha ottenuto una larga diffusione sul territorio nazionale. Lo scopo di questo registro è stato analizzare le principali caratteristiche cliniche della popolazione di pazienti sottoposti a impianto MC nel nostro territorio regionale, valutare i valori di outcome a distanza e definirne gli scostamenti nei confronti dei più importanti registri internazionali.
Metodi. La partecipazione a questo Registro retrospettivo è stata proposta a tutti i Laboratori di Emodinamica impegnati in un programma operativo di impianto MitraClip in Regione Campania. Ai responsabili dei Laboratori è stata inviata una scheda di registrazione dati, comprendente le seguenti informazioni: numero, dati anagrafici e clinici dei pazienti trattati, eziologia primaria o secondaria della insufficienza mitralica (IM), incidenza di complicanze intraospedaliere, di morte e di riospedalizzazione a 12 mesi, presenza o meno di Ambulatorio dello Scompenso o di Interventistica Strutturale nel centro in cui opera il Laboratorio.
Risultati. Tutti i laboratori impegnati in programma di impianto MC in Regione Campania hanno provveduto ad inviare i dati di tutta la loro attività operativa a partire dal marzo 2012. Fino a marzo 2017 sono stati trattati 488 pazienti, con una media di 61± 40 per centro, per un totale di 750 clip (media 1.54 per paziente). I pazienti avevano un'età media di 71.62±4.51 anni e il 62.70% di questi erano maschi. I pazienti mostravano mediamente un rischio chirurgico elevato (EuroSCORE logistico: 13.87±5.97, EuroSCORE II: 7.15±3.44%). Il 75% dei pazienti era in III classe NYHA e il 22.95% in IV classe NYHA. Il principale meccanismo fisiopatologico alla base della IM era funzionale (84.67%); nel 54.47% dei casi la disfunzione ventricolare sinistra post-ischemica era responsabile della IM; il 77.7% dei pazienti mostrava IM di grado severo. La complicanza post-procedurale più frequente è stata il distacco precoce di lembo (4.24%). La mortalità totale a 12 mesi è stata del 13.93% (del 6.97% quella non cardiaca). La riospedalizzazione per scompenso è stata del 13.11%.
Conclusioni. In Campania sono stati trattati con impianto MitraClip 488 pazienti a partire da marzo 2012 (il 17.9% dell'intera popolazione nazionale). Il profilo di rischio dell'intera popolazione risulta mediamente elevato. La correzione della IM degenerativa tocca il 20% dell'intera attività nei centri a più alto volume operativo. I valori di outcome hard i sono sovrapponibili a quelli registrati nelle letteratura mondiale. Nella maggioranza dei Centri sono attivi ambulatori dedicati per lo Scompenso.

C19

IMPACT OF DIFFERENT AORTIC STENOSIS PATHOPHYSIOLOGICAL SUBTYPES ON ACUTE AND LATE RESULTS AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION

Carolina Moretti, Chiara Marcelli, Miriam Compagnone, Paola Battistini, Giulio Rodinò, Marina Cannizzo, Matteo Chiarabelli, Maria Letizia Bacchi Reggiani, Cinzia Marrozzini, Tullio Palmerini, Paolo Ortolani, Claudio Rapezzi, Francesco Saia
Polo Cardio-Toraco-Vascolare, Policlinico S. Orsola-Malpighi, Bologna, Italy

Background. Transcatheter aortic valve implantation (TAVI) has emerged as an alternative therapeutic option to surgical aortic valve replacement for the treatment of severe aortic stenosis (AS). The aim of the present study was to compare acute and long-term clinical outcome after TAVI in four different pathophysiological subtypes of AS: HG (high gradient), LF-LG (low flow, low gradient), PLF-LG (paradoxical low flow, low gradient), NF-LG (normal flow, low gradient).
Methods. This is an observational prospective study, that included 398 consecutive patients with severe AS (aortic valve area (AVA)<1cm2) referred to Policlinico S. Orsola-Malpighi for TAVI (January 2008-December 2016). We excluded the valve in valve procedures for

degenerated aortic bioprosthesis (n=23) and patients whose stroke volume could not be traced (n=32). The 343 patients who composed the study population were divided into four groups based on mean transvalvular aortic gradient (TAG), left ventricular ejection fraction (LVEF) and stroke volume index (SVI): 207 were classified HG AS [TAG >40 mmHg]; 35 LF-LG AS [TAG ≤40 mmHg, LVEF <50%, SVI ≤35 ml/m^2]; 47 PLF-LG AS [TAG ≤40 mmHg, LVEF ≥50%, SVI ≤35 ml/m^2]; and 54 NF-LG AS [TAG ≤40 mmHg, LVEF ≥50%, SVI >35 ml/m^2]. In hospital outcome was evaluated according to Valve Academic Research Consortium-2 (VARC-2) definitions (myocardial infarction, stroke, bleeding, vascular complications, acute kidney injury, pacemaker implantation, sepsis), while long-term follow up was performed by clinical outpatient evaluations at 1 month, 12 months and yearly thereafter and/or telephonic interviews.

Results. Mean age was 82.9± 5.9 years. No significant differences were observed in the entire population in gender, diabetes mellitus, hypertension and clinical presentation at hospital admission. Conversely, LF-LG patients had significantly higher incidence of previous MI, previous coronary artery bypass grafting (CABG) and rate of coronary artery disease. Logistic EuroSCORE and EuroSCORE II were also significantly higher in this group in comparison with HG-AS, PLF-LG and NF-LG groups. The results of echocardiographic investigations were consistent with the previously described subgroup classification. Transfemoral route (71.4%) and Edwards Sapien (58.3%) were used in the majority of cases. Overall VARC-2 device success was 93.8%. The need for a second valve (valve in valve deployment) was numerically low (2.9%) but significantly higher in HG-AS group compared to the other groups. In hospital mortality was 5%. The 30-day mortality and procedural complications after TAVI was not different among the four groups. At long term follow-up, mean duration 26.6±25.8 months, the survival rate was significantly lower in the LF-LG group. In the multivariate analysis LF-LG AS (hazard ratio [HR] 2.38, 95% CI 1.41-4.00 ; p=0.001), age (HR 1.05, 95% CI 1.02-1.09; p=0.003) and creatinine at hospital admission (HR 1.15, 95% CI 1.02-1.31; p=0.024) were the only independent predictors of overall mortality.

Conclusions. In-hospital outcome after TAVI was similar in all AS pathophysiologic subgroups, whereas patients with LF-LG AS had worse long term outcome.

C20

EFFICACIA E SICUREZZA DELL'IMPIANTO DI VALVOLA AORTICA TRANSCATETERE PER VIA SUCCLAVIA NEL PAZIENTE OBESO: CONFRONTO PROPENSITY-MATCHED CON LA VIA TRANSFEMORALE

Andrea Baldo[1], Paola Martina[1], Luigi Vittonati[1], Corrado Lettieri[2], Bernhard Reimers[3], Carmine Musto[4], Claudia Fiorina[5], Marianna Adamo[5], Giuseppe Bruschi[6], Marco Angelillis[7], Cristina Giannini[7], Marco Barbanti[8], Corrado Tamburino[8], Mauro Agnifili[9], Andrea Garatti[9], Arnaldo Poli[1]

[1]ASST Ovest Milanese Ospedale di Legnano, Legnano, Italy, [2]AO Carlo Poma, Mantova, Italy, Istituto Clinico Humanitas, Rozzano, Milano, Italy, [4]AO San Camillo-Forlanini, Roma, Italy, [5]ASST Spedali Civili, Brescia, Italy, [6]ASST Niguarda General Hospital "De Gasperis" Cardio Center, Milano, Italy, [7]AOUP Ospedale Cisanello, Pisa, Italy, [8]AOU Policlinico Vittorio Emanuele, PO Ferrarotto, Catania, Italy, [9]IRCCS Policlinico San Donato, San Donato Milanese, Milano, Italy

Introduzione. I pazienti obesi con stenosi aortica severa vengono considerati candidabili preferenzialmente ad una sostituzione valvolare transcatetere (TAVI) poiché presentano un rischio operatorio aumentato nel corso di intervento di sostituzione valvolare chirurgica. L'obesità condiziona negativamente anche l'approccio transcatetere e rende più difficoltosa la gestione dell'accesso vascolare femorale e aumenta il rischio di complicanze. La TAVI per via succlavia con CoreValve® si è già dimostrata paragonabile a quella transfemorale sia per sicurezza sia per efficacia e potrebbe rappresentare pertanto un'alternativa via di accesso nel paziente obeso.

Metodi. I pazienti studiati derivano dall'archivio dati italiano CoreValve (Italian Clinical Service® Project, NCT01007474) dal 2007 al febbraio 2017. Gli endpoint primari sono le complicanze vascolari, i sanguinamenti maggiori causati dall'accesso vascolare e le complicanze della ferita chirurgica. Si valuteranno inoltre successo procedurale, paravalvular leak, valve-in-valve, sopravvivenza a lungo termine e un endpoint composito con anche disfunzione valvolare e ricoveri. I pazienti operati per via succlavia verranno confrontati a quelli per via femorale con il propensity score matching che ha compreso: malattia vascolare periferica, BPAC, EuroSCORE logistico, funzione renale, pregressa PCI, sesso.

Risultati. Sono stati considerati 924 pazienti obesi dei 2600 pazienti dell'archivio italiano Corevalve®: 95 operati per via succlavia, 829 per via femorale. Dopo il propensity score matching, abbiamo studiato 76 pazienti per gruppo che non differiscono per caratteristiche basali. La C-statistica è 0.82. La via femorale ha portato più complicanze vascolari (15.8% vs. 5.3%), p=0.035 a parità di diametro degli introduttori. Si sono verificati più sanguinamenti maggiori legati all'accesso (9.2% femorale, 1.3% succlavia, p=0.029), legati prevalentemente alla via percutanea (7.7% percutanea, 0.0% chirurgica, 1.3% succlavia, p=0.115). La ferita chirurgica ha maggiori complicanze nel gruppo femorale (10.5% vs. 2.6%, p=0.050), per infezioni e deiscenze. Il successo procedurale è stato maggiore nella via succlavia (98.7% vs. 90.8%, p 0.029). Il paravalvular leak moderato-severo è risultato maggiore nel gruppo femorale (26% vs. 10.8%, p=0.017). Sono state rilevate 5 valve-in-valve in procedure femorali (percutanee), in nessuna procedura per via succlavia (p=0.021). Le curve di sopravvivenza a lungo termine sono simili tra i gruppi (1 anno: 81.6% succlavia, 84.2% femorale; 3 anni: 67% vs. 75.3%, p=0.295). Analogamente le curve degli endpoint compositi sono simili tra i gruppi.

Tabella 1. Caratteristiche cliniche basali dei 76 impianti per via transucclavia e dei 76 per via transfemorale. Per le variabili categoriche si riportano casi (percentuali), mentre per le variabili continue si riporta media ± DS.

	Totale (n=152)	Transucclavia (n=76)	Transfemorale (n=76)	p
Malattia vascolare periferica	104 (68.4)	51 (67.1)	53 (69.7)	0.727
Pregresso BPAC	19 (12.5)	8 (10.5)	11 (14.5)	0.462
Pregressa PCI	73 (48)	34 (44.7)	39 (51.3)	0.417
Log-EuroSCORE	23.2 ± 16.5	24.4 ± 16.9	22.0 ± 16.1	0.234
GFR <30 mL/min	22 (14.5)	12 (15.8)	10 (13.2)	0.645
Sesso (maschi)	83 (54.6)	43 (56.6)	40 (52.6)	0.625
Età alla procedura (anni)	81 ± 7	81 ± 7	80 ± 7	0.315
BMI (kg/m^2)	30.6 ± 4.0	30.7 ± 4.6	30.6 ± 3.4	0.636
STS Score	9.5 ± 10.8	8.2 ± 7.8	10.5 ± 12.7	0.661
Ipertensione	141 (92.8)	73 (96.1)	68 (89.5)	0.118
Diabete mellito	47 (32.9)	23 (31.5)	24 (34.3)	0.724
Pregresso Stroke/TIA	16 (10.5)	7 (9.2%)	9 (11.8)	0.597
Pregresso IMA	38 (25)	19 (25)	19 (25)	1.000
BPCO severa	49 (32.2)	27 (35.5)	22 (28.9)	0.386
Emoglobinemia d'ingresso (g/dL)	11.6 ± 1.8	11.5 ± 1.7	11.6 ± 1.9	0.789
Creatininemia d'ingresso (mg/dL)	1.5 ± 1.1	1.6 ± 1.4	1.3 ± 0.7	0.091
Gradiente trans-aortico massimo (mmHg)	84.1 ± 19.2	83.0 ± 19.2	85.1 ± 19.2	0. 661
Gradiente trans-aortico medio (mmHg)	51.3 ± 12.8	50.6 ± 13.0	52.1 ± 12.6	0. 502

BMI, indice di massa corporea; BPAC, bypass aortocoronarico; BPCO, broncopneumopatia cronica ostruttiva; DS, deviazione standard; GFR, velocità di filtrazione glomerulare; IMA, infarto miocardico acuto; PCI, intervento percutaneo coronarico; STS, Società dei Chirurghi Toracici; TIA, attacco ischemico transitorio.

Tabella 2. Endpoint delle 76 procedure per via transucclavia e delle 76 per via transfemorale. Per le variabili categoriche si riportano casi (percentuali).

	Totale (n=152)	Transucclavia (n=76)	Transfemorale (n=76)
Complicanze dell'accesso vascolare	16 (10.5)	4 (5.3)	12 (15.8)
Sanguinamenti maggiori legati all'accesso	8 (5.3)	1 (1.3)	7 (9.2)
Complicanze della ferita	10(6.6)	2 (2.6)	8(10.5)
Successo procedurale	144 (94.7)	75 (98.7)	69 (90.8)
PVL moderato/severo	27 (18.4)	8 (10.8)	19 (26.0)
Valve in Valve	5 (3.4)	0 (0.0)	5 (6.8)

PVL, rigurgito della bioprotesi valvolare.

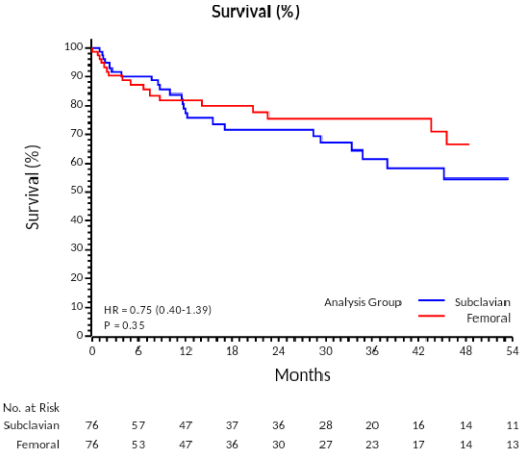


Figura 1. Curve di Kaplan-Meier della sopravvivenza cumulativa dei due gruppi. Rischio valutato con test dei ranghi logaritmici. In basso riportati i pazienti a rischio per ogni intervallo temporale.

Conclusioni. La TAVI per via succlavia nel paziente obeso si è dimostrata più sicura della via femorale per minori complicanze vascolari, minori sanguinamenti maggiori legati all'accesso e minori complicanze della ferita chirurgica. Inoltre ha un maggior tasso di successo procedurale e minore paravalvular leak, in presenza di sopravvivenza a lungo termine simile. Questi risultati suggeriscono che nei pazienti obesi la via transucclavia potrebbe essere la via più adatta negli impianti di CoreValve®.

C21

DETECT FRACTIONAL FLOW RESERVE OF EPICARDIAL STENOSES WITH GUIDING CATHETER DISENGAGEMENT: DISENGAGE STUDY

Mariano Pellicano[1], Giovanni Ciccarelli[1], Panagiotis Xaplanteris[1], Anastasios Milkas[1], Giuseppe Di Gioia[2], Angelo Cioppa[3], Marc Vanderheyden[1], Luigi Salemme[3], Jozef Bartunek[1], Carlos Van Mieghem[1], Tullio Tesorio[3], William Wijns[1], Bernard De Bruyne[1], Emanuele Barbato[1]

[1]Cardiovascular Center Aalst, OLV Hospital, Aalst, Belgium, [2]Division of Cardiology, Department of Advanced Biomedical Sciences, University of Naples "Federico II", Naples, Italy, [3]Clinica Montevergine, Mercogliano (AV), Italy

Aims. During FFR measurement, the simple presence of the guiding catheter might impede the hyperemic flow. We investigated the impact of the selective guiding catheter engagement on serial FFR measurements and related clinical decision-making.

Methods. Between October 2015 and December 2016, FFR was prospectively measured in 202 intermediate isolated stenosis (DS 46±10%; MLD 1.6±0.4 mm; RVD 3.0±1.6 mm; LL 15±8 mm) of 173 patients with stable angina (93%), silent ischemia (5%), and ACS (2%, in non-culprit lesion). Stenoses were located on left anterior descending artery (n=124), diagonal branch (n=3), left circumflex artery (n=28), obtuse marginal branch (n=14), intermediate branch (n=5) and right coronary artery (n=28). Patients with diffuse disease, tandem lesions, left main and aorto-ostial stenosis, and culprit lesions of STEMI and NSTEMI were excluded. FFR were measured with a 0.014-inch pressure guidewire (Pressure Wire Certus, St. Jude Medical, St. Paul, MN, USA) with intra-coronary adenosine at the dose of 100 µg for the RCA and 200 µg for the LCA. For each stenosis, FFR was measured twice: with the guiding catheter engaged (FFR_{eng}) and with the guiding catheter disengaged (FFR_{diseng}). To assure the quality of the measurements, the equalization was checked with both guiding catheter engaged and disengaged, likewise the position of the wire was filmed to document the stability of the pressure sensor during the manipulation of the guiding catheter.

Results. Overall FFR did not significantly change when re-measured after disengaging the guiding catheter: FFR_{eng} 0.84±0.08 vs. FFR_{diseng} 0.80±0.08, p=0.92. In 102 stenoses (50%), ΔFFR (FFR_{eng}–FFR_{diseng}) was ≥0.04 (twice the value of the test-retest repeatability of FFR). Of interest, in 38 stenoses (22%) whose FFR values were mostly located in the 0.81-0.85 stratum, guiding catheter disengagement was associated with a shift from above to below the clinical-decision making threshold of 0.80.

Conclusions. Guiding catheter disengagement is associated with a slight albeit non-significant decrease in FFR values overall. Yet, guiding catheter disengagement resulted into a shift of FFR values from above to below the clinical-decision making threshold of 0.80 in 1 out of 5 measurements. Therefore it might be advisable to reassess FFR after disengaging the guiding catheter in case of FFR values close to 0.80.

BRS

C22

ABSORB BIORESORBABLE VASCULAR SCAFFOLD VS EVEROLIMUS-ELUTING METALLIC STENT IN SMALL VESSEL DISEASE: A PROPENSITY MATCHED ANALYSIS OF COMPARE II, RAI AND MAASSTAD-ABSORB PROSPECTIVE STUDIES

Alberto Barioli[1], Giulia Masiero[1], Marco Mojoli[1], Luca Nai Fovino[1], Gianpiero D'Amico[1], Valeria Paradies[2], Bernardo Cortese[3], Gaetano di Palma[3], Attilio Varricchio[4], Alfonso Ielasi[5], Bruno Loi[6], Mostafa Rabea Abdelhaleem Badawy[7], Paola Tellaroli[8], Giuseppe Steffenino[9], Georgios Vlachojannis[10], Pieter Smits[10], Giuseppe Tarantini[1]

[1]Dipartimento di Scienze Cardiache, Toraciche e Vascolari, Università di Padova, Padova, Italy, [2]National Heart Research Institute and National Heart Centre Singapore, Singapore, Singapore, [3]UO Cardiologia, ASST Fatebenefratelli-Sacco, PO Fatebenefratelli, Milano, Italy, [4]Cardiology Division, Santa Maria della Pietà Hospital, Napoli, Italy, [5]Ospedale Bolognini, Seriate, Italy, [6]Interventional Cradiology Unit, AO Brotzu, Cagliari, Italy, [7]Cardiology Department, Minia University Hospital, Minia, Egypt, [8]Biostatistics, Epidemiology and Public Health Unit of Department of Cardiac, Thoracic and Vascular Sciences, University of Padua Medical School, Padova, Italy, [9]US Emodinamica, ASO S. Croce e Carle, Cuneo, Italy, [10]Department of Cardiology, Maasstad Hospital, Rotterdam, Netherlands

Background. Small vessel disease (SVD) is a predictor of adverse outcome in patients treated by percutaneous coronary intervention (PCI), both in terms of patient- and device-related events. Concerns have been raised with bioresorbable vascular scaffolds (BVS) in this subset. We aimed to compare outcomes of BVS versus a 2nd generation metallic stent in the SVD setting by pooling patients from three large, prospective studies.

Methods. Patients with SVD and treated with Absorb BVS were identified in the multicenter RAI Registry and the single-centre MAASSTAD-Absorb registry, while control patients treated with XIENCE V/PRIME or PROMUS metallic stents were identified in the COMPARE II trial. SVD was defined as target lesion(s) with a reference vessel diameter (RVD) ≤2.75 mm by QCA. Patients with a bypass graft stenosis or with multiple target lesions including non-SV lesions (RVD >2.75 mm) were excluded. We compared clinical outcomes of patients treated by BVS or everolimus-eluting stents (EES) by performing a propensity score matching analysis using several pre-procedural clinical and angiographic variables. Implantation technique was not object of matching, being device-specific.

Results. Out of total 4635 enrolled subjects, 1147 belonged to the SVD population. After matching, 337 pairs of patients were obtained. Pre-procedural characteristics of matched groups were highly comparable, with a high degree of clinical and angiographic complexity in both groups. As expected, pre- and post-dilation rates were significantly higher in the BVS group. No differences were found between BVS versus EES in terms of device-oriented composite end-point (DOCE) at 1-year (HR 1.08, 95% CI 0.5-2.3, p=0.8) and 2-year follow-up (HR 1.28, 95% CI 0.68-2.43, p=0.45). Notwithstanding, higher incidence of definite/probable stent/scaffold thrombosis (ST) was observed in the BVS vs. EES group at 1 year (1.8% vs. 0.3%, HR 4.7, 95% CI 0.8-31.4, p=0.08) and 2 years (2.1% vs. 0.3, HR 8.34 95% CI 1.1-60.2, p=0.04).

Conclusion. In this propensity-matched analysis pooling SVD patients of three large prospective studies, the incidence of device-related events was comparable between BVS and EES, apart from a higher ST rate in the BVS group.

C23

LONG-TERM FOLLOW-UP OF BRS IMPLANTATION FOR COMPLEX CORONARY LESIONS: A MULTICENTRE EXPERIENCE

Damiano Regazzoli[1], Azeem Latib[1], Ezhumalai Babu[2], Satoru Mitomo[1], Pier Pasquale Leone[1], Paolo Del Sole[1], Marco Bruno Ancona[1], Antonio Mangieri[1], Daisuke Hachinohe[1], Francesco Giannini[1], Ashok Seth[2], Antonio Colombo[1]

[1]San Raffaele University Hospital, Milano, Italy,[2] Fortis Escort Heart Institute, New Delhi, India

Aims. Incidence of late BRS thrombosis is of concern. Clinical experiences have shown that 'dedicated implantation technique' is a key to decrease ST. The aim of this study was to evaluate the use of 'dedicated implantation technique' in the outcome of BRS.

Methods and Results. We retrospectively analyzed consecutive patients that underwent BRS implantation in three high-volume, experienced centers (2 in Italy and 1 in India) before December 2014, in order to have at least two years of clinical follow-up. A total of 492 patients were identified for a total of 763 lesions implanted with BRS using a dedicated implantation strategy from the beginning. Mean age was 60±11 (male sex 90%), 35% of patients were diabetics, left ventricular systolic function (54±8%) and renal function (eGFR 90±25 ml/min) were preserved. The coronary anatomy was predominantly complex, with type B2 or C lesions in 75%, CTOs in 5.6%, bifurcations in 31% and severely calcific lesions in 13%. The dedicated implantation technique included good lesion preparation and debulking (when necessary): predilatation was performed in 99% of cases (cutting balloon 3.5%, scoring balloon 8%, rotational atherectomy 5%). OCT and IVUS were used in 15% and 37% of cases, respectively. Mean scaffold length was 31±16 mm, with a 1:1 high-pressure (21±4atm) postdilatation rate of 99.9%. Angiographic success was achieved in 99.9% of cases. All patients were discharged with dual antiplatelet therapy (usually ASA and clopidogrel) while a de-escalation therapy with 3 months of prasugrel or ticagrelor followed by 12 months of clopidogrel was prescribed in about 10% of patients. At a mean follow-up of 939±286 days definite or probable scaffold thrombosis occurred in 0.6% (3 pts) of patients, while possible ST occurred in 0.5% (3 pts); notably only 1 case of probable ST occurred more than 1-year after the procedure. Rates of target lesion revascularization (TLR), target vessel revascularization (TVR), MACE (death, any MI, revascularization) and TLF (cardiovascular death, target vessel MI, TLR) were 6.5% and 9.5%, 16% and 5.5% respectively.

Conclusions. These long-term results from a complex real-world population appear to be reassuring in regards to the incidence of scaffold thrombosis when BVS are implanted by experienced operators with a dedicated implantation technique. In fact, the rate of ST is lower than the one observed in Absorb II trial, despite the higher clinical and anatomical complexity of the treated population. However, longer follow-up data in a larger population are needed in order to support this preliminary evidence.

C24

ABSORB BIORESORBABLE VASCULAR SCAFFOLD IN PATIENTS WITH OR WITHOUT DIABETES MELLITUS: A SUB-ANALYSIS OF THE ITALIAN MULTICENTER RAI REGISTRY (CLINICALTRIALS.GOV IDENTIFIER: NCT02298413)

Giulia Masiero[1], Giuseppe Tarantini[1], Marco Mojoli[1], Bruno Loi[2], Bernardo Cortese[3], Alfonso Ielasi[4], Attilio Varricchio[5], Luciano Moretti[6], Leonardo Misuraca[7], Giampaolo Pasquetto[8], Paolo Calabrò[9], Donatella Corrado[10], Giuseppe Steffenino[11]
[1]Department of Cardiac, Thoracic and Vascular Sciences, University of Padua, Padova, Italy, [2]Cardiology Division, AO Brotzu, Cagliari, Italy, [3]UO Cardiologia, ASST Fatebenefratelli-Sacco, PO Fatebenefratelli, Milano, Italy, [4]Cardiology Division, AO Bolognini, Seriate, Italy, [5]Cardiology Division, Santa Maria della Pietà Hospital, Nola, Italy, [6]Cardiology Division, Mazzoni Hospital, Ascoli Piceno, Italy, [7]Interventional Cardiology, UO Cardiologia-Emodinamica, Ospedale della Misericordia, Grosseto, Italy, [8]Cardiology Division, ULSS 17, Este, Italy, [9]Division of Cardiology, Department of Cardio-Thoracic Sciences, Università degli Studi della Campania "Luigi Vanvitelli", Napoli, Italy, [10]Mario Negri Research Institute, Milano, Italy, [11]US Emodinamica, ASO S. Croce e Carle, Cuneo, Italy

Background. Diabetes mellitus (DM) is a major predictor of poor prognosis following percutaneous coronary intervention. We aimed to assess the interplay between the use of bioresorbable scaffold (BRS) and DM in a large multicentre registry.

Methods. The RAI (Registro Absorb Italiano) Registry is a large, prospective registry, investigating the outcomes of the Absorb BVS (ABBOTT Vascular, Santa Clara, CA) implantation in an "all-comers" setting. We identified patients with at least 12-month follow-up and assessed the clinical outcomes of diabetic patients compared to non-DM controls. Patients treated with Absorb BVS because of in-stent restenosis or bypass graft disease were excluded from the current analysis.

Results. Out of 1505 consecutively enrolled patients, 1183 were eligible for this analysis (DM, 231 patients; non-DM, 952 patients). Acute coronary syndromes were >55% in both cohorts. Compared to controls, DM patients were significantly older (62 vs. 58 years, p<0.001), with higher SYNTAX score (13±7 vs. 11±7, p=0.005), prevalence of multivessel disease (69% vs. 54%, p<0.001) and calcified lesions (29% vs. 19%, p<0.001). A similar number of BRS per patient were used in both groups (1.5±0.7), but with higher average scaffold length in the DM group (38±23 mm vs. 34±22, p=0.04). Pre- and post-dilatation rates were similar (>96%) between groups. At 1-year follow-up, no differences were found between groups in terms of a device-oriented composite end-point (DOCE) (4.3% vs. 6.6%; p=0.6) or its individual components (cardiac death, target-vessel myocardial infarction and ischemia-driven TLR). Conversely, the incidence of the patient-oriented composite end-point (POCE) was significantly higher in DM vs. non-DM cohorts (16% vs. 11%; p=0.02), mainly driven by a greater rate of non-TLRs. Definite and probable scaffolds thrombosis (ST) rate was similar (2.2% vs. 1.2%, p=0.2).

Conclusions. In this sub-analysis of the large RAI Registry, diabetic and non-diabetic patients had similar incidence of device-related events at 1-year follow-up. Conversely, patient-related adverse events were significantly higher in the DM group compared to non-DM controls.

C25

ESPERIENZA INIZIALE CON SCAFFOLD RIASSORBIBILE IN LEGA DI MAGNESIO MAGMARIS NEL REGISTRO MAGNIFICENT (MAGNESIUM SIROLIMUS BIORESORBABLE SCAFFOLD INITIAL CLINICAL MONOCENTRIC EXPERIENCE)

Massimo Leoncini, Claudio Rapetto, Raffaele Scardala
SSD Cardiologia Invasiva Endovascolare, Sanremo, Italy

Scopi. Valutare gli outcome clinici (OC) acuti e al follow-up (FU) a lungo termine dello scaffold vascolare bioriassorbibile (BVS) in lega di magnesio a eluizione di sirolimus Magmaris in una popolazione di pazienti (pz) "real world".

Metodi e Risultati. Tutti i pz consecutivi trattati con BVS Magmaris nell'emodinamica di Sanremo da agosto 2016 a maggio 2017 sono stati inclusi in questo registro osservazionale. Gli OC registrati sono: successo angiografico (SA), morte cardiovascolare (MCV), infarto miocardico del vaso target (TV-IMA), trombosi di scaffold (ScT), ischemia-driven target lesion revascularization (ID-TLR), target vessel revascularization (TVR) e target vessel failure (TVF), composito di MCV, TV-IMA e TVR. Il SA è definito come impianto effettivo del BVS con stenosi residua (SR) <30% e flusso Thrombolysis in Myocardial Infarction (TIMI) 3 nel vaso target. Un totale di 15 pz (età 58.5±6.5 anni; maschi 15, 100%; ≥3 fattori di rischio cardiovascolare 9, 60%) sono stati inclusi nel registro, sono state eseguite 15 PCI (radiale 14, 93.3%) su 15 lesioni con impianto di 17 BVS. Nessuna procedura è stata IVUS o OCT assistita. 5 PCI (33.3%) sono state eseguite in pazienti con angina instabile o NSTEMI. La localizzazione principale delle stenosi era su CX (8, 53.3%); 10 lesioni (66.7%) erano di tipo B2/C. Oltre all'aspirina 14 pz (93.3%) hanno assunto i nuovi inibitori P2Y12 (ticagrelor 80%). La QCA preprocedurale ha mostrato una stenosi dell'83.3±13.2%, con lunghezza di 16.5±4.8 mm. La predilatazione, a 17.8±4.2 atmosfere (atm), è stata eseguita nel 100% dei casi e con rapporto pallone-arteria 1:1 in 15 BVS (88.2%). Il BVS è stato rilasciato a una pressione di 13.0±2.7 atm; 2 pz (13.3%) presentano un overlap marker-to-marker. Non sono presenti overlap BVS-DES. La postdilatazione, alla pressione di 22.8±2.6 atm è avvenuta in tutti i BVS (100%) e con pallone sovradimensionato di 0.5 mm in 6 (35.3%). La QCA postprocedurale ha mostrato una SR di 10.9 ± 3.9%, in nessun caso si è avuta SR >30%, flusso TIMI <3 finale o failure nell'impianto del BRS configurando un SA del 100%. A un FU mediano di 127 giorni (range interquartile 76-166) non si sono verificate MCV (0%) mentre si è verificata 1 ScT definita a 80 gg (6.7%) con conseguente TV-IMA (6.7%; NSTEMI con sola Troponina T positiva), 1 TVF (6.7%), 1 TVR (6.7%), 1 ID-TLR (6.7%). Allo studio OCT lo scaffold trombizzato presentava un profilo irregolare e ovalare con una zona di malapposizione in assenza di rimodellamento positivo del vaso mentre nella PCI index il sizing del BVS risultava corretto e l'espansione del pallone NC da postdilatazione uniforme e completa con ottimo risultato angiografico. Abbiamo ipotizzato che un vasospasmo, occorso quando il BVS era ancora presente ma aveva iniziato a perdere scaffolding, possa aver parzialmente crushato il device, generando una malapposizione tardiva una volta risoltosi.

Conclusioni. Nella nostra esperienza preliminare, con i limiti insiti in un registro, l'impianto di BVS Magmaris in una popolazione "real world" è associata a buon SA in acuto, resta da comprendere se la rapida perdita di scaffolding possa invece essere fonte di eventi avversi a medio termine.

C26

ESPERIENZA INIZIALE CON SCAFFOLD BIORIASSORBIBILE IN MAGNESIO (MAGMARIS) IN LESIONI CORONARICHE DE NOVO. RISULTATI ACUTI E A MEDIO TERMINE DELL'ESPERIENZA INIZIALE IN CENTRI ITALIANI

Stefano Galli[1], Piero Montorsi[1], Sarah Troiano[1], Altin Palloshi[2], Claudio Rapetto[3], Franco Fabbiocchi[1], Giovanni Teruzzi[1], Massimo Leoncini[3], Michele Bianchi[1], Paolo Ravagnani[1], Antonio Bartorelli[1]
[1]Centro Cardiologico Monzino IRCCS, Milano, Italy, [2]Istituto Clinico Città Studi, Milano, Italy, [3]Cardiologia Invasiva Endovascolare, Sanremo, Sanremo, Italy

Scopo. Valutazione dei risultati acuti e a medio termine in termini di efficacia e sicurezza dello scaffold bioriassorbibile in magnesio (Magmaris) in lesioni coronariche de-novo, esperienza iniziale nei primi centri italiani.

Metodi. 89 pazienti con 93 lesioni coronariche de-novo sono stati arruolati in 3 centri italiani. Tutte le lesioni sono state trattate con impianto di stent Magmaris con scaffold bioriassorbibile in magnesio (prodotto da Biotronik, Bülach, Svizzera). Per l'impianto del BRS Magmaris era mandatorio rispettare la regola 'PSP': predilatazione 1: 1 con pallone NC, corretto 'sizing' (consigliata valutazione mediante IVUS o OCT) e post-dilatazione con pallone NC. La durata della DAPT era consiglia 12 mesi, ma possibile almeno 6 mesi. I risultati procedurali, clinico-angiografici e MACCE (morte cardiaca / non cardiaca, IMA, stroke, TLR e trombosi di stent) sono raccolti a 1, 6 e 12 mesi.

Risultati. Le caratteristiche cliniche erano: età media 61,1±9,7 anni; sesso maschile nell'85% e 21% diabetici. Nell'86% dei casi la PCI era elettiva (angina stabile e/o ischemia silente), mentre nel 16% dei casi per SCA-NSTEMI. Le 93 lesioni de-novo, range di diametro del vaso di riferimento da 2.7 a 4.2 mm, erano localizzate su IVA nel 44%; su CFX nel 27% e su CD nel 26% dei casi. In 4 pazienti sono stati trattati 2 vasi e in altri 8 pazienti sono stati impiantati 2 Magmaris in overlapping. La lunghezza media della lesione era di 15.1±6.3 mm, la percentuale di stenosi era dell'81.9±10.4%. La predilatazione è stata eseguita in tutti i casi con utilizzo di pallone NC 1:1 con pressione media 15.8±3.25 atm. Il diametro medio del BRS utilizzato è stato di 3.28±0.25mm mentre la lunghezza media di 20.4±3.9. La postdilatazione è stata eseguita con pallone NC (diametro medio di 3.5±0.4 a pressione media di 18.6±3.2 atm) ed il diametro del palloncino NC non doveva superare 0.5 mm per evitare sovradimensionamenti dello scaffold stesso. Tutti i Magmaris sono stati impiantati con successo (successo device 100%) e nel 56% dei casi è stato utilizzato l'imaging (OCT/IVUS). Il successo procedurale era del 100% (93/93 les.), mentre il successo clinico era del 97% (87/89 pazienti): 2 pz. hanno presentato solo movimento enzimatico post-procedurale IMA procedurale. A 30 giorni non sono stati osservati eventi avversi. Al F/U a medio termine (completato nel 50%) sono stati osservati 2 eventi: 1 NSTEMI per trombosi tardiva a 3 mesi e un caso di ISR, entrambi trattati con successo con impianto di DES in scaffold.

Conclusioni. L'esperienza iniziale con Magmaris in lesioni de-novo "real-world" in centri italiani conferma l'efficacia e la sicurezza già osservate in studi controllati. Questi risultati preliminari necessitano di essere confermati in serie maggiori ed in lesioni più complesse.

TAVI

C27

PROGNOSTIC SIGNIFICANCE OF CHANGE IN THE LEFT VENTRICULAR EJECTION FRACTION AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION IN PATIENTS WITH SEVERE AORTIC STENOSIS AND LEFT VENTRICULAR DYSFUNCTION

Marco Angelillis[1], Cristina Giannini[1], Marco De Carlo[1], Marianna Adamo[2], Antonio Colombo[3], Francesco Bedogni[4], Corrado Tamburino[5], Giuseppe Bruschi[6], Arnaldo Poli[7], Roberto Violini[8], Anna Sonia Petronio[1]
[1]Azienda Ospedaliero-Universitaria Pisana, Pisa, Italy, [2]Ospedale Civile, Brescia, Italy, [3]Istituto Scientifico San Raffaele, Milano, Italy, [4]IRCCS Policlinico San Donato, San Donato Milanese, Italy, [5]Ospedale Ferrarotto, Catania, Italy, [6]Ospedale Niguarda, Milano, Italy, [7]Ospedale Civile, Legnano, Italy, [8]Istituto Clinico Humanitas, Rozzano, Italy

Patients with severe aortic stenosis and reduced left ventricular ejection fraction (LVEF) have a poor prognosis compared to patients with preserved LVEF. To evaluate the impact of early LVEF recovery in patients with baseline dysfunction on clinical outcomes after TAVI**,** we included all consecutive patients undergoing TAVI from the Italian ClinicalService® registry with LVEF ≤ 45% at baseline who had 1-month LVEF data. Patients who experienced previous coronary artery by-pass graft, previous valve replacement or previous myocardial infarction were excluded from the analysis. Therefore, 131 patients with improvement in LVEF <10% (No-R group) were compared to 121 patients with improvement in LVEF ≥10% (R-group). The primary end point was the rate of death of any cause. Multivariable analysis was performed to determine independent predictors of lack in LVEF recovery. Early LVEF recovery occurred in 48% of patients, generally before discharge. One-year all-cause mortality and major adverse cardiac and cerebrovascular events were significantly higher in the no–early recovery group (log rank test p=0.005 and p=0.003; respectively). Baseline severe LV dysfunction and previous percutaneous coronary intervention (PCI) were identified as independent predictors to warn the lack of improvement in LVEF. In conclusion, nearly 50% of patients with preoperative left ventricular dysfunction demonstrated a significant early improvement in LVEF after TAVI. Lack of early LVEF recovery is associated with a worse clinical outcome and is most likely among patients with severely abnormal baseline LVEF and previous PCI.

C28

TRANSFEMORAL AORTIC VALVE IMPLANTATION WITH NEW-GENERATION DEVICES: THE REPOSITIONABLE LOTUS VALVE VS. THE BALLOON-EXPANDABLE EDWARDS SAPIEN 3 VALVE

Luca Nai Fovino[1], Mostafa Rabea[1], Chiara Fraccaro[1], Francesco Bedogni[2], Luca Testa[2], Rocco Antonio Montone[2], Matteo Montorfano[3], Fausto Castriota[4], Anna Sonia Petronio[5], Andrea Garatti[2], Sabino Iliceto[6], Alberto Barioli[1], Gianpiero D'Amico[1], Giulia Masiero[1], Marco Mojoli[1], Benedetta Schiavon[1], Paola Purita[1], Alessandro Schiavo[1], Massimo Napodano[1], Giuseppe Tarantini[1]
[1]UOD Emodinamica e Cardiologia Interventistica, Università di Padova, Padova, Italy, [2]IRCCS Policlinico San Donato, Milano, Italy, [3]IRCCS Ospedale San Raffaele, Milano, Italy, [4]Maria Cecilia Hospital, Cotignola, Italy, [5]Ospedale Cisanello, Università di Pisa, Pisa, Italy, [6]UOC Cardiologia, Università di Padova, Padova, Italy

Background. New-generation transcatheter heart valves (THV) have been developed to reduce complications of transcatheter aortic valve implantation (TAVI). With this study we sought to compare procedural and 30-day outcomes of the new-generation repositionable Boston Scientific Lotus (Lotus) and the balloon-expandable Edwards Sapien 3 (ES3) THV.
Methods. A total of 315 patients with severe symptomatic aortic stenosis undergoing transfemoral TAVI with Lotus or ES3 and included in two large Italian registries were considered for this analysis. After propensity matching, 93 matched pairs of patients were included. Outcomes were evaluated according to VARC-2 definition at discharge and 30-day.
Results. There were no differences in baseline characteristics, except for lower mean aortic gradient and larger mean aortic annulus in the ES3-treated patients. VARC-2 defined device success was high and comparable between groups (97.8 for Lotus vs. 98.9% for ES3, p=0.09). The frequency of moderate/severe paravalvular leak (PVL) was low and similar for both devices (2.2% vs. 1.1%, p=0.10). At 30-day, both groups showed low all-cause mortality (5.4 vs. 1.1%, p=0.10) and rates of disabling stroke (3.2 vs. 1.1%, p=0.31). New pacemaker (PM) implantation was more common after Lotus deployment (31.7 vs. 10.5%, P<0.001).
Conclusions. Transfemoral TAVI with both Lotus and ES3 resulted in favorable clinical and hemodynamic 30-day outcomes. Rates of significant PVL was low with both devices. The Lotus valve was associated with higher risk of PM implantation.

C29

IFR ASSESSMENT OF CORONARY ARTERY DISEASE IN PATIENTS WITH SEVERE AORTIC STENOSIS UNDERGOING TAVI

Roberto Scarsini, Gabriele Pesarini, Mattia Lunardi, Carlo Zivelonghi, Anna Piccoli, Federico Marin, Claudia Zanetti, Michele Bellamoli, Valeria Ferrero, Flavio Luciano Ribichini
Division of Cardiology, Department of Medicine, University of Verona, Verona, Italy

Aims. We sought to assess eventual changes in iFR measurements in patients with aortic stenosis (AS) before and after TAVI in coronary lesions with different degree of angiographic severity.
Methods and Results. The functional relevance of 145 coronary lesions was assessed by on-line iFR and FFR measurement in 66 patients with severe AS before and after TAVI, during the same procedure. The iFR-FFR classification agreement was calculated for pre- and post-TAVI measurements. Mean iFR values remained identical before and after TAVI, irrespective of the angiographic severity of the coronary stenosis (0.89±0.12 vs 0.89±0.12, p=0.66). However, individual iFR values varied widely after TAVI and the 0.89 iFR threshold was crossed by 15% of the investigated coronary lesions. Higher iFR variation was related to a higher trans-aortic gradient drop after valve intervention. The diagnostic accuracy of iFR in predicting a FFR ≤0.8 was poor (65%) in lesions with severe obstructions, and tended to increase post-TAVI.
Conclusions. Although overall values did not change after TAVI, iFR presented significant and mostly erratic individual variations after the valve replacement. The iFR-delta was influenced by the extent of the trans-aortic gradient drop induced by TAVI. Therefore, caution is advisable in iFR interpretation in presence of AS.

C30

EARLY EXPERIENCE WITH THE SYMETIS BIOPROSTHESIS IN REAL WORLD PATIENTS: THE MILAN REGISTRY

Paolo Pagnotta[1], Cristina Panico[1], Francesco Giannini[2], Marco Luciano Rossi[1], Luca Baldetti[2], Francesco Cannata[1], Matteo Montorfano[2], Mauro Chiarito[1], Alaide Chieffo[2], Azeem Latib[2], Bernhard Reimers[1], Antonio Colombo[2]
[1]Istituto Clinico Humanitas, Rozzano, Italy, [2]San Raffaele Hospital, Milano, Italy

Aims. Transcatheter aortic valve implantation (TAVI) has emerged as a feasible and effective alternative to surgical aortic valve replacement in patients at high and intermediate surgical risk. Although improvements of both materials and implantation techniques have led to better outcomes, bleeding, vascular complications, conduction disorders and paravalvular leak (PVL) remain frequent procedure-related complications. Over the past decade, several transcatheter devices have been developed and tested in order to decrease complications and improve clinical outcomes. The purpose of this study was to report the first Milan experience with the new generation self-expandable SYMETIS Acurate neoTM TF valve.
Methods and Results. Consecutive patients who underwent TAVI with SYMETIS Acurate neoTM TF valve at Humanitas Research Hospital (Rozzano, Milan, Italy) and at San Raffaele Scientific Institute (Milan, Italy) were included in a prospective registry between July 2015 and June 2017. Clinical and echocardiographic assessment was performed at baseline, after the procedure, and at early follow up. Baseline characteristics and outcomes were assessed according to valvular academic research consortium (VARC-2) criteria. Atrioventricular and intraventricular conduction delays were assessed on ECGs acquired prior to TAVI and before discharge. A total of 85 patients were included, with a mean age was 82.7 ± 5.7 years and a mean Society of Thoracic Surgeons score of 5.7±3.8%. Device success was achieved in 83 (87.1%) patients and only one patient required an immediate second valve-in-valve implantation due to valve migration. Valve implantation resulted in a significant reduction in mean transvalvular gradient (48.32±14.54 mmHg vs 7.93±3.18 mmHg, p<0.001). Moderate to severe paravalvular leak was present in 6 (7.8%) patients at discharge. New conduction disturbances occurred in 29 (34.5%) patients but new permanent pacemaker implantation was required in only 5 (6%) patients. Major bleedings occurred in 5 (6%) patients, major vascular complications in 2 patients (2.4%). There were no peri-procedural deaths, myocardial infractions or strokes. At early follow up (mean of 150 days), 5 patients (5.9%) died, 2 (2.4%) of which for cardiovascular causes.
Conclusions. The preliminary findings of this prospective registry indicate that the new-generation SYMETIS Acurate neoTM TF valve is a safe and effective in routine clinical practice, with a low rate of procedural complications and favorable early clinical outcomes.

C31

EARLY CLINICAL OUTCOMES OF THREE DIFFERENT SECOND-GENERATION TRANSCATHETER AORTIC VALVE PROSTHESES

Giuliano Costa, Sergio Buccheri, Marco Barbanti, Denise Todaro, Andrea Picci, Emanuela Di Simone, Gerlando Pilato, Ketty La Spina, Paolo D'Arrigo, Simona Gulino, Antonino Indelicato, Daniela Giannazzo, Sebastiano Immè, Claudia Tamburino, Martina Patanè, Carmelo Sgroi, Wanda Deste, Piera Capranzano, Davide Capodanno, Corrado Tamburino

Divisione di Cardiologia, PO Ferrarotto, Azienda Policlinico Vittorio Emanuele, Catania, Italy

Background. A detailed characterization of the aortic valve anatomy by computerized tomography (CT) may guide the selection of a suitable second generation aortic valve prosthesis for transcatheter implantation.

Methods and Results. This was a single center, prospective, observational study. All consecutive patients undergoing transfemoral transcatheter aortic valve implantation (TAVI) for severe aortic stenosis with second generation prostheses (Edwards SAPIEN 3, Medtronic Evolut R and Symetis Acurate NEO TF) were included in the study. We accounted for differences in baseline clinical characteristics between groups using propensity score weighting. From September 2014 to June 2017, a total of 460 patients underwent TAVI at our Institution. Of these, 155 patients were treated with Edwards SAPIEN 3 prosthesis, 229 with Medtronic Evolut R and 77 with the Symetis Acurate NEO TF. The mean age for the entire study cohort was 81.1±5.3 years while the STS predicted risk of mortality was 4.4±2.9%. Rates of complications in the study were low at 30 days (all-cause mortality 1.7%, cardiovascular mortality 1.3%, major stroke 0.9%, permanent pacemaker implantation 8.3%, VARC-2 defined composite safety endpoint 13.5%). In propensity score weighted analyses, second generation TAVI prostheses did not differently impact on 30-day all-cause (p=0.644 and p=0.693 for SAPIEN 3 and Symetis vs. EvolutR, respectively), and cardiovascular mortality (p=0.861 and p=0.907 for SAPIEN 3 and Symetis vs. EvolutR, respectively). A trend toward an increased rate of permanent pacemaker implantation was found in patients treated with the EvolutR valve (p=0.068 and p=0.159 vs. SAPIEN 3 and Symetis, respectively). The VARC-2 defined composite safety endpoint was more frequently encountered in patients treated with the Evolut R prosthesis as compared to the SAPIEN 3 valve (p<0.01).

Conclusions. TAVI using second generation prostheses was associated with low complication rates. In adjusted head-to-head comparisons between different devices, the EvolutR valve yielded a numerical increase in permanent pacemaker implantation and increased rates of VARC-2 defined composite safety endpoint.

DES/DEB

C32

REGISTRO MULTICENTRICO ITALIANO SULL'UTILIZZO DEL PALLONE MEDICATO NELLE IN-STENT RESTENOSIS. RISULTATI IN ACUTO E SU LUNGO PERIODO

Stefano Galli[1], Piero Montorsi[1], Paolo Ravagnani[1], Sarah Troiano[1], Alfonso Ielasi[2], Maurizio Tespili[2], Giampaolo Niccoli[3], Andrea Celestini[4], Francesco Amico[5], Giampaolo Pasquetto[6], Roberto Ceravolo[7], Leonardo Paloscia[8], Marco Contarini[9]

[1]Centro Cardiologico Monzino IRCCS, Milano, Italy, [2]AO Bolognini, Seriate, Italy, [3]Policlinico Gemelli, Roma, Italy, [4]Ospedale Bel Colle, Viterbo, Italy, [5]PO Sant'Elia, Caltanissetta, Italy, [6]ULSS 17, Este, Italy, [7]AO Pugliese Ciaccio, Catanzaro, Italy, [8]Ospedale Spirito Santo, Pescara, Italy, [9]AO Umberto I, Siracusa, Italy

Scopo. L'utilizzo degli stent medicati (DES) nel trattamento della in-stent restenosis (ISR) è una terapia efficace e consolidata, nonostante questo il pallone medicato (DCB) può esserne considerato una valida alternativa. Lo scopo di questo studio è valutare sicurezza, efficacia e risultati clinici di un DCB innovativo, nelle ISR, con particolare attenzione alle DES-ISR e alle lesioni complesse.

Metodi e Risultati. Da aprile 2013 a marzo 2016 sono stati arruolati 199 pazienti, trattati con un pallone medicato al paclitaxel (3 µg/mm^2), di ultima generazione (Pantera Lux®, Biotronik, Bülach, Switzerland). La tecnica di impianto prevedeva la predilatazione e un rapporto 1:1 fra i diametri di pallone e lesione. Il crossover a DES era previsto per prolasso severo di placca, dissezione limitante il flusso o chiusura improvvisa del vaso. La terapia DAPT, per protocollo, è stata prescritta per almeno 3 mesi. I follow-up sono stati programmati a 30 giorni e a 12 mesi, con controllo telefonico. L'endpoint primario dello studio sono gli eventi avversi maggiori (MACE) a 12 mesi, costituiti da morte cardiaca e non, infarto miocardico (MI), target lesion revascularization (TLR) e stent thrombosis (ST) nella lesione target, in accordo con la definizione ARC. Gli endpoint secondari sono i MACE a 1 mese e il successo in acuto (composto da successo del device, procedurale e clinico). Tutti i 199 pazienti arruolati (età media 68.6±10.4 anni) avevano una pregressa PCI e nel 29% dei casi erano diabetici. La procedura era elettiva nel 59% dei casi (angina stabile o ischemia silente), mentre nel restante 41% i pazienti avevano sindrome coronarica acuta (ACS), rispettivamente con il 19% di angina instabile, il 18% di MI-NSTEMI e il 4% di MI-STEMI. Sono state trattate 214 lesioni (78% DES-ISR). La classificazione Mehran delle ISR è la seguente: 2% di tipo IA; 14% IB, 43% IC, 4% ID, 25% di tipo II, 10% di tipo III and 2% di tipo IV, per un totale di ISR complesse del 37%. I vasi maggiori trattati sono stati: discendente anteriore (LAD) nel 43% dei casi, circonflessa (LCx) nel 25%, coronaria destra (RCA) 23%, tronco comune (LM) 3%. La lunghezza delle restenosi era 15 mm (valore mediano, IQ: 12-20 mm), per una stenosi dell'80% (valore mediano, IQ: 70-90%). È stata applicato un singolo gonfiaggio (60 s, valore mediano, IQ: 45-60 s) a 12 atm (valore mediano, IQ: 10-12). Il diametro medio del DCB è 3.1±0.5 mm, la lunghezza è 20 mm (valore mediano, IQ: 15-20 mm). Tutti i DCB hanno avuto successo nel rilascio, il crossover a DES è accaduto nel 3% dei casi per motivi di: dissezione (1%), shift di placca (0.5%), stenosi residua maggiore del 30% (0.5%) e recoil acuto (1%). Il successo procedurale e clinico è stato del 98% (195/199). Al follow-up al primo mese, con una compliance del 97%, le curve Kaplan-Meier mostrano una sopravvivenza ai MACE del 96.9% (CI: 93.15-98.6%) e una sopravvivenza agli infarti del 98.4% (CI: 95.1-99.5%). A 12 mesi, con una compliance dell'89.8% (176/196) l'analisi finale mostra una sopravvivenza ai MACE dell'82.9% (CI: 73.1-89.3%), con 6 casi di decesso (3.4%), di cui due morti cardiache (1.1%), 3 casi di MI (1.7%) e 15 casi di TLR (8.5%); la sopravvivenza agli infarti invece rimane il 98.4% (CI: 95.1-99.5%).

Conclusioni. Questo studio conferma che il DCB è un trattamento sicuro ed efficace nelle lesioni ISR. Il dispositivo Pantera Lux® mostra buoni risultati sia in acuto che a 12 mesi post procedura, persino nel trattamento delle ristenosi più complesse, in particolare da DES. Per concludere questo dispositivo è una valida alternativa per evitare l'uso di stent-in-stent nel trattamento delle restenosi.

C33

BIODEGRADABLE-POLYMER VS DURABLE-POLYMER DRUG-ELUTING STENTS IN ACS PATIENTS: THE AVERSA REGISTRY

Gianluca Caiazzo, Mario De Michele, Luca Golino, Vincenzo Manganiello, Giuseppe Fiorillo, Assunta Chianese, Pietro Fabbiano, Giuseppina Fresolone, Antonio Iovine, Giancarlo Menale, Valeria Piccolo, Maria Riccardi, Rosaria Pellegrino, Dario Leosco, Luciano Fattore

Laboratorio di Emodinamica, UOC Cardiologia-UTIC, P.O. San Giuseppe Moscati, Aversa, Italy

Background. Recent randomized trials have indicated similar safety and efficacy outcomes of biodegradable polymer drug-eluting stents (BP-DES) and durable-polymer drug-eluting stents (DP-DES). Aim of our registry was to compare BP-DES and DP-DES in a real world scenario of complex ACS patients at mid-term clinical follow-up.

Methods and Results. We evaluated 752 consecutive ACS patients undergoing PCI of at least one native coronary artery and receiving alternatively BP-DES or DP-DES from February 2015 to December 2016 in our center. BP-DES were implanted in 202 patients whereas DP-DES were implanted in 550 patients. There were no significant differences in baseline characteristics between groups. In the overall population, STEMI patients were 40.2% (BP-DES: 35.6% and DP-DES: 41.9%, p=0.13) and the percentage of complex coronary lesions, defined as b2-c AHA/ACC-type, was 70%. At a median follow-up period of 14.5±8.5 months, there were no significant differences in TLR (BP-DES: 4.4% vs DP-DES: 3%; p=0.36), TVR (BP-DES: 7.1% vs. DP-DES: 4.4%; p=0.42) and definite/probable stent thrombosis (BP-DES: 0.7% vs. DP-DES: 0.5%; p=0.12). There was also no difference in MACCE between groups (BP-DES: 11.6% vs. DP-DES: 9.4%, p=0.49).

Conclusions. In our registry, patients with ACS undergoing BP-DES implantation reported similar clinical outcomes compared to patients receiving DP-DES at mid-term follow-up period.

C34

ONE-YEAR CLINICAL OUTCOME OF BIODEGRADABLE POLYMER SIROLIMUS-ELUTING STENT IN ALL-COMERS POPULATION OF ULISSE REGISTRY (ULTIMASTER ITALIAN MULTICENTER ALL COMERS STENT REGISTRY)

Cosmo Godino[1], Alessandro Beneduce[1], Carlo Andrea Pivato[1], Mauro Chiarito[2], Alberto Cappelletti[1], Giuseppe Ferrante[2], Giulia Perfetti[1], Giulia Perfetti[1], Franco Fabbiocchi[3], Stefania Falcone[4], Alfonso Ielasi[5], Adele Pierri[6], Valeria Magni[1], Matteo Montorfano[1], Stefano De Martini[3], Rosario Parisi[7], David Rutigliano[8], Nicola Locuratolo[8], Alberto Margonato[1], Alberto Benassi[9], Angelo Anzuini[4], Bernhard Reimers[2], Maurizio Tespili[5], Carlo Briguori[6], Antonio Bartorelli[3], Antonio Colombo[1]

[1]Ospedale San Raffaele, Milano, Italy, [2]Istituto Clinico Humanitas, Milano, Italy, [3]Centro Cardiologico Monzino, Milano, Italy, [4]Ospedale Humanitas Mater Domini, Castellanza, Italy, [5]Ospedale Bolognini, Seriate, Italy, [6]Clinica Mediterranea, Napoli, Italy, [7]Ospedali Riuniti Marche Nord, Pesaro, Italy, [8]Ospedale San Paolo, Bari, Italy, [9]Ospedale Hesperia, Modena, Italy

Background. The delay of re-endothelialisation as well as inhibition of vascular repair after drug-eluting stent (DES) implantation, in part related

to permanent polymers, are consider important part of target vessel failure (TVF) and stent thrombosis (ST) pathophysiology mechanism during follow-up.
Methods. The ULISSE study is a multicentre-independent, single-arm, all-comers, observational registry designed to assess safety and efficacy after biodegradable-polymer sirolimus-eluting stent (BP-SES) at 9 different centres in Italy. 1544 consecutive patients (2267 lesions) treated with BP-SES between July 2014 and August 2016 were retrospectively enrolled. The primary and secondary endpoints were target vessel failure (TVF) and target lesion revascularization (TLR) at 1 year, respectively.
Results. 655 (45%) patients were treated for at least one complex lesion (chronic total occlusion 9%, bifurcation 19%, very long lesion [>35 mm] 24%, unprotected left-main 4%) and most of them (51%) presented a high-risk clinical profile (diabetes mellitus 29%, chronic kidney disease 11%, previous CABG 13%, low LVEF (<35%) 5%, STEMI as clinical presentation 11%).1-year follow-up was available for 1286 patients (83%) and TVF occurred in 81 (6.3%) patients: cardiac death 24 (1.9%), myocardial infarction 24 (1.9%) and target vessel revascularization 58 (4.5%). TLR occurred in 44 (3.4%) patients. Definite ST rate was 12 (0.93%).
Conclusion. This study provides preliminary evidence for mid-term safety and efficacy of biodegradable-polymer sirolimus-eluting stent in all-comers daily practice cohort of Italian patients, including complex lesions.

C35

ONE-YEAR CLINICAL OUTCOME OF BIODEGRADABLE POLYMER SIROLIMUS ELUTING STENT IN DIABETES MELLITUS PATIENTS: INSIGHT FROM THE ULISSE REGISTRY (ULTIMASTER ITALIAN MULTICENTER ALL COMERS STENT REGISTRY)

Cosmo Godino[1], Alessandro Beneduce[1], Carlo Andrea Pivato[1], Mauro Chiarito[2], Alberto Cappelletti[1], Giuseppe Ferrante[2], Giulia Perfetti[1], Franco Fabbiocchi[3], Stefania Falcone[4], Alfonso Ielasi[5], Adele Pierri[6], Valeria Magni[1], Matteo Montorfano[1], Stefano De Martini[3], Rosario Parisi[7], David Rutigliano[8], Nicola Locuratolo[8], Alberto Margonato[1], Alberto Benassi[9], Angelo Anzuini[4], Bernhard Reimers[2], Maurizio Tespili[5], Carlo Briguori[6], Antonio Bartorelli[3], Antonio Colombo[1]
[1]Ospedale San Raffaele, Milano, Italy, [2]Istituto Clinico Humanitas, Milano, Italy, [3]Centro Cardiologico Monzino, Milano, Italy, [4]Ospedale Humanitas Mater Domini, Castellanza, Italy, [5]Ospedale Bolognini, Seriate, Italy, [6]Clinica Mediterranea, Napoli, Italy, [7]Ospedali Riuniti Marche Nord, Pesaro, Italy, [8]Ospedale San Paolo, Bari, Italy, [9]Ospedale Hesperia, Modena, Italy

Background. Despite several improvements in drug-eluting stent (DES) technology, patients with diabetes mellitus (DM) are affected by higher rate of adverse events after PCI, mainly in terms of target lesion revascularization (TLR). Biodegradable polymer sirolimus-eluting stent (BP-SES) has not been extensively studied in DM patients.
Methods. 1544 consecutive patients (2267 lesions) treated with BP-SES between July 2014 and August 2016 were retrospectively enrolled in the ULISSE registry and divided in two groups: DM (449 patients, 681 lesions) and non-DM (1095 patients, 1586 lesions). Primary and secondary endpoints were TLR and target vessel failure (TVF) at 1 year, respectively.
Results. Diabetic patients were more frequently affected by chronic kidney disease (p<0.001), more frequently dialyzed (p=0.018) and they had a lower ventricular ejection fraction (p<0.001). At 1-year follow-up TLR occurred in 44 (3.4%) overall patients, and it was similar in DM and non-DM patients (4.8% vs 2.2%, respectively, p=0.233). The secondary endpoint (TVF) occurred in 81 (6.3%) overall patients and was higher in DM patients (9.4% vs 4.3%, respectively, p=0.001), due to more cardiac deaths (4.6% vs 1.3%, p=0.011), myocardial infarction and TVR. Furthermore, the primary endpoint was similar between insulin and non-insulin dependent DM patients (4.9% vs 3.2%, p=0.465), instead a higher rate of secondary endpoint affected the first group (14.6% vs 6.4%, p=0.009).
Conclusion. The results of this large, real-world, multicentre-independent registry show that BP-SES has similar efficacy profile in DM as well as non-DM patients undergoing PCI. TVF and other stent safety endpoints were still higher in DM.

C36

IMPACT OF ULTRA-THIN STRUTS ON RESTENOSIS AFTER CHRONIC TOTAL OCCLUSION RECANALIZATION: INSIGHT FROM PRISON IV TRIAL

Carlo Zivelonghi[1], Koen Teeuwen[1], Josè Henriques[2], Maarten Suttorp[1], Pierfrancesco Agostoni[1]
[1]Department of Cardiology, Sint Antonius Ziekenhuis, Nieuwegein, Netherlands, [2]Department of Cardiology, Academic Medical Center, University of Amsterdam, Amsterdam, the Netherlands

Background. In the PRISON IV randomized multicentre trial successfully recanalysed coronary chronic total occlusion (CTO) lesions were randomly allocated in a 1:1 fashion to stent implantation with an hybrid ultrathin-strut (60μm for stents up to 3.0 mm diameter and 80μm for larger stents) sirolimus-eluting stent (SES) platform with biodegradable polymer or a thin-strut (81μm) everolimus-eluting stents (EES) with durable polymer. The SES study device did not meet the primary non-inferiority endpoint of in-segment late lumen loss (LLL) estimated by Quantitative Coronary Analysis (QCA) at 9 month of angiographic follow-up, caused mainly by an increased rate of focal in-stent restenosis in the SES group. Aim of the present analysis is to shed "hypothesis-generating" light on the mechanical features related to the SES potentially implicated in the less favourable angiographic outcome described in the PRISON IV trial.
Methods and Results. In the present analysis, we investigated the hypothesis that the thinner struts platform of the SES with diameter ≤3 mm may have been responsible for the inferior angiographic outcome observed in the Prison IV trial. For this reason, patients were further divided into the following groups according to the diameter size of the stent received: Group A (n=178), patients receiving only stents with diameter ≤3 mm; Group B (n=59), patients receiving only stents with diameter >3 mm; Group C (n=93), patients receiving both stents with diameter >3 mm and ≤3 mm; Endpoints of this analysis included angiographic outcomes as in-stent late lumen loss, MLD, in-stent percentage of diameter stenosis, binary restenosis and re-occlusions at 9 months. Basal demographic and angiographic (including J-CTO score) data between the two devices were evenly distributed in all the three sub-groups. In Group A, the 9-month follow-up QCA disclosed a trend towards lower in-stent minimal lumen diameter (MLD) in the SES group vs the EES group (2.06±0.61 mm vs 2.21±0.48 mm, p=0.08), with a strong tendency to higher in-stent diameter stenosis (DS) (26.04±18.59% and 21.24±12.84% respectively, p=0.06). Moreover, the binary restenosis rate was significantly higher in the SES group: 8 (10.3%) vs 1 (1.3%), p=0.03. In Group B and C, instead, these trends were not observed, with comparable outcomes in terms of all QCA measurements between SES and EES.
Conclusions. In this sub-analysis from the PRISON IV trial, patients receiving hybrid SES with diameter ≤3 mm demonstrated a significant worse outcome in terms of MLD, DS and incidence of binary restenosis when compared with patients receiving EES of the same diameter. A possible explanation for this phenomenon could derive from a relatively sub-optimal performance of the ultra-thin struts in the settings of highly complex and calcified lesions as those of CTO.

Miscellaneous 2

C37

EFFETTI DELL'ALLOPURINOLO (300 MG) SUI FARMACI INIBITORI DEL P2Y12 IN PAZIENTI DIABETICI NON CORONAROPATICI IN TERAPIA CON ASA E INSULINA

Marina Polacco, Carlo Gaudio, Cesare Greco
Policlinico Umberto I, Roma, Italy

Background. È ampiamente noto che il diabete mellito è associato a complicanze microvascolari e macrovascolari, che si manifestano come cardiopatia ischemica precoce, eventi cerebrovascolari e grave arteriopatia periferica, oltre che come nefropatia e retinopatia. Infatti, i pazienti diabetici mostrano un incremento del rischio di cardiopatia ischemica, stroke e arteriopatia periferica di 2-4 volte rispetto ai pazienti non diabetici. Inoltre, i pazienti diabetici, quando vanno incontro a un evento vascolare maggiore, hanno una prognosi peggiore rispetto ai soggetti non diabetici. Sono stati proposti vari meccanismi fisiopatologici che possano chiarire le cause dell'elevata incidenza di eventi CV nei pazienti diabetici. In particolare, si è indagato il ruolo della disfunzione endoteliale, dello stato proinfiammatorio e della alterata funzionalità piastrinica nel determinismo delle complicanze vascolari del diabete mellito. L'iperaggregabilità piastrinica nei pazienti diabetici era riportata già nel 1965. Studi recenti indicano che l'alterata funzione piastrinica, caratteristica dei pazienti diabetici, potrebbe essere correlata a vari meccanismi, tra cui le alterazioni metaboliche, lo stress ossidativo e la disfunzione endoteliale presenti in tali pazienti. Di conseguenza, sono state valutate e sono ancora in corso di valutazione varie strategie antiaggreganti, allo scopo di ridurre le complicazioni trombotiche dell'aterosclerosi nei pazienti diabetici. Sulla base delle evidenze riportate in letteratura, viene raccomandato l'uso dell'ASA nei pazienti diabetici ad alto rischio CV. Ciononostante, alcuni pazienti diabetici trattati con ASA mostrano un'elevata incidenza di eventi trombotici, attribuibile all'"aspirino-resistenza" individuale. L'allopurinolo, farmaco comunemente impiegato per il trattamento della gotta, similmente ai farmaci antiaggreganti, induce un aumento dei livelli di cAMP per inibizione della fosfodiesterasi e potrebbe pertanto potenziare l'efficacia della terapia antiaggregante. Allo stato attuale non ci sono evidenze scientifiche a supporto di questa ipotesi. Allo stesso tempo, l'atorvastatina, farmaco appartenente alla classe delle statine, dimostra benefica attività anti-infiammatoria.
Scopo. Valutare la possibile diminuzione della reattività piastrinica, dopo la somministrazione di allopurinolo alla dose di 300 mg e atorvastatina alla dose di 80 mg, in pazienti diabetici non coronaropatici.

Materiali e metodi. Lo studio è stato effettuato su 200 pazienti diabetici in assenza di malattia coronarica documentata ed in terapia con cardioaspirina 100 mg ed insulina secondo lo schema stabilito individualmente. Le variazioni di attività piastrinica sono state valutate attraverso il Verify Now, ed espresse in PRU (Platelet Reaction Units). Il PRU nei pazienti è stato misurato al basale (T0), dopo 30 giorni di somministrazione di atorvastatina 80 mg (T1) a cui è seguito un wash-out di 5 giorni e successivamente ulteriori 30 giorni di allopurinolo 300 mg (T2) con successivo washout e ulteriori 30 giorni di co-somministrazione di atorvastatina 80 mg e allopurinolo 300 mg (T3).
Risultati. La singola somministrazione di atorvastatina ha provocato, rispetto al basale una riduzione, statisticamente significativa (p=0.005), della reattività piastrinica, in tutti i pazienti così come l'allopurinolo, assunto singolarmente (p=0.002). La reattività piastrinica si è ridotta in modo statisticamente significativo a seguito della co-somministrazione di atorvastatina e allopurinolo (p=0.0001).
Conclusioni. Questi dati dimostrano che la co-somministrazione di allopurinolo e atorvastatina in pazienti diabetici in terapia con ASA e insulina provoca una significativa riduzione della reattività piastrinica e potrebbe pertanto costituire o una strategia terapeutica molto promettente per diminuire il rischio trombotico in questo subset di pazienti.

C38

ACUTE AND SHORT-TERM PERFORMANCE OF MAGMARIS BIORESORBABLE SCAFFOLD IMPLANTATION IN COMPLEX LESIONS: A MULTICENTER EXPERIENCE

Enrico Cerrato[1], Salvatore Geraci[2], Massimo Leoncini[3], Alfonso Ielasi[4], Francesco Granata[5], Paolo Sganzerla[6], Simone Biscaglia[7], Chiara Bernelli[8], Dario Buccheri[2], Giorgio Quadri[1], Francesco Tomassini[1], Fabio Ferrari[1], Cristina Rolfo[1], Luigi Salemme[5], Gianluca Campo[7], Giuseppe Caramanno[2], Claudio Rapetto[3], Ferdinando Varbella[1]
[1]Ospedale degli Infermi, Rivoli (TO) e Azienda Ospedaliero-Universitaria San Luigi Gonzaga, Orbassano (TO), Italia, Rivoli, Orbassano, Italy, [2]Ospedale San Giovanni di Dio, Agrigento, Italy, [3]Ospedale di San Remo, San Remo (IM), Italy, [4]Azienda Socio Sanitaria Territoriale Bergamo Est, Seriate (BG), Italy, [5]Casa di Cura Montervergine, Mercogliano (AV), Italy, [6]Ospedale di Treviglio, Treviglio (BG), Italy, [7]Azienda Ospedaliero-Universitaria di Ferrara, Ferrara, Italy, [8]Ospedale Bassini, Milano, Italy

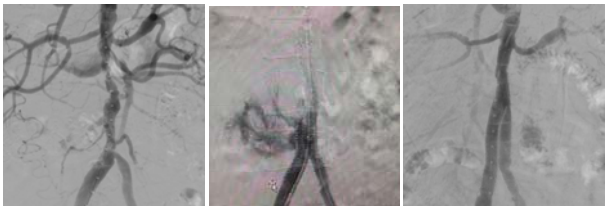
Background. Although recent discouraging data on poly-L-lactic bioresorbable scaffolds (BrS), there is still a strong rationale in scaffold employment for coronary stenosis treatment. New magnesium- made BrS Magmaris showed promising results in clinical trials in terms of efficacy and safety nevertheless few data regarding its implantation in real world and complex lesions are available.
Methods. All consecutive patients undergoing PCI with implantation of at least one Bioresorbable (BrS) Magmaris Scaffold (Biotronik, Buelach, Switzerland) in 7 Italian Institutions with high volume PCI were included. Device acute success defined as 1) successful BrS delivery and implantation; 2) post-procedural residual diameter stenosis <20% within the treated segment; 3) restoration of Thrombolysis in Myocardial Infarction (TIMI) grade 3 antegrade flow was evaluated. In-hospital and 30-day Device Oriented Cardiac Events (DOCE) were also registered..
Results. Between July 2016 and July 2017, 91 stenoses in 87 patients were included. They were mainly males (n=72; 82.8%) with a mean age of 61.1±8.8 years with preserved ejection fraction (56.0±8.7%). Stable CAD (n=40; 45.9%) or ACS/NSTE (n=48; 55.2%) were the most common admission diagnoses. Among ACS/NSTEMI patients, culprit-lesion was target for revascularization in 19 cases (21.8%). Mean lesion length was 25.8.3± 17.6 mm treated with a mean of 1.4±0.8 MAGMARIS scaffolds (mean scaffold diameter 3.2±0.2). ACC/AHA type B2/C lesions were 71 (78.0%). BrS predilatation was performed in 100% and post-dilatation in 95.6% of cases using non-compliant balloon in 58% and 100% of cases respectively. Intravascular imaging was used in almost half the cases (n=41; 45%; 29 OCT and 12 IVUS). Provisional bifurcations treatment occurred in 16 (17.5%) cases with final side branch balloon dilatation in 4 cases. An overlapping technique was used 36 times in 22 lesions (24.2%; marker-to-marker in 82% of cases). Device acute success was achieved in all cases without any in-hospital event. At thirty-days follow-up (available in 89.6%, n=79) 2 DOCE occurred (2.2%): 1 in-stent restenosis and 1 subacute stent thrombosis, all successfully treated with DES implantation.
Conclusion. Magmaris BrS implantation is feasible with an high intraprocedural success also in complex lesions. Longer follow-up data and larger samples are required.

C39

A CASE OF AORTIC PERFORATION COMPLICATING AORTO-ILIAC INTERVENTION

Kumara Gurupparan Ganesan, Yahya Shaiful Azmi
Department of Cardiology, National Heart Institute, Kuala Lumpur, Malaysia

Aortic perforation is a devastating complication of aortic intervention, which can rapidly lead to fatality if not dealt with swiftly. We present a case of a 52-year-old lady with stable coronary artery disease, diabetes mellitus, hypertension complaining of bilateral lower limb claudication despite optimized medical therapy. An aortogram revealed severe bilateral aortoiliac disease - severe stenosis at the distal abdominal aorta and severe stenosis at the left aortoiliac junction. The distal aorta was stented with an EPC 14/60 self-expending stent. Both the iliacs were stented simultaneously in a V stenting strategy using Express 10/37 and Express 8 x 37 balloon expendable stents respectively.
During simultaneous deployment of the stents, the patient developed sudden abdominal pain with acute hypotension. An aortogram revealed an acute aortic perforation. Balloon tamponade could not manage to contain the bleeding. Two covered stents – Advanta V12 10/59 and 10/38 were deployed from both right and left iliac arteries. Post dilatation was successful and closing off the perforation.



C40

A VALIDATION STUDY OF IMAGE-BASED FRACTIONAL FLOW RESERVE (FFR_{ANGIO}) DURING CORONARY ANGIOGRAPHY

Mariano Pellicano[1], Ifat Lavi[2], Bernard De Bruyne[1], Hana Vaknin-Assa[3], Abid Assali[3], Orna Valtzer[3], Yonit Lotringer[2], Giora Weisz[4], Yaron Almagor[4], Panagiotis Xaplanteris[1], Giovanni Ciccarelli[1], Ajay J. Kirtane[5], Pablo Codner[3], Martin B. Leon[5], Ran Kornowski[3]
[1]Cardiovascular Center Aalst, OLV Hospital, Aalst, Belgium, [2]CathWorks Ltd, Ra'anana, Israel, [3]Rabin Medical Center, Petach Tikva, Israel, [4]Shaare Zedek Medical Center, Jerusalem, Israel, [5]Columbia University Medical Center/New York-Presbyterian Hospital, New York, NY, USA

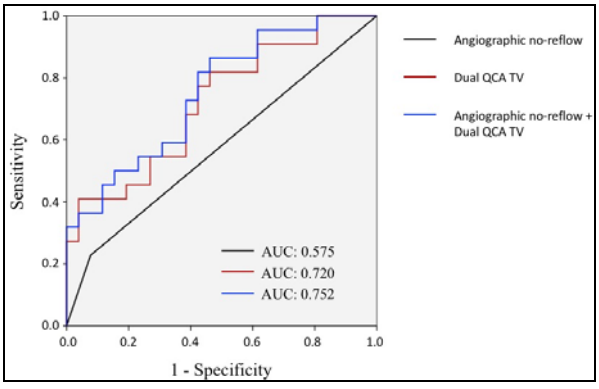
Background. Fractional flow reserve (FFR) is the standard of reference to evaluate the ischemic potential of coronary stenosis. Moreover, FFR is increasingly being used in clinical trials or to validate new diagnostic modalities.
Purpose. To assess the diagnostic performance and interobserver reproducibility of angiography-based FFR (FFR_{angio}), in comparison with invasive FFR, in patients with stable coronary artery disease.
Methods. FFR_{angio} provides a 3D functional angiography mapping of the coronary tree with superimposed, color-coded, FFR values. This is accomplished automatically by reconstructing the geometry of the tree, including its centerlines and cross-sections at each point along them, as well as the exact topology. The reconstruction is based on the known geometry of two or more projections, from single-plane angiograms, and utilizes epi-polar ray tracing together with mathematical constraints enforcing the tree's structure. The coronary tree, represented by position and diameter values for all vessels, can then be surfaced using a triangular mesh, and rendered to display a 3D coronary model. Next, the system scans the entire reconstructed tree in 3D, and analyzes each branch as well as each bifurcation (or trifurcation), looking for narrowed regions. The last step is the hemodynamic evaluation, where the contribution of each narrowing to the total flow resistance is taken into account, allowing the pressure drops and the flow rates to be estimated. All lesions (VE 50-90%) indicated for invasive FFR measurement were analyzed by FFR_{angio} from multiple views of a regular angiogram. FFR_{angio} was compared to invasive FFR at the exact location of the sensor. To ensure complete blinding, invasive FFR's were locked in a database exclusively controlled by an independent CRO (TechnoSTAT). The FFR_{angio} calculations were performed offline in a remote location by two operators not present in the catheterization laboratory and totally blinded to each other and to invasive FFR. Then, the FFR_{angio} results were sent to the CRO for comparison.
Results. A total of 184 patients were enrolled in 4 centers. FFR_{angio} was obtained in 203 lesions (118 LAD; 30 LCX; 9 OM; 39 RCA; 5 Intermediate; 2 Diagonal) by two different operators. 67% of the invasive FFR values were between 0.70 and 0.90, and 35% between 0.75 and 0.85. The average intraclass correlation coefficient (ICC) for the two measurements of FFR_{angio} conducted by two different operators was 0.962 (95% CI: 0.95-0.971; p<0.001). Applying an FFR cut-off value of 0.80, the sensitivity, specificity, diagnostic accuracy for FFR_{angio} were 88%, 95%, 94%, respectively. The area under the ROC was 0.97 (95% CI: 0.906-0.993) which was significantly larger than that of the 2D and 3D QCA.
Conclusions. In the present study, conducted in a totally blinded manner, FFR_{angio} shows a superior concordance with invasive FFR. Therefore, FFR_{angio} is a promising cost and time saving tool to ease FFR-based decision-making.

C41

PRE-STENTING THROMBUS VOLUME ASSESSED BY DUAL QUANTITATIVE CORONARY ANGIOGRAPHY ENHANCES PREDICTION OF MICROVASCULAR OBSTRUCTION AFTER PRIMARY PERCUTANEOUS CORONARY INTERVENTION: A MAGNETIC RESONANCE IMAGING STUDY

Rocco Vergallo, Domenico D'Amario, Gianmarco Annibali, Mattia Galli, Vincenzo De Marzo, Antonio Maria Leone, Giampaolo Niccoli, Francesco Burzotta, Carlo Trani, Filippo Crea, Italo Porto
Fondazione Policlinico Universitario A. Gemelli, Università Cattolica del Sacro Cuore, Roma, Italy

Background. Coronary microvascular obstruction (CMVO) is a frequent occurrence after primary percutaneous coronary intervention (PPCI), and is associated with adverse left ventricular (LV) remodeling and worse clinical outcome. Distal embolization of atherothrombotic material is one of the most important mechanism at the basis of CMVO. Dual-quantitative coronary angiography (QCA) has been recently introduced for advanced assessment of intracoronary thrombus volume.
Objectives. The aims of this study were: 1) to evaluate the correlation between dual-QCA thrombus volume and the presence and severity of CMVO assessed by cardiac magnetic resonance (CMR); 2) to assess the performance of dual-QCA thrombus volume in predicting CMVO as compared with traditional angiographic indices of no-reflow.
Methods. Forty-eight patients with ST-segment elevation myocardial infarction (STEMI) undergoing PPCI, and receiving CMR imaging 4 to 7 days after admission were included. Pre-stenting dual-QCA thrombus volume was calculated as the difference between edge-detection and video-densitometry area functions along the culprit lesion. Delayed-enhancement CMVO volume was quantified by using a manual region of interest to trace the areas of low signal within the areas of brightly enhancing infarcted myocardium and expressed in grams (CMVO mass) and normalized to LV mass (CMVO%). Angiographic no-reflow was defined as post-PCI TIMI <3 or TIMI 3 with myocardial blush grade 0-1.
Results. Pre-stenting dual-QCA thrombus volume was significantly greater in patients with CMVO compared to those without (5.85 mm^3 [2.05–16.71] vs. 1.88 mm^3 [1.03–6.92], p=0.009). After dividing the study population in tertiles according to the dual QCA thrombus volume, patients in the third tertile showed higher prevalence of CMVO compared to those in the second and first tertiles (62% vs. 50.0% vs. 25.0%, p=0.035), as well as higher values of CMVO mass (113.3 g [0.0–203.8] vs. 58.5 g [0.00–144.4] vs. 0.0 gr [0.0–60.225], p=0.031) and CMVO% (2.17% [0.00–5.25] vs. 0.46% [0.00–3.87] vs. 0.0% [0.0–0.32], p=0.087). The best cut-off value of dual-QCA thrombus volume for predicting the presence of CMVO was 2.07 mm^3 (AUC: 0.720). Dual QCA thrombus volume's predictive value for the presence of CMVO at CMR analysis was superior to that of the traditional angiographic definition of no-reflow (Figure).
Conclusions. Pre-stenting dual-QCA thrombus volume predicts the presence of CMVO assessed by CMR in patients with STEMI undergoing PPCI. This novel methodology may aid the identification of patients at higher risk of developing CMVO and adoption of preventive strategies.



C42

THE USEFULNESS OF HYBRID IFR-FFR APPROACH IN PATIENTS WITH AORTIC STENOSIS UNDERGOING TAVI

Roberto Scarsini, Gabriele Pesarini, Mattia Lunardi, Claudia Zanetti, Michele Bellamoli, Federico Marin, Andrea Gratta, Valeria Ferrero, Flavio Luciano Ribichini
Division of Cardiology, Department of Medicine, University of Verona, Verona, Italy

Background. Physiology of coronary circulation in patients with coronary artery disease (CAD) associated with aortic stenosis (AS) is not well established, and the behavior of conventional ischemic indexes such as fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) in this setting is unclear.
Methods. The functional relevance of 141 coronary lesions was assessed by on-line iFR and FFR measurement in 62 patients with severe AS before and after TAVI, during the same procedure. A linear-mixed-model was used to verify interaction of TAVI effect with iFR measurements. A hybrid iFR-FFR strategy was then applied to test the overall diagnostic agreement with the FFR-only strategy.
Results. iFR values remained identical before and after TAVI, irrespective of the angiographic severity of the coronary stenosis (0.89±0.12 vs 0.89±0.12, p=0.66). A "deferral value" iFR>0.93 yielded a negative predictive value of 98.4% (91.7%-99.9%) to exclude FFR non-significant stenosis (>0.80), and a "treatment value" iFR <0.83 had a positive predictive value of 91.3% (72%-98.9%) to identify FFR-significant stenosis (≤0.80). A hybrid decision-making strategy based on iFR and FFR spared 63% of patients from adenosine, while maintaining 97% overall agreement with FFR lesions classification.
Conclusions. Severe AS did not influence iFR measurements in coronary arteries with different degree of CAD. This supports an iFR pre-intervention physiologic evaluation. A hybrid iFR-FFR diagnostic strategy is feasible in patients with severe AS undergoing TAVI and allows to spare 63% of patients from adenosine, while maintaining an elevated agreement with FFR classification of coronary lesions.

C43

EARLY AND MIDTERM RESULTS IN PATIENTS SUPPORTED WITH VA-ECMO FOR CARDIOGENIC SHOCK FOLLOWING MECHANICAL COMPLICATIONS OF ACUTE MYOCARDIAL INFARCTION

Francesco Formica[1], Pietro Vandoni[2], Leonello Avalli[3], Stefano D'Alessandro[1], Fabio Sangalli[3], Fabrizio Corti[1], Maria Cristina Costa[4], Giovanni Paolini[1]
[1]UOC Cardiochirurgia, Ospedale San Gerardo, Università di Milano-Bicocca, Monza, Italy, [2]UOC Cardiologia, Ospedale di Desio, ASST Monza, Monza, Italy, [3]UOSD Terapia Intensiva Cardiochirurgica, Ospedale San Gerardo, ASST Monza, Monza, Italy, [4]Servizio Circolazione Extracorporea, Ospedale San Gerardo, Monza, Italy

Aim. Ventricular septal defect (VSD), left ventricle free wall rupture (LVFWR) and papillary muscle rupture (PMR) or mitral valve are infrequent but catastrophic mechanical complications of acute myocardial infarction (AMI). The effects of veno-arterial extracorporeal membrane oxygenation (VA-ECMO) are undefined. The aim of this study was to evaluate the early and late outcome in patients underwent surgical repair of mechanical complications of AMI and supported by the VA-ECMO during the perioperative period.
Methods. Seventy-one consecutive patients (age 70±8 years; 66.2% male) underwent surgery for VSD or LVFWR or PMR post-MI from January 2000 through April 2017. Nineteen patients (26.7%) were supported by VA-ECMO during the postoperative period.
Results. Overall 30-day mortality was reported in 20 patients (28.2%). Univariate logistic regression analysis revealed that VA-ECMO support was associated with higher 30-day mortality [63.2% vs 15.4%, odds ratio (OR) 9.42; p<0.0001], cardiac arrest at presentation (OR 8.51; p<0.0001), right ventricular failure at presentation (OR 4.88; p=0.001), resternotomy for bleeding/tamponade (OR 3.39; p=0.02), blood transfusion (OR 7.29; p=0.03), acute kidney injury (OR 3.80; p=0.02), dialysis (OR 8.55; p=0.02) and pneumonia (OR 3.33; p=0.03). Multivariate logistic regression analysis revealed cardiac arrest (OR 29.09; 95% CI 7.61-111.12; p<0.0001) and right ventricular failure (OR 6.44; 95% CI 1.63-25.43; p=0.008) as independent predictors of 30-day mortality. Overall 5-year survival was 40.5%±6.1%. Five-year survival of 30-day survivors was 59.9%±7%. Comparing patients supported by VA-ECMO with not supported patients, 5-year survival of 30-day survivors were 57.1%±18.7% and 70.8%±7.2%, respectively (p=0.15).
Conclusions. Surgery for AMI mechanical complications involves a notable operative mortality, mainly in patients presented with cardiac arrest and right ventricular failure. VA-ECMO is an important rescue tool but in-hospital mortality remains high. Survival after surgery is promising even for those patients survived after VA-ECMO support. These encouraging results emphasize the importance of an aggressive and rapid therapeutic approach for patients affected by mechanical complications after AMI.

C44

MALATTIA CRITICA DEL TRONCO COMUNE E UTILIZZO DI STENT AUTOESPANDIBILE: L'ESPERIENZA DEL NOSTRO CENTRO

Erica Ferrara, Paola Martina, Raffaela Fetiveau, Fabio Barlocco, Arnaldo Poli
Divisione di Cardiologia, ASST Ovest Milanese, Sede di Legnano, Legnano, Italy

Razionale. Il gold standard terapeutico nel trattamento della malattia del tronco comune (TC) è stato per molti anni la rivascolarizzazione miocardica chirurgica (CABG). Tuttavia, negli ultimi anni, la rivascolarizzazione miocardica percutanea (PCI) si è affermata come valida alternativa al GABG, grazie soprattutto al progresso nella terapia antiaggregante e allo sviluppo degli stent medicati (DES).Numerosi fattori anatomici (diametro elevato del TC, discrepanza di calibro tra TC e IVA) e

tecnici (trattamento della biforcazione con 1 o 2 stent, deformazione dello stent, possibilità d'accesso al vaso collaterale (VC)) possono rendere meno efficace e prevedibile il risultato della PCI sia a breve sia a lungo termine. Lo Stentys DES è uno stent autoespandibile, in nitinolo, a rilascio di paclitaxel o sirolimus (nell'ultima versione), dotato di proprietà elastiche che ne permettono l'adattamento al calibro vasale e costituito da ponti che possono essere facilmente disconnessi tramite pallone per ottenere un'apertura delle maglie verso il VC.
Scopo. Abbiamo valutato fattibilità, sicurezza ed efficacia a breve-medio termine dell'uso di Stentys nel trattamento di stenosi coinvolgenti la biforcazione del TC.
Metodi. tra ottobre 2014 e maggio 2017 abbiamo trattato 25 pazienti con Stentys, di cui 20 maschi, età media 66±10 anni, range 48-88 anni. 10 pazienti con storia di cardiopatia ischemica nota già trattata con PCI, 11 ricoverati per SCA.
Risultati. in accordo alla classificazione di Medina, 6 pz mostravano una lesione 1-1-1, 7 pz una lesione 1-1-0, 10 pz una lesione 0-1-0, 3 pz una lesione 0-1-1. La procedura è stata eseguita in tutti i casi attraverso l'arteria femorale, con un introduttore da 6F o 7F. Le dimensioni degli Stentys utilizzati sono state 2.5-3.0 mm (small) in 2 pz, 3.0-3.5 mm (medium) in 11 pz e 3.5-4.5 (large) in 11 pz. In tutti i casi è stata eseguita predilatazione dell'asse TC-IVA. Lo Stentys è stato impiantato con successo in 24 pz (in 1 caso impossibilità di superare la lesione calcifica in tratto curvo TC-IVA) e sempre sull'asse TC-IVA. In tutti i casi lo stent è stato rilasciato nella posizione "target", senza necessità di posizionare ulteriori stent a monte o a valle. In 24 pz è stato possibile "ricrossare" il VC e disconnettere le maglie dello Stentys mediante dilatazione con pallone. In 6 pz è stato impiantato un DES all'ostio del VC (TAP technique) per residua stenosi critica. In 23 pz è stata eseguita post dilatazione dello Stentys. Non ci sono state complicanze (infarto miocardico acuto, morte, stroke) intraprocedurali e/o intraospedaliere. Al follow-up medio di 9 mesi (range 1-27 mesi), si sono verificati 2 decessi (per morte extracardiaca), 4 pz hanno mostrato ripresa di angina: in 2 pazienti era presente malattia critica dell'ostio di CX su cui è stato possibile posizionare DES, mentre in 2 era presente restenosi critica intrastent di Stentys e sono stati indirizzati al CABG.
Conclusioni. In questa iniziale esperienza l'uso di Stentys si è rivelato sicuro ed efficace nel trattamento della malattia della biforcazione del TC associandosi ad un soddisfacente risultato clinico a breve e medio termine. Il principale vantaggio tecnico offerto dal device nel trattamento di tali lesioni è rappresentato dalla facilità di accesso al VC e di eseguire su di esso un "provisional stenting" (anche a distanza di tempo).

C45

ACCESS SITE CROSSOVER IS ASSOCIATED WITH INCREASE IN BLEEDING RISK BUT NOT RADIATION EXPOSURE IN INVASIVELY MANAGED PATIENTS WITH ACUTE CORONARY SYNDROMES

Silvia Mauri[1], Alessandro Mandurino Mirizzi[1], Sergio Leonardi[2], Alessandra Repetto[2], Marco Ferlini[2], Barbara Marinoni[2], Gabriele Crimi[2], Rita Camporotondo[2], Massimiliano Gnecchi[2], Marta Arpellini[2], Monica Portolan[2], Arianna Elia[2], Chiara Castelli[1], Alberto Barengo[1], Luigi Oltrona Visconti[2], Gaetano Maria De Ferrari[3], Maurizio Ferrario Ormezzano[2]
[1]University of Pavia, Pavia, Italy, [2]Fondazione IRCCS Policlinico S. Matteo, Pavia, Italy, [3]University of Pavia e Fondazione IRCCS Policlinico S. Matteo, Pavia, Italy

Background. Radial access (RA) is the recommended access in patients with acute coronary syndrome (ACS) managed invasively but it has been associated with higher operator and patient radiation exposure. RA may also be more technically demanding and potentially associated with greater incidence of access site crossover as compared to femoral access (FA).
Purpose. To describe prevalence of access crossover and incidence of access site complications, including bleeding events, in patients with ACS managed invasively as well as radiation exposure and total contrast media use in patients who underwent access site crossover.
Methods. As a part of a quality improvement initiative, we designed a prospective single-center observational study with the aim of exploring prevalence and clinical impact of access crossover in patients with ACS managed invasively. In-hospital access complications were defined as any vascular complication related to the arterial access. Bleeding events were classified using Bleeding Academic Research Consortium (BARC) standardized definitions. Clinically relevant bleeding events were defined as BARC type 3 or higher. Radiation exposure was assessed by using fluoroscopy time (FT, expressed in minutes), that accounts the time spent using fluoroscopy and cumulative air Kerma (CAK, expressed in mGy), that is the amount of energy per unit mass absorbed by the air at the assumed location of the skin. Association between access crossover and bleeding event was evaluated using logistic regression analysis.
Results. We enrolled a total of 910 consecutive patients (53% STEMI, 46% NSTEACS), with a mean age of 65.34 years (SD 12.78). RA was the first intended approach to coronary angiography in 656 pts (72%); in 3 cases (0.3%) ulnar access was used. Overall, in 43 patients (4.7%) a switch from the first-choice access site to a different one was required; in 93% of them from radial to another access. In patients who underwent access crossover, there were no significant differences in FT (10 vs 11 min, p=0.764) and CAK (837 vs 823 mGy, p=0.925) as well total contrast media use (185 vs 170 ml, p=0.393). As compared with RA (7.6%) and FA (20.6%) alone, access complications were more common in patients who required access site crossover (29.3%, p<0.001). Access crossover was associated with higher risk of any bleeding (OR 2.77, 95% CI 1.48-5.13; p=0.001) as well as access-site bleeding events (OR 4.15, 95% CI 2.02-8.11; p<0.001), but not of clinically relevant bleedings (OR 0.44, 95% CI 0.05-3.7; p=0.45).
Conclusions. In patients with ACS managed invasively, access site crossover is more common using RA and is associated with increased mild in-hospital access complication and a 4-fold increase in bleeding risk while no increase was observed in radiation exposure or clinically relevant bleedings.

	Access Crossover (n=43)	No Access Crossover (n=867)	p
Fuoroscopy time, median(IQR)	10 (6.8, 17.5)	11 (7, 17.4)	0.764
Total contrast media, median(IQR)	185 (150, 250)	170 (120, 240)	0.393
Cumulative air Kerma, median(IQR)	837 (483.5, 1272)	823 (501, 1268.5)	0.925
Access complication, n (%)	12 (29.3)	99 (11.4)	0.002
Access complication requiring surgical treatment, n (%)	1 (2.4)	15 (1.7)	0.526
Any bleeding, n (%)	20 (48.8)	221 (25.5)	0.002
Access-site bleeding, n (%)	13 (31.7)	82 (9.5)	<0.001
Access-site bleeding BARC >2, n (%)	1 (7.7)	13 (15.9)	0.684

C46

OUTCOMES OF PERCUTANEOUS REVASCULARIZATION OF CHRONIC TOTAL OCCLUSIONS IN PATIENTS WITH VS. WITHOUT CHRONIC KIDNEY DISEASE: THE IMPACT OF CONTRAST-INDUCED ACUTE KIDNEY INJURY

Susanna Benincasa[1], Soledad Ojeda[2], Alessio La Manna[3], Barbara Bellini[1], Luciano Candilio[1], Francisco Hidalgo[2], Joren Maeremans[4], Masaki Tanabe[4], Giacomo Gravina[3], Eligio Miccichè[3], Guido D'Agosta[3], Giuseppe Venuti[3], Corrado Tamburino[3], Manuel Pan[2], Mauro Carlino[1], Antonio Colombo[1], Lorenzo Azzalini[1]
[1]Interventional Cardiology Unit, Cardio-Thoracic-Vascular Department, San Raffaele Scientific Institute, Milan, Italy, [2]Division of Interventional Cardiology, Reina Sofia Hospital, University of Córdoba, Maimonides Institute for Research in Biomedicine of Córdoba (IMIBIC), Cordoba, Spain, [3]Division of Cardiology, Ferrarotto Hospital, University of Catania, Catania, Italy, [4]Department of Cardiology, Ziekenhuis Oost-Limburg, Genk, Belgium

Background. We aimed to study the outcomes of chronic total occlusion (CTO) percutaneous coronary intervention (PCI) in patients with vs. without chronic kidney disease (CKD), and the impact of contrast-induced acute kidney injury (CI-AKI) in these patients.
Methods. Multicenter registry of patients undergoing CTO PCI at 5 centers between July 2011 and April 2017. CKD was defined as an estimated glomerular filtration rate <60 ml/min/1.73 m^2. CI-AKI was defined as an increase in serum creatinine ≥0.3 mg/dl or ≥50% from baseline within 72 h (Acute Kidney Injury Network definition).Major adverse cardiac events (MACE) were a composite of cardiac death, any myocardial infarction and any revascularization on follow-up. Target-vessel failure (TVF) was a composite of cardiac death, target-vessel myocardial infarction and ischemia-driven target-vessel revascularization on follow-up.
Results. A total of 1054 patients were included (CKD n=205, no CKD n=849). CKD patients were older and had higher prevalence of cardiovascular conditions. Coronary artery disease burden was higher in patients with CKD. Occlusion complexity as assessed with the PROGRESS-CTO score was higher (1.1±0.8 in CKD vs. 0.9±0.9 in no CKD, p=0.008), and proximal cap ambiguity and calcification were more frequent in CKD patients. Crossing strategies were similar between groups. Contrast volume was lower in CKD (268±117 vs. 315±134 ml, p<0.001). Technical (81% vs. 87%, p=0.03) and procedural (81% vs. 86%, p=0.11) success were lower in CKD. CI-AKI occurred in 10.5%, and its incidence was higher in CKD (20.0% vs. 8.2%, p<0.001). One CI-AKI patient with CKD required in-hospital dialysis (0.5% vs. 0%, p=0.04).CI-AKI was observed more frequently in patients who also suffered tamponade or major bleeding. Mean follow-up was 675±491 days. At 24 months, CKD patients suffered a higher incidence of cardiac death (9.2% vs. 1.0%, p<0.001) and new need for dialysis (1.3% vs. 0.1%, p=0.03), and a trend towards higher incidence of MACE (24.9% vs. 19.7%, p=0.14) and TVF (15.0% vs. 10.1%, p=0.06).Patients who developed CI-AKI suffered a higher rate of 24-month cardiac death (7.4% vs. 2.1%, p=0.002), but similar incidence of MACE (21.5% vs. 20.6%, p=0.84), TVF (11.6% vs. 11.0%, p=0.86), and new need for dialysis (1.2% vs. 0.3%, p=0.18).
Conclusions. CTO PCI in CKD patients is associated with lower success rates and higher incidence of CI-AKI. On follow-up, CKD patients suffer an increased rate of cardiac death and new need for dialysis. Subjects who develop CI-AKI are at higher risk for cardiac death, but not for new need for dialysis.

Top-ranked oral presentations 2

C47

SUBADVENTITIAL CROSSING AND CRUSHING TO RECANALIZE IN-STENT CHRONIC TOTAL OCCLUSIONS: A MULTICENTER REGISTRY

Susanna Benincasa[1], Aris Karatasakis[2], James Spratt[3], Peter Tajti[4], Robert F. Riley[5], Iuiz F. Ybarra[6], Stefan P. Schumacher[7], Barbara Bellini[1], Luciano Candilio[1], Peter Henriksen[3], Francisco Hidalgo[8], Leo Timmers[9], Adriaan O. Kraaijeveld[9], Pierfrancesco Agostoni[10], James Roy[11], David R. Ramsay[11], James C. Weaver[11], Paul Knaapen[7], Boris Starcevic[12], Soledad Ojeda[8], Manuel Pan[8], Khaldoon Alaswad[13], Wiliam L. Lombardi[5], Stephane Rinfret[6], Mauro Carlino[1], Emmanouil S. Brilakis[2], Antonio Colombo[1], Lorenzo Azzalini[1]

[1]Interventional Cardiology Unit, Cardio-Thoracic-Vascular Department, San Raffaele Scientific Institute, Milan, Italy, [2]Interventional Cardiology Unit, North Texas Healthcare System and University of Texas Southwestern Medical Center at Dallas, Dallas, TX, USA, [3]Department of Cardiology, New Royal Infirmary of Edinburgh, Edinburgh, UK, [4]Minneapolis Heart Institute, Minneapolis, MN, USA, [5]Division of Cardiology, Department of Medicine, University of Washington Medical Center, Seattle, WA, USA, [6]Interventional Cardiology, McGill University Health Centre, Montreal, Canada, [7]Department of Cardiology, VU University Medical Center, Amsterdam, Netherlands, [8]Division of Interventional Cardiology, Reina Sofia Hospital, University of Córdoba, Maimonides Institute for Research in Biomedicine of Córdoba (IMIBIC), Cordoba, Spain, [9]Department of Cardiology, University Medical Centre Utrecht, Utrecht, Netherlands, [10]Department of Cardiology, St. Antonius Hospital, Nieuwegein, Netherlands, [11]Department of Cardiology, St. George Hospital, Sydney, Australia, [12]Department of Cardiology, Clinical Hospital Dubrava, Zagreb, Croatia, [13]Interventional Cardiology Unit, Edith and Benson Ford Heart and Vascular Institute, Henry Ford Hospital, Detroit, MI, USA

Background. Crossing chronic total occlusions (CTOs) due to in-stent restenosis (ISR) can sometimes be achieved with subadventitial crossing and crushing (SC+C) of the occluded stent, when conventional approaches have failed. We aimed at evaluating the outcomes of this technique.

Methods. We examined the acute and follow-up outcomes of ISR-CTO percutaneous coronary intervention (PCI) performed at 14 centers between July 2011 and June 2017. Target-vessel failure (TVF) was defined as a composite of cardiac death, target-vessel myocardial infarction (TV-MI), and ischemia-driven target-vessel revascularization (TVR).

Results. A total of 422 in-stent CTO PCIs were performed during the study period, of which 32 (7.6%) were recanalized with SC+C. Class III-IV angina was present in 50% of patients. The most frequent CTO vessel was the right coronary artery (72%), and mean J-CTO score was 3.1±0.9. SC+C was performed after failure of other crossing techniques in all but 2 patients. The CrossBoss catheter was used in 38%. SC+C was antegrade in 53%, and retrograde in 47%. Part of the occluded stent was crushed in 37%, while the whole stent was crushed in 63%. Intravascular imaging was performed in 59%. Total newly implanted stent length was 106±35 mm, contrast volume was 305±144 ml, and fluoroscopy time was 79±45 min. One patient(3.1%) suffered tamponade. Angiographic follow-up was performed in 10/32 patients at a mean of 148±123 days: the stents were patent in 6 cases, 1 had mild ISR, and 3 had severe ISR at the site of SC+C. Clinical follow-up was available for 29/32 patients for a mean of 388±303 days. The incidence of TVF was 20.7% (n=6), including cardiac death 3.4% (n=1, unrelated to SC+C), TV-MI 3.4% (n=1, due to stent thrombosis proximal to the SC+C site), and TVR 20.7% (n=6).

Conclusions. This is the first systematic study of SC+C for treating CTOs due to ISR. This technique is rarely performed, usually as last resort, to recanalize complex occlusions. SC+C is associated with favorable acute and mid-term outcomes, but given the small sample size of our study additional research is warranted.

C48

CLOSING PATENT FORAMEN OVALE AND OPENING TO ANTICOAGULATION? AN UPDATED META-ANALYSIS ON THE RISK OF ATRIAL FIBRILLATION AFTER PATENT FORAMEN OVALE CLOSURE

Federico Fortuni[1], Sergio Leonardi[2], Arturo Raisaro[3], Luigi Oltrona Visconti[3], Gaetano Maria De Ferrari[2], Maurizio Ferrario[3], Gabriele Crimi[3]

[1]Scuola di Specializzazione in Malattie dell'Apparato Cardiovascolare, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy, [2]Unità di Terapia Intensiva Cardiologica, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy, [3]SC Cardiologia, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy

Rationale. About one third of ischemic stroke are cryptogenic. Paradoxical embolism through patent foramen ovale (PFO) has been identified as a possible cause for a relevant proportion of them. Therefore PFO closure has been considered for secondary prevention of cryptogenic ischemic stroke. Recently a concern has been raised about a possible increase in atrial fibrillation (AF) risk after PFO closure, which may be due to the left atrial wall stress after this procedure.

Aim. To examine if PFO closure is associated with an increased risk of AF.

Methods. We systematically searched PubMed for randomized controlled trial (RCT) that compared PFO closure with medical therapy and reported AF incidence during follow up. The risk of AF after PFO closure has been investigated according to 2 subgroup analyses: 1) the type of device implanted (i.e. Amplatzer SJM versus STARFlex NMT, which are the two most commonly used devices); 2) The indication (i.e. secondary prevention of ischemic stroke vs alternative indications). A Chi-Square test for heterogeneity has been used in order to test for interaction between the subgroup and the outcome.

Results. Five studies met our inclusion criteria and were included for a total of 2559 patients. Of these, 1279 underwent PFO closure and 1280 patients were treated medically. Three studies investigated the effect of PFO closure on stroke recurrence risk after a cryptogenic stroke while in the two others the indication was reducing headache attacks with aura.

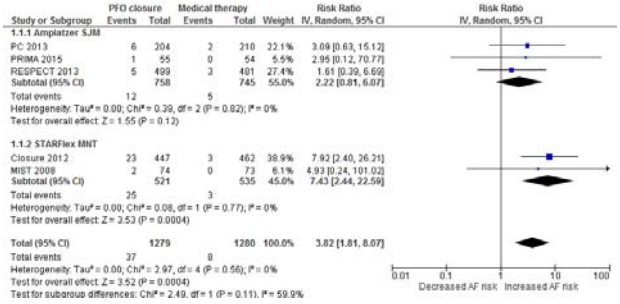


Figure 1. Forest plot of PFO closure vs medical therapy on AF risk stratified by type of device.

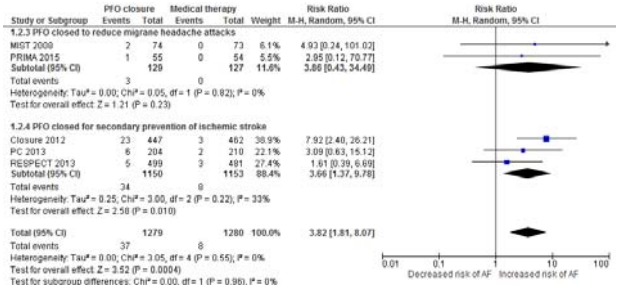


Figure 2. Forest plot of PFO closure *versus* medical therapy on AF risk stratified by indication.

The risk of developing AF was higher for patients who underwent PFO closure compared to medically treated patients (RR 3.82 ; 95% CI 1.81-8.07; Z=3.52; p=0.0004). This risk was consistent according to indication to PFO closure (Chi^2 = 0; df = 1; p=0.96) and type of device used (Chi^2 = 2.49; df = 1; p=0.11).

Conclusion. As compared to medical therapy, PFO closure is associated with a ≈4-fold risk of incident AF regardless of indication or type of device implanted. This risk may have important implications for long term monitoring and management of patients undergoing this procedure.

C49

EFFETTI DELL'ALLOPURINOLO (300 MG) SULL'EFFICACIA CLINICA DEL CLOPIDOGREL E DEI NUOVI INIBITORI DEL P2Y12 IN PAZIENTI CON INFARTO MIOCARDICO ACUTO SOTTOPOSTI A RIVASCOLARIZZAZIONE PERCUTANEA E DOPPIA TERAPIA ANTIAGGREGANTE

Marina Polacco, Carlo Gaudio, Cesare Greco

Policlinico Umberto I, Roma, Italy

Background. L'allopurinolo, attraverso la sua azione sulla xantina-ossidasi, provoca un aumento della concentrazione diipo-xantina e xantina a livello intracellulare. Una maggior concentrazione di queste molecola determina un aumento dell'inibizione della fosfodiesterasi e quindi provoca un incremento dei livelli intracellulari di cAMP, molecola inibitore dell'aggregazione piastrinica. Anche i farmaci antiaggreganti, inibitori del recettore P2Y12, agiscono attraverso un aumento intracellulare di cAMP. L'utilizzo dell'allopurinolo potrebbe, quindi, potenziare l'efficacia clinica dei farmaci inibitori del recettore P2Y12 migliorando la risposta antipiastrinica a tali farmaci, capisaldi del trattamento delle sindromi coronariche acute.

Obiettivi. Scopo dello studio è stato quello di valutare il potenziale effetto dell'allopurinolo sull'efficacia clinica del clopidogrel e dei nuovi farmaci antiaggreganti (inibitori del P2Y12) prasugrel ed il tigagrelor.

Materiali e metodi. Sono stati arruolati un totale di 300 pazienti in doppia terapia antiaggregante (DAPT), sottoposti a PCI per IMA STEMI e trattati con rivascolarizzazione percutanea, in un periodo compreso tra maggio 2016 e maggio 2017, con caratteristiche cliniche simili. I pazienti sono stati suddivisi in 3 gruppi; 1) pazienti in DAPT con clopidogrel 75 mg in aggiunta ad ASA 100 mg (n=33); 2) pazienti in doppia terapia antiaggregante con prasugrel (10 mg/die) in aggiunta ad ASA (100 mg/die) (n=66); 3) pazienti in DAPT con ticagrelor (90 mg x 2/die) in aggiunta ad ASA (100 mg/die) (n=33). Tutti i pazienti, sono stati sottoposti alla valutazione della reattività piastrinica basale (espressa come P2Y12 Unità di Reazione [PRU], attraverso l'utilizzo del VerifyNow assay (Accumetrics, San Diego, CA). Un valore di PRU ≥208 è stato ritenuto compatibile con una elevata reattività piastrinica. Per un periodo di 30 giorni, tutti i pazienti hanno assunto 300 mg di allopurinolo a cui è seguito un wash-out di 5 giorni. La reattività piastrinica è stata misurata al basale, dopo i 30 giorni di assunzione di allopurinolo 300 mg e dopo i successivi 5 giorni di wash-out.
Risultati. Nel gruppo di pazienti in terapia con prasugrel (10 mg/die), rispetto ai valori basali (PRU 171.3±1.34) il valore di PRU si è ridotto in modo significativo (PRU 163.8±1.41; p=0.0002) dopo assunzione di allopurinolo 300 mg. Allo stesso modo, nel gruppo di pazienti in terapia con ticagrelor (90 mg x 2/die), rispetto ai volari basali (PRU 174.3±1.16), il valore di PRU si è ridotto in modo significativo (PRU 168.1±1.2; p=0.0002) dopo assunzione di allopurinolo. Infine, nel gruppo di pazienti in terapia con clopidogrel (75 mg/die), rispetto ai valori basali (PRU 176.6±1.2), il valore di PRU si è ridotto in modo significativo (PRU 172.2±1.20; p=0.001) dopo assunzione di allopurinolo.
Conclusioni. L'analisi dei risultati ottenuti suggerisce dunque che l'allopurinolo, alla dose di 300 mg, dimostra azione sinergica con i farmaci antiaggreganti. Necessari ulteriori studi di conferma sulla base dei quali si potrebbe auspicare una sua aggiunta alla terapia antiaggregante al fine di potenziare e migliorare l'azione espletata dai farmaci antiaggreganti.

C50

IMPACT OF DIABETES MELLITUS ON 1-YEAR OUTCOMES OF ABSORB BIORESORBABLE VASCULAR SCAFFOLD VS. EVEROLIMUS-ELUTING METALLIC STENT: A PROPENSITY MATCHED ANALYSIS OF COMPARE II, RAI AND MAASSTAD-ABSORB PROSPECTIVE REGISTRIES

Marco Mojoli[1], Giulia Masiero[1], Valeria Paradies[2], Bernardo Cortese[3], Gaetano di Palma[3], Giuseppe Steffenino[4], Attilio Varricchio[5], Alfonso Ielasi[6], Bruno Loi[7], Daisuke Ueshima[8], Paola Tellaroli[9], Georgios Vlachojannis[10], Pieter Smits[10], Giuseppe Tarantini[1]
[1]Department of Cardiac, Thoracic and Vascular Sciences, University of Padua, Padova, Italy, [2]National Heart Research Institute and National Heart Centre Singapore, Singapore, Japan, [3]UO Cardiologia, ASST Fatebenefratelli-Sacco, PO Fatebenefratelli, Milano, Italy, [4]US Emodinamica, ASO S. Croce e Carle, Cuneo, Italy, [5]Cardiology Division, Santa Maria della Pietà Hospital, Nola, Italy, [6]Ospedale Bolognini, Seriate, Italy, [7]Interventional Cradiology Unit, AO Brotzu, Cagliari, Italy, [8]Tokyo Medical and Dental University, Tokyo, Japan, [9]Biostatistics, Epidemiology and Public Health Unit of Department of Cardiac, Thoracic and Vascular Sciences, University of Padua Medical School, Padova, Italy, [10]Maasstad Hospital, Rotterdam, Netherlands

Background. Diabetes mellitus (DM) is associated with increased risk of subsequent events after PCI. To evaluate the impact of Absorb bioresorbable vascular scaffold (BVS) in this setting, we aimed to assess the 1-year outcomes of Absorb BVS versus 2nd generation drug-eluting stents by pooling diabetic patients from three large, prospective studies.
Methods. Patients with medically-treated DM and treated by Absorb BVS in the Italian multicenter RAI Registry and in the single-centre MAASSTAD-Absorb registry, or treated by XIENCE V/PRIME or PROMUS metallic stents in the COMPARE II trial, were pooled for analysis. A propensity score matching analysis of several pre-procedural clinical and angiographic variables was used. The implantation technique was not object of matching, being device-specific. The primary endpoints were a device-oriented composite endpoint (DOCE) including cardiac death, target vessel myocardial infarction and target lesion revascularization, and stent thrombosis.
Results. Out of total 4635 enrolled subjects, 935 were diabetics. After matching, there were 189 matched pairs of patients. Clinical and angiographic characteristics of matched groups were highly comparable. As expected, pre-dilatation (98% vs. 67%, d-value 0.9) and post-dilatation (94% vs. 36%, d-value 1.3) rates remained significantly higher in the BVS group. At 30-day follow-up, we observed a numerically but not statistically significant increase of DOCE (1.6% vs. 05%, HR 3.0 [95% CI 0.3-28.9], p=0.3) and definite/probable stent thrombosis (ST) (1.6% vs. 05%, HR=3.0 [0.3-28.9], p=0.3) in the BVS vs. EES group. Conversely, 1-year DOCE was significantly higher in the BVS group (5.8% vs. 1.6%, HR 4.2 [1.1-15.4], p=0.03) mainly due to a higher TLR rate. Similarly, higher rates of ST were observed in the BVS group (3.2% vs. 0.5%, p=0.06, HR 6.1 [0.7-51.7], p=0.1) at 1-year follow-up.
Conclusion. This propensity-matched analysis pooling diabetic patients of three large prospective studies, and comparing BVS versus 2nd generation DES, showed a higher rate of DOCE and ST in BVS-treated patients at 1 year.

C51

IMPIANTO DI BVS ABSORB CON TECNICA PSP E OUTCOMES A LUNGO TERMINE NEL REGISTRO REABSORBS (REGISTRO ABSORB SANREMO)

Massimo Leoncini, Claudio Rapetto, Raffaele Scardala
SSD Cardiologia Invasiva Endovascolare, Sanremo, Italy

Scopi. Valutare l'impatto della tecnica di impianto PSP dello scaffold vascolare bioriassorbibile (BVS) a eluizione di everolimus Absorb sugli outcome clinici (OC) acuti e al follow up (FU) a lungo termine in una popolazione di pazienti (pz) "real world".
Metodi e Risultati. Tutti i pz consecutivi trattati con BVS Absorb nell'emodinamica di Sanremo da dicembre 2012 a marzo 2017 sono stati inclusi in questo registro osservazionale. Gli OC registrati sono: successo angiografico (SA), morte cardiovascolare (MCV), infarto miocardico del vaso target (TV-IMA), trombosi di scaffold secondo i criteri Academic Research Council (ARC ScT), ischemia-driven target lesion revascularization (ID-TLR), target vessel revascularization (TVR) e target vessel failure (TVF), composito di MCV, TV-IMA e TVR. Il SA è definito come impianto effettivo del BVS con stenosi residua (SR) <30% e come flusso Thrombolysis in Myocardial Infarction (TIMI) 3 nel vaso target. Un totale di 220 pz di età 58.6±9.5 anni (maschi n=188, 85.5%; diabetici n=35, 15.9%, con ≥3 fattori di rischio cardiovascolare n=121, 55.0%) sono stati inclusi nel registro, sono state eseguite 253 PCI (n=229, 90.5% con accesso radiale) su 321 lesioni con impianto di 376 BVS. Il supporto di IVUS o OCT è avvenuto in 17 PCI (6.7%). In totale 166 PCI (65.6%) sono state eseguite in pazienti ad alto rischio (con STEMI o SCA-NSTEMI). La localizzazione principale delle lesioni era su IVA (n=168, 52.3%), sono state comunque trattate lesioni su tutti i rami a eccezione del tronco comune; 210 lesioni trattate (65.4%) erano di tipo B2 o C. Oltre all'aspirina 152 pz (69.1%) hanno ricevuto ticagrelor, 35 (15.9%) prasugrel e 33 (15.0%) clopidogrel. La QCA preprocedurale ha mostrato una stenosi media dell'83.7±15.2%, con lunghezza media di 21.6±11.3 mm. La predilatazione, alla pressione media di 19.6±3.8 atm è stata eseguita in 366 casi (97.3%) e con rapporto pallone-arteria 1:1 in 282 casi (77.0%); lo stenting diretto è stato eseguito solamente in caso di dissezione, spontanea o iatrogena, in assenza di placca ateromasica. Il BVS è stato rilasciato a una pressione media di 12.9 ± 2.7 atm; 30 pz (11.9%) hanno ricevuto ≥56 mm BVS sullo stesso vaso. 195 BRS (51.9%) presentano un overlap marker-to-marker, 47 (18.6%) hanno un overlap BVS-DES. La postdilatazione, alla pressione media di 21.8±4.2 atm è avvenuta in 376 casi (100%) e con pallone sovradimensionato di 0.5 mm rispetto al diametro del BVS in 156 casi (41.5%). La QCA postprocedurale ha mostrato una SR di 13.6±6.0%, in nessun caso si è avuta una SR >30%; 3 PCI con flusso TIMI <3 finale sul vaso target e 1 failure nell'impianto del BRS configurano un SA nel 98.9% dei BVS. A un follow-up mediano di 596 giorni (range interquartile 371-963) si sono verificati 2 MCV (0.9%) non correlate al BVS, 2 very late definite ARC-ScT (0.9%), 6 TV-IMA (2.7%), 13 TVF (5.9%), 11 TVR (5.0%), 6 ID-TLR (2.7%).
Conclusioni. Nella nostra esperienza, con i limiti insiti in un registro, l'impianto di BVS Absorb in una popolazione "real world" impiegando routinariamente una tecnica PSP è associata a buon SA in acuto e ad un accettabile numero di OC a un follow-up mediano di 20 mesi.

Primary angioplasty

C52

IS THERE STILL A ROLE FOR MANUAL THROMBUS-ASPIRATION IN ST-ELEVATED MYOCARDIAL INFARCTION? RESULTS FROM A REAL-WORLD DESCRIPTION AND ANALYSIS

Michele Bellamoli, Gabriele Pesarini, Roberto Scarsini, Carlo Zivelonghi, Giovanni Benfari, Claudia Zanetti, Giulia Vinco, Mattia Lunardi, Federico Marin, Andrea Gratta, Flavio Luciano Ribichini
Divisione di Cardiologia, Università di Verona, Verona, Italy

Background. ST-elevated myocardial infarction (STEMI) is mainly caused by rupture of vulnerable atherosclerotic plaques with subsequent thrombotic pathways activation and clot formation. Therefore, in addition to balloons and coronary stents used in primary Percutaneous Coronary Intervention (pPCI), thrombectomy devices have been developed. Recently, large randomized trials questioned the usefulness of manual thrombectomy devices. However, some STEMI patients with specific features might still benefit from this approach in clinical practice.
Purpose. We aimed to investigate the impact of preventive thrombus-aspiration (pTA) in a real world STEMI population treated with pPCI in terms of procedural results and mid-term follow-up.
Methods. We retrospectively included all-comers STEMI patients who underwent coronary angiography and percutaneous revascularization of the culprit lesion at our Institution between February 2009 and December 2013. Patients with previous PCI on the same culprit vessel, and patients undergoing rescue PCI after failed thrombolysis were excluded. Baseline clinical features, angiographic findings, procedural data, in-hospital and mid-term follow-up were collected. The primary endpoint was the

angiographic procedural success defined as final TIMI 3 flow. The secondary endpoint was a composite of death, re-infarction rate and need for revascularization at mid-term follow-up.
Results. Data were obtained for 478 consecutive STEMI patients. pTA was performed in 190 (39.7%) patients. Patients in the pTA group showed higher angiographic complexity as compared to the non-pTA patients, i.e, total vessel occlusion rate (80.5 vs. 59% in pTA vs. non-pTA, p<0.0001), more frequent evidence of massive intraluminal thrombosis (99.5 vs. 88.5% in pTA vs. non-pTA, p<0.0001), and worse baseline TIMI flow (grade 0-1 rates was 85.8 vs 64.2% in pTA vs. non-pTA, p<0.0001). Despite the worse initial angiographic presentation, when pTA was adopted, a trend towards better final TIMI flows was observed (p=0.06). When only patients with baseline TIMI 0-1 were analyzed (348/478), pTA yielded significantly higher final TIMI 3 flow rates (82.8 vs. 73%, p=0.03). During a mean follow-up of 14±10 months, a similar event-free survival rate was observed between the two groups (89% for both, p log-rank=0.9).
Conclusions. In clinical practice, the use of preventive thrombus-aspiration in STEMI patients is mostly performed in patients with more unfavorable angiographic presentation. Among those with worse baseline TIMI flow, pTA provided significantly better angiographic results in our experience. However, confirming the clinical findings of large randomized studies, the procedural success did not entail significant clinical benefit in terms of lower cardiovascular major events at mid-term follow-up.

C53

TARGET REGISTRY: PROSPECTIVE, OBSERVATIONAL AND MULTICENTER REGISTRY WITH AMPHILLIMUS ELUTING STENT IN ACUTE MYOCARDIAL INFARCTION

Davide D'Andrea[1], Gerardo Carpinella[1], Alessandro Bellis[1], Fulvio Furbatto[1], Fabio Minicucci[1], Mario Scarpelli[1], Tiziana Attisano[2], Renato Bianchi[3], Plino Lorenzo Cirillo[4], Orlando Piro[5], Pasquale Spadaro[6], Ciro Mauro[1]
[1]UOSC Cardiologia-UTIC, AORN A. Cardarelli, Napoli, Italy, [2]Cardiologia Interventistica, AOU San Giovanni di Dio e Ruggi d'Aragona, Salerno, Italy, [3]Cardiologia, Dipartimento di Scienze Cardio-Toraciche e Respiratorie, Università della Campania "Luigi Vanvitelli", Napoli, Italy, [4]Cardiologia, Dipartimento di Scienze Biomediche Avanzate, Università "Federico II", Napoli, Italy, [5]UOC Cardiologia Interventistica, Azienda Ospedaliera Specialistica dei Colli, Napoli, Italy, [6]UOC Cardiologia Interventistica-UTIC, Ospedale Loreto Mare, Napoli, Italy

Oggi esistono pochi stent medicati disegnati specificamente per minimizzare i rischi di trombosi late- e very-late, relativamente alla presenza del polimero, specialmente nelle situazioni ad alto rischio trombotico come nei pazienti con STEMI. Tra gli stent medicati disponibili, i Cre8 hanno caratteristiche uniche: la piattaforma con i reservoirs in cui si trova il farmaco (in formulazione Amphillimus) ed il rilascio dello stesso che avviene solo sul versante abluminale. Queste caratteristiche favoriscono la biodisponibilità del farmaco e la sua distribuzione alla parete del vaso, lasciando uno strato ultra sottile di carbonio in contatto con il sangue, minimizzando i rischi di infiammazione e trombosi. Scopo di questo registro è stato quello di valutare efficacia e sicurezza nell'uso del Cre8 nell'ambito dei pazienti con STEMI.
Sono stati arruolati in un registro osservazionale, prospettico e multicentrico pazienti con STEMI nei principali centri HUB in Campania dal maggio 2014 al maggio 2015. I criteri di inclusione prevedevano la presenza di STEMI (criteri ECGrafici) ed età maggiore di 18 anni; i pazienti con shock cardiogeno o con controindicazioni all'angioplastica primaria erano esclusi dall'arruolamento. Dei 202 pazienti arruolati solo uno è deceduto durante la degenza in ospedale (6 ore dopo l'angioplastica): si tratatava di un caso con malattia coronarica multivasale, a presentazione tardiva e con ridotta funzione sistolica globale (FE 41%). 5 decessi sono stati osservati nei 24 mesi di follow-up, di cui 2 per tumore, 2 per trauma e 1 per sanguinamento fatale (intracranico), avvenuto in un paziente in DAPT con acido acetilsalicilico e ticagrelor, circa 4 mesi dopo l'angioplastica.
In un caso il controllo angiografico, effettuato per la comparsa di angina da sforzo, ha evidenziato una TLR, trattata con re-angioplastica ed impianto di stent medicato. Un paziente con patologia multivasale, al quale, dopo aver trattato la culprit lesion durante il ricovero per l'infarto, era stata programmato un completamento della rivascolarizzazione per via percutanea, ha deciso d'accordo con il proprio cardiologo di sottoporsi ad un intervento chirurgico per completare la rivascolarizzazione. Non sono stati riportati durante il periodo di follow-up infarti miocardici o ulteriori morti di natura cardiaca, probabili o possibili. Nello stesso periodo non si sono verificate trombosi acute o sub-acute di stent (certe, possibili e /o probabili).
Dai dati in nostro possesso possiamo affermare la sicurezza, ma anche l'efficacia dell'utilizzo dello stent con amphillimus in un particolare setting clinico come quello dello STEMI, in cui sicuramente il milieu trombotico è particolarmente elevato ed in cui l'utilizzo di uno stent polymer-free potrebbe essere un vantaggio da sfruttare. Analisi su sottogruppi come pazienti diabetici, uso di GpIIbIIIa, tromboaspirazione sono in corso.

C54

INTRAVENOUS VERSUS ORAL ACETYLSALICYLIC ACID IN PATIENTS WITH HIGH RISK ACUTE MYOCARDIAL INFARCTION

Nicola Marchese[1], Antonio Fernando Savino[2], Antonio Longo[2], Giovanni Pio Siena[1], Aldo Russo[1], Carlo Vigna[1]
[1]Department of Cardiology, Casa Sollievo della Sofferenza Hospital IRCCS, San Giovanni Rotondo, Italy, [2]Department of Laboratory Medicine and Transfusion Medicine, Casa Sollievo della Sofferenza IRCCS, San Giovanni Rotondo, Italy

Background. Fast and effective platelet inhibition is crucial in acute coronary syndromes, but there is limited data with regards to the most appropriate acetylsalycilic acid (ASA) dose and route of administration. The aim of our observational study was to evaluate the platelet inhibition in patients with high-risk myocardial infarction by using 300 mg oral and 200 mg intravenous aspirin administration (o-ASA and iv-ASA, respectively).
Methods. Platelet reactivity was assessed one hour after oral (300mg) or intravenous (200 mg) ASA administration by Multiplate ASPI test in 50 aspirin-naive patients with myocardial infarction (ST- and non-ST-elevation with need of urgent coronary angiography).
Results. The baseline characteristics were not different among the two groups. Platelet reactivity, as assessed by ASPI test, was significantly higher in o-ASA than in iv-ASA patients (469.5±361.9 vs 208.8±160.3, p=0.006). More, the ASPI values were more dispersed in o-ASA in comparison with iv-ASA group, reflecting a high interindividual variability of response. The prevalence of non-responders (ASPI upper quintile) was significantly higher in o-ASA group (36% vs 4%; p=0.005). No ischemic or hemorrhagic complications were seen during hospitalization and at 6-month clinical follow-up.
Conclusions. The use of intravenous route of ASA is associated with a faster and stronger platelet inhibition in patients with acute myocardial infarction and need of urgent coronary angiography.

C55

CLINICAL FINDINGS AFTER BIORESORBABLE VASCULAR SCAFFOLD IMPLANTATION IN AN UNRESTRICTED COHORT OF PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION (FROM THE RAI REGISTRY)

Elisabetta Moscarella[1], Alfonso Ielasi[2], Attilio Varricchio[3], Bruno Loi[4], Giuseppe Tarantini[5], Paolo Calabrò[1], Bernardo Cortese[6], Giuseppe Steffenino[7]
[1]Seconda Università di Napoli, Napoli, Italy, [2]Division of Cardiology, ASST Bergamo Est, Bolognini Hospital, Seriate, Italy, [3]Department of Cardiology, Ospedale Santa Maria della Pietà Nola, Napoli, Italy, [4]Department of Cardiovascular Sciences, Brotzu Hospital, Cagliari, Italy, [5]Department of Cardiac, Thoracic and Vascular Sciences, University Hospital of Padua, Padova, Italy, [6]Division of Cardiology, ASST Fatebenefratelli-Sacco, Fatebenefratelli Hospital, Milano, Italy, [7]Interventional Cardiology Unit, Santi Croce e Carle Hospital, Cuneo, Italy

Background. Bioresorbable vascular scaffold (BVS) technology may be an appealing option in ST-segment elevation myocardial infarction (STEMI) patients. However, the available evidence on its use in this challenging subset is limited.
Methods. Registro Absorb Italiano (RAI) is a multicenter, prospective registry that aims to assess BVS performance through 5-year follow-up of all consecutive patients undergone at least 1 successful BVS implantation. As a part of it, a subgroup analysis in STEMI patients was performed and the outcomes of this cohort compared to the remaining population (defined as "non-STEMI") are reported here.
Results. Among the 1505 patients enrolled, 317 (21.1%) had STEMI on admission. Among those, 232 (73.2%) underwent primary percutaneous coronary intervention (PCI) within 12 hours from symptoms onset; 64 (20.2%) were late-comers (>12 hours); 16 (5%) underwent PCI after successful thrombolysis while 5 (1.6%) underwent rescue-PCI. At median follow-up time of 12 months (IQR 6-20 months) no differences were noticed between STEMI and "non-STEMI" groups in terms of Device-oriented composite endpoint (4.1% vs. 5.6%; p=0.3) and its singular components: ischemia-driven target lesion revascularization (3.2% vs. 3.6%; p= 0.7), target-vessel myocardial infarction (3.2% vs. 2.8%; p=0.7) and cardiac death (0.6% vs. 0.6%; p=0.9). The rate of definite/probable scaffold thrombosis (ScT) was numerically higher but not significant in the STEMI group (2.5% vs. 1.3%; p=0.1).
Conclusions. BVS implantation in an unrestricted cohort of STEMI patients is associated with a numerically higher rate of ScT compared to non-STEMI group. Further studies exploring the potential clinical impact of a pre-specified BVS implantation strategy in this high-risk clinical setting are needed.

C56

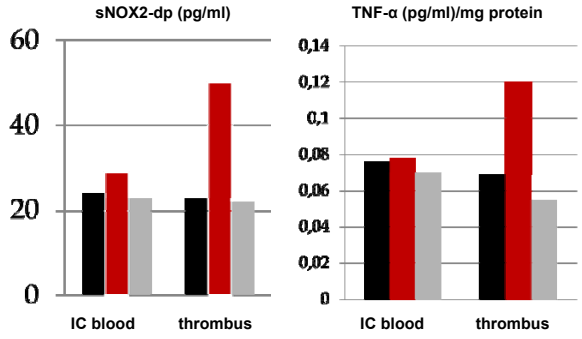
AN INCREASED OXIDATIVE STATUS IS ASSOCIATED WITH THROMBUS GROWTH IN STEMI PATIENTS

Massimiliano Scappaticci[1], Nicola Viceconte[2], Alessio Arrivi[3], Pierpaolo Confessore[1], Daniel Todaro[1], Roberto Carnevale[4], Francesco Versaci[1], Marcello Dominici[3], Gaetano Tanzilli[2], Francesco Violi[5]
[1]Interventional Cardiology Unit, Santa Maria Goretti Hospital, Latina, Italy, [2]Department of Heart and Great Vessels "Attilio Reale", Sapienza University of Rome, Rome, Italy, [3]Santa Maria Hospital, Terni, Italy, [4]Department of Medico-Surgical Sciences and Biotechnologies, Sapienza University of Rome, Latina, Italy, [5]Department of Internal Medicine and Medical Specialties, Sapienza University of Rome, Rome, Italy

A growing body of evidence suggests that thrombus formation is a dynamic process dependent by multiple factors which can act locally and determine its healing or growth. Plaque instability frequently occurs days or weeks before occlusive coronary thrombosis. Clearly, plaque disruption is only part of the process. The reason why a non-occlusive coronary thrombus apparently heals at first but subsequently gives rise to occlusive thrombosis days to weeks later remains to be elucidated. Inflammation and oxidative stress seem to play a key role in platelet activation and coronary thrombus growth.

Methods. Fifty patients with STEMI underwent manual thrombectomy during primary percutaneous coronary intervention (PPCI). Adequate thrombus material was retrieved in 35 of them. Oxidative stress, assessed by NoxOX2 activity, and inflammation, assessed by TNFα serum levels, were measured in coronary thrombi and in aspirated intra-coronary blood, respectively.

Results. Black= pre-PCI; Red= aspiration; Grey= post-PCI.



Conclusions. In the setting of STEMI, coronary thrombus is characterized by an increased inflammatory and oxidative status. This biochemical status represents a toxic microenvironment that may promote thrombus growth and stabilization

Pharmacology

C57

ANTIPLATELET PRESCRIPTION AFTER AN ACUTE CORONARY SYNDROME: REAL-WORLD EVIDENCE ON MORE THAN 12 000 000 ITALIAN SUBJECTS

A.P. Maggioni[1], L. Dondi[2], A. Pedrini[2], N. Martini[3]
[1]Centro Studi ANMCO, Firenze, Italy, [2]CORETeam, Bologna, Italy, [3]Accademia Nazionale di Medicina, Roma, Italy

Background. Coronary thrombosis is a frequent cause of death and myocardial infarction most often explained by superimposition of a platelet-rich thrombus on existing coronary artery disease. Therefore, antiplatelet drugs are essential in the treatment and secondary prevention of acute coronary syndromes (ACS). Several novel antiplatelet regimens are now available and recommended by current International guidelines. However, it is not known how these treatments are implemented in clinical practice.

Aim. To assess the prescription pattern of antithrombotic drugs after an admission for ACS in a large sample of subjects well representing the Italian country.

Methods and Results. A record linkage analysis was carried out of patient demographics, drug prescriptions, hospital discharge, specialty procedures from the ARCO Observatory, including 12 185 229 subjects. Accrual lasted from January 1 to December 31, 2014. This analysis is focused just on the prescription patterns of antiplatelets. Among these subjects, 23,941 were discharged alive after an admission for ACS. Median age of ACS patients was 71 years (77 for females, 68 for males). Female gender accounted for 30.8% of the total population. Between ACS patients, 25.0% were diabetics, 73.7% with hypertension, 16.6% with COPD, 10.7% with depression. In the first month after discharge, 19 333/23 941 (80.8%) received at least one antiplatelet drug.

The prescription pattern of antiplatelets is reported in the Table. Overall dual antiplatelet therapy (DAPT) was prescribed in 12 476 (52.1%) of the patients discharge alive.

Antiplatelet treatment	N. pts	%
Aspirin alone	3558	18.4
Clopidogrel alone	1973	10.2
Other thienopyridine alone	1019	5.3
Aspirin and clopidogrel	6816	35.3
Aspirin and other thienopyridine	5660	29.3
Other antiplatelets	307	1.5

Conclusion. This analysis shows that patients of real world practice are largely different from those included in randomized clinical trials, specifically they are older and of female sex. In this population of patients the adherence to guidelines in prescribing DAPT seems to be at least suboptimal. Among patients treated with DAPT, the association of aspirin and clopidogrel remains the most frequently prescribed.

C58

PREVALENCE AND PREDICTORS OF DUAL ANTIPLATELET THERAPY PROLONGATION BEYOND ONE YEAR IN PATIENTS WITH ACUTE CORONARY SYNDROME: INSIGHTS FROM THE REAL-WORLD START-ANTIPLATELET REGISTRY

Ilaria Cavallari[1], Giuseppe Patti[1], Rossella Marcucci[2], Emilia Antonucci[3], Paolo Calabrò[4], Plinio Cirillo[4], Paolo Gresele[5], Vittorio Pengo[6], Pasquale Pignatelli[7], Elisabetta Ricottini[1], Gualtiero Palareti[3]
[1]Dipartimento di Scienze Cardiovascolari, Università Campus Bio-Medico di Roma, Roma, Italy, [2]Dipartimento di Medicina Sperimentale e Clinica, Università di Firenze, Firenze, Italy, [3]Arianna Anticoagulazione Foundation, Bologna, Italy, [4]Seconda Università di Napoli, Napoli, Italy, [5]Dipartimento di Medicina, Sezione di Medicina Interna e Cardiovascolare, Università di Perugia, Perugia, Italy, [6]Dipartimento di Scienze Cardiologiche, Toraciche e Vascolari, Università di Padova, Padova, Italy, [7]Dipartimento di Medicina Interna e Specialità Mediche, Sapienza Università di Roma, Roma, Italy

Background. To date, there are limited real-world data regarding prevalence and predictors of prolongation of dual antiplatelet therapy (DAPT) with aspirin plus a P2Y12 inhibitor beyond one year after acute coronary syndrome (ACS). We have explored such issue in the START-ANTIPLATELET, a branch of the START-Register (ClinicalTrials.gov Identifier: NCT02219984).

Methods. START-ANTIPLATELET is a prospective, observational, multicenter, Italian registry including patients admitted for ACS and followed up to one year. For the purpose of this analysis, we have included only patients receiving DAPT throughout one year after ACS and we have considered separately patients according to the decision of the treating cardiologist to continue or not DAPT beyond one year.

Results. 596 out of 840 ACS patients completed 12-month follow-up on DAPT; DAPT was prolonged beyond one year in 13% of patients (N=79). The strongest predictors of DAPT continuation were further cardiovascular events after the index admission (OR 3.3, 95% CI 1.4-7.7), the absence of bleeding complications (OR 3.2, 95% CI 1.2-8.3) and no anemia during one-year follow-up (OR 2.6, 95% CI 1.1-5.9). Other independent predictors of DAPT prolongation were at least moderate renal failure (OR 2.5, 95% CI 1.3-5.0) and peripheral artery disease (OR 1.8, 95% CI 1.1-3.0). The choice of DAPT prolongation was not associated with younger ager, diabetes status, coronary angioplasty as initial treatment strategy or drug-eluting stent implantation.

Conclusions. This study provides a real-world snapshot on the factors influencing the option to continue DAPT beyond one year after ACS; moreover, it may be useful to illustrate the relative contribution of low bleeding risk versus high ischemic risk features for DAPT prolongation.

C59

IN-HOSPITAL SWITCH OF P2Y12 DRUGS IN PATIENTS PRESENTING WITH ACUTE CORONARY SYNDROME: A META-ANALYSIS OF 14 STUDIES INCLUDING 10 955 PATIENTS

Matteo Bianco[1], Enrico Cerrato[2], Akshay Bagai[3], Leonardo De Luca[4], Simone Biscaglia[5], Fabrizio D'Ascenzo[6], Francesco Tomassini[7], Alessandra Chinaglia[8], Sean Goodma[3], Roberto Pozzi[1], Gianluca Campo[5], Ferdinando Varbella[7]
[1]Division of Cardiology, University Hospital San Luigi Gonzaga, Orbassano, Italy, [2]Interventional Cardiology Unit, University Hospital San Luigi Gonzaga, Orbassano, Italy, [3]Division of Cardiology, St. Michael's Hospital, Toronto, Canada, [4]Division of Cardiology, S. Giovanni Evangelista Hospital, Tivoli (RM), Italy, [5]Division of Cardiology, University of Ferrara, Ferrara, Italy, [6]Division of Cardiology, Hospital "Città della Salute e della Scienza di Torino", Torino, Italy, [7]Interventional Cardiology Unit, Degli Infermi Hospital, Rivoli, Italy, [8]Division of Cardiology, Maria Vittoria Hospital, Torino, Italy

Introduction. Despite recently data published from clinical registries, efficacy and safety of switching among P2Y12 inhibitors (P2Y12i

clopidogrel, prasugrel, ticagrelor) remain unclear. Thus, we sought to assess the clinical outcomes of switching among P2Y12i versus maintaining the same regimen performing a comprehensive review and meta-analysis of available data.
Methods. MEDLINE/PubMed/SCOPUS/Cochrane were systematically screened for studies regarding P2Y12i management and switching in clinical practice reporting a follow-up within 30 days. Comparisons between patients undergoing or not switching were performed reporting major cardiac events (MACE), any and major bleeding.
Results. 10 955 patients from 14 studies were included in the final analysis. Unstable angina/non-ST-elevation myocardial infarction [62.0%, interquartile range (IQR) 39%-69%)] was the most common clinical presentation followed by ST-elevation myocardial infarction [37.0%, IQR 27-50)]. The most common type of switch was the upgrade that occurred in 2737 (25.0%) of patients more often from clopidogrel to prasugrel. Downgrade to clopidogrel or change between new P2Y12 were much less common (3.1% and 0.7%, respectively). Total number of switch was 3167 (28.9%). There were no significant difference in MACE (OR 1.02 [95% CI 0.63-1.65]), however risk of any bleeding (OR 1.74 [95% CI 1.34-2.36) as well as major bleeding (OR 1.69 [95% CI 1.19-2.40) was higher among switched patients.
Conclusions. In clinical practice, in-hospital P2Y12i switching occurs often. Switching P2Y12 drugs was not associated with an improvement in MACE, however switching was associated with increased bleeding risk.

C60

DIRECT ANTICOAGULATION IN ADDITION TO ANTIPLATELET THERAPY AFTER ACUTE CORONARY SYNDROMES: AN UPDATED META-ANALYSIS

Mauro Chiarito[1], Francesco Cannata[1], Davide Cao[1], Cosmo Godino[2], John H. Alexander[3], Bernhard Reimers[1], Gianluigi Condorelli[1], Giulio Giuseppe Stefanini[1]
[1]Humanitas Clinical and Research Center, Rozzano, Milan, Italy, [2]San Raffaele Scientific Institute, Milan, Italy, [3]Duke University Medical Center, Duhram, NC, USA

Background. Advances in pharmacological and revascularization therapies have markedly improved survival of patients after acute coronary syndromes (ACS). However, this population remains at high risk for cardiovascular events and recurrence of myocardial infarction. Oral anticoagulation represents an attractive strategy for secondary prevention after ACS, although it entails a high risk of bleeding.
Objective. We performed a meta-analysis of randomized controlled trials (RCT) evaluating safety and efficacy of direct oral anticoagulants (DOAC) on top of standard antiplatelet therapy after ACS, focusing on treatment effects according to clinical presentation.
Methods. PubMed, EMBASE, Google scholar database, were searched for all RCTs investigating DOAC in addition to antiplatelet therapy after ACS. Only trials in which patients had access to percutaneous coronary intervention (PCI) for the index event were included. The primary efficacy endpoint was the composite of cardiovascular death, myocardial infarction/urgent revascularization, and stroke. The primary safety endpoint was the composite of major and clinically relevant bleedings.
Results. A total of seven studies were included in the present meta-analysis (n=20 018). At mid-term follow-up, the risk of the primary efficacy endpoint was significantly lower in patients treated with DOAC as compared with the control group (odds ratio [OR] 0.82; 95% CI 0.74-0.90, p<0.001). Yet, DOAC addition was associated with a higher risk of major or clinically relevant bleedings (OR 2.36; 95% CI 2.11-2.64, p<0.001). Notable differences were observed between the number needed to treat (NNT) and the number needed to harm (NNH) in patients with a NSTE-ACS as index event (NNT: 83, NNH: 52), Conversely, in patients with STEMI presentation NNT and NNH were comparable (64 and 51, respectively).
Conclusions. This meta-analysis confirms that the addition of DOAC on top of antiplatelet therapy after an ACS improves ischemic outcomes while significantly increasing the risk of bleeding. Our findings, however, indicate that the risk-benefit profile of DOAC in addition to antiplatelet therapy may be more favorable among specific subgroups such as patients with STEMI.

C61

IMPACT OF PRE-PROCEDURAL DUAL ANTIPLATELET THERAPY ON PERIPROCEDURAL MYOCARDIAL INFARCTION IN PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTIONS WITH ADJUNCTIVE TIROFIBAN

Monica Verdoia[1], Lucia Barbieri[2], Paolo Nicola Marino[1], Harry Suryapranata[3], Giuseppe De Luca[1]
[1]Azienda Ospedaliera-Universitaria "Maggiore della Carità", Università del Piemonte Orientale, Novara, Italy, [2]Ospedale S. Andrea, Vercelli, Italy, [3]UMC St Radboud, Nijemegen, Netherlands

Background. Recent trials have failed to demonstrate any clinical benefit from pre-treatment with dual antiplatelet therapy (DAPT) in patients undergoing percutaneous coronary interventions, (PCI), even in the setting of acute coronary syndrome. However, suboptimal platelet inhibition during (PCI) has been shown to enhance the risk of acute ischemic complications, such as stent thrombosis and periprocedural myocardial infarction (PMI), thus raising the attention on the potential advantages of adjunctive glycoprotein IIbIIIa inhibitors to obviate to the delayed onset of action of oral antiplatelet drugs. The aim of the present study was then to evaluate the impact of platelet reactivity and pre-procedural DAPT on PMI in patients undergoing PCI with adjunctive tirofiban.
Methods. In a consecutive cohort of patients undergoing PCI with tirofiban (intracoronary/intravenous ± prolonged infusion), periprocedural myonecrosis was defined as troponin I increase by 3 times the ULN or by 50% of an elevated baseline value, whereas PMI as CKMB increase by 3 times the ULN or 50% of baseline. Platelet function was assessed by impedance aggregometry.
Results. A total of 168 patients were included, 77 (45.8%) of whom were on DAPT at the time of PCI. Patients on DAPT had more often a history of previous PCI (p=0.03), higher ACS at admission (p<0.001) and creatinine levels (p=0.03). Coronary calcifications and type C lesions were more frequent in patients without DAPT (p=0.02 and p=0.03, respectively), as much as TIMI flow <3 (p=0.03), while procedural characteristics were comparable. Baseline platelet reactivity was significantly reduced in DAPT treated patients (p<0.001 for ASPI, COL and ADP tests). However the rate of periprocedural myonecrosis did not differ according to pre-procedural DAPT (68.4%vs 67%, p=0.87; adjusted OR[95%CI]=1.34[0.71-2.53],p=0.36) and neither the occurrence of PMI (13.3% vs 12.6%, p=0.99; adjusted OR[95%CI]=1.24[0.51-3.1],p=0.64). Furthermore, baseline platelet reactivity was similar in patients with and without PMI/myonecrosis with no relationship between platelet function and Troponin I peak.
Conclusion. In patients undergoing PCI with adjunctive GP IIb/IIIa inhibitors, preprocedural DAPT and baseline platelet reactivity are not associated to the risk of periprocedural myocardial infarction or myonecrosis. These data further support the role of periprocedural Gp IIb-IIIa inhibitors in order to overcome any suboptimal inhibition of platelet aggregation at the time of the procedure due to drug-resistance or delayed (downstream) administration of ADP antagonists, especially in complex high-risk procedures.

Non-coronary interventions 2

C62

YOUNG PATIENT WITH ADVANCED HF NO LONGER A CANDIDATE TO HEART TRANSPLANTATION AFTER MITRACLIP PROCEDURE

Andrea Scotti[1], Cosmo Godino[1], Eustachio Agricola[1], Carlo Andrea Pivato[1], Mauro Chiarito[1], Stefano Stella[1], Massimo Maccherini[2], Alberto Margonato[1], Antonio Colombo[1]
[1]Cardio-Thoracic-Vascular Department, San Raffaele Scientific Institute, Milan, Italy, [2]Cardiothoracic Surgery Department, Ospedale Policlinico Santa Maria alle Scotte, Siena, Italy

Mitral regurgitation (MR) is the second most common form of valvular heart disease needing surgery in Europe. This case reviews a 36-year-old woman with end-stage heart failure secondary to chemotherapy-induced cardiotoxicity, complicated by severe MR. She was listed for heart transplantation and underwent percutaneous MitraClip implantation in order to preclude further clinical deterioration awaiting a suitable donor. The 2-year follow-up showed strong improvement of symptoms and mostly reverse left ventricular remodeling with consequent removal from the heart transplantation list.

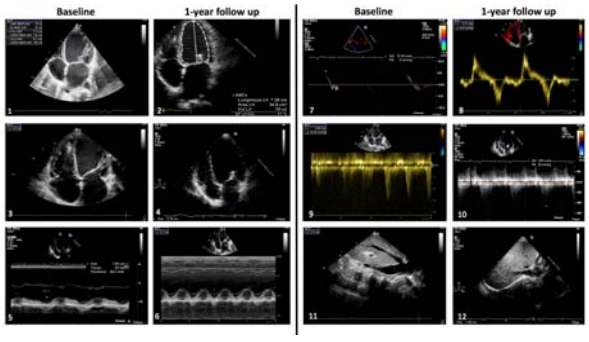


Figure. Comparison between baseline and 1-year follow-up echocardiography. 1) Baseline left ventricle ejection fraction (LVEF), 2) 1-year follow-up LVEF, 3) Baseline right ventricle end-diastolic diameter (RVEDD), 4) 1-year follow-up RVEDD, 5) Baseline tricuspid annular plane systolic excursion (TAPSE), 6) 1-year follow-up TAPSE, 7) Baseline systolic wave with tissue Doppler imaging (S' TDI), 8) 1-year follow-up S' TDI, 9) Baseline systolic pulmonary artery pressure (sPAP), 10) 1-year follow-up sPAP, 11) Baseline inferior vena cava (IVC), 12) 1-year follow-up IVC.

C63

INCIDENCE, TIMING AND PREDICTORS OF RE-HOSPITALIZATION IN PATIENTS UNDERGOING PERCUTANEOUS MITRAL VALVE REPAIR WITH THE MITRACLIP SYSTEM

Antonio Popolo Rubbio, Carmelo Grasso, Davide Capodanno, Sergio Buccheri, Maria Elena Di Salvo, Stefano Cannata, Salvatore Scandura, Sarah Mangiafico, Tatiana Salerno, Silvia Farruggio, Giuseppe Ronsivalle, Giuseppe Castania, Marco Barbanti, Piera Capranzano, Corrado Tamburino

Divisione di Cardiologia, Ospedale Ferrarotto, Catania, Italy

Objectives. We sought to characterize the rate, cause and predictors of re-hospitalization (RH) at 30 days (early RH) and within twelve months (late RH) after MitraClip.

Background. To date, no studies have systematically reported causes and predictors of unplanned RH(s) after MitraClip implantation.

Methods. From a single center, a total of 322 consecutive patients treated with MitraClip from October 2008 to June 2016 were finally included. Two different groups [RH group and no-RH group (respectively if the patients experienced unplanned RH after MitraClip or not)] were compared. RH definition according to the MVARC criteria was employed.

Results. Eighty-nine patients (27.6%) were readmitted to hospital during the study period and early RH accounted for 27% of the total. The mean time from clip to RH was 132±111 days (median 99 days, IQR 29-232). RH was mostly related to cardiovascular causes (66.3%). Of note, it should be underlined that patients were most frequently hospitalized for primary HF (due to impaired LVEF, 20.2%) rather than for recurrent MR (7.9%). Anemia (5.6%) and gastrointestinal bleeding (5.6%) were the most frequent non-cardiovascular indications for RH. Independent predictors of early RH were length of stay during MitraClip hospitalization ≥3 days (p=0.015), reduction of left ventricular ejection fraction ≥5% after MitraClip (p=0.022) and severe systolic pulmonary artery pressure ≥60 mmHg at discharge (p=0.020). Independent predictors of late RH were technical failure (p=0.022) and systolic pulmonary artery pressure ≥60 mmHg at discharge (p=0.048). In patients with early RHs, mortality was significantly higher at 12 months as compared to patients with late RH (p<0.001 by Kaplan-Meier analysis).

Conclusions. RH is not uncommon after MitraClip implantation and cardiovascular causes represents the most frequent etiology. Early RH may reflect patients' frailty and impact on subsequent mortality.

C64

MULTICENTER EXPERIENCE OF MITRACLIP THERAPY IN PATIENTS WITH ISCHEMIC AND NON-ISCHEMIC FUNCTIONAL MITRAL REGURGITATION: 2-YEAR OUTCOMES

Andrea Scotti[1], Cosmo Godino[1], Marianna Adamo[2], Mauro Chiarito[1], Francesco Melillo[1], Alessandro Beneduce[1], Carlo Andrea Pivato[1], Luca Arrigoni[1], Anna Salerno[1], Alberto Cappelletti[1], Valeria Magni[1], Stefano Stella[1], Andrea Munafò[1], Gabriele Fragasso[1], Matteo Montorfano[1], Eustachio Agricola[1], Federica Ettori[2], Alberto Margonato[1], Antonio Colombo[1]

[1]Cardiothoracic Vascular Department, San Raffaele Scientific Institute, Milan, Italy, [2]Cardiac Catheterization Laboratory, Cardiothoracic Department, Spedali Civili, Brescia, Italy

Background. MitraClip implantation has evolved as a new tool for treatment of inoperable or high-risk patients with severe functional mitral regurgitation (FMR) due to dilated cardiomyopathy (DCM). Limited data are available regarding MitraClip outcomes comparing patients with ischemic and non-ischemic DCM.

Methods. From 2008-2016, 171 patients received MitraClip for FMR at three institutions. Patients were stratified according to MR aetiology in non-ischemic FMR (n=64) and ischemic FMR (n=107). Preoperative risk factors, operative variables and outcomes up to 2-year were evaluated.

Results. As expected, patients with ischemic FMR had significantly more risk factors and comorbidities, were more male (86% vs. 67%) and with higher Logistic EuroSCORE (21±17 vs. 14±17). Overall procedural success rate was 90% and in-hospital mortality was 3% without significant differences between aetiology. Despite a trend towards a worsening survival in patients with ischemic etiology, two-year overall (32% vs. 18%, p=0.083) and cardiac (24% vs. 13%, p=0.109) mortality rates were comparable. No differences were detected in terms of re-hospitalization rates (31%), needed for LVAD implantation (4%) and mitral valve surgery (1%). Both groups had significant improvement in MR grade and 6-minute walking test; non-ischemic FMR patients demonstrated a greater reduction in NYHA class and left ventricle volumes. Logistic EuroSCORE ≥13 and LVEDV ≥210 were the strongest independent predictors of 2-year mortality.

Conclusions. The ischemic or non-ischemic etiology of DCM did not significantly affect in-hospital and 2-year outcomes after MitraClip in patients with FMR, despite a trend towards a worsening survival is present in those with ischemic DCM.

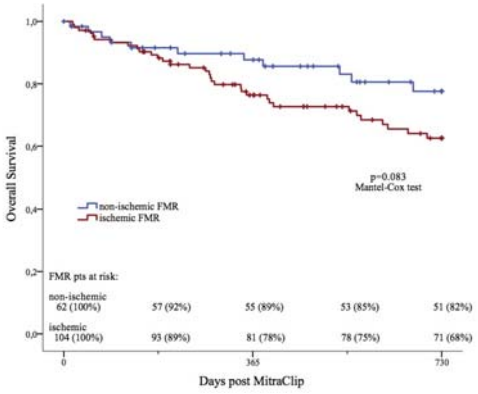


Figure 1. Kaplan-Meier analysis of overall survival rates are shown for FMR patients stratified in ischemic (red line) and non-ischemic dilated cardiomyopathy (blue line).

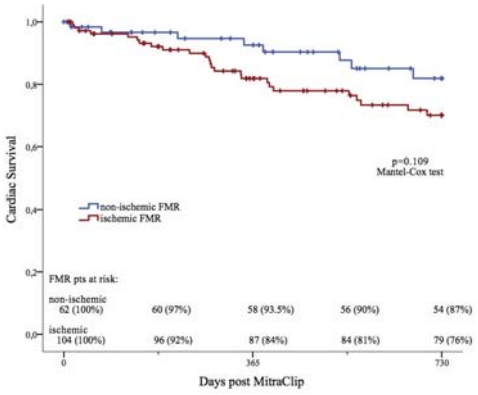


Figure 2. Kaplan-Meier analysis of cardiac survival rates are shown for FMR patients stratified in ischemic (red line) and non-ischemic dilated cardiomyopathy (blue line).

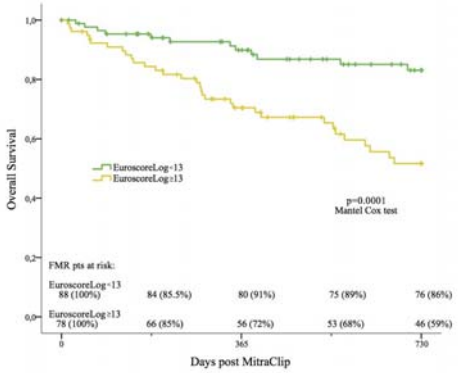


Figure 3. Kaplan–Meier analysis of overall survival rate is shown for patients with Logistic EuroSCORE ≥13 (yellow line) and with Logistic EuroSCORE <13 (green line).

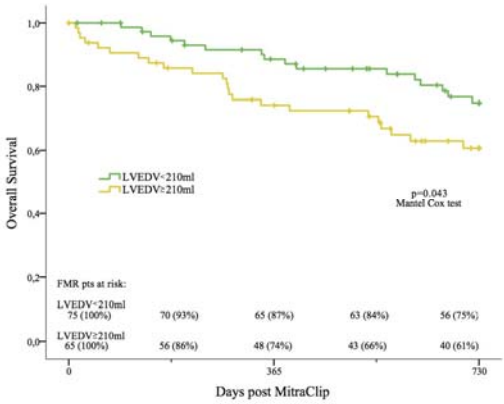


Figure 4. Kaplan–Meier analysis of overall survival rate is shown for patients with LVEDV ≥210ml (yellow line) and with LVEDV <210ml (green line).

C65

SCORE PREDICTED VS OBSERVED SURVIVAL UP TO 5 YEARS AFTER MITRACLIP IN PATIENTS WITH FUNCTIONAL MITRAL REGURGITATION

Andrea Scotti[1], Cosmo Godino[1], Marianna Adamo[2], Alessia Giannattasio[1], Antonio Sisinni[1], Mauro Chiarito[1], Francesco Melillo[1], Alessandro Beneduce[1], Carlo Andrea Pivato[1], Luca Arrigoni[1], Anna Salerno[1], Alberto Cappelletti[1], Valeria Magni[1], Stefano Stella[1], Gabriele Fragasso[1], Matteo Montorfano[1], Eustachio Agricola[1], Federica Ettori[2], Alberto Margonato[1], Antonio Colombo[1]

[1]Cardiothoracic Vascular Department, San Raffaele Scientific Institute, Milan, Italy, [2]Cardiac Catheterization Laboratory, Cardiothoracic Department, Spedali Civili, Brescia, Italy

Background. No data are available regarding the observed mortality after MitraClip in patients with symptomatic heart failure (HF) and significant functional mitral regurgitation (FMR) compared to the mortality predicted by the available HF scores.

Methods and Results. From 2008-2016, 199 patients with moderate-to-severe HF received MitraClip at three institutions. Patients were stratified according to etiology in non-ischemic FMR (n=75) and ischemic FMR (n=123). The observed mortality was compared with that predicted by the Seattle Heart Failure Model (SHFM), the heart failure calculator of the meta-analysis global group in chronic heart failure (MAGGIC) and the Cardiac and Comorbid Conditions HF (3C-HF) Score after 1 year: 20% observed, 20% by SHFM (Δ=0), 26% by MAGGIC (Δ=-6%) and 45% by 3C-HF (Δ=-25%). At 2 years: 32% observed vs. 34% by SHFM (Δ=-2%). At 3 years: 44% observed vs. 52% by MAGGIC (Δ=-8%). At 5 years: 63% observed vs. 60% by SHFM (Δ=+3%). Patients with non-ischemic FMR had the lowest mortality after 1 year (12%) compared to that predicted by SHFM (17.5%, Δ=-5.5%), MAGGIC (24%, Δ=-12%) and 3C-HF (41%, Δ=-29%).

Conclusion. In patients symptomatic for HF due to significant FMR the mortality rate after MitraClip procedure was consistent with that predicted by SHFM score and lower than those predicted by MAGGIC and 3C-HF scores at 1, 2, 3 and 5 years. Patients with non-ischemic FMR showed the greatest difference in mortality rates compared to the HF scores.

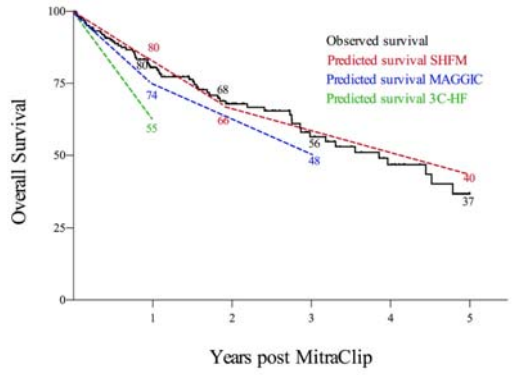


Figure 1. Kaplan-Meier analysis of overall survival compared to the predicted by the available HF scores in all FMR patients.

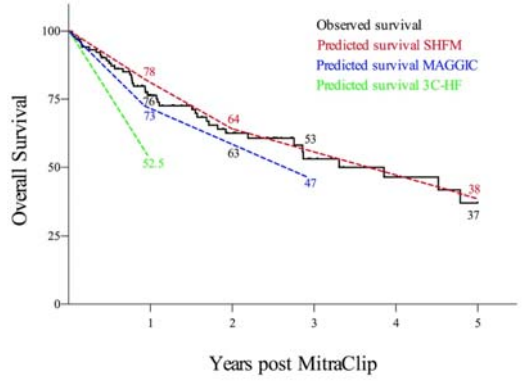


Figure 2. Kaplan-Meier analysis of overall survival compared to the predicted by the available HF scores in ischemic FMR patients.

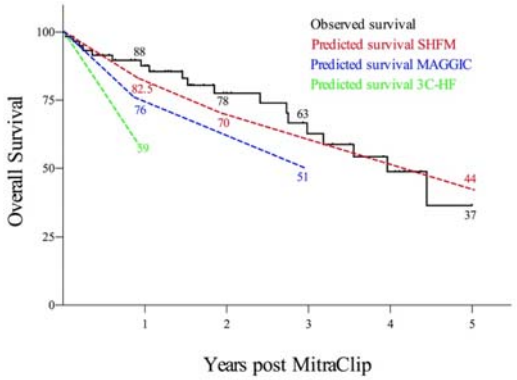


Figure 3. Kaplan-Meier analysis of overall survival compared to the predicted by the available HF scores in non-ischemic FMR patients.

C66

MULTICENTER ANALYSIS OF INCIDENCE AND PREDICTORS OF LEFT VENTRICULAR NEGATIVE REMODELING AFTER MITRACLIP TREATMENT IN PATIENTS WITH FUNCTIONAL MITRAL REGURGITATION

Andrea Scotti[1], Cosmo Godino[1], Maurizio Taramasso[2], Marianna Adamo[3], Marco Russo[2], Carlo Andrea Pivato[1], Luca Arrigoni[1], Evelina Toscano[1], Barbara Bellini[1], Alberto Cappelletti[1], Stefano Stella[1], Gabriele Fragasso[1], Matteo Montorfano[1], Eustachio Agricola[1], Alberto Margonato[1], Federica Ettori[3], Francesco Maisano[2], Antonio Colombo[1]

[1]Cardiothoracic Vascular Department, San Raffaele Scientific Institute, Milan, Italy, [2]Division of Cardiac Surgery, University Hospital Zurich, Zurich, Switzerland, [3]Cardiac Catheterization Laboratory, Cardiothoracic Department, Spedali Civili, Brescia, Italy

Background. MitraClip implantation has evolved as a new tool for treatment of inoperable or high-risk patients with severe functional mitral regurgitation (FMR) due to dilated cardiomyopathy (DCM). Limited data are available regarding incidence and predictors of left ventricular negative remodeling (LVNR) after MitraClip treatment.

Methods. From 2008-2016, 314 patients received MitraClip for FMR at four institutions. Preoperative risk factors, operative variables and outcomes were evaluated. LVNR was defined as an increase at least of 10% in left ventricular end-diastolic volume (LVEDV).

Results. The study population included 314 patients with FMR. There were more male (74%), a mean Logistic EuroSCORE of 18±17, and a mean LV ejection fraction of 31%. Overall procedural success rate was 90% and in-hospital mortality was 3%. Up to 1-year follow-up, the incidence of LVNR was observed in 79 patients (26%). At baseline, those with LVNR were characterized by lower LVEDV (188 ml vs. 233 ml), lower LVESystolicV (133 ml vs. 174 ml), higher LVEF (33% vs. 29.5%), previous myocardial infarction (MI, 40% vs. 22%), residual MR <2 (33% vs. 17%). At multivariate logistic regression analysis, history of MI was the strongest independent predictor of LVNR (odds ratio 3.5).

Conclusions. Left ventricular negative remodeling was observed in 26% of patients after MitraClip treatment of FMR. The presence of previous myocardial infarction is the strongest independent predictor of LVNR.