Comunicazioni orali

Structural intervention 1

C1

FEASIBILITY AND SAFETY/EFFICACY PROFILE OF PERCUTANEOUS PATENT FORAMEN CLOSURE: NOBLESTITCH EL VS. OTHER DEVICES

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

Aim. To compare the feasibility, safety and efficacy of percutaneous PFO closure using two different techniques, the NobleStitch™ system and traditional devices (Amplatzer, and GORE).

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

Results. The main indications to PFO closure were represented by transient ischemic attack in 44 patients (57.1%), cryptogenic stroke in 17 patients (22.1%), decompression sickness in professional diving in 8 patients (10.4%), and disabling migraine with aura in 8 patients (10.4%). Successful device deployment was obtained in all patients. No major intraprocedural complications were observed. There was no significant difference between the two groups (Group A vs. Group B) in terms of mean days of follow-up (164±138 vs. 169± 171), and no significant residual right-to-left shunt (RLS grade ≤1): 35 patients (94.6%) in Group A, 40 patients (100%) in Group B, respectively; 2 significant RLS were registered in Group A, and none in Group B. There were no device-related complications in Group A, while a symptomatic thrombosis of the device at 60 days in Group B was found.

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

C2

PERCUTANEOUS TRANSSEPTAL MITRAL VALVE-IN-VALVE AND VALVE-IN-RING PROCEDURE IN HIGH-RISK PATIENTS: PROCEDURAL AND EARLY OUTCOMES IN THE VENETO REGION

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Percutaneous transseptal mitral valve implantation in degenerated bioprosthetic valves (TSMVIV) or failed ring annuloplasty (TSMVIR) is a valid emergent therapeutic alternative to the transapical approach for surgical re-do in high-risk patients.

Objective. The aim of this study is to report clinical characteristics, interventional techniques and early procedural outcomes of patients undergoing TSMVIV or TSMVIR in two centres, Mestre and Treviso hospitals - Veneto Region.

Methods. We prospectively enrolled patients who underwent TSMVIV or TSMVIR with Sapien 3 balloon expandable bioprostheses for failed previous surgical correction of mitral valve disease from January 2017. Demographics, clinical, procedural data at enrollment and early outcomes were collected. Follow-up is scheduled at 30 days, 6 months and 1 year.

Results. From January 2017 to July 2018, 18 consecutive patients were enrolled, 17 receiving TSMVIV with Edwards Sapien 3 (S3) 29 mm, and 1 TSMVIR with S3 26 mm. Mean age was 78±12 years, 11 males (61%), mean STS score was 21±15. 17 procedures were performed under general anesthesia, one implant under conscious sedation. Procedural success, defined as successful valve implantation without complications and absence of residual significant valve insufficiency was achieved in 17 patients (95%). One patient died of pericardial tamponade. One patient died 45 days after the procedure, during rehabilitation, because of intracranial bleeding. Average procedural time was 144±59 min. Mean ICU stay was 1,4 days. 17 of 18 patients (95%) were discharged without in hospital complications and were evaluated at 30 days reporting improvement of functional class (NYHA) without hospital readmission.

Conclusion. Percutaneous transseptal implantation of balloon expandable bioprosthesis in degenerated mitral valve bioprosthesis or in patients with failed surgical ring annuloplasty represents an effective option to the transapical approach in high-risk surgical redo. TSMVIV and TSMVIR outcomes reported in this study are consistent with previous published findings in terms of procedural safety/efficacy and early outcomes.

C3

LEFT VENTRICULAR REVERSE REMODELLING PREDICTS LONG-TERM OUTCOMES IN PATIENTS WITH FUNCTIONAL MITRAL REGURGITATION UNDERGOING MITRACLIP THERAPY: RESULTS FROM A MULTICENTRE REGISTRY

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

Background. The prognostic role of LVRR after MitraClip has never been investigated.

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

Results. Compared with non-LVRR, LVRR patients were more likely to be females, less likely to have an ischaemic aetiology of MR or a prior (<6 months) HF hospitalization and had smaller LV dimensions. NYHA class improved from baseline up to 1-year follow-up in both groups. Two-year survival free from all-cause and cardiovascular (CV) death, HF hospitalization and combined endpoint (CV mortality or HF hospitalization) was higher in LVRR vs. non-LVRR group (87.3% vs. 75.2%, p=0.039; 92.4% vs. 83.8%, p=0.070; 77.2% vs. 60%, p=0.020; and 74.7% vs. 55.2%, p=0.012, respectively). LVRR was associated with a significant reduction in the adjusted relative risk of mortality, HF hospitalization and combined endpoint (HR 0.44, 95% CI [0.20-0.96], p=0.040; HR 0.55, 95% CI [0.32-0.97], p=0.038; and HR 0.54, 95% CI [0.32-0.92], p=0.023, respectively). Female gender, absence of diabetes, freedom from prior HF hospitalization, non-ischaemic aetiology of MR and LVEDD <75 mm resulted as independent predictors of LVVR.

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

C4

PERCUTANEOUS SUTURE-MEDIATED PATENT FORAMEN OVALE CLOSURE WITH THE NOBLESTITCH EL SYSTEM: CENTER EXPERIENCE EFFECT

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Background. Suture-based percutaneous closure of patent foramen ovale (PFO) with the NobleStitch EL (Heartstitch, Fountain Valley, CA) system was shown to provide safe and effective closure of PFO. This approach appeared to be more technically demanding than typical occluder implantation. Whether this characteristic is a feature of the

system or is simply due to limited knowhow with a novel technique is undetermined. We aimed at assessing the effect of experience in the largest single-center NobleStitch EL database currently available.
Methods. Between June 2016 and May 2018, 147 patients (44±13 years, 93 women) with cryptogenic stroke or transient ischemic attack and grade ≥2 (scale 0-3) atrial right-to-left shunt (RLS) underwent percutaneous suture-mediated PFO closure in our Institution. Patients were 36 (25%) in 2016, 65 (44%) in 2017 and 46 (31%) in 2018. Atrial septal aneurysm (≥10 mm) was present in 19% of patients, maximal RLS was 2.8±0.4, mean RoPE score was 7.6±1.3.
Results. In 135 patients the procedure could be successfully completed without complications. Transesophageal echocardiography was used in 52 procedures (67%, 35% and 11% of the procedures in 2016, 2017 and 2018, respectively). Median procedure duration was 59 min (IQR 46-75), fluoroscopy time was 16 min (IQR 13-22), and contrast volume 200 ml (IQR 150-250). Parameters significantly decreased over time. Median procedure duration was 60 min in 2016, 60 min in 2017, and 50 min in 2018 (p=0.006); median fluoroscopy time was 17 min in 2016, 15 min in 2017, and 13 min in 2018 (p=0.018); and median contrast volume was 200 ml in 2016, 200 ml in 2017, and 160 ml in 2018 (p=0.004). At 181±153 days follow-up, contrast transthoracic echocardiography with Valsalva maneuver revealed no residual RLS in 78% of patients. No late complications were reported at follow-up.
Conclusions. This study confirms the efficacy and safety of percutaneous suture-mediated PFO closure and shows progressive and significant reduction in procedure duration, fluoroscopy time, contrast volume and transesophageal echocardiography guidance. These data suggest an important and beneficial impact of experience on percutaneous suture-based PFO closure.

Pharmacology

C5

LONG VS. SHORT DUAL ANTIPLATELET THERAPY IN ACS PATIENTS TREATED WITH PRASUGREL OR TICAGRELOR AND CORONARY REVASCULARIZATION: A PROPENSITY SCORE ANALYSIS FROM THE RENAMI REGISTRY

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Introduction. The benefits of short vs. long term dual antiplatelet therapy (DAPT) using the 3rd generation P2Y12 antagonists prasugrel or ticagrelor in patients with acute coronary syndromes (ACS) treated with percutaneous coronary intervention (PCI) remain to be defined, due to evidence currently limited to patients treated with clopidogrel.
Methods. All ACS patients from the RENAMI (REgistry of New Antiplatelets in patients with Myocardial Infarction) registry undergoing PCI and treated with aspirin prasugrel or ticagrelor were stratified according to the length of DAPT, i.e. shorter than 12 months (D1), 12 months (D2) and longer than 12 months (D3). The groups were compared before and after propensity score matching. NACE (including all cause death, myocardial infarction and BARC 3-5 bleeding) was the primary end point, while MACE (including all cause death and MI) the secondary one. Single components of NACE and MACE were co-secondary end points, along with BARC 2-5 bleeding and stent thrombosis.
Results. A total of 4424 patients from the RENAMI registry with data about length of DAPT available were included in the model. 985 received DAPT less than 12 months, 2216 DAPT for 12 months, and 1223 DAPT longer than 12 months. After propensity score matching, 628 patients from each group were selected. At 20 months of follow-up, DAPT for 12 months and DAPT for longer than 12 months significantly reduced the risk of NACE compared to DAPT for less than 12 months (D1 11.6% vs. D2 6.7% vs. D3 7.2%, p=0.003), and of MACE (10% vs. 6.2% vs. 2.4%, p<0.001), mainly driven by a reduced risk of all cause death (7.8% vs. 1.3% vs. 1.6%, p<0.001), CV death (5.1% vs 1.0% vs. 1.2%, p<0.0001) and recurrent MI (8.3% vs. 5.2% vs. 3.5%, p=0.002) despite higher risk of BARC 2-5 bleeding (4.6% vs. 5.7% vs. 6.2%, p=0.04) and a trend towards BARC 3-5 bleedings (2.4% vs. 3.3% vs. 3.9% p=0.06). In particular, DAPT beyond 12 months reduced the risk of MACE compared to DAPT for 12 months (6.2% vs. 2.4%, p<0.001), due to a reduced risk of MI (5.2% vs. 3.5% p=0.016), despite a higher risk of BARC 3-5 and 2-5 bleedings (respectively 3.3% vs. 3.9% and 5.7% vs. 6.2%, all p<0.05) resulting in a not significant trend for higher NACE (6.7% vs. 7.2%, p=0.74).
Conclusion. In unselected real world ACS patients treated with PCI, the benefit of prolonged DAPT with prasugrel or ticagrelor beyond 12 months markedly reduced fatal and non-fatal ischemic events and offset the increased risk derived from bleedings.

C6

PRECISE-DAPT SCORE IN PATIENTS UNDERGOING PCI IN REAL WORLD PRACTICE

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Background. PRECISE DAPT score has been suggested by recent ESC guidelines on DAPT as a useful tool to tailor DAPT duration in patients undergoing PCI. However, data about this score in real world populations are lacking.
Purpose. To evaluate DAPT duration in a real world population undergoing PCI according to the ESC focus update on DAPT.
Methods. In this single-centre prospective observational study we calculated PRECISE-DAPT score (using baseline blood tests) in every patient undergoing PCI in our cath-lab from September 1st 2017 to January 31st 2018. Exclusion criteria were failure of PCI and angioplasty without stenting. In addition, we calculated HAS-BLED score in patients with indication to OAC.
Results. A total of 258 patients were enrolled in our centre during the study period. Thirty patients were excluded because of failed PCI (n=10) or because of angioplasty without stenting (n=20). Out of 228 patients included, 143 (62.7%) presented with ACS and 85 (37.3%) with stable angina. Mean age was 68±12 years and 80% were males. The mean PRECISE DAPT score was 21±15 (23±15 considering also patients with indication to OAC). 33.1% of patients undergoing PCI resulted at high risk of bleeding. If patients with indication to OAC and high HAS-BLED were included, a total of 88 patients (40.3%) resulted at high risk of bleeding and should have received a shorter period of DAPT. Mean stent length in these patients was 32±19 mm and in 47 (53.4%) cases PCI was performed in a crucial coronary segment (LM/proximal LAD) and/or with placement of 3 or more stents.
Conclusion. A strict application of the PRECISE-DAPT indications in patients undergoing PCI would result in one third of the population to be treated with a shorter duration of DAPT. Combining this data with the HAS-BLED score in patients with indication to OAC, more than 40,3% of the population would receive a shorter duration of therapy. At present, limited data are available in the literature about this matter. For this reason, a strict application of the ESC recommendations would drastically impact in the management of our patients in a real world setting: in our study more than one third of the population would have received a shorter period of DAPT, nevertheless 53.4% of them underwent a delicate PCI.

C7

REGISTRY OF NEW ANTIPLATELET THERAPY IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION (RENAMI)

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Introduction. Limited data have been provided about difference between prasugrel and ticagrelor in real-life acute coronary syndrome (ACS) patients treated with PCI.
Methods. 4424 ACS patients undergone PCI from REgistry of New Antiplatelet therapy in patients with acute Myocardial Infarction (RENAMI) were enrolled and discharged with dual antiplatelet therapy (DAPT) with prasugrel or ticagrelor. Long term NACE was the primary end-point, while MACEs the secondary ones, along with their single components.

Subgroup analysis for freedom from NACE and MACE were performed according to length of DAPT and to clinical presentation (STEMI-ACS) vs. (NSTEMI-ACS).
Results. 1699 were enrolled in the Prasugrel group and 2725 in the Ticagrelor group, resulting after propensity score matching in 1290 for each cohort. At 12 months, the incidence of NACE was lower in prasugrel patients (5.3% vs. 8.5%, p 0.0001), as that of MACE (6.05% vs. 8.1%, p=0.001), mainly driven by a reduction in recurrent MI (2.4% vs. 4.0%, p=0.029) and a lower rate of BARC 3-5 bleeding (1.5% vs. 2.9%, p 0.011). The benefit of prasugrel for NACE and MACE was confirmed for NSTEMI patients and for those discharged with a DAPT regimen of 12 months or less, while only a trend in reduction for of NACE and MACE was noted for STEMI or for those treated with longer DAPT.
Conclusion. Head-to-head comparison suggests better efficacy and safety of prasugrel versus ticagrelor used in combination with aspirin after NSTEMI, while not in STEMI patients. No differences were found for events occurring after 12 months.

C8

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

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Introduction. Safety and efficacy of prasugrel and ticagrelor in patients with diabetes mellitus (DM) presenting with acute coronary syndrome (ACS) and treated with PCI remain to be assessed.
Methods. All DM patients admitted for ACS and enrolled the REgistry of New Antiplatelets in patients with Myocardial Infarction (RENAMI) were compared before and after propensity score with matching. Net adverse cardiovascular events (NACE; composite of death, myocardial infarction [MI] and BARC 3-5 bleedings), and major adverse cardiovascular events (MACE; composite of death and MI), were the co-primary endpoints. Single components of primary endpoints were secondary ones.
Results. Among 4424 patients enrolled in the RENAMI registry, 462 and 862 diabetics treated with prasugrel and ticagrelor respectively, were considered. After propensity score with matching, 386 patients from each group were selected. At 19±5 months, MACE were similar in the prasugrel and ticagrelor group (4.9% vs. 2.8%, p= 0.14), while a non-significant trend against prasugrel in terms of NACE emerged (6.5% vs. 3.6%, p=0.07). Ticagrelor was associated with lower risk of death compared to prasugrel (2.8% vs. 0.8%, p=0.031), with less BARC 2-5 bleeding (6.0% vs. 2.6%, p=0.02) and only a trend for a reduction of BARC 3-5 bleeding (2.3% vs. 0.8%, p=0.08). There were no significant differences in MI recurrence and stent thrombosis.
Conclusion. Diabetic patients admitted for ACS seem to benefit equally in terms of MACE from ticagrelor or prasugrel use. Ticagrelor was associated with a trend for reduced NACE and a significant reduction in all cause death and bleedings, without differences in recurrent ischemic events. Large randomized comparison between these two drugs are needed for solid conclusion.

Aortic valve disease

C9

IMPACT OF ASCENDING AORTA DILATATION ON OUTCOME AFTER TAVI

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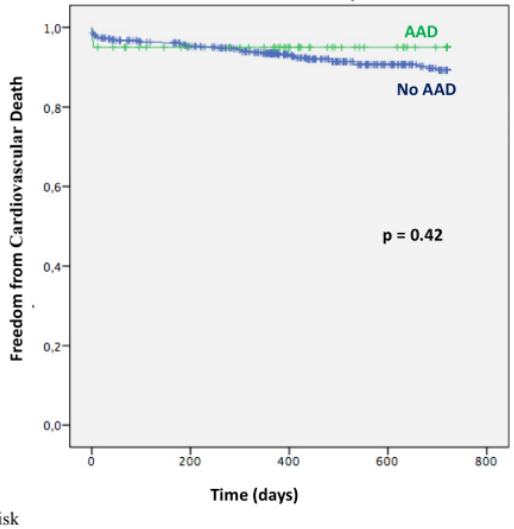
Aims. Ascending aorta dilatation (AAD) is often associated with aortic valve stenosis. In case of surgical aortic valve replacement, combined correction of the aortic aneurysm is often performed, in order to reduce the risk of rupture. The aim of this is study is to evaluate the impact of AAD on acute and midterm outcome of patients receiving only aortic stenosis treatment through TAVI procedure.
Methods. This is a single center retrospective study including all patients who underwent transfemoral TAVI at San Raffaele Hospital, Milan, from January 2008 to December 2016. Patients with any kind of previous surgery involving the LVOT, the aortic valve complex and the ascending aorta (except for CABG) or a previous TAVI were excluded from the study as well as patients without a pre-operative CT scan or patients with congenital aortic defects. Five hundred and eighty-three patients were ultimately included in the analysis. Patients with cross section diameter of the ascending aorta ≥40 mm were defined as having AAD. All cause-mortality and cardiovascular-related mortality at 2 years were then compared between groups using Kaplan-Meyer analysis.
Results. Among the included patients, 220 (37.7%) were implanted with a balloon-expandable valve (9 Edwards Sapien, 132 Edwards Sapien XT, 79 Edwards Sapien 3), 213 (36.6%) were implanted with a self-expanding valve (110 Medtronic Corevalve, 79 Medtronic Corevalve Evolut R, 23 St Jude Portico), 74 (12.7%) patients were implanted with a mechanical expanding valve (Boston Scientific Lotus) and 76 (13%) patients received a prosthesis that is no longer available (Direct Flow valve). Sixty patients (10.3%) presented AAD. Of note, only 8 patients (1.3%) presented an ascending aorta diameter >45 mm. Baseline clinical characteristics were similar in the two groups. AAD does not appear to impact on periprocedural outcome (moderate-to-severe paravalvular leak, procedural success, peri-procedural death, permanent pace-maker implantation). According to Kaplan-Meier analysis, there was no difference in freedom from cardiovascular mortality at 2 years between patients with and without AAD (95.0% vs. 91.6%, p=0.42).
Conclusion. The incidence of AAD in our population was 10.3%. AAD does not appear to impact on acute and midterm outcome after TAVI. However, caution must be paid: there were few patients presenting moderate (diameter >45 mm) or severe (diameter >50 mm) AAD; a theoretical increased risk of aortic rupture after TAVI in this setting should not be excluded. Further studies are needed to assess the safety of TAVI in case of severe AAD.



Patients at risk				
AAD	60	48	37	23
No AAD	523	448	328	224

C10

INTRAVASCULAR LITHOTRIPSY TO FACILITATE TRANSFEMORAL TAVI IN SEVERE OBSTRUCTIVE ILIAC DISEASE. PRELIMINARY MULTICENTER EXPERIENCE

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

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

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

Results. Between January 2018 and June 2018, 13 patients were enrolled in the registry (mean age 83.5±3.7 years; 6 males), all undergoing TAVI due to severe aortic stenosis. Femoral access was obtained in all but two cases percutaneously with pre-implantation of two Proglides or one Prostar. Two patients were electively instrumented after surgical endarterectomy of a calcific cast in common femoral artery. The TL location was in all cases the common and/or external iliac artery (left in 46% of the cases). Mean reference vessel diameter was 8.9±1.8 mm with the TL minimum diameter of 4.3±1.1 mm inducing a stenosis of 55.2±15.8% with a mean length of 24.7±12.3 mm and an arc of calcium of 281±96 degrees. In 1 case with a subocclusive stenosis the lesion was pre-dilated with a 4.0 mm coronary balloon via a long brachial sheath. In all other cases, 60 mm long peripheral IVL catheters could be easily advanced over a 0.014 in wire. Balloon diameter was 7 mm in the majority of cases; in 2 cases a 6.5 mm balloon and in 3 cases a 6.0 mm was preferred due to a small diameter of the external iliac. Only in one case a second treatment with a 7.0 mm balloon was required for advancing the valve delivery system after initial treatment with a 6.0 mm balloon. After IVL the 14 or 16 Fr delivery system of the Evolut R (61%) or EvolutPRO (15%) self-expanding valves and the 14 stretchable E-sheath of 23 or 26 mm Sapien 3 valve (24%) could cross the TL and the valve was successfully implanted across the aortic annulus. After the procedure no TL perforation or severe dissection or residual stenosis was present, with no need for iliac balloon dilatation or stent. Access puncture site could be easily closed with the transcatheter sutures or elective surgery. Because of residual bleeding despite prolonged dilatation and reversal of heparin, in one case a covered stent was implanted in cross-over to the common femoral.

Conclusions. Iliac artery lithotripsy with a Shockwave Peripheral IVL catheter enables transfemoral TAVI in patients with severe calcific stenoses normally considered as absolute contraindications for transfemoral TAVI.

C11

PREDICTORS AND SAFETY OF NEXT-DAY DISCHARGE AFTER MINIMALISTIC TRANSFEMORAL AORTIC VALVE IMPLANTATION

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

Methods and results. This is a single-center, retrospective analysis obtained from a prospective local TAVI registry. From June 2007 to March 2018, 1221 patients underwent transfemoral TAVI in our institution. Almost all the procedures (99.6%) were performed using a minimalistic approach, under local anesthesia with conscious sedation and using only an angiographic guidance. Among these, 134 patients (11%) with a mean age of 81±5.9 years and a STS score of 4.2±2.3, were discharged within 24 hours after the procedure. Baseline predictors of next day-discharge were prior PM implantation (odds ratio [OR] 2:18; confidence interval [CI] 1.35-3.53) and NYHA class (OR 0.69; CI 0.50-0.93). After TAVI new onset atrial fibrillation (OR 0.30; CI 0.11-0.85) and major or life-threatening bleedings (OR 0.09; CI 0.03-0.28) were negative predictors of NDD. Patients were treated using a balloon-expandable (29.5%) or a self-expandable prosthesis (70.5%). During hospitalization, no major vascular complication, life-threatening or major bleeding, strokes or acute kidney injury were reported. Two patients (1.6%) underwent pacemaker implantation, due to complete atrio-ventricular block immediately after procedure. At 30-day, 1 patient with liver cirrhosis died 13 days after discharge due to acute liver failure and 1 patient developed high-degree AV block requiring pacemaker implantation 4 days after discharge. No other patients were re-hospitalized within 30 days and the vast majority (94%) of them were in NYHA class I or II.

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

C12

THE COST-EFFECTIVENESS OF TRANSCATHETER AORTIC VALVE IMPLANTATION: THE ITALIAN NATIONAL HEALTH SYSTEM PERSPECTIVE

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

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

Results. Over 5-years, TAVI implied incremental costs and also additional LYG with the ICER being about €24 000/LYG, €20 000/LYG and €8000/LYG respectively for intermediate-, high-risk and inoperable patients due to both incremental costs and incremental LYG. When considering a 15-year time-horizon ICERs were about €8000/LYG, €12 000/LYG and €6000/LYG respectively for intermediate-, high-risk and inoperable patients. OWSA and PSA suggested that results were consistent to variation of model parameters in almost all risk groups, with mortality being the most relevant driver in all the analyses.

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

Structural intervention 2

C13

INCIDENCE, PREDICTORS AND CEREBROVASCULAR CONSEQUENCES OF LEAFLET THROMBOSIS AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION: A SYSTEMATIC REVIEW AND META-ANALYSIS

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

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

Results. Fifteen studies encompassing 9133 patients evaluating incidence of LT were included. Pooled incidence of LT was 0.37 events per 100 person-month (0.17-0.62, I^2=97%). Pooled incidence of subclinical LT was 1.98 events per 100 person-months (95% CI 0.69-3.83, I^2=95%). Clinical LT was less frequent (0.04 events per 100 person-months, 95% CI 0.00-0.19, I^2=93%). LT increased risk of stroke (OR 6.99, 2.3-21.29), and was more frequent in patients with valve of 28 mm of

diameter (OR 2.89, 1.55-5.8), for balloon expandable (OR 8, 2.1-9.7) or after valve-in-valve procedures (OR 17.1, 3.1-84.9). Oral anticoagulation therapy (OAT) both reduced risk of LT (OR 0.33, 0.17-0.67, I^2=55%, all CI 95%) and restore normal mean transvalvular gradient after LT diagnosis.
Conclusions. LT represents an infrequent event after TAVI, although increasing risk of stroke. Given its full reversal with warfarin, in high-risk patients (those with valve in valve procedures, balloon expandable or large-size devices) a protocol with control CT appears reasonable to tailor a patient-specific antithrombotic therapy.

C14

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

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Background. Transcatheter aortic valve implantation (TAVI) is now a well-established technique in patients with severe aortic stenosis who are at high or intermediate risk for surgical aortic valve replacement (AVR). Risk score are important tools integrated into the decision-making process of heart team in order to choose the most appropriate strategy for these patients though the usefulness of these scores to predict mortality and adverse events after TAVI is still debated. Indeed, after a successful procedure, prognosis may be determined by comorbidities and conditions not included in these models. Thus, appropriate tools to predict short and long-term outcome following TAVI is currently not available. The aim of this study was to evaluate and compare the performance of the STS (Society of Thoracic Surgeons score), ACEF I (age, creatinine, ejection fraction) and II and OBSERVANT (Observational Study Of Appropriateness, Efficacy And Effectiveness of AVR-TAVR Procedures For the Treatment Of Severe Symptomatic Aortic Stenosis) scores as predictors of 30-day mortality and adverse events in patients undergoing TAVI.
Methods. 504 consecutive patients (54.8% female, mean age 82.2±7.9 years) who underwent TAVI between July 2015 to February 2018 in our department were included in the study. Baseline risk was calculated according to STS, ACEF I, ACEF II and OBSERVANT scores. Thirty-day follow-up was performed and available in each patient. Primary endpoint of the study was 30-day mortality. Secondary endpoint clusters several adverse events (death, Ictus/TIA, bleeding, renal impairment, major vascular complications) defined according to the Valve Academic Research Consortium Consensus on Event Definition, occurred during the first month after procedure. In order to define the quality of discrimination, the area under the receiver operating characteristic (ROC) curve was calculated. Brier score and Hosmer-Lemeshow was used respectively for calibration and global accuracy of models.

Table 1. Baseline characteristics of the study population.

	Overall	Events (n=63)	No Events (n=441)
Age (yrs)	82.2±7.9 (84.0, 79.0-87.0)	82.8±6.8 (83.0, 79.0-88.0)	82.2±8.0 (84.0, 79.0-87.0)
Gender			
Female	276 (54.8)	38 (60.3)	238 (54.0)
Male	228 (45.2)	25 (39.7)	203 (46.0)
NYHA class			
I	3 (0.6)	2 (3.2)	1 (0.2)
II	50 (9.9)	6 (9.5)	44 (10.0)
III	437 (86.7)	51 (81.0)	386 (87.5)
IV	14 (2.8)	4 (6.4)	10 (2.8)
DM	142 (28.2)	23 (36.5)	119 (27.0)
Prior valvuloplasty	40 (8.0)	6 (9.5)	34 (7.7)
Every event 30 days after TAVI	63 (12.5)	63 (100)	-
Stroke/TIA	7 (1.4)	7 (11.1)	-
Bleeding	20 (4.0)	20 (31.8)	-
Renal impairment	15 (3.0)	15 (23.8)	-
Death	19 (3.8)	19 (30.2)	-
Major vascular complications	10 (2.0)	10 (15.9)	-
Hb	12.0±1.9 (12.1, 10.7-13.2)	11.4±1.5 (11.3, 10.2-12.8)	12.1±1.9 (12.2, 10.8-13.3)
HTC	36.5±5.1 (36.6, 33.1-39.9)	35.0±4.2 (34.9, 31.8-38.3)	36.7±5.2 (36.8, 33.5-40.0)
Plt	205918.2±73007.3 (20000, 15600-24500)	190660.7±78925.3 (185000, 137000-233000)	207947.72±72040.6 (201000, 158000-24500)
ALT	17.2±16.2 (13.0, 10.0-18.0)	20.4±23.0 (14.0, 10.0-20.0)	16.8±15.1 (13.0, 10.0-18.0)
AST	20.3±13.6 (18.0, 15.0-22.0)	24.1±23.1 (18.0, 13.5-25.0)	19.8±11.8 (18.0, 15.0-22.0)
Bilirubin	0.60±0.48 (0.49, 0.35-0.71)	0.62±0.37 (0.51, 0.37-0.76)	0.60±0.50 (0.48, 0.35-0.69)
Creatinine pre-TAVI	1.36±0.97 (1.15, 0.88-1.46)	1.80±1.55 (1.37, 0.86-1.73)	1.30±0.83 (1.13, 0.88-1.42)
Creatinine clearance pre-TAVI	53.8±20.7 (54.0, 38.0-69.0)	46.2±23.8 (42.0, 31.0-64.0)	54.9±20.0 (55.0, 40.0-70.0)
STS score	5.77±3.97 (4.60, 3.10-7.30)	7.17±4.87 (6.20, 3.80-9.40)	5.57±3.79 (4.50, 3.00-7.00)
ACEF	5.30±7.90 (2.95, 2.34-4.92)	6.68±10.51 (3.14, 2.37-7.07)	5.10±7.46 (2.94, 2.29-4.68)
ACEF II	5.32±6.36 (2.89, 2.24-5.73)	6.80±7.42 (3.94, 2.56-8.38)	5.11±6.19 (2.78, 2.20-5.39)
OBS score	4.15±3.27 (3.23, 1.80-4.97)	5.46±3.93 (4.31, 3.22-7.59)	3.96±3.13 (3.23, 1.80-4.31)

Data are presented as: mean ± standard deviation (median, interquartile range), or n (percentage).

Table 2. Logistic analysis for all events.

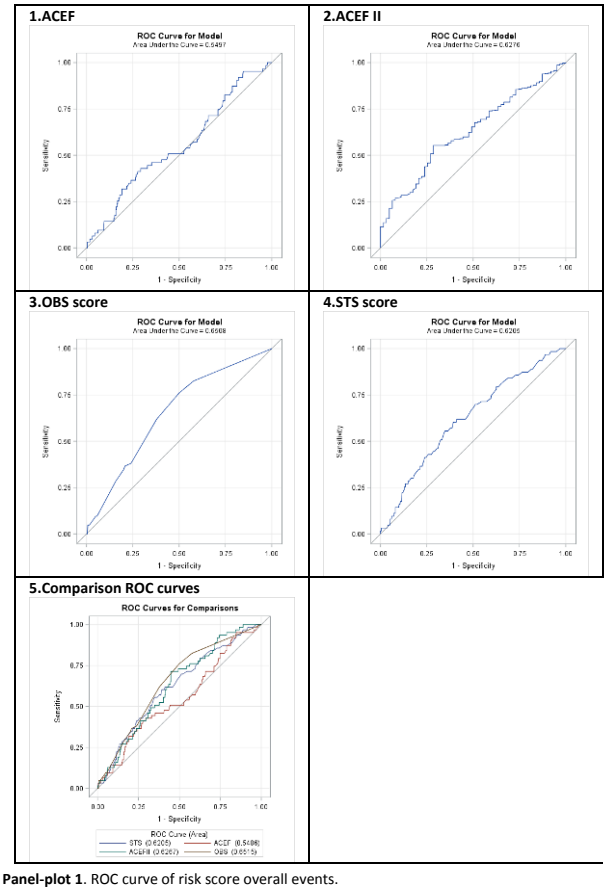
	AUC (SE)	Sensitivity	Specificity	Cut-off max sens* spec	Brier score	Hosmer e Lemeshow	ROC Contrast Estimation	ROC Contrast
ACEF	0.55 (0.04)	0.43	0.71	4.1	0.109	0.09	0.06	0.02
ACEF II	0.63 (0.03)	0.71	0.55	3.0	0.109	0.01	0.87	
OBS score	0.65 (0.04)	0.62	0.62	3.2	0.107	0.06	0.41	
STS score	0.62 (0.04)	0.60	0.61	5.3	0.107	0.71	Ref	Ref

Table 3. Logistic analysis for mortality event

	AUC (SE)	Sensitivity	Specificity	Cut-off max sens*spec	Brier score	ROC Contrast Estimation	ROC Contrast
ACEF	0.51 (0.08)	0.47	0.64	3.5	0.036	0.003	0.02
ACEF II	0.60 (0.07)	0.47	0.78	6.1	0.036	0.12	
OBS score	0.63 (0.06)	0.58	0.60	3.2	0.036	0.24	
STS score	0.70 (0.05)	0.74	0.57	5.1	0.036	Ref	Ref

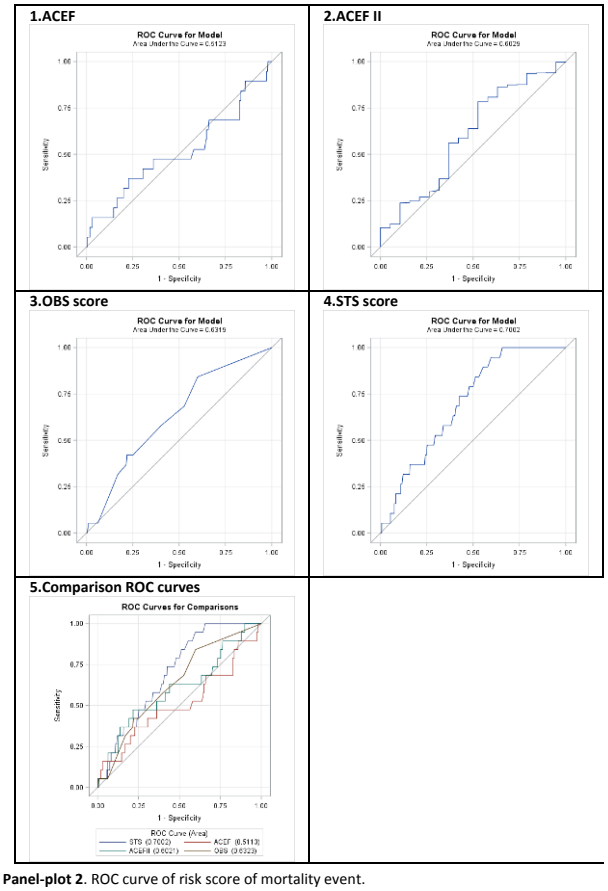
Table 4. Sensitivity and specificity of risk score

	Cut off 5%		Cut off 3%	
	Sensitivity	Specificity	Sensitivity	Specificity
ACEF	34.9	77.1	50.8	51.0
ACEF II	36.5	79.4	71.4	55.1
OBS score	41.3	73.7	76.2	49.9
STS score	61.9	56.0	87.3	23.6



Panel-plot 1. ROC curve of risk score overall events.

Results. Overall, the 30-day mortality rate was 3.8% (n=19), and the cumulative 30-day adverse events rate was 12.5% (n=63). In receiver operating characteristics analysis, neither of the investigated scores could accurately predict the 30-day mortality or adverse events. Area under the receiver-operating curve (AUC) for the scores was as follows: STS AUC 0.70 for 30-day mortality and 0.62 for adverse events; ACEF AUC 0.51 for 30-day mortality and 0.55 for adverse event; ACEF II AUC 0.60 for 30-day mortality and 0.63 for adverse events, OBSERVANT AUC 0.63 for 30-day mortality and 0.65 for adverse events. The differences between curves were not significant except for STS vs. ACEF for 30-day mortality prediction (ROC Contrast Estimation 0.003). The Hosmer-Lemeshow test and Brier score indicated acceptable calibration and global accuracy for all scores. Furthermore, we estimate that for our population the cut off for reaching the best sensitivity and specificity was different from the standard value proposed as references. Notably our cut off for ACEF, ACEF II, OBSERVANT and STS were respectively 3.5, 6.1, 3.2 and 5.1.
Conclusions. All the investigated risk scales proved to be inaccurate in predicting 30-day mortality and adverse outcome in patients referred to TAVI. These results underscore the primary role of heart team in decision making process for selection of patients suitable for TAVI. Furthermore, this study highlights the need for a new TAVI tailored risk model that might incorporate comorbidities that affect outcome in percutaneous procedure such as frailty syndrome.



Panel-plot 2. ROC curve of risk score of mortality event.

C15

A NOVEL METHOD FOR THE MANAGEMENT OF VASCULAR ACCESS DURING TRANSCATHETER AORTIC VALVE IMPLANTATION: A MONOCENTRIC EXPERIENCE WITH DOUBLE PROGLIDE "EXTERNALIZED"

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Background. Transcatheter aortic valve implantation (TAVI) is a real alternative to surgical aortic valve replacement (SAVR) in high- and intermediate-risk patients with symptomatic severe aortic stenosis (AS). Procedure-related complications, acute kidney failure, stroke and most importantly vascular complications are associated with a significant increase in mortality and morbidity. We present the experience achieved by our Interventional Cardiology Unit in the management of vascular access during the TAVI procedure performed transfemoral (TF) percutaneously.
Methods. We performed >200 TAVI procedures with a TF, transapical and trans-subclavian approach. We analyzed 150 consecutive patients undergoing TAVI TF and we compared two vascular closure systems: the Prostar XL vs Proglide system (PGs) (Abbott Vascular, Santa Clara, CA, USA). Both of these closure systems require the 'pre-closing' before advancing the larger introducers (16-20F), to then obtain vascular haemostasis once the procedure is completed. Contrary to the recommendations, we applied a different implantation modality of the PGs through the systematic 'outsourcing' of the suture threads pre-inserted in the femoral access site.
Results. In the PGs group in comparison to the Prostar group we have documented the reduction of VARC 2 major and minor complications (respectively, 0 vs. 3.2% and 10.3 vs. 14.5%), acute closure device failure (2.3 vs. 3.2%), major bleeding (0 vs. 3.2%) and vascular perforation (1.1 vs. 4.8%) without achieving statistical significance. Femoral pseudoaneurysms were significantly reduced (4.6 vs. 14.5%, p=0.03).
Conclusion. We propose the systematic use of 'externalizing' the suture threads of the PG system during TAVI procedures via TF as this procedure has proved to be effective, safe and associated with a reduction of major vascular complications. To our knowledge, this is the first consecutive series of TAVI patients via TF who underwent access management via externalized PGs.

C16

ATRIAL SEPTAL DEFECTS CLOSURE IN THE ELDERLY: EXPERIENCE AND LONG-TERM FOLLOW-UP OF A HIGH VOLUME CENTRE

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Objectives. Ostium secundum atrial septal defects (ASDs) are a common congenital heart disease. An early diagnosis allows ASD closure before the development of pulmonary hypertension. In some cases, these defects are not diagnosed in childhood, but only at the time of onset of symptoms and signs and when pulmonary artery pressure increases. Elderly patients (>60 years) are a complex subgroup to treat with several complications and hemodynamic limitations.
Methods. From March 2000 to April 2018, 1075 patients underwent ASD closure at our institution. 62 were elderly patients (>60 years). Right heart catheterization was performed to evaluate pulmonary artery pressures and to address the closure. Every patient was followed up through electrocardiographic and echocardiographic evaluation.
Results. Among these elderly patients, 23 (37%) had pulmonary hypertension (mean pulmonary artery pressure >25 mmHg) and 14 (22.5%) had a pulmonary wedge pressure ≥15 mmHg (but wedge pressure did not increase significantly during the occlusion test). 21 patients (33.8%) showed atrial fibrillation on admission. Percutaneous closure was effective in all patients and no major complications were recorded. At a mean follow-up of 8.4 years, no mortality or morbidity related to the procedure were recorded and no patients developed new onset arrhythmias.
Conclusion. ASD closure in elderly patients is challenging for interventional cardiology above all because of the high pulmonary artery pressures. Right heart catheterization (with an occlusion test for patients with high pulmonary wedge pressure) can be helpful to guide decision making of interventional cardiology. No mortality or morbidity related to the procedure occurred during follow-up.

Mitral intervention

C17

THIRTY-DAY AND ONE-YEAR OUTCOME OF PATIENTS WITH ESTIMATED LOW OR INTERMEDIATE SURGICAL RISK WHO UNDERWENT PERCUTANEOUS EDGE-TO-EDGE MITRAL VALVE REPAIR WITH THE MITRACLIP SYSTEM

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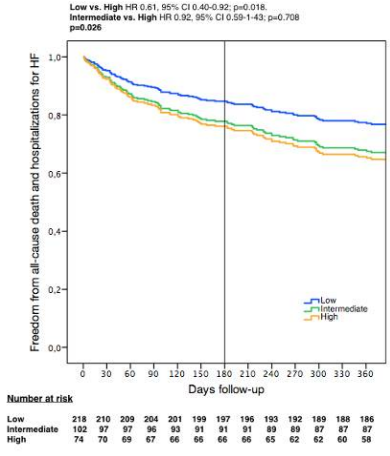
Background. The MitraClip system has emerged as an established treatment in high-risk patients with moderate-to-severe mitral regurgitation (MR) who are demanded inoperable. Outcomes among patients with estimated low- or intermediate-risk according to the Society of Thoracic Surgeons-Predicted Risk of Mortality (STS-PROM) remain to be determined.
Objective. We sought to evaluate the clinical early (30-day) and mid-term (one-year) outcome among patients with estimated low- or -intermediate risk that underwent MitraClip procedure in a single center.

Methods. This is a retrospective observational analysis of all consecutive patients undergoing MitraClip implantation at our Institution. From October 2008 to June 2017, a total of 394 patients were included in the study. Patients were categorized in low-risk group (STS-PROM <4%; n=218), intermediate-risk group (STS-PROM >4% and <8%; n=102) and high-risk group (STS PROM >8%; n=74).
Results. Significant differences were encountered among the three groups (low-risk vs. intermediate-risk vs. high-risk) for age (75 vs. 71 vs. 77, p≤0.001), diabetes (27.1 vs. 33.3 vs. 56.8%, p≤0.001), prior heart failure (50.2 vs. 52 vs. 70.3%, p=0.010), chronic kidney disease (61.5 vs. 66.7 vs. 82.4%; p=0.004), NYHA class IV (7.3 vs. 16.7 vs. 25.7%, p≤0.001), ischemic functional MR (32.6 vs. 49 vs. 23.4%, p=0.003), non-ischemic functional MR (45.9 vs. 27.5 vs. 39.6%, p=0.007). The low-risk patients presented the lowest device and procedural time (respectively p=0.047 and p=0.016) and lowest MR grade post-implant (99.5 vs. 96.1 vs. 95.9%, p=0.048), with lower length of stay (p=0.024) if compared with the other two groups. No differences were encountered regarding the peri-procedural complications or the rate of technical success. Device and procedural successes according to the MVARC criteria were high at 30-day follow-up in all groups. No remarkable differences were observed up to one-year regarding the single rate of death, MR 3+/4+ and heart failure. At one-year, the low-risk group presented the highest incidence of combined freedom from all-cause death and heart failure, according to an estimated Mantel-Cox analysis [low vs. high HR 0.61 (95% CI 0.40-0.92), p=0.018; intermediate vs. high HR 0.92 (95% CI 0.59-1-43), p=0.708; cumulative p=0.026).
Conclusions. Based on our single-center experience, MitraClip therapy is not limited to high-risk patients according to the estimated STS-PROM and procedural allocation should be justified by the interdisciplinary decision of the Heart Team with an evaluation "case by case". Compared with patients at high-risk, patients at low- or -intermediate risk, according to the STS-PROM, presented a favorable outcome up to 30-day and one-year. Definitely, low-risk patients presented the best encouraging outcome in terms of freedom from all-cause death and heart failure.



C18

PERCUTANEOUS REPAIR OF FUNCTIONAL MITRAL REGURGITATION IN HEART FAILURE PATIENTS: A META-ANALYSIS OF 23 STUDIES ON MITRACLIP IMPLANTATION

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Background. A gap of evidence on the clinical performance of MitraClip (MC) in functional mitral regurgitation (MR) and on the prognostic predictors of outcome still remains in daily practice.
Purpose. To investigate short- and long-term survival, clinical status and echocardiographic findings of heart failure patients with severe functional MR undergoing MC treatment and to explore the prognostic impact of their baseline characteristics on clinical and functional outcome.
Methods. Randomized and observational studies including patients with functional MR undergoing MC were collected in a meta-analysis finalized to evaluate the overall survival in-hospital and at 1, 6, 12 and 24 months, the New York Heart Association (NYHA) class and the echocardiographic changes after MC treatment. The baseline features associated to overall mortality and to the echocardiographic changes at follow-up were also investigated in order to identify predictors of outcome.
Results. After a comprehensive MEDLINE, COCHRANE, ISI Web of Sciences, and SCOPUS search, 23 studies enrolling 3253 patients were included in the analysis. The overall death rate was 2.31 (95% CI 0.14-4.48) in-hospital, 5.37 (95% CI 2.90-7.84) at 1 month, 11.87 at 6 months (95% CI 8.60-15.30), 18.47 (95% CI 15.59-21.35) at 1 year and 31.08 (95% CI 24.59-37.57) at two years. MR grade 1+ or 2+ was observed in 92.76% (95% CI 90.46-95.07) at discharge and in 83.36% (95% CI 79.22-87.50) at a mean follow-up of 11.7±3.5 months. The 76.63% (95% CI 71.57-81.69) of patients were in NYHA class I or II at mean follow-up of 11.5±5.0 months. A significant reduction of left ventricular (LV) volumes (end-diastolic: -21.96±4.94 mL, p<0.0001; end-systolic: -15.32±7.44 mL, p=0.0395) and systolic pulmonary arterial pressures (7.85±1.10 mmHg, p<0.0001) associated with a significant increase of LV ejection fraction (+2.40±1.12, p=0.0315) were observed at a median follow-up of 12.4±4.8 months. Meta-regression analysis showed a statistically significant negative effect of atrial fibrillation (AF) on 1-year survival (β:0.18±0.06, p=0.0047) and on the reduction of LV end-diastolic (β:-1.05±0.47, p=0.0248) and end-systolic volumes (β:-2.60±0.53, p=0.0024) was observed.
Conclusions. In patients with heart failure and severe functional MR, MC treatment is safe and results in a durable MR reduction associated with a significant clinical and echocardiographic improvement. Owing to the negative prognostic impact on LV reverse remodeling and on 1-year survival, AF should be carefully considered in the selection of patients candidate to MC and during the follow-up.

C19

PERCUTANEOUS REPAIR OF FUNCTIONAL MITRAL REGURGITATION VS. OMT IN CHRONIC ADVANCED HEART FAILURE: DATA FROM A REAL-LIFE EXPERIENCE

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Background. The benefit of percutaneous mitral valve repair (PMVR) in patients with advanced heart failure (AHF) and severe symptomatic functional mitral regurgitation (FMR) is unclear.
Methods. Data of patients with AHF and FMR evaluated in our center were collected. Patients that underwent MitraClip implantation were compared to those refused for anatomical reasons, and thus leaved in optimal medical therapy (OMT). The primary endpoint was a composite of cardiovascular death, left ventricular assist device implantation and hospitalization at follow-up. The secondary one was the improvement of NYHA class at follow-up.
Results. Sixty-eight (70,8%) patients underwent MitraClip implantation (group 1), while 28 (29,2%) were followed in OMT (group 2). Mean age was 68 years, Seattle Heart Failure Model estimated 1-year mortality 39.4%, 18 (18.8%) patients were in NYHA class IV, the others in class NYHA III. Eleven (11.5%) patients were dependent from inotropes. No between groups difference in baseline characteristics were found, except to left ventricular ejection fraction (LVEF) (27.5 vs. 32.8%, p=0.04) and NT-proBNP (6932 vs. 19986, p<0.01). At 500 days of follow-up, a significant between-group difference in the primary endpoint was found (41.8% vs. 61.6%, p=0.01). If the primary endpoint was corrected by LVEF and NT-proBNP, group 1 continued to show a lower, although not statically significant, CV death, LVAD implantation and/or hospitalization compared to group 2 (41% vs. 63%, p=0.06). Excluding from group 2 patients that underwent surgical repair/replacement of the mitral valve, a significant improvement of the NYHA class was observed in MitraClip patients (64.5% vs. 30.5%, p=0.01).
Conclusions. MitraClip procedure in advance heart failure reduces the cardiovascular death, left ventricular assist device implantation and hospitalization compared to optimal medical therapy. Moreover it is associated with an improvement of clinical profile in this selected, high-risk population.

C20

SYNTAX II SCORE VS. SYNTAX SCORE TO PREDICT LONG-TERM PATIENT OUTCOME AFTER LEFT MAIN STENTING WITH SECOND-GENERATION DES: INSIGHT FROM THE FAILS-II MULTICENTRE REGISTRY

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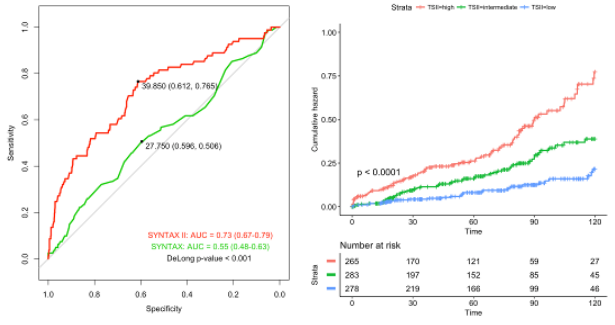
Aims. The aim of this study was to evaluate the capacity of the SYNTAX Score-II (SS-II) to predict long-term mortality in patients undergoing left

main percutaneous coronary intervention (LM-PCI) treated with second-generation drug-eluting stents (DES).
Methods and results: SYNTAX score (SS) and SYNTAX score II (SS-II) were calculated in 854 patients with de novo left main coronary artery disease undergoing PCI included in FAILS-2 multicenter registry (Failure in Left Main Study With 2nd Generation Stents-Cardiogroup III Study), followed up to 10 years. Patients were divided into tertiles according to the SS-II: low SS-II (SS-II ≤33, n=288), intermediate SS-II (SS-II between 33 and 44, n=291), and high SS-II (SS-II ≥44, n=275). The survival curves were estimated by the Kaplan-Meier method. Cox proportional hazard regression analyses were performed to evaluate associations between the SS-II and long-term mortality or major adverse cardiovascular events (MACE). Area under the receiver operator curve (AUC) and net reclassification improvement (NRI) were assessed comparing SS with SS-II. Mean SS-II was 39.2±5.5. At a mean follow-up of 5.2±3.6 years mortality rates were 4%, 7.4%, and 17.4%, respectively among patients in the 3 groups (p<0.001). SS-II score showed a more accurate prediction of mortality than SS score (AUC = 0.73, 95% CI 0.67-0.79 vs. AUC = 0.55, 95% CI 0.48-0.63, p<0.001). For all-cause mortality, the NRI was 71% (p<0.001).
Conclusion. In real-world high-risk patients with LM-PCI treated with a second-generation DES, the SS-II demonstrated a superior predictability compared with the SS. Besides, other factors not included in the SS-II like ACS at presentation and T2DM has to be considered as an additive marker of poor outcome.



C21

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

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Introduction. Outcomes of patients with orthotopic heart transplantation (OHT) undergoing percutaneous coronary intervention (PCI) remain to be defined, especially according to kind of stent and to use of intracoronary imaging.
Methods. All studies evaluating the impact of PCI on OHT patients were included. MACE, a composite and mutually exclusive end point of all cause death, target lesion revascularization (TLR) and stent thrombosis (ST) was the primary end point, while its components along with cardiovascular death were the secondary ones Meta-regression analysis was used to assess the impact of coronary stent medications (everolimus and sirolimus), of IVUS, and of anti-reject drugs on TLR.
Results. 21 studies with 1031 patients were included, with a median time from OHT of 7.1 years (6.5-8.7). Elective angiographic control was the most frequent indication (65% of patients): multivessel disease was reported in 38.8% (28.9-39.0), IVUS was used in 57% (29-80) and drug eluting stents (DES) were implanted in 62.2% (53.5-10). After 1.3 years, MACE occurred in 39.4% of patients (20.82-57.98), mainly driven by TLR (11.78% [5.57-17-98] for patients with DES and 34.23% [22.21-46.25] for BMS), while ST occurred in 2.03% [0.57-2.30]. At meta-regression, IVUS reduced TLR (-0.035:-0.045:-0.021), while the type of antiproliferative drug coating the stents or the adjunctive immunosuppressant therapy did not impact subsequent revascularization.
Conclusion. Patients with OHT undergoing PCI are at high risk of recurrent revascularization, which are reduced by use of intracoronary imaging and DES. Although DES is preferable to BMS in preventing restenosis in OHT lesions, the type of antiproliferative drug in the DES did not impact TLR. Further studies are needed to evaluate the effectiveness of adjuvant immunosuppressant therapy.

C22

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

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Background. A polymer-free biolimus A9 coated and eluting stent (PF-BCS) followed by 1-month dual antiplatelet therapy has been shown to be safer and more effective than a bare-metal stent in high bleeding risk (HBR) patients undergoing PCI in a clinical trial setting. However, little is known about the performance of this PF-BCS in patients encountered during every day, routine clinical practice.
Purpose. This study aimed at assessing the performance of a PF-BCS (Biofreedom™) in real-world HBR patients with severe coronary artery disease (CAD).
Methods. A retrospective, cohort analysis was performed on all comers patients with severe CAD underwent PCI in 11 Italian centers. Primary safety endpoint was to assess the incidence of a composite of cardiac death, target-vessel myocardial infarction (TV-MI), or definite/probable stent thrombosis (ST). The primary efficacy endpoint was target lesion revascularization (TLR). The incidence of type 3 and 5 bleedings according to the Bleeding Academic Consortium (BARC) were also evaluated.
Results. A total of 923 HBR patients (1196 lesions) received a PF-BCS during the study period. Among the patients treated 219 (23.7%) required oral anticoagulation, 77 (8.3%) patients had cancer while 76 (8.2%) experienced a prior major bleeding. More than half of the patients (601, 65%) were admitted because of acute coronary syndrome while 33 (33.9%) were diabetics. Among the 1196 lesions treated, 291 (24.3%) were bifurcations, 211 (17.6%) heavily calcified, 132 (11%) unprotected left main while 75 (6.2%) aorto-ostial. Angiographic success was obtained in 99.2% of the cases while the rate of peri-procedural MI was 10.4%. At a median of 9 months of follow-up (IQR 3-19), the incidence of the composite safety endpoint was 1.9% (cardiac death 1.1%, TV-MI 0.5% and definite/probable ST 0.3%) while the incidence of TLR was 1.1%. BARC defined type 3 and 5 bleedings rate was 3.4%.
Conclusions. In our real-world experience, the implantation of a PF-BCS in real-world patients is associated with favorable clinical results, pointing toward the overall mid-term efficacy and safety of this novel device in complex clinical scenarios.

C23

EARLY RESULTS FOLLOWING MAGNESIUM BIORESORBABLE VASCULAR SCAFFOLD IMPLANTATION IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION

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Background. A sirolimus-eluting bioresorbable magnesium scaffold (Mg-BRS) has demonstrated encouraging clinical outcomes in selected patients with stable coronary artery disease. However, very little is known about the performance of this novel device in patients suffering from an acute myocardial infarction (AMI).
Objectives. To assess the feasibility and the short-term clinical outcomes following PCI with Mg-BRS implantation in patients with AMI (STEMI and NSTEMI).
Methods. A retrospective, multicenter cohort analysis was performed on consecutive AMI patients treated with Mg-BRS in 11 Italian Centers between July 2016 and May 2018. Primary end-point of this analysis was a composite of cardiac death, target vessel myocardial infarction (TV-MI)

and ischemia-driven target lesion revascularization (ID-TLR) at the longest follow-up actually available. The occurrence of Mg-BRS thrombosis was also evaluated.
Results. A total of 75 patients with acute myocardial infarction (n=27, STEMI) were treated with at least one Mg-BRS during the study period. Mean patient's age was 58.0±9.3 years. Diabetes mellitus was present in 7 (9.3%) patients while the vast majority of the patients were males (n=67, 89.4%). All the patients were in Killip class I-II at presentation. Procedural success was obtained in all the cases with the deployment of the Mg-BRS at the culprit site. Pre- and post-dilatation were performed both, in 74 (98.6%) of the cases while intravascular imaging in 33 (44%). A median of 1.4±0.7 Mg-BRS were implanted per procedure and Mg-BRS overlapping was required in 23 (30.6%) cases. No in-hospital events were reported and the vast majority of the patients (n=70, 93.3%) were discharged with the strongest DAPT actually available (including ticagrelor or prasugrel) for 12 months. At a median of 9-month follow-up of any cardiac death, TV-MI, ID-TLR or Mg-BRS were reported.
Conclusions. Our retrospective analysis assessing the performance of a Mg-BRS in patients with acute MI suitable for BRS implantation showed encouraging results similar to that reported in patients with SCAD. Larger studies and longer-term follow-up are strongly needed to better understand the potential benefits associated with the implantation of this novel bioresorbable coronary device.

PCI: lesion/patient subsets 2

C24

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

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Background. Prospective registries on New magnesium- made bioresorbable scaffolds (BrS) Magmaris enrolled patients with simple coronary lesions. The present report was sought to give preliminary findings about feasibility and safety of implantation of overlapped scaffolds in long coronary lesions.
Methods. From July 2016 and May 2018, we collected data encompassing patients treated with at least two overlapped BrS Magmaris (Biotronik, Buelach, Switzerland) in 11 Italian centres involved in the MAGIC registry (MAGnesIum alloy scaffold for coronary artery disease). Endpoints of interest were successful overlap implantation according to edge-to-edge technique and 30 days target lesion failure (TLF), including cardiac death, target vessel myocardial infarction and ischemia-driven target lesion revascularization.
Results. A total of 100 Magmaris overlaps were performed in 46 patients, which were mainly males (83.0%) with a mean age of 59.2±10.2 years. The majority of them presented with NSTE-ACS (52.2%). Left anterior descending artery was target for revascularization in 58.7% of cases. Mean lesion length was 44.4±20.9 mm treated with a mean of 2.2±0.8 Magmaris scaffolds. Scaffold predilatation and postdilatation were performed in all the patients (100%). Edge-to-edge implantation technique was attempted in all cases, following current technical recommendation supported by enhancement viewers tools. Almost two-third of cases (63.0%) underwent intravascular imaging guided procedure (OCT 25-IVUS 4); successful overlap was performed in 98.0% of attempts with 2 failures due to geographical missing, resolved with bailout BrS and DES (drug-eluting stent) implantation, respectively. Device acute success was achieved in all cases without any in-hospital event. At a mean follow-up of 9.3±4.4 months (available in 89.1% of patients) no DOCE occurred.
Conclusion. Multiple Magmaris implantation using an edge-to-edge technique is feasible with acceptable risk of geographical miss, probably due to the low radiopacity of tantalium markers. Clinical outcomes need to be confirmed in trials with longer follow-up.

C25

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

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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 rationale behind CTO recanalization is the improvement of anginal status, left ventricular ejection fraction and quality of life, the reduction of surgical revascularisation and long-term coronary patency. Procedural success depends upon careful review of the angiogram including stump morphology, length of occlusion, calcification and presence and extent of collaterals (J CTO score). Despite the high prevalence, only 8-15% of patients undergo PCI. The prognostic value of postprocedural high-sensitivity troponin T (hsTnI) after CTO procedure is unclear.
Aim. In our retrospective registry, we aimed to assess the prognostic value of elevated hsTnI after elective CTO procedure.
Methods. The current registry included 104 patients undergoing elective CTO procedure between January 2015 and January 2018. Clinical, angiographic and procedural characteristics were correlated with any or at least five times the 99th percentile 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 85% (84/104); in 42% (43/104) 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 210 (±35) days postprocedural hsTnI elevation is not associate with major adverse events (death, myocardial infarction and cerebrovascular events).
Conclusion. 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 follow-up in our small study population, suggestive of the limited long-term impact of troponin elevation.

C26

OPTIMAL MEDICAL THERAPY VS. CORONARY REVASCULARIZATION FOR PATIENTS PRESENTING WITH CHRONIC TOTAL OCCLUSION: A META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS AND PROPENSITY SCORE ADJUSTED STUDIES

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Introduction. The optimal management of patients with coronary chronic total occlusions (CTO) remains controversial. This meta-analysis aims to compare percutaneous coronary intervention of CTO (CTO-PCI) versus optimal medical therapy (OMT) in CTO patients.
Methods. A literature search with highly specific terms was conducted using MEDLINE, EMBASE, and Web of Science to identify most relevant randomized controlled trials (RCTs) and observational studies with propensity score matching (PSMs) evaluating differences in between CTO-PCI versus OMT. The primary endpoint was the incidence of major adverse cardiac events (MACEs, composite of cardiovascular death, acute coronary syndrome, and repeat PCI, re-PCI) while its single components were defined as secondary endpoints.
Results. A total of 8 studies was included, 4 RCTs and 4 PSMs. 3971 patients were included in the analysis (2050 CTO-PCI versus 1921 OMT) with a mean follow-up of 3 years. No significant differences were found regarding overall MACE, whereas a significant reduction of CV death only was found in the CTO-PCI patients (OR 0.52, 0.33-0.81, p<0.01).
Conclusions. As compared to OMT, CTO-PCI was associated with a significant reduction in CV mortality at 3 years.

C27

URGENT INVASIVE STRATEGY FOR OUT-OF-HOSPITAL CARDIAC ARREST SURVIVORS IS ASSOCIATED WITH BETTER SURVIVAL

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Background. Out of hospital cardiac arrest (OHCA) is a leading cause of adult death in industrialized world. Hospital survival rates ranging from 21% to 40% have not improved in recent years. Acute coronary occlusion is the leading cause of cardiac arrest, however, because of limited data,

the indications and timing of coronary angiography (CA) and angioplasty (PCI) in this setting are controversial except for ST-elevation on 12-lead electrocardiogram (ECG).
Aims. The aim of our study is to understand etiology and survival of patients admitted to our hospital with return of spontaneous circulation (ROSC) after OCHA and whether a strategy that leads to an urgent CA and PCI, if required, can improve the outcome.
Methods and Results. Observational retrospective study. Between January 2006 and December 2009, 70 patients with ROSC after OHCA were referred to our hospital. Mean age was 69.5±13.9; 63% male; 11% previous coronary artery disease (CAD), first rhythm was ventricular tachycardia/ventricular fibrillation (VT/VF) in 62%; in 41% diagnosis was acute coronary syndrome (ACS) based upon ECG and enzyme. Hospital survival rate was 48.5%. One year survival rate was 76% of dismissed. Postresuscitation neurologic injury (PNI): 32.8%. According to the presence of ACS: patients with ACS are mostly male, without differences in age or previous CAD vs. no ACS patients. VT/VF is the most frequent presentation rhythm in ACS patients (89% vs. 40%; p<0.01). Only in 34% of ACS patients first ECG showed signs of myocardial infarction/ischemia. VT/VF is the first rhythm equally in both STEMI and NSTEMI. Early sign of PNI generally are associated with underuse of CA and PCI and worst prognosis. Successful urgent CA and PCI are associated with improved hospital survival in patients with ACS (equally in STEMI 83% vs. 51%, p=0.003, and NSTEMI 81% vs. 55%, p=0.004); and in FV/TV as first rhythm (90% vs. 38%, p>0.001).
Conclusions. In OHCA survivors successful urgent PCI is associated with improved in-hospital survival in STEMI, NSTEMI and in patients with VT/VF as first recorded rhythm.

Physiology

C28

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

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Background. Management of coronary artery disease (CAD) in patients undergoing transcatheter aortic valve implantation (TAVI) is uncertain. Fractional flow reserve (FFR) has never been validated in aortic stenosis (AS). Safety of deferring negative FFR coronary lesions in AS is not established.
Objectives. The study aim was to investigate FFR-guided revascularization in TAVI patients, with focus on clinical outcome of deferred patients (FFR negative: >0.80).
Methods. Patients with severe AS (n=413) underwent coronary angiography during workup for TAVI between March 2010 and November 2017. Patients with significant CAD (coronary narrowing >50% in the proximal segment of the main coronary branches) were included in this retrospective analysis and divided into two groups: angiographically-guided (109/192, 56.8%) vs FFR-guided revascularization (83/192, 43.2%), and followed for 24 months.
Results. Most lesions in the FFR group resulted negative (96/125, 77%) and were deferred. Less patients were treated with PCI in the FFR-guided group (23% vs 32%) with a significantly better MACCE-free survival compared with the angio-guided group (94% vs. 83.5%, p=0.024). A similar effect was observed in deferred patients against those who underwent angio-guided treatment (96.9% vs. 71.4%, p<0.001). When the clinical outcome of deferred patients with FFR values between 0.75-0.85 was compared with those with FFR >0.85, no significant difference was observed (MACCE-free 94.1% vs. 95.3%, p=0.83).
Conclusions. FFR-guided revascularization in patients undergoing TAVI is safe (94% MACCE-free survival at 24 months). Prospective randomized trials are needed to better investigate the long-term effects of FFR-guided revascularization against angiographic guidance alone in patients with AS.

C29

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

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Background. Patency of coronary artery bypass grafts (CABG) is known to be higher in arterial grafts than in venous grafts. However, CABG long-term natural history based on hemodynamic guidance-strategy (angiography vs. fractional flow reserve [FFR]) remains poorly documented.
Methods. All consecutive patients having undergone CABG surgery between 2006 and 2010 with repeated angiograms during follow-up were retrospectively included. All grafts were classified according to their hemodynamic guidance-strategy into two groups: an FFR-guided group and an angiography-guided group.
Results. Repeated angiograms were available in 512 grafts from 171 patients. 384 (75.0%) were angiography-guided while 128 (25.0%) were FFR-guided. At 6 years, 76/512 (14.84%) grafts were occluded. The proportion of occluded venous grafts was higher than the proportion of arterial grafts (23.78% vs. 9.78%, respectively; p<0.001). Overall, the proportion of occlusion was higher in the angiography-guided group than in the FFR-guided group (16.9% vs. 8.6%, respectively, p=0.022). However, when looking at the type of grafts, the difference in term of patency according to guidance was only significant among the arterial grafts (16.9% vs. 8.6%, respectively; p=0.028). When comparing the baseline characteristics of occluded arterial grafts with patent arterial grafts, FFR-guidance was the only factor statistically significantly different between the two groups (p=0.028).
Conclusions. FFR-guidance is associated with a higher CABG patency at 6 years. Long-term patency of arterial grafts is higher when implanted on coronary arteries evaluated by FFR.

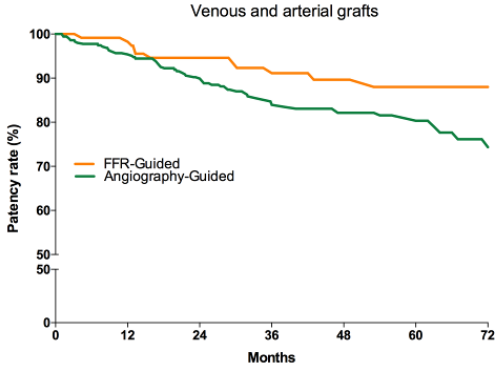

Figure 1. Kaplan-Meier graph reporting the patency rate (Log rank : 0.024; p=0.022) in all the grafts based on guidance.

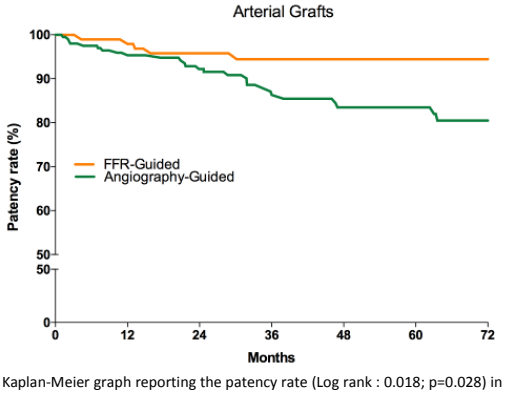

Figure 2. Kaplan-Meier graph reporting the patency rate (Log rank : 0.018; p=0.028) in arterial grafts based on guidance.

C30

UTILIZZO DELLA QUANTITATIVE FLOW RATIO NELLA STRATIFICAZIONE DELLE STENOSI NON CULPRIT IN PAZIENTI CON STEMI E MALATTIA MULTIVASALE

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Razionale e background. Circa il 50% dei pazienti con infarto miocardico con ST sopraelevato (STEMI) presenta anche una malattia coronarica multivasale; il corretto trattamento delle lesioni "non culprit" è ancora dibattuto. Dati recenti dimostrano come la rivascolarizzazione completa possa essere superiore, in termini di eventi, rispetto al trattamento della sola lesione culprit. Stanno inoltre emergendo sempre maggiori evidenze che l'uso della rivascolarizzazione funzionalmente guidata potrebbe migliorare la corretta stratificazione delle lesioni non culprit anche nel setting dello STEMI[1]. Tuttavia, la fractional flow reserve (FFR) è ancora poco utilizzata, anche nella coronaropatia stabile dove possiede un'elevata indicazione. Lo scarso utilizzo della fisiologia coronarica

potrebbe essere spiegato da un prolungamento della procedura, dai costi o dai possibili effetti avversi dell'adenosina. La quantitative flow ratio (QFR) rappresenta una nuova metodica atta a valutare la significatività di una lesione; essa si basa su una ricostruzione anatomica 3D del vaso e sul contrast frame counting, ottenuta a partire da due proiezioni angiografiche ortogonali, senza necessità di una guida di pressione o della somministrazione di adenosina (Fig. 1). Come già dimostrato in diversi studi[2,3], la QFR ha mostrato un'ottima correlazione con la FFR nei pazienti con malattia coronarica stabile.

Obiettivi. L'obiettivo di questo studio[4] è quello di validare, per la prima volta, tale metodica nell'ambito dello STEMI. Lo studio ha come finalità principale quello di dimostrare una elevata correlazione con la FFR, nonché una forte capacità di stratificare correttamente le lesioni non culprit nel paziente con STEMI e malattia multivasale.

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

Resultati. La Coorte A ha incluso 31 pazienti e 34 lesioni non culprit. La QFR ottenuta durante la PCI primaria ha dimostrato una buona correlazione con quella ottenuta sulla procedura staged (r=0.98). L'analisi mediante Bland-Altman ha mostrato una differenza media di solo 0.004 (Fig. 2). La Coorte B ha incluso 45 pazienti w 49 lesioni non culprit entrambe valutate con FFR e QFR durante la PCI primaria. La QFR ha dimostrato una elevate correlazione con la FFR invasiva (r=0.90). Alla Bland-Altman la differenza media è stata di -0.011 [-0.106 – 0.084] (Fig. 3). La sensibilità, specificità, valore predittivo positivo e valore predittivo negativo erano rispettivamente 88%, 97%, 94%, e 94%; l'accuratezza

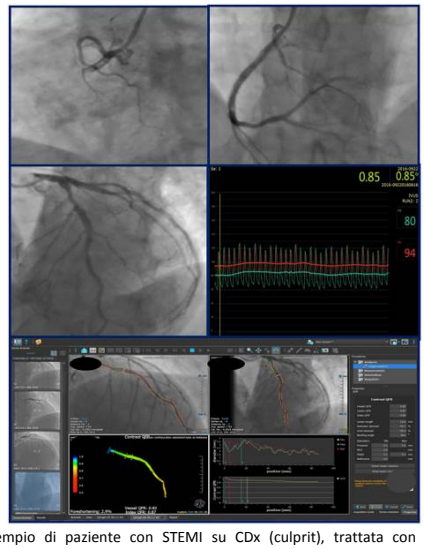

Figura 1. Esempio di paziente con STEMI su CDx (culprit), trattata con PCI, e stenosi intermedia di IVA prossimale. QFR su IVA risultata negativa e sovrapponibile alla FFR durante PCI primaria.

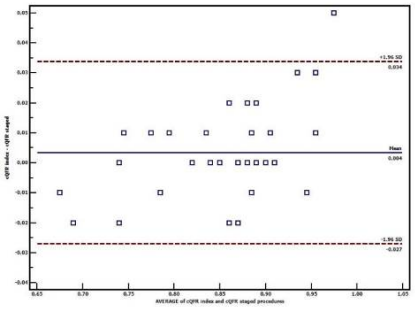

Figura 2. Bland-Altman relativa alla Coorte A.

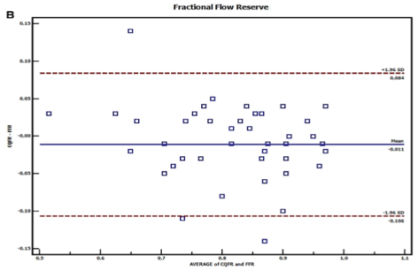

Figura 3. Bland-Altman relativa alla Coorte B.

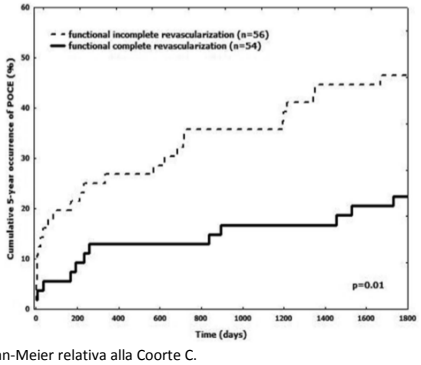

Figura 4. Kaplan-Meier relativa alla Coorte C.

diagnostica era 94% per il cut-off di 0.80. La Coorte C ha incluso 110 pazienti. Dopo aver calcolato il NI-FSS, abbiamo ottenuto 54 (50%) pazienti che hanno ricevuto una rivascolarizzazione funzionale completa (NI-FSS=0), e 56 (50%) che hanno ricevuto una rivascolarizzazione funzionale incompleta (NI-FSS >0). Ad un follow-up di 5 anni 39 (35%) pazienti hanno manifestato un evento avverso. Il rate di eventi era significativamente più elevato nel gruppo che aveva ricevuto una rivascolarizzazione funzionale incompleta (46% vs. 24%; p=0.01) (Fig. 4).

Conclusione. Il nostro studio è basato su di un piccolo campione di popolazione, ma è stato il primo studio a dimostrare la fattibilità e l'efficacia della QFR nello stratificare correttamente le lesioni non culprit riscontrate in corso di STEMI e malattia multivasale. Il nostro studio rappresenta inoltre il primo studio in cui il rate di eventi avversi viene valutato sulla base del NI-FSS, derivato mediante QFR, senza l'utilizzo di una guida di pressione e senza l'utilizzo di farmaci per indurre l'iperemia massimale.

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C31

PROGNOSTIC IMPACT OF CONTRAST FFR

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

Methods and Results. 481 patients undergoing functional evaluation with FFR and cFFR were divided into two groups on the basis of FFR and cFFR agreement (FFR ≤0.80 with cFFR ≤0.85 or FFR >0.80 with cFFR >0.85, n=431, mean follow-up 18 months) or disagreement (n=56, mean follow-up 14 months). We found no differences in major adverse cardiac events (MACE, 14% and 14% respectively, p=0.56), death (3% and 5.3%, p=0.3), myocardial infarction (4.4% and 0%, p=0.16) and myocardial revascularizations (7.8% and 14%, p=0.05).

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

Imaging and physiology

C32

FRACTIONAL FLOW RESERVE IN PATIENTS WITH AORTIC STENOSIS AND CORONARY ARTERY DISEASE: CORRELATION WITH MYOCARDIAL PERFUSION IMAGING

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

Methods and Results. FFR and SPECT were performed in a consecutive series of 28 patients with severe AS and 41 borderline coronary lesions during the work-up for valve replacement. Angiographic significant obstructions (diameter stenosis >50%) were observed in 31/41 lesions (76%) and SPECT signs of ischemia were identified in 15 (37%) of the territories supplied by these 41 stenotic vessels. FFR detected ischemia in 19/41 (46%) of the cases. Overall, the concordance rate between FFR and SPECT was 85%. The presence of ischemia was independently associated with FFR (OR 0.001, CI 0.00-0.02, p=0.003) but not with the angiographic severity of the lesions (OR 1.08, CI 0.98-1.19, p=0.1). At ROC curve analysis, FFR demonstrated an AUC=0.91, negative predictive value of 95% and positive predictive value of 74% in detecting myocardial perfusion defects at SPECT. The optimal FFR cut-point was ≤0.78 (sensitivity 87%, specificity 88%), providing an overall agreement of 88% with stress MPI.

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

C33

CORONARY PHYSIOLOGY PREDICTS THE EXTENT OF MYOCARDIAL INJURY AFTER PRIMARY PCI IN STEMI. INSIGHTS FROM THE OXAMI STUDY

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

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

Results. At ROC curve analysis, CFR, IMR and RER performed similarly in predicting the extent of infarction at 48h from PPCI (p=ns for all comparison). However, RER (AUC_{RER}=0.84, CI 0.69-0.99) was superior compared to both CFR (AUC_{CFR}=0.67, CI 0.48-0.86) and IMR (AUC_{IMR}=0.70, CI 0.52-0.88) in predicting IS >15% at 6 months (p<0.05). More in detail, patients with RER <2 units showed larger 48h-IS% (27.4 [14.5-42.5] vs. 15.4 [8.3-26], p=0.018), MVO (3.5 [0-5.97] vs. 0 [0-0.89], p=0.026), 6-months-IS% (22.7 [10.2-35] vs. 8.8 [6.9-12.3], p=0.006), higher rate of adverse remodeling (22.2% vs. 0%, p=0.04) and lower myocardial salvage index (34% [22-8-59.2 vs. 53.2% [37.7-71], p=0.032) compared with other patients. CFR (1.48±0.87 vs. 1.47±0.61, p=0.94) and IMR (58.04±37.7 vs. 55.01±49.6, p=0.72) did not improve after PPCI in patients with RER <2, whereas they improved significantly in patients with RER ≥2 (CFR: 1.37±0.43 vs. 1.93±0.49, p=0.018; IMR: 56.8±31.2 vs. 35.9±26.5, p=0.003).

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

C34

ADENOSINE-FREE INDEXES VS. FFR FOR FUNCTIONAL EVALUATION: A SYSTEMATIC META-ANALYSIS

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Background. The achievement of maximal hyperemia is a fundamental requirement to assess fractional flow reserve (FFR) but also a limiting factor. Adenosine free indexes (AFI), like resting Pd/Pa, instantaneous wave-free ratio (iFR) and contrast-FFR (cFFR) have been proposed to circumvent the use of vasodilators in the functional evaluation of coronary stenoses.

Methods and Results. We conducted a systematic review and meta-analysis of observational studies in which AFI were compared to FFR as a reference. After systematic literature search, 18 studies were included in this meta-analysis. Overall, 2907 patients and 3662 lesions were evaluated by iFR, 2023 patients and 2122 lesions by cFFR, 2606 patient and 2775 lesions by resting Pd/Pa (mean age 66.5 years, diagnosis at the admission: 57% stable coronary artery disease; 26% acute coronary syndromes). The overall Pearson's correlations were 0.91(I^2 79%) for FFR vs cFFR, 0.78 (I^2 75%) for FFR vs. iFR and 0.79 (I^2 82%) for FFR vs. resting Pd/Pa (p<0.0001). The area under the ROC curve was higher for the cFFR (0.94; 95% CI 0.92-0.97, I^2 48%) compared to iFR (0.90; 95% CI 0.88-0.92, I^2 68%) and resting Pd/Pa (0.87; 95% CI 0.82-0.92, I^2 64%). The diagnostic accuracy was higher for cFFR (89%, 95% CI 85%-93%, I^2 88%), followed by iFR (82%, 95% CI 80%-84%, I^2 19%) and resting Pd/Pa (79%,95% CI 77%-82%, I^2 39%).

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

C35

CULPRIT PLAQUE MORPHOLOGY IN PATIENTS WITH AND WITHOUT PREINFARCTION ANGINA: INSIGHTS FROM OPTICAL COHERENCE TOMOGRAPHY IMAGING IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION

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

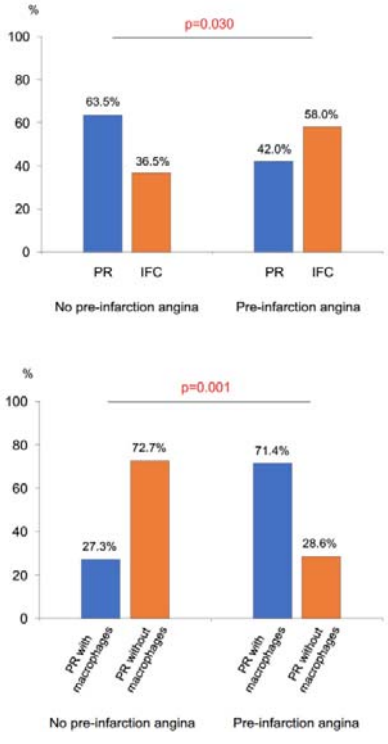
Objectives. To study the culprit plaque morphology in patients with AMI with or without preinfarction angina using optical coherence tomography (OCT) imaging.

Methods. A total of 102 patients with AMI (32 STEMI, 70 NSTEMI) who underwent OCT imaging before percutaneous coronary intervention were enrolled. Patients were classified as: i) having either intermittent chest pain in the six hours preceding the final episode of pain, or unstable

angina (or both) in the week preceding AMI (preinfarction angina group); or ii) having a single episode of chest pain without unstable symptoms in the preceding week (no preinfarction angina group). Culprit plaque was classified as plaque rupture (PR) or intact fibrous cap (IFC), as previously described. Prati thrombus score was calculated, and the prevalence of calcification, neovascularization, and OCT-defined macrophage accumulation was assessed.

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

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



BRS

C36

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

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Centro Cardiologico Monzino, Milano, Italy

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

Metodi. Tra settembre 2016 e aprile 2017, sono stati arruolati prospetticamente 200 soggetti con 214 lesioni coronariche *de-novo,* che hanno completato il FU a 12 mesi. Lo studio prevede l'arruolamento di pz. con lesioni compatibili con lo scaffold Magmaris, rispettando la strategia d'impianto delle 4P (Paziente/lesione; Predilatazione Proper-sizing e Postdilatazione) e le IFU. L'endpoint primario è la TLF a 12 mesi di follow-up. Le visite di follow-up clinico sono programmate a 6, 12, 24, 36, 48 e 60 mesi. Tutti gli eventi avversi seri e gli eventi relativi alla procedura/dispositivo sono stati giudicati da un comitato per gli eventi clinici indipendente.

Risultati. Tra i primi 200 pazienti (224 lesioni), arruolati in 28 centri, in 12 differenti paesi, 193 (97%) hanno completato il follow-up a 12 mesi. L'età media era 62.3±11.1 anni; 77% di sesso maschile e il 21% erano diabetici (14% insulino-dipendente). L'indicazione al trattamento era angina stabile (ischemia documentata nel 66.5%; l'angina instabile nel 18% mentre il 14.5% dei pazienti si presentava per NSTEMI. Il vaso target era: IVA 51.4%; CFX 19.6% e CD nel 29%, rispettivamente. Il 64% delle lesioni era B1/B2 mentre il 17.3% B2/C, con 6.5% di lesioni con calcificazioni moderate/severe. La lunghezza della lesioni e i diametri del vaso di riferimento medi erano 14.5±4.2 mm e 3.2±0.4 mm, rispettivamente. Il follow-up a 6 mesi mostrava TLF di 5/198 pazienti (2.5%) con 1 (0.5%) trombosi di scaffold subacuta da sospensione di DAPT, mentre a 12 mesi 9/198 (4.6%) dovuti solo a TLR, senza più trombosi di stent (0.5% a 12 mesi). L'unica trombosi si è verificata per sospensione precoce di DAPT dopo la procedura nell'ambito di rivascolarizzazione ibrida con bypass mininvasivo (MIDCAB).

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

C37

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

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

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

Results. After propensity score, out of 3001 patients 1400 patients (700 in each group) were selected: 352 patients treated on ULM and 1'048 on non-LM bifurcation lesions. In the overall population, rates of MACE were similar (12.3% vs. 11.6%, p 0.74) as of secondary endpoint at a median follow-up of 16 (12-22) months. Regarding two stents strategy, patients treated with BP-DES revealed a better outcome in terms of MACE (20.4% vs. 10%, p=0.03) and TVR (12% vs. 4.6%, p=0.05) and a trend towards TLR (10.2% vs. 3.8%, p=0.08). In non-LM bifurcation BP-DES seems to significantly reduce definite ST (1.7% vs. 0.8%, p<0.001).

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

C38

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

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Background. Bioresorbable vascular scaffolds (BRS) provide temporary mechanical support and may help restore normal vessel reactivity, positive remodeling, and reduce chronic inflammation. The Fantom scaffold (REVA Medical) is a sirolimus-eluting BRS, manufactured from TyroCore™, a unique radiopaque tyrosine based polymer.

Methods. FANTOM II is a prospective, multi-center, safety and performance study of patients with myocardial ischemia or a positive functional study. The study included patients with single *de novo* lesions in native coronary vessels ranging in diameter from 2.5 to 3.5 mm and lesion lengths up to 20 mm. The primary objective of the study is to demonstrate safety and performance of the Fantom sirolimus-eluting

bioresorbable scaffold by assessing the incidence of major adverse cardiac events (MACE) and late lumen loss at 6 months.
Results. FANTOM II enrolled 240 patients across 28 clinical centers in 8 countries. Two separate sequential cohorts followed patients with a 6-month (Cohort A, n=117) vs. 9-month (Cohort B, n=123) angiographic assessment. A subset of Cohort A patients returned for serial angiographic follow-up at 24 months. We report 24-month adjudicated clinical endpoints. Acute technical success, acute procedural success, and clinical procedural success were 95.8%, 99.1% and 99.6%, respectively. The primary safety endpoint of MACE at 24 months was 5.0%. Late lumen loss at 6 months in Cohort A was 0.25±0.35 mm In-Scaffold and 0.17±0.29 mm In-Segment. At 24 months, the subset of Cohort A patients (n=36) demonstrated stable late lumen loss values of 0.23±0.49 mm In-Scaffold and 0.21±0.49 mm In-Segment.
Conclusions. FANTOM II demonstrates safe and stable performance of the REVA BRS at 24-months.

C39

ESPERIENZA MULTICENTRICA ITALIANA CON SCAFFOLD BIORIASSORBIBILE IN MAGNESIO (MAGMARIS). RISULTATI CLINICI A LUNGO TERMINE A COMPLETO RIASSORBIMENTO

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Scopo. Il nuovo scaffold bioriassorbibile in magnesio (MagmarisTM) con lega di metallo-Mg, a bassa trombogenicità, breve tempo di 'scaffolding' e completo riassorbimento a 12 mesi mostra caratteristiche completamente diverse rispetto agli scaffold basati su PLLA.
Metodi. Sono stati analizzati i risultati clinici a 12 mesi, in termini di TVF (combinazione di morte, IM, CABG, TLF e TLR) e trombosi da scaffold, in pazienti "real world" con lesioni compatibili con l'utilizzo di Magmaris secondo le istruzioni d'uso. L'impianto dello scaffold doveva rispettare la strategia delle 4P (''Pt/lesion selection, Predilatation, Proper size and Postdilatation''). La durata della DAPT era consigliata 12 mesi.
Risultati. Dal luglio 2016 in 4 Centri italiani sono stati arruolati 207 pazienti con 209 lesioni coronariche de-novo con follow-up completo a 12 mesi. Le caratteristiche cliniche erano: età media 60.7±9.9 anni; sesso maschile nell'84% e 15% diabetici. Nell'78% dei casi la PCI era elettiva (angina stabile e/o ischemia documentata), mentre nel 22% dei casi per SCA-NSTEMI con 8% di impianto in STEMI. Le lesioni erano localizzate su IVA nel 51%, su CD nel 30% e su CFX nel 19% dei casi. Il 63% delle lesioni coinvolgeva il tratto prossimale-medio del vaso, dovuto alla disponibilità di scaffold con diametro 3.0 and 3.5 mm. Le lesioni di tipo A-B1 erano il 56% and B2-C il 44%, rispettivamente. La lunghezza media dello scaffold era 20.8±3.9 e il diametro medio 3.27±0.25. Nel 84% dei casi è stato impiantato un singolo scaffold mentre nel 16% dei pazienti in lesioni multiple o più stent in overlapping. La strategia delle 4P è stata rispettata nel 95% e nel 47% dei casi l'impianto è stato imaging guidato (OCT/IVUS). Il successo procedurale era del 99%, mentre il successo clinico era del 98% con un IM periprocedurale (1.5%). Il follow-up clinico a 12 mesi è stato completato in 132/207 pazienti (63%): il 93% dei pazienti era libero da eventi e non sono stati osservati casi di morte. In particolare: 1 NSTEMI per trombosi tardiva a 4 mesi (0.7% definite ST rate), 4.5% di TLR (5 pz per ISR and 1 paziente con dismantling intraluminale dello scaffodl); 3 casi (2.2%) re-PCI per progressione della lesione nel vaso target, tutte trattate con successo con impianto di DES in scaffold. Il totale delle TVF a 12 mesi era di 7/132 (5.3%).
Conclusioni. I risultati a lungo termine di questa serie multicentrica confermano l'efficacia e la sicurezza già osservate in studi controllati, con un'incidenza di trombosi paragonabile a quella dei DES di nuova generazione. Il completo riassorbimento a 12 mesi, la bassa trombogenicità del Mg ed il rispetto della strategia di impianto (4P), peculiari dello scaffold Magmaris risultano dei fattori essenziali per ridurre gli eventi a lungo termine.

PCI

C40

SUSTAINABILITY OF NEOINTIMAL INHIBITION OVER TIME BY REGULAR VS. LOWER DOSE DENSITY PACLITAXEL COATED BALLOONS IN A PERIPHERAL MODEL OF IN-STENT RESTENOSIS IN YUCATAN MINISWINE

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Background. Paclitaxel-coated balloons (PCBs) employ different coating technologies to deliver the antirestenotic drug without permanent polymer carrier. The ideal formulation should maximize the neointimal inhibition with the least drug possible, while ensuring adequate healing and containing the particulate release from the coating. We have investigated if lowering the dose density impacts the durability of the antirestenotic effect using porcine model of iliofemoral in-stent restenosis.
Methods. In-stent restenosis was induced in 20 iliofemoral arteries of 10 Yucatan miniswine by 130% balloon overstretch followed by self-expandable stent placement. Four weeks later (Day 0) all lesion sites were evaluated by optical coherence tomography (OCT) and then treated with regular dose density (3.5 μg/mm^2) or lower dose (2 μg/mm^2) density PCB. Serial angiographic and OCT follow-up was used at 60 and 90 days after treatment to characterize the neointimal response over time.
Results. Nearly identical in-stent obstruction was present in both groups on Day 0 before PCB treatment, making the head-to-head randomized comparison reliable. A trend toward more robust neointimal inhibition was observed at 60 days with the regular dose density PCB, reaching statistical significance at 90 days for neointimal thickness and % area stenosis.
Conclusions. Attempts to lower the dose density of PCB may have implications for sustainability of antirestenotic effect over time. Further investigation over longer follow-up time, as well as long-term clinical head-to-head PCB comparisons are necessary to validate these preliminary experimental findings.

	Lumen Area (mm^2)			Stent area (mm^2)		
	Regular dose density	Lower dose density	p	Regular dose density	Lower dose density	p
Day 0	8.40	8.03	0.76	20.25	20.64	0.76
Day 60	14.82	12.84	0.16	25.67	26.02	0.76
Day 90	13.85	11.25	0.06	25.89	25.54	0.75

	Neointimal thickness (mm)			Percent area stenosis (%)		
	Regular dose density	Lower dose density	p	Regular dose density	Lower dose density	p
Day 0	0.96	1.02	0.65	58	61	0.58
Day 60	0.72	0.91	0.06	42	51	0.08
Day 90	0.80	1.01	0.03	46	56	0.04

C41

RUOLO DELLA RIVASCOLARIZZAZIONE CORONARICA URGENTE NEL PAZIENTE CON ARRESTO CARDIACO EXTRAOSPEDALIERO (OHCA) DOPO RIPRESA DI CIRCOLO (ROSC): L'ESPERIENZA DELLA PROVINCIA AUTONOMA DI TRENTO

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Background. Vi sono evidenze cliniche che una strategia invasiva di esecuzione in emergenza del cateterismo cardiaco (CGF) in pazienti con ROSC dopo OHCA sia fattibile. Le linee guida dell'European Resuscitation Council del 2015 ne raccomandano l'indicazione nei pazienti con ST sopraslivellato o con BBSx di nuova insorgenza. L'EAPCI ne raccomanda l'indicazione anche nei pazienti senza evidenti causa coronariche o con instabilità emodinamica. Rimane comunque controversa tale indicazione nei pazienti senza sopraslivellamento ST.
Metodi. La Provincia Autonoma di Trento si estende per circa 6.200 km^2, è un territorio completamente montuoso ed ha una popolazione di poco più di 500 000 abitanti. Sulla base di un protocollo provinciale i pazienti con OHCA vengono centralizzati all'Ospedale S. Chiara di Trento (centro Hub), dotato di servizio di Emodinamica h24, mediante un sistema organizzativo di tipo "Hub&Spoke", implementato sulla medesima rete attiva per lo STEMI. Abbiamo eseguito una analisi retrospettiva del nostro data base provinciale dei pazienti con ROSC ricoverati e sottoposti a CGF dal gennaio 2012 al dicembre 2015. Sono stati valutati i dati coronarografici, la rivascolarizzazione, la mortalità e l'outcome neurologico mediante il Cerebral Performance Category score (CPCs) alla dimissione e a 6 mesi.
Risultati. Nel periodo in esame sono giunti al centro Hub 277 pazienti dopo ROSC. Di questi, 115/277 (42%) non sono stati sottoposti a CGF: 44/115 (38%) mostravano una evidente causa non cardiaca di arresto e 71/115 (62%) non stati ritenuti idonei alla CGF per cause differenti: lungo tempo preROSC, età molto avanzata, ecc. 162/236 (59%) pazienti giunti al centro Hub dopo ROSC stati sottoposti a CGF urgente. Il quadro elettrocardiografico post ROSC mostrava: STEMI in 62 pazienti (38%), NSTEMI in 17 pazienti (11%) e alterazioni aspecifiche (AS) in 80 pazienti (49%). Di 3 pazienti il dato risultava mancante. La percentuale di vaso occluso, subocculso o con patologia critica nei 3 gruppi era rispettivamente: 41/62 (66%), 8/62 (13%) e 6/62 (10%) nel gruppo STEMI, 9/17 (53%), 2/17 (12%) e 0/17 (0%) nel gruppo NSTEMI, 17/80 (21%), 13/80 (16%) e 8/80 (10%) nel gruppo con AA. Gli altri pazienti mostravano patologia coronarica non critica. 26/97 (27%) dei pazienti presentavano un quadro angiografico di occlusione coronarica acuta senza segni ECG di STEMI. In un caso è stata documentata la presenza di una dissezione coronarica a carico di

CD, con quadro ECG di STEMI, e trattato in maniera conservativa. 88/162 (54%) dei pazienti sottoposti a CGF sono stati sottoposti a rivascolarizzazione coronarica: 81/88 (92%) mediante PCI urgente e 8% mediante BAC differito. La percentuale di rivascolarizzazione nei tre gruppi è stata: 53/62 (85%) nel gruppo STEMI (51/53 – 96% con PCI), 12/17 (71%) nel gruppo NSTEMI (100% con PCI), 22/80 (28%%) nel gruppo AA (18/22 – 23% con PCI). L'accesso radiale è stato eseguito con successo in 107/162 pazienti (66%). L'impiego di IGP IIb/IIIa è stato del 9%. In 32/162 (20%) è stato posizionato un IABP. Nel 100% dei pazienti sottoposti a PCI in urgenza è stata trattata solo la culprit lesion. La sopravvivenza alla dimissione e a 6 mesi era 104/162 (64%) e 87/162 (54%). L'outcome neurologico valutato con il CPCs era pari a 1 in 74/162 (46%) alla dimissione. Nella popolazione ROSC non sottoposta a CGF da noi valutata (74/236 pazienti, 31%) la sopravvivenza alla dimissione e a 6 mesi era 27% (20/74) e 15% (11/74). L'outcome neurologico valutato con il CPCs era 1 in 5/74 pazienti (7%) alla dimissione.

Conclusioni. 1) La nostra strategia invasiva di gestione del paziente con ROSC dopo OHCA ha portato oltre la metà della popolazione in oggetto ad essere sottoposta a studio emodinamico urgente. 2) Oltre il 50% è stato sottoposto a rivascolarizzazione coronarica urgente (oltre il 90% con PCI). 3) Il 27% dei pazienti mostrava una occlusione coronarica acuta senza un quadro ECG di STEMI. 4) Una strategia di CGF estesa anche ai pazienti senza chiara ischemia all'ECG ha permesso la rivascolarizzazione urgente di quasi un quarto di questa sotto-popolazione. 5) La sopravvivenza dei pazienti sottoposti a CGF alla dimissione ed ai 6 mesi è superiore al 50% con buon outcome neurologico alla dimissione.

C42

LONG-TERM AND IN-HOSPITAL OUTCOMES OF PATIENTS WITH ACUTE CORONARY SYNDROME AND HISTORY OF CORONARY ARTERY BY-PASS GRAFTING UNDERGOING PERCUTANEOUS CORONARY INTERVENTION

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

Methods and Results. From January 2010 to December 2016, 200 patients with history of surgical revascularization admitted at our institution for ACS (78% non-ST elevation) underwent coronary angiography. Culprit lesion was identified on graft in 45.5% of cases. Almost half of patients had a non-culprit graft occluded at index angiography, that was previously not known in 53%. One hundred sixty-one (80.5%) patients received a successful percutaneous revascularization; PCI on a native vessel was performed in 57.6%. In-hospital and long term (median 695 days) all-cause mortality was 5.5% and 8.6%, respectively, for the entire population. There was no significant difference between group 2 and 3 in terms of in-hospital (p=0.240) and long-term (log rank p=0.780) all-cause mortality. Secondary composite end-point of all-cause death, myocardial infarction (MI) and non-urgent PCI was also not different between these two groups (log rank p=0.231).

Conclusions. Patients with ACS previously treated with CABG are a high-risk population. Percutaneous treatment of native coronary vessel compared to the graft did not influence in-hospital and long-term outcome.

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

Basal characteristics	Group 1 n=28	Group 2 n=99	Group 3 n=73	p-value Group 2 vs. Group 3
Age, mean ± SD	67.6 ± 9.9	72.9 ± 8.6	71.4 ± 8.3	0.246
Male sex, n (%)	20 (71.4)	87 (87.9)	63 (86.3)	0.759
History of Stroke/TIA, n (%)	3 (10.7)	10 (10.2)	14 (19.2)	0.095
Smoker, n (%)	8 (28.6)	47 (48.0)	33 (45.2)	0.864
Diabetic, n (%)	9 (32.1)	33 (33.7)	31 (42.5)	0.240
CKD (creatinine level >2.5 mg/dl), n (%)	3 (10.7)	18 (18.4)	10 (13.7)	0.414
Hypertension, n (%)	24 (85.7)	83 (84.7)	65 (89.0)	0.410
Dyslipidaemia, n (%)	17 (60.7)	63 (64.3)	47 (64.4)	0.989
Family history of CAD, n (%)	11 (39.3)	36 (36.7)	33 (45.2)	0.264
History of ACS, n (%)	20 (71.4)	65 (66.3)	47 (64.4)	0.791
History of percutaneous coronary revascularization, n (%)	12 (42.9)	46 (46.9)	33 (45.2)	0.822
CABG indication, n (%) ACS	12 (44.4)	42 (42.4)	27 (35.5)	0.517
Stable CAD	15 (55.6)	57 (57.6)	45 (62.5)	
Days from CABG median [IQR]	3562 [1961-5094]	3950 [1699-5984]	5224 [4328-6605]	0.003
CABG graft, n (%)				
Single	3 (10.7)	9 (10.1)	0	0.037
Double	8 (28.6)	28 (28.3)	13 (18.1)	
Triple	12 (42.9)	36 (36.4)	32 (44.4)	
Quadruple	5 (17.9)	21 (21.2)	23 (31.9)	
> Quadruple	0	4 (4.0)	4 (5.6)	
CABG + Valve replacement, n (%)	0	5 (5.1)	3 (4.2)	0.787
Index presentation, n (%) STEMI	2 (7.1)	20 (20.2)	22 (30.1)	0.134
NSTEMI/UA	26 (92.9)	79 (79.8)	51 (69.9)	
Ejection fraction, mean ± SD	50 ± 10	48 ± 12	50 ± 11	0.220
Killip Class, n (%)				
I	23 (82.1)	77 (77.8)	59 (80.8)	0.630
II	2 (7.1)	15 (15.2)	8 (11.0)	
III	1 (3.6)	3 (3.0)	1 (1.4)	
IV	2 (7.1)	4 (4.0)	5 (6.8)	
Angiographic features				
Femoral access, n (%)	24 (85.7)	78 (78.8)	57 (78.1)	0.911
Contrast media, ml ± SD	220 ± 60	288 ± 91	288 ± 83	0.995
In-stent restenosis/thrombosis, n (%)	0	14 (14.1)	7 (9.6)	0.367
LM native >50%, n (%)	8 (28.6)	41 (41.8)	34 (46.6)	0.500
Graft culprit, n (%)	6 (21.4)	14 (14.1)	71 (97.3)	<0.001
Arterial	5 (17.9)	6 (6.1)	7 (9.6)	0.387
Venous	4 (14.3)	8 (8.1)	65 (89.0)	<0.001
Native culprit, n (%)	1 (3.6)	83 (83.8)	13 (17.8)	<0.001
Graft occluded not-culprit, n (%)	8 (28.6)	50 (50.5)	35 (47.9)	0.740
Previously unknown	3 (10.7)	29 (29.3)	18 (24.7)	0.500
Known	6 (21.4)	21 (21.2)	19 (26.0)	0.460
Interventional procedure				
Treatment, n (%)				
Conservative	28 (100)			
Revascularization		94 (94.9)	67 (91.8)	0.401
Failed revascularization		5 (5.1)	6 (8.2)	
POBA only, n (%)		5 (5.1)	2 (2.7)	0.448
POBA/stent implantation, n (%)		96 (97.0)	70 (95.9)	0.703
DES, n (%)		85 (85.9)	57 (78.1)	0.184
BMS, n (%)		8 (8.1)	11 (15.1)	0.148

TIA, transient ischemic attack; CKD, chronic kidney disease; CAD, coronary artery disease; ACS, acute coronary syndrome; CABG, coronary artery by-pass graft; IQR, interquartile range; STEMI, ST-elevation myocardial infarction; NSTEMI/UA, non ST-elevation myocardial infarction/unstable angina; SD, standard deviation; LM, left main; POBA, plain old balloon angioplasty; DES, drug eluting stent; BMS, bare metal stent.

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

Discharge parameters	Group 1 n=28	Group 2 n=99	Group 3 n=73	p-value Group 2 vs. Group 3
Ejection fraction at discharge, mean SD	49 ± 9	46 ± 12	47 ± 10	0.445
In-hospital stay, days, mean± SD	11 ± 14	9 ± 13	8 ± 5	0.434
Follow-up, days, median [IQR]	941 [478-1484]	678 [381-1150]	642 [401-1096]	0.476
In-hospital outcomes				
All-cause mortality, n (%)	3 (10.7)	3 (3.0)	5 (6.8)	0.240
MI, n (%)	0	1 (1.0)	0	0.389
Post discharge outcomes				
All-cause mortality, n (%)	1 (4.0)	11 (11.7)	4 (6.0)	0.217
MI, n (%)	3 (12.0)	15 (16.0)	14 (20.9)	0.422
Non-urgent PCI, n (%)	1 (4.0)	2 (2.0)	8 (11.9)	0.011
All-cause mortality + MI, n (%)	4 (16.0)	26 (27.7)	17 (25.4)	0.747
All-cause mortality + MI + Non-urgent PCI, n (%)	5 (20.0)	28 (29.8)	21 (31.3)	0.837
Outcome since admission				
All-cause mortality, n (%)	4 (14.3)	14 (14.4)	9 (12.5)	0.717
MI, n (%)	3 (12.0)	16 (17.0)	14 (20.0)	0.534
Non-urgent PCI, n (%)	1 (3.6)	2 (2.1)	8 (11.1)	0.014
All-cause mortality + MI, n (%)	7 (25.0)	29 (29.9)	22 (30.6)	0.927
All-cause mortality + MI + Non-urgent PCI, n (%)	8 (28.6)	31 (32.0)	26 (36.1)	0.572

SD, standard deviation; IQR, interquartile range; OAC/NOAC, oral anticoagulant/novel oral anticoagulant; MI, myocardial infarction; PCI, percutaneous coronary intervention.

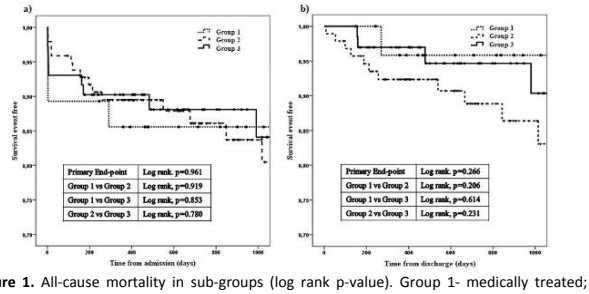

Figure 1. All-cause mortality in sub-groups (log rank p-value). Group 1- medically treated; Group 2- patients who underwent revascularization on native vessel, Group 3- patients who underwent revascularization on the graft.

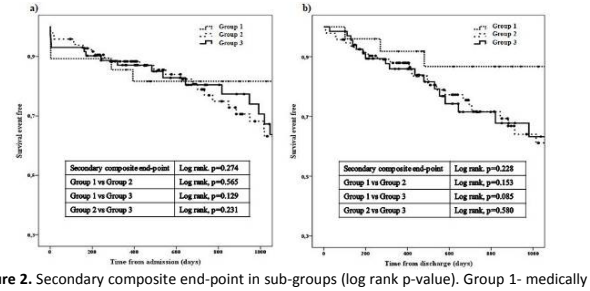

Figure 2. Secondary composite end-point in sub-groups (log rank p-value). Group 1- medically treated; Group 2- patients who underwent revascularization on native vessel, Group 3- patients who underwent revascularization on the graft

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LA SCELTA DI PERCORSI DIVERSIFICATI NEL FOLLOW-UP POST-PTCA. UNO STUDIO PROSPETTICO OSSERVAZIONALE

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Background. Il ricorso ad esami strumentali ed in particolare ai test provocativi nel corso del follow-up post-PTCA si deve basare su percorsi differenziati a seconda del grado di rischio del paziente. Questo concetto è raccomandato tra l'altro dal consensus proposto da ANMCO e GISE (Rossini et al. 2015). Tuttavia, nonostante ciò, nel mondo reale è ancora comune il ricorso routinario al test provocativo. L'obiettivo di questo studio osservazionale prospettico è verificare quali siano stati i determinanti che hanno portato alla scelta dei diversi percorsi proposti nel nostro modello ambulatoriale.

Materiali e metodi. L'organizzazione del nostro ambulatorio post-PTCA prevede una visita con ECG ad 1 mese ed una visita con ECG a 12 mesi. A 6 mesi sono possibili i seguenti percorsi: (A) visita con ECG ed ecocardiogramma, (B) visita con test ergometrico, (C) visita dopo l'esecuzione di scintigrafia miocardica con test da sforzo o stress farmacologico, (D) follow-up telefonico. Dal 15/2 al 15/6 2018 sono stati arruolati 326 pazienti consecutivi (età media 67.86 anni di cui il 22.09% di sesso femminile). A questi pazienti è stato assegnato un percorso (A-B-C-D) nel corso della prima visita, effettuata da cardiologi interventisti, pienamente consapevoli delle indicazioni della letteratura, ma liberi di scegliere il percorso più appropriato per il singolo paziente.

Risultati. I risultati sono sintetizzati nella Tabella. L'analisi statistica è stata effettuata con il T test per le variabili continue ed il chi quadro per le variabili categoriche. In sintesi, in circa la metà dei casi si è ricorso ad un test provocativo ed i follow-up telefonici sono stati il 13.8%. L'età, il genere e la presentazione clinica non incidono sulla scelta del percorso. Una bassa FE determina invece l'indicazione ad un ecocardiogramma a sei mesi. Il diabete e le variabili anatomiche come la prossimalità delle lesioni, la multivasalità e la presenza di lesioni intermedie suggeriscono la scelta di un test provocativo (in particolare la scintigrafia nel caso di PTCA multivaso). La rivascolarizzazione incompleta invece non sembra avere alcun impatto.

Conclusioni. Percorsi diversificati nell'ambito del follow-up post-PTCA sono ormai necessari nell'ottica dell'ottimizzazione delle risorse. Il diabete, la bassa FE e le variabili anatomiche si sono dimostrati i determinanti che correlano con il ricorso ad esami strumentali. Tuttavia, sono necessari ulteriori studi che ci permettano di chiarire quali siano i setting di pazienti che realmente beneficiano in termini prognostici dei percorsi di follow-up più complessi.

PCI and STEMI.

	Pazienti n (%)	Percorso A n (%)	Percorso B n (%)	Percorso C n (%)	Percorso D n (%)	p-value
Totale	326 (100)	124 (38.04)	66 (20.24)	91 (27.91)	45 (13.80	
Età	67.86±11.15	67.91±11.12	67.88±11.21	67.92±16.11	67.83±11.16	NS
Maschi	254 (77.91)	93 (28.53)	56 (17.18)	69 (21.16)	36 (11.04)	NS
Diabete	73 (22.39)	17 (5.21)	9 (2.76)	41 (12.57)	6 (1.84)	<0.01
STEMI	120 (36.81)	46 (14.11)	30 (9.20)	25 (7.67)	13 (3.99)	NS
NSTEMI	157 (48.16)	59 (18.1)	27 (8.28)	52 (15.95)	19 (5.83)	NS
Cardiopatia ischemica cronica	49 (15.03)	19 (5.83)	9 (2.76)	14 (4.25)	7 (2.15)	NS
FE ≤45%	60 (18.40)	35 (10.74)	5 (1.53)	20 (6.13)	0 (0)	<0.01
Tronco comune-DA prossimale	66 (20.24)	12 (3.68)	18 (5.52)	35 (10.74)	1 (0.31)	<0.01
Rivascolarizzazione incompleta	42 (12.88)	15 (4.6)	5 (1.53)	13 (3.99)	6 (1.84)	NS
Multivasalità	136 (41.72)	52 (15.95)	10 (3.07)	61 (18.71)	9 (2.76)	<0.01
Lesioni ≤50%	34 (10.43)	8 (2.45)	5 (1.53)	16 (4.91)	4 (1.23)	<0.01

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ON-TREATMENT PLATELET REACTIVITY IN PERIPHERAL AND CORONARY ARTERIAL BLOOD IN PATIENTS UNDERGOING PRIMARY PCI FOR ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

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Dual antiplatelet therapy is recommended in patient with undergoing primary percutaneous intervention (p-PCI) for ST-segment elevation myocardial infarction (STEMI). Pre-analytical variables may influence platelet function analysis results. Our aim was to evaluate the on-treatment platelet reactivity in peripheral artery vs coronary blood in patients with STEMI. We enrolled one hundred and nine patients who consecutively underwent p-PCI at Cardiology Unit of Padua University Hospital between June 2014 and June 2015. Before the procedure, all patients received intravenous aspirin 250mg and either of the thienopyridines; clopidogrel 600 mg, prasugrel 60 mg or ticagrelor 180 mg. ASPI-test and ADP-test using multiple electrode aggregometry (MEA) were performed in samples collected from both a peripheral artery and the culprit coronary artery. 'Low responders' were patients with an ASPI- test or ADP-test value greater than or equal to a pre-established normal range. No significant differences were observed in ASPI-test values between peripheral (19 (median) [3–49 (10–90 percentiles)] U) vs. coronary (12 [1–40] U, p1⁄4.06) blood and in ADP-test (40 [14–82] U vs. 33 [7–79] U, p=0.68) blood. In peripheral blood, fifteen (14%) patients were 'low aspirin' and forty-one (38%) 'low thienopyridines' res- ponders. The prevalence of 'low clopidogrel' responders was higher (45%) than prasugrel (36%) and ticagrelor (33%). Similar results were observed in coronary blood. In patients undergoing p-PCI for STEMI, MEA platelet function observed in coronary arteries was consistent with peripheral artery blood's independently of the antiplatelet drug used. The clinical significance of peripheral and coronary on-aspirin/thienopyridines platelet reactivity needs further clarification.

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SUCCESSFUL TREATMENT OF HIGH THROMBUS BURDEN STEMI

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Background. In ST elevation myocardial infarction (STEMI) the early and complete recanalization of the infarct-related artery (IRA), occluded by a thrombus is of mainstream importance to restore myocardial perfusion and avoid distal embolization and microvascular obstruction. Manual thrombus aspiration (MTA) during primary PCI failed to demonstrate clear benefit in routine use.

Aim. The aim of this observational experience is to evaluate the effect on vessel patency, ST resolution and myocardial function of the use of low-dose intracoronary rtPA on top of tirofiban administration in patients with high residual thrombus burden (>4) after failed manual thrombectomy.

Methods. In our centre all consecutive patients with large anterior myocardial infarction are routinely treated with a regimen of high-dose bolus tirofiban (i.v.) and of heparin 70 UI/kg mg. In presence of high thrombus burden (>4) manual thrombectomy is usually performed. Patients with persistent evidence of high residual thrombus burden are treated with an intracoronary bolus of 25 mg of rtPA and a further treatment by MTA 10 minutes apart.

Results. In the study period, 30 patients were treated following this protocol: the mean age was 56±12 years, 22% had a Killip Class ≥2, and TIMI risk score was 4.4±1.7. After the treatment, a complete thrombus resolution was observed in 24 patients (82%). Two patients with residual thrombus evidence (grade <3) showed a complete resolution at the angiographic control at 30 minutes, whereas 2 subjects exhibited a reduced but persistent residual thrombosis (grade <3). All of the patients were finally treated with angioplasty and stenting. No reflow phenomenon was never observed. A TIMI 3 flow was obtained in 95% of cases. None of the patients had major bleeding episodes, while 2 subjects had minor bleeding. Electrocardiogram, performed 1 hour after PCI, showed ST resolution more than 70% in 90% of subjects. Ejection fraction (echocardiography at discharge) was 49±5.

Conclusions. This preliminary experience shows that in patients with high residual thrombus burden after failed manual thrombectomy a strategy of intracoronary infusion of low-dose rtPA on top of tirofiban administration is effective in relieving the thrombus and restoring myocardial perfusion and myocardial function with no major bleeding episodes.

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CLINICAL SIGNIFICANCE OF HEALED CORONARY PLAQUES: AN OPTICAL COHERENCE TOMOGRAPHY STUDY WITH LONG-TERM FOLLOW-UP

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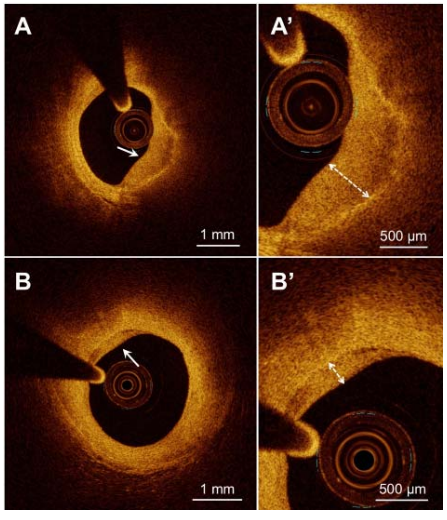
Background. At one end of the spectrum of coronary artery disease there are patients with multiple recurrent acute coronary syndromes (rACS), and at the other end those with long-standing stable angina pectoris (ls-SAP). Predicting the natural history of these patients based on individual "vulnerable plaques" imaging is challenging, as unstable plaques often heal without resulting in ACS.

Objectives. To assess the prevalence, characteristics, and clinical significance of healed coronary plaques (HCPs), as well as their role in the prediction of future adverse coronary events.

Methods. A total of 105 patients were enrolled, and classified into 3 groups: i) patients with rACS (n=30), defined as history of ≥3 acute myocardial infarctions (AMIs) or ≥4 ACS with at least 1 AMI; ii) patients with ls-SAP (n=37), defined as a minimum 3-year history of stable angina without any episode suggestive of an acute event; iii) patients with a

single AMI followed by a minimum 3-year period of clinical stability (sAMI) (n=38). Non-culprit segments were analyzed by optical coherence tomography (OCT) for assessment of plaque features. HCP was defined as a plaque with at least one heterogeneous signal-rich layer of different optical signal intensity clearly demarcated from the underlying tissue (Figure). The incidence of major adverse cardiac events (MACE), including cardiac death, non-fatal AMI, and re-hospitalization due to unstable angina, was assessed at follow-up.
Results. Median time of clinical stability was 8 years [4.5-14.5] in the ls-SAP group, and 9 years [5.0-15.0] in the sAMI group. Patients in the rACS and sAMI groups showed similar prevalence of thin-cap fibroatheroma [40.0% vs. 34.2%, p=0.623], which was significantly higher than in those with ls-SAP [8.1%, p=0.006]. In contrast, OCT-defined macrophage accumulation was significantly more frequent in patients with rACS than in those with ls-SAP or sAMI (53.3% vs. 18.9% vs. 18.4%, p=0.002). HCPs were rarely observed in patients with rACS, whereas their prevalence was significantly higher in patients with ls-SAP and sAMI [3.3% vs. 29.7% vs. 28.9%, p=0.014]. After a median follow-up of 36.8 months (18.3-56.2), the incidence of MACE was significantly higher in patients without HCP than in those with HCP (31.2% vs. 8.3%, p=0.012), primarily driven by higher rates of non-fatal AMI (13.0% vs. 0.0%, p=0.041). At multivariate analysis, HCP was an independent predictor of better clinical outcome (HR 0.13, 95% CI 0.03-0.64, p=0.012).
Conclusions. HCPs in non-culprit segments represent a novel marker of long-term clinical stability, probably reflecting the prevalence of reparative mechanisms over destabilizing stimuli.



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

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Introduction. Best strategy for patients presenting with cardiogenic shock (CS) following myocardial infarction (MI) with multivessel (MV) disease remain to be elucidated.
Methods and Results. A meta-analysis of all randomized controlled trial (RCT) and observational studies with multivariate adjustment evaluating the impact of MV-PCI (percutaneous coronary intervention) vs. culprit only (C)-PCI in patients admitted for CS and multivessel disease was performed. Primary endpoint was short-term mortality at multivariate analysis; long-term mortality, MI and acute renal injury (AKI) were the secondary ones. 6886 patients in 12 studies (one randomized and 11 observational ones) were included, 2042 treated with MV-PCI and 5841 with C-PCI. MV-PCI was not associated with an increased risk of short-term death compared with C-PCI both at univariate and multivariate analysis (OR 1.14, 95% CI 0.87-1.48, p=0.35, and OR 1.0, 95% CI 0.7-1.43, p=1.00). Meta-regression analysis suggested worse in-hospital survival with MV-PCI vs. C-PCI for shocked patients needing dialysis (beta 0.123, 95% CI 0.049-0.198; p=0.001) while in anterior MI patients a survival benefit could be seen (beta -0.022, 95% CI -0.033 to -0.012; p<0.001). MV-PCI strategy was associated with more frequent need for dialysis or CIN after revascularization (OR 1.36, 95% CI 1.06-1.75, p=0.02).
Conclusion. MV-PCI appears more favorable in patients with MV disease admitted for CS after anterior MI. The increased risk for AKI and its negative prognostic impact should be considered in decision making process.

Coronary intervention

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ACCESSO TRANSRADIALE ED EMOSTASI ULTRARAPIDA SENZA SOMMINISTRAZIONE DI EPARINA

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Introduzione. L'accesso transradiale offre importanti vantaggi rispetto all'accesso transfemorale sia per il confort del paziente e per la possibilità di una dimissione rapida sia in termini di riduzione delle complicanze emorragiche e vascolari, dei costi e soprattutto degli eventi aversi e della mortalità. Tuttavia l'accesso radiale è associato a possibili complicanze tra cui la più importante è l'occlusione dell'arteria radiale. In virtù della duplice irrorazione arteriosa della mano, l'occlusione dell'arteria radiale è un evento generalmente asintomatico ma purtroppo pregiudica la possibilità di un futuro utilizzo dell'arteria radiale occlusa per la preparazione di una fistola artero-venosa, per interventi di bypass aorto-coronarico o di chirurgia ricostruttiva e in particolare per ulteriori procedure di cardiologia interventistica. La somministrazione di eparina ha dimostrato di ridurre il rischio di occlusione dell'arteria radiale che tuttavia aumenta con la durata della compressione emostatica. Non è attualmente noto se il non utilizzo dell'eparina possa favorire una riduzione di durata della compressione emostatica e in secondo luogo del rischio di occlusione dell'arteria radiale.
Metodi. In 40 pazienti successivi (65±11 anni, 27 uomini) con indicazione a coronarografia transradiale con finalità esclusivamente diagnostica, è stato utilizzato un introduttore Slender 4/5 French e un catetere diagnostico Tiger 5F. Dopo l'accesso veniva somministrata un bolo di nitroglicerina e soluzione fisiologica senza l'utilizzo di eparina. È stato effettuato il cronometraggio del tempo trascorso tra inserimento dell'introduttore e la rimozione dello stesso a fine procedura e registrazione della pressione arteriosa radiale a fine procedura, sia prima che dopo somministrazione di un bolo di nitroglicerina. Successivamente è stato attuato un protocollo ultrarapido di emostasi pervia che prevedeva sgonfiaggio del bracciale compressivo fino alla comparsa di gemizio con immediato arresto e re-insufflazione di 1 ml di aria e rimozione di 2 ml di aria ogni 5 minuti. I pazienti sono stati infine sottoposti a controllo ecografico dell'arteria radiale con sonda vascolare lineare ad alta frequenza a 24 ore dalla procedura.
Risultati. In tutti i pazienti è stata ottenuta l'emostasi con rimozione del dispositivo di compressione emostatica in un tempo compreso tra 15 e 35 minuti. La durata della compressione emostatica non era in rapporto con l'età, il peso, l'altezza, la durata della procedura, la pressione arteriosa radiale al termine della procedura sia prima che dopo somministrazione di bolo di nitroglicerina. Al controllo ecografico a 24 ore dalla procedura l'arteria radiale risultava pervia in tutti i pazienti.
Conclusioni. Nei pazienti sottoposti a coronarografia con finalità esclusivamente diagnostica, la non somministrazione di eparina favorisce un'emostasi pervia ultrarapida associata a un rischio nullo di occlusione dell'arteria radiale. Tale osservazione preliminare richiede conferma in studi appropriatamente disegnati.

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PTCA VS. CABG NEL PAZIENTE CON CORONAROPATIA TRIVASALE E/O DEL TRONCO COMUNE. ANALISI DI UNA CASISTICA SELEZIONATA DI PAZIENTI VALUTATI IN HEART TEAM

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Introduzione. I pazienti con evidenza angiografica di coronaropatia trivasale e/o del tronco comune (TC) sottoposti a rivascolarizzazione, sono ad alto rischio di eventi cardiovascolari. Tuttavia questo sottogruppo di pazienti è stato relativamente poco valutato nei principali trial clinici poiché ad alta complessità. Pertanto abbiamo condotto uno studio su questo particolare gruppo di pazienti, valutandoli caso per caso in Heart Team, facendo riferimento alla pratica clinica quotidiana.
Obiettivi. Descrivere le caratteristiche demografiche e cliniche dei pazienti rivascolarizzati per via percutanea (PTCA) e per via chirurgica (CABG). Valutare la prognosi e stratificare il rischio nei pazienti affetti da coronaropatia trivasale e/o del TC sottoposti a PTCA, rispetto ai pazienti sottoposti a CABG.

Pazienti e metodi. Studio osservazionale, retrospettivo, monocentrico. Sono stati arruolati 415 pazienti consecutivi ricoverati presso la struttura complessa di cardiologia del Policlinico di Modena nel periodo compreso tra il 01/04/2011 e il 01/04/2016 che, dopo essere stati sottoposti a studio angiografico, hanno presentato coronaropatia trivasale e/o del TC. Dopo essere stati valutati dall'Heart Team, sono stati sottoposti a PTCA (c/o il Policlinico di Modena) o a CABG (c/o Hesperia Hospital). La mortalità è stata valutata alla mediana del follow-up (1108 giorni), così come il reintervento, lo stroke e l'infarto acuto del miocardio (IMA) (mediana 775 giorni).
Risultati. Dei 415 pazienti arruolati nello studio, 262 (63%) sono stati sottoposti a PTCA, 153 (37%) a CABG. La mortalità globale è risultata maggiore nel gruppo PTCA (p=0.005), in particolare nei pazienti con interessamento del TC, SYNTAX score >32, età >75 anni (p<0.05), ma non con età >80 anni (p=0.39). Tuttavia, le curve di mortalità non divergevano in modo significativo (p>0.05), quando i pazienti venivano stratificati per i seguenti parametri: BMI ≥30, diabete mellito tipo 2, insufficienza renale cronica (IRC), BPCO, abitudine tabagica attiva, SYNTAX score ≤32, presentazione come STEMI e interessamento di 3 vasi isolati, sebbene per quest'ultimo parametro si sia osservato un trend di significatività (p=0.07). L'incidenza di stroke e IMA è risultata simile nei due gruppi (p>0.05), mentre i pazienti sottoposti a PTCA avevano una più alta incidenza di reintervento, indipendentemente dal SYNTAX score (p>0.001). I due gruppi di pazienti erano omogenei per età, BMI, diabete mellito tipo 2, IRC, BPCO, abitudine tabagica attiva e SYNTAX score. Invece il numero di pazienti con EF <30% (13% vs. 4%), presentazione come STEMI (50% vs. 11%) o shock cardiogeno (8% vs. 1%) e STS score elevato, era nettamente maggiore (p<0.05) nel gruppo PTCA. Pertanto trattasi di pazienti a elevato o molto elevato rischio.
Conclusione. Nella nostra esperienza, l'attitudine dell'Heart Team è stata di assegnare il trattamento con PTCA ai pazienti a più alto rischio di morte e complicanze e a più elevato livello di complessità rispetto al CABG. Il nostro studio documenta anche che la mortalità globale e la frequenza di reintervento sono maggiori nel gruppo PTCA rispetto al gruppo CABG, mentre la frequenza di stroke e IMA è risultata simile tra i due gruppi. Nei pazienti con SYNTAX score <32 o affetti da STEMI, interessamento di 3 vasi isolati o importanti comorbidità (diabete mellito tipo 2, IRC, BPCO, abitudine tabagica attiva, BMI ≥30), la PTCA non è risultata inferiore al CABG nel ridurre la mortalità e le complicanze a lungo termine, rappresentando quindi un valido approccio terapeutico.

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

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Introduzione e obiettivi. Il principio della "vascular reparative therapy", secondo cui è possibile trattare lesioni coronariche con device che si dissolvono nel tempo portando ad una "restitutio ad integrum" del vaso, ha sempre intrigato e in questi anni si è diffuso tra i cardiologi interventisti. Nonostante il "first in men trial ABSORB" abbia mostrato come a due anni si possa avere il riassorbimento del BVS (Bioresorbable everolimus-eluting vascular scaffold) "Absorb" impiantato in lesioni coronariche semplici e pazienti selezionati, con un basso tasso di trombosi, i risultati clinici a lungo termine su sicurezza ed efficacia di BVS nella normale pratica clinica sono ancora limitati. I recenti dati di follow-up a lungo termine su ABSORB BVS riportano outcome significativamente più scarsi rispetto al best in class DES XIENCE. Di contro è stato dimostrato come una tecnica di impianto scrupolosa e predeterminata (PSP), che rispetti passaggi mandatori quali preparazione della lesione, accurato sizing, e postdilatazione, possa migliorare significativamente gli outcome. Al fine di fornire elementi in più per la comprensione dei risultati clinici a lungo termine degli scaffold riassorbibili, riportiamo qui i dati sull'outcome clinico a 5 anni dopo impianto di BVS Absorb dal nostro registro monocentrico AG-SORB.
Metodi. AG-SORB è un registro prospettico, monocentrico e open-label, ha arruolato in modo continuo tutti i pazienti sottoposti a impianto di BVS Absorb con tecnica standardizzata e predeterminata dal Settembre del 2012 presso l'Ospedale San Giovanni di Dio di Agrigento, sino alla sospensione della distribuzione del device. La scelta dell'impianto di BVS è stata lasciata all'operatore caso per caso, ma motivata da fattori precisi: età <80 anni, lesione lunga, vasi <4 mm e superiori a 2.5 mm, malattia monovasale del discendente anteriore, lesioni non estremamente calcifiche. La strategia di impianto e ottimizzazione del BVS Absorb adottata nel nostro centro è standardizzata e prevede predilatazione mandatoria con pallone di diametro uguale o al massimo 0.5 mm inferiore al reference vessel diameter (RVD) con stenosi residua post-dilatazione inferiore al 30%; rilascio dello scaffold a 11 atm; postdilatazione mandatoria con palloni non complianti di diametro pari o 0.5 mm superiore a quello del BVS, espansi a pressioni superiori al nominale. Tutti i pazienti del registro dopo l'impianto dello scaffold Absorb hanno programmato un follow up telefonico a 30 giorni, 6 mesi, 1 anno, 3 anni, 4 anni e 5 anni. Ad oggi 200 pazienti consecutivi sono stati inclusi nel registro. L'outcome primario è rappresentato da un device-oriented composite endpoint (DOCE), la TLF (target lesion failure), definito come combinazione di morte cardiaca, infarto del vaso target e ID-TLR (ischemia-driven target lesion revascularization).
Risultati. Il follow-up clinico minimo è stato è stato di 5 anni, eseguito su 57 pazienti trattati mediante impianto di BVS. Tutti i pazienti hanno ricevuto prescrizione per doppia terapia antiaggregante (DAPT) di durata non inferiore a 12 mesi, 2 pazienti (3.4%) hanno discontinuato la DAPT tra 6 e 12 mesi per patologie intercorrenti. Oltre l'80% dei pazienti che non presentavano alto rischio di sanguinamento hanno esteso la DAPT con ASA e clopidogrel a 18 mesi, il 25% a 24 mesi. L'età media dei pazienti era di 59±10 anni; I maschi rappresentavano il 79% della popolazione esaminata. Il 37% dei pazienti era affetto da diabete mellito, il 69% da ipertensione arteriosa e il 37% era fumatore attivo. Le lesioni complesse (tipo B2/C, secondo la classificazione ACC/AHA) hanno rappresentato il 29% del totale, lesioni tipo B1 il 57%, lesioni tipo A il 14%. Con un Syntax score medio di 11.5 ± 6. 73 scaffold sono stati impiantati in 59 lesioni su 57 pazienti. La lunghezza media degli scaffold impiantati per lesione è stata di 29±16 mm con un rapporto BVS/paziente di 1.28 e una percentuale di overlap del 24%. Il ramo discendente anteriore (LAD) ha rappresentato il vaso target nel 49.5% dei casi. Nel registro, grazie alla

Caratteristiche cliniche di base	
Sesso maschile	79%
Età media (anni)	58 ± 10
Ipertensione arteriosa	69%
Diabete	37%
Insulino-dipendente	27%
Fumatori	37%
Ex fumatori	26%
Familiarità per coronaropatie	50%
Dislipidemia	47%
Pregressa CABG	3%
Pregressa PCI	13%
Creatininemia (mg/dl)	0.95 ± 0.2
eGFR <60 ml/min	3%
Presentazione clinica	
Angina stabile	33%
Angina instabile	31.5%
NSTEMI	24%
STEMI	11.5%
Caratteristiche delle lesioni	
MVD	70%
Syntax score	11.5 ± 6
LAD trattata con BVS	50%
LCX trattata con BVS	25%
RCA trattata con BVS	25%
Tipo di lesione (ACC-AHA)	
A	14%
B1	57%
B2	24%
C	5%
Lunghezza lesione (mm)	24 ± 12
Lesioni >28 mm	24%
Antiaggregazione in dimissione	
ASA+clopidogrel	24%
ASA+prasugrel	53%
ASA+ticagrelor	23%
Durata minima prescritta della DAPT	12 mesi
Sospensione precoce della DAPT	3.4%
Follow-up – endpoints	
Follow-up medio	47 ± 5 mesi
Morte cardiaca	0 (0%)
DOCE per lesione	n=59
Clinically-driven target lesion revascularization	3 (5%)
Infarto del vaso target	1 (1.7%)
Trombosi dello scaffold	1 (1.7%)
In scaffold restenosis	2 (3.4%)
DOCE per paziente	n=57
Clinically-driven target lesion revascularization	3 (5.2%)
Infarto del vaso target	1 (1.75%)
Trombosi dello scaffold	1 (1.75%)
Caratteristiche procedurali	
Accesso arterioso radiale	90%
Imaging invasivo (OCT-IVUS)	11.5%
Predilatazione	100%
% Stenosi residua dopo predilatazione	18.5 ± 7
Postdilatazione	98.6%
Pressioni di postdilatazione in atm	13.4 ± 1.9
Rapporto pallone da postdilatazione/BVS ≥1	100%
Pallone da postdilatazione >0.5 mm del BVS	2.5%
Caratteristiche dei BVS	
BVS totali	73
BVS per paziente	1.4 ± 0.8
Pazienti con 4 BVS	1
Pazienti con 2 BVS	13
Pazienti con 1 BVS	43
Lesioni trattate con più di 1 BVS	14 (24%)
BVS con overlapping	14 (24%)
Diametro medio BVS in mm	3.1± 0.4
Lunghezza media BVS per lesione in mm	29 ± 16
Pressione minima di rilascio dei BVS in atm	11

tecnica d'impianto standardizzata, il 100% dei pazienti ha eseguito predilatazione e il 98.6% postdilatazione con le caratteristiche sopra citate nel paragrafo sui metodi. L'incidenza dei DOCE, analizzando la popolazione per lesione trattata, è stata del 5%, con 1 trombosi di BVS (1.7%) che ha causato riospedalizzazione per NSTEMI a 696 giorni dalla procedura indice, 2 ristenosi critiche in BVS (3.4%) che hanno portato a riospedalizzazione per angina instabile. Non è accorsa nessuna morte cardiaca. Nello specifico la trombosi del BVS si è verificata a 696 giorni dall'impianto su paziente di 62 anni, diabetico, iperteso e dislipidemico, la diagnosi di ingresso al ricovero indice era NSTEMI e il paziente aveva impiantato un BVS 3/18 mm su LAD, il paziente aveva sospeso a 18 mesi la DAPT ed assumeva solo cardioaspirina 100 mg. Il paziente è stato trattato con PCI ed impianto di DES su LAD. È da riportare inoltre una singola TLR (non clinically-driven) a 5 anni dall'impianto in paziente ospedalizzato per stress test cardiaco positivo ma con concomitante stenosi subocclusiva di altro vaso coronarico. Da segnalare inoltre il totale riassorbimento dello scaffold all'OCT eseguito in casi selezionati a 5 anni dall'impianto.
Conclusioni. La frequenza dell'outcome primario a lungo termine, oltre i 5 anni, dopo impianto di BVS in una popolazione real world, risulta relativamente bassa nel registro AG-SORB, con un solo episodio di trombosi dello scaffold, 2 ID-TLR e nessuna morte cardiaca. I risultati del nostro registro mostrano una buona performance del device in termini di sicurezza ed efficacia nella normale pratica clinica quotidiana con l'utilizzo di una strategia di impianto predeterminata e costante e il prolungamento della DAPT a 18 mesi nella maggioranza dei pazienti. Tuttavia AG-SORB è gravato dai limiti di un registro monocentrico, pertanto ampi studi randomizzati con scrupolosa tecnica di impianto predeterminata, alla luce delle nuove evidenze, sono necessari per chiarire meglio il profilo di sicurezza ed efficacia a lungo termine del BVS Absorb, nonché il suo potenziale spettro di utilizzo nella normale pratica clinica quotidiana. A ciò si aggiunge la necessità di ulteriori dati per la definizione ottimale della durata della DAPT, già estesa nel nostro registro a 18 mesi nei pazienti non ad elevato rischio di sanguinamento (80%).

C51

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

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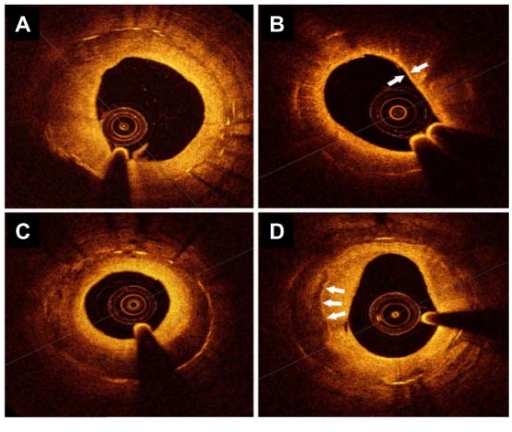
Background. The effect of chronic kidney disease (CKD) on coronary stent healing and the development of neoatherosclerosis is largely unknown.
Objectives. To assess the prevalence and characteristics of neointimal hyperplasia (NIH) and neoatherosclerosis (NA) in patients with and without CKD.
Methods. A total of 105 patients who underwent follow-up optical coherence tomography (OCT) imaging of a previously implanted stent were enrolled, and classified into 3 groups: 1) patients without CKD (n=69), defined as an estimated glomerular filtration rate (eGFR) >60 mL/min/1.73 m^2; 2) patients with mild-to-moderate CKD (mCKD) (n=27), defined as an eGFR between 60 and 30 mL/min/1.73 m^2; and 2) patients with severe CKD (sCKD) (n=9), defined as an eGFR <30 mL/min/1.73 m^2. NA was defined as the presence of lipid-laden neointima and/or neointimal calcification (Figure). Prevalence of thin-cap fibroatheroma (TCFA)-like neointima and neovascularization was also assessed.
Results. Median time from stent implantation was 51.8 months (IQR, 16.6–85.1), and was not different among the three groups. Analyzed stents were 58 drug-eluting stents and 47 bare metal stents. NIH volume with sCKD (1.64 ± 0.84 mm^3 vs. 2.45 ± 1.30 mm^3 vs. 2.61 ± 0.85 mm^3, was significantly lower in patients with mCKD than in those without CKD and respectively, p=0.007). Prevalence of neoatherosclerosis was significantly lower in patients with mCKD than in those without CKD and with sCKD (7.4% vs. 33.3% vs. 44.4%, respectively, p=0.019). In addition, the number of frames with neoatherosclerosis was significantly lower in patients with mCKD than in those without CKD and with sCKD (3.85 ± 4.55 vs. 7.45 ± 6.88 vs. 7.67 ± 5.32, respectively, p=0.038). Neointimal calcifications tended to be more frequent in patients with sCKD than in those with mCKD and without CKD (22.2% vs. 7.4% vs. 4.3%, respectively, p=0.127). No differences in the prevalence of TCFA-like neointima and neovascularization were observed among the three groups.
Conclusions. Our results suggest that patients with mild-to-moderate CKD may be relatively protected from the development of NIH and NA. These findings are not observed in patients with severe CKD, in whom NA and neointimal calcifications appear significantly more frequent. The molecular mechanisms at the basis of these observations need to be investigated in future studies.



Complications

C52

BLOOD REINFUSION DURING IATROGENIC CARDIAC TAMPONADE: A USEFUL TRICK UP THE SLEEVE OF THE INTERVENTIONAL CARDIOLOGIST. SAFETY AND FEASIBILITY IN A COHORT OF 30 PATIENTS

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Background. A rare, life-threatening complication of percutaneous coronary and structural intervention, is hemopericardium with cardiogenic shock. In these cases, prompt pericardiocentensis is mandatory. The blood aspirated by the pericardium, can be reinfused into a central vein, through a closed circuit, in order to support the circulation and stabilize the patient avoiding a rapid fall of hematocrit. This technique, routinely adopted in our institute, is not systematically performed in the catheterization laboratories, due to a certain reluctance to reinfuse unfiltered blood. The main potential risks are hemocoagulative disorders and septic complications.
Aim. To verify the feasibility and safety of the reinfusion of blood aspirated from the pericardium, into a femoral vein, in case of cardiac tamponade caused by an interventional procedure.
Methods. We reviewed all the cases of tamponade occurred in our cath lab from 2007 to 2017, treated with immediate re-infusion of whole blood, with a closed circuit in a femoral vein. Clinical and procedural data were obtained from the review of the medical records. Thirty days and one year follow-up has been collected.
Results. During 10 years, 30 cases of iatrogenic hemopericardium have been treated in our institute, with blood reinfusion through a pericardial-femoral circuit. Twenty-one (70%) coronary perforations during angioplasty, 6 cases of rupture during structural procedures (4 TAVI, 1 PFO closure, 1 mitral valvuloplasty), 2 perforations of the right ventricle during biopsy, 1 case of VT ablation. Cardiogenic shock occurred in all the patients. Intra-aortic counter-pulsation was used in 4 cases, homologous blood transfusion in 6 patients. In 4 cases cardiac surgery was necessary to seal the bleeding site. During hospitalization there were two thrombotic events (a post-infarction left ventricular apical thrombosis and a pulmonary embolism in a bedridden patient). Four patients (13%) died at 30 days (3 in the cath lab). No further deaths occurred at one year follow-up.
Conclusions. Autotransfusion of whole blood from the pericardium into a femoral vein, in case of iatrogenic tamponade complicating interventional procedures, is feasible and safe. In our experience, it contributes substantially to the restoration of acceptable hemodynamic conditions, limiting the use of homologous blood transfusions and mechanical circulatory support.

C53

IMPACT OF 719 TRP>ARG POLYMORPHISM OF KIF 6 GENE ON CONTRAST-INDUCED NEPHROPATHY AND MODULATION OF STATIN THERAPY EFFECTIVENESS

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Background. Contrast-induced nephropathy (CIN), is a common complication of procedures that foresee the use of contrast media. Great

efforts have been done to identify new risk factors and potential preventive strategies, such as statin therapy administration. Kinesis-Like Protein 6 (KIF 6) is an omodimeric protein expressed in coronary arteries and other vascular tissues, that is involved in microtubular transport. The impact of KIF 6 gene on cardiovascular risk modulation has been investigated since 2007 due to the presence of a single nucleotide polymorphism with the replacement of Trp 719 with arginine (Arg). Several studies assessed the association between this genetic variant and a significant increase of cardiovascular risk, while, several other clinical trials showed a significant association between "pleiotropic" effects of statin therapy and a reduction in cardiovascular events in the population with the risk allele, due to the documented modulation of response to statin treatment by KIF 6 polymorphism.

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

Results. KIF 6 Arg mutation was found in 669 patients (heterozygotes n = 525, homozygotes n = 144). Patients without polymorphism were more often in therapy with angiotensin receptor blockers, beta blockers, but less with acetylsalicylic acid and clopidogrel and they have higher haemoglobin levels at admission. The total prevalence of CIN in our population was 12.5% and we did not find any significant association between KIF 6 polymorphism and the development of CIN (Group 1 11.3%, Group 2 13.7%, Group 3 13.2%, p=0.30) (Figure 1). This result was confirmed by multivariate analysis after correction for baseline confounding factors (adjusted OR [95% CI] 1.12 [0.86-1.46], p=0.38). At subgroups analysis we found a higher prevalence of CIN among homozygous patients treatment "naïve" in comparison to wild-type patients (20.7% vs. 11.3%, p=0.05), while patients with statin therapy at admission showed a lower CIN development without reaching a statistical significant result (8.6% vs. 13.2%, p=0.28) (p interaction =0.03). No other significant differences between homozygous KIF 6 polymorphism and CIN development according to main risk factors for CIN such as diabetes, renal failure, gender, older age and PCI (Figure 2).

Conclusion. We found that statin therapy at admission did not influence the development of CIN, while, KIF 6 homozygous Arg was associated with a significant increase in the risk of CIN only among statin naive patients. Future additional studies are certainly needed to confirm our findings and to evaluate the beneficial effects of statin therapy especially in this subset of patients.

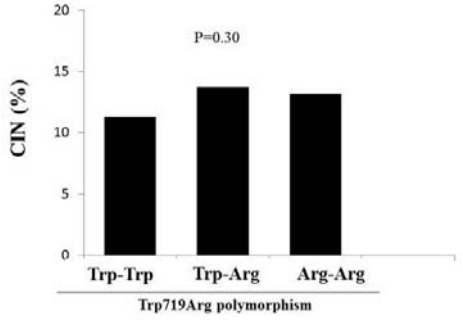

Figure 1

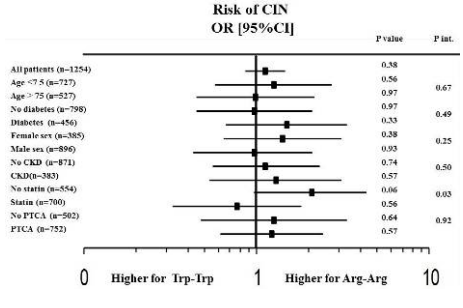

Figure 2

C54

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

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New materials and the increasing utilization of radial access have contributed to improve safety and reduce the rate of complications in the cath lab. The use of small-caliber arteries such as radial or ulnar arteries, however, is not completely risk-free. We must be careful of ischemic risk, perforation, spasm, pseudoaneurysms formation and also kinking of the angiographic catheters, in particular with the diagnostic material.

We report the case of a 66 years old patient, active smoker, with hypertension and diabetes. He suffered one year before of an inferior myocardial infarction treated with angioplasty and implantation of multiple medicated stent on the right coronary artery and the circumflex branch. He underwent subsequent elective revascularization with stenting of the anterior descending artery and the main diagonal branch. The patient presented to the emergency department with symptoms of unstable angina six months after the last revascularization and an angiographic study was perfomed. Due to the absence of a right radial pulse, a left radial approach was chosen using a Judkins right 3.5 6F diagnostic catheter.

During the cannulation maneuvers of the right coronary artery there was a kinking effect of the catheter body at the left subclavian artery level with impossibility to untie it or cross the tortuosity with a guidewire (Fig. 1). After some ineffective attempts to straighten the JR 3.5 percutaneously with a gooseneck catheter (Fig. 2) from right femoral access, a multipurpose catheter was used, with a balloon over the wire inside, to anchor the distal portion of the kinked catheter from the inner lumen (Fig. 3). While inflating the balloon with high pressure, a clockwise rotation of the proximal part of the JR 3.5 catheter was performed with successful kinging resolution and extraction of the catheter from the radial access (Figs. 4 and 5). The subsequent transfemoral coronary angiography has documented an intrastent critical restenosis both of the right coronary and of the anterior descending artery treated with drug eluting balloon. The patient left the hemodynamic room after 1 hour and 30 min without complications in vascular access. No vascular damage was shown by angiography of the left upper limb at the end of the procedure (Fig. 6). In the hemodynamic room it can happen to face unexpected complications and it is necessary to know all the available materials and device that can help in the specific setting while maintaining the concentration in order to avoid further risks for the patient. It may also be necessary to think out of the box in search of unconventional solutions to avoid or minimize collateral damage.

There are standardized solutions and materials dedicated to various type of complications but sometimes it may be necessary to opt for different strategies using the "craftmanship" that is part of the cultural baggage of every interventional cardiologist.

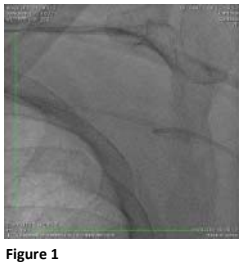

Figure 1

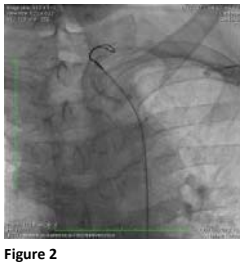

Figure 2

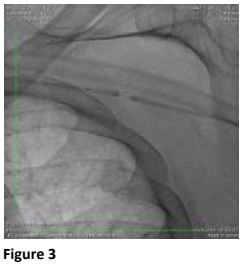

Figure 3

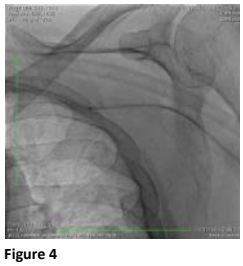

Figure 4

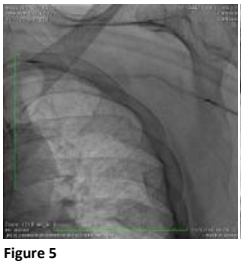

Figure 5

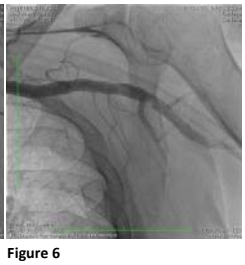

Figure 6

C55

ULTRASOUND-ENHANCED CATHETER-DIRECTED THROMBOLYSIS FOR PATIENTS WITH ACUTE PULMONARY EMBOLISM AT HIGH OR INTERMEDIATE-HIGH RISK AND WITH CONTRAINDICATION TO SYSTEMIC FIBRINOLYSIS

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

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

Results. Mean RV/LV ratio (1.38±0.3 vs. 0.97±0.16; p<0.0005); QI (27.06±2.6 vs. 18.8±7.8; p<0.001) and SPAP (71.1±12 mmHg vs. 45.2±16 mmHg; p<0.001) significantly decreased within 72 hours after the procedure. Also heart rate and percentage of arterial oxygen saturation significantly improve after EKOS. One patient died due to a severe bleeding. Six patients experienced moderate bleeding, 3 of them had active bleeding and low haemoglobin levels at the time of the procedure. Femoral hematoma was observed in 2 subjects. Mean length of stay in-hospital and in ICU was 13±6 and 6±2.9 days respectively. An 89-year-old patient (PESI score 139), died from multiple organ failure at 12 days from the procedure. No other patients died after the discharge within 30-day follow-up.

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

Miscellaneous

C56

DRUG COATED-BALLOON WITH OR WITHOUT DIRECTIONAL ATHERECTOMY FOR PERCUTANEOUS REVASCULARIZATION OF THE SUPERFICIAL FEMORAL ARTERY: A SINGLE CENTRE RETROSPECTIVE ANALYSIS

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

Methods. Patients treated with DCB or DA+DCB for *de novo* SFA lesions from January 2012 to December 2017 at a single institution were included in the present analysis. Patients undergoing stent implantation were excluded, unless stenting was performed as a bailout strategy. Baseline clinical and procedural data were collected. All patients were followed-up for at least six months with clinical control and colorDoppler ultrasound. Need for bailout stenting represented the main procedural outcome. Presence of symptoms (claudicatio intermittens) and significant restenosis were assessed at 6 months and at the long-term follow-up.

Results. Overall, 164 patients were included, with a mean age of 69.1±8.4 years; 125 (76.2%) were of male gender, 146 (89.0%) had hypertension, 74 (45.1%) had diabetes. One-hundred thirty-three (81.1%) patients had coronary artery disease, whereas 26 (15.9%) chronic kidney disease (CKD). A total of 75 (45.8%) patients had lesions classified as TASC C or D. In 10 chronic total occlusions procedural failure occurred; therefore, in the analysis were included 154 (93.9%) successful procedures performed with DCB (n=122) and with DA+DCB (n=32). No significant differences were observed between patients treated with DCB and DA+DCB, excepted for CKD (n=16, 13.1% vs. n=9, 28.1%, p=0.040) and Fontaine classification. Bailout stenting was significantly less frequent among patients treated with DA+DCB (n=34, 27.8% vs. n=3, 9.3%, p=0.035); this result was confirmed at multivariate analysis (OR 0.232, 95% CI 0.062-0.877, p=0.031). Among 108 patients with a mean follow-up of 677±359 days, 23 (21.3%) patients developed a significant restenosis, 17/87 (19.5%) in the DCB group vs. 6/21 (28.6%) in the DA+DCB group (p=0.36). Moreover, 9/31 (29.0%) patients with bailout stenting developed a restenosis vs. 14/77 (18.2%) not requiring bailout stenting (p=0.21). Seven patients died during follow-up without significant differences between the two study groups.

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

C57

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

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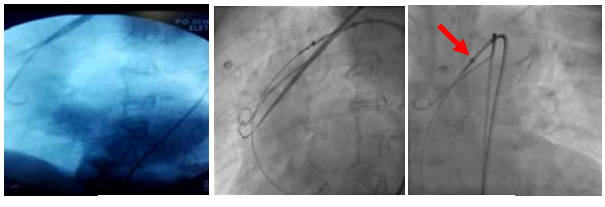
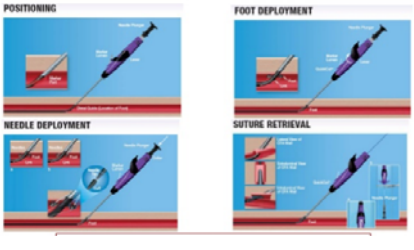
L.G. donna di 92 anni. Nota per ipertensione arteriosa, diabete, IRC lieve-moderata, vasculopatia carotidea, diverticolosi del colon e GERD; storia di extrasistolia ventricolare con brevi tratti di TVNS in terapia con amiodarone, con beneficio. Un ecocardiogramma TT (07/2017) documentava stenosi aortica lieve-moderata, conservata funzione contrattile. Accesso in PS (27/07/2017) per sincopi recidivanti occorsi negli ultimi 3 giorni, a riposo. ECG: blocco AV completo con FC 40 b/min e blocco bifascicolare. La paziente veniva sottoposta ad una procedura posizionamento di PM mediante puntura selettiva della vena succlavia sinistra e posizionamento di catetere introduttore 9Fr. Alla rimozione del dilatatore, evidenza di fuoriuscita di sangue ad alta pressione con caratteristiche arteriose. Si ricontrolla radiograficamente la posizione della guida, si esegue EGA che conferma la presenza di sangue arterioso. La paziente si manteneva emodinamicamente stabile ed asintomatica (PAO 120/75). ECG: ritmo di scappamento giunzionale con FC 40 b/min. Si ricollocava il dilatatore lasciando in sede il sistema introduttore-guida e veniva contattato l'emodinamista per conferma del sito di incannulamento. Nel sospetto inserimento dell'introduttore in arteria succlavia sinistra in sala di EP si eseguiva arteriografia con accesso da arteria femorale destra per valutare la sede di inserimento e l'eventuale chiusura della breccia mediante posizionamento di stent coperto. Purtroppo si evidenzia il posizionamento di introduttore 9 Fr in arco aortico. Veniva quindi valutata in urgenza la possibilità di chiusura della breccia con Plug in nitinolo ma sia in considerazione delle dimensioni del Plug rispetto all'introduttore (formato minimo 4 mm, introduttore 9 fr equivale a 2.7 mm), che dell'eventuale protrusione entro il lume aortico che avrebbe determinato la necessità di un'antiaggregazione prolungata della paziente si è optato per chiudere la breccia con sistema di chiusura suture-medicated (Proglide). Veniva quindi posizionato un pallone in arco aortico, sfilato il catetere introduttore e applicato un punto di sutura con



Perclose ProGlide



sistema Pro-glide. All'aortografia di controllo non evidenza di spandimento di mezzo di contrasto.
Veniva posizionato un PM provvisorio dalla vena femorale destra e si decideva di sottoporre la paziente ad angio-TAC di controllo che documentava presenza di anomalia vascolare dell'arteria succlavia destra che origina dall'arco aortico con decorso retroesofageo (arteria succlavia destra lusoria). Non versamento pericardico. Nelle fasi contrastografiche arteriosa e tardiva eseguite, non evidenti segni di spandimento ematico attivo. Non PNX. Discreta falda di versamento pleurico declive bilaterale, più cospicuo a destra con atelettasia del parenchima polmonare contiguo. Enfisema delle parti molli latero toraciche di sinistra. Filo elettrostimolatore che attraverso la vena cava inferiore raggiunge il ventricolo destro. Successivamente si è proceduto a tentativo di impianto del PM previa venografia con accesso periferico dal braccio sinistro fallita per impossibilità a transitare in vena succlavia per estrema esiguità del vaso con decorso tortuoso. Veniva quindi effettuato impianto senza complicanze da vena succlavia destra.
In letteratura sono descritti 4 casi di posizionamento di elettrocatetere in ventricolo sinistro a seguito di erronea puntura venosa. La reale incidenza di questa complicanze non è nota. In ogni caso il riscontro è stato tardivo ed a seguito della valutazione radiografica del torace, eseguita a distanza. Nel 75% casi si è scelto di mantenere il catetere in sede, anticoagulando il paziente; in 1 caso si è proceduto alla rimozione del catetere in team combinato tra cardiochirurgo ed elettrofisiologo.

C58

PERCUTANEOUS CORONARY INTERVENTION WITH AGENT™ PACLITAXEL-COATED BALLOON: REAL-WORLD MULTI-CENTRE EXPERIENCE

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Background. The Agent™ paclitaxel-coated balloon (PCB) is a new drug-coated balloon technology, with a limited real-world available data. Our study sought to assess the safety and efficacy of a new PCB during percutaneous coronary intervention (PCI) in different types of coronary lesions in a multicenter and, prospective, registry.
Methods. All comers patients undergoing PCI with use of Agent™ PCB in 3 Italian cites between September 2014 and March 2018 were included in this registry. Major adverse cardiac events (MACE) were defined as the composite of cardiac death, recurrent non-fatal myocardial infarction (MI), target lesion revascularization (TLR), or any stent thrombosis (ST). Procedural success was also evaluated.
Results. Among 354 patients (with 450 lesions treated with 508 PCBs) included in the registry, Agent™ PCBs were used for the treatment of in-stent restenosis, small vessel disease, bifurcation lesions and for other de novo lesions in 33.1%, 32.4%, 30.2% and 4.2%, respectively. The implant of Agent PCBs was safe and with a high final procedural success rate (99.5%). At a mean follow-up of 560 (±312) days the rate of MACE was 11.0% (cardiac death 1.9%, any MI 3.4%, TLR 8.4% (per patient),TLR 6.6% (per lesion), any ST 0.2%).
Conclusion. The use of Agent™ PCB during PCI appears safe and effective in a large real-world experience.

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TREATMENT OF BIFURCATION LESIONS WITH AGENT™ PACLITAXEL-COATED BALLOON: A REAL-WORLD MULTI-CENTRE EXPERIENCE

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Background. To date, data on drug coated balloon (DCB) angioplasty on bifurcation lesions are very limited, with very small cohorts and short term follow up. The Agent™ paclitaxel-coated balloon (PCB) is a new drug-coated balloon technology, with a limited real-world available data. Our study sought to assess the safety and efficacy of a new PCB during percutaneous coronary intervention (PCI) in bifurcation lesions.
Methods. All comers patients undergoing PCI with use of Agent™ PCB on bifurcation lesions in 3 Italian cites between September 2014 and March 2018 were included in this registry. Major adverse cardiac events (MACE) were defined as the composite of cardiac death, recurrent non-fatal myocardial infarction (MI), target lesion revascularization (TLR), or any stent thrombosis (ST). Procedural success was also evaluated.
Results. 98 patients with 135 bifurcation lesions were treated with 152 DCBs. Mean age was 69 ± 10 and 29.5% of patients were diabetic. All DCBs were successfully delivered to the target lesion. Overall there were 6 lesions (4.4%) that required bailout stenting. Procedural success was obtained in all lesions and in all DCBs. At a mean follow-up of 512 (±336) days the rate of MACE was 8.1% (cardiac death 1%, any MI 1%, TLR 7.1%(per patient), 5.1% (per lesion), any ST 0%).
Conclusion. The use of Agent™ PCB during PCI appears safe and effective in bifurcation lesions in a large real-world experience. This is one of the largest studies and with the longest follow-up available on DCB angioplasty in bifurcation lesions.