Comunicazioni orali

Mitral valve interventions

C1

VALUTAZIONE DELLA PERFORMANCE DEGLI SCORE DI RISCHIO DELLO SCOMPENSO CARDIACO A FRAZIONE DI EIEZIONE RIDOTTA IN PAZIENTI CON INSUFFICIENZA MITRALICA FUNZIONALE SEVERA SOTTOPOSTI AD IMPIANTO DI MITRACLIP

Luca Esposito[1], Angelo Silverio[1], Marco Di Maio[2], Angela Iannicelli[1], Giuseppe Fierro[1], Federica Di Feo[1], Generoso Mastrogiovanni[1], Massimo Simeone[1], Rodolfo Citro[1], Gennaro Galasso[1], Cesare Baldi[1]
[1]Dipartimento Cardio-Toraco-Vascolare, A.O.U. San Giovanni e Ruggi d'Aragona, Salerno, [2]Dipartimento Cardiotoracico e Respiratorio, Università della Campania Luigi Vanvitelli, Ospedale Monaldi, A.O.R.N. Ospedale dei Colli, Napoli

Premessa. La selezione dei pazienti con insufficienza mitralica (IM) funzionale severa da candidare ad intervento di riparazione percutanea con dispositivo MitraClip è un processo complesso e multiparametrico e, ad oggi, non esistono score di rischio derivati e validati in questa particolare categoria di pazienti. Lo scopo dello studio è di valutare l'accuratezza discriminativa e calibrativa in termini di morte cardiaca e morte per tutte le cause degli score prognostici dello scompenso cardiaco a frazione d'eiezione ridotta (HFrEF) in una popolazione di pazienti con IM funzionale severa sottoposti a riparazione percutanea dell'IM con dispositivo MitraClip.

Materiali e metodi. Sono stati raccolti prospetticamente i dati di tutti i pazienti con IM severa che tra Marzo 2012 e Novembre 2018 sono stati sottoposti consecutivamente ad intervento di riparazione percutanea della valvola mitrale mediante impianto MitraClip presso il nostro Istituto. Per tutti i pazienti sono stati analizzati i parametri demografici, clinici, ecocardiografici e di laboratorio. In fase pre-procedurale è stato valutato il test da sforzo cardiopolmonare (CPET). Sono stati calcolati retrospettivamente i seguenti score prognostici validati su coorti di pazienti con HFrEF: MECKI, 3C-HF, HFSS, SHFM e MAGGIC. Sono stati considerati i seguenti eventi all'ultimo follow-up disponibile: morte per tutte le cause e morte cardiaca.

Risultati. Lo studio ha incluso 75 pazienti. La popolazione mostrava un elevato rischio chirurgico (EuroSCORE logistico, 20.0±14.2%; EuroSCORE II, 8.0±6.0%) ed una capacità funzionale compromessa con valori medi di picco di consumo di ossigeno (VO2) al CPET di 10.5±3.1 ml/kg/minuto. Il follow-up medio è stato di 891.6 giorni. Sono state osservate 38 morti di cui 24 per causa cardiaca. I valori di area sotto la curva (AUC) degli score per i due eventi analizzati ad 1, 2, 3, 4 e 5 anni sono riportati in Tabella.

Tabella. Capacità discriminativa degli score prognostici per gli eventi morte cardiaca e morte per tutte le cause.

	MECKI	3CHF	SHFM	MAGGIC	HFSS
Morte cardiaca					
1 anno	75.92 [63.7,88.12]	66.95 [47.89,86.02]	59.34 [38.3,80.35]	63.78 [45.11,82.46]	72.3 [58.65,85.95]
2 anni	77* [64.95,89.04]	66.94 [50.23,83.65]	59.25 [41.04,77.46]	71.08 [55.16,87]	72.12 [56.94,87.3]
3 anni	85.85 [73.82,97.87]	67.18 [50.55,83.8]	63.82 [45.9,81.73]	65.73 [48.99,82.46]	72.9 [56.69,89.12]
4 anni	85.74 [73.29,98.19]	66.21 [48.63,83.8]	69.61 [52.79,86.44]	70.57 [53.82,87.31]	70.83 [54.12,87.53]
5 anni	86.12 [71.7,100.55]	68.72 [49.32,88.13]	65.34 [46.78,83.91]	68.83 [49.1,88.55]	71.79 [53.83,89.75]
Morte totale					
1 anno	73.96 [62.58,85.34]	67.98* [53.56,82.41]	60.02* [43.67,76.37]	64.88* [50.19,79.57]	62.82* [48.79,76.85]
2 anni	75.52 [63.46,87.58]	72.07 [59.09,85.06]	55.48* [39.99,70.96]	72.69 [60.04,85.34]	66.04 [52.4,79.68]
3 anni	86.5 [76.01,97]	74.36 [61.31,87.4]	65.87 [51.18,80.57]	69.88* [55.88,83.89]	71.45 [58.16,84.75]
4 anni	83.96 [71.61,96.31]	71.28 [56,8 6.56]	72 [58.57,85.43]	74.67 [60.28,89.06]	70.59 [56.25,84.93]
5 anni	86.3 [73.77,98.83]	73.21 [54.91,91.52]	69.24* [54.02,84.45]	72.09 [53.27,90.92]	73.01 [56.4,89.63]

La capacità discriminativa è espressa come AUC [CI].
AUC, area sotto la curva; CI, intervallo di confidenza; MECKI, Metabolic Exercise, Cardiac, Kidney Index; 3C-HF, Cardiac and Comorbid Conditions Heart Failure; HFSS, Heart Failure Survival Score; SHFM, Seattle Heart Failure Model; MAGGIC, gruppo di meta-analisi in insufficienza cardiaca cronica.
*Endpoint originario sul quale è stato derivato lo score.

Per la morte cardiaca, il MECKI ha mostrato un potere discriminativo maggiore rispetto agli altri score analizzati. L'analisi ROC ha anche mostrato un andamento crescente della capacità discriminativa del MECKI score dal primo fino al quinto anno di osservazione. Anche per la morte per tutte le cause, il MECKI ha mostrato un potere discriminativo maggiore rispetto a quello degli altri score per ciascuna delle finestre temporali analizzate, ed un incremento negli anni della sua capacità discriminativa. Il MECKI score ha mostrato una accuratezza discriminativa significativamente maggiore rispetto a quella di tutti gli altri score, fatta ad eccezione dell'HFSS, per l'occorrenza sia della morte cardiaca che della morte per tutte le cause a 3, 4 e 5 anni ($p<0.05$). L'analisi di Hosmer-Lemeshow ha mostrato una buona capacità calibrativa di tutti gli score per l'evento morte cardiaca. La capacità calibrativa del MECKI score è risultata subottimale nell'analisi della morte per tutte le cause.

Conclusioni. L'utilizzo di score prognostici disegnati per la predizione di eventi nello HFrEF può contribuire ad una migliore stratificazione prognostica pre-procedurale di questa categoria di pazienti. Il MECKI score, che include ben due parametri del CPET, ha dimostrato la migliore performance in termini di capacità discriminativa tanto per la mortalità totale che per la mortalità cardiaca, soprattutto al follow-up lungo termine.

C2

TWO-YEAR CLINICAL AND ECHOCARDIOGRAPHIC OUTCOMES AFTER PERCUTANEOUS EDGE-TO-EDGE MITRAL VALVE REPAIR WITH MITRACLIP: A RETROSPECTIVE ANALYSIS FROM A HIGH VOLUME CENTRE

Luca Nai Fovino[1], Mauro Massussi[1], Michael Salama[1], Daniele Bottigliengo[2], Andrea Scotti[1], Francesco Cardaioli[1], Giulio Rodinò[1], Giulia Masiero[1], Tommaso Fabris[1], Giuseppe Tarantini[1]
[1]Dipartimento di Scienze Cardio-Toraco-Vascolari, [2]Biostatistica, Università degli Studi, Padova

Background. Mitral regurgitation (MR) is the most common valvulopathy in Western countries. Although surgery still represents the gold standard treatment, many patients are considered inoperable due to comorbidity or advanced age. Percutaneous edge-to-edge mitral valve repair with MitraClip is a currently approved and less invasive alternative to surgery for high-risk patients but data on clinical and echocardiographic outcomes are limited. The aim of our study was to investigate the clinical and echocardiographic outcomes of inoperable/high- risk patients treated with MitraClip implantation for severe symptomatic MR at the Interventional Cardiology Unit of the University of Padova.

Methods. All consecutive patients treated with the MitraClip system at the Cath Lab of University Hospital of Padova were included in our retrospective analysis. Baseline clinical and echocardiographic characteristics as well as procedural data were collected in a dedicated database. Both clinical and echocardiographic follow up was planned at discharge, at 30 days, at 1 year and at 2 years. Clinical endpoints were all-cause and cardiovascular mortality, readmission for congestive heart failure, LVAD implantation/heart transplantation and redo surgery on mitral valve. Left ventricular volumes, ejection fraction, pulmonary arterial pressures and residual MR were also evaluated at each time point. Results were stratified by MR etiology (functional vs. organic).

Results. 62 patients (71% men) were included with a median age of 75 years and a median EuroSCORE II of 4.67%. Median left ventricular end-diastolic volume (iEDV) and left ventricular ejection fraction (LVEF) were respectively 106 ml/m2 and 35%. The median effective regurgitant orifice area (EROA) was 0.31 cm/m2. Patients with functional MR were younger (73 vs. 81 years, p=0.001) and they had higher iEDV (115 vs. 83.5 ml/m^2, $p<0.001$) and lower EF (32.5 vs 54.5%, $p<0.001$) if compared with the organic-MR group. No patient died during the procedure and periprocedural complication rates were as low as 2%. Post-procedural MR was ≤2+ in 97% of patients. The 30-day all-cause mortality was 5% and 88% of the subjects were in NYHA class I or II. The 1-year all-cause mortality was 27% and 29% of the patients were readmitted for congestive heart failure. One patient underwent LVAD implantation and one patients received heart transplant. 82% of the patients were in NYHA class I or II and 93% of them had ≤2+ residual MR at 1-year follow-up. Mean iEDV decreased from baseline to 30-day (-7.89 ml/m^2, p=0.07) and up to 1-year follow-up (-15.5 ml/m^2, p=0.02), while no significant change was documented in EF. Kaplan-Meier curves showed no significant difference in the incidence of all-cause mortality (p=0.9) and readmission for HF/LVAD implantation/heart transplant (p=0.5) between the functional-MR group and the organic MR-group.

Conclusions. Our data demonstrate that MitraClip implantation is feasible, safe and effective. Procedural complications are extremely rare and over 70% of patients are free from hospital readmissions for

congestive heart failure during a 1-year follow-up period. However, given the patients' high baseline risk characteristics, 1-year mortality is as high as 27%. Outcomes are similar for patients with functional and organic MR.

C3

TRANSCATHETER MITRAL VALVE REPAIR WITH THE MITRACLIP XTR IN FUNCTIONAL VERSUS DEGENERATIVE MITRAL REGURGITATION: EARLY RESULTS FROM THE GIOTTO REGISTRY

Francesco Bedogni[1], Antonio Popolo Rubbio[1], Luca Testa[1], Federico De Marco[1], Giovanni Bianchi[1], Carmelo Grasso[2], Salvatore Scandura[2], Maurizio Tusa[1], Paolo Denti[3], Ottavio Alfieri[3], Arturo Giordano[4], Paolo Ferraro[4], Antonio L. Bartorelli[5], Annalisa Mongiardo[6], Anna S. Petronio[7], Cristina Giannini[7], Cosmo Godino[8], Matteo Montorfano[8], Francesco De Felice[9], Marianna Adamo[10], Fausto Castriota[11], Cesare Baldi[12], Giulia Masiero[13], Giuseppe Tarantini[13], Corrado Tamburino[2] and GISE Registry

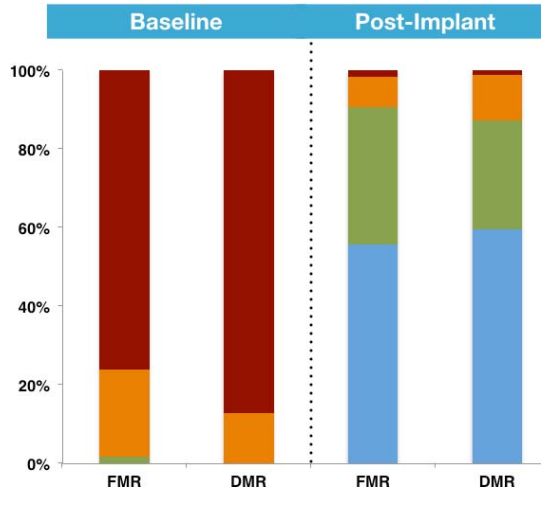
[1]IRCCS Policlinico San Donato, San Donato Milanese, Milano, [2]Centro Alte Specialità e Trapianti (CAST), Azienda Ospedaliero-Universitaria Policlinico-Vittorio Emanuele, Catania, [3]Cardiac Surgery Department, San Raffaele University Hospital, Milano, [4]Pineta Grande Hospital, Castelvolturno, [5]Centro Cardiologico Monzino, Milano, [6]University Magna Graecia, Catanzaro, [7]Azienda Ospedaliero Universitaria Pisana, Pisa, [8]Cardio-Thoracic-Vascular Department, San Raffaele University Hospital, Milano, [9]Azienda Ospedaliera S. Camillo Forlanini, Roma, [10]Spedali Civili Brescia, Brescia, [11]Humanitas Gavazzeni Hospital, Bergamo, [12]University Hospital Scuola Medica Salernitana, Salerno, [13]Interventional Cardiology Unit, University of Padua, Padova

Background. The MitraClip XTR represents a new version of the MitraClip device with longer arms and grippers to simplify leaflet grasping in difficult and challenging anatomies. We sought to evaluate the acute performance and early outcome of the new MitraClip XTR in functional versus degenerative MR (FMR vs. DMR).

Methods. We used data from the Italian Society of Interventional Cardiology (GIse) Registry Of Transcatheter Treatment of Mitral Valve RegurgitaTiOn (GIOTTO), which is an ongoing single-arm, multicenter, prospective registry that started enrollment in February 2016. Since its introduction in Italy in 2018, MitraClip XTR was employed in 186 patients. After exclusion of 44 patients with mixed etiology, 142 patients were finally recruited and stratified according to MR etiology (FMR n=63 vs. DMR n=79).

Results. Patients with FMR were younger if compared to DMR (median age 77 vs. 83, respectively; p≤0.001), mostly men (57.6 vs. 42.4; p≤0.001) and with higher surgical risk (median EuroSCORE II 5.6 vs. 3.8; p≤0.001). The median number of clip XTR implanted was similar between the two groups (p=0.637). In the overall population, the 23.9% required multiple clips XTR, whereas another 26% required also concomitant implantation of clips NTR. MVARC technical success was 94.4% (FMR 96.8% vs. DMR 92.4%; p=0.256) and MR grade 1+/2+ post implant was comparable (FMR 90.5% vs. DMR 87.3%; p=0.557). Differences in post-procedural transmitral gradient were encountered (median FMR 3 mmHg vs. DMR 4 mmHg; p=0.032). Single clip detachment occurred in 1.4% and only in the DMR population (2.5%). The rate of in-hospital MAEs was similar between the two groups (FMR 7.9% vs. DMR 13.9%; p=0.262). Kaplan-Meier 90-day freedom from death was comparable (FMR 87.6% vs. DMR 91.3%; p=0.789)

Conclusions. Transcatheter mitral valve repair with the new MitraClip XTR is comparably feasible and effective in patients with FMR and DMR at early follow-up.



C4

A NOVEL "DIRECTIONAL" TECHNIQUE FOR PERCUTANEOUS MITRAL BALLOON VALVULOPLASTY

Cristina Aurigemma, Francesco Burzotta, Enrico Romagnoli, Francesca Graziani, Gabriella Locorotondo, Daniela Pedicino, Aniello Zambrano, Carlo Trani

Istituto di Cardiologia, Dipartimento di Scienze Cardiovascolari e Toraciche, Fondazione Policlinico Universitario A. Gemelli IRCCS, Roma

Background. Percutaneous mitral valvuloplasty (PMV) has been established as the procedure of choice for severe mitral stenosis beyond surgical treatment. The Inoue technique is considered the most widely practiced technique for PMV. Yet, it is based on an original equipment and technical steps that differ from other contemporary structural heart interventions. This made PMW cumbersome even for operators who are deeply involved in other structural interventions programs. On such bases, we developed a novel "directional" technique for percutaneous mitral balloon valvuloplasty that is based on the original combination of catheters and valvuloplasty balloons that are usually not selected for PMW.

Methods. The procedure is performed using the femoral vein to perform the PMV and the right or left radial artery for the introduction of a pigtail catheter in left ventricle to monitor the procedure. The key procedure steps are: (i) trans-septal puncture under transesophageal echocardiographic guidance; (ii) the 12F bi-directional steerable guiding sheath (DiRex Boston Scientific) facilitates the crossing of the guidewire through the stenotic orifice allowing us to deflect its tip to face towards the mitral valve orifice; (iii) the conventional valvuloplasty balloon inflation under rapid ventricular pacing, performed using the left ventricular stimulation by the stiff guidewire, to stabilize the balloon position; (iv) the balloon size according to the maximal inter-commissural distance of the mitral valve provided by echocardiography (not according to the conventional height-based balloon reference sizing) to avoid possible mistakes when determining the size of the balloon and to prevent possible severe MR.

Results. We have performed PMV according to this novel "directional" modified antegrade technique in six patients (M/F 1/5, age 48±10 years old), who suffered from symptomatic mitral valve stenosis. The PVM was successful in all patients with an adequate final mitral valve area (MVA) of >1.5 cm^2 with no significant mitral regurgitation (MR) (not more than 2/4 in all patients).

Conclusions. The novel "directional" technique for percutaneous mitral balloon valvuloplasty allows to perform PMW using devices that can also be used in other structural interventions. This technique has the following strengths: (i) easy antegrade mitral valve crossing; (ii) reduced size of the atrial septal defect after trans-septal puncture; (iii) possibility of stepwise multiple inflations without need for valve recrossing; (iv) facilitated transmitral pressure gradient control.

Coronary interventions 1

C5

INTRAVASCULAR LITHOTRIPSY: A NOVEL TREATMENT OF CALCIFIC CORONARY ARTERY STENOSIS

Giulia Nardi, Alessio Mattesini, Carlotta Sorini Dini, Maria Federica Crociani, Brunilda Hamiti, Carlo Di Mario

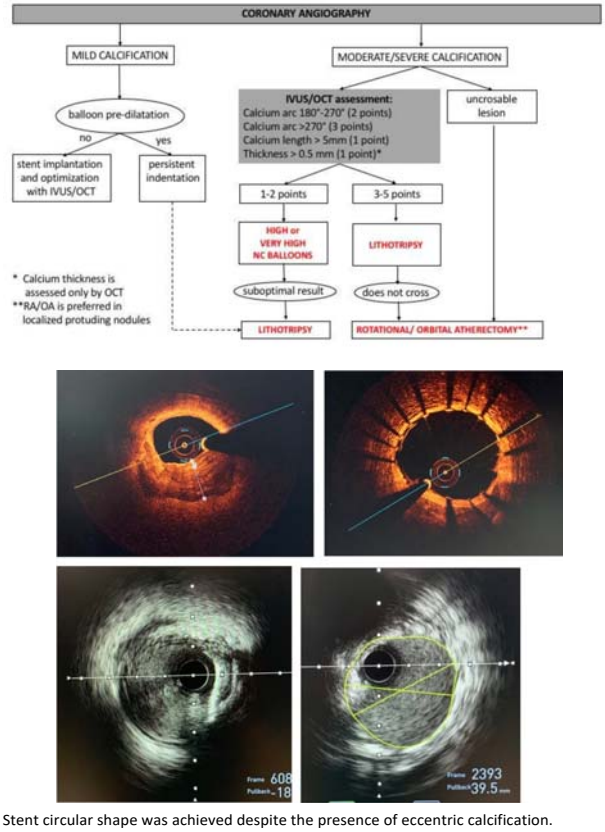
DAI Cardiotoracovascolare, AOUC Careggi, Cardiologia Interventistica Strutturale, Firenze

Background. Heavily calcified coronary lesions still represent a challenge for coronary angioplasty, with greater risk of immediate complications and late failure due to stent under-expansion and malapposition. The presence of coronary calcification is a predictor of worse clinical outcome, associated with higher mortality, major adverse cardiovascular events (MACE) and target vessel failure (TVF). The aim of this study was to evaluate efficacy and safety (peri-procedural complications and one-month clinical outcomes) of intravascular lithotripsy (IVL) in patients undergoing complex percutaneous coronary intervention (PCI) of calcific stenosis.

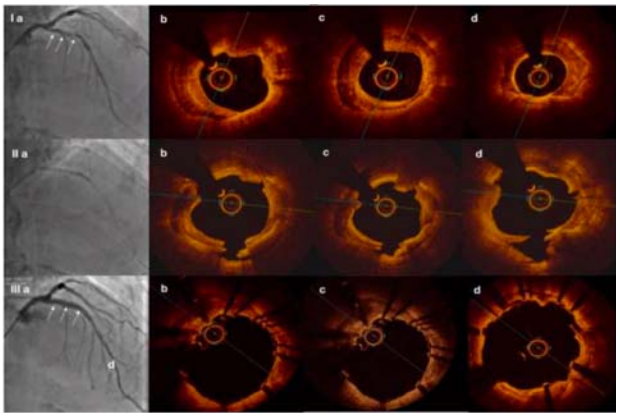
Methods. For each patient lesion calcification was evaluated in our Cath lab both by angiography and intravascular imaging, IVUS or OCT according to the operator discretion. The approach followed in our practice to calcific lesions is reported in the flow-chart of Figure 1. Mild calcifications underwent IVL only if a suboptimal expansion of a non compliant balloon sized 1:1 to the vessel size was observed. In case of moderate/severe calcification a score was developed based on intravascular imaging in order to discriminate between lesions in need of direct treatment with IVL and lesions requiring lesion preparation with NC balloons (Figure 1). In case of uncrossable lesions requiring rotablator IVL was performed if balloon expansion was still suboptimal despite rotational atherectomy. In order to perform the analysis of optimal stent deployment, according to the presence of concentric or eccentric calcification, our population was also divided into 2 subgroups depending on the calcium arc measured with intravascular imaging techniques, using a cut-off of

180 degrees. For each lesion the following angiographic parameters were evaluated: lesion length, percentage of area stenosis, lesion tortuosity, presence of calcification as "single" or "double "track in the worst angiographic view. In our series for each patient we collected procedural aspects such as pre-dilatation whether performed, IVL balloons and stent size, number of pulses delivered by the device, number of atm of inflation, post-dilatation (if performed). For all lesions OCT or IVUS assessment was performed at baseline and repeated post stent deployment in order to evaluate stent performance. The following optimal deployment indexes were assessed with OCT and IVUS: minimal stent area (MSA) and residual area stenosis (RAS) in order to evaluate stent expansion and incomplete strut apposition (ISA) to detect malapposition. Further parameters evaluated included eccentricity index, symmetry index, strut fracture, and edge dissection. The degree of circumferential extent of calcification was quantified by measuring the maximal calcification arc for each lesion. Pre and post-procedural blood tests and peri-procedural complications (coronary dissection and perforation, pericardial effusion, slow or no flow, stent failure, stent thrombosis, peri- procedural MI, post procedural ST-elevation, access site complications, in hospital cardiac death) were collected.

Results. Twenty-nine patients with 31 moderate-severe calcified stenosis were treated with IVL between November 2017 and May 2019, in Structural Interventional Cardiology Division of the Careggi University Hospital of Florence. All the procedures were guided with intravascular imaging. Intravascular ultrasound (IVUS) was performed in 10 lesions, whereas optical coherence tomography (OCT) was used in 21. After optimization a satisfactory lumen enlargement (acute gain 1.28 0.46 mm) was observed with good stent expansion (residual area stenosis >20% in 2 lesions, 6.5%). Peri-procedural complications were limited to 1 dissection at the distal edge requiring an additional stenting and 3 peri-procedural myocardial infarctions. There were no in-hospital coronary perforations, no pericardial effusions, no stent failure or thrombosis, no deaths. Clinical outcome was evaluated at 30-days with one sudden death on day 10 likely due to cerebral hemorrhage and no rehospitalization for cardiac events in the other 28 patients occurred (no stent thrombosis, no target vessel revascularization or target lesion revascularization, no myocardial infarction). Our population was also divided into 2 subgroups depending on the calcium arch measured with intravascular imaging techniques: 20 lesions showed a calcium arch >180° (250° on average) and 11 lesions <180° (140° on average). The following stent performance indexes were assessed with OCT and IVUS: minimal lumen area (MLA), residual area stenosis (RAS), incomplete strut apposition (ISA), eccentricity index, symmetry index, strut fracture, and edge dissection. The presence of concentric calcific stenosis was not associated with a higher level of incomplete strut apposition and there were no significant differences in the eccentricity and symmetry index.



Stent circular shape was achieved despite the presence of eccentric calcification.



Line I: OCT baseline lesion assessment; b-c: concentric calcified plaque (calcium arc >270°, calcium thickness 0.90 mm); d: MLA 2.81 mm². Line II: OCT assessment after intravascular lithotripsy. b-c-d: deep calcium fracture with lumen enlargement MLA 6.3 mm². Line III: OCT assessment after stent implantation; b-c-d: excellent symmetric stent expansion with no stent malapposition. MLA 12.5 mm².

Conclusions. Heavily calcified coronary lesions will be a growing issue, due to ageing population, increased rates of diabetes mellitus and chronic renal disease. An approach characterized by multimodality imaging techniques and use of dedicated devices is the keystone to improve patients outcome. Despite the small sample size and short follow-up that could represent a limitation of this study, we can confirm the safety and efficacy of IVL to achieve optimal acute results with PCI of complex calcific coronary stenosis.

C6

INTRAVASCULAR LITHOTRIPSY FOR THE TREATMENT OF SEVERELY CALCIFIED CORONARY LESIONS IN HIGH-RISK PATIENTS

Sara Giannone, Fabio Mangiacapra, Elisabetta Ricottini, Marco Miglionico, Paolo Gallo, Rosetta Melfi, Annunziata Nusca, Antonia Ascrizzi, Gian Paolo Ussia
Policlinico Universitario Campus Biomedico di Roma

Background. Severely calcified coronary lesions represent a challenge for successful percutaneous coronary intervention (PCI), especially in patients with either clinical or angiographic high-risk features. Current therapies used to facilitate PCI of calcified lesions include high-pressure balloons, cutting/scoring balloons and atherectomy, all of which imply highly traumatic manipulation of coronary arteries. Recently, a novel tool for modification of heavily calcified coronary plaques based on intravascular lithotripsy (IVL) has been introduced. This technology is based on the use of a balloon catheter that uses pulsatile mechanical energy to disrupt calcified lesions. We present our early experience with IVL-assisted PCI in high-risk patients with severely calcified coronary lesions.

Methods. This prospective, observational, single-center study enrolled patients with severely calcified coronary lesions undergoing PCI and treated with IVL between January 2019 and May 2019. All patients presented at least one of the following high-risk features: left ventricle ejection fraction (LVEF) <40%, chronic kidney disease (CKD), severe valvular disease, multivessel PCI, aorto-ostial lesion, left main stem lesion. In-hospital and 30-day clinical outcomes were monitored.

Results. We enrolled a total of 15 patients (53.3% male; age, 76 ± 6.7 years). Indication for PCI was acute coronary syndrome in one patient (6.7%). Two patients (13.3%) underwent transcatheter aortic valve implantation during the same procedure. Left main stem was treated in 4 patients (26.7%). Eight patients (53.3%) underwent multivessel IVL-assisted PCI. IVL use was planned upfront in 3 patients (20%), whereas it was used as a bailout strategy in the remaining cases (n=12, 80%). Angiographic success (residual stenosis >30%) was obtained in all cases. No procedural complications were recorded, although in 10 cases (66.7%) premature ventricular contractions were observed during IVL without clinical consequences. No adverse events were recorded in-hospital and at 30-day follow-up.

Conclusions. Our early experience suggests that IVL-assisted PCI is effective and safe in treating high- risk patients with severely calcified coronary lesions. This technology is feasible in most clinical and procedural scenarios, allowing efficient plaque modification without increasing procedural time and complexity.

C7

UTILIZZO DEGLI SCAFFOLD BIORIASSORBIBILI A RILASCIO DI EVEROLIMUS PER IL TRATTAMENTO DELA VASCULOPATIA DELL'ALLOGRAFT CARDIACO (CART)

Michele Pighi[1], Fabrizio Tomai[2], Giuseppe Tarantini[3], Leonardo Spedicato[4], Bruno Loi[5], Alessandro Petrolini[2], Marco Ferlini[6], Natalia Tovar Forero[7], Joost Daemen[7], Flavio Ribichini[1]
[1]Azienda Ospedaliera Universitaria Integrata di Verona, Verona, [2]European Hospital, Roma, [3]Università di Padova, Padova, [4]Università di Udine, Udine, [5]A.O. "Brotzu", Cagliari, [6]Università di Pavia, Pavia, [7]Thoraxcenter, Rotterdam, Netherlands

Background. Cardiac allograft vasculopathy (CAV) is a form of accelerated atherosclerosis, which represents the leading cause of late morbidity and mortality after heart transplantation. The bioresorbable vascular scaffolds (BVS) could represent a potential novel therapeutic tool for the treatment of coronary stenosis in the setting of CAV.

Methods. In this multicentre, single-arm, prospective, open-label study we enrolled 35 heart transplant recipients affected by CAV and presenting with significant (diameter stenosis >50%) coronary stenosis. A total of 44 coronary lesions were treated by using 51 bioresorbable scaffolds (second-generation everolimus-eluting BRS). The primary endpoint was in-segment restenosis rate at 1-year post-procedure as assessed by quantitative coronary analysis. Secondary endpoint was the composite of cardiac death, myocardial infarction and target lesion revascularization.

Results. The primary endpoint was observed in 13,5% of the lesions (5/37). At 1 year of follow-up the composite endpoint of cardiac death, myocardial infarction and target lesion revascularization was detected in 5 (14,2%) patients. One case of late scaffold thrombosis was observed resulted in the only cardiac death (2,9%) of a total of three deaths (8,6%).

Conclusions. CAV treatment with BRS is a valid therapeutic option with results comparable with previous reported experience with drug eluting stent

C8

SPONTANEOUS CORONARY ARTERY DISSECTION: ACUTE MANAGEMENT AND MEDICAL THERAPY AT DISCHARGE. THE DISCO (DISSEZIONI SPONTANEE CORONARICHE) ITALIAN REGISTRY

Giorgio Quadri[1], Enrico Cerrato[1], Italo Porto[2], Chiara Cavallino[3], Luca Bettari[4], Francesco Tomassini[5], Alfonso Franzè[6], Federico Giacobbe[8], Massimiliano Scappaticci[7], Fabio Ferrari[8], Mario Iannacone[9], Marco Pavani[10], Francesco Rametta[11], Alessandra Truffa Giachet[12], Luca Lo Savio[13], Gianluca Campo[14], Andrea Demarchi[3], Cristina Rolfo[15], Fabio Mariani[16], Dario Buccheri[17], Elisabetta Bordoni[18], Andrea Rognoni[19], Vincenzo Infantino[20], Andrea Gagnor[21], Alfonso Gambino[22], Fabrizio D'Ascenzo[23], Francesco Cassano[24], Ferdinando Varbella[25]
[1]Ospedale degli Infermi di Rivoli, Rivoli, [2]University of Genova, Cardiovascular Unit, Department of Internal Medicine and Specialties (DIMI) & IRCCS Ospedale Policlinico San Martino, Genova, [3]Ospedale Sant'Andrea, Vercelli, [4]Fondazione Poliambulanza, Brescia, [5]Rivoli and San Luigi Gonzaga University Hospital, [6]Infermi Hospital, Rivoli, [7]Policlinico Umberto I, Rome, [8]San Luigi Gonzaga University Hospital, Orbassano, [9]Savigliano Hospital, Savigliano, [10]Mauriziano Hospital, Turin, [11]S. Andrea Hospital, Vercelli, [12]Ospedale Civile Cardinal Massaia, Asti, [13]Ospedale degli Infermi, Rivoli, [14]Cardiovascular Institute, Ferrara University, Ferrara, [15]Interventional Cardiology Unit, San Luigi Gonzaga University Hospital, Orbassano and Infermi Hospital, Rivoli, [16]Interventional Cardiology Unit, San Luigi Gonzaga University Hospital, Orbassano and Infermi Hospital, Rivoli, Orbassano, [17]Ospedale Sant'Antonio Abate, Trapani,, [18]Ospedale Santa Maria della Misericordia, Perugia, [19]AOU Maggiore della Carità, Novara, [20]Ospedale Civile, Ciriè-Ivrea, [21]Ospedale Maria Vittoria, Torino, [22]Ospedale S. Croce, Moncalieri, [23]Città della Salute e della Scienza, Torino, [24]Ospedale SS. Annunziata, Taranto, [25]Infermi Hospital, Rivoli

Background. Spontaneous coronary artery dissection (SCAD) is a challenging clinical scenario and represents an increasingly studied cause of acute coronary syndrome (ACS). In-hospital management (conservative versus interventional strategy) and antiplatelet therapy at discharge are to date a matter of debate since no randomized control trial is available.

Methods. DISCO-IT (DIssezioni Spontanee COronariche) is an Italian multicenter registry enrolling patients admitted with a diagnosis of SCAD. Baseline, procedural characteristics, in-hospital management and outcomes of SCAD patients were collected. Major adverse cardiovascular events (MACE) were defined as the composite of all cause death, non-fatal myocardial infarction and any PCI performed.

Results. SCAD patients included in the DISCO-IT register were mainly female (77.3%) with a mean age of 54.5 ± 11.7 years and 30.1% of patients reported a trigger factor related to the acute event. STEMI (ST-segment elevation myocardial infarction) was the main admission diagnosis (49.1%), followed by NSTE (non-ST-segment elevation)-ACS (acute coronary syndrome (45.8%) and stable coronary artery disease (5.1%). Type 2b SCAD (23.9%) was the main finding at coronary angiography and LAD was the predominant artery affected (56%). More than half of patients were initially treated with medical therapy (55.6%), while PCI (percutaneous coronary intervention) or CABG (coronary artery bypass graft) were performed in 40.7% and 3.7% of them, respectively. PCI procedural success was reached in 78.6% of cases. Dual antiplatelet therapy (DAT) was prescribed in 58.3% of patients medically-treated only. In these patients ticagrelor and clopidogrel were the P2Y12 inhibitors of choice. In-hospital MACE rate was 9.2%. In particular all cause death, non-fatal myocardial infarction, and any PCI performed occurred in 1.4%, 7.4% and 10.2% of patients, respectively. At a mean follow-up of 20 ± 27 months MACE rate was 14.3%. Considering only medically treated population, a single antiplatelet therapy (SAT) resulted to be a protective factor compared to DAT in terms of MACE (5.6% vs 23.4%; log-rank p = 0.01). In those patients managed conservatively and discharged with DAT, ticagrelor was associated with a higher MACE rate than clopidogrel (33.3% vs. 10.7%; log-rank p = 0.024). However, there was no difference in MACE occurrence between new and old P2Y12 inhibitors in patients discharged with DAT after PCI and stenting (12.5% vs 11.1% log-rank p = 0.975). Notably, all bleeding events (4 BARC within 2 and 1 BARC 3b) occurred in patients on DAT.

Conclusions. SCAD affects predominantly young and middle age women and medical therapy represents the initial treatment of choice in the majority of patients. A non-negligible rate of MACE is associated with this disease with most of the events occurring during hospitalization. In conservatively treated patients SAT rather than DAT seems to be a protective factor against adverse events at follow-up. Conversely, in case of PCI + stenting in SCAD patients, a more aggressive treatment with new P2Y12 inhibitors can be chosen as there is no difference with clopidogrel in long-term prognostic impact.

Structural interventions 1

C9

LONG-TERM CLINICAL AND ECHOCARDIOGRAPHIC RESULTS AFTER PFO CLOSURE WITH OCCLUTECH FIGULLA FLEX II DEVICE: A SINGLE CENTER PROSPECTIVE REGISTRY

Daniela Trabattoni, Giulia Santagostino Baldi, Giovanni Teruzzi, Franco Fabbiocchi, Giuseppe Calligaris, Piero Montorsi, Stefano Galli, Paolo Ravagnani, Manuela Muratori, Antonio Bartorelli
Centro Cardiologico Monzino, Milano

Background. Patent foramen ovale closure has been demonstrated to be superior to medical therapy and recommended for the secondary prevention of stroke by current guidelines. However, long-term clinical and echo data are not commonly available.

Methods. Between January 2012 and December 2018, 688 consecutive patients undergoing PFO closure with Occlutech Figulla Flex II device (Occlutech GmbH, Jena, Germany) in a single high-volume center, were enrolled in a prospective, observational registry. Contrast transthoracic echo (TTE) or TEE and transcranial Doppler were performed 6 months after closure and then TEE yearly. Primary end-point was residual shunt and secondary endpoints were: any death, stroke or TIA and arrhythmias after the procedure.

Results. Of the 688 PFO closure, a total of 546 (mean age 46.2 ± 12.6 years; 58.8% female) were performed as secondary prevention of stroke, TIA or arterial paradoxical embolism. Atrial septal aneurysm and a large shunt were present in 170 (24.7%) and in 468 (68%) patients, respectively. The procedure was performed under local anesthesia with intracardiac echo guidance (UltraICE plus, Boston Scientific Corp, MA, USA). Mean procedural time was 16 ± 8 min with an X-ray time of 3.4 ± 2.4 min (mean DAP 520 ± 538 Gy/cm^2). Procedural success was 98.8%. Patients were discharged on single, dual antiplatelet therapy or anticoagulation in 87.2%, 11.6% and 1.2% of cases, respectively. In-hospital vascular complications occurred in 2 (0.3%) patients and supraventricular arrhythmias/ paroxysmal atrial fibrillation were detected in 50 (7%) pts between 24 hours and 30 days. Residual shunting was observed in 80 (11.3%) pts after procedure and in 54 (7.8%: trivial in 5% and mild in 2.7%) at 6 months. Clinical and echocardiographic follow-up is currently available in 605 (88%) pts up to 7.5 years (mean 3.5 ± 2.0 years). A total of 3 (0.4%) non-cardiac deaths and 3 (0.4%) TIAs due to severe carotid disease (n=2) or atrial fibrillation (n=1) occurred during follow-up.

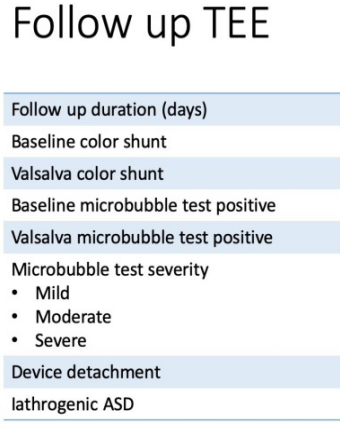
Conclusions. In our long-term, single center registry, PFO closure with the Figulla device was achieved safely and effectively, with high acute procedural success and very low incidence of residual shunts.

C10

CHIUSURA PERCUTANEA SUTURA-MEDIATA DI PFO CON NOBESTITCH: EFFICACIA AL FOLLOW-UP ECOCARDIOGRAFICO TRANSESOFAGEO A 3 MESI

Marco B. Ancona[1], Francesco Moroni[1], Alessandro Beneduce[1], Giulio Falasconi[2], Abdallah Abba Aji[1], Barbara Bellini[1], Luca Ferri[1], Cristina Capogrosso[2], Stefano Stella[2], Francesco Ancona[2], Alaide Chieffo[1], Eustachio Agricola[2], Matteo Montorfano[1]
[1]Emodinamica e Cardiologia Interventistica, [2]Ecocardiografia, San Raffaele, Milano

Premessa. La chiusura percutanea sutura-mediata della pervietà del forame ovale (PFO) con il dispositivo NobleStitch (HeartStitch, Fountain Valley, CA, USA) è stata già dimostrata sicura ed efficace. Ciononostante, la pervietà del forame ovale al follow up dopo questa procedura è stata valutata solo con test alle microbolle con ecocardiogramma transtoracico (TT): tale esame presenta una sensibilità non ottimale nel determinare la presenza di shunt residuo destro-sinistro. Lo scopo del presente studio è quello di valutare la pervietà del forame ovale tre mesi dopo la procedura con Noblestith con ecocardiogramma transesofageo (TE).
Materiali e metodi. Sessanta pazienti sono stati sottoposti a chiusura di PFO con NobleStitch all'Ospedale San Raffaele di Milano da Dicembre 2017 a Maggio 2018. Tutti i pazienti hanno effettuato una valutazione preprocedurale dell'anatomia del PFO e dell'entità dello shunt basale destro-sinistro con ecocardiogramma TE e test alle microbolle dopo manovra di Valsalva. Di questi 60 pazienti, 28 hanno già effettuato l'ecocardiogramma TE a 3 mesi e sono stati inclusi nella presente analisi. La presenza ed entità dell'eventuale shunt residuo è estata valutata con ecocardiogramma TE e test alle microbolle dopo manovra di Valsalva.
Risultati. Quindici dei 28 pazienti era di sesso maschile. Lo shunt basale destro-sinistro era lieve nel 28% dei pazienti, moderato nel 54% e severo nel 18%. Il dispositivo NobleStitch è stato efficacemente impiantato nel 100% dei pazienti. Vi è stata un'unica complicanza peri-procedurale, relativa ad una fistola artero-venosa femorale al sito di puntura percutanea. Il follow-up medio con ecocardiogramma TE è stato di 101 giorni. Non si sono verificate recidive di eventi ischemici cerebrali. Non sono stati documentati distacchi del dispositivo mentre è stato documentato un piccolo difetto interatriale iatrogeno. Lo shunt dx-sx è stato documentato come assente nell'82% dei pazienti, lieve nel 7% e moderato nell'11%. Non sono stati documentati shunt severi dx-sx al follow-up.
Conclusioni. Sebbene si tratti di uno registro monocentrico su un piccolo campione di pazienti, il presente è il primo studio a valutare l'efficacia al follow-up della chiusura di PFO con Nobelstitch tramite ecocardiogramma TE. Uno shunt dx-sx minore o uguale a lieve è stato documentato nel 89% dei pazienti. L'efficacia della chiusura di PFO con NobleStitch valutata con ecocardiogramma TE appare sovrapponibile a quanto già riportato in letteratura e valutato con ecocardiogramma TT.



C11

BALLOON AORTIC VALVULOPLASTY: A PILOT EXPERIENCE OF SAME-DAY DISCHARGE WITH A TRANSRADIAL APPROACH

Marco Balducelli, Matteo Aquilina, Giuseppe Vecchi, Elisabetta Varani, Luca Fileti, Carolina Moretti, Andrea Rubboli
Dipartimento Cardiovascolare, Ospedale S. Maria delle Croci, Ravenna

Background. Severe aortic stenosis (AS) represents a common and significant clinical problem in elderly patients, leading to frequent hospitalizations mostly for heart failure symptoms. Many patients cannot be treated in a timely manner with transfemoral prosthetic valve implantation (TAVI) and require a palliative procedure to gain time or are not eligible to TAVI due to an excessive burden of comorbidities. Some other patients need to be treated with balloon aortic valvuloplasty (BAV) in order to undergo non cardiac surgery and others are simply too frail or choose a less invasive although palliative procedure instead of TAVI. Many of these patients can be treated with an elective BAV with a short hospital stay. Recently an innovative vascular access (transradial BAV, TRBAV) has been adopted and proved feasible and safe.
Methods. At the Cardiology Department in Ravenna, Italy, we started to perform TRBAV in January 2018. On April 30, 2018 we started to admit elective patients to be discharged the same day. Inclusion criteria were good radial pulses, ability to stand up and be rapidly mobilized, a Clinical Frailty Score <4. Exclusion criteria were mental impairment, familial or social environmental inadequacy, severe renal failure (creatinine clearance (CCl) <15 ml/min), unless zero contrast procedure was deemed feasible, hemodynamic instability during or after the procedure, any complications. Patients were planned to be discharged after radial compression device (TR Band™) was removed and effective haemostasis (usually after 6 hours since procedure completion) was ascertained. All patients gave written inform consent as part of an Italian multicentre registry of TRBAV (Softly). Clinical and procedural data were prospectively collected and a clinical follow up at 30 days and 1 year scheduled.
Results. From April 30, 2018 until June, 26, 2019, we performed 52 TRBAV (68% of total BAV procedures), 13 scheduled as same day discharge. 12 out of 13 patients were effectively discharged the same day. Mean age was 89±3 years, 8 patients were males, 69% had significant comorbidities (mostly cancer). Mean NYHA class, CCl, and haemoglobin were 3±1, 38±11 ml/min, and 12.6±1.6 g/dl, respectively. 46% of patients had AF and were on warfarin or DOAC, 31% had mitral regurgitation grade >2, mean EF was 55±11% and 31% had a low flow, low gradient severe AS. 1 patient had PCI pre BAV and two had simultaneous BAV and PCI procedure. Eleven out of 13 patients had a bilateral radial access. All patients had rapid pacing during VPA via transaortic stiff guidewire. Mean invasive aortic gradients before and after VPA were 40±17 and 25±11 mmHg, respectively. In hospital and 30 days mortality was 0%. At one month follow up a patient developed a right radial pseudoaneurysm treated surgically. There was only one radial loss.
Conclusions. Same day discharge TRBAV is feasible, effective and safe.

C12

FORAME OVALE PERVIO, DALLA CHIUSURA MEDIANTE "DISPOSITIVO" OCCLUSIVO ALLA TECNICA "NOBLESTITCH". ESPERIENZA DI UN CENTRO

Gianluca Tomassoni, Gianluigi Marrone, Manuela Benvenuto, Benedetta Ruggeri, Licia Petrella, Alberto Lavorgna, Donatello Fabiani, Franco De Remigis, Cosimo Napoletano
Dipartimento Cardiovascolare, Ospedale Mazzini, Teramo

Premessa. La prevalenza del PFO nella popolazione generale è del 20-25% nella popolazione adulta. Circa il 40-50% dei pazienti affetti da ictus criptogenetico, ha un PFO che rappresenta la concausa dell'evento attraverso il meccanismo di embolizzazione paradossa. Dopo i risultati del trial RESPECT che aveva mostrato riduzione di eventi ischemici cerebrali in pazienti sottoposti a chiusura percutanea rispetto a quelli trattati con terapia medica, è stata approvata la chiusura del PFO mediante device. Tali dati sono stati confermati da due successivi trials Gore REDUCE e CLOSE. Recentemente è stato introdotta una nuova tecnica di sutura, che non utilizza dispositivi metallici ma che consente una sutura diretta del PFO senza l'impianto di alcuna protesi. I potenziali vantaggi di tale sistema sono relativi all'assenza di metallo e di protesi di grandi dimensioni (con i possibili rischi connessi quali sviluppo di FA, impossibilità di eseguire future procedure transettali, rischio di dislocazione e/o di trombosi del device).
Materiali e metodi. Nel nostro centro dal 2000 ad oggi sono state eseguite 476 procedure di chiusura di PFO di cui 48 secondo tecnica Nobles Stitch (NobleStitch EL, Heartstich; USA) e 399 con impianto di device Amplatzer (Amplatzer PFO Occluder, Abbott). Tutti i pazienti trattati presentavano storia di ictus criptogenetico, una positività al doppler transcranico con microbolle e uno shunt dx-sin attraverso il forame ovale, rilevato all'ecocardiogramma transtoracico con microbolle. Dal settembre 2016 ad oggi tutti i pazienti con indicazione alla chiusura del PFO sono stati successivamente sottoposti a ETE per valutare le caratteristiche anatomiche del PFO (lunghezza ed ampiezza), presenza di shunt a riposo, setti cribiformi, aneurisma del setto e lipomatosi del setto. Sulla base dell'esame ETE sono stati sempre esclusi pazienti con shunt a riposo e con setti multifenestrati.
Conclusioni. L'analisi ecocardiografica pre-procedurale rappresenta indubbiamente il momento fondamentale per la scelta del device da utilizzare. I punti di forza dell'uso di NobleStitch EL nel trattamento del PFO sono l'assenza di dispositivi impiantati, nessuna indicazione per la terapia antipiastrinica o altra terapia medica, la mancanza di rischio di trombosi o dislocazione del dispositivo e l'assenza di controindicazioni per future procedure transettali. Ciò che è ancora più importante è la maggiore semplicità logistica della procedura; in particolare l'assenza di assistenza alla rianimazione, correlata all'intubazione oro-tracheale e alla ventilazione meccanica e all'ecocardiografia transesofagea. Ad oggi, con questa nuova tecnica mini-invasiva non si sono verificati eventi avversi periprocedurali, confermandosi come una metodica semplice, efficace e sicura.

Coronary interventions 2

C13

INCIDENZA ED IMPATTO DELLE COMPLICANZE CORRELATE ALL'UTILIZZO DI IMPELLA: UN SOSTTOSTUDIO DEL REGISTRO IMP-IT

Marco B. Ancona[1], Alaide Chieffo[1], Francesco Burzotta[2], Vittorio Pazzanese[3], Carlo Briguori[4], Carlo Trani[2], Tommaso Piva[5], Federico De Marco[6], Maurizio Di Biasi[7], Paolo Pagnotta[8], Gavino Casu[9], Gennaro Giustino[10], Matteo Montorfano[1], Federico Pappalardo[3], Giuseppe Tarantini[11]

[1]Emodinamica e Cardiologia Interventistica, San Raffaele, Milano, [2]Fondazione Policlinico Universitario A. Gemelli, Roma, [3]Programma di Assistenza Ventricolare, San Raffaele, Milano, [4]Mediterranea Cardiocentro, Napoli, [5]Ospedali Riuniti di Ancona, Ancona, [6]IRCCS Policlinico San Donato, San Donato Milanese, [7]Ospedale Luigi Sacco, Milano, [8]Humanitas Research Hospital, Rozzano, [9]Ospedale San Francesco, Nuoro, [10]The Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, USA, [11]Università di Padova, Padova

Premessa. Il supporto meccanico del circolo con Impella è in grande aumento sia per il trattamento dello shock cardiogeno (CS) che nelle procedure di angioplastica coronarica ad alto rischio (HR-PCI). Scopo del presente studio è valutare l'incidenza delle complicanze correlate al dispositivo (device-related complications – DRC) e valutare l'impatto delle medesime sulla mortalità ad un anno.

Materiali e metodi. Lo studio IMP-IT è un registro nazionale multicentrico che ha arruolato tutti i pazienti trattati con Impella 2.5, Impella CP, Impella 5.0 and Impella RP, sia per CS che per HR-PCI, in 17 centri italiani dal 2004 al giugno 2018. Le DRC sono state definite come un endpoint composito di: sanguinamento correlato all'accesso vascolare, emolisi, ischemia dell'arto, necessità di rivascolarizzazione endovascolare dell'arto, danno dell'aorta, perforazione del ventricolo sx.

Risultati. Sono stati inclusi nello studio un totale di 406 pazienti: 229 per CS (56.4%) e 177 per HR-PCI (43.6%). L'incidenza complessiva di DRC è risultata 37.1% nel gruppo CS e 10.7% nel gruppo HR-PCI. Il sanguinamento correlato all'accesso vascolare è occorso nel 10.9% dei CS e nel 7.9% delle HR-PCI, l'emolisi è occorsa nel 20.5% dei CS e nello 0.5% delle HR-PCI; l'ischemia dell'arto è avvenuta nel 12.6% dei CS e nel 2.8% delle HR-PCI; la rivascolarizzazione endovascolare dell'arto si è resa necessaria nel 6.9% dei CS e nel 2.8% delle HR-PCI. Sono stati documentati un caso di danno dell'aorta ed un caso di perforazione del ventricolo sx nel gruppo CS. I più forti predittori indipendenti di DRC sono risultati essere lo shock cardiogeno alla presentazione (OR 4.96, p < 0.0001) e la malattia vascolare periferica (OR 2.22, p = 0.045). La mortalità ad un anno nella corte di pazienti con CS risulta essere il 61.3% nei pazienti che hanno presentato DRC contro il 54.3% dei pazienti che non hanno presentato questa complicanza. Se all'analisi univariata sembra esserci una correlazione tra DRC e mortalità ad un anno (HR 1.60, 95% CI: 1.14-2.26), tale associazione non è stata confermata in un modello multivariato HR 0.87, 95% CI: 0.57-1.32).

Conclusioni. Nel registro nazionale multicentrico IMP-IT, l'incidenza di complicanze correlate al dispositivo (DRC) appare elevata nella popolazione di pazienti trattata per shock cardiogeno, in gran parte dovuta ad incidenza non trascurabile di emolisi; al contrario l'incidenza di DRC nella popolazione di HR-PCI appare relativamente bassa. Il predittore principale di DRC risulta lo shock cardiogeno alla presentazione. Tali complicanze non sembrano tuttavia impattare in maniera indipendente sulla sopravvivenza ad un anno.

C14

IMPACT OF UNTREATED CORONARY ARTERY DISEASE AFTER PRIMARY PERCUTANEOUS CORONARY INTERVENTION ON TWO-YEAR CLINICAL OUTCOME: THE RESIDUAL ADDED INDEX

Mafalda Esposito, Luigi Di Serafino, Fabio Magliulo, Plinio Cirillo, Eugenio Stabile, Bruno Trimarco, Giovanni Esposito

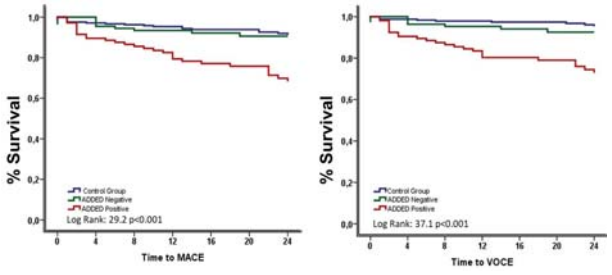
Cardiologia, AOU Federico II, Napoli

Premessa. La rivascolarizzazione incompleta dopo PCI è una prassi comune, in particolare nei pazienti che presentano sindromi coronariche acute ed è associata ad una prognosi peggiore rispetto alla rivascolarizzazione completa. Nei pazienti con sindrome coronarica acuta STEMI e malattia multivasale, una rivascolarizzazione completa basata sull'FFR riduce significativamente il rischio di eventi futuri. L'Added Index, vale a dire il rapporto tra il diametro minimo del lume (MLD) ed il Duke Jeopardy Score (DJS), ha mostrato un'accuratezza elevata nel predire i valori di FFR e potrebbe essere utilizzato per rilevare una stenosi coronarica funzionalmente significativa con un valore soglia di 2,23. Lo scopo del presente studio è di esaminare il valore prognostico del Residual Added Index dopo PCI primaria (pPCI) in pazienti con sindrome coronarica acuta STEMI.

Materiali e metodi. Abbiamo incluso 605 pazienti con STEMI sottoposti a pPCI efficace. Sono stati esclusi i pazienti con pregresso intervento di bypass coronarico (CABG) o che presentavano shock cardiogeno. I pazienti sono stati divisi in 3 gruppi: 1) Pazienti senza stenosi residua di un'arteria coronaria (n = 321, gruppo di controllo); 2) Pazienti con almeno una stenosi residua dell'arteria coronaria con indice ADDED inferiore a 2,23 (n = 145, gruppo ADDED negativo); 3) Pazienti con almeno una stenosi residua dell'arteria coronaria con indice ADDED uguale o superiore a 2,23 (n = 139, gruppo ADDED positivo). Gli endpoint primari sono stati: 1) evento cardiaco avverso maggiore (MACE), definito come morte per tutte le cause, infarto del miocardio, necessità di successive rivascolarizzazioni; 2) evento cardiaco avverso non associato al target vessel (VOCE), definito come morte per tutte le cause, infarto del miocardio non correlato al target vessel, necessità di rivascolarizzazione urgente o meno, non correlata al target vessel.

Risultati. I pazienti inclusi nel gruppo ADDED positivo erano più anziani con una maggiore prevalenza di diabete mellito, ipertensione ed arteriopatia obliterante periferica rispetto al gruppo controllo ed al gruppo ADDED negativo. Inoltre, la pPCI dell'arteria coronaria sinistra è stata eseguita più spesso sia nel gruppo di controllo che nel gruppo ADDED negativo rispetto al gruppo ADDED positivo in cui ha prevalso la pPCI dell'arteria coronaria destra. Il follow-up è stato ottenuto nell'80% dei pazienti con una mediana di 24 mesi (14-36 mesi). All'analisi multivariata, il tasso di MACE era significativamente più elevato nel gruppo ADDED positivo rispetto al gruppo ADDED negativo e controllo (rispettivamente 29 [27%] vs 9 [8%] vs 18 [7%], hazard ratio 2,43 [1,38-4,29], p = 0,002]) e il tasso di VOCE (rispettivamente 25 [23%] vs 7 [6%] vs 9 [4%], hazard ratio 4,87 [2,17-10,00], p <0,001]).

Conclusioni. Posticipare il trattamento di una stenosi dell'arteria coronaria con un indice ADDED ≥2,23 dopo PCI primaria è associato ad un rischio significativamente più elevato di eventi cardiovascolari.



C15

PICCOLETO II: DRUG-COATED BALLOONS VS DRUG-ELUTING STENTS FOR SMALL VESSEL DISEASE TREATMENT; RESULTS OF 6-MONTH CLINICAL AND ANGIOGRAPHIC FOLLOW-UP

Bernardo Cortese[1], Dario Pellegrini[2], Gaetano Di Palma[1], Marcos Garcia-Guimaraes[3], Davide Piraino[4], Pedro Silva Orrego[5], Gianluca Campo[6], Dario Buccheri[7], Andrea Erriquez[6], Fernando Rivero[8], Gianluca Zambelli[9], Romano Seregni[5], Fernando Alfonso[8]

[1]Clinica San Carlo, Milano, [2]Radboud UMC, Nijmegen, Netherlands, [3]The Heart Hospital Baylor Plano, Madrid, Spain, [4]Unità di Emodinamica, Università degli Studi di Palermo, Palermo, [5]Ospedale Fatebenefratelli Oftalmico, Milano, [6]Università degli Studi di Ferrara, Ferrara, [7]Ospedale San Giovanni di Dio, Agrigento, [8]Hospital Universitario de la Princesa, Madrid, Spain, [9]Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone, Palermo

Background. Small vessel coronary artery disease (SVD) represents one of the most attractive fields of application of drug-coated balloons (DCB). In the last years new generation DCB have been developed, with improved trackability, drug delivery and retention in the vessel wall. We sought to compare the performance of a new DCB (Elutax, AB Medica, Italy) with that of everolimus-eluting stent (EES, Xience, Abbott, USA) in patients with de novolesions in SVD.

Methods. PICCOLETO II was an academic, multicenter, open-label, prospective randomized clinical trial where patients with de novolesions in SVD (diameter <2.75 mm) and a clinical indication for intervention, were randomized to angioplasty with DCB versus implantation of EES. Primary study endpoint was late lumen loss (LLL) at 6 months analyzed by an independent central core-lab. Non- inferiority between the 2 study arms was hypothesized. Secondary endpoints were: minimal lumen diameter (MLD), % diameter stenosis, and binary restenosis rate at angiographic follow up, and the occurrence of major adverse cardiac events (MACE), a composite clinical endpoint of cardiac death, non-fatal myocardial infarction, target lesion revascularization, and its single components.

Results. Between January 2015 and May 2018, a total of 220 patients were enrolled at 4 centers from Italy and Spain. There were no significant differences regarding the major baseline clinical characteristics between the two groups. After 6 months, in-lesion LLL was lower in the DCB group (0.04 vs. 0.17 mm, p=0.03 for superiority). Percent diameter stenosis, MLD, and binary restenosis rate (25.1% vs. 21.6%, p=0.37; 1.85±0.49 vs 2.12±0.53, p=0.34; 6.3% vs. 6.5%, p=0.98, respectively).were not significantly different between DCB and EES At 6 months clinical follow-up, events were low with a rate of MACE similar in the 2 arms (5.5 vs. 4.5, p=0.7).

Conclusions. In this randomized clinical trial in patients with de novo lesions in SVD a new-generation DCB was found superior to EES in terms of angiographic performance.

C16

CLINICAL OUTCOMES OF PATIENTS WITH NON OBSTRUCTIVE CORONARY ARTERY DISEASE: A SINGLE CENTER EXPERIENCE

Barbara Bellini, Alaide Chieffo, Marco B. Ancona, Luca A. Ferri, Mauro Carlino, Matteo Montorfano
Cardiologia Interventistica, Ospedale San Raffaele, Milano

Background. Recent studies have shown that the prevalence of non obstructive coronary artery disease (NOCAD) in patients undergoing elective coronary angiography is higher than usually estimated. The incidence of major cardiac adverse events (MACE) related to this condition is not negligible.
Objectives. To evaluate clinical outcomes of patients with NOCAD in terms of angina symptoms or equivalents and occurrence of MACE and to characterize contemporary management (diagnostic and therapeutic) of these patients in our Center.
Methods. We enrolled consecutive patients with suspected chronic ischemic heart disease referred to our hospital for "clinically indicated" coronary angiography and with no evidence of obstructive coronary artery disease. The primary study objective was major cardiac events (MACE). The secondary endpoint was presence of angina symptoms or equivalents at follow-up.
Results. From January 2016 to September 2017 a total of 1441 patients underwent clinically indicated coronary angiography in our Center. A total of 1112 patients has been diagnosed at coronary angiograms to have obstructive CAD whereas 329 patients (22.8%) had NOCAD and were included in the present study. Of these, 61.3% of patients had "normal coronary arteries" (epicardial vessel stenosis <20%), while 38.6% of patients presented "mild disease" (stenosis of 20% -70% with fractional flow reserve >0.81). At a median follow-up of 374 days the rate of MACE was 14.8%, mainly driven by rehospitalizations for cardiac reasons (13%), whereas angina symptoms were observed in 19.7% of the patients. At multivariate analysis, independent predictors of MACE were age (HR 1.04 [1.01-1.07], p=0.005 and the presence of mild disease (HR 1.83 [1.01-3.32], p=0.044.
Conclusions. In this "real-world" single center study, NOCAD patients experienced a relatively high rate of angina and MACE at follow-up.

Structural interventions 2

C17

TRANSCATHETER AORTIC VALVE IMPLANTATION IN CARDIOGENIC SHOCK: TAVI- SHOCK REGISTRY RESULTS

Chiara Fraccaro[1], Rui Campante Teles[2], Didier Tchétché[3], Francesco Saia[4], Francesco Bedogni[5], Matteo Montorfano[6], Claudia Fiorina[7], Francesco Meucci[8], Mauro De Benedictis[9], Ornella Leonzi[10], Marco Barbierato[11], Nicolas Dumonteil[3], Miroslava Stolcova[8], Diego Maffeo[10], Miriam Compagnone[4], João Brito[2], Alaide Chieffo[6], Giuseppe Tarantini[12]
[1]Department of Cardiac, Thoracic and Vascular Sciences, Interventional Cardiology Unit, University of Padua, Padova, [2]Hospital de Santa Cruz, Lisboa, Portugal, [3]Clinique Pasteur, Toulouse, France, [4]Cardio-Thoraco-Vascular Department, University Hospital of Bologna, Bologna, [5]Department of Cardiology, IRCCS Policlinico S. Donato, [6]San Raffaele Scientific Institute, Milan, [7]Cardiothoracic Department Spedali Civili Brescia, Brescia, [8]Cardio-Toraco-Vascular Department, Careggi University Hospital, Florence, [9]Department of Cardiology, Mauriziano Hospital, Turin, [10]Department of Cardiology, Fondazione Poliambulanza, Brescia, [11]Emodinamica Aziendale AULSS 3 Serenissima, Dipartimento Cardio-Toraco-Vascolare, Mestre, [12]University of Padua, Padova

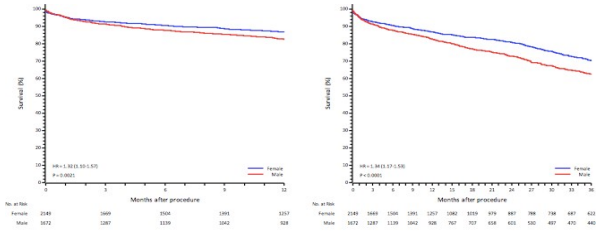
Background. In clinical practice, balloon aortic valvuloplasty (BAV) is the first line treatment for patients with severe aortic stenosis (AS) presenting with cardiogenic shock (CS), but the reported outcome is very poor. Moreover, emergent transcatheter aortic valve implantation (TAVI) could be adopted also for CS patients due to aortic bioprosthesis dysfunction. Notwithstanding, data on the safety and feasibility of TAVI in CS are scarce. Aim of this study is to evaluate safety, feasibility and mid-term outcome of TAVI in CS.
Methods. From March 2008 to February 2019, 51 patients with AS/degenerated aortic bioprosthesis and CS treated by urgent/emergent TAVI in 11 European centers were included into this retrospective multicenter registry. Demographic, clinical and procedural data were collected, as well as clinical and echocardiographic follow up.
Results. Mean age was 75.81±12.93, 49% were women, mean STS Score was 19.24±15.03%. Device success was achieved in 94.1%, with a 5% incidence of moderate/severe paravalvular leak. At 30-day mortality was 11.8%, stroke rate was 2.0%, vascular complications 5.9% and acute kidney injury 34%. VARC-2 early safety endpoint was reached in 35.3% of cases. At 1-year follow up, mortality rate was 25.7% and the recurrence of congestive heart failure was 8.6%.
Conclusions. TAVI seems to be a feasible, safe and effective therapeutic option for patients with severe aortic valvulopathy or degenerated aortic bioprosthesis and CS. Compared to high risk but stable patients there is a higher 30-day mortality, but lower than that reported for BAV alone in this setting. The long-term outcome is satisfactory and considerably better.

C18

LONG-TERM CLINICAL OUTCOMES IN WOMEN AFTER TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR): RESULTS FROM THE ITALIAN CLINICAL SERVICE PROJECT, A REAL-WORLD MULTICENTER PROSPECTIVE REGISTRY

Andrea Denegri[1], Michele Romano[2], Cristina Giannini[3], Anna S. Petronio[3], Luca Testa[4], Francesco Bedogni[4], Corrado Tamburino[5], Marco Barbanti[5], Claudia Fiorina[6], Marianna Adamo[6], Giuseppe Bruschi[7], Matteo Montorfano[8], Carlo Trani[9], Francesco Burzotta[9], Massimo Fineschi[10], Alessandro Iadanza[11], Andrea Cortellesi[12], Diego Maffeo[13], Arnaldo Poli[14], Michev Iassen[15], Elena De Angelis[16], Alessandro Decio[17], Elvis Brscic[17], Bernhard Reimers[18], Franco Fabbiocchi[19], Corrado Lettieri[2]
[1]Cardiology Division, Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Policlinico di Modena, Modena, [2]Division of Cardiology, Ospedale Carlo Poma, Mantova, [3]Cardiothoracic and Vascular Department, Azienda Ospedaliero-Universitaria Pisana, Pisa, [4]Department of Cardiology, Policlinico San Donato, Milano, [5]Division of Cardiology, Policlinico-Vittorio Emanuele Hospital, University of Catania, Catania, [6]Cardiothoracic Department, Spedali Civili Brescia, Brescia, [7]Department of Cardiology, ASST Grande Ospedale Metropolitano Niguarda, [8]Interventional Cardiology Division, Cardio- Thoracic-Vascular Department, San Raffaele Scientific Institute, Milano, [9]Department of Cardiovascular and Thoracic Sciences, Fondazione Policlinico Universitario A. Gemelli IRCCS, Roma, [10]Department of Internal, Cardiovascular and Geriatric Medicine, [11]Department of Internal, Cardiovascular and Geriatric Medicine, University Hospital of Siena, Siena, [12]Division of Cardiology, S. Camillo-Forlanini Hospital, Roma, [13]Cardiac Surgery, Poliambulanza Foundation, Brescia, [14]Interventional Cardiology Unit, ASST Ovest Milanese, Legnano Hospital, [15]Cardiovascular Department, IRCCS MultiMedica Hospital, Milano, [16]Interventional Cardiology, A.O.U. San Giovanni di Dio e Ruggi d'Aragona, Salerno, [17]UO Cardiologia, Maria Pia Hospital, Torino, [18]Department of Cardiology, Istituto Clinico Humanitas, [19]Cardiology Unit, Centro Cardiologico Monzino, Milano

Background. Transcatheter aortic valve replacement (TAVR) has been demonstrated to be a feasible safe alternative treatment to surgical aortic valve replacement (SAVR) for severe aortic stenosis (AS), however discrepant data have been reported in relation to gender. The study aimed to examine gender differences in long-term clinical outcomes in a real-world TAVR cohort.
Methods. All comer intermediate- to high-risk patients with severe AS treated with TAVR with a Medtronic valve (Corevalve, Evolut R and Evolut Pro) across 17 Italian sites were prospectively included in the Italian ClinicalService Project (clinicaltrials.gov NCT01007474) between July 2007 and May 2019. The primary endpoint was 1- and 3-years all cause of death.
Results. Out of 3821 patients, 2149 (56.2%) women were enrolled. Compared to men, women were older (83±6 vs 81±6, p<0.001), more likely to present severe renal impairment (GFR ≤30ml/min, 26.3% vs 16.3%, p<0.001) but less previous cardiovascular disease (p<0.001). Mean European System for Cardiac Operative Risk Evaluation (EuroSCORE) I was not significantly different between males and females (19.8 ± 15.5% vs 19.2 ± 13.3%, p=0.355), while mean Society of Thoracic Surgeons (STS) score was higher in women (7.8 ± 7.1% vs 7.2 ± 7.5, p<0.001). Women presented a more pronounced mean aortic gradient (52.4±15.3 vs 47.3±12.8, p<0.001), and a better left ventricular ejection fraction (54.3± 11.2 vs 49.7± 12.7, p<0.001). TAVR was performed more frequently via transfemoral access in women (87.2% vs 82.1%, p<0.001).



Major vascular complications and life-threating bleeding happened more frequently in women (3.9% vs 2.4%, p=0.012 and 2.5% vs 1.4%, p=0.024, respectively). The primary endpoint occurred in 248 patients (11.5% female vs 15.0% male, p=0.002) at 1 year and in 425 patients (19.8% female vs 24.9% male, p<0.001) at 3 years. KM-curves showed a higher all-cause death risk at 1- and 3-years in men compared to women (HR1yr

1.32, 95%IC 1.10- 1.57, p= 0.002 and HR3yr 1.34, 95%IC 1.17-1.53, p<0.001). After adjustment for significant confounding variables by a stepwise regression model, men remained at higher risk of death at 1- and 3-years (Adj. HR1yr 1.47, 95%IC 1.18-1.82, p< 0.001 and Adj. HR3yr 1.42, 95%IC 1.21-1.68, p<0.001).
Conclusions. Intermediate to high-risk women included in this multicenter prospective real-world contemporary TAVR project experienced a 1-year and 3-year lower mortality compared to men, but with a significant higher risk of major vascular complications and life-threating bleeding. These data suggest that women present a higher and earlier vascular risk compared to men, however a better long-term survival after TAVR.

C19

LONG-TERM OUTCOMES AND HEMODYNAMIC PERFORMANCE FOLLOWING TRANSCATHETER AORTIC VALVE-IN-VALVE: A 10-YEAR SINGLE CENTER EXPERIENCE

Chiara Fraccaro, Giuseppina Masitto, Giulia Masiero, Antonio Landi, Luca Nai Fovino, Gianpiero D'Amico, Tommaso Fabris, Alessandro Di Liberti, Francesco Cardaioli, Andrea Scotti, Giulio Rodinò, Mauro Massussi, Andrea Pavei, Massimo Napodano, Giuseppe Tarantini
Interventional Cardiology Unit, Department of Cardiac, Thoracic and Vascular Sciences, University of Padua Medical School, Padova

Background. Transcatheter aortic valve-in-valve (ViV) implantation is an alternative for the treatment of patients with degenerated bioprostheses at high surgical risk and is associated with favorable early outcomes. However, durability and long-term outcomes related to this treatment are unknown. The aim of the study is to evaluate medium and long-term clinical outcomes and hemodynamic performance of transcatheter aortic ViV for failed surgical bioprostheses.
Methods. This study is an observational retrospective registry of patients with degenerated aortic bioprostheses who underwent transcatheter aortic ViV in our center between 2008 and 2018. Baseline demographic, procedural and echocardiographic data were collected. 1-year and long-term clinical and echocardiographic follow-up was also obtained. All events were defined according to VARC-2.
Results. Data of 41 patients (18 females, 23 males) with symptomatic degeneration of surgical bioprostheses were included in our registry. Mean patient age was 76.9±10.1 years and the mean Society of Thoracic Surgeons (STS) score was 7.4±6.2%. Bioprostheses degeneration (stenosis or regurgitation) occurred 9.9±4.6 years after surgical aortic valve replacement. In 71% of patients a transfemoral access was performed and a balloon-expandable prosthesis was chosen in 81% of patients (23 mm in 65% of cases). Device success was obtained in all patients. The rate of 30-day and 1-year mortality was 5% and 10%, respectively. At 6 years, the overall Kaplan-Meier curves show a cardiovascular mortality of 30%. Mean trans-aortic gradient decreased from 37.2±19.4 mmHg at baseline to 18±9.2 mmHg at 30-day and was stable over 1-year follow-up. On the other hand, effective orifice area (EOA) increased from 1.2±0.6 cm^2 at baseline to 1.4 +/- 0.5 cm^2 and 1.6±0.5 cm^2 at 30-day and 1-year follow-up, respectively. Moreover, moderate-to-severe aortic regurgitation was reduced from 59% pre-ViV to 0% at follow-up. New York Heart Association (NYHA) functional class also improved, with 96% of patients in class I or II at follow- up.
Conclusions. Trancatheter aortic ViV implantation is feasible and related to good procedural and early outcomes. Moreover, at long-term follow-up, it is associated with good survival, optimal hemodynamic performance and functional outcomes.

C20

FACTORS INFLUENCING THE CHOICE BETWEEN TRANSCATHETER AND SURGICAL TREATMENT OF SEVERE AORTIC STENOSIS IN PATIENTS YOUNGER THAN 80 YEARS: RESULTS FROM THE OBSERVANT STUDY

Luca Nai Fovino[1], Giuseppe Tarantini[1], Giulio Rodinò[1], Paola D'Errigo[2], Stefano Rosato[2], Marco Barbanti[3], Corrado Tamburino[3], Marco Ranucci[4], Gennaro Santoro[5], Gabriella Badoni[2], Fulvia Seccareccia[2] and OBSERVANT Research Group
[1]Dipartimento di Scienze Cardio-Toraco-Vascolari, Azienda Ospedaliera di Padova, Padova, [2]Istituto Superiore di Sanità, Roma, [3]Dipartimento Cardio-Toraco-Vascolare, Università di Catania, Catania, [4]Anestesia e Rianimazione Cardiotoracovascolare, IRCCS Policlinico San Donato, Milano, [5]Fondazione "G. Monasterio" CNR/Regione Toscana per la Ricerca Medica e la Sanità Pubblica, Firenze

Background. Patients treated with transcatheter aortic valve implantation (TAVI), independently of surgical risk score, are mostly older than 80 years. We aimed to analyze the baseline features and clinical outcomes of patients younger than 80 years undergoing transfemoral TAVI or surgical aortic valve replacement (SAVR) enrolled in the OBservational Study of Effectiveness of SAVR-TAVR procedures for severe Aortic steNosis Treatment (OBSERVANT) real-world study, focusing on variables guiding Heart Team decision towards TAVI.
Methods. OBSERVANT is a multicenter, observational, prospective cohort study that enrolled patients with symptomatic severe aortic stenosis (AS) who underwent SAVR or TAVI from December 2010 to June 2012 in 93 Italian participating hospitals. For this analysis, baseline characteristics, therapeutic approach and outcomes up to 5 years of follow up of 4801 patients under 80 years of age were collected. Patients were stratified by age classes (<65, 65-74 and 75-79 years).
Results. Patients <80 years of age with severe symptomatic AS undergoing TAVI (n=483) had significantly higher Logistic EuroSCORE (10.84% vs 5.22%, p<0.001) and prevalence of comorbidities compared to subjects undergoing SAVR (n=4318). The decision to perform TAVI over SAVR was driven by anatomical factors, mainly previous cardiac surgery (OR 24.73, CI 12.71-48.10, p<0.001) and the presence of porcelain aorta (OR 17.44, CI 6.67-45.55, p<0.001), and clinical factors, mainly moderate-severe frailty score (OR 5.49, CI 3.33-9.07, p<0.001), oxygen dependency (OR 7.42, CI 2.75-20.04, p<0.001) and need for dialytic treatment (OR 5.24, CI 1.54-17.80, p<0.008). Among patients undergoing TAVI, those under 65 years had the highest baseline risk profile (despite a low Logistic EuroSCORE) and the highest 5-year mortality compared to those 65-74 and 75-79-year-old (65.22% vs. 48.54% vs. 55.24%, log-rank p=0.061).
Conclusions. Among patients under 80 years of age with symptomatic severe AS, only 10% underwent TAVI. These patients were at higher baseline risk compared to those undergoing SAVR. The decision to perform TAVI was driven by the presence of both anatomical and clinical factors beyond surgical risk scores. Patients under 65 years of age, despite the low Logistic EuroSCORE, had the highest pre-operative risk profile and carried the worse outcome.

Coronary interventions 3

C21

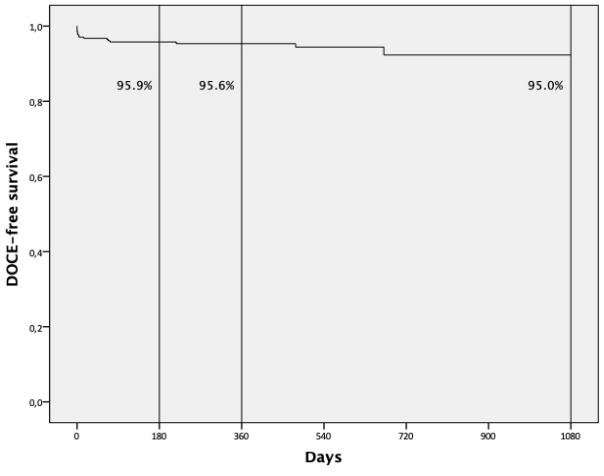
INCIDENZA DI EVENTI AVVERSI DOPO IMPIANTO DI STENT MEDICATO ORSIRO IN PAZIENTI CON STEMI: RISULTATI DAL REGISTRO MULTICENTRICO HEROES

Vincenzo De Marzo[1], Rosario Alessandro Parisi[2], Marco Caruso[3], Domenico D'Amario[4], Gianmarco Annibali[4], Vincenzo Manganiello[5], Rocco Vergallo[4], Michael Donahue[6], Alfonso Ielasi[7], Leonardo Misuraca[8], Luca Altamura[9], Bernardo Cortese[10], Marco Canepa[1], Claudio Larosa[11], Italo Porto[1]
[1]Cardiovascular Unit, Department of Internal Medicine and Specialties (DIMI), Universiy of Genoa, IRCCS Ospedale Policlinico San Martino, Genova, [2]AO Ospedali Riuniti Marche Nord, Pesaro, [3]Ospedale Civico, Palermo, [4]Gemelli Foundation Hospital, Catholic University of the Sacred Heart, Roma, [5]Ospedale San Giuseppe Moscati, Aversa, [6]Ospedale Casilino, Roma, [7]Bolognini Hospital, Seriate, [8]Misericordia Hospital, Grosseto, [9]European Hospital, Roma, [10]Fatebenefratelli Hospital, Milano, [11]Lorenzo Bonomo Hospital, Andria

Premessa. L'angioplastica percutanea primaria (pPCI) con stent ad eluizione di farmaco (DES) rappresenta il gold standard del trattamento dell'infarto miocardico acuto con sopraslivellamento del tratto ST (STEMI). Il successo a medio-lungo termine di tale procedura è fortemente influenzato sia dal tipo di polimero dello stent che dalle diverse strategie utilizzate per controllare il rilascio del farmaco in esso integrato. Orsiro, un nuovo stent di terza generazione ad eluizione di sirolimus con polimero biodegradabile, è potenzialmente associato ad un minor tasso di malapposizione, ridotta infiammazione, minore danno meccanico ed un ridotto tasso di trombosi indotta dallo stent stesso. Nel registro HEROES abbiamo valutato la sicurezza e l'efficacia dello stent Orsiro in pazienti con STEMI sottoposti a pPCI, delineando i risultati dell'utilizzo di tale stent nel "real-world" e fornendo dati sulle caratteristiche dei pazienti, i pattern di cura e le relative misure di performance di Orsiro.
Materiali e metodi. Da Gennaio 2012 a Marzo 2018 in 9 centri Italiani abbiamo arruolato tutti i pazienti con diagnosi di STEMI sottoposti a pPCI con impianto di almeno uno stent Orsiro in un vaso culprit. L'endpoint primario dello studio era un endpoint composito device-oriented (DOCE) costituito da morte cardiaca, infarto del miocardio (MI) chiaramente attribuibile al vaso culprit dello STEMI (TVMI) e rivascolarizzazione ischemia-relata su vaso culprit (ID-TLR) occorsi ad 1 anno di follow-up. Gli endpoints secondari erano: 1) DOCE a 6 mesi e 3 anni di follow-up; 2) qualsiasi definita o probabile trombosi di stent (probabile o definita); 3) qualsiasi sanguinamento maggiore secondo i criteri TIMI (avvenuto durante il ricovero, entro 7 giorni dalla pPCI e durante il follow-up).
Risultati. La popolazione dello studio era costituita da 338 pazienti con un'età media di 64.9±12.0 anni; 255 (75.4%) pazienti erano uomini, 69 (20.4%) erano affetti da diabete mellito e 59 (17.5%) da insufficienza renale cronica. Il follow-up mediano è stato di 10.5 (intervallo 0-67) mesi. Il vaso culprit è stato l'arteria discendente anteriore in 167 (49.4%) pazienti, la coronaria destra in 97 (28.7%), l'arteria circonflessa in 42 (12.4%); in 32 (9.5%) pazienti il vaso culprit ha coinvolto altri rami coronarici. 178 (52.7%) pazienti erano caratterizzati da malattia coronarica multivasale, 106 (31.4%) avevano una lesione culprit a livello di una biforcazione. In 155 (45.9%) pazienti la lesione culprit era in sede

prossimale, in 154 (45.6%) pazienti era, invece, medio-distale. Il rapporto stent per lesione era 1.3±0.6. All'angiografia il thrombus grade era di 0-2 in 236 (69.8%) pazienti e di 3-5 in 102 (30.2%). Ad 1 anno di follow-up abbiamo osservato un'incidenza di DOCE pari al 4.4%, costituito da 13 (3.8%) morti cardiache, 1 (0.3%) TVMI e 1 (0.3%) ID-TLR. Abbiamo registrato 1 (0.3%) solo caso di trombosi definita di stent durante il ricovero e 4 (1.2%) sanguinamenti maggiori occorsi durante il follow-up. Le curve Kaplan-Meier hanno dimostrato una sopravvivenza libera da DOCE pari al 95.9% a 6 mesi di follow-up, 95.6% ad 1 anno e 95.0% a 3 anni.

Conclusioni. Lo stent Orsiro sembra essere caratterizzato da buona efficacia e sicurezza nell'ambito delle pPCI. Le innovative caratteristiche di questo stent contribuiscono alla bassa incidenza di eventi avversi durante il follow-up e ad una sopravvivenza libera da eventi assolutamente comparabile rispetto a quella osservata negli studi di registro dei più moderni DES.



C22

LE DISSEZIONI CORONARICHE SPONTANEE: UNA SFIDA DIAGNOSTICA E TERAPEUTICA

Luigi Fiocca, Giulio Guagliumi, Paolo A. Canova, Angelina N. Vassileva, Orazio Valsecchi, Michele Senni

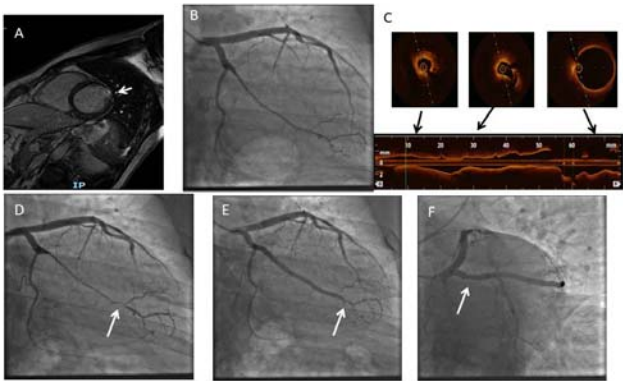
Dipartimento Cardiovascolare, Ospedale Papa Giovanni XXIII, Bergamo

Premessa. Le dissezioni coronariche spontanee (SCAD) rappresentano una sfida diagnostica e terapeutica. Spesso si assiste alla guarigione spontanea, per cui ove possibile, l'atteggiamento conservativo è consigliabile. L'angioplastica coronarica nelle SCAD presenta delle insidie ed ha spesso risultati subottimali.

Materiali e metodi. La presentazione prende lo spunto da un caso non usuale di SCAD con decorso instabile e progressivo che ha necessitato di rivascolarizzazione percutanea. Presentiamo inoltre la nostra casistica di 28 casi osservati negli ultimi 10 anni.

Risultati. Case report: paziente maschio di 44 anni senza FRCV. Dopo una seduta di jogging accusa angor; l'ECG è negativo, l'ecocardiogramma mostra una circoscritta ipocinesia laterale basale. La troponina I (TI) raggiunge i 36 µg/L. La coronarografia (CGF) mostra normale aspetto angiografico. La RMN mostra late enhancement transmurale laterale basale. In pre-dimissione con diagnosi di MINOCA, recidiva di angor con nuovo picco di TI. Si ripete una CGF con evidenza di lieve riduzione di calibro del ramo per il margine ottuso (MO). La scansione OCT mostra ematoma intramurale, piccole interruzioni dell'intima in assenza di segni di aterosclerosi (SCAD tipo II). Indicazione a terapia con ASA e betabloccante. Nei giorni seguenti ancora fugaci dolori toracici, andamento altalenante degli enzimi di miocitolisi, comparsa di onde T negative in D1 e aVL, un run di 24 battiti di TVNS. Nuova CGF con evidenza di progressione della lesione su MO con subocclusione distale. Si esegue PCI multistent con "full metal Jacket" del ramo MO ed evidenza di estensione dell'ematoma agli edge prossimale e distale. Successivo decorso regolare. Casistica monocentrica 2009-2019: i dati presentati in tabella riguardano 28 pazienti con diagnosi di SCAD osservati nel nostro centro negli ultimi 10 anni. Di questi l'82% erano donne di età media 53 anni. Esordio con NSTEMI nel 46,4% e STEMI nel 53,6% dei casi. Nel 78,6% i pazienti sono stati trattati conservativamente, una PCI è stata effettuata nel 17,9% ed un caso (3,5%) è stato sottoposto a CABG. Recidive si sono osservate nel 28,6% dei casi, equamente distribuite tra precoci (entro 30 gg) e tardive. Una paziente è deceduta nei primi 30 gg (3,5%).

Conclusioni. Il sospetto clinico e talora l'utilizzo di imaging intravascolare, sono indispensabili per la corretta diagnosi di SCAD. Il trattamento conservativo rappresenta la prima scelta ma in alcuni casi è necessario ricorrere alla PCI, che può risultare insidiosa e complessa.



A: RMN con late enhancement laterale (freccia). *B*: seconda CGF. *C*: OCT del ramo MO. *D*: terza CGF, subocclusione MO (freccia). *E,F*: risultato finale dopo stenting. Migrazione prossimale e distale dell'ematoma (frecce).

C23

PERCUTANEOUS CORONARY INTERVENTION PERFORMANCE IN SPONTANEOUS CORONARY ARTERY DISSECTION: INSIGHT FROM AN ITALIAN MULTICENTER REGISTRY

Enrico Cerrato[1], Giorgio Quadri[1], Chiara Cavallino[2], Italo Porto[3], Luca Bettari[4], Alfonso Franzè[5], Fabio Mariani[6], Federico Giacobbe[1], Luca Lo Savio[5], Andrea Demarchi[7], Francesco Rametta[8], Massimiliano Scappaticci[9], Umberto Barbero[10], Cristina Rolfo[11], Marco Pavani[12], Fabio Ferrari[1], Alessandra Truffa Giachet[13], Gianluca Campo[14], Dario Buccheri[15], Elisabetta Bordoni[16], Andrea Rognoni[17], Angelo Di Leo[18], Annamaria Nicolino[19], Federico Beqaraj[20], Giuseppe Pietro Greco Lucchina[21], Francesco Cassano[22], Fabrizio D'Ascenzo[23], Francesco Tomassini[11], Ferdinando Varbella[11]

[1]San Luigi Gonzaga University Hospital, Orbassano, [2]Ospedale Sant'Andrea, Vercelli, [3]University of Genova, Cardiovascular Unit, Department of Internal Medicine and Specialties (DIMI) & IRCCS Ospedale Policlinico San Martino, Genova, [4]Fondazione Poliambulanza di Brescia, Brescia, [5]Infermi Hospital, Rivoli, [6]San Luigi Gonzaga University Hospital, Orbassano, [7]Ospedale Sant'Andrea, Vercelli, [8]S. Andrea Hospital, Vercelli, [9]Policlinico Umberto I, Roma, [10]Savigliano Hospital, Savigliano, [11]Infermi Hospital, Rivoli, [12]Mauriziano Hospital, Turin, [13]Ospedale Civile Cardinal Massaia, Asti, [14]Ferrara University, Ferrara, [15]Interventional Cardiology Unit, Ospedale Sant'Antonio Abate, Trapani, [16]Ospedale Santa Maria della Misericordia, Perugia, [17]AOU Maggiore della Carità, Novara, [18]Ospedale di Ciriè, Ciriè, [19]Ospedale Santa Corona, Savona, [20]Ospedale Maria Vittoria, Torino, [21]Santa Croce Hospital, Moncalieri, [22]Ospedale "Di Venere", Bari, [23]Città della Salute e della Scienza, Turin

Background. Spontaneous coronary artery dissection (SCAD) optimal treatment is still unclear. However, when percutaneous coronary intervention (PC)I is attempted, techniques and devices used to ensure true lumen recanalization may be different compared to a standard PCI in atherosclerotic disease.

Methods. DISCO (DIssezioni Spontanee COronariche) is an Italian multicenter registry enrolling patients admitted with a diagnosis of SCAD. Baseline, procedural characteristics, in-hospital management and outcomes of SCAD patients were collected. Major cardiovascular events (MACE) were defined as the composite of all cause death, non-fatal Myocardial infarction and any PCI performed.

Results. Among 216 patients included, women were 77.4% with a mean age of 54±12 year. Eighty-eight (40.7%) patients underwent PCI as a first approach. Besides, 12 (10.0%) patients initially managed conservatively required an urgent PCI due to retrograde propagation of dissection including left main abrupt occlusion in 1 case. A TIMI (Thrombolysis in Myocardial Infarction) flow was 0-1 in the most of the cases (55.6%) and Left Anterior Descending artery was mainly the target (56.3%). In the majority of cases a workhorse guidewire was chosen by the interventional cardiologist (92.3%). PCI with stent implantation was necessary in 78.2% of cases (with DES 86.4%; only BRS 6.1%; hybrid DES-BRS 3.0%) with a median stent/scaffold length of 40 mm (IQR range 24-68). Remaining cases required only balloon-angioplasty, including 2 cases with successful hematoma fenestration using an undersized cutting-balloon. An Imaging technique to optimize the PCI result was performed only in 25.0% of the cases. Overall, TIMI 3 flow at the end of PCI was obtained in 79.5% of the patients. PCI failure occurred in 18 patients (21.4%): in three of them a second PCI procedure was accomplished after discharge (>1 month), while the others cases where managed conservatively. In-hospital events occurred in 22 patients (10.1%, cardiac death= 2; non-fatal MI= 9, any PCI= 20). Follow-up (>3 months) after discharge was to-date available in156 patients (72.2%) with a mean length of 28±28.4 months. A total of 32 MACE (14.8%) was registered (cardiac death= 3; non-fatal MI= 16, unplanned PCI= 23).

Conclusions. PCI in case of SCAD continue to be hampered by a non-negligible rate of failure or subsequent hard events. Different techniques like only-balloon, cutting balloon or BRS could be considered in order to limit extensive stenting in such young population.

C24

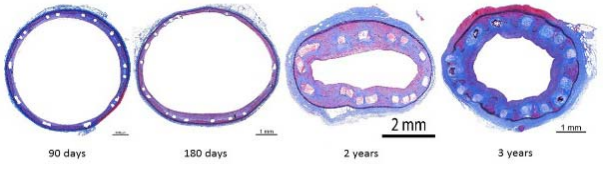
LONG-TERM BIOCOMPATIBILITY AND RESORPTION PROFILE OF A NOVEL BIORESORBABLE SCAFFOLD FOR PERIPHERAL ARTERIES: A 3.3-YEAR STUDY IN YUCATAN MINISWINE

Marco Ferrone[1], Gilberto Melnick[2], Yanping Cheng[3], Gerrard B. Conditt[3], Paula Corts[3], Serge Rousselle[4], Juan F. Granada[3], Grzegorz L. Kaluza[3]
[1]CRF - Skirball Center for Innovation, Cardiovascular Research Foundation, NY, New York, USA States, [2]Department of cardiology, Universidade Federal do Parana, Curitiba, Brazil, [3]CRF - Skirball Center for Innovation, Cardiovascular Research Foundation, NY, Orangeburg, [4]Alizee Pathology, Alizee Pathology, Thurmont, USA

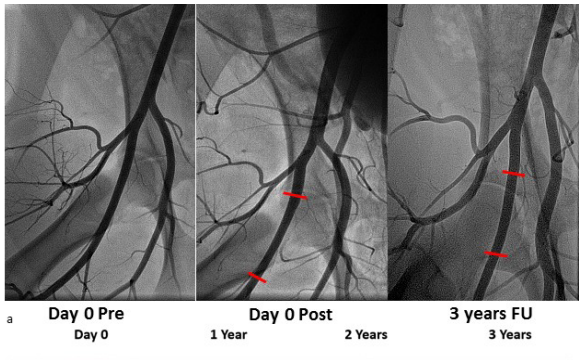
Background. Peripheral arteries are constantly exposed to external forces (elongation, twisting, shortening, compression) making this vascular territory particularly challenging for bioresorbable scaffolds (BRS). We evaluated the performance of a novel sirolimus-eluting balloon-expandable BRS (Credence BRS, Meril Life Sciences, Vapi, India) in peripheral arteries of Yucatan miniswine over 3.3 years.

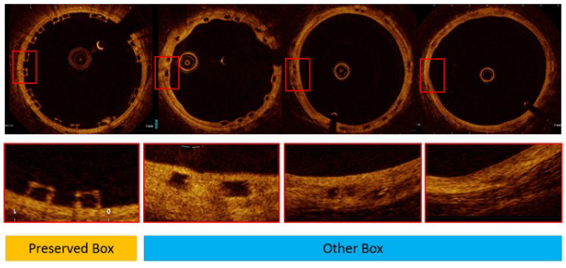
Methods. A total of 14 BRS were deployed in iliofemoral arteries of 7 Yucatan miniswine. Angiographic and OCT data were collected in all animals at 0, 30, 90, 180 days, 1, 2 and 3.3 years. Animals were sacrificed at 90 days (n=2), 180 days (n=2), 2 years (n=1) and 3.3 years (n=2) for histology (all timepoints) and for PLLA degradation analysis (at 3.3 years).

Results. Angiographic acute recoil was 4.1±5.4%. Other key results are summarized in the Table. Imaging showed that all scaffolds were widely patent and showed late lumen gain between 1 and 3 years. Histopathology revealed optimal healing at 90 and 180 days, mild to moderate formation of mature fibro- muscular, endothelialized neointima covering all scaffold struts with no residual fibrin or thrombosis. At 3.3 years histology revealed evident erosion and prominent hyaline hydrolysis of struts with notable fragmentation and moderate phagocytosis. PLLA degradation analysis showed 97% decrease in molecular weight and mass.



Credence BRS	Post implant	30 days	90 days	180 days	1 year	2 years	3 years	p value
Reference area, mm2	15.00±1.22	15.15±3.52	15.17±1.08	15.56±5.91	17.84±3.88	21.21±4.10	21.27±7.81	<0.05
Lumen area, mm2	17.03±3.99	9.66±3.99	9.87±3.30	10.06±4.33	14.70±3.58	22.04±3.81	25.45±7.07	<0.01
Scaffold area, mm2	20.33±4.43	12.80±4.27	13.34±3.25	14.39±5.44	19.18±3.79	27.58±4.64	28.29±7.63	<0.01
Neointimal area, mm2	n/a	3.13±0.51	3.47±0.63	4.33±1.77	4.48±0.52	5.42±0.75	6.84±0.79	<0.01
Area of stenosis, %	n/a	26±7	27±9	31±9	24±4	19±4	18±4	<0.05
Neointimal thickness, mm	n/a	0.11±0.04	0.13±0.07	0.17±0.09	0.17±0.04	0.17±0.02	0.28±0.04	<0.01





Conclusions. In this preclinical feasibility study, the Credence peripheral BRS showed acceptable acute and chronic biomechanical performance and satisfactory biocompatibility over 3.3 years in the iliofemoral arteries of Yucatan miniswine.

Coronary interventions 4

C25

SIROLIMUS-COATED BALLOON USE IN ACS PATIENTS: SINGLE CENTER EXPERIENCE

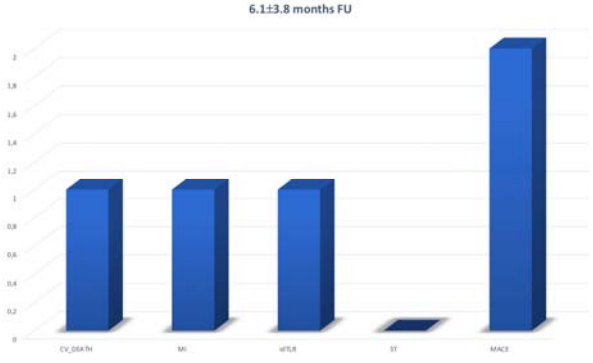
Gianluca Caiazzo, Michele Cimmino, Mario De Michele, Luca Golino, Vincenzo Manganiello, Assunta Chianese, Luciano Fattore
Cardiologia, Ospedale S. G. Moscati, Aversa

Background. Sirolimus-coated balloons (SCB) represent a novel therapeutic option for both in-stent restenosis and de novo coronary lesions treatment.

Methods. We included 52 consecutive patients with Acute Coronary Syndrome (ACS) undergoing PCI with at least 1 SCB used for in-stent restenosis and/or de novo coronary lesion treatment at our institution.

Results. Mean age was 6611 years and STEMI patients were 20.4%. Among lesion settings, 63.4% were de novo lesions whereas in-stent restenosis were 36.5%. Small vessels (<2.5 mm diameter) were 42.3% and complex (b2-c type) lesions were treated in 27%. Both procedural and clinical success occurred in 100% of the cases. At mid-term follow-up (mean follow-up 6.13.8 months), MACE were 3.8%. Cardiac death occurred in 1 (1.9%) patient, non-fatal MI and ischemia-driven TLR in 1 (1.9%) patient. No definite/probable acute or sub-acute thrombosis and no major bleeding occurred.

Conclusions. In the current prospective registry, SCB showed good safety and efficacy profile for the treatment of coronary lesions, both in-stent restenosis and/or de novo, in a complex ACS population of patients at mid-term follow-up.



C26

IMPIEGO E PERFORMANCE PROCEDURALE DEL DES BIOMIME MORPH

Francesco Greco, Angelo Leone, Daniela Chiappetta, Federico Battista, Roberto Caporale
UOC Cardiologia Interventistica, Azienda Ospedaliera di Cosenza, Cosenza

Premessa. Il Biomime Morph è uno stent medicato a rilascio di Sirolimus in lega Cr-Co L605, con rivestimento polimerico completamente biodegradabile. La struttura sinusoidale a celle ibride, aperte e chiuse, e lo spessore di maglia di 65 micron garantiscono una eccellente forza radiale ed estrema flessibilità. Il disegno tapered o tronco-conico (0.5 mm di differenza nel diametro prossimale-distale) e la disponibilità in lunghezze extra 40-50-60 mm consentono un impiego esclusivo nel trattamento single-device di una malattia coronarica estesa.

Materiali e metodi. Riportiamo di seguito la nostra iniziale esperienza con il DES Biomime Morph in un arco temporale relativo a 6 mesi di attività del laboratorio.

Risultati. Nelle 26 settimane analizzate abbiamo impiantato 12 Biomime Morph che corrispondono all'2.6% dei DES totali impiantati. Le misure impiegate sono state nell'80% dei casi comprese tra 50 e 60 mm in lunghezza e nel 60% dei casi 3.0 x 2.5 mm nel diametro. La coronaria destra è stata quella più trattata (50% dei casi). In 4 casi è stato necessario l'ausilio di un estensione di catetere (Guideliner - VS o Guidezilla - BSC) per raggiungere il sito di impianto. Tutti i 12 impianti sono stati IVUS guidati e hanno tutti compreso step di pre-dilatazione e post-dilatazione; non si è registrata alcuna failure procedurale in termini di trombosi acuta, slow/no-reflow, perdita side branch >2 mm. Dieci pazienti trattati si sono presentati con sindrome coronarica acuta (di cui 2 con STEMI) e due con angina da sforzo.

Conclusioni. Da questa nostra iniziale esperienza con lo stent medicato a rilascio di Sirolimus Biomime Morph emergono alcune considerazioni: la caratteristica struttura tronco-conica e le misure di lunghezza extra disponibili consentono il trattamento "smart" e in "one shot" di diffusi e lunghi tratti di malattia coronarica con mismatch di calibro. L'impiego di questo dispositivo all'interno di un laboratorio può attestarsi intorno al 3% coprendo le esigenze cliniche e anatomiche quotidiane. Le performance nel raggiungere il sito target rispecchiano quelle dei dispositivi superiori ai 30 mm in lunghezza, e l'impiego di un estensione di catetere può essere previsto fino al 33% dei casi. La sicurezza e la efficacia procedurale di questo dispositivo sono razionalmente legati ad un sistematico impiego di guida IVUS.

C27

BIORESORBABLE VASCULAR SCAFFOLDS: LONG-TERM, REAL WORLD, SINGLE CENTER EXPERIENCE USING OPTIMIZED IMPLANTATION TECHNIQUE

Stefano Albani[1], Francesco Giannini[2], Enrico Fabris[1], Antonio Mangieri[2], Alessandra Laricchia[2], Francesco Gallo[2], Gianfranco Sinagra[1], Antonio Colombo[2]

[1]Cardio-Thoraco-Vascular Department, Division of Cardiology and Postgraduate School in Cardiovascular Sciences, University of Trieste, Trieste, [2]Interventional Cardiology Unit, GVM Care & Research Maria Cecilia Hospital, Cotignola, Ravenna

Background. Bioresorbable vascular scaffold (BVS) is a technology introduced with the aim of avoiding the adverse events related to permanent metallic stents. Former randomized controlled trial failed to demonstrate the same outcomes of BVS against second generation drug eluting stent (DES). However recent randomized trials suggest a non-inferiority of BVS against DES when recommended implantation technique is performed suggesting that the optimal technique used at the time of implantation has a central role for BVS outcomes. However real world long-term data of BVS implanted with optimized technique are lacking.

Methods. To assess the real world long-term clinical outcome of BVS (Absorb; Abbott Vascular) with optimized implantation technique in a cohort of 164 all comers patients, (mean age 66±10 years, 90% males, 73% multivessel disease, 19% diabetic patients) with stable coronary artery disease. The primary end point of the study was to assess the safety of BVS in a real world setting in terms of target lesion failure (TLR), target vessel failure (TVF) and scaffold thrombosis (ST) at long-term follow-up.

Results. Total implanted BVS were 372, median lesion length was 14 mm (IQR 9-21), mean BVS length 18±5.9 mm, 288 (77.4%) B2/C lesions, 150 (40.3%) ostial/proximal lesions, 36 (9.7%) calcific lesions, 35 (9.4%) bifurcations. IVUS/OCT was used in 98.3% of the procedures, post-dilatation was performed in 79% of the delivered BVS (ATM 21±4 mmHg). At long-term follow-up (median 45 [29-59] months) TLR was 48 (12.9%), TVR 29 (7.8%) and 1 (0.3%) ST.

Conclusions. Our real world long-term data confirm the safety of using BVS with optimized implantation technique according to ABSORB IV results.

C28

IMPACT OF HIGH BLEEDING RISK (HBR) FEATURES ON ANTITHROMBOTIC MANAGEMENT AND LONG-TERM OUTCOMES IN PATIENTS WITH ACUTE CORONARY SYNDROME: DATA FROM THE MULTICENTER START-ANTIPLATELET REGISTRY

Paolo Calabrò[1], Felice Gragnano[1], Elisabetta Moscarella[1], Arturo Cesaro[1], Pia Clara Pafundi[2], Fabio Fimiani[1], Raffaella Antonia Vitale[1], Giuseppe Patti[3], Ilaria Cavallari[4], Emilia Antonucci[5], Plinio Cirillo[6], Pasquale Pignatelli[7], Gualtiero Palareti[5], Ferdinando Carlo Sasso[2], Vittorio Pengo[8], Paolo Gresele[9], Rossella Marcucci[10]

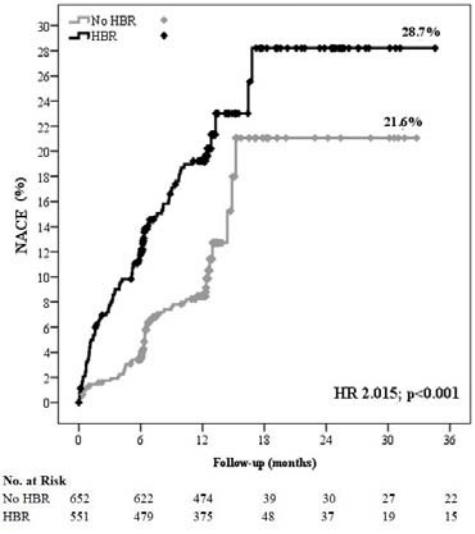
[1]Department of Translational Medical Sciences, University of Camapania "Luigi Vanvitelli", Caserta, [2]Department of Advanced Medical and Surgical Sciences, University of Camapania "Luigi Vanvitelli", Napoli, [3]Università degli Studi, L'Aquila, [4]Dipartimento di Malattie dell'Apparato Cardiovascolare, Policlinico Campus Bio-Medico, Roma, [5]Arianna Anticoagulazione Foundation, Bologna, [6]Department of Advanced Biomedical Sciences, "Federico II" University, Napoli, [7]Department of Internal Medicine and Medical Specialties, La Sapienza University of Rome, Roma, [8]University Hospital of Padua, Padua, [9]University of Perugia, Perugia, [10]University of Florence, Firenze

Background. The identification of patients at high bleeding risk (HBR) and their antithrombotic management after an acute coronary syndrome (ACS) remain urgent and challenging open issues in contemporary practice. We sought to investigate the antithrombotic strategies used in and the long-term ischemic and bleeding outcomes of patients with ACS fulfilling HBR criteria who were enrolled in the prospective multicenter START-ANTIPLATELET registry.

Methods. The START-ANTIPLATELET is a prospective, multicenter, real-world registry (branch of the START registry, NCT02219984) enrolling consecutive ACS patients. For the present analysis, 1,209 patients were stratified as HBR (n=553), if fulfilling clinical and/or biochemical HBR criteria – including advanced age, indication to oral anticoagulants, history of bleeding, history of stroke, known anemia, severe chronic kidney disease, low platelet count, and/or PRECISE-DAPT score ≥25 – or non-HBR (n=656) patients. Antithrombotic regimen – either drugs type, dose, and duration – was systematically recorded, also collecting any regimen modifications at follow-up. The primary endpoint was the net adverse clinical endpoints (NACE) rate, defined as a composite of all-cause death, myocardial infarction, stroke, coronary revascularization, and major bleeding. The secondary endpoints were individual components of NACE.

Results. Among the pre-specified criteria, HBR patients were more frequently identified by advanced age (79% of patients), PRECISE DAPT ≥25 (69% of patients), and use of oral anticoagulants (20.5% of patients). The coexistence of more than 1 HBR criteria per patient was frequent (79% of HBR patients fulfilling at least 2 criteria). Compared with patients without any criteria, those with 1 or more HBR criteria were more frequently treated with clopidogrel (17.5% vs. 50.9%, respectively; p<0.001), and less frequently treated with ticagrelor (42.8% vs. 55.9%, respectively; p<0.001), prasugrel (6.3% vs. 18.9%, respectively, p<0.001), and/or DAPT regimen (96.5% vs. 89.5%, respectively; p<0.001). HBR patients had worse outcomes, owing to higher death and bleeding risk. NACE occurred in 17.2% of the HBR and 8.7% of the non-HBR patients (hazard ratio [HR] 2.01; 95% confidence interval [CI] 1.45-2.79; p<0.001), driven by lower rate of all- cause death (12.1% vs. 2.6%; HR 4.72; 95%; CI 2.77-8.05; p<0.001) and major bleeding (3.1% vs. 1.1%; HR 2.99; 95% CI 1.24-7.23; p=0.015) in the HBR group, whereas ischemic events did not differ between groups.

Conclusions. Among patients with ACS, those with HBR features are common in clinical practice, and less frequently treated with potent P2Y12 inhibitors and/or DAPT as compared with those without. HBR patients experienced a worse long-term outcome compared with non-HBR patients, mainly driven by a higher risk of death and major bleeding.



Coronary interventions 5

C29

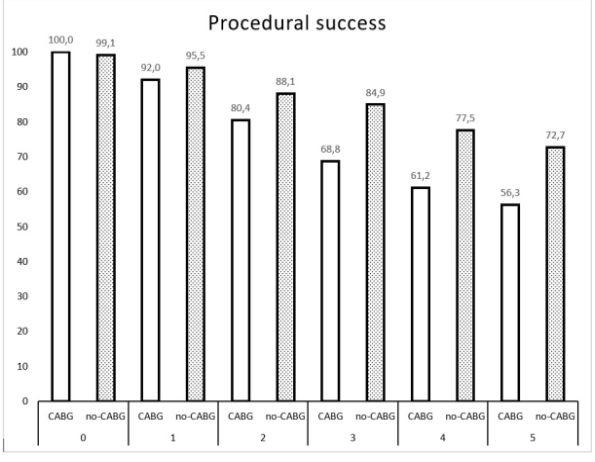
IMPACT OF CORONARY ARTERY BYPASS GRAFT HISTORY IN PATIENTS UNDERGOING CHRONIC TOTAL OCCLUSION-PERCUTANEOUS CORONARY INTERVENTION: PROCEDURAL AND CLINICAL OUTCOMES FROM THE REGISTRY OF CROSSBOSS AND HYBRID PROCEDURES IN FRANCE, THE NETHERLANDS, BELGIUM AND UNITED KINGDOM (RECHARGE)

Simone Budassi[1], Carlo Zivelonghi[1], Joseph Dens[2], Simon Walsh[3], Paul Knaapen[4], Alexandre Avran[5], James Spratt[6], Pierfrancesco Agostoni[1]

[1]HartCentrum, ZNA Middelheim, Antwerp, [2]Department of Cardiology, Ziekenhuis Oost-Limburg, Genk, Belgium, [3]Department of Cardiology, Belfast City, Belfast, UK, [4]Department of Cardiology, VU University Medical Center, Amsterdam, the Netherlands, VU University Medical Center, Amsterdam, Netherlands, [5]Department of Cardiology, Clinique de Marignane, Marignane, France, [6]Department of Cardiology, Forth Valley Royal Hospital, Edinburgh, UK

Background. Chronic total occlusions (CTO) in patients with history of coronary artery bypass graft (CABG) show more advanced and complex

atherosclerotic pathology, with respect to those in patients without CABG. The aim of our study is to compare procedural and clinical outcomes in patients undergoing CTO percutaneous coronary intervention (PCI) with previous CABG versus those without in the prospective REgistry of Crossboss and Hybrid procedures in FrAnce the NetheRlands, BelGium and UnitEd Kingdom (RECHARGE).
Methods. The RECHARGE cohort (1252 patients undergoing CTO PCI) was divided in two groups according to the presence of previous CABG or not. The aim of our post-hoc sub-analysis was to assess procedural outcomes, techniques adopted and complications in both groups. We also focused, in the post- CABG group only, on a comparison between CTO attempted in previously grafted vessels versus CTO in non- grafted vessels.
Results. The 217 post-CABG patients were older and with higher prevalence of diabetes, atrial fibrillation, previous myocardial infarction and chronic kidney insufficiency. The CTO complexity scores were higher in the CABG group. The success rate was lower in the CABG group (71.9% vs 88.7%, p < 0.001), this difference was mainly driven by higher failure rates in CTO with high complexity scores. The rate of in- hospital complications was similar between the 2 groups. In the post-CABG group, CTO located in previously grafted vessels were more calcified and more tortuous than CTO in vessels not previously grafted, despite a statistically similar CTO complexity scores. Despite these differences, the procedural success was comparably suboptimal (73.1% vs 68%, p=0.47).
Conclusions. Patients undergoing CTO PCI with prior CABG have worse patient characteristics and more complex lesion features. In the CABG population the success rate is significantly lower, mainly when the CTO have high complexity scores, however the rate of complications is comparable. Interestingly, in the post-CABG population, CTO appear difficult to open independently from the presence of a previous graft on the vessel.



C30

FOLLOW-UP DEI PAZIENTI CON STENOSI CORONARICHE NON CRITICHE IN RELAZIONE AL VALORE DI FRACTIONAL FLOW RESERVE

Niccolò Chiriatti, Mauro Maioli, Anna Toso, Gabriele Grippo, Nicola Musilli, Massimiliano Nieri, Mario Leoncini, Francesco Bellandi
Cardiology Unit - Prato, USL Toscana Centro, Prato

Premessa. La fractional flow reserve (FFR) è una tecnica ben validata per la valutazione funzionale di stenosi coronariche nei pazienti con cardiopatia ischemica (CAD). Scopo dello studio è stato valutare il follow-up dei pazienti (pts) con stenosi coronariche non critiche (FFR >0.80) in relazione al valore di FFR rilevato.
Materiali e metodi. Da gennaio 2002 a dicembre 2018 sono stati valutati con FFR 527 pts con stenosi coronariche intermedie all'angiografia, 280 pts presentavano stenosi con valore di FFR >0.80: 156 pts erano già stati precedentemente rivascolarizzati (95% PCI) e 124 pts erano "naïve" (età media 68±11 anni; 68.5% CAD stabile e 31.5% ACS). I pts "naive", oggetto della presente analisi, sono stati suddivisi in due sottogruppi in base al valore di FFR: Gruppo A: FFR >0.80 e ≤0.90; Gruppo B con FFR >0.90. Gli end point (EP) considerati sono stati: EP1= morte cardiaca, sindrome coronarica acuta (ACS) e rivascolarizzazione, EP2 = ACS e rivascolarizzazione.
Risultati. Tra le variabili cliniche e angiografiche l'unica differenza significativa tra i due gruppi è risultata la prevalenza del genere femminile (Gruppo A 24.5% e 50.7% Gruppo B, p=0.005). Il follow up medio è stato di 58 ± 40 mesi; 2 pts sono stati persi al follow up. Gli eventi registrati sono stati: 16 decessi (3 non cardiaci), 10 ACS (1 STEMI), 11 rivascolarizzazioni per CAD stabile. All'analisi Kaplan Meier a 5 e 10 anni si osserva una significativa minor incidenza di eventi nel gruppo B sia per EP1 (5 anni: log rank 5.1, p=0.023, Figura 1; 10 anni: log rank 7.9, p=0.005) che per EP2 (5 anni: log rank 5.2, p=0.023, Figura 2; 10 anni: log rank 6.71, p=0.01).

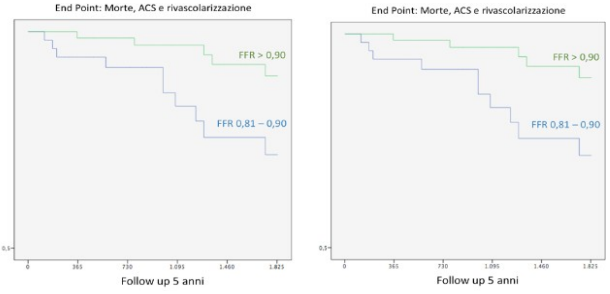


Figura 1 e Figura 2. Incidenza di eventi a 5 anni in relazione al valore di FFR indice.

Conclusioni. Nell'ambito di pts con cardiopatia ischemica e lesioni coronariche funzionalmente non critiche, il valore di FFR >0.80 e ≤ 0.90 è risultato associato ad una maggior incidenza di eventi avversi al follow-up.

C31

PRESSURE-BOUNDED CORONARY FLOW RESERVE TO PREDICT THE EXTENT OF MICROVASCULAR DYSFUNCTION IN PATIENTS WITH ST-ELEVATION ACUTE MYOCARDIAL INFARCTION

Roberto Scarsini[1], Giovanni L. De Maria[1], Mayooran Shanmuganathan[1], Rafail Kotronias[1], Alessandra Borlotti[1], Jeremy Langrish[1], Andrew Lucking[2], Rajesh Kharbanda[2], Vanessa Ferreira[2], Robin Choudury[2], Keith Channon[2], Adrian Banning[2]
[1]Oxford Heart Centre, [2]Oxford University Hospital, Oxford, UK

Background. Pressure-bounded coronary flow reserve (pb-CFR) has been proposed as an estimate of coronary flow reserve (CFR) which avoids the requirement for thermodilution or doppler-velocity measurements. Assessment of microvascular function in patients with ST-elevation acute myocardial infarction (STEMI) may be useful to determine treatment strategy and the possible role of pb-CFR in this setting has not been determined.
Methods. Thermodilution-pressure-wire assessment of the infarct-related artery was performed in 148 patients with STEMI before stenting (immediately after flow restoration) and/or at completion of primary percutaneous coronary intervention (PPCI). The extent of the acute and final myocardial injury was assessed with cardiovascular magnetic resonance imaging at 48 hours and 6 months after STEMI.
Results. Post-PPCI Pb-CFR was impaired (<2) and normal (>2) in 69.9% and 9.0% of the cases respectively. In the remaining 21.1% of the patients pb-CFR was indeterminate. The index of microcirculatory resistance (IMR) was significantly different across the pb-CFR subgroups (32.5 U [20.3-55.4] vs 26.0 U [13.3-41.0] vs 20.2 U [16.5-37.0], p=0.03). Similarly, significant differences were observed in microvascular obstruction (MVO) (2.0% [0.0-4.43] vs 1.0% [0.0-10.0] vs 0.0% [0.0-2.2], p=0.003), myocardium area-at-risk (46.1% [37.0-55.6] vs 39.7% [31.5-53.0] vs 33.3% [27.1-40.2], p=0.005) and 48-hours infarct size (IS) (28.7% [20.4-39.3] vs 30.0% [18.0-41.0] vs 15.5% [8.3-25.0], p=0.01). A trend towards lower 6-month IS was observed in patients with high (>2) post-PPCI pb-CFR (21.8% [13.3-30.3] vs 30.0% [18.0-41.0] vs 12.9% [5.5-21.8], p=0.18). At ROC curve pb-CFR presented inferior prognostic value compared with IMR in predicting MVO and the extent of final IS.
Conclusions. pb-CFR was able to stratify the extent of microvascular dysfunction after STEMI but had inferior performance when compared with IMR in predicting MVO and the extent of the final myocardial injury.

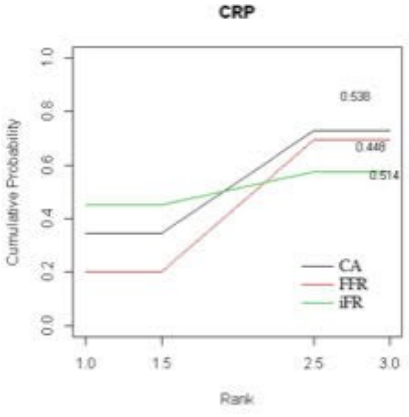
C32

L'FFR E L'IFR COME GUIDA PER LA PCI IN PAZIENTI CON SINDROME CORONARICA ACUTA SENZA SOPRASLIVELLAMENTO ST E STENOSI "CULPRIT" DI GRADO INTERMEDIO O SEVERO: UNA NETWORK META-ANALISI DI STUDI RANDOMIZZATI

Cristiano Massacesi[1], Michele Di Mauro[2], Federico Archilletti[3], Livio Giuliani[4]
[1]Dipartimento Cuore, ASL 2 Lanciano Vasto Chieti, [2]Dipartimento Cuore, ASL 2 Lanciano Vasto Chieti Clinica Cardiochirurgica, [3]Dipartimento Cuore, ASL 2 Abruzzo Lanciano Vasto Chieti, [4]Dipartimento Cuore, ASL 2 Lanciano Vasto Chieti UOSD Emodinamica, Chieti

Premessa. Nei pazienti stabili, la fractional flow reserve (FFR) e l'instantaneous wave-free ratio (iFR) sono i metodi di riferimento per la valutazione funzionale della severità di stenosi coronariche di grado intermedio (40-90%). È tuttavia pratica comune valutare il significato funzionale delle lesioni coronariche di grado intermedio sia con FFR sia con iFR anche nei pazienti con sindrome coronarica acuta (ACS), ma mancano evidenze di beneficio in questo contesto clinico. Lo scopo della nostra ricerca è di confrontare gli esiti clinici della rivascolarizzazione percutanea (PCI) guidati da FFR o iFR rispetto alla PCI guidata dall'angiografia coronarica (CA) nei pazienti che presentano sindromi coronariche acute senza sopraslivellamento ST (NSTE-ACS) e stenosi coronarica culprit di grado intermedio o severo.
Materiali e metodi. È stata eseguita una revisione sistematica basata

sulle linee guida Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). È stata effettuata una ricerca Pubmed e MEDLINE fino a giugno 2019 per studi clinici che confrontavano i risultati di rivascolarizzazione guidata da FFR, iwFR e CA di lesioni culprit in NSTE-ACS. I principali eventi avversi cardiaci (MACE) sono stati definiti come un endpoint composito di morte per tutte le cause, infarto non fatale e tasso di nuova rivascolarizzazione. Abbiamo eseguito una network meta-analisi con un approccio bayesiano, confrontando la rivascolarizzazione miocardica guidata da FFR, iFR e CA nei pazienti con NSTE-ACS.
Risultati. Due studi che confrontavano FFR e CA (FAME e FAMOUS-NSTEMI) e uno studio che confrontava FFR e iFR (iFR-SWEDEHEART) rispondevano ai criteri di inclusione. Lo studio iFR- SWEDEHEART ha valutato solo stenosi di grado intermedio (40-80% di diametro); lo studio FAME (stenosi >50%) e lo studio FAMOUS-NSTEMI (stenosi > 30%) includeva anche stenosi di grado severo. Non sono state trovate differenza significative nei MACE tra i 3 approcci,con un trend di risultati migliori a favore della PCI guidata da CA (AUC –Area under the Curve- per PCI guidata da CA: 0.54; AUC PCI guidata da FFR 0.45; AUC per PCI guidata da iFR: 0.51) [Fig. 1], con una loop inconsistency (I2LA) <0.2.
Conclusioni. Nei pazienti con NSTE-ACS, la valutazione funzionale di stenosi culprit di grado intermedio (40-90%) e severo (90-99%), sia essa condotta con FFR o con iFR non migliora gli esiti clinici se confrontata alla PCI guidata da CA.



Miscellaneous 1

C33

DOSE MONITORING FOR PHYSICIANS' LENS IN THE CATHETERIZATION LAB: INTER- CENTER SURVEY

Niccolò Chiriatti[1], Margherita Betti[2], Mauro Maioli[1], Sara Bicchi[2], Anna Toso[1], Gabriele Grippo[1], Nicola Musilli[1], Massimiliano Nieri[1], Mario Leoncini[1], Francesco Bovenzi[3], Marco Comeglio[4], Luca Bernardi[2], Francesco Bellandi[1]
[1]Cardiology Unit, Prato, [2]Medical Physics Unit, Prato and Pistoia, USL Toscana Centro, Prato, [3]Cardiology Unit, Lucca, USL Toscana Nord Ovest, Lucca, [4]Cardiology Unit, Pistoia, USL Toscana Centro, Pistoia

Background. The immediate consequence of the new International Commission on Radiological Protection limit of equivalent dose for the eye lens was a change in the international and European Basic Safety Standards (BSS) and the adoption of the new limit in the interventional cardiology laboratories. The most recent literature reports a poor correlation between the radiation dose detected at chest and lens level. Aim of this study was to evaluate the relationship between the clinical and procedural parameters and the operator's lens dose.
Methods. From January 2017 to December 2018, 4711 coronary angiographic procedures (70% radial and 30% femoral accesses) have been recorded and analyzed. Operators, who used the ceiling suspended screen in all cases, were monitored throughout three thermoluminescence dosimeters (TLDs): chest TLD (placed at the chest level, under the lead apron), hand TLD (on the wrist) and lens TLD (at the eye level, under the shielded glasses). Patient dose values (kerma area product, KAP), clinical and procedural parameters were recorded and analyzed.
Results. Patient mean KAP per procedure was 8249±4445 mGyxcm2 and mean beam-on-time per procedure was 15.4±6.6 min. Mean operator hand-dose resulted associated with the type of procedure (only diagnostic vs therapeutic procedure). A weak correlation was found between the hand-dose and the total KAP for all procedures performed by each operator (Figure 1). The lens-dose was not correlated with any of the clinical or procedural parameters (Figure 2).
Conclusions. Monitoring the dose at lens level is extremely complex and several factors influence its result: the dosimeter position, the type of procedure, the operator's experience and also the patient clinical conditions. The same dosimeters applied at the chest and the hand level do not seem adequate for monitoring the dose at the lens level.

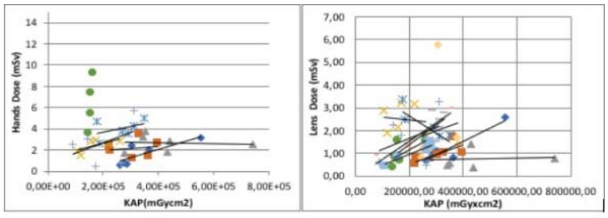


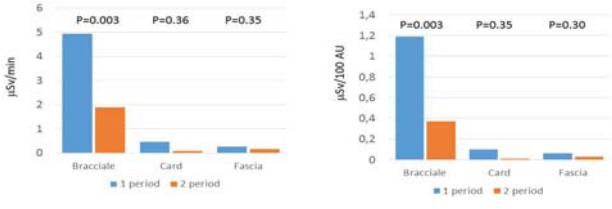
Figure 1 and 2. Correlation between the hand-dose and the kerma area product (KAP) and lens-dose and the KAP for all procedures performed by the different operators involved in the study.

C34

OPERATORS' RADIATION EXPOSURE REDUCTION DURING CARDIAC CATHETERIZATION USING A REMOVABLE SHIELD

Alessio Arrivi[1], Giacomo Pucci[2], Gaetano Vaudo[2], Carlo Bock[1], Matteo Casavecchia[1], Marco Bazzucchi[1], Marcello Dominici[1]
[1]Interventional Cardiology Unit, [2]Unit of Internal Medicine, "Santa Maria" University Hospital, Terni

Background. Cardiac catheterization through radial access is associated with significant radiation exposure for the operator. We aimed at evaluating whether a removable shield placed upon the patient could reduce the burden of radiation exposure.
Methods. We designed a pre-post study in order to compare radiation exposure in a total of five operators under standard protection procedures (first period) and applying a removable shield placed upon the patient during cardiac catheterization through radial access (second period). Radiation exposure was measured through three dosimeters (left bracelet, card under the lead apron, neck band) on each operator. Each period included all the procedures performed in about one year. The overall number of procedures and characteristics of each procedure, such as the number of operators participating to each procedure, fluoroscopy time (FT), and the dose area product (DAP), were collected.
Results. A total of 1608 procedures were performed during the first period, and 1671 during the second period. Each operator performed on average 412 exams during the first period, and 433 during the second period (p=0.18). For each operator, the average fluoroscopy time per procedure did not differ between the two periods (13.2 vs 12.8 min, p=0.78), whereas average DAP per procedure was slightly higher in the second period (5474 vs 6370 mGy/cm2, p=0.02). The use of a removable shield significantly reduced operators' radiation dose at the left bracelet (1.89±0.50 uSv/min vs 4.94±1.32 uSv/min, p=0.002). This remained significant even after adjustment for the number of operators participating to each procedure (p=0.003), whereas no significant difference was observed for card (0.08±0.03 uSv/min vs 0.47±0.88 uSv/min, p=0.36) and neck band (0.17±0.19 uSv/min vs 0.26±0.38 uSv/min, p=0.35) dosimeters.
Conclusions. The use of a removable shield during cardiac catheterization reduces the operator radiation exposure at the left bracelet dosimeter, with no difference in the dosage recorded at the card under the lead apron and neck band dosimeters. This innovative approach may help in reducing the radiation exposure for operators performing cardiac catheterization.



C35

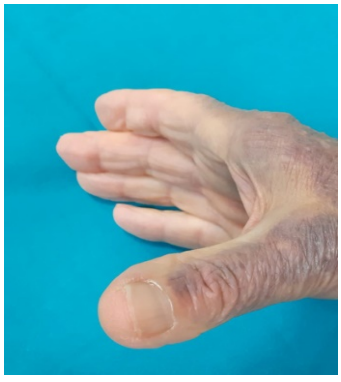
ACCESSO ARTERIOSO RADIALE DISTALE: NUOVA FRONTIERA PER LA CARDIOLOGIA INTERVENTISTICA?

Federica Valli, Stefano Lucreziotti, Lucia Barbieri, Simone Persampieri, Diego Salerno Uriarte, Carlo Sponzilli, Stefano Carugo
Emodinamica, Ospedale San Paolo, Milano

Premessa. L'accesso arterioso radiale distale (ARd) è stato recentemente presentato come alternativa all'accesso radiale tradizionale (ARt) per procedure di coronarografia (CNG) e angioplastica coronarica (PCI). La capacità di preservare la pervietà dell'arcata palmare superficiale rappresenta uno dei principali punti di forza di questa metodica. Tuttavia, l'ARd risulta essere più complesso rispetto all'ARt e i dati sulla fattibilità e sui risultati non sono ad oggi conclusivi. Scopo del presente studio è quello di valutare la fattibilità, l'efficacia e la sicurezza dell'ARd in pazienti non selezionati.
Materiali e metodi. La tecnica di ARd è stata valutata prospetticamente in pazienti candidati a coronarografia (CNG) e/o angioplastica coronarica

(PCI) nel laboratorio di Emodinamica dell'Ospedale San paolo di Milano. Previa anestesia locale con Lidocaina e sotto guida palpatoria, l'arteria è stata punta con tecnica diretta ed incannulata con introduttore 6F (Terumo 25 cm) secondo la metodica di Seldinger. La somministrazione di eparina (4000 U in caso di CNG o 75-100 U/Kg se PCI) e vasodilatatori (isosorbide dinitrato 300 mcg dopo l'inserzione dell'introduttore, eventualmente ripetibile in caso di spasmo +/- Verapamil
2.5 mg) è stata eseguita in tutti i pazienti, secondo protocollo standard. L'emostasi al termine della procedura è stata ottenuta con compressione manuale o posizionamento di TR Band (Terumo). Sono stati valutati: 1) la percentuale di successo dell'ARd; 2) la pervietà dell'arteria radiale alla dimissione mediante palpazione del polso arterioso; 3) le complicanze in sede di accesso vascolare; 4) l'esposizione radiologica e la quantità di mezzo di contrasto utilizzato.
Risultati. Sono stati arruolati 55 pazienti (73% maschi, 69 anni ± 12), di cui il 71% per procedura elettiva (vd. Tabella). La percentuale di successo dell'ARd è stata dell'84% (46 pazienti). Un totale di 12 pazienti (22%) ha avuto necessità di crossover ad altro accesso vascolare: oltre ai 9 casi di insuccesso dell'ARd, 2 casi per tortuosità degli assi arteriosi a monte e 1 caso per necessità di cateteri ad ampio lume per procedura complessa. I principali fattori di rischio cardiovascolare (FRCV), l'età, il BMI e i valori di pressione arteriosa pre- procedurale non sono risultati associati al successo dell'ARd, mentre emerge una correlazione con l'esperienza dell'operatore (operatore I: 40 procedure, tasso di successo 90%; operatore II: 11 procedure, tasso di successo 64%; p = 0.05). La pervietà dell'arteria radiale è stata rilevata nel 100% dei pazienti in dimissione. 6 pazienti (14%) hanno sviluppato ematoma in sede di accesso arterioso, in uno dei quali si è osservata anche la comparsa di pseudoaneurisma risolto con compressione prolungata. Tra le variabili cliniche e procedurali considerate solamente l'età >75 anni (p=0.032) è risultata associata ad un maggior rischio di complicanze.

Caratteristiche basali della popolazione	
Età, anni	69 ± 12
Sesso maschile, n (%)	40 (73)
BMI, Kg/mq	27 ± 5
IPA, n (%)	43 (78)
DM, n (%)	21 (38)
Dislipidemia, n (%)	40 (73)
Fumo, n (%)	23 (42)
EGFR < 60 ml/min, n (%)	15 (27)
Vasculopatia periferica, n (%)	17 (31)
PAS, mmHg	137 ± 18
PAD, mmHg	76 ± 11
FEVS, %	51 ± 11
Indicazione alla procedura, n (%)	
- SCA-NSTE	16 (29)
- Elezione	39 (71)
Caratteristiche procedurali	
Successo della puntura arteriosa, n (%)	46 (84)
Tasso Crossover, n (%)	12 (22)
-Insuccesso	9 (75)
-Marcata tortuosità dei vasi arteriosi a monte	2 (17)
-Procedura complessa	1 (8)
Procedure completate per via Ard, n (%)	43 (78)
-angiografia coronarica	27 (63)
-angioplastica coronarica	16 (37)
Emostasi, n (%)	
-TR band	35 (64)
-Manuale	13 (24)
-Non applicata	7 (12)
DAP, mGy*cmq	39190 ± 27133
Tempo scopia, min	11,7 ± 6,6
MDC, ml	184 ± 76,5
FU post-procedurale	
Occlusione dell'arteria radiale all'avambraccio,n (%)	0 (0)
Complicanze in sede di puntura arteriosa, n (%)	
-Ematoma	6 (14)
EASY I	2 (33)
EASY II	4 (67)
-Pseudoaneurisma	1 (2)



Conclusioni. I dati del nostro studio confermano la fattibilità dell'ARd in pazienti non selezionati, candidati a CNG e/o PCI. L'ARd si propone quindi come una valida alternativa all'ARt. Con i limiti della limitata numerosità della nostra casistica, l'ARd sembra essere associato ad una maggiore pervietà dell'arteria radiale ma risulta anche gravato da un maggiore tasso di complicanze rispetto ai dati della letteratura sull'ARt (0.1-2.9%), in particolare nei soggetti anziani. Studi più ampi, prospettici e randomizzati, sono necessari per un confronto diretto tra le metodiche di ARd e ARt.

C36

MECHANICAL CIRCULATORY SUPPORT WITH THE IMPELLA DEVICE IN THE PERCUTANEOUS TREATMENT OF PATIENTS WITH SEVERE AORTIC VALVE STENOSIS

Mauro Chiarito[1], Paolo A. Pagnotta[1], Jorge Sanz-Sanchez[2], Giuseppe Ferrante[1], Martina Briani[1], Gennaro Petriello[1], Damiano Regazzoli Lancini[1], Gabriele L. Gasparini[1], Elena Corrada[1], Giulio G. Stefanini[1], Bernhard Reimers[1], Elisa Nicolini[3], Carlo Briguori[4]
[1]Cardio Center, [2]Humanitas Research Hospital, Rozzano, [3]Interventional Cardiology and Clinical Research, Ospedali Riuniti, Ancona, [4]Clinica Mediterranea, Napoli

Background. Both aortic stenosis (AS) and regurgitation (AR) are considered relative contraindication for the use of different percutaneous mechanical circulatory support (MCS). Therefore, their use in this subset of patients is extremely limited, leading to lack of data regarding the outcome of patients with AS or AR needing for MCS. However, a limited number of studies have shown that the use of Impella (Abiomed Inc., Danvers, Massachusetts) in patients with severe AS needing for balloon aortic valvuloplasty (BAV), transcathether aortic valve replacement (TAVR) and/or protected percutaneous coronary intervention (PCI) is safe and feasible, demonstrating promising results in selected high risk patients. Notwithstanding, there was high heterogeneity between these few studies regarding timing of PCI with respect to timing of BAV or TAVR. Therefore, in high-risk patients with severe AS needing for PCI with the aid of the Impella as MCS, it is unknown if there could be any differences performing PCI before or after BAV. Lastly, no data are available regarding the use of the Impella device in patients with AR. Driven by these preliminary data and by the paucity of pooled data on the outcomes of patients affected by AS or AR and needing for MCS, we aim to evaluate the outcome of these subset of patients supported with the use of the Impella device.
Methods. All consecutive patients with moderate-severe or severe AS or AR undergoing high-risk PCI, aortic valvuloplasty or transcathether valve replacement, supported by micro-axial continuous flow percutaneous left ventricular assist device (Impella 2.5, Impella CP) were enrolled in this multicenter retrospective registry.
Results. A total of 19 patients with AS (n=17, 89%) or AR (n= 2, 11%) were enrolled in the present study. The Impella device was placed electively prior to percutaneous procedure in all cases except for two patients (11%). The majority of patients underwent BAV with concomitant PCI (n= 15, 79%), while 2 patients (11%, 1 with AS and 1 with AR) underwent TAVR without PCI, and 2 patients (one with AS and one with AR) underwent PCI due to high-risk NSTEMI followed by TAVR during the same hospital stay. The patient with AR treated with TAVR without concomitant PCI was also affected by severe functional mitral regurgitation and underwent percutaneous mitral edge-to-edge repair during the same procedure. The only periprocedural complication was an acute severe mitral regurgitation due to mitral chordal rupture, probably caused by removal of the Impella device from the left ventricle. This patient was successfully treated with percutaneous mitral edge-to-edge repair after 4 days. All the other patients were discharged without any major clinical events.
Conclusions. These preliminary results suggest that the Impella device should be considered a feasible option for patients with AS and AR undergoing percutaneous procedures, with a very low rate of periprocedural complication. Further prospective large studies are needed to confirm our data.

Structural interventions 3

C37

PREDITTORI E VALORE PROGNOSTICO DELLE INFEZIONI ESORDITE ENTRO 30 GIORNI DALL'IMPIANTO DI VALVOLA AORTICA TRANSCATETERE: ESPERIENZA DI UN SINGOLO CENTRO

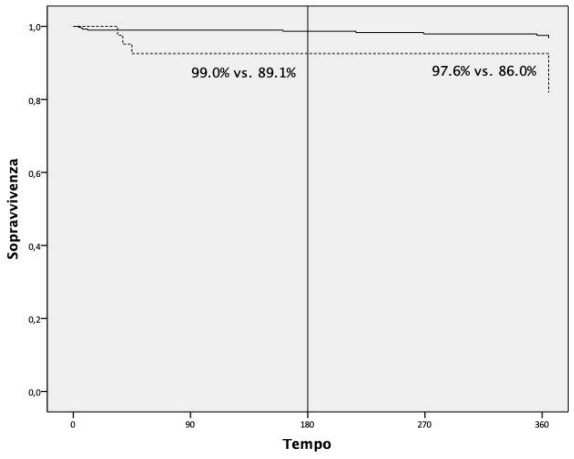
Vincenzo De Marzo[1], Silvia Dettori[2], Angelo Buscaglia[1], Laura Ambra Nicolini[2], Marco Canepa[1], Valentina Boasi[3], Stefano Benenati[1], Manrico Balbi[1], Italo Porto[1]
[1]Cardiovascular Unit, Department of Internal Medicine and Specialties (DIMI), [2]Infective Unit, Department of Internal Medicine and Specialties (DIMI), Universiy of Genoa, IRCCS Ospedale Policlinico San Martino, Genova, [3]Cardiovascular Unit, Sanremo Hospital, Sanremo

Premessa. L'impianto di valvola aortica transcatetere (TAVI) rappresenta ormai una procedura caratterizzata da risultati globalmente comparabili alla chirurgia, pur assicurando minore invasività. Diversi studi hanno messo in luce il beneficio derivante da un ridotto tasso di infezioni post-procedurali nei pazienti sottoposti a TAVI. Nel nostro studio abbiamo valutato la frequenza, il pattern microbiologico, i predittori e gli outcome delle infezioni secondarie a TAVI descrivendo inoltre il ruolo dei batteri multi-farmacoresistenti (MDR) ed estensivamente resistenti (MDR).

Materiali e metodi. Lo studio ha incluso 462 pazienti sottoposti a TAVI tra Gennaio 2014 e Aprile 2019 (con impianto del device ottimale secondo i criteri VARC-2) in cui è stata posta diagnosi di infezione entro 30 giorni dalla procedura con almeno 1 isolamento microbiologico di natura batterica. I batteri sono stati definiti come MDR in base alla resistenza ad almeno 1 antibiotico in 3 o più categorie di antimicrobici e XDR in caso di resistenza ad almeno 1 antibiotico in 2 categorie antimicrobiche.

Risultati. L'età media dei pazienti inclusi nello studio era di 82.7±7.7 anni, 196 (42.4%) pazienti erano di sesso maschile, 92 (19.9%) erano affetti da broncopneumopatia cronica ostruttiva (BPCO) e 148 (32.0%) da insufficienza renale cronica. Al ricovero 436 (47.6%) pazienti erano in classe NYHA I-II, i restanti, in classe NYHA III-IV. La durata media della procedura è stata pari a 116.3±45.9 minuti. 440 (95.2%) TAVI sono state condotte per via transfemorale, 19 (4.1%) erano valve-in-valve e 191 (41.3%) valvole impiantate erano autoespandibili. La durata media del follow-up è stata di 17.1±13.5 mesi. La mortalità a 6 mesi e ad 1 anno dall'impianto è risultata rispettivamente pari al 1.9% e al 3.5%. Al follow-up abbiamo osservato 46 (9.9%) infezioni sviluppatesi entro 30 giorni dalla procedura, di cui 42 (9.1%) durante il ricovero. Il tempo medio di sviluppo dell'infezione è stato 7.2±6.9 giorni. Abbiamo registrato 10 sepsi primarie, 8 infezioni del tratto urinario (di cui 1 con sepsi) e 22 infezioni del tratto respiratorio (di cui 1 con sepsi). Tra gli isolamenti microbiologici 12/29 (41.4%) batteri sono risultati Gram+ (4 S. aureus, 1 S. hominis, 1 S. capitis, 1 S. haemolyticus, 2 S. epidermidis, 1 S. agalactiae, 2 E. faecalis), 17/29 (58.6%) Gram- (4 P. aeruginosa, 1 E. cloacae, 1 K. pneumoniae, 2 H. influenzae, 4 E. coli, 1 K. oxytoca, 1 P. mirabilis, 2 S. marcescens, 1 S. maltophilia); in 5 casi sono stati registrati isolamenti di multiple specie batteriche, mentre sono stati osservati solo 4 (16.7%) MDR e nessun XDR. Ventidue (4.8%) pazienti si sono presentati con segni e sintomi tipici di infezione in assenza di isolamenti microbiologici. All'analisi multivariata, l'insufficienza renale acuta (IRA) (OR: 3.06, 95%CI: 1.32-7.07) e le complicanze vascolari definite secondo i criteri VARC-2 (OR: 2.95, 95%CI: 1.09-7.96), la BPCO (OR: 2.54, 95%CI: 1.01-6.35) e la durata dell'intervento (OR: 1.01 per minuto, 95%CI: 1.01-1.02, tutte le p<0.04). si sono dimostrati predittori significativi dello sviluppo di infezioni entro 30 giorni dalla TAVI. L'incidenza di infezioni esordite entro 30 giorni è risultata maggiore tra i pazienti deceduti entro 6 mesi (10.9% vs. 1.0%) e 1 anno dalla procedura (13.0% vs. 2.4%, tutte le p<0.001). Nel modello multivariato corretto per gli altri predittori significativi di morte a 6 mesi (disabilità neurologica, IRA) e ad 1 anno dalla procedura (BPCO), le infezioni sviluppate entro 30 giorni dalla TAVI sono risultate indipendentemente associate sia alla morte entro 6 mesi (OR: 7.36, 95%CI: 1.69-31.97, p=0.008) che alla morte entro 1 anno (OR: 4.34, 95%CI: 1.32-14.28, p=0.016). La sopravvivenza della coorte di pazienti con infezione entro 30 giorni è risultata significativamente minore sia a 6 mesi (89.1% vs. 99.0%) che ad 1 anno (86.0% vs. 97.6%, tutte le p<0.001) di follow-up. Caratteristicamente, il coinvolgimento di germi MDR non ha modificato significativamente l'associazione fra le infezioni esordite entro 30 giorni e la mortalità a 6 mesi e ad 1 anno dalla procedura (p per interazione=0.54).

Conclusioni. Nel nostro studio le infezioni esordite entro 30 giorni dalla TAVI si sono verificate in circa il 10% della popolazione, prediligendo soprattutto i pazienti con multimorbilità ed incidendo significativamente sulla mortalità a breve termine a prescindere dallo spettro di resistenza antimicrobica del germe coinvolto. Risulta quindi essenziale instaurare un'adeguata sorveglianza microbiologica ed un appropriato trattamento farmacologico delle infezioni nei pazienti sottoposti a TAVI al fine di migliorare i risultati della procedura e ridurre la mortalità globale.



C38

30-DAY AND LONG-TERM OUTCOMES OF CORONARY OSTIA PROTECTION IN VALVE-IN-VALVE TRANSCATHETER AORTIC VALVE IMPLANTATION: A SINGLE CENTER EXPERIENCE

Matteo Casenghi, Federico De Marco, Antonio Popolo Rubbio, Mauro Agnifili, Nedy Brambilla, Luca Testa, Francesco Bedogni
IRCCS Policlinico San Donato, San Donato Milanese

Background. Acute and delayed coronary obstruction is a serious life-threatening complication during valve in valve transcatheter aortic valve implantation (ViV-TAVI). Risk factors for coronary obstruction are low coronary ostia, narrow sinotubular junction, narrow sinuses of Valsalva and previous stentless or externally mounted pericardial leaflet bioprosthesis implantation (wrap pericardial valves).

Methods. Between February 2016 and June 2019, on a total of 657 patients treated with TAVI, 24 high risk patients with failed aortic valve bioprosthesis treated with ViV-TAVI underwent coronary ostial stenting with systematic and consistent protrusion into the aortic root to treat acute or to prevent delayed coronary obstruction and were enrolled in the study.

Results. The mean age was 85 ± 5.4 years and the mean Society of Thoracic Surgeons score was 7.1 ± 6. Mean left coronary artery (LCA) height from the lowermost part of the bioprosthetic frame was 7.6 ± 3.1 mm, mean right coronary artery (RCA) height was 12.4 ± 4.5 mm; mean sinus of Valsalva diameter was 27.8 ± 4.6 mm. Eighteen (75%) patients had a degenerated Mitroflow bioprosthesis while three (12,5%), two (8,3%) and one (4,2%) had, respectively, a failed Trifecta, Freedom SOLO and Freestyle valves. The vast majority of patients (87,5%) underwent ViV-TAVI with Portico, 8,3% with Evolut-R and 4.2% with Acurate NEO. Twenty-one patients (87.5%) received a stent in ostial LM, in sixteen cases (66.7%) both coronary arteries were stented. In one case a bare metal stent (BMS) has been implanted; drug eluting stents (DES) were implanted in the remaining cases. Two patients (8.3%) underwent successful urgent stenting due to acute coronary occlusion; of interest, both had a failed Trifecta valve. Mean LM stent length was 27.7 ± 6.7 mm with a mean stent diameter of 4.1± 0.3 mm; mean RCA stent length was 28.4 ± 6.7 mm with a mean stent diameter of 3.7± 0.5 mm. VARC-2-defined procedural success was 75% with five patients (20,8%) who had residual gradient > 20 mmHg and one patient (4,2%) with > moderate PVL. One patient sustained pericardial tamponade and required conversion to open surgery. We didn't observe any valvular embolization or need for a second valve implant. At 30-day follow-up, no patients died and seven (29%) had a mean aortic gradient > 20 mmHg. After a median follow-up of 315 days (IQR 344 days), five patients died (21%); two of these (8,3%) died for cardiovascular reasons (one for sinus of Valsalva and stent thrombosis and one for heart failure).

Conclusions. This preliminary study shows that ostial stenting with consistent protrusion to prevent acute and delayed coronary occlusion during ViV-TAVI is feasible and has an acceptable clinical acute and long-term outcome and is effective in solving acute coronary occlusion and could be effective in preventing delayed coronary occlusion. Larger studies are needed to confirm these results.

C39

USE OF TWO-DIMENSIONAL ULTRASONOGRAPHY-GUIDED ACCESS FOR TAVR TO REDUCE VASCULAR COMPLICATIONS

Elisa Nicolini, Tommaso Piva
Scienze Cardiovascolari, Ospedali Riuniti Ancona, Ancona

Background. Our objective was to describe the routine use of ultrasound guided femoral artery access in transfemoral TAVR and how this technique has helped to improve vascular and bleeding complications.

Methods. This is a single-centre prospective cohort study, including all patients who underwent a TAVR procedure from September 2017 to May 2019 where a routine 2D-US was used. An accurate preinterventional screening using multidetector computed tomography of iliac-femoral

arteries was performed. We analyzed: minimal lumen diameter and area of common femoral and iliac artery, SFAR ratio, pattern of calcification at the puncture site subdivided in four quadrant and described as follow: none or calcification spot on posterior wall (<25% of the circumference), calcification extended to medial and/or lateral wall (>25% but <75%), level of femoral bifurcation and of inferior border of epigastric artery and their correspondence to femoral head, depth of femoral artery, ileo-femoral tortuosity, extent and complexity of atherosclerosis. Pre-closure was done with a double Proglide system. A final digital subtraction angiography was made through the left radial artery, to evaluate adequate hemostasis and assess vascular patency. Our outcome were access site-related major and minor vascular complications, life-threatening, major and minor bleeding and the need for packed red blood cell transfusion. Definition were based on the VARC-2 criteria.

Results. The study cohort included 210 patients: median age was 83 years, with 56,6% being women, predicted mortality was 7,2% by EuroSCORE II and 8±4% by STS score, diabetes 28%, chronic renal failure 59%, history of peripheral vascular disease 18%, obesity 23,4% with 9% of morbid obesity, dialysis 4,1% and 24,8% of urgent TAVR. We implanted: Evolute R (36,6%), Evolute Pro (10,3%), Sapien3 (35,3%), Acurate Neo (15,8%) and Portico (2%). According to CTA imaging, mean minimal diameter of the CFA was 7 ±1,2 mm, 37% of patients had CFA <6,5 mm, median SFAR of 1,01 ±0,16 with 22% of patients having a SFAR >1,05; in 23% of cases femoral bifurcation was judged high, the distance between the inferior border of epigastric artery and femoral bifurcation was <3 cm in 48% of cases, with a small target zone for puncture. Calcifications on lateral and or medial quadrant were present in 41,5% of cases of which 23% had calcifications in both quadrants. In 31,8% of patients CFA depth was > 4 cm. Even though these high risk features, none access site-related major vascular complications were observed. 3 minor vascular complications (1,4%) occurred: a covered self expanding Viabahn stent was used because of a vascular dissection and 2 major extravasation. In all 3 cases, patients were women, with severe chronic renal disease and with a small CFA (minimal diameter 5,7±0,2mm, SFAR >1,05). Percutaneous angioplasty with an Armada balloon from left radial artery was performed in 13 cases to optimize hemostasis and to resolve arterial stenosis. The proportion of major bleeding (4,6%) and access-related transfusion was very low (4,5%). In reference to major bleeding, 1 case was access-related due to a self-limited retroperitoneal hematoma occurred after 3 days in a patient taking anticoagulant therapy.

Conclusions. The routine use of 2D-ultrasound in our TAVR cohort, associated with an accurate preinterventional CT screening, was associated with substantial reduction in access-related vascular and bleeding complications even in a high risk population.

C40

CORONARY ANGIOGRAPHY AND INTERVENTION AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION: RESULTS ON INCIDENCE, FEASIBILITY AND SAFETY

Luca Nai Fovino, Andrea Scotti, Mauro Massussi, Francesco Cardaioli, Giulio Rodinò, Antonio Landi, Alessandro Di Liberti, Tommaso Fabris, Gianpiero D'Amico, Giulia Masiero, Chiara Fraccaro, Andrea Pavei, Massimo Napodano, Giuseppe Tarantini

Department of Cardiac Thoracic and Vascular Sciences, University Hospital of Padua, Padova

Background. Transcatheter aortic valve implantation (TAVI) has gained widespread recognition as the treatment of choice for severe aortic stenosis in inoperable patients and as a reasonable alternative to conventional surgical aortic valve replacement (SAVR) in patients with high and intermediate surgical risk. As TAVI indication expands to younger and lower-risk patients who have better long-term prognoses, there will be an increasing need for repeat coronary angiography (CA) and percutaneous coronary intervention (PCI) due to progressive coronary artery disease (CAD) and development of acute coronary syndrome in the follow up period after TAVI. However, there is a paucity of data documenting the feasibility of either CA and/or PCI after TAVI.

Methods. From 2007 to 2018, 929 patients with aortic stenosis were treated with TAVI at our institution (Padua). All the commercially available devices have been used and included in this study. We performed a retrospective analysis in order to assess the incidence, feasibility and safety of CA or PCI following TAVI.

Results. 48/929 (5%) patients underwent 57 procedures of CA or PCI following TAVI (mean of 874±794 days). The following types of valves were implanted in this population: 36 Edwards (Sapien/ Sapien XT/ Sapien 3), 8 CoreValve (CoreValve/R/ PRO), 2 Lotus and 2 Jena Valve. The left coronary artery showed a higher rate of selective cannulation if compared to the right one (97% vs. 80%, p=0.022). Left main and left anterior descendent artery were the vessels most commonly treated (17 and 11 interventions, respectively). A 98% of PCI success was achieved; one death occurred after the index procedure.

Conclusions. CA or PCI after TAVI is a safe procedure. The success rate of selective cannulation is lower in right coronary arteries if compared to the left ones. Differences in success rates among the implanted types of bioprosthesis require larger studies for a better validation.

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C41

COMPARISON BEETWEN RFRAND FFR IN ALL-COMERS ACS PATIENTS. A SINGLE CENTER EXPERIENCE

Vincenzo Manganiello, Gianluca Caiazzo, Luca Golino, Mario De Michele, Maria Riccardi, Valeria Piccolo, Michele Cimmino, Luciano Fattore

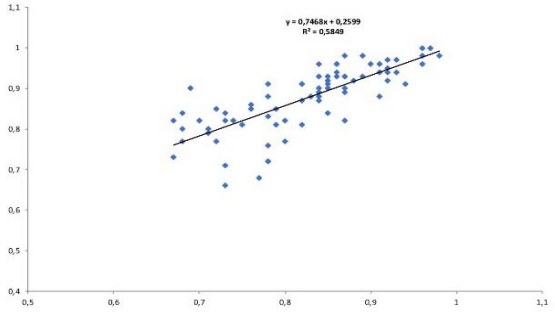
Cardiologia, Ospedale S. G. Moscati, Aversa

Background. Physiology based coronary revascularization by FFR guidance improve clinical outcomes compared to angiography-guided PCI. Instantaneous wave-free ratio (iFR) has been proven to be non inferior to FFR for MACE at 1 year. RFR (Resting Full-cycle Ratio) is a novel non-hyperemic index of coronary stenoses severity based on unbiased identification of Pd/Pa ratio independent of the ECG and waveform landmark identification that scans for the largest drop in pressure over the entire cardiac cycle. In VALIDATE- RFR study, RFR was highly correlated to iFR. In RE-VALIDATE-RFR, diagnostic performance between RFR and iFR in a real world population was tested, resulting in a substantially diagnostic equivalence. RFR showed a significant correlation with iFR (R=0.979) higher than with FFR (R=0.822, 79.2% overall accuracy, similar to other non-hyperemic pressure ratios).

Methods. From September 2018 to June 2019 a total of 62 all comers consecutive ACS patients (77 lesions) were investigated for epicardial stenosis of equivocal angiographic severity. In STEMI patients, after treatment of culprit coronary lesion, investigation of non-culprit lesions of doubtful significance were deferred after three days on average and maximal hyperemia was obtained via continuous intravenous Adenosine infusion. In UA/NSTEMI patients, instead, the physiology assessment of unclear or borderline angiographic coronary stenoses were performed at time of the index procedure. Obviously, PCI treatment strategy was FFR-value guided.

Results. 77 total lesions from 62 consecutive ACS patients (STEMI: 6, NSTEMI: 29, Unstable Angina: 27, Male: 46, Female: 16, Diabetes: 22, CKD: 11) were investigated. RFR and FFR values were inserted in our database. Lesions location: DA: 53, Diagonal branches: 5, Circumflex: 13, RCA: 6. In our population we reported only 5 discordant value out of 77 lesions (3 DA, 1 RCA, 1 Cx) resulting in a 93.5% concordance between RFR and FFR value, (Correlation= 0.74387; R2= 0,5849) similar than reported in recent literature.

Conclusions. In our population (62 all-comers ACS patients, 77 lesions) the new resting index RFR showed good correlation to the gold standard FFR, similar than reported in recent literature.



C42

LONG-TERM OUTCOMES AFTER LEFT MAIN TREATMENT WITH EVEROLIMUS ELUTING STENTS: A SINGLE CENTER GENDER-BASED PERSPECTIVE

Sebastiano Gili, Daniela Trabattoni, Giovanni Teruzzi, Piero Montorsi, Franco Fabbiocchi, Giuseppe Calligaris, Luca Grancini, Stefano Galli, Paolo Ravagnani, Antonio Bartorelli

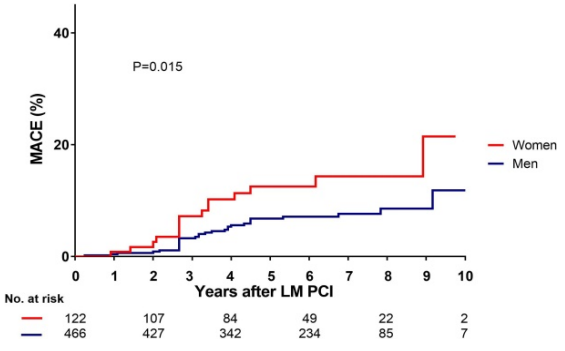
Cardiologia Interventistica, Centro Cardiologico Monzino, IRCCS, Milano

Background. Everolimus-eluting stents are largely used for left main (LM) percutaneous coronary interventions (PCI). Long-term follow-up of patients undergoing LM PCI in a real world clinical setting, in particular women, have been scarcely reported.

Methods. Consecutive patients undergoing LM PCI with EES at a single Institution from December 2006 to April 2016 were included. Baseline clinical features, including procedural data, were collected. Main outcome assessed was the occurrence of major adverse cardiovascular events (MACE) as a composite of death, myocardial infarction or target lesion revascularization at follow-up.

Results. Overall, 589 patients (20.8% women), were included in the present analysis. Women were older, had lower BMI and more frequently hypertensive compared to men. Main clinical presentation was stable CAD; unstable angina was more frequently observed in women compared to men, whereas STEMI was less frequent. After 69.7 ± 28.3 months of follow-up, 47 patients overall experienced MACE (1.43 per 100*patients/year). MACE rate was higher in female compared to male

patients, with a rate of 2.49 and 1.17 per 100*patients/year, respectively (P=0.015). The difference was driven mainly by higher mortality in women (0.89 vs. 0.15 per 100*patients/years, P=0.002). At multivariable Cox regression, female gender was independently associated with an increased risk of MACE at follow-up (HR 2.21, 95% CI 1.20-4.08, P=0.011).
Conclusions. EES can be safely and effectively adopted for LM PCI. Women, in particular, should be carefully selected and monitored, as they might experience a higher rate of adverse events at follow-up.



C43

TROPPO VECCHI PER ESSERE SOTTOPOSTI A RIVASCOLARIZZAZIONE PERCUTANEA DELLE OCCLUSIONI CORONARICHE CRONICHE (CTO)? EFFICACIA E SICUREZZA DELLA PROCEDURA NELLA POPOLAZIONE ANZIANA

Mattia Squillace, Martina Nuzzo, Luca Mircoli
Medicina Interna, Malattie dell'Apparato Cardiovascolare, Ospedale Maggiore Policlinico IRCCS Cà Granda, Milano

Premessa. La rivascolarizzazione percutanea (PCI) delle CTO è uno dei trattamenti più efficaci nel trattamento dell'angina refrattaria. Sebbene la rivascolarizzazione di una CTO migliori i sintomi e la qualità della vita, quest'ultima risulta comunque una procedura ad alto rischio se paragonata ad un'angioplastica elettiva di routine. Per questo motivo la CTO PCI troppo spesso non è considerata una valida opzione per i pazienti più anziani con angina refrattaria. Lo scopo di tale lavoro è pertanto valutare l'efficacia e la sicurezza della CTO PCI in una popolazione anziana (età >75 anni) rispetto ad una popolazione più giovane.
Materiali e metodi. Sono stati analizzati i dati di tutti i pazienti sottoposti a CTO PCI dal 01/01/2013 al 31/12/2018 nel nostro centro. Come endpoint primario di efficacia si è considerato l'incidenza di eventi cardiaci avversi maggiori (MACE) durante il follow-up nei due gruppi della popolazione oggetto di studio (età superiore e inferiore ai 75 anni). Come endpoint di sicurezza, invece, si sono valutate le complicanze legate alla procedura durante il periodo di ospedalizzazione e nei 15 giorni successivi. Per valutare i tassi di sopravvivenza libera da MACE tra i due gruppi si è usata l'analisi Kaplan-Meier.
Risultati. Nello studio sono stati inclusi 121 pazienti, 28 dei quali di età superiore ai 75 anni (23%). La maggior parte dei pazienti è di sesso maschile (86%). Il 32% dell'intera popolazione oggetto di studio era affetto da diabete, l'8% da insufficienza renale cronica (creatinina uguale o superiore a 2 mg/ml), il 76% era iperteso e il 40% riferiva familiarità per cardiopatia ischemica. Non sono riportate differenze statisticamente significative nella distribuzione dei fattori di rischio tra i due gruppi d'età. Durante il follow-up sono stati riscontrati 8 eventi MACE (4 morti per arresto cardiaco, 3 target vessel revascularization, 1 target lesion revascularization). Degli eventi totali, 2 (7%) si sono verificati nel gruppo con più di 75 anni d'età e i restanti 6 casi (6,5%) nell'altro gruppo. Tale minima differenza non è risultata statisticamente significativa. Il tempo medio di follow-up è stato di 9 mesi per i pazienti con più di 75 anni e di 12 mesi per quelli sotto i 75 anni. L'analisi di Kaplan-Meier dei tassi di sopravvivenza liberi da MACE non differisce significativamente tra i due sottogruppi. Sono state riportate solo 3 complicanze relative alla procedura (2,5%) e si tratta in tutti i casi di perforazioni coronariche, una delle quali ha richiesto una pericardiocentesi urgente. Il tasso di successo della procedura di rivascolarizzazione tra i due gruppi è stato analogo (80% per quelli sopra i 75 anni contro il 82% del gruppo più giovane).
Conclusioni. L'efficacia e la sicurezza della CTO PCI non sembra essere influenzata dall'età. Nonostante sia necessario realizzare altre valutazioni, la CTO PCI al momento potrebbe rappresentare una valida opzione per l'angina refrattaria anche nei pazienti più anziani.

C44

GENDER-RELATED DIFFERENCES AMONG PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION UNDERGOING PRIMARY ANGIOPLASTY: A PROPENSITY SCORE MATCHED ANALYSIS FROM A LARGE REAL-WORLD COHORT INCLUDING 1981 PATIENTS

Francesco Tomassini[1], Enrico Cerrato[2], Cristina Rolfo[1], Matteo Bianco[2], Luca Lo Savio[1], Alicia Quirós[3], Mauro Echavarria-Pinto[4], Sara Giolitto[1], Emanuele Tizzani[1], Antonella Corleto[1], Giorgio Quadri[1], Rosario Tripodi[1], Federico Giabobbe[2], Alfonso Franzè[1], Alessandro Careggio[2], Davide Belliggiano[2], Davide Minniti[1], Ferdinando Varbella[1]
[1]Ospedale degli Infermi, Rivoli, [2]San Luigi Gonzaga University Hospital, Orbassano, [3]Hospital Clinico San Carlos, Madrid, Spain, [4]Hospital General ISSSTE, Querétaro, Mexico

Background. Female gender is believed to be a significant risk factor for mortality among patients with ST- segment elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary interventions (pPCI).
Methods. We collected data on all consecutive STEMI patients treated with pPCI within 12 hours comparing males vs. females. Primary endpoint was long-term mortality after the first months from hospital discharge, secondary endpoint were 30-days mortality, 30 days and long term BARC ≥ 2 bleeding.
Results. From March 2006 to December 2016, 1981 patients underwent pPCI at our hospital, 484 (24.4%) females. Compared to men, women were older (mean age 71.3 ± 11.6 vs 62.9 ± 11.8 years, P<0.001), less smokers (26.7% vs 72.7%, P<0.001), more diabetic (28.0% vs 22.3%, P<0.002), more hypertensive (69.6% vs 61.3%, P<0.001), presented more with shock at baseline (13.2% vs 9.0%, P=0.006), had a higher symptoms-to-balloon time (5.36 ± 3.97 vs 4.47 ± 3.67 hours, P<0.001).Moreover, women were less likely to receive glycoprotein IIb-IIIa inhibitors (59.5% vs 71.4%, P <.001) and stent (79.5% vs 86.6%, P=0.01). At 30 days and long-term follow-up (mean 4.9 ± 3.2 years) female sex was associated with higher mortality (8.9% vs 4.0%, P <.001 and 23.8% vs 18.4%, P=0.01 respectively). After a propensity score matching, 379 men and 379 women were selected. Female sex continued to be associated with higher death rate at 30 days (9.5% vs 5.5%, P=0.039) but not in the long term among survivors (25.6% vs 21.4%, P=0.170).
Conclusions. Compared with men, women with STEMI undergoing pPCI had higher 30-days mortality. However, among survivors, long-term mortality was similar. Even if residual confounders cannot be rule out, this difference in outcome could be in part explained by biological sex-related differences.

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HIGH BLEEDING RISK (HBR) STATUS IN ELDERLY PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTION: EVALUATION OF THREE DIFFERENT RISK SCORES

Maria Scalamogna, Cristina Iapicca, Luca Sperandeo, Domenico Florimonte, Alessandra Spinelli, Anna Franzone, Luigi Di Serafino, Eugenio Stabile, Plinio Cirillo, Bruno Trimarco, Raffaele Piccolo, Giovanni Esposito
Division of Cardiology, Department of Advanced Biomedical Sciences, University of Naples Federico II, Naples

Background. Aging is an emerging global problem. After percutaneous coronary intervention (PCI), elderly people have a higher risk of mortality than the younger counterpart. Bleeding related to antithrombotic therapy and ischemic events associated with disease progression are the main causes. Few data are available on high bleeding risk (HBR) status among elderly patients undergoing PCI. The aim of this study was to evaluate the high bleeding risk status among elderly patients undergoing PCI.
Methods. Patients aged 75 years or more undergoing PCI with drug-eluting stents at the Federico II University Hospital from March 2013 until April 2019 were included in this study. Three bleeding risk scores (DAPT score, PARIS score and PRECISE-DAPT score) were calculated for each patient.
Results. A total of 629 patients (mean age 79.9±4.1 years, 65.3% males) was examined. The proportion of HBR status was 86% according to the DAPT score, 87% according to the PARIS score, and 68% according to the PRECISE-DAPT score. The difference in HBR status was statistically significant between DAPT and PRECISE-DAPT scores (p=0.019) and between PARIS and PRECISE-DAPT scores (p<0.001). HBR status in elderly patients was not associated with aging by using the DAPT score (p=0.60), whereas the probability of HBR increased with age when PARIS and PRECISE-DAPT scores were applied (p<0.001 for both). The discrepancy in HBR status across the three scores was more evident between 75 and 80 years (86%, 59%, and 75% according to DAPT, PARIS and PRECISE-DAPT scores), while patients aged 80 years or more tended to qualify as HBR irrespective from the type of score.
Conclusions. HBR status in elderly patients (≥75 years) undergoing PCI is present in about 9 out of 10 patients by using the DAPT and PARIS scores and in about 7 out 10 patients by using the PRECISE-DAPT score.

C46

REALIZE STUDY: RIVAROXABAN TREATMENT IN CAD POPULATION AT HIGH RESIDUAL RISK: PERSONALIZED EVALUATION

Francesco Summaria[1], Alessio Stanzione[2], Marina Mustilli[3], Gregory A. Sgueglia[1], Fabrizio D'Errico[2], Gaetano Gioffrè[1], Giuseppe Ferraiuolo[3], Achille Gaspardone[1]
[1]UOC Cardiologia, [2]UOC Cardiologia, ASL Roma 2, Ospedale Sant'Eugenio, Roma, [3]UOC Cardiologia, ASL Roma 2, Ospedale Sandro Pertini, Roma

Premessa. Sebbene negli ultimi 20 anni la mortalità per infarto miocardico e ictus si sia ridotta rispettivamente del 40% e del 50%, nel mondo gli eventi cardiocerebrovascolari sono la prima causa di mortalità e morbilità. Fra i pazienti che sopravvivono ad un infarto del miocardio o ad un ictus, il 10% incorre in un ulteriore evento entro 1 anno ed il 20% entro 4 anni. In ambito di prevenzione secondaria mentre la terapia antiipertensiva è notevolmente migliorata e passi in avanti significativi si stanno compiendo per l'ottimizzazione della terapia ipocolesterolemizzante la gestione del rischio aterotrombotico a medio e lungo termine ancora non ha trovato una strategia di trattamento definitiva. I pazienti dimessi con diagnosi di sindrome coronarica acuta (SCA) al termine della finestra protettiva della della duplice terapia antiaggregante (DAPT) convenzionalmente fissata a 12 mesi entrano in una fase ''vulnerabile'' in cui la probabilità di recidive ischemiche o di nuovi eventi cerebrovascolari diventa significativamente più alta. I risultati dello studio COMPASS forniscono nuove possibilità di trattamento per i pazienti dopo una SCA.

Materiali e metodi. Come prosecuzione operativa della recente survey nazionale condotta dal GISE sulla conoscenza dello studio COMPASS, per un periodo di osservazione di tre mesi, nelle UTIC e nelle Unità di Cardiologia Interventistica della ASl Roma 2, un Heart Prevention Team (cardiologo intensivista, cardiologo clinico, cardiologo interventista) valuterà tutta la popolazione SCA per un triplo rischio combinato: rischio di recidiva coronarica, rischio di stroke e rischio di sanguinamento. Inoltre utilizzando i criteri di arruolamento del COMPASS verranno selezionati tutti i pazienti che potrebbero beneficiare di un trattamento con rivaroxaban a dose vascolare e ASA al termine della DAPT. Allo scopo di ottimizzare gli interventi di prevenzione secondaria nel periodo di follow-up, favorendo quindi un data-sharing con chi gestirà la presa in carico nel periodo post-dimissivo, ogni paziente avrà in allegato alla propria lettera di dimissione un foglio aggiuntivo/card/pen drive in cui verranno riportati i criteri di inclusione nella categoria ad alto rischio aterotrombotico, un bilancio rischio-beneficio ad iniziare la terapia di associazione rivaroxaban + ASA e gli altri target (pressori e di colesterolo LDL) raggiunti o da raggiungere con interventi terapeutici mirati.

Risultati. Questo registro prospettico i cui risultati verranno presentati in occasione del Congresso Nazionale GISE 2019 ha lo scopo di identificare, la popolazione a più alto rischio di eventi, definirne il peso epidemiologico e le caratteristiche basali, indirizzando verso strategie il più possibile complete di trattamento del rischio residuo.

Conclusioni. La prevenzione secondaria in pazienti con SCA è volta a ridurre in maniera significativa la probabilità di recidiva attraverso un approccio globale alla gestione del rischio residuo. Dopo una SCA la probabilità di evento non è solo legata alla riduzione degli episodi ischemici coronarici ma anche alla riduzione degli eventi cerebrovascolari che come ampiamente dimostrato in letteratura sono altamente prevalenti in questa popolazione.

C47

POST-DISCHARGE BLEEDING AFTER AN ACUTE CORONARY SYNDROME AMONG PATIENTS WITH ADVANCED AGE TREATED WITH DIFFERENT DUAL ANTIPLATELET THERAPY REGIMENS: A REPORT OF 16,653 PATIENTS FROM TWO REAL-WORLD MULTINATIONAL REGISTRIES

Matteo Bianco[1], Enrico Cerrato[2], Alessandro Careggio[1], Giorgio Quadri[2], Paola Destefanis[1], Alessia Luciano[1], Federico Giacobbe[1], Maria Giulia Perrelli[1], Davide Belliggiano[1], Ilaria Meynet[3], Fabrizio D'Ascenzo[4], Laura Montagna[1], Ferdinando Varbella[2]
[1]Cardiology Division, San Luigi Gonzaga University Hospital, Orbassano, [2]Interventional Cardiology Unit, Infermi Hospital and San Luigi Gonzaga University Hospital, Rivoli and Orbassano, [3]Cardiology Division, Infermi Hospital, Rivoli, [4]Cardiology Division, Città della Salute e della Scienza Hospital, Torino

Background. Despite latest guidelines recommend administration of dual antiplatelet therapy (DAPT) with more potent P2Y12 inhibitors such as prasugrel or ticagrelor in acute coronary syndrome (ACS) patients, the safety of this strategy in elderly patients is still a matter of debate due to the intrinsic risk of bleeding in such population as experienced in "everyday clinical practice". The perceived higher risk of bleedings in elderly patients often leads to an undertreatment in case of ACS using clopidogrel instead of ticagrelor. We sought to assess the incidence of major bleedings (MB) in patients with ACS who underwent PCI and treated with DAPT by comparing elderly patients, defined as >75 and >80 years of age versus a younger population of ACS patients in order to evaluate the safety of ticagrelor versus clopidogrel in a population considered at high bleeding risk.

Methods. A patient-level analysis was conducted merging together two large real-world databases: the BLEEMACS, an international multicenter investigator-initiated retrospective registry including 16 centres across 10 countries, and the RENAMI, a retrospective, observational, multicenter, and international registry involving the participation of 11 centres from 6 European countries. Both registries enrolled patients discharged with a definitive diagnosis of ACS who underwent PCI and treated with DAPT. Baseline clinical features were recorded, including cardiovascular history and risk factors, medications, type of stent and vascular access. MB were defined as: intracranial bleeding or any other bleeding leading to hospitalization and/or red blood cell transfusion. We divided our population in two groups: <75 years old (y.o) vs >75 y.o (GROUP A), <80 y.o vs >80 y.o (GROUP B). We excluded patients treated with prasugrel because its use is not allowed in patients > 75 years old and patients treated with oral anticoagulants. Cumulative incidences of bleedings were calculated using the Kaplan-Meier method.

Results. We included in the analysis 16.653 patients (13153 pts <75 years, 3500 pts >75 years, 1717 pts >80 years). The most common clinical presentation of ACS was UA/NSTEMI in elderly patients (Group A: (<75 years) 41.3% vs 51% (>75 years) p<0.0001; Group B (<80 years) 42.5% vs 51.1% (>80 years) p<0.0001). Ticagrelor was significantly underutilized among elderly patients (Group A: (<75 years) 20.8% vs 16.3% (>75 years) p<0.0001; Group B (<80 years) 20.5% vs 13.9% (>80 years) p<0.0001). The Kaplan-Meier curve did not show statistical differences in major bleedings incidence between patients treated with ticagrelor or clopidogrel irrespectively of age.

Conclusions. Considering these two real-world multinational registries we did not find any substantial difference in the incidence of bleeding between patients <75 or <80 years and older patients treated with ticagrelor or clopidogrel. The age does not seem to represent a contraindication per se to the use of ticagrelor favouring clopidogrel in the setting of ACS in order to reduce MB. Further studies focused on elderly patients could provide more information regarding safety of DAPT in this expanding clinical category.

C48

CLIMATE CHANGES AND ST-ELEVATION MYOCARDIAL INFARCTION TREATED WITH PRIMARY PERCUTANEOUS CORONARY ANGIOPLASTY

Massimiliano Scappaticci[1], Francesco Versaci[1], Giuseppe Biondi-Zoccai[1], Angela Dei Giudici[1], Enrica Mariano[2], Antonio Trivisonno[3], Sebastiano Sciarretta[1], Valentina Valenti[1], Antonino Stipo[1], Antonio Di Matteo[1], Rebecca Casati[1], Francesco Romeo[2]
[1]UOC UTIC-Cardiologia-Emodinamica, Ospedale Santa Maria Goretti, Latina, [2]Cattedra di Cardiologia, Tor Vergata University, Rome, [3]UOC Cardiologia, Ospedale A. Cardarelli, Campobasso

Background. The incidence of acute myocardial infarction is influenced in a complex fashion by climate changes, with most data suggesting that lower temperatures are associated with an increased risk. The impact of seasonal changes on this association has been incompletely appraised, especially in the modern era of primary percutaneous coronary intervention (PPCI). We aimed to appraise the overall and season-specific impact of climate changes on the daily rate of PCCI.

Methods. Details on PPCI and climate changes were retrospectively collected in three high- volume Italian institutions with different geographical features. The association between rate of PPCI and temperature, atmospheric pressure (ATM), humidity and rainfall was appraised with Poisson mixed models, with overall analyses and according to season of the year.

Results. Details on 6880 days with a total of 4132 PPCI were collected. Overall adjusted analysis showed that higher minimum atmospheric pressure 3 days before PPCI were associated with lower risk (regression coefficient=0.999 [95% confidence interval 0.998-1.000], p=0.030). Focusing on season, in Winter PPCI rates were increased by lower same day mean temperature (0.973 [0.956-0.990], p=0.002) and lower rainfall (0.980 [0.960-1.000], p=0.049). Conversely, in Spring greater changes in atmospheric pressure 3 days before PPCI were associated with increased risk (1.023 [1.002-1.045], p=0.032), with similar effects in Summer for minimum temperature on the same day (1.022 [1.001-1.044], p=0.040).
Conclusions. Climate has a significant impact on the risk of PPCI in the current era, with a complex interplay according to season. Higher risk is expected with lower minimum atmospheric pressure in the preceding days, lower rainfall in Winter, greater changes in atmospheric pressure in Spring, and higher temperatures in Summer. These findings have important implications for prevention strategies.

Coronary interventions 8

C49

NO-REFLOW COMPLICATING CHRONIC TOTAL OCCLUSION CORONARY REVASCULARIZATION

Gianni Dall'Ara[1], Luca Testa[2], Alessio Mattesini[3], Carlo Tumscitz[4], Gabriele Luigi Gasparini[5], Simone Grotti[1], Mario Bollati[2], Fabio Tarantino[1], Carlo Di Mario[3], Jacopo Andrea Oreglia[6]

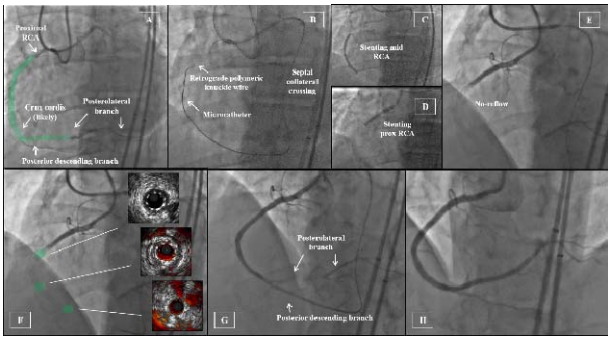
[1]UO Cardiologia, Ospedale Morgagni-Pierantoni, Forlì, [2]Cardiologia, IRCCS Policlinico San Donato, San Donato Milanese, Milano, [3]Structural Interventional Cardiology, Careggi University Hospital, Firenze, [4]Cardiology, University of Ferrara, Ferrara, [5]Department of Invasive Cardiology, Humanitas Research Hospital, Rozzano, Milano, [6]Interventional Cardiology Unit, Niguarda Hospital, Milano

Background. No-reflow phenomenon is usually not considered among complications of CTO PCI, with only limited data reported in few patients, often with dramatic clinical consequences. The aim of the study was to assess the incidence of no-reflow in patients undergoing chronic total occlusion (CTO) percutaneous coronary intervention (PCI), analyze possible causes, differential diagnosis, and identify useful management approaches.

Methods. In this multicenter observational study, all CTO PCI procedures performed between January 2018 and April 2019 were reviewed to collect no-reflow complications, defined as thrombolysis in myocardial infarction (TIMI) flow ≤1 in a patent epicardial artery. Patient clinical, anatomical and procedural characteristics were analyzed.

Results. Out of 461 PCIs, 2 were complicated by no-reflow (0.43%). In one case PCI was performed on a long segment of the right coronary artery, after use of a dissection-reentry technique by knuckle wiring. In the second patient, no-reflow developed after proximal left anterior descending artery stenting, with a short subintimal tracking. Intravascular ultrasound was used to exclude complications in the epicardial vessel in both cases. Distal embolization seems the most plausible cause, and intracoronary adenosine effectively improved flow. Both patients had a type 4a myocardial infarction, asymptomatic in the first case, in the second associated with chest pain, ECG changes and new regional wall motion abnormality at echocardiography.

Conclusions. No-reflow in CTO recanalization is rare but associated with a high risk of periprocedural myocardial infarction, with incomplete protection from ischemia offered by the preexisting collateral network.



C50

LONG-TERM OUTCOMES AND PREDICTORS OF MAJOR ADVERSE CARDIAC EVENTS IN A HIGH RISK POPULATION UNDERGOING PCI FOR LEFT MAIN CORONARY ARTERY DISEASE: A REAL-WORLD STUDY

Salvatore Davide Tomasello, Salvatore A. Azzarelli, Simone Finocchiaro, Francesco Scardaci, Vincenzo Argentino, Francesco Amico

Ospedale Cannizzaro, Catania

Background. Nowadays randomized trials suggest that percutaneous coronary intervention (PCI) is an acceptable or perhaps preferred alternative to CABG in selected patients with severe left main trunk stenosis (LMTS). Although it is still a matter of debate whether the indications are appropriate or not, the proportion of LMTS treated with PCI is bound to rise in the near future. This manuscript is aimed to evaluate the clinical and procedural outcomes in a "real-world" high risk cohort of patients with LMTS which underwent PCI.

Methods. This study includes consecutive patients, underwent PCI with (drug eluting stens) for severe de novo LMTS; the choice of revascularization strategy was at operator discretion, taking into account the clinical presentation of patients and in some cases the patient's refuse to undergo coronary artery by-pass surgery. All patients who underwent angioplasty were prospectively entered into a dedicated database.

Results. Since January 2013 to December 2017 a total of 174 consecutive patients underwent to LMTS PCI. Notably, in most of the cases the clinical presentation at the time of index procedure was an acute coronary syndrome (55.2%). the population was at high coronary anatomy complexity and a high risk of cardiovascular events (Syntax score, STS score and EuroSCORE II respectively 29±10, 8±13 and 16.7±16.7). The mean of left ventricular ejection fraction was 46±9%. The intra aortic balloon pump was used in 56.3% of cases. Angiographic success was achieved in 96.5% of cases with a rate of complete revascularization obtain in 71.3% of patients. At an average of 34.8±27.6 months the rate of death was 23% (40/174). Ten patients dead at hospital (5.7%) for clinical complication related to the initial clinical presentation and or procedural complication (cardiogenic shock 4/10, ventricular arrhythmias 4/10 and acute stent thrombosis 2/10). The cumulative cardiac death was 17.2% (30/174), 6 patients died for cancer, 2 for gastro-intestinal bleeding and 2 due to an acute peritonitis. The late thrombosis occurred in four patients (2.2%) while very late thrombosis in only two cases (1.1%). A multivariate analysis was performed in order to sort out the predictor of major adverse cardiac events and only the presence of high STS score was recognised as independent predictors of MACE at adjusted Cox proportional-hazard analysis (HR 3.883; 95% CI 1.51 9,98; p=0.005). Of note, the analysis did not show any influence of EuroSCORE II, Syntax score and other clinical factor of patient complexity.

Conclusions. This study reports a long-term clinical outcome of a real world cohort of high-risk patients treated with PCI for LMTS. Although the outcomes were worst in comparison with data derived from recent randomized trials, in a cohort of consecutive high risk patients were achieved a long-term survival in 77% of cases. The study findings could be used as hypothesis generating for future randomized study, which need to be executed in the setting of very high risk patients affected by LMTS.

C51

OUTCOMES A LUNGO TERMINE DELL'IMPIANTO DI BVS ABSORB NEL REGISTRO REABSORBS

Massimo Leoncini, Claudio Rapetto, Raffaele Scardala

SSD Cardiologia Interventistica, Ospedale Civile Sanremo, Sanremo

Premessa. 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".

Materiali e metodi. 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.

Risultati. 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. La complessità delle lesioni è data principalmente dalla lunghezza ≥20 mm (161, 50.2%), dalla presenza di biforcazioni (92, 28.7%) o di trombo (100, 31.2%), mentre calcificazioni lievi-moderate (mai severe) erano presenti solo in 16 lesioni (5.0%). 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 atmosfere (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 FU mediano di 1346 giorni (range interquartile 1121-1713) si sono verificati 3 MCV (1.4%) non correlate al BVS, 2 very late definite ARC-ScT (0.9%), 6 TV-IMA (2.7%), 19 TVF (8.6%), 15 TVR (6.8%), 10 ID-TLR (4.5%), 9 restenosi (4.1%).

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 su lesioni non calcifiche è associata a buon SA in acuto e ad un accettabile numero di OC a un follow-up mediano di 45 mesi.

C52

FAST ON DAPT CON CANGRELOR DURANTE PCI: EFFICACIA E SICUREZZA IN UN REGISTRO MONOCENTRICO

Dario Formigli[1], Tullio Niglio[2], Francesco Moscato[1], Vitangelo Franco[1], Marino Scherillo[1]
[1]Azienda Ospedaliera San Pio, Benevento, [2]PO Santa Maria della Pietà, Nola

Premessa. Un adeguato livello di antiaggregazione piastrinica è fondamentale nella prevenzione delle complicanze ischemiche post-PCI. Considerando il tempo necessario per l'attivazione farmacologica degli anti P2Y12 orali, i livelli intraprocedurali di inibizione piastrinica possono non essere adeguati, nonostante la pronta somministrazione del farmaco, soprattutto nel setting acuto con trombogenicità elevata. Cangrelor, antagonista selettivo del recettore P2Y12 piastrinico, garantisce una rapida inibizione dell'aggregazione piastrinica prontamente reversibile con la sua sospensione.
Materiali e metodi. Questo registro monocentrico ha valutato prospetticamente l'efficacia clinica e la sicurezza di cangrelor in 85 pazienti, di età media di 66.5 ± 10.3 anni, ad alto rischio ischemico, sottoposti a PCI. Il 64.7% erano affetti da SCA di cui il 51% con diagnosi di SCA-STEMI. 12 pazienti (14.1%) presentavano fibrillazione atriale. Posta indicazione a PCI, cangrelor veniva somministrato secondo protocollo e, dopo l'infusione, veniva effettuato il carico di anti-P2Y12 orale. L'endpoint primario era il composito intraospedaliero di morte cardiaca, infarto periprocedurale e TVR. L'endpoint di sicurezza era l'incidenza di sanguinamenti maggiori clinicamente rilevanti (BARC ≥2).
Risultati. Nel 97.6% dei casi si è ottenuto il completo successo procedurale, mentre in due casi non si è riusciti ad impiantare lo stent per motivi tecnici. Nel 96.4% dei casi il flusso coronarico post PCI è stato ottimale, con 3 episodi di no-reflow, di cui 2 completamente reversibile dopo adenosina intracoronarica. Non vi è stata necessità di utilizzo di inibitori GPIIb/IIIa in bailout. L'incidenza dell'endpoint composito di efficacia è stata dell'8.2%, con 5 casi di infarto periprocedurale (5.8%) e 2 decessi (2.4%), di cui uno intraprocedurale e l'altro, durante la degenza, come arresto cardiaco (probabile trombosi dello stent), mentre non si sono verificate trombosi dello stent definite e/o TVR. Sono stati registrati 4 casi di sanguinamento (4.7%), di cui 3 BARC 2, di cui due casi di ecchimosi in corrispondenza del sito di puntura procedurale ed un caso di ematoma della tasca, sede di impianto di pacemaker durante il ricovero ed 1 caso di BARC 3c per emorragia intracranica e successivo intervento neurochirurgico. In linea con l'elevato profilo di rischio ischemico nel registro, i livelli di troponina ultrasensibile post PCI sono risultati significativamente aumentati rispetto al basale (7.6±21.2 vs 28.7±41.6 µg/mL; p=0.01)
Conclusioni. In questo registro, cangrelor sembra essere efficace e avere buoni margini di sicurezza, in pazienti ad alto rischio sottoposti a PCI e naive da anti P2Y12.

Miscellaneous 2

C53

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

Andrea Rognoni, Martina Solli, Marco Mennuni, Roberta Rosso, Vincenzo Galiffa
Cardiologia, Dipartimento Cardio-Toraco-Vascolare, Novara

Background. Chronic total occlusion (CTO) is usually defined as a total obstruction (TIMI-0 flow) of a coronary artery greater than three months duration. They account for about one-third of the coronary lesions. The rational behind CTO recanalization is the improvement of anginal status, left ventricular ejection fraction and quality of life, the reduction of surgical revascularisation and the coronary long term patency. Procedural success depends upon careful review of the angiogram including stump morphology, length of occlusion, calcification and presence and extent of collaterals (J CTO score). Despite of high prevalence, only 8%–15% of the patients undergo PCI. The prognostic value of postprocedural high-sensitivity troponin T (hsTnI) after CTO procedure unclear. Aim: We aimed to assess, in our retrospective registry, the prognostic value of elevated hsTnI after elective CTO procedure.
Methods. The current registry included 134 patients undergoing elective CTO procedure between January 2015 and January 2010. Clinical, angiographic and procedural characteristics were correlated with any or at least five times the 99th percentile hsTnI elevation, as well as a 1-year combined endpoint of major adverse cardiac, cerebrovascular events and mortality.
Results. Post CTO hsTnI elevation was observed in 79% (83/134); in 42% (31/134) of cases hsTnI elevation was more frequent in more complex patients (postcoronary artery bypass grafting, peripheral vascular disease, chronic kidney disease, heart failure and multivessel disease) as well as in the more complex CTO procedures (JCTO scores 3). After a medium follow-up of 250 (21) days postprocedural hsTnI elevation is not associate with major adverse events (death, myocardial infarction and cerebrovascular events).
Conclusions. In patients undergoing elective CTO procedure, postprocedural hsTnI elevation is frequent, but is not correlated with higher adverse cardiac events and mortality rates after 1-year FU in our small study population, suggestive of the limited long term impact of troponin elevation.

C54

INTRAVASCULAR LITHOTRIPSY FOR THE MANAGEMENT OF UNDILATABLE CORONARY STENT: THE SMILE REGISTRY

Alfonso Ielasi[1], Gaetano Gioffrè[2], Gaetano Morabito[3], Bernardo Cortese[4], Salvatore Colangelo[5], Francesco Arioli[6], Mauro Maioli[7], Fabrizio Tomai[8], Piergiuseppe Greco Lucchina[9], Fabrizio Ugo[5], Stefano Benedetto[10], Matteo Pennesi[11], Gabriele Tumminello[12], Massimo Leoncini[13], Francesco Bedogni[14], Maurizio Tespili[15]
[1]Cardio-Toracico, Istituto Clinico S. Ambrogio, Milano, [2]U.O. Cardiologia, Ospedale S. Eugenio, Roma, [3]Ospedale S. Anna, Catanzaro, [4]San Carlo Clinic, Milan, [5]Ospedale San Giovanni Bosco, Torino, [6]Ospedale Fatebenfratelli, ASST Fatebenefratelli-Sacco, Milano, [7]S. Stefano Hospital, Prato, [8]European Hospital, Roma, [9]Santa Croce Hospital, Moncalieri, [10]Ospedale Galliera, Genova, [11]Ospedale Careggi, Firenze, [12]S. Andrea Hospital, Vercelli, [13]Sanremo Civil Hospital, Sanremo, [14]IRCCS Policlinico San Donato, San Donato Milanese, [15]Istituto Clinico S. Ambrogio, Milano

Background. Stent underexpansion is a well known risk factor for major adverse cardiac events. Existing tools to optimize stent expansion (e.g. non compliant balloons, very high pressure non compliant balloons) are sometimes ineffective, not readily available (e.g. excimer laser) or potentially associated with high risk of procedural complications (e.g. rotational atherectomy). Intravascular lithotripsy (IVL) has been recently shown to be effective and safe in dilating heavily calcified lesions in native coronary arteries but little is known about its performance in the management of under- expanded stents. Aim of this study was to evaluate the feasibility, effectiveness and safety of IVL in improving stent expansion when high/very high pressure non-compliant balloon inflation was ineffective
Methods. A multicenter, retrospective cohort analysis was performed in consecutive patients who underwent IVL to treat under-expanded stent following high/very high pressure non-compliant balloons expansion failure. The primary endpoint of successful IVL dilatation was defined as IVL balloon delivery at the target site followed by an increase of at least 1 mm2 in minimal stent cross-sectional area (MSA) on intracoronary imaging or an increase of at least 20% in minimal stent diameter (MSD) by quantitative coronary angiography (QCA). Secondary endpoints were peri-procedural cardiac death, target-vessel myocardial infarction (MI) and target lesion revascularization (TLR).
Results. Between January 2018 and April 2019, 34 patients with 39 under-expanded stents despite high and/or very high pressure balloon inflation were included. The majority of the under-expanded stents were second generation drug-eluting stents –DES- (n=26, 66.6%) implanted in the left anterior descending artery (n=18, 46.1%). Two cases (5.1%) of multiple layer of stents were treated as well as one case (2.5%) of acutely under-expanded DES. The median IVL balloon diameter was 3.1 mm (IQR: 2.5-3.5 mm) while the number of median pulses emitted was 56.7 (IQR: 30-80). IVL-assisted stent dilatation was successful in 33 cases (84.6%), with a significant improvement in MSD by QCA (post: 3.23 mm [IQR 3-3.3.5 mm] vs. pre: 0.81 mm [IQR: 0.35-1.2] pre-, p<0.00001) and MSA by intracoronary imaging (post: 7.81 mm2 [IQR: 6.43-7.79 mm2] vs. pre: 3.35 [IQR: 2.8-4 mm2], p<0.00001). DES-in-stent implantation following successful IVL assisted stent expansion was performed in 24 (72.7%) lesions while drug-coated balloon inflation in 9 (27.3%) lesions. Non-fatal peri-procedural ST-elevation MI occurred in one case (2.5%) because of the rupture of the IVL balloon. No cardiac death and TLR were reported.
Conclusions. Our data demonstrated the feasibility, efficacy ad safety of bail-out IVL to improve stent expansion in already undilatable stented lesions. Larger studies are needed to confirm our preliminary findings.

C55

INCIDENCE, PREDICTORS AND OUTCOMES OF VALVE-IN-VALVE TAVI: A SYSTEMATIC REVIEW AND META-ANALYSIS

Francesco Bruno[1], Francesca Giordana[1], Federico Conrotto[1], Andrea Saglietto[1], Fabrizio D'Ascenzo[1], Walter Grosso Marra[1], Stefano Salizzoni[2], Michele La Torre[2], Anna Chiara Trompeo[2], Maurizio D'Amico[1], Mauro Rinaldi[2], Gaetano De Ferrari[1]
[1]Cardiologia, [2]Cardiochirurgia, A.O.U Città della Salute e della Scienza, Torino

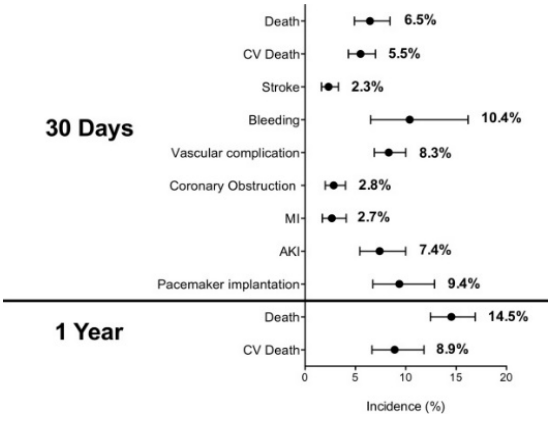
Background. Surgical aortic valve replacement has been the treatment of choice for patients with aortic valve disease before the arrival of

transcatheter aortic valve replacement (TAVI), although limited by degeneration of the bioprosthesis. "Redo" intervention itself is burdened by high risk of complications and valve-in-valve (ViV) TAVI could be a valid strategy of redo for patients with comorbidities. The aim of this meta-analysis is to give an overview of the state of the art of ViV TAVI, analysing efficacy, safety, intra-hospital outcomes and one year follow-up outcomes in literature and assess with meta-regression some possible predictors of survival at short and mid-term follow-up.

Methods. In this systematic review and meta-analysis, two independent reviewers (FB and FG) screened all studies investigating patients undergoing ViV TAVI. Mortality at 30 days and at 1 year were the primary end point, while procedural and short-term outcomes and echocardiographic parameters at hospital discharge were the secondary end points.

Results. Of 286 studies identified, 26 articles were included in this review, representing a combined total of 1448 patients. Median age was 78.8 years, 57.7% of the patients were male. Median STS-predicted risk of mortality was 9.4% while median Logistic EuroSCORE was 31.3%. Median age of the bioprosthesis was 10 years. Stenosis (45%), followed by regurgitation (31%) and mixed defects (21%) were the causes of prosthesis failure. Transfemoral approach was preferred (76%), with a prevalence of balloon expandable valve (73.3%). The diameter of the degenerated valve was ≤21 mm in 25.4%, 22-25 mm in 55% and >25 mm in 11.7% of the patients. Mean follow-up was 376 days. Overall and cardiovascular mortality at 30 days was 6.5% and 5.5% respectively, while at 1 year it was 14.5% and 8.9% respectively (Fig. 1). Short term outcomes are shown in Fig. 1. At meta-regression analysis study year (p<0.001), Logistic EuroSCORE (p<0.01) and valve diameter ≤21 mm (p<0.05) at 30 days, and stenosis as reason for failure (p=0.05) at 1 year were identified as possible source of heterogeneity.

Conclusions. ViV TAVI offers a valid strategy to treat high risk patients with a failure of bioprosthesis with satisfying results in terms of short and mid-term mortality. The short and mid-term outcomes are substantially superimposable to those of TAVI but future studies are needed to find predictors of long terms outcomes and to investigate outcomes in lower risk patients.



C56

LONG-TERM ANTICOAGULANT THERAPY AND INCIDENCE OF CONTRAST-INDUCED NEPHROPATHY IN PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTION

Sara Giannone, Elisabetta Ricottini, Rosetta Melfi, Camilla Cavallaro, Marzia Albano, Annunziata Nusca, Fabio Mangiacapra, Marco Miglionico, Paolo Gallo, Gian Paolo Ussia, Francesco Grigioni, Germano Di Sciascio
Policlinico Universitario Campus Biomedico di Roma, Roma

Background. Contrast-induced nephropathy (CIN) is associated with an impaired clinical outcome in patients undergoing percutaneous coronary intervention (PCI). Recent studies have suggested an association between deterioration of renal function and long-term oral anticoagulant therapy (OAT). The anticoagulation-related nephropathy (ARN) seems to be more common among patients treated with Vitamin K antagonists (VKAs) compared to patients treated with new oral anticoagulants (NOACs). The aim of the study was to investigate whether long-term treatment with VKAs was associated with an increased incidence of CIN compared to NOACs in patients treated with PCI.

Methods. This is a retrospective study enrolling patients on long term OAT (≥12 months) undergoing PCI. Blood samples were drawn before and at 24 and 48 hours after PCI for measurement of serum creatinine, with further determinations if clinically indicated; for this study, the post-procedure peak value was used. All patients received intravenous hydration with normal saline at 1 ml/hour/kg body ≥24 hours after intervention. The primary end point was incidence of CIN defined as a postintervention increase in serum creatinine ≥0.5 mg/dl or >25% from baseline according two different treatment.

Results. 112 patients were enrolled, 50 patients were treated with VKAs and 62 patients received NOACs. Incidence of CIN in the study was 6.25% (7 patients). Only one patient (1.26%) in NOACs group developed CIN compared to six patients (12%) in VKAs group (P=0.02). Baseline and post-procedural value of serum creatinine are not significantly different (respectively 1.10±0.28 vs 1.05±0.25 mg/dl, P=0.43 and 1.08±0.25 vs 1.06±0.25 mg/dl, P=0.67). No significant difference was identified in baseline and post- procedural creatinine clearance between two groups (respectively 66.05±23.68 ml/min vs 69.38±24.29 ml/min P=0.47 and 66.91±23.83 vs 69.12±28.49 ml/min, P=0.65). A shorter post-procedural hospital stay was identified in NOACs group (1.52±0.92 vs 2.26±2.68, P=0.045).

Conclusions. The present hypothesis generating study suggests that long-term treatment with VKAs is associated with a higher incidence of CIN compared to NOACs in patients undergoing PCI. These results support the use of NOACs in patients with high risk of exposure to contrast based procedure. Further studies are needed to define the pathophysiological pathways underlying this association.