Comunicazioni orali

Non-coronary interventions – 1

C1

CORONARY SINUS REDUCER IMPLANTATION FOR THE TREATMENT OF CHRONIC REFRACTORY ANGINA: A SINGLE CENTER EXPERIENCE

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Aims. To evaluate the safety and clinical efficacy of the Coronary Sinus (CS) Reducer in attenuating angina severity in patients suffering from severe refractory angina, in a real-world population.

Methods. Thirty patients with refractory angina, objective evidence of myocardial ischemia and unsuitable for revascularization were treated with CS Reducer implantation at our center from March 2015 to June 2016. Safety endpoints included procedural success and no device-related adverse events. Efficacy endpoints, assessed at 3-month follow-up, were a reduction in Canadian Cardiovascular Society (CCS) angina score, improvement in quality of life assessed by Seattle Angina Questionnaire (SAQ), improvement in exercise tolerance assessed by six-minute walk test (6MWT), and reduction in pharmacological anti-anginal therapy.

Results. Out of a total of thirty patients who underwent CS Reducer implantation during the study period, complete 3-month follow-up was obtained in 18 patients. Regarding the safety endpoint, procedural success was obtained in all patients and there were no device-related adverse effects observed during the procedure or follow-up period. Regarding the efficacy endpoint, 11 out of 18 patients (61%) had an improvement of at least 2 CCS classes ($p<0.001$) with a mean reduction of CCS class of 1.8±0.8 per patient. All SAQ items improved significantly (mean improvement on 100-point scale was 30±7.4). Regarding exercise tolerance, we reported a significant improvement assessed by 6MWT with a mean distance of 402±124 metres at 3-month follow-up compared with the mean distance reported at baseline (263±97) metres ($p=0.002$). Thirteen patients (72%, $p=0.009$) had a reduction of at least 1 anti-anginal drug and 3 patients (16%, $p<0.001$) had a reduction of 2 or more anti-anginal drugs.

Conclusions. In our real-world single center experience, the implantation of the CS Reducer appears safe, and is associated with an improvement in anginal symptoms and quality of life in patients with refractory angina who were not candidates for revascularization.

C2

AORTOILIAC STENO-OCCLUSIVE DISEASE ENDOVASCULAR TREATMENT: A VALID ALTERNATIVE TO SURGERY

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Introduction. Usual management of infrarenal aortic disease involves endarterectomy for focal lesions or surgical bypass for more extensive aortoiliac disease and is characterized by favourable long-term results even if burdened by a 5-10% rate of major complications. Endovascular treatment has been proposed as a feasible and safe alternative in patients at high surgical risk for its limited invasiveness, lower morbidity and costs. We present our experience in the elective management of steno-occlusive abdominal aortic disease with primary or direct stenting (stenting with or without balloon predilation respectively) and mid-term results.

Case report. Over the past 2 years we treated 3 patients (1 woman and 2 men range 63- 79 years) with Leriche syndrome (claudication and femoral pulselessness associated in one case with impotence) who were unfit for surgical repair due to many comorbidities. One patient had subtotal occlusion of the infrarenal aorta (TASC II classification of aortoiliac lesions type B) and two patients had critical stenosis of the infrarenal aorta involving the carrefour and the origin of both the common iliac arteries (TASC II type D). Pre-procedural assessment with computed tomography angiography to evaluate lesion site, length, morphology, vessel diameters, involvement of the inferior mesenteric artery and ilio-femoral vessels was performed. Risk factors included smoking, hypertension, cardiac disease or family history of, hyperlipidemia, diabetes. All of them were in class 2 or 3 according to the Leriche Fontaine Classification. All patients underwent percutaneous access of both the common femoral arteries and two 0.035-in stiff hydrophilic curved guide wires (Glidewire, Terumo) were positioned through the femoral arteries reaching the aortic arch. The stenoses were pre-dilated and subsequently a self-expandable stent (SES; Sinus-XL Optimed) was positioned in the infrarenal aorta before the carrefour in type B. Two more SES (Sinus-XL Optimed and Protegè EverFlex™ Self-Expanding Peripheral Stent System) were delivered in kissing stent technique reconstructing the carrefour in type D. Final kissing balloon was performed stopping the post-dilatation when the patient reported pain. Immediate post-procedure results were assessed with angiography to establish stent patency and optimal expansion and to exclude complications such as dissection and/or distal embolism or thrombosis. Follow-up with vascular Doppler ultrasound and clinical assessment 1, 6, 12 and 24 months after the procedure showed stent patency and no recurrence of claudicatio.

Conclusion. In our experience and according to current literature endovascular treatment, in particular primary or direct stenting, may be considered the treatment of choice for steno-occlusive lesions of the abdominal aorta, as it provides excellent early and mid-term results with very low complication rates. Also, the endovascular strategy does not preclude the surgical management in case of procedural failure or disease progression and does not interfere with sexual function. Additional studies with larger series and longer follow-ups are needed.

C3

RUOLO DEL DOPPLER TRANSCRANICO NELLA INDICAZIONE ALLA CHIUSURA DELLA PERVIETÀ DEL FORAME OVALE IN PAZIENTI CON STROKE CRIPTOGENICO

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La pervietà del forame ovale (PFO) è presente in circa il 25% della popolazione generale. Di solito il PFO è del tutto asintomatico, sebbene sia stato evidenziato che la sua persistenza sia associata ad un incrementato rischio di stroke criptogenico in pazienti con età inferiore a 55 anni. L'ecocardiografia transesofagea (TEE) costituisce il gold standard nella diagnostica del PFO, permettendone di localizzare la sede e di valutarne l'entità dello shunt destro-sinistro (RLS) ad esso correlato.

Il Doppler transcranico (TCD) è un'opzione diagnostica scarsamente invasiva, di semplice esecuzione che si è dimostrata sensibile e specifica per la dimostrazione di RLS senza però fornire informazioni sulla sua sede. Essa permette un'ottimale collaborazione del paziente a differenza del TEE nell'esecuzione della MV, potendone anche dimostrare la perfetta esecuzione andando a valutare il profilo velocimetrico del flusso cerebrale all'analisi Doppler.

Recenti evidenze scientifiche hanno dimostrato l'importanza della valutazione dell'entità dello RLS nella classificazione del profilo di rischio per stroke; RLS più ampi sono associati ad un più alto rischio di eventi cerebrovascolari in soggetti con stroke criptogenico. Scopo dello studio è stato il confronto tra TEE e TCD nella valutazione dell'entità dello RLS in pazienti con stroke criptogenico e con persistenza del PFO. Da giugno 2015 a giugno 2016 sono stati arruolati 85 pazienti con precedente ictus ischemico criptogenico con il sospetto di PFO. Si procedeva dapprima all'esecuzione del TCD e successivamente del TEE: in entrambi i test le acquisizioni venivano eseguite a livello basale e dopo esecuzione della manovra di Valsalva. Durante l'esecuzione di entrambe le metodiche veniva usato come mezzo di contrasto soluzione salina miscelata energicamente con aria. In 62 pazienti il TCD è risultato negativo per RLS ed il TEE è risultato negativo per la presenza di PFO. Nei restanti 23 pazienti, invece, il TCD è risultato positivo per la presenza di RLS ed in 22 di questi pazienti il TEE è risultato positivo per la presenza di PFO. Dodici di questi pazienti che presentavano un profilo di rischio elevato sono stati avviati a chiusura percutanea mediante dispositivo Amplatzer di tale difetto. Confrontando i dati ottenuti dai due test diagnostici oggetto del nostro studio si è evidenziato che nella valutazione dell'entità dello RLS a livello basale i dati ottenuti risultano pressoché sovrapponibili, mentre quelli ottenuti dopo l'esecuzione della MV presentano differenze significative.

Il TCD è una metodica sicura, scarsamente invasiva, utile nell'individuazione e nella valutazione dell'entità di RLS associato a PFO nei pazienti con ictus criptogenico, fornendoci informazioni indispensabili per indirizzare tali pazienti ad intervento di chiusura percutanea.

C4

THIRD VS SECOND GENERATION STENT-GRAFT FOR ENDOVASCULAR ANEURYSM REPAIR (EVAR): A DEVICE SPECIFIC ANALYSIS

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Objective. To analyze outcomes of endovascular aneurysm repair (EVAR) in patients treated with Excluder endograft (W.L. Gore and Assoc, Flagstaff, AZ), comparing 2nd generation featuring SIM-PULL delivery system (ExSP), and 3rd generation, featuring C3 (ExC3), in general population and in patients

with unfavorable anatomy, with especial regard to radiation and contrast medium exposure.

Methods. In our single-center, comparative study, we retrospectively analyzed all patients undergoing elective EVAR with Excluder from May 2008 to December 2015. This cohort was firstly divided according to the design of the endograft used and then two subgroups of complex procedures were identified according to International Standards. Preliminary end points were early- and mid-term outcomes (i.e. overall survival and aneurysm related mortality [ARM], technical success, intra- and peri-procedural complications, graft-related adverse events [GRAE]). Main end points were procedural data (i.e. procedural and fluoroscopy time, radiation dose [DAP] and contrast medium amount).

Results. The study included 64 patients (24 ExSP and 40 ExC3) with a mean follow-up of 31.6±22.9 months. Patients in ExC3 group had significantly more risk factors and comorbidities, as well as a more complex anatomy. Concerning preliminary outcome measure, no significant difference was noted between the two groups both in the general population and in complex cases. As for intra-operative data, procedure duration was significantly shorter: 120 vs 151 min (p=0.002) in the overall population and 129 vs 173 min (p=0.004) in complex cases. A significant reduction was also found in fluoroscopy time and radiation exposure: 24084 vs 32548 cGy/cm^2 (p=0.020) in the overall population and 26770 vs 41104 cGy/cm^2 (p=0.003) in complex cases. No significant difference was found for contrast volume.

Conclusions. The study shows that the new C3 Excluder enables to reduce radiation exposure and procedural time both in the overall population and especially in cases with unfavorable anatomy. C3 Excluder results are comparable to those of the previous device in spite of more comorbidities and complex anatomy of the treated patients. Further studies are needed to assess device performance on longer-term follow-up.

C5

CORONARY SINUS REDUCTION IMPROVES MYOCARDIAL PERFUSION RESERVE INDEX ASSESSED BY DIPYRIDAMOLE STRESS CARDIAC MAGNETIC RESONANCE

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Background. While the Coronary Sinus (CS) Reducer has been shown to improve symptoms and quality of life, little is known regarding the effect of this device on myocardial ischemia. Accordingly, the aim of this study was to evaluate the efficacy of the CS Reducer in improving myocardial perfusion, assessed by myocardial perfusion reserve index (MPRI) using stress cardiac magnetic resonance (CMR) three months after the procedure.

Methods. Thirty patients with refractory angina, objective evidence of myocardial ischaemia and no option for revascularization were treated with CS Reducer implantation at our center. Among them, thirteen patients without contraindications underwent stress-rest CMR perfusion imaging (stressor agent: dipyridamole 0.56 mg/kg infused over 4 minutes) to assess MPRI at baseline. MPRI was the ratio between stress and rest relative maximum upslope (RU), with RU defined as the ratio between the maximum unslope of the first pass myocardial perfusion divided by the maximum unslope of the first-pass left ventricle cavity time-intensity curve (MPRI = RU stress/RU rest). Mean MPRI was the average of 16 AHA segments.

Results. Five out of the 13 patients completed the early follow-up including a second stress CMR performed 3 months after Reducer implantation. As evidenced in the Figure, we reported an increase of MPRI in 4 out of 5 patients (80%), from a baseline mean MPRI of 1.5±0.4 to a post-implantation mean MPRI of 2.4±0.7, with a mean improvement of MPRI of 0.7±0.5 per patient (p=0.075). One patient with no evidence of significant epicardial coronary disease and evidence of inducible ischemia did not improve MPRI after Reducer implantation (basal 1.7, post-implant 1.6).

Conclusions. We reported a significant trend in improving MPRI, assessed by dipyridamole stress CMR perfusion, three months after CS Reducer implantation. Further studies are needed to evaluate this further.

C6

FIRST IN MAN PROLONGED PRESSURE-CONTROLLED INTERMITTENT CORONARY SINUS OCCLUSION TO TREAT REFRACTORY LEFT VENTRICULAR DYSFUNCTION AND ISCHEMIA

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Aims. Pressure-controlled Intermittent Coronary Sinus Occlusion (PICSO) intermittently increases the pressure in the cardiac venous outflow tract using a balloon-tipped catheter introduced percutaneously into the coronary sinus. It aims to improve microvascular perfusion in STEMI patients during PCI, thus improving infarct healing. Its successful administration was associated with an improvement in myocardial recovery four months after primary PCI as compared to control. However, it has never been used in other settings or for a prolonged period (more than 90 minutes). The aim of this study was to report on the feasibility and efficacy of prolonged PICSO to treat refractory left ventricular dysfunction and ischemia.

Methods and Results. Two consecutive patients with refractory left ventricular dysfunction and ongoing ischemia with epicardial coronary artery spasm and probable underlying microvascular dysfunction were treated with prolonged off-label PICSO utilization. A medium of 23990 mmHg PICSO quantity was achieved. After PICSO placement, both patients showed significant improvement of myocardial ischemia and recovery of left ventricular systolic function.

Conclusion. Prolonged PICSO utilization was feasible and effective in two consecutive patients. These cases highlight a novel application of PICSO technology: redistribution of venous blood and improvement in microvascular perfusion that might be a new target in cases of refractory LV dysfunction and ongoing ischemia in the setting of patent epicardial coronary arteries.

C7

VERY LONG-TERM RESULTS OF AMPLATZER DEVICES FOR PERCUTANEOUS PATENT FORAMEN OVALE CLOSURE

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Aims. We observed the very long-term results of percutaneous patent foramen ovale (PFO) closure with Amplatzer devices.

Methods and Results. Between 1999 and 2002, 139 patients showed follow-up longer than 10 years in our single center registry of PFO treated by transcatheter closure. They were analyzed in terms of major adverse cardiovascular events (MACE) at follow-up, including cardiac death and recurrent embolic events, and atrial fibrillation occurrence. Also procedural and in-hospital complications were observed. Women were 54% and mean age was 51.4 years old. Ischemic events occurred in 85.5% of the cases (33 stroke, 78 TIA, 4 peripheral, 1 combined) and 14.5% closed PFO for other causes. Atrial septal aneurysm was detected in 56.8% of the patients. All the implanted devices belonged to the Amplatzer family. No MACE occurred during the index procedure and hospital stay. One patient suffered for access site complications requiring surgery. Follow-up has been fully completed with a mean time of 12.9 years. The rate of MACE was 3.6% (1 stroke after 8 years, 1 TIA after 2.5 years, 3 TIA after >10 years). Six (4.3%) non cardiac death occurred. New atrial fibrillation was observed in 9 (6.5%) patients, and usually affected patients older than 55 years at least after 7 years from the index procedure. Residual shunt was present in 9 (6.6%) cases without significant entity. Half patients continued antrithrombotic therapy at follow-up.

Conclusion. Very long-term follow-up after percutaneous PFO closure with Amplatzer devices showed low rate of adverse events, including MACE, atrial fibrillation and residual shunt.

BVS

C8

MULTISLICE COMPUTED TOMOGRAPHY FOLLOW-UP AFTER BIORESORBABLE SCAFFOLD IMPLANTATION IN PATIENTS WITH COMPLEX CORONARY ARTERY DISEASE

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Background. Over the last five years, bioresorbable vascular scaffolds (BVS) have become an attractive option in the percutaneous coronary intervention field due to the complete reabsorption process that occurs post-implantation. A potential advantage of such a scaffold may include the possibility to use noninvasive imaging techniques such as computed tomography (CT) angiography for follow-up.

Aims. This study aims to clarify the role of computed tomography follow-up in a complex subset of patients treated with BVS.

Methods and Results. Consecutive patients treated with BVS in two high volume centers were enrolled between May 2012 and August 2015. Primary endpoint was the quality of CT scan images acquired, according to a 3-point

scale: 1 (poor), the coronary vessel was not well visualized; 2 (good), the vessel was adequately visualized; and 3 (excellent), the vessel was very well visualized. Forty-one patients underwent a radiological follow-up, for a total of 53 lesions (1.3±0.7 lesions per patient). Population data are reported in Table 1. A high rate of complex lesions (77.4% of type B2 or C), bifurcations (58.5%) and chronic total occlusions (5.7%) was reported. We followed a specific protocol for BVS implantation, with a high rate of predilation (98%) and postdilation (100%). In all patients it was possible to obtain excellent (grade 3, 94.3%) or good (grade 2, 5.7%) MSCT evaluation. Furthermore, the peculiar BVS radiolucent composition allowed a reliable evaluation of mean reference area and diameter (6.6±1.7 mm^2 and 2.9±1.4 mm) as well as minimal scaffold area (4.9±1.4 mm^2) and diameter (2.5±1.4 mm). MSCT data are shown in Table 2.

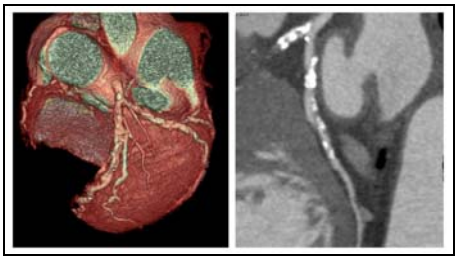
Conclusions. Noninvasive assessment of the coronary arteries with computed tomography after treatment with BVS seems to be feasible also in this complex population. The feasibility and accuracy that multislice CT showed in analysis of bioresorbable scaffolds could indicate a new era for non-invasive assessment of patients treated with these devices.

Table 1. Lesion and procedural data.

	n=53 lesions, 41 patients
Target vessel	
Left anterior descending artery	36 (67.9%)
Left circumflex artery	13 (24.5%)
Right coronary artery	4 (7.6%)
Left main trunk	0 (0%)
No. lesions per patient	1.3±0.7
ACC/AHA class B2 or C	41 (77.4%)
Bifurcation, n (%)	31 (58.5%)
In-stent restenosis, n (%)	0 (0%)
Chronic total occlusion, n (%)	3 (5.7%)
Severe calcification, n (%)	13 (24.5%)
Pre-dilation, n (%)	52 (98%)
Total scaffold number per lesion	1.6±0.7
Total scaffold length per lesion, mm	35.7±17.2
Total scaffold number per patient	2.0±1.1
Total scaffold length per patient, mm	46.1±28.5
Post-dilation, n (%)	53 (100%)

Table 2. CT scan follow-up; median follow-up 390 days (interquartile range 302-588 days).

	n=83 scaffolds, 53 lesions, 41 patients
Qualitative CT scan evaluation, per lesion	
Excellent - Grade 3 (%)	50 (94.3%)
Good - Grade 2 (%)	3 (5.7%)
Poor - Grade 1 (%)	0 (0%)
In scaffold restenosis (%)	1 (1.9%)
Area analysis, scaffold segment	
Mean reference area, mm^2	6.6±1.7
Minimal scaffold area, mm^2	4.9±1.4
Area stenosis, %	25 (IQR 15-35)
Diameter analysis, scaffold segment	
Reference vessel diameter, mm	2.9±1.4
Minimal lumen diameter, mm	2.5±1.4
Percentage stenosis, %	15 (IQR 10-20)
Lesion length, mm	12.8±4.9



C9

STENT THROMBOSIS IN PATIENTS TREATED WITH BIORESORBABLE VASCULAR SCAFFOLDS: A META-ANALYSIS OF 7 STUDIES AND 2568 PATIENTS

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Introduction. Bioresorbable vascular scaffolds (BVSs) are an innovative technology for patients undergoing percutaneous coronary interventions. Controversial data regarding incidence of stent thrombosis (ST) following BVS implantation have been reported.

Methods. Medline/PubMed were searched for studies evaluating BVSs with ≥50 patients and follow-up of ≥6 months. ST was the primary endpoint, and adverse cardiac events (death, myocardial infarction and target lesion revascularization) were the secondary endpoints.

Results. Seven studies with 2568 patients were included in the present analysis. Diabetes mellitus was present in 22% of the patients. The target vessel was the proximal left anterior descending coronary artery in 46%, with 15% of lesions involving a bifurcation. 25% of lesions were classified as type C, with moderate or severe calcification in 13% and thrombus in 15%. After a mean follow-up of 6.5 months (range 6-12), the rates of any and definite/probable ST were 1.5% (0.7-2.3) and 1.4% (0.6-2.2), while sub-acute and late ST occurred in 0.9% (0.2-1.6) and 0.5% (0.2-0.9) of the patients. MACE occurred in 6.5% (4.7-8.2) of patients, driven by 3.3% (1.7-4.9) target lesion revascularization and 2.8% (2.2-3.5) myocardial infarction. By meta-regression, the risk of any ST was increased in patients with ST-segment elevation myocardial infarction and those with long lesions, and was reduced with intravascular imaging and with post-dilatation.

Conclusions. The rate of MACE within the first year after BVS appears to be acceptable. The rate of ST after BVS has varied among studies and depending on the clinical setting, and appears to be greater in patients presenting with STEMI and in long lesions. ST after BVS may be reduced by post-dilatation and with the use of intravascular imaging technologies.

C10

PLASTIC HEALING OF SPONTANEOUS CORONARY ARTERY DISSECTION USING BIORESORBABLE VASCULAR SCAFFOLDS: A MULTICENTER REPORT

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Background. Spontaneous coronary artery dissection (SCAD) is a rare pathology, but is the cause of about 9% of ACS in young women. In this setting evidences about optimal treatment are lacking: generally the pathology has a good prognosis with vascular healing, but recurrences and angina relapse are not rare. When PCI is deemed to be necessary, use of bioresorbable scaffolds is particularly appealing: in fact, considering the absence of atherosclerosis, temporary scaffolding could restore vessel reactivity and prevent late stent malapposition due to vessel wall healing.

Aim. The aim of our study was to assess feasibility and safety of BRS implantation in SCAD needing vessel wall restoration due to flow-limiting lesions or persistent/relapsing ischemia.

Methods. The study is based on a multicenter, prospectively-designed registry including 27 retrospectively or prospectively identified patients, enlisted by 12 Italian Hospitals. Primary endpoints were device success, angiographic success and procedural success. Device success was defined as the successful delivery and deployment of the study scaffold at the intended target lesion. Angiographic success was defined as the final TIMI flow 3 together with residual stenosis <30%. Procedural success was defined as the angiographic success without the occurrence of death, myocardial infarction or target vessel revascularization during the hospital stay.

Results. Mean age of SCAD population was 47.2±7.5 and 92.6% were women with low rates of atherosclerotic risk factors. Multivessel involvement has been observed in 18.5% of our patients, 2 of whom has been treated with BVS even on the second SCAD vessel. Mean BVS total length has been 57.4±28 mm and 93.1% of lesions were longer than 20 mm. Device success was obtained in 96.6% of cases, such as angiographic success. Procedural success was achieved in 92.6% of patients. Target vessel revascularization (TVR) rate was 3.7% during hospitalization, and another case of TVR was reported at 1 year follow up. Imaging follow-up was performed in 10 patients with 1 year follow-up and attested BVS patency in 9 of 10 cases. One case of recurrent SCAD and one case of SCAD persistence were registered.

Conclusion. BRS implantation seems feasible and safe in spontaneous

coronary artery dissection, with high rates of device and procedural success. Potential application of BRS in this setting to promote vessel healing needs further evaluation in larger studies.

C11

SCAFFOLD BIORIASSORBIBILI DI SECONDA GENERAZIONE: ESPERIENZA DI UN SINGOLO CENTRO

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Introduzione. Gli scaffold bioriassorbibili (BRS) rappresentano una grande innovazione nel campo dell'interventistica coronarica percutanea (PCI). Questi device forniscono un supporto vascolare temporaneo associato al rilascio di farmaco antiproliferativo, prima di scomparire completamente nell'arco di circa 1-2 anni. Tuttavia sono emerse alcune problematiche tecniche prevalentemente correlate a difetti "strutturali" dei primi modelli, tra cui riassorbimento troppo rapido con scarso supporto vascolare, recoil acuto post-impianto da insufficiente forza radiale, frattura delle maglie da rapida o eccessiva espansione dello scaffold oltre il diametro nominale. Questi problemi hanno portato allo sviluppo di nuovi BRS con caratteristiche avanzate. Lo scaffold DESolve può essere considerato il BRS di "seconda generazione", per via di caratteristiche innovative quali profilo di bioriassorbimento ottimizzato, autocorrezione di malapposizioni al diametro nominale ed elevata resistenza alle fratture.
Scopo. Descrivere la performance di un BRS di seconda generazione in differenti setting clinici.
Metodi. Da gennaio a dicembre 2015, è stato impiantato lo scaffold DESolve in 30 pazienti con età media 51.8 anni. In 20 pazienti (66.7% dei casi) l'angioplastica è stata eseguita per sindrome coronarica acuta e in 7 (23.3%) durante PCI Primaria per STEMI. Il posizionamento dello scaffold ha richiesto l'utilizzo dell'Ultrasonografia Intravascolare (IVUS) in 13 procedure (43.3%), tomografia a coerenza ottica (OCT) in 15 procedure (50%) e la riserva di flusso frazionale (FFR) è stata utilizzata per valutare lesioni intermedie in 5 casi (16.7%). Le misure degli scaffold utilizzati variavano da 2.5 a 3.5 mm di diametro.
Risultati. Il diametro luminale minimo (MLD), valutato all'angiografia quantitativa in tutti i pazienti, è aumentato da 0.93±0.35 preimpianto a 2.85±0.38 mm postprocedura ed il diametro percentuale di stenosi si è ridotto da 68.8±12.6 a 12.4±7.8%. L'IVUS ha mostrato un incremento di MLD da 0.89±0.40 mm a 2.3±0.5 mm postimpianto, e dell'area luminale minima (MLA) da 2.15±0.56 mm^2 a 4.9±1.5 mm^2; ha inoltre mostrato un solo caso di apposizione incompleta di scaffold (ISA), trattato mediante postdilatazione con pallone non-compliante. L'OCT ha mostrato un incremento di MLD da 0.90±0.38 mm a 2.6±0.4 mm post-procedura, mentre la MLA è incrementata da 2.34±0.65 mm^2 a 5.3±1.6 mm^2; questa metodica ha rivelato ISA in 3 casi, di cui 2 risolti autonomamente mediante meccanismo di autocorrezione di questo device ed uno trattato con postdilatazione. Nessun caso di frattura di maglie è stato evidenziato all'OCT. In tutti i casi di STEMI (7/7) è stato ottenuto un flusso finale TIMI 3.
Conclusioni. La PCI con impianto di BRS di ultima generazione ha dimostrato degli ottimi risultati post-procedurali in un piccolo gruppo di pazienti di un singolo centro. La nostra esperienza con lo scaffold DESolve non ha mostrato incidenza delle più comuni problematiche tecniche correlate all'impianto di BRS di prima generazione, quali recoil acuto o fratture di scaffold, confermando le caratteristiche funzionali innovative di questo device tra cui le proprietà di autocorrezione e di resistenza alle fratture.

C12

SCAFFOLD BIORIASSORBIBILE: L'ESPERIENZA CLINICA DELLA REGIONE EMILIA-ROMAGNA

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Background. Gli scaffold vascolari bioriassorbili (BVS) rappresentano un'alternativa agli stent medicati metallici (DES) con il vantaggio rappresentato dalla scomparsa del device dopo il suo riassorbimento e con il conseguente recupero della fisiologica integrità funzionale dell'arteria trattata. A novembre 2013, la Commissione Regionale Dispositivi Medici e la Commissione Cardiologica e Cardiochirurgica della Regione Emilia-Romagna (RER) hanno redatto una valutazione tecnico-scientifica dell'unico dispositivo che era al momento l'unico disponibile sul mercato (ABSORB® BVS, Abbott Vascular). Il documento era finalizzato a fornire indicazioni per l'introduzione dei BVS ricalcando una metodologia già impiegata per l'introduzione dei DES, con lo scopo di individuare, in accordo con i professionisti e nell'attesa del consolidamento dei dati di sicurezza ed efficacia, quei pazienti che potessero maggiormente trarne beneficio. Sono state individuate 5 indicazioni preferenziali: (1) lesioni coronariche lunghe (>28 mm); (2) pazienti con lesioni ostiali (escluso tronco comune); (3) rivascolarizzazione completa in pazienti di età <50 anni; (4) patologia diffusa (>40 mm) o coinvolgente il tratto medio/distale del ramo discendente anteriore in pazienti con età <70 anni; (5) dissezione coronarica spontanea. Nel complesso, era stato stimato un fabbisogno di BVS di circa il 5% rispetto al numero totale dei DES impiegati ogni anno nei laboratori di Emodinamica della RER.
Metodi. L'indicazione clinica e tecnica all'impianto di BVS e la corrispondenza con le indicazioni del documento regionale è stata retrospettivamente valutata in tutti i pazienti trattati in RER fino a giugno 2016.
Risultati. Da marzo 2013 a giugno 2016, 328 pazienti (età media 57.4±10.5 anni) sono stati trattati con 546 BVS. La percentuale d'impiego rispetto al totale degli stent è pari all'1.5% ma con distribuzione annuale crescente: 0.3% nel 2013, 0.9% nel 2014, 3.2% nel 2015. Le indicazioni cliniche sono state: STEMI in 74 pazienti (22.6%), NSTE-ACS in 129 (39.3%), coronaropatia stabile in 94 (28.7%), altro in 31 (9.5%). L'IVUS è stato utilizzato in 81 pazienti (24.7%), con notevole variabilità tra i centri (range 0-58.3%; 4 centri 50-60%, 4 centri 10-15%, 3 centri 0). In 85 pazienti (25.9%) è stata eseguita una PCI "ibrida" BVS/DES. Le indicazioni regionali sono state rispettate nel 61.0% dei casi (200/328). La principale indicazione è stata il trattamento di lesioni lunghe in vasi di calibro >2.5 mm (67%), seguita dal trattamento di pazienti giovani (31.5%) o del tratto medio-distale del ramo discendente anteriore (28%).
Conclusioni. L'approccio dei centri della RER all'impiego dei BVS è stato decisamente prudente e l'utilizzo inferiore alle previsioni, anche se con una crescita significativa nel 2015 e nei primi 6 mesi del 2016. Si evidenzia un'elevata variabilità tra i centri sia riguardo alle percentuali di utilizzo dei BVS sia riguardo l'impiego di IVUS. Infine, vi è stata una buona aderenza alle indicazioni regionali, con discreta omogeneità tra i singoli centri.

C13

RUOLO DEI PALLONCINI A RILASCIO DI PACLITAXEL PER IL TRATTAMENTO DELLA RISTENOSI INTRASTENT MEDICATI O INTRA SCAFFOLD BIORIASSORBIBILI IN PAZIENTI CON CORONAROPATIA DEL CUORE TRAPIANTATO: RISULTATI IN UNA SERIE DI PAZIENTI CONSECUTIVI

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Background. Il trattamento ottimale della coronaropatia del cuore trapiantato (CAV) non è definita. Le procedure interventistiche coronariche sono considerate un trattamento palliativo a causa dell'elevato tasso di ristenosi, ma restano tuttavia un'alternativa alla terapia definitiva del re-trapianto. Gli stent a rilascio di farmaco (DES) sono superiori agli stent metallici e recentemente gli scaffold bioriassorbibili (BRS) sono stati proposti per il trattamento della CAV, ma vi sono pochi dati clinici. In caso di ristenosi intrastent (ISR) intra DES o intra-BRS inoltre non è definito quale sia il trattamento ottimale. L'eluizione di paclitaxel evitando l'apposizione di un ulteriore strato metallico potrebbe essere un'opzione interessante in questo particolare sottogruppo di lesioni.
Metodi. Tra novembre 2012 e gennaio 2015 abbiamo trattato 12 ISR in 9 pazienti trapiantati (età mediana 48 anni, anni mediani dal trapianto 12.3). Tra le caratteristiche cliniche: 3 pazienti avevano insufficienza renale cronica, 6 serologia positiva per infezione da Cytomegalovirus. Sei pazienti avevano avuto una storia di rigetti e un paziente aveva un rigetto cronico. La frazione di eiezione media era 54%. Everolimus era assunto da 4 pazienti e tacrolimus da due. Tra le caratteristiche delle lesioni: 8 erano la I recidiva di ISR (6 in DES e 2 in BRS), mentre 4 erano ISR ricorrenti in segmenti coperti da multistrati di stent metallici. Il diametro di riferimento medio era 2.3±0.48 mm e la lunghezza media delle lesioni 21.4±11.9 mm. Tuttel lesioni eccetto una erano sono state classificate come diffuse-proliferative. Il tempo tra impianto di stent e ISR era <12 mesi in 7 casi. Prima dell'applicazione di paclitaxel, 7 lesioni sono state predilatate con palloncino "scoring" e 5 con palloncino non compliante. In 8 lesioni abbiamo usato il palloncino a rilascio di paclitaxel (PCB) InPactFalcon (Medtronic Inc., Minneapolis, Minnesota), in 2 Panthera-Lux (Biotronik, Bulach, Switzerland), and in 2 RestoreDEB (Cardionovum GmbH, Bonn, Germania). In 3 lesioni abbiamo usato >1 PCB. Imaging endovascolare è stato utilizzato in due casi. La doppia antiaggregazione è stata continuata per 12 mesi in caso di sindrome coronarica acuta o impianto di DES in altra lesione e per 3 mesi dopo solo PCB in angina stabile.
Risultati. Il follow-up mediano è stato di 342 giorni. Abbiamo osservato 2 nuove rivascolarizzazioni della lesione bersaglio (TLR), una morte cardiaca, una morte non cardiaca e un inserimento in lista di trapianto. Al follow-up angiografico a 12 mesi in 7 pazienti (8 lesioni), abbiamo osservato due ristenosi ricorrenti, entrambe in segmenti coperti da multistrati di stent metallici. Il "late lumen loss" è risultato pari a 0.49±0.83 mm. Un paziente con rigetto cronico ha sviluppato disfunzione del cuore trapiantato e a 30 mesi aveva una recidiva di ISR occlusiva in 3 lesioni in vasi differenti per cui è stato reinserito in lista di trapianto.
Conclusioni. In questa serie di pazienti trapiantati con coronaropatia del graft e ISR, la nostra esperienza suggerisce che il trattamento con PCB di nuova

generazione sia sicuro ed efficace, con un soddisfacente risultato clinico e angiografico a medio termine. Ulteriori studi sono necessari per definire se questa strategia si associ a miglior sopravvivenza e preservazione funzionale del cuore trapiantato.

C14

PROCEDURAL AND MID-TERM OUTCOMES OF BIORESORBABLE SCAFFOLDS VERSUS DRUG-ELUTING STENTS IN CHRONIC TOTAL OCCLUSIONS: THE BONITO REGISTRY

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Objectives. To investigate the clinical outcomes of patients with a chronic total occlusion (CTO) treated with bioresorbable scaffolds (BRS) or drug-eluting stents (DES).

Background. There is little evidence regarding the efficacy and safety of BRS for the percutaneous treatment of CTO.

Methods. We performed a multicenter registry of consecutive CTO patients treated with BRS (Absorb, Abbott Vascular, Santa Clara, CA) and second-generation DES, at five institutions specialized in the percutaneous treatment of CTO. Mid-term target-vessel failure (TVF: a composite of cardiac death, target-vessel myocardial infarction and ischemia-driven target-lesion revascularization [ID-TLR]) was the primary endpoint of this study. Inverse probability of treatment weight (IPTW)-adjusted Cox regression analysis was used to account for pre-treatment differences between the two groups.

Results. A total of 537 patients (n=153 BRS, n=384 DES) were included. BRS patients were younger (60.0±9.3 vs. 63.6±10.3 years, p<0.0001), and had lower prevalence of comorbidities. Overall mean SYNTAX and J-CTO score were 18.6±8.8 and 1.43±1.16, respectively, with no differences between groups. Procedural success was achieved in 99.3% and 96.6% of BRS- and DES-treated patients, respectively (p=0.07). At a median follow-up of 703 days (interquartile range: 426-989 days), there were no differences in TVF between BRS and DES (4.6% vs. 7.7%; unadjusted hazard ratio [HR] 0.59, 95% confidence interval [CI] 0.26-1.35, p=0.21). By IPTW-adjusted Cox regression analysis there were still no significant differences between BRS and DES (adjusted HR 1.54, 95% CI 0.69-3.72, p=0.34).

Conclusions. BRS implantation in CTO was technically feasible and associated with acceptable clinical outcomes at mid-term follow-up, as compared with second-generation DES.

C15

FIVE YEAR SERIAL EVALUATION OF IMAGING OUTCOME AFTER ABSORB BIORESORBABLE SCAFFOLD IMPLANTATION

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Background. Bioresorbable scaffolds (BRS) are an attractive option for percutaneous treatment of coronary artery disease, able to provide transient vessel support with drug delivery capability, without the long-term caveats of permanent metallic stents. The sequential imaging assessment by optical coherence tomography (OCT) and intravascular ultrasound (IVUS) over 5 years aims at assessing changes in lumen area and potential late lumen enlargement.

Methods. We performed both OCT and IVUS analysis of 7 patients enrolled in the ABSORB Cohort B trial at our center. According to the protocol, the patients underwent serial angiography and intravascular imaging evaluation (OCT at 3 and 5 years). OCT cross sectional analysis was performed at 1 mm longitudinal intervals within the treated segment which included in total 95 analyzed cross-sections. Measurements included mean lumen area (MLA) and minimal lumen area (MinLA). Eccentricity index was calculated as: (maximum lumen diameter – minimal lumen diameter)/ maximum lumen diameter.

Results. At 5 year follow-up, no struts could be identified. Between 3 and 5 years, both lesion-level and cross section-level OCT findings showed a significant increase in MLA (4.67±1.66 mm^2 vs 5.57±1.57 mm^2; p=0.04) as well as MinLA (5.98±1.98 mm^2 vs 6.73±1.87 mm^2; p=0.04). Moreover, eccentricity index showed a significant reduction between 3 and 5 years (0.28±0.35 mm^2 vs 0.16±0.06 mm^2; p=0.04). In this line, IVUS analysis confirmed significant increase in MLA (7.15±1.29 vs 7.35±1.64 mm^2; p=0.02) and MinLA (6.2±1.33 vs 6.3±1.28 mm^2; p=0.04).

Conclusions. In our OCT series of 5 years FU on ABSORB BRS, enlargement of MLA and MinLA between 3 to 5 years was observed. These findings provide reassuring long-term data about preservation of lumen dimensions after treatment with BRS.

C16

DUE GENERAZIONI DI SCAFFOLD BIORIASSORBIBILI A CONFRONTO: FOLLOW-UP CLINICO, ANGIOGRAFICO E CON TOMOGRAFIA COMPUTERIZZATA

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Introduzione. Alcune problematiche tecniche riguardanti il primo e più diffuso modello di scaffold bioriassorbibile (BVS) sono emerse con la pratica clinica, legate ad imperfezioni strutturali quali scarso supporto vascolare da insufficiente forza radiale, riassorbimento rapido o lento, frattura di maglie da eccessiva dilatazione. Questi fenomeni, insieme all'incidenza di reinfarto e trombosi di scaffold nel primo anno, hanno portato allo sviluppo di un BVS di nuova generazione con caratteristiche innovative: profilo scaffolding/ riassorbimento, autocorrezione di malapposizioni e resistenza alle fratture.

Scopo. Valutare la performance a medio-lungo termine di due diverse generazioni di BVS in una popolazione di pazienti trattati in un singolo centro e l'attendibilità dell'esame Coronaro-TC per lo studio non invasivo dei BVS.

Metodi. I pazienti sottoposti ad impianto di due generazioni di BVS, Absorb (Abbott Vascular) e DESolve (Elixir Medical) tra gennaio 2014 e dicembre 2015 presso l'Ospedale "Cardarelli" di Campobasso, sono stati sottoposti a follow-up clinico (medio 18 mesi) e TC Coronarica di controllo. È stata eseguita analisi coronarica quantitativa (QCA) del segmento coinvolto, pre- e postimpianto di BVS, con stima di: minimal lumen diameter e area (MLD e MLA); diameter ed area stenosis %. Le immagini TC sono state post-processate con analisi quantitativa semi-automatica.

Risultati. In 2 anni, 50 pazienti (M/F= 4/1; età media 54±8 anni) sono stati trattati con impianto di BVS: 26 Absorb e 24 DESolve. La presentazione clinica era: angina stabile 15 (30%); angina instabile/NSTEMI 26 (52%); STEMI 9 (18%). Il diametro medio degli scaffold utilizzati era maggiore nel gruppo Absorb (3.25±0.4 vs 2.97±0.39 DESolve; p=0.016), mentre i diametri di postdilatazione sovrapponibili (3.44±0.5 Absorb vs 3.24±0.54 DESolve; p=0.2) per la maggiore confidenza a postdilatare il DESolve. La TC ha evidenziato 4 casi di restenosi (Absorb), di cui solo 2 (50%) confermati alla coronarografia. Il confronto QCA pre- e postimpianto ha mostrato un significativo acute gain, nella popolazione e nei due sottogruppi. Il confronto tra misure postimpianto e follow-up TC non ha evidenziato differenze significative dopo circa 18 mesi, sia per popolazione totale che per gruppo Absorb; nel gruppo DESolve è risultato un significativo guadagno di lume tardivo, di MLD (2.13±0.5 vs 2.33±0.5; p=0.03) e MLA (3.73±1.6 vs 4.45±2; p=0.033). Le misure ottenute con metodiche diverse (QCA e TC) hanno mostrato un grado significativo di correlazione. L'analisi di confronto Absorb vs DESolve non ha mostrato differenze, neanche per "entità di variazione" al follow-up.

Conclusioni. La nostra casistica ha mostrato una buona performance generale dei BVS, senza eventi clinici maggiori e con due soli casi di restenosi al follow-up nel gruppo Absorb, forse per via dalla maggiore durata del follow-up rispetto al DESolve, di più recente introduzione. La TC ha mostrato grande utilità per la valutazione quantitativa, con misure correlate a quelle QCA. Un significativo guadagno acuto di lume è risultato, senza recoil postimpianto, nonché un mantenimento dei calibri luminali al follow-up. Il DESolve ha mostrato un maggiore e più precoce guadagno di lume rispetto al precedente BVS, spiegato dalle sue caratteristiche innovative.

C17

6 YEAR EXPERIENCE WITH THE ABSORB BIORESORBABLE VASCULAR SCAFFOLD: THE MAASSTAD ABSORB REGISTRY

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Background. The safety and efficacy of the Absorb (Abbott) bioresorbable scaffold (BRS) has been documented in lower-risk patient and lesion subsets with "real-world" outcome data being scarce. Here we report a daily practice experience with a long-term follow-up at a high-volume Dutch center.

Methods. Between July 2009 and June 2015, 321 patients (363 lesions) were treated with BRS in our center. Registry data collection is ongoing and gathered prospectively in-hospital, at 1 and 6 months and then yearly up to 6 years.

Results. Mean follow-up time was 21.64 months±14.08 with 75.38% of patients having at least 1 year of follow-up. Clinical presentation of patients (72.9% male, mean age 58.8±11.6 years, 15.9% diabetics, 23.4% with previous PCI and/or CABG) was ACS in 56.5%. Multivessel treatment was performed in 18.6% (n=60). Lesion complexity was B2/C in 55.64% with 13% of moderate/sever calcification lesions and 16.3% of bifurcation treatment; mean lesion length by QCA was 23.90±12.13 mm and mean RVD was 2.52±0.62 mm. Pre-dilatation was performed in 91.9% and post-dilatation in 56.9%. The mean scaffold length was 27.54±15.11 mm with 26.3% of cases using overlapping scaffolds. OCT or IVUS was used in 25.2%. Device success was 98.2% (failure to expand in 1 patient and deliver in 5 patients). Over the entire follow-up period, death occurred in 2.8% (9/321), myocardial infarction (MI) in 4.9% (total of 16 cases, 1 of peri-procedural), target lesion

revascularization in 6.8%, target vessel revascularization (TVR) in 8.0%, non-target vessel revascularization in 2.8%. Overall MACE (death, MI, TVR) rate was 11.2% (36/321). Definite stent thrombosis (ST) occurred in 10 patients (2.7%) and probable ST in 1 patient (0.3%). All ST events are tabulated.

Conclusions. This registry including patients with ACS and complex lesion characteristics documents a good safety and efficacy profile of the BRS. However, ST rates in particular early after BRS implantation have to be closely monitored. More data including complex patient and lesion subsets as well as longer follow-ups are needed to define the role of BRS in daily practice.

	BRS (n=313)	BRS (n=304)	BRS (n=277)	Total BRS (n=321)
Follow-up time (months)	1	6	12	21.64
Def./Prob.ST total	11 (3.5%)	7 (2.3%)	7 (2.5%)	11 (3.4%)
Early	8 (2.5%)	7 (2.3%)	7 (2.5%)	8 (2.5%)
Late	2 (0.6%)	2 (0.6%)	2 (0.7%)	2 (0.6%)
Very Late	1 (0.3%)	1 (0.3%)	1 (0.3%)	1 (0.3%)

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C18

THE INFLUENCE OF CORONARY PLAQUE MORPHOLOGY ASSESSED BY OCT ON FINAL MICROVASCULATURE FUNCTION AFTER STENTING IN PATIENTS WITH ST ELEVATION INFARCTION

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Aim. The index of microcirculatory resistance (IMR) provides a reproducible assessment of the status of coronary microvasculature in patients with ST elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PPCI). Frequency-domain optical coherence tomography (FD-OCT) allows detailed assessment of the morphology of coronary plaque. We sought to determine the influence of the initial culprit coronary plaque anatomy and whether changes in plaque appearance within the infarct related artery (IRA) influenced final IMR after stenting in STEMI patients.

Methods and Results. In 25 STEMI patients (age: 58.2±10.0) IMR was measured using a pressure wire (Certus, St. Jude Medical, St. Paul, Minnesota) immediately before and after stent implantation. FD-OCT imaging was performed at the same time-points and (athero)-thrombotic volume before stenting, prolapsed+floating athero-thrombotic volume after stenting, and delta (athero)-thrombotic volume were measured adopting three different strategies. There were no relationships between pre-procedural IMR and FD-OCT parameters. Pre-stenting IMR resulted to be related only to pain to wire time (p: 0.02). Irrespectively of the Method adopted, final IMR was related with pre-stenting (athero)-thrombotic volume (rho=0.44, p=0.03 for Method I, rho=0.48, p=0.02 for Method II and rho=0.30, p=0.06 for Method III) and with delta (athero)-thrombotic volume (rho=0.41, p=0.04 for Method II and rho=0.44, p=0.03 for Method III).

Conclusions. IMR measured before stenting is independent of the appearances of the culprit coronary plaque within the IRA. IMR after stenting, and more importantly the change in IMR after stenting, reflect the degree of distal embolization during stent implantation.

C19

HEMODYNAMIC PREDICTOR OF MORTALITY IN PATIENTS WITH ADVANCED CHRONIC HEART FAILURE AWAITING HEART TRANSPLANTATION

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Background. Pulmonary hypertension (PH) secondary to left heart disease is frequently found in patients with advanced chronic heart failure with reduced ejection fraction (HFrEF) and it is associated with worse prognosis. However little is known about the best hemodynamic predictor of mortality in the specific setting of patients awaiting heart transplantation (HT). Pulmonary arterial compliance (PAC) is a strong predictor of survival in other forms of PH. The aim of this study is to evaluate the prognostic relevance of PAC in patients enlisted for HT.

Methods. Between January 2007 and December 2015, 93 patients affected by advanced HFrEF underwent right heart catheterization at our Institution during the evaluation for HT and were clinically followed until death, HT or any censoring events. Left ventricular assist device (LVAD) implantation was considered a censoring event. PAC was calculated as the ratio between stroke volume (SV) and the pulmonary pulse pressure (PP). Cox regression analysis was used to test the prognostic value of potential hemodynamic predictor of mortality. Multivariate Cox models were used to test the independent predictive value of PAC against other hemodynamic measurements.

Results. During a mean follow-up time of 15.6±23 months, 28(30.1%) patients died, 25 (26.8%) underwent heart transplantation, 23 (24.7%) underwent LVAD implantation and 17 (18.3%) were alive without transplantation at follow-up contact. No patient was lost to follow-up. At ROC curve analysis the best cut-off of PAC associated with mortality was 2 ml/mmHg. Patients with PAC <2 ml/mmHg had significantly higher pulmonary pressures, right atrial pressure and worse cardiac index but similar ejection fraction and cardiac chambers volume. At univariate analysis the following hemodynamic parameters were significantly associated with mortality: right atrial pressure (HR=1.03, 95%CI 1.01-1.05, p=0.001), mPAP (HR=1.05, 95%CI 1.02-1.08, p=0.002), pulmonary pulse pressure (HR=1.047, 95%CI 1.01-1.08, p=0.007), PCWP (HR=1.06, 95%CI 1.023-1.11, p=0.002), CI (HR=0.32, 95%CI 0.14-0.71, p=0.005), SV (HR=0.97, 95%CI 0.95-0.99, p=0.014), PAC (HR=0.49, 95%CI 0.32-0.75, p=0.001). When inserted into a multivariate Cox regression model only right atrial pressure (HR=1.031, 95%CI 1.01-1.06, p=0.012) and PAC (HR=0.37, 95%CI 0.16-0.87, p=0.024) were independently associated with worse survival.

Conclusion. Impaired PAC and elevated right atrial pressure were associated with mortality in a highly selected cohort of patients enlisted for HT. Other hemodynamic parameters add no significant prognostic information.

C20

ABSORB VS DESOLVE: AN OPTICAL COHERENCE TOMOGRAPHY COMPARISON OF ACUTE MECHANICAL PERFORMANCES

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Aims. The aim of the study was to compare retrospectively the acute mechanical performance of the Absorb vs DESolve scaffolds in terms of appropriate deployment with OCT.

Methods and Results. Final post-deployment OCT pullbacks of consecutive patients treated with either Absorb or DESolve were reviewed. The following parameters were calculated and compared: mean and minimal lumen area (MLA), residual in-scaffold area stenosis (RAS), incomplete strut apposition (ISA), tissue prolapse area, eccentricity index, asymmetry index, strut fracture and edge dissection. A total of 72 patients were included. The Absorb group consisted of 35 patients treated with 63 Absorb scaffolds and was compared to a well-matched group of 37 patients treated with 50 DESolve scaffolds. Baseline characteristics did not differ significantly between the two groups. Procedural characteristics were different with respect to maximal balloon inflation pressure (Absorb vs. DESolve: 21.5±0.4 atm vs 16.8±3.8 atm, p<0.01) and mean NC balloon diameter used for post-dilatation (Absorb vs. DESolve 3.3±0.4 mm vs 3.5±0.4 mm, p<0.01). OCT analysis showed similar MLA (Absorb vs DESolve: 5.8±1.9 mm^2 vs 6.1±2.6 mm^2, p=0.43) and mean luminal area (Absorb vs DESolve: 7.1±2.2 mm^2 vs 7.2±1.9 mm^2, p=0.77). The mean eccentricity index was 0.85±0.05 with Absorb and 0.80±0.05 with DESolve, p<0.01. There was no difference in the incidence of overall ISA. A smaller prolapse area was found with Absorb (Absorb vs DESolve 1.0±1.1 mm^2 vs 3.6±6.2 mm^2, p<0.01).

Conclusions. The two scaffolds showed similar MLA while there was a trend towards a lower RAS and a larger maximum and minimum scaffold diameter with DESolve. The DESolve scaffold was more eccentric as compared to the Absorb. These results might be related to the DESolve's unique expansion properties or they may reflect baseline and procedural differences which cannot be excluded in a retrospective study. Randomised studies are needed to address this aspect.

C21

PROSPECTIVE RANDOMIZED STUDY ON SIX MONTH EVALUATION, THROUGH OPTICAL COHERENCE TOMOGRAPHY, OF ENDOTHELIALIZATION AND MALAPPOSITION OF THREE NEW GENERATION CORONARY DRUG ELUTING STENTS: PRELIMINARY RESULTS

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Introduction. The use of drug eluting stents (DES) has decreased, with respect to bare metal stents, the incidence of restenosis, though it has been previously associated with a higher rate of late and very late stent thrombosis, due mainly to the presence of many non-coated or malapposed struts. This has been ascribed to specific drug-polymer combination, so research has been addressed to improve the association of these two components leading to the creation of new generation DES.

Purpose. Our prospective randomized study aims to evaluate at 6 months, through Optical Coherence Tomography (OCT), the endothelialization and malapposition of the struts of three different types of new generation DES: Xience, Biomatrix and Cre8.

Methods and Results. From September 2013 to July 2015, 60 patients with coronary artery disease and indication for percutaneous coronary intervention

were enrolled and randomly submitted to implantation of three different second-generation DES (20 patients with Xience: group A, 20 with Biomatrix: Group B and 20 with Cre8: Group C). We analyzed 1289 frames for a total of 10728 struts. No statistically significant differences were found either in the Neointimal Hyperplasia (NIH) area or in struts covering between the three different types of stent. However, a higher, though not significant, minimum and maximum thickness was observed for Biomatrix (B: 0.09±0.19 mm, A: 0.04±0.01 mm and C: 0.05±0.11 mm, p=0.424; B: 0.21±0.21 mm, A: 0.15±0.05 mm and C: 0.15±0.12 mm, p=0.315, respectively). Statistically significant differences were found in the number of covered protruded struts (A: 13.2±8.5; B: 26.2±18.1; C: 33.9±12.6; p<0.001), the percentage of malapposed struts (A: 0.0 (0.0-0.0); B: 0.9 (0.0-2.9); C: 0.7 (0.0-2.1); p=0.040) and the maximum distance of malapposition. Non-coated struts and areas of stent thrombosis were not found for any of the three stent types.
Conclusion. In our study we were able to report the different coating reactions in the three stent types; in particular, the Biomatrix thickness resulted higher than that of both Xience and Cre8. Moreover, Biomatrix and Cre8 showed a statistically significantly greater proportion of vulnerable struts (malapposed and protruded) that can be associated, along the vessel lumen, with a more turbulent flow, possibly increasing the risk of restenosis and late and very late thrombosis. Finally, Xience resulted to have a more homogenous endothelization since it showed lower standard deviation in all the parameters explored with respect to Biomatrix and Cre8.

C22

SAFETY AND EFFICACY OF SINGLE VS DUAL ANTIPLATELET THERAPY IN PATIENTS UNDERGOING TRANSCATHETER AORTIC VALVE IMPLANTATION: A PROPENSITY MATCHED ANALYSIS FROM THE ITER REGISTRY

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Background. Safety and efficacy of single vs. dual antiplatelet therapy (DAPT) in patients undergoing transcatheter aortic valve implantation (TAVI) remain to be addressed.
Methods. All consecutive enrolled in the ITER registry were included. Patients discharged after TAVI with aspirin alone were compared to those assuming DAPT before and after propensity score with matching. Prosthetic heart valve dysfunction at follow-up was the primary end point whereas all cause death, cardiovascular death, bleedings, vascular complications and cerebrovascular accidents were the secondary ones.
Results. 1364 consecutive patients were enrolled, 605 treated with aspirin and 759 with DAPT. After a median follow-up of 45.0±14 months, prosthetic valve dysfunction, all-cause mortality and risk of stroke and TIA did not differ although with higher risk of major bleedings (1.2% vs 3.6%, p<0.001). At 30 days, all-cause mortality was lower in patients with aspirin (1.5% vs 4.1%, p=0.003), mainly due to reduced risk of major vascular complications (5.3% vs 10.7%, p<0.001) and major bleedings (6.6% vs 11.5%, p<0.001). The propensity score with matching analysis showed reproducible results compared to the total study cohort.
Conclusion. After TAVI with balloon-expandable prosthesis, aspirin alone does not increase risk of prosthetic valve dysfunction, and reduces risk of peri-procedural complications and of 30 days all cause death.

DES

C23

LONG TERM FOLLOW-UP OF "FULL METAL JACKET" OF DE NOVO CORONARY LESIONS WITH NEW GENERATION ZOTAROLIMUS-ELUTING STENTS

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Background. Diffuse coronary artery disease treatment still remains a challenge for interventional cardiologists and cardiac surgeons. There are few data on full metal jacket (FMJ) stenting, especially with new-generation drug-eluting stents. We aimed to assess the efficacy and safety of FMJ with new-generation zotarolimus-eluting stents (n-ZES).
Methods and Results. All patients who underwent FMJ with n-ZES (≥60 mm stent length) in eleven Italian interventional centers participating in the Clinical Service® project were included in this analysis. The project population consisted on 120 patients and 122 lesions. Mean age was 67±10 years and 95 (79.2%) patients were male. A chronic total occlusion was present in 34 lesions (27.9%). The number of stents implanted per lesion was 2.9±0.8, and the diameter of the stents was 3.0±0.5 mm. Predilation and post-dilatation were performed in 107 (87.7%) and 92 (75.4%) patients, respectively. At 41±21 month follow-up there were 2 sub-acute definite stent thrombosis, 6 patients (5.0%) had cardiac death and 5 patients (4.2%) had non-fatal myocardial infarction. Seven patients (5.8%) underwent clinically-driven target lesion revascularization. Fourteen patients (11.7%) had at least one major adverse cardiac event.
Conclusion. The treatment of diffuse coronary artery disease with FMJ stenting with n-ZES appears to be effective and safe. Late and very-late ST does not seem an issue and the rate of restenosis and of major cardiac adverse events after more than 3-year follow up is rather low.

C24

LONG-TERM (≥10 YEARS) SAFETY OF PERCUTANEOUS TREATMENT OF UNPROTECTED LEFT MAIN STENOSIS WITH DRUG-ELUTING STENTS

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Percutaneous coronary intervention (PCI) of unprotected left main disease (ULM) with drug eluting stents (DES) is hampered by lack of information on long-term (≥10 years) safety data. All patients treated with PCI on ULM in 9 international centers with at least 10 years follow up were enrolled. Baseline and procedural features were recorded. Re-PCI on ULM at 10 years was the primary end point. Secondary endpoints included MACE (major adverse cardiac events) and its components (cardiac and non-cardiac death, myocardial infarction, re-PCI not on ULM and stent thrombosis). Sensitivity analysis was performed according to presence of isolated ULM disease: 284 patients were enrolled. 70 (21%) performed a re-PCI on ULM, 39 in the first year and 31 between 1 and 10 years (only 5 overall performed for acute coronary syndrome). Patients with re-PCI on ULM did not show differences in baseline and procedural features, or experience higher rates of cardiovascular death (12% vs. 11%, p=0.65), myocardial infarction (11% vs. 6%, p=0.56), or of re-PCI on non-ULM disease (31% vs 27%, p=0.76) compared to those without re-PCI on ULM. At Kaplan-Meier analysis, patients with PCI in other coronary vessels were at higher risk of MACE, driven by target vessel revascularization (20.4% vs. 32.9%, p=0.009), as confirmed at multivariate analysis (stenosis other than LM: HR 2:1.4-2.7, all CI 95%).In conclusion, despite of using first-generation stents, PCI on ULM is safe, with low rates of recurrent events due to index-revascularization. Progression of atherosclerotic lesions on other coronary vessels represents the only independent predictive factor for prognosis.

C25

OPTIMAL DURATION OF DUAL ANTIPLATELET THERAPY (DAPT) AFTER SECOND GENERATION DRUG-ELUTING STENT (DES) IMPLANTATION IN ELDERLY PATIENTS: THE SECURITY-ELDERLY SUBSTUDY

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Background. The randomized SECURITY trial (NCT00944333) showed non-inferiority of 6 vs 12 month DAPT after DES implantation in a low-risk population treated with PCI.

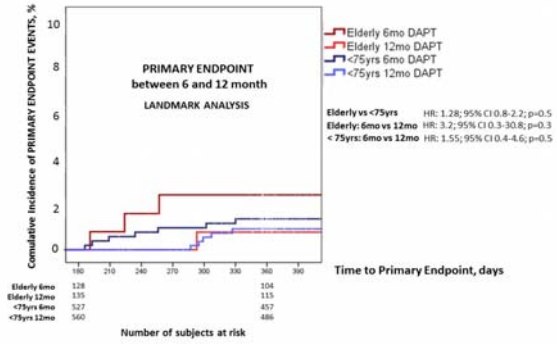
Objectives. To assess the outcome of elderly (≥75 years old) in comparison to younger (<75 years old) patients and the association between DAPT duration and outcome in elderly patients.

Methods. In this subanalysis from the SECURITY, all elderly (EP) were compared to younger (YP) patients. The primary endpoint (PE) was a composite of cardiac death (CD), myocardial infarction (MI), stroke, definite/probable stent thrombosis, BARC 3/5 bleeding at 12 months. The secondary endpoint (SE) was a composite of CD, MI, stroke, any bleeding at 24 months.

Results. Of the 1399 patients enrolled, 279 (19.9%) were elderly. EP showed similar baseline characteristics and were associated with a higher incidence of the primary (6.8% vs 3.7%, p=0.02) and secondary (9.7% vs 4.6%, p<0.001) end points, with similar rate of bleeding (1.2% vs 0.9%, p=0.8). Between EP, we observed a trend towards an increase in the primary end point occurrence in the 6 month group (9.4% vs 4.3%, p=0.08) (see Figure and Table).

Conclusions. In a low risk population undergoing PCI with DES, EP were associated with worse ischemic outcome and similar bleeding rate. Between EP, we observed a trend towards a higher incidence of primary endpoint in patients assigned to 6 month DAPT.

	<75 years			≥75 years		
	6m DAPT (n=543)	12m DAPT (n=577)	p	6m DAPT (n=139)	12m DAPT (n=140)	p
Primary endpoint						
Primary efficacy composite endpoint						
6 months	13 (2.4)	16 (2.8)	0.69	10 (7.2)	5 (3.6)	0.17
12 months	20 (3.7)	21 (3.6)	0.97	13 (9.4)	6 (4.3)	0.08
Secondary endpoint						
Secondary efficacy composite endpoint						
12 months	22 (4.1)	23 (4.0)	0.96	13 (9.4)	6 (4.3)	0.08
24 months	26 (4.8)	25 (4.3)	0.72	15 (10.8)	12 (9.6)	0.49
Cardiac mortality	1 (0.2)	5 (0.9)	0.12	6 (3.6)	1 (0.7)	0.09
Myocardial Infarction	16 (2.9)	12 (2.1)	0.36	6 (4.3)	6 (4.3)	0.96
Def. or prob. stent thrombosis	2 (0.4)	2 (0.3)	0.95	1 (0.7)	1 (0.7)	0.94
Stroke	3 (0.6)	1 (0.2)	0.29	3 (2.2)	2 (1.4)	0.61
Type 3 or 5 BARC bleeding	3 (0.6)	7 (1.2)	0.24	2 (1.4)	1 (0.7)	0.55



C26

RADIAL VS FEMORAL ACCESS FOR THE TREATMENT OF LEFT MAIN LESION IN THE ERA OF SECOND-GENERATION DRUG ELUTING STENTS: DATA FROM THE FAILS 2 REGISTRY

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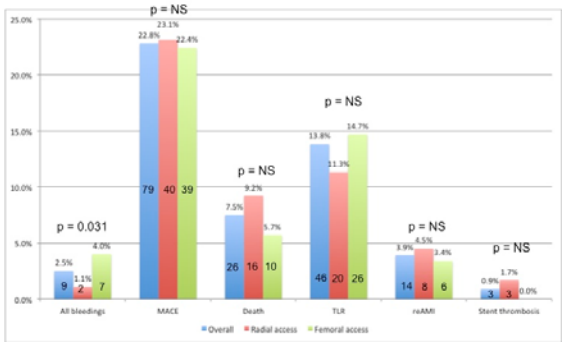
Background. Trans-radial access (TRA) is often avoided in favour of the trans-femoral access (TFA) during percutaneous coronary interventions (PCI) on the left main coronary artery (LM), due to technical and safety concerns. Aim of this study was to compare the performance of TRA and TFA in the treatment of LM with second-generation drug-eluting stents (DES2).

Methods. Consecutive patients undergoing PCI on the LM with DES2 were retrospectively enrolled in the multicenter FAILS 2 registry. Patients were stratified according to the arterial access. Choice between TRA and TFA was left to each operator's preferences. Bleedings during index hospitalization were the primary end-point. Secondary end-points were MACE (death, reinfarction, target lesion revascularization (TLR)) and the single components of MACE at follow-up. Propensity score matching was executed to account for possible confounding.

Results. Overall, 1247 patients were enrolled (289, 23.2%, of female sex, mean age 70.2±10.2 years). Diagnosis at presentation was stable angina in 603 (48.7%) cases, NSTE-ACS in 465 (37.3%), STEMI in 117 (9.5%). Mean follow-up was 726±654 days. After propensity score matching, 354 patients were included. As reported in the figure, the primary end-point was significantly reduced in patients treated with TRA (2.0% vs 4.0%, p=0.042), while no differences emerged pertaining the secondary end-points, including TLR and reinfarction.

Conclusion. TRA may reduce in-hospital bleedings in patients undergoing percutaneous treatment of the LM, without increasing the rate of adverse cardiovascular events at follow-up. TRA may be safely used in the treatment of the LM.



C27

SAFETY AND EFFICACY OF ROTATIONAL ATHERECTOMY FOR THE TREATMENT OF UNDILATABLE UNDEREXPANDED STENTS IMPLANTED IN CALCIFIC LESIONS

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Objectives. Coronary stent underexpansion is a known risk factor for in-stent restenosis and stent thrombosis. There are limited options once non-compliant balloons (NCB) have failed to achieve optimal stent expansion. Excimer Laser Coronary Angioplasty with contrast medium injection (ELCA) is one possibility, but not readily available. Rotational atherectomy (RA) is an alternative, but has been described only in case reports and concerns exist regarding safety.

Methods. All consecutive patients undergoing RA for symptomatic in-stent restenosis due to stent underexpansion resistant to NCB postdilatation between January 2005 and December 2015 were analyzed.

Results. A total of 16 patients underwent treatment during the study period: the clinical indication was effort angina with inducible ischemia in 14 cases (87.5%) and acute coronary syndrome in 2 cases (12.5%); the mean age of the patients treated was 65±13.8 years and the mean ejection fraction of

49.7±8.9%. The vessel treated was left anterior descending artery in 7 cases (43.8%), left circumflex in 4 cases (25%), right coronary artery in 5 cases (31.2%). The mean size of the burr used was 1.7±0.2 mm with a mean burr size/lumen ratio of 0.6±0.06, rotating at the mean speed of 171.2±5.8rpm. The procedure was successful in 14 cases (87.5%): after RA full NCB expansion was achieved in all cases and the target lesion was treated with a second generation drug eluting stent in 13 cases, 1 case being treated with drug eluting balloon. The mean post-procedural minimal lumen diameter increased by 2.3±0.8mm and percentage diameter stenosis decreased from 82.17±17.2% to 11.9±9.1%. Intraprocedural complications occurred in 2 patients (burr entrapment successfully managed percutaneously and periprocedural myocardial infarction). At 1-year follow-up, the incidence of target lesion revascularisation was 13.3% (2 out of 15 patients), and 1 patient died from non-cardiac death.

Conclusion. RA seems an effective and safe treatment option for symptomatic stent underexpansion resistant to balloon dilatation.

TAVI – 1

C28

MIGLIORAMENTO DELL'EMODINAMICA DOPO PROCEDURE DI TAVI: UN NUOVO MARKER

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Background. Attualmente la TAVI rappresenta il trattamento di scelta per i pazienti affetti da stenosi aortica severa, per i quali sussiste un rischio chirurgico elevato. Il posizionamento della protesi con conseguente riduzione del gradiente transvalvolare, determina un importante miglioramento dell'emodinamica con riduzione immediata del post-carico ventricolare e agevolazione del circolo ematico in tutti i distretti corporei. Questo miglioramento si traduce in un incremento della perfusione degli organi nobili (in primis cervello, reni e lo stesso miocardio). Questo nuovo assetto emodinamico si manifesta in genere con un miglioramento del quadro clinico (aumento della tolleranza allo sforzo, riduzione della dispnea e della classe NYHA).

Scopi. Lo scopo del nostro studio è quello di dimostrare come il miglioramento della perfusione tissutale che si verifica dopo TAVI giovi anche sulla funzione endoteliale. Essa può essere valutata in maniera non invasiva mediante misurazione della flow mediated dilation (FMD) al livello dell'arteria brachiale, ovvero l'aumento di calibro dell'arteria (espresso in percentuale) nei minuti successivi ad ischemia controllata ottenuta mediante insufflazione di un bracciale di sfigmomanometro. Questo valore negli adulti normali oscilla tra 5 e 10%. Una riduzione è associata ad un grado più o meno elevato di disfunzione endoteliale.

Materiali e metodi. Sono stati arruolati 46 pazienti (18 uomini, età media 81.3±5.1 anni) sottoposti a TAVI presso il Policlinico di Bari (EuroSCORE 21.6±15.4%; STS score:20.9±14.9%). Ciascun paziente è stato sottoposto il giorno prima della procedura (ed ad almeno 1 settimana dalla esecuzione di angio-TC con mezzo di contrasto per lo studio della valvola nativa e/o dalla coronarografia) a valutazione della FMD brachiale (baseline). Tale valutazione è stata poi ripetuta a distanza di un mese dalla procedura (follow-up), in occasione del controllo cardiologico di routine. Sono stati esclusi i pazienti in cui è stato rilevato al controllo ecocardiografico un gradiente max residuo superiore a 20mmHg. Le variazioni di FMD per ciascun paziente sono state confrontate mediante test di T-Student. Una $p<0.05$ è stata considerata significativa.

Risultati. Per tutti i pazienti è stato utilizzato l'accesso percutaneo transfemorale. Sono state impiantate 5 valvole Direct Flow Medical; 11 valvole Sapien XT e 30 valvole Sapien 3. Come atteso, i valori di FMD alla baseline, in considerazione dell'età dei pazienti, della patologia di base e delle comorbidità, sono risultati piuttosto bassi (media: 3.18±0.72%). I valori di FMD ad un mese dall'intervento pur mostrando valori al di sotto della media della popolazione adulta normale (media: 4.25±0.85%), sono risultati significativamente più alti rispetto a quelli della baseline con una $p=0.0074$.

Conclusioni. Pur con un campione piuttosto esiguo questo studio dimostra come il miglioramento dell'emodinamica e della perfusione tissutale conseguente a risoluzione della stenosi aortica mediante TAVI, si accompagni ad un consensuale incremento dell'FMD brachiale che è un indice di miglioramento della funzionalità endoteliale.

C29

SINGLE VERSUS DUAL ANTIPLATELET THERAPY IN PATIENTS WITH SEVERE AORTIC STENOSIS TREATED WITH TAVI. INSIGHT FROM PARMA-TAVI REGISTRY

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Purpose. Transcatheter aortic valve implantation (TAVI) has become over the years a valid alternative over surgical replacement for the treatment of severe aortic stenosis. After valve implantation, a regimen of dual antiplatelet therapy with ASA and clopidrogrel is a common practice, used to reduce the incidence of ischemic events and differs from which usually done after surgical replacement, where a single antiplatelet therapy regimen is preferred. The lack of common guidelines on the use of antiplatelet therapy after TAVI procedures is mainly due to the absence of an adequate scientific data comparing dual versus monotherapy. In view of this, we sought to test the non-inferiority of a single antiplatelet regimen compared with dual antiplatelet therapy.

Materials and methods. 120 patients, taken from the PARMA-TAVI registry, were divided into two cohorts, one in which patients were discharged with a regimen of three months dual antiplatelet therapy (DAPT) after the procedure and the other one, in which patients were discharged with a regimen of single antiplatelet therapy (SAPT). Primary endpoint was a composite of all cause death, cardiovascular death, bleedings, vascular complications and cerebrovascular accidents at 30 days of follow-up. All the end points were adjudicated according to VARC-2 (Valve Academic Research Consortium) definitions.

Results. No statistical significance difference in the OR was found for the 30 days-VARC combined endpoint among the two populations. At 30 days bleeding complications were lower in the SAPT group despite a major rate of stroke events, without statistical significance evidence.

C30

6 YEARS (2010-2015) OF TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI) EXPERIENCE: LANDMARK ANALYSIS OF 235 PATIENTS OUTCOMES

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Background. Nowadays TAVI is a consolidated therapeutic option for high-risk patients with symptomatic aortic stenosis. Thanks to the developments of technology and the increase of operators' expertise, the rate of overall mortality and complications are expected being decreasing over time. We aim to show a comprehensive overview of 6-years TAVI experience in our Center.

Methods. We prospectively collected data of short- and long-term outcomes of patients who underwent TAVI between 2010 and 2015 in our Center. Patients had close follow-up at 30 days, and then every 6 months. They were divided into two groups according to the year of the procedure (from 2010 to 2012-group 1, from 2013 to 2015-group 2) to detect differences in long-term over-all and cardiovascular mortality.

Results. 235 patients were enrolled. Mean age was 82±7, 60% female, mean Log EuroSCORE I and STS score were respectively 21±13% and 8±5%. Left ventricular ejection fraction was generally preserved (55±15%). 142 CoreValve, 79 Edwards Sapien, 10 Engager and 4 Lotus were implanted. 30-days VARC mortality was 6.4% (from 13% in 2010 to 6% in 2015, $p=0.5$), with a device success of 86.4%. Moderate or severe aortic regurgitation was registered in 8.5% (from 3.3% in 2010 to 6% in 2015, $p=0.9$). Major vascular complications occurred in 12% (from 23% in 2010 to 12% in 2015, $p=0.8$) of patients. The incidence of pacemaker implantation was 19%, with a difference between first and second generation valves: Sapien XT and Sapien 3 (20% vs 8% $p<0.001$) and between CoreValve I generation and Corevalve Evolute (25% vs 15% $p<0.001$). Mean follow-up was 739±567 days, median 657 days. At follow-up 11.3% were in NYHA class 3-4, from 74.9% at baseline ($p<0.001$). The freedom from all-cause re-hospitalization was 51%. One-year overall and cardio-vascular mortality was 20% and 8%, while at 3 years was 43% and 15%, respectively. Stratifying the population according to the years of implantation, a trend of reduction both in overall (1 year: 26% group 1 vs 17% group 2, 3-year 50% group 1 vs 36% group 2, respectively, $p=0.07$) and cardiovascular (1 year: 11% group 1 vs 6% group 2, 3-year 20% group 1 vs 7% group 2, respectively, $p=0.09$) mortality was registered. Independent predictors of long-term mortality were VARC device success ($p<0.001$) and VARC major vascular complications ($p<0.001$).

Conclusions. In the landmark analysis of our population, we found a trend of improvement in short term outcomes, i.e. 30-days VARC mortality and vascular complication. There also appeared a reduction in long-term overall and cardiovascular mortality between TAVI performed in the first group (2010-2012) and in the second one (2013-2015), although not statistically significant, maybe due to the small size of the sample population. These findings give evidence that improvements in operator's technical skills and in the selection of the patients, together with the technological advancements, do enable to optimize procedural results and increase long-term survival.

C31

SAFETY AND EFFECTIVENESS OF TRANSSUBCLAVIAN APPROACH FOR TAVI: SINGLE-CENTER EXPERIENCE

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Introduction. TAVI is an effective treatment for severe aortic stenosis. Besides the transfemoral approach, common transthoracic approaches are the

transapical and transaortic routes. Yet, these are associated with morbidity. The transsubclavian approach is an effective alternative to minimize invasiveness.
Purpose. We present a single-center TAVI series through the transsubclavian arterial approach (TSA) using the CoreValve Evolut R device with a 14F introducer profile. We analyze safety and effectiveness of this strategy in terms of outcomes, complications and hospital stay.
Methods. Twelve consecutive patients (9 males; age: 80.1±9.2 years) with symptomatic SAS at excessive surgical risk (Logistic EuroSCORE: 4.22±3.71%) underwent TAVI via TSA. A CoreValve Evolut R was used in all cases (surgical exposure and catheterization of the left subclavian artery). No sheath was employed; the 14F delivery system was directly introduced into the artery.
Results. Procedures were performed under general anesthesia within a hybrid operative theater. Procedural success was 100%; fluoroscopy time was 19.5±2 min; contrast agent volume was 91.7±27 ml. Patients were extubated after 1.9±0.94 hours. Mean hemoglobin drop was 0.55±0.28 g/dl (no transfusion was needed). There were no vascular, access-related, heart block or other complications (according to VARC-2). Mean aortic gradient dropped from 53.7±16.3 mmHg before TAVI to 8.9±3.8 mmHg after TAVI, p<0,001). Significant periprosthetic regurgitation occurred in one case (+3). Hospital stay was 4.5±1.4 days; 4 patients were addressed to rehabilitation and the remainders were discharged home.
Conclusions. This initial series suggests safety and effectiveness of TSA. It is associated with very limited morbidity, patient's mobilization on the first day, short hospitalization. The 14F profile allows adaptation to challenging arterial anatomies. TSA could be considered as the second less invasive approach for TAVI after the transfemoral.

C32

CONFRONTO DEI RISULTATI INTRAOSPEDALIERI E A 1 ANNO DELLA TAVI CON SAPIEN XT RISPETTO ALLA SAPIEN 3 NEL TRATTAMENTO DELLA STENOSI VALVOLARE AORTICA SEVERA

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Background. Transcatheter aortic valves are rapidly evolving in order to reduce procedural complications and to improve acute and long-term outcomes of aortic stenosis (AS) treatment.
Aim. To compare in a single-center experience in-hospital and 1-year results of severe AS treatment with Sapien XT (SXT) and Sapien 3 (S3) transcatheter aortic valves (Edwards Lifesciences, Irvine, CA) in a large patient cohort.
Methods. Between May 2010 and May 2016, 407 patients with severe symptomatic AS and high surgical risk underwent TAVR in our center. Patients were deemed high risk by Heart Team clinical assessment or if STS score was ≥8. From March 2014, SXT valve was replaced by S3 valve at our institution. A total of 265 patients were treated with SXT and 142 with S3. The two groups were similar as regards demographic characteristics, with the exception of higher female prevalence in SXT group (63.3% vs 45.1%, p<0.01) and higher rate of prior PCI in S3 group (45% vs 27.5%, p<0.01). STS score was 5.76 in SXT and 5.83 in S3 (p=0.8).
Results. Transapical approach was used in 6.4% vs. 4.2% (p=0.36), predilation in 97.3% vs. 69% (p<0.001) and postdilation in 4.5% vs. 15.4% (p<0.001) of SXT and S3 patients, respectively. Procedural time and contrast volume decreased from 199 to 76 min. and from 208 to 153 ml in SXT and S3 procedures, respectively (p<0.01 for both). In-hospital mortality was 3.7% vs 1.4% (p=0.17), stroke 0.7% vs 0.7% (p=0.95), stage-3 AKI 6.7% vs 0.7% (p=0.016), major vascular complications 7.9% vs 0.7% (p=0,002) in SXT and S3 patients, respectively. At 30 days, peak/mean aortic gradients were 20.2/10.6 vs. 22.6/12.4 mmHg in SXT and S3 (p<0.01). Paravalvular leak (≥ moderate) was seen in 4.2% SXT vs 0.7% S3 (p=0.05). Permanent pacemakers were implanted in 5.6% SXT and 7.7% S3 patients (p=0.41). At 1-year follow-up, 27/265(10.2%) SXT and 2/42 (4.8%) S3 patients died. Paravalvular leak (≥moderate) was 4.9% vs 0.9% (p=0.46) in SXT and S3 patients.
Conclusion. This single-center retrospective analysis suggests that S3 performance is superior to SXT in severe (AS) treatment in terms of paravalvular leak, major vascular complication and AKI reduction, with a trend toward lower in-hospital and 1-mortality.

Intravascular imaging

C33

CLINICAL IMPACT OF OPTICAL COHERENCE TOMOGRAPHY FINDINGS ON CULPRIT PLAQUE IN ACUTE CORONARY SYNDROME: THE OCT-FORMIDABLE STUDY REGISTRY

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Background. Aim of this study was to evaluate the clinical impact of the culprit plaque features assessed by optical coherence tomography (OCT) in patients with acute coronary syndrome (ACS).
Methods and Results. The OCT-FORMIDABLE register enrolled retrospectively all consecutive patients who perform OCT on culprit plaque in patients with ACS in 9 European centres. The primary endpoint was the correlation of culprit plaque characteristics at OCT with incidence of major adverse cardiovascular events (MACEs, defined as the composite of death from cardiac causes, non- fatal MI, clinically driven target vessel revascularization). The evaluation of the impact of plaque characteristics on therapy (both stent and medical treatment) efficacy was the secondary endpoint 285 patients were included in the study. Mean age was 60.4±12.8 years old, 20.4% of the patients were of female gender. Main clinical presentation was ST-elevation myocardial infarction (STEMI, 49.8%). At OCT analysis culprit plaque rupture (CPR) was present in 65.3% of cases, 61.1% presented thin cap fibro-atheroma, while 33.8% presented necrotic core with macrophage infiltrations (NCMI). During follow-up (11.7±13.7 months) 12.3% of the patients experienced MACEs. At the multivariate analysis presence of CPR (HR 3.8, 1.5-10, p<0.01) and NCMI (HR 3.2, 1.5-6.5, p<0.01) were independent predictors for MACEs while the implantation of a second generation drug eluting stent (DESs, HR 0.3, 0.1-0.6, p<0.01) and dual antiplatelet therapy with prasugrel or ticagrelor at discharge (HR 0.4, 0.1-0.9, p=0.03) were protective. The protective impact of second generation drug eluting stents and of new antiplatelet drugs was reported only in patients with CPR while in patients without any of the baseline clinical or procedural features impacted on MACEs.
Conclusions. CPR and the presence of NCMI are independent predictors of worse outcome. Patients with CPR seem to benefit more of an intensive therapy, both from a pharmacological and interventional point of view. (NCT02486861)

C34

CLINICAL IMPACT OF SUBOPTIMAL STENTING AND RESIDUAL INTRASTENT PLAQUE/THROMBUS PROTRUSION IN PATIENTS WITH ACUTE CORONARY SYNDROME: THE CLI-OPCI ACS STUDY

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Aims. Clinical consequences of optical coherence tomography (OCT) high-definition visualization of plaque/stent structures in acute coronary syndrome (ACS) patients remain undefined. The aim of this study was to assess the clinical impact of post-procedural culprit lesion optical coherence tomography (OCT) findings in patients with acute ACS.
Methods and Results. From the Centro per la Lotta contro l'Infarto-Optimisation of Percutaneous Coronary Intervention (CLI-OPCI) database, we retrospectively analyzed post-procedural OCT findings in ACS patients undergoing percutaneous coronary intervention (PCI) and explored the impact of suboptimal stent deployment (specifically that of residual intrastent plaque/thrombus protrusion) on outcome. A total of 507 patients (588 lesions) were included. Post-procedural OCT assessment of the treated culprit lesion revealed suboptimal stent implantation in 55.2% of cases, with an associated increased risk of major cardiac adverse events (MACE) during follow-up (17.6% vs. 6.4%, p<0.01). In particular, significant residual intrastent plaque/thrombus protrusion was observed in one-third of the cases

and was more frequent in patients experiencing MACE (OR 2.31, 95% CI 1.3-4.3, p<0.01), together with in-stent minimum lumen area (MLA) <4.5mm^2 (OR 2.88, p<0.01), dissection >200µm at the distal stent edge (OR 4.58, p<0.01), and reference lumen area <4.5mm^2 at either distal (OR 10.04, p<0.001) or proximal (OR 17.29, p<0.001) stent edges. Using multivariable Cox hazard analysis, both the presence of suboptimal OCT stent deployment (HR=4.05, 95% CI 1.8-9.0, p=0.001) and residual intrastent plaque/thrombus protrusion (HR=2.96, 95% CI 1.4-6.3, p=0.005) were confirmed as independent predictors of MACE.
Conclusions: OCT suboptimal stent deployment at the culprit lesion in ACS patients increased the risk of MACE occurrence. In particular, the presence of residual intrastent plaque/thrombus protrusion was an independent predictor of adverse outcomes.

C35

ROLE OF RESIDUAL ACUTE STENT MALAPPOSITION IN PERCUTANEOUS CORONARY INTERVENTIONS: A CLI-OPCI PROJECT SUBSTUDY

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Objectives. We sought to assess clinical consequences of acute stent malapposition (ASM) in the context of the multicenter Centro per la Lotta contro l'Infarto-Optimisation of Percutaneous Coronary Intervention (CLI-OPCI) registry.
Background. ASM as important determinant of stent thrombosis risk remains controversial.
Methods. From the CLI-OPCI database we retrospectively analyzed prevalence and magnitude of ASM in 1020 stented lesions out of 864 patients and explored possible correlation with outcome.
Results. Post-procedural optical coherence tomography (OCT) revealed a variable grade of ASM in 72.3% of stents without correlation between maximal strut-vessel distance and longitudinal extension (R=0.164, p<0.01). Regardless of its magnitude, ASM did not affect risk of following major cardiac adverse events (MACE); residual ASM was comparable in terms of thickness (median [interquartile range] 0.21 [IQ 0.1-0.4] vs. 0.20 [IQ 0.0-0.3], p=0.397) and length (2.0 [IQ 0.5-4.1] vs. 2.2 [IQ 0.0-5.2], p=0.640) in patients with versus without MACE. Also the ASM cut-offs of >0.2 mm in thickness and >2.1 mm in length, showing best predictive accuracy for outcome (C-statistic 0.52, 95% CI 0.47-0.58, p=0.394), did not identify patients at increased risk of MACE, including TLR (HR 0.80, 95% CI 0.5-1.4) and stent thrombosis (HR 0.71, 95% CI 0.3-1.5). Likewise, timing to MACE was not influenced by the presence of such an ASM with a similar rate of acute-subacute (HR 1.09, 95% CI 0.6-1.9), late (HR 0.91, 95% CI 0.5-1.8), and very late (HR 1.23, 95% CI 0.5-2.9) events
Conclusions. ASM was a common finding after stent implantation, but was not associated to increased risk of stent failure during follow-up, regardless of its magnitude.

C36

FIVE YEAR SERIAL OCT FOLLOW-UP OF JAILED SIDE BRANCHES AFTER TREATMENT WITH ABSORB BIORESORBABLE SCAFFOLDS

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Background. Expansion in indication using bioresorbable scaffolds (BRS) has led to increased bifurcation treatments with a provisional approach being the default strategy. Although BRS struts at the side branch (SB) orifice have been shown to be subject to the regular bioresorption process, little is known about the long term development of the tissue bridges covering the struts at the SB ostium.
Methods. We performed both 2D and 3D OCT analysis of patients treated within the ABSORB Cohort B at our center. According to the protocol the patients underwent serial angiography and intravascular imaging evaluation (OCT at 3 and 5 years). Orifice SB area and mean thickness of tissue bridge covering SB were calculated from 2D assessment. The number of SB orifice compartments separated by BRS struts was analyzed by using 3D OCT reconstruction.
Results. We identified a total of 4 SBs ostia in the segments treated with BRS, with one of them not being jailed by BRS struts. Between 3 and 5 years of follow-up a significant decrease of mean tissue bridge thickness covering SBs ostia was observed (423±75 µm at 3 years vs. 270±87 µm at 5 years; p=0.03; Figure). Moreover, there was a trend towards an increase of calculated SBs area (3.36±2.51 mm^2 at 3 years vs. 3.76±2.88 mm^2 at 5 years; p=0.06). Using 3D reconstruction, visual assessment showed a decrease in number of compartments in two out of three SBs ostia.
Conclusions. In our serial OCT series of BRS struts covering SBs ostia, we observed a consistent SB orifice area enlargement from 3 to 5 years. Importantly, significant decrease of tissue bridge formation might contribute to late patency of jailed ostia by BRS. These findings may further elucidate scaffold mechanical features in bifurcations lesions treatment.

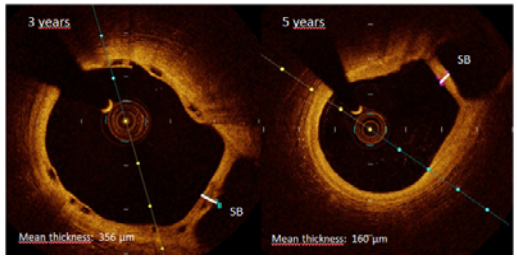

Figure. Tissue bridge measurement on SB ostium.

C37

CULPRIT PLAQUE CHARACTERISTICS IN JUVENILE ACS EVALUATED BY OPTICAL COHERENCE TOMOGRAPHY: CHANGING THE INGREDIENTS WILL CHANGE THE RECIPE?

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Culprit plaque characteristics in young patients who experience an acute coronary syndrome (ACS) evaluated by optical coherence tomography (OCT) have to be defined. The OCT-FORMIDABLE is a multicentre retrospective registry enrolling consecutive patients with ACS who performed OCT in 9 European centres. Patients were divided in two groups according to age at presentation: juvenile-ACS (age ≤50 years) and not juvenile-ACS (age >50 years). Primary end-point was the prevalence of plaque rupture (PR). Secondary end point was the prevalence of thin cap fibro atheroma (TCFA), fibrocalcific and fibrotic plaque. 285 patients were included, 71 (24.9%) in juvenile-ACS group and 215 (75.1%) in not juvenile-ACS group. Younger patients showed a trend for a higher prevalence of plaque rupture (70% vs 64%, p=0.29), thin cap fibro atheroma (70% vs 58%, p=0.06) and thrombus presence (62% vs 51%, p=0.1). Of interest patients younger than 35 years showed a higher prevalence of PR compared to patients aged between 35-45 or 45-50 years (100% vs 72% vs 55%, p=0.03). Culprit plaque in juvenile-ACS group showed more frequently a reduced mean cap thickness (119±66 vs 155±95 nm, p=0.05) and less frequently fibrotic (32% vs 57%, p<0.001) or fibrocalcific (17% vs 36%, p=0.003) characteristics. In conclusion, young patients with ACS show a trend for a higher prevalence of culprit plaque rupture, a thinner cap and less fibrotic or fibrocalcific components.

Mitral repair

C38

SCORE DI RISCHIO CHIRURGICO (SRCH) E SCORE DI RISCHIO NON CHIRURGICO (SRNCH) IN PAZIENTI CON INSUFFICIENZA MITRALICA (IM) SEVERA E SINTOMATICA SOTTOPOSTI A IMPIANTO DI MITRA-CLIP® (MC®): PROPOSTA DI MODELLO PILOTA DI PREDIZIONE DI MORTE A DISTANZA

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Razionale. Il processo decisionale della scelta del paziente candidato a impianto MC® è complesso e gravato da criticità: da un lato è affidato a SRCh derivati da coorti in cui questa popolazione di pazienti non è rappresentata, dall'altro può orientarsi a trattare soggetti che non riceveranno alcun beneficio in termini di sopravvivenza e di miglioramento della qualità della

vita. Allo stato attuale non si dispone di uno score di rischio dedicato a predirne il profilo di rischio individuale.
Obiettivo. Calcolare i valori di mortalità attesa secondo SRCh e SRnCh, confrontarli con i valori di mortalità osservati a 1 anno di distanza dall'impianto MC® e costruire un modello predittivo dedicato a questa popolazione.
Metodi. Oggetto del nostro studio è stata una popolazione di 69 pazienti affetti da IM severa sintomatica e sottoposti consecutivamente a procedura di impianto MC®. La candidabilità alla procedura è stata definita sulla base di EuroSCORE logistico, EuroSCORE II ed STS mortalità; sono stati calcolati i valori di tre SRnCh: il Seattle Heart Failure Model (SHFM), il 3C-HF, e, sulla base del Simple Frail Index di Robinson, un indice di fragilità modificato. L'endpoint primario è stato considerato il potere predittivo della morte a distanza per tutte le cause definito sia dagli SRCh che dagli SRnCh o dalla combinazione di variabili incorporate al loro interno. È stata eseguita una analisi della sopravvivenza, utilizzando modelli a rischi proporzionali di Cox; la accuratezza predittiva di ogni modello è stata definita attraverso analisi delle curve ROC; è stato infine costruito un modello predittivo, utilizzando come variabile esplicativa lo SRCh con la più elevata capacità predittiva e testando nel modello tutte le variabili incorporate negli SRnCh.
Risultati. Gli SRCh presentano una modesta capacità predittiva, sia pure statisticamente significativa: i livelli di migliore performance sono stati osservati nell'EuroSCORE II con HR di 1.10 (IC [1.03,1.66], R2: 0.109) e con accuratezza predittiva che ha mostrato, nella curva ROC, una AUC di 0.78, ed il migliore cut off (6.24) per valori combinati di sensibilità e di specificità pari a 0.86 ed a 0.66, rispettivamente. L'analisi dell'associazione tra valori degli SRnCh e morte a lungo termine ha documentato che nessuno dei tre score, analizzato isolatamente, ha mostrato una performance predittiva superiore all'EuroSCORE II. Alla regressione multivariata di Cox, il modello che ha mostrato migliore performance in termini di forza di associazione ed accuratezza predittiva è composto dalle seguenti variabili: EuroSCORE II, Timed Up and Go test (variabile dell'indice di fragilità), FA permanente (variabile del 3C-HF), grazie a una forte significatività statistica (p=0.0013), una discreta bontà di accostamento (R2: 0.215, doppia rispetto all'EuroSCORE II) ed una elevata accuratezza diagnostica (AUC: 0.80, sensibilità 0.93 e specificità 0.66 al migliore cut-off di 8.17).
Conclusioni. Il modello pilota costruito sulla base di SRCh e SRnCh aumenta il loro potere predittivo di morte per tutte le cause a distanza della procedura, riducendo in tal modo il rischio di utilizzo futile dell'impianto MC®.

C39

PERCUTANEOUS EDGE-TO-EDGE MITRAL VALVE REPAIR FOR THE TREATMENT OF ACUTE MITRAL REGURGITATION COMPLICATING MYOCARDIAL INFARCTION: A SINGLE CENTRE EXPERIENCE

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Background. Limited evidence is available about Mitraclip therapy in patients with acute mitral regurgitation (MR) complicating acute myocardial infarction (MI).
Methods and Results. Among 80 consecutive patients undergoing MitraClip treatment, 5 (6.3%) had been admitted for acute MI complicated by severe MR. Mean age was 73±6 years and 3 were males. At the time of admission they were in cardiogenic shock (80%) or pulmonary oedema (20%), with severe MR, left ventricular dysfunction and pulmonary hypertension. The indication to MitraClip treatment was based on severe hemodynamic instability with dependence on i.v. therapy and mechanical supports despite percutaneous coronary revascularization with a high surgical risk of 27.1±13% and 10.2±6% using EuroSCORE II and STS score respectively. The MitraClip procedure was performed at 53±33 days from admission. One or two clips were employed in 2 and 3 patients respectively. Procedural success (MR ≤2+) was achieved in all patients without complications and with successful weaning from mechanical supports and intravenous drugs in all but one patient who underwent LVAD implantation at 60 days from the MitraClip procedure. MR recurrence occurred at 30-day follow-up in one patient who had concomitant aortic regurgitation. One patient died during follow-up for non-cardiovascular cause. However, recovery of hemodynamic balance with significant and persistent SPAP reduction and functional status improvement up to 2-year follow-up was observed in most of the patients.
Conclusions. Critical patients with acute ischemic MR post-MI at high risk for surgery may benefit from MitraClip therapy acutely with favourable long-term follow-up results.

C40

LONG-TERM OUTCOMES OF MITRAL VALVE TRANSCATHETER ANNULOPLASTY SYSTEM FOR MITRAL RECONSTRUCTION: A MULTI-CENTER TRIAL

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Aims. The aim of this multi-center study was to evaluate the feasibility, safety and outcomes up to 24 months after Cardioband implantation in patients with functional mitral regurgitation (FMR).
Methods and Results. Cardioband system enables percutaneous implantation of an adjustable "surgical-like" device for mitral reconstruction and mitral regurgitation reduction using a transseptal approach. Between February 2013 and November 2015, 50 high-risk patients with significant FMR were enrolled at 7 sites in Europe. All patients were screened by echocardiography and cardiac CT to assess feasibility. Mean age was 71±8 years, thirty-nine patients were males (78%). Mean EuroSCORE II was 7.5%. At baseline, 84% of patients were in NYHA class III-IV with mean left ventricular ejection fraction of 33±11%. Device implantation was feasible in 100% patients. At discharge 88% of patients had MR ≤2+. After device cinching, an average ~30% reduction of the septo-lateral diameter was observed (from 37±4 mm to 26±4 mm; p<0.01). Thirty-day mortality was 4% (adjudicated as unrelated to the device). At 12-month follow-up (n=25) 92% of patients had MR ≤2+, 75% of patients presented with NYHA class I-II and with significant improvement in quality of life (MLWHFQ) from 40 to 19 (p<0.01) and exercise tolerance (6MWT) from 289 to 367 meters (p<0.01). At 24-month follow-up (n=10), 90% of patients had MR ≤2+ and 73% of patients presented with NYHA class I-II. A trend for significance was shown for exercise tolerance (6MWT) from 323 to 348 meters (p=0.61) and a significant improvement reported in quality of life (MLWHFQ) from 38 to 21 (p<0.05).
Conclusions. Transseptal mitral repair with the Cardioband device resulted in MR reduction by reconstruction of the mitral annulus. Safety profile is comparable to other transcatheter mitral procedures. MR severity reduction and clinical benefit are stable up to 24 months.

C41

EARLY DISCHARGE AFTER TRANSCATHETER MITRAL VALVE REPAIR WITH THE MITRACLIP SYSTEM: FEASIBILITY, PREDICTORS AND SAFETY OUTCOMES FROM THE GRASP REGISTRY

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Background. Percutaneous mitral valve repair with the MitraClip system recently emerged as an effective treatment modality for patients with severe mitral regurgitation (MR). Length of post-procedural hospital stay may represent a modifiable cost associated with Mitraclip therapy. We looked at feasibility, predictors and safety of early discharge (ED), defined as hospital discharge within 72 hours, in patients undergoing MitraClip.
Methods. Consecutive patients treated with MitraClip from October 2008 to December 2015 were analyzed. Primary outcomes of interest were cardiovascular and non-cardiovascular mortality, re-hospitalization for heart failure (HF) and major adverse events (MAEs) at 30 and 90 days.
Results. A total of 269 patients were included in the study. Of these, 115 patients were early discharged (ED group). Rates of ED increased from 25.9% for the biennium 2008-2009 to 59.1% in 2014-2015 (p<0.001 for trend). In a penalized multivariate logistic regression model, male gender (OR=2.16, 95% CI 1.44-4.49), a recent procedural year (OR=2.02, 95% CI 1.49-2.79) were independently associated with a higher probability of ED. Conversely, MVARC bleeding (OR=0.07, 95% CI 0.01-0.56), increasing degree of post-procedural MR (OR=0.61, 95% CI 0.38-0.94), atrial fibrillation (OR=0.50, 95% CI 0.29-0.86), higher NT-proBNP levels (OR=0.75, 95% CI 0.61-0.93) were less likely associated with ED. In propensity score-weighted analyses, overall survival, freedom from HF and MAEs at 30 and 90 days were not different in ED and LD groups (weighted log-rank p-value >0.05).
Conclusions. ED in selected patients undergoing MitraClip may be feasible and safe. This strategy can be useful to optimize health resources allocation.

C42

VALORE PROGNOSTICO DEI TEST FUNZIONALI IN PAZIENTI SOTTOPOSTI A RIPARAZIONE PERCUTANEA DI INSUFFICIENZA MITRALICA (IM) SINTOMATICA MEDIANTE IMPIANTO DI MITRACLIP (MC®)

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Razionale. I pazienti sottoposti a impianto MC® sono anziani, con forme avanzate di scompenso cardiaco (SC) e non rappresentati nelle popolazioni di derivazione dei più comuni score di rischio chirurgico; l'outcome clinico della procedura non è adeguatamente prevedibile.
Obiettivo. Determinare la correlazione del test del cammino (6MWT) e del test cardiopolmonare (CPET) con l'outcome clinico e la capacità predittiva di morte a distanza dalla procedura.
Metodi. Oggetto del nostro studio è stata una popolazione di 69 pazienti affetti da IM severa sintomatica e sottoposti consecutivamente a procedura di impianto MC®. La candidabilità alla procedura è stata definita sulla base di EuroSCORE logistico, EuroSCORE II ed STS mortalità. Prima e 6 mesi dopo la procedura sono stati determinati all'ECO volume telediastolico indicizzato

(EDVi), volume telesistolico indicizzato (ESVi), FE, TAPSE, pressione arteriosa polmonare sistolica (PAPs), e sono stati effettuati il 6MWT ed il test CPET, con il calcolo di VO2 max, VE/VCO_2 slope e carico di esercizio. La correlazione tra i test e la NYHA ed i parametri eco è stata effettuata mediante regressione lineare semplice; la analisi della sopravvivenza con il modello a rischi proporzionali di Cox.

Risultati. *In fase preprocedurale* sono stati studiati 69 pazienti (48 uomini e 21 donne; età media di 72.4±10.3 anni). I valori medi di EuroSCORE logistico, EuroSCORE II e STS-mortalità sono risultati 22.7±15.9% e 8.37±6.6% e 5±5.6%, rispettivamente. I valori medi di FE, di EDVi e di ESVi sono risultati 37.76±11.06%, 92.17±41.13 ml/m² e 59.91±32.89 ml/m², rispettivamente; il valore medio del TAPSE 16.24±4.27 mm e della PAPs 47.68±12.69 mmHg. 59 pazienti hanno eseguito il 6MWT; i metri totali percorsi erano in media 244.3±92.7 m. In 48 pazienti è stato effettuato il CPET con valori medi di VO_2 max, VE/VCO_2 slope e lavoro svolto rispettivamente 12.26±3.51 ml/kg/min, 39.28±8.56 e 43.14±19.62 W. A *distanza di 6 mesi* è stata registrata una significativa riduzione media di EDVi (8.14 ml/m²; p=0.01132) e di ESVi (5.9 ml/m²; p=0.02533), in assenza di modifiche di FE ed una riduzione della PAPs (differenza media di -5.18); il percorso al 6MWT è aumentato in media di 121.6 metri (p=0.00002), mentre i valori di VO_2 max (11.3±3.25) e di VE/VCO2 slope (43.82±14.67) non sono risultati significativamente differenti rispetto a quelli di base. I coefficienti delle relazioni con la NYHA al follow-up erano 0.083 per il VO_2 max (p= 0.295), 0.023 per il VE/VCO_2 slope (p=0.0057) e -0.003 per il 6MWT (p=0.00003). I valori dei parametri del CPET di base sono risultati significativamente associati a morte (il VO_2 max ha mostrato un HR di 0.77 (IC [0.63,0.94]), mentre i metri percorsi al 6MWT prima della procedura non hanno mostrato una correlazione significativa con la mortalità a lungo termine.

Conclusioni. Il 6MWT si è rivelato uno strumento utile nella definizione di efficacia dell'impianto MC®, mentre il CPET, pur meno efficace nella valutazione del miglioramento funzionale della procedura, ha mostrato un significativo potere predittivo sulla incidenza di eventi.

TAVI – 2

C43

INTERVENTIONAL TREATMENT OF SEVERE AORTIC STENOSIS IN A CRITICAL CLINICAL PHASE: THE CAMPANIA "BAV for LIFE" MULTIDISCIPLINARY COURSE. PRELIMINARY EXPERIENCE

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Introduction. A sizable percentage of patients with severe aortic stenosis are not suitable for either AVR or TAVI, mainly because of coexisting illnesses. Current valvular heart disease guidelines admit BAV as a bridge treatment to Surgery or TAVI in hemodynamically unstable patients, as well as a standalone, palliative measure, when any other intervention is contraindicated. With an aging population and since TAVI becomes available, BAV procedures exponentially increased in clinical practice and are currently performed regardless to the presence of cardiac surgery on site, as reported by many investigators.

Our Region includes 11 TAVI Centres, each one with onsite cardiac surgery and 12 Non-TAVI Centres without (10 of which with proven H24 expertise). Up to now BAV has been performed in TAVI Centres exclusively.

The Campania SICI-GISE Community has promoted an experimental, multidisciplinary course, in order to spread the procedure to each high standards quality criteria Cath-lab.

The so-called "BAV for LIFE Course" has been agreed by all Campania TAVI-Centre Directors and sponsored by the Campania SICI-GISE Society. It focuses on a 7-month frequency program and has enabled interventional cardiologists, physicians and echocardiographers from non TAVI Centres, to acquire the BAV experience along the path from live clinical and echocardiographic selection to Cath-lab performance.

The participants have been divided into four groups (a, b, c, d), each with a previously defined traveling route; the meetings format has to be repeated monthly in different TAVI Centres. The "opening", on 24th of February at the d'Aragona University Hospital in Salerno, has benefited from three well-known experts (A. Marzocchi, A. Santarelli and R. Violini) and the course will finish on February 24th, 2017, in Salerno, when the experts (testimonial) will release a graduation certificate to all participants.

Preliminary results. To date, after the first three meetings, the first Non-TAVI Cath-lab has already performed its first three BAV procedures. As organizer of the course we have to say that what has encouraged us is the knowledge that, to do something, you must first know and try. Now, it may be a coincidence, but the fact is that the number of of BAV procedures both, "as bridge to TAVI" or "to destination", is increasing.

C44

ANTITHROMBOTIC THERAPY POST-TAVR: TWO CENTER EXPERIENCE

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Transcatheter aortic-valve replacement (TAVR) is established therapy for patients with severe aortic stenosis (AS) who are not candidate for surgery or who are at high risk for complication due to surgery. Despite improving experience and techniques, ischemic and bleeding complication remains prevalent in periprocedural period and months after transcatheter aortic-valve replacement (TAVR). Dual antiplatelet therapy (DAPT) is currently recommended with considerable differences about duration and association with oral anticoagulant (OAC). Moreover, restricted data about TAVR and new anticoagulant oral (NAO). The aim of our retrospective registry was to assess prevalence, timing and prognosis of different antithrombotic/anticoagulant strategies employed in TAVR patients.

A total of 121 consecutive patients, undergoing TAVR at Montevergine Clinic and San Giovanni di Dio e Ruggi d'Aragona Hospital, have been enrolled in our study, from January 2015 to June 2016. Fifty-three (64.13%) patients were in aspirin, of which thirty-two (38.72%) were in DAPT (most for recent coronary stent). Clopidogrel alone was administered in thirty-four (41.14%) patients for peripheral artery disease or aspirin intolerance.

Twenty-four (29.04%) patients, with atrial fibrillation (AF) and $CHADS_2$ score >1, had an indication to OAC pre-TAVR, of which 22 (26.62%) on vitamin K antagonist (VKA) and 2 (2.42%) on new oral anticoagulant (NAO). Ten (12.10%) patients were naive for antithrombotic/anticoagulant therapy at the procedure. At discharge, sixty-three (76.23%) had indication to DAPT at least for 3 months. Of 24 patients with indication to OAC, 22 (26.62%) were discharged on OAC and clopidogrel, of which 20 (24.20%) on VKA and clopidogrel and 2 (2.42%) on NAO and clopidogrel. Patients with PAD or aspirin intolerance were confirmed on clopidogrel. In the total cohort there were 7 (8.47%) deaths, 6 ischemic stroke and 4 major bleeding event at follow up of 18 months. Of 6 patients with ischemic stroke, 3 were not on baseline OAC.

In conclusion, post-procedural antithrombotic/anticoagulant therapy post-TAVR is highly variable. Particularly in patients with high risk of adverse event as like those with AF, should be evaluated prospectively in future randomized trials.

C45

TAVI FOR NATIVE AND BIOPROSTHETIC AORTIC VALVE PURE SEVERE REGURGITATION: A SINGLE CENTER EXPERIENCE

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Aims. Surgical therapy is the standard of care for pure severe aortic regurgitation affecting native and bioprosthetic valves. We sought to evaluate the results of transcatheter aortic valve implantation (TAVI) in this population.

Methods and Results. We retrospectively evaluated data on baseline characteristics, imaging, procedural parameters and in-hospital outcomes of 13 patients who underwent TAVI for pure severe aortic regurgitation in our institution. The mean age of the patients was 75 ± 6 years and the majority were male (77%). 9 patients (69.2%) had a failure of a bioprosthesis previously implanted, 3 patients (23%) had a native valve severe regurgitation and 1 patient (7.8%) had a severe aortic regurgitation following a valve sparing David procedure. None of these patients had significant aortic stenosis and 12 of them (92.3%) showed absent (grade I) or mild (grade II) annular calcifications on computed tomography. The mean Society of Thoracic Surgeons Score for predicted risk of mortality was 10%. In all patients a transfemoral approach was used. The mean annulus size was 24±2.8 mm and for native valves it was measured with computed tomography. For bioprosthetic valves we used the internal diameter of the prosthesis as a surrogate for annulus diameter. A Medtronic CoreValve was implanted in 12 patients (92.3%) and just in one case a balloon expandable Edwards Sapien 3 was used for a valve in valve procedure. In 46% of patients a 29 mm or 31 mm valve was implanted and in 100% of cases the implant was successful using only one valve. In 12 out of 13 patients (92.3%) post procedural aortic regurgitation evaluated with angiography or echocardiography was absent or grade 1 and just in one case it was grade 2. There were neither major access site complications nor major bleedings according to Valve Academic Research Consortium 2 definition. In hospital mortality was 7.7% (1 patient with concomitant atrial fibrillation and severe mitral regurgitation died for refractory heart failure and multiple organ failure after a successful procedure with only grade 1 residual aortic regurgitation).

Conclusions. The results of our single center registry of patients treated with TAVI for severe aortic regurgitation showed the feasibility and safety of this procedure in the presence of a failed bioprosthetic valve but also to treat native valve regurgitation. A high rate of successful implantation with no significant residual aortic regurgitation has been achieved even in the absence of relevant annular calcification.

Top ranked oral presentations – 2

C46

ACUTE AND MEDIUM-TERM OUTCOMES OF TRANSCATHETER AORTIC VALVE IMPLANTATION IN PATIENTS WITH CIRRHOSIS

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Aims. Cirrhotic patients undergoing cardiac surgery are exposed to a higher risk of bleeding, kidney injury and mortality. Therefore, TAVI may be a valid alternative to surgery in this high-risk subgroup.

Methods and Results. A retrospective analysis of all patients that underwent TAVI at our institution between January 2008 and December 2015 was performed. Patients with either a histological or clinical and radiological diagnosis of cirrhosis were selected. Study endpoints were 30-day mortality and VARC-defined adverse outcomes (bleeding, vascular complications, acute kidney injury, stroke, and pacemaker implantation), and long-term mortality. Among 951 TAVI procedures performed during the 8-year inclusion period, 47 (5%) were performed in patients with cirrhosis. Of these, 34 (73%) patients were in Child-Pugh class A, 12 (25%) in class B and 1 (2%) in class C; median Child-Pugh score was 6 (interquartile range 5-7). The most common etiology of cirrhosis were: hepatitis C (68%) and B (9%) virus infection, followed by alcoholic liver disease (6%), advanced right-heart failure (2%) and primary biliary cirrhosis (2%); in 6 patients (13%) the cause was unknown. Forty-nine percent of patients were men. Mean age was 74.2±8.3 years. Predicted surgical risk was high: mean STS score was 7.0±6.7% for mortality and 28.6±16.5% for combined mortality and morbidity, while mean Logistic EuroSCORE I was 17.6±16.5%. Mean ejection fraction was 53±12%. TAVI procedures were performed mostly via the transfemoral approach (81%), with only a marginal share of patients treated via the trans-subclavian (8%) or transapical (11%) routes. The most frequently implanted valves were Edwards (55%) and CoreValve (36%), followed by Direct Flow Medical (7%) and Engager (2%). Acute bleeding was the most common complication: 1 patient (2%) suffered a life threatening pericardial tamponade, treated with pericardiocentesis and multiple blood transfusions; major and minor bleedings were reported in 9% of patients each. The incidence of acute kidney injury was 23%: 14% stage I, 6% stage II and 3% stage III. Stroke and pacemaker implantation rates were 4% and 13%, respectively. Thirty-day mortality was 3%. One-year mortality was 13%. Median follow-up was 458 (interquartile range 82-888) days. Overall mortality was 30%.

Conclusions. Our findings suggest that TAVI is a feasible option to treat severe aortic valve stenosis in patients with cirrhosis. As expected, the most frequent complications are related to bleeding. However, medium-term follow-up suggests that these patients have a favorable prognosis with a transcatheter approach, despite the predicted high surgical risk.

C47

BALLOON AORTIC VALVULOPLASTY IN THE TAVI ERA: ROLE AND RESULTS IN HIGH-RISK POPULATION WITH SEVERE AORTIC STENOSIS

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Background. The advent of transcatheter aortic valve implantation (TAVI) has redefined the role of the percutaneous balloon aortic valvuloplasty (BAV) in the treatment of high-risk patients (pts) with severe aortic stenosis (SA) and serious contraindication for surgical aortic valve replacement (AVR).

Methods. From January 2012 to May 2016 at our cath lab submitted to BAV for SA 82 consecutive pts, 51% male, mean age 81.4 aa (61- 97 aa). 50% symptomatic for heart relapsing failure, 25% for worsening dyspnea, 7% for acute pulmonary edema, 14% for lipothymia-syncope, 4% in cardiogenic shock. 54% in NYHA functional class III, 5.5% in the IV. 28% were in permanent atrial fibrillation. 7% with PMK and 8.3% with ICD. 12.5% had a postinfarction heart disease, 33.5% results of PCI, 15.3% of CABG. The mean left ventricular ejection fraction was 45% with moderate mitral regurgitation in 20%, moderate-severe in 4%, pulmonary hypertension in 21%. 30% had chronic obstructive lung disease, 41% chronic renal failure, diabetes 31%, 10% cirrhotic liver disease, the 5.5% of stroke outcomes, 19% severe peripheral arterial 5.5% with previous thromboendoarterectomy carotid.21% was in FU for heteroplasia, 81% in antihypertensive therapy.

Results. Ventricular pacing for the stabilization of the balloon on the valve was used in 100%. In 98% it was used only a semi-compliant balloon for BAV, of 18 mm diameter in the 58%, of 20 mm in 41%, obtaining a mean gradient aortic decrease of 15 mmHg (maximum of 33). 1 pt presented a transient ischemic attack in post-BAV, 4 pts moderate aortic regurgitation, a complete transient AV block 1 pt, 2 pts a femoral arterial dissection. 4 pts underwent two BAV procedures. 10% of the pts underwent the same session PCI and BAV. No periprocedural mortality, 4.2% to 30 days. 69.2% was subsequently subjected to TAVI, in 14-week average, 4.4% in ARV. In FU the mortality of the total pts undergoing BAV but not directed to TAVI or AVR is 65%.

Conclusion. The BAV is a feasible, repeatable and safe procedure in a very high-risk population. The BAV is a possible bridge to TAVI/AVR but remains a brief temporizing procedure with a poor mid and long-term outcome without subsequent definitive treatment.

C48

IMPACT ON MORTALITY OF COMPLETE REVASCULARIZATION IN STEMI PATIENTS WITH MULTI-VESSEL DISEASE: AN UPDATED META-ANALYSIS OF RANDOMIZED CLINICAL TRIALS

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Background. The impact on mortality of the revascularization approach for multi-vessel coronary disease (MVD) in patients with ST-elevation myocardial infarction (STEMI) undergoing infarct-related artery (IRA) percutaneous coronary intervention is unknown.

Methods and Results. We searched Medline, Scopus and the Cochrane Library database up to the 22 October 2015. Only prospective randomized trials comparing complete versus IRA-only revascularization for the management of MVD in STEMI patients were included. Odds ratios (ORs) and 95% confidence intervals (95% CI) were calculated with random-effects models using the DerSimonian–Laird method. After screening, 7 randomized trials (n = 2,006 patients) were considered eligible and included in the final analysis. After a weighted mean follow-up of 25.3±2.7 months, a significant lower cardiovascular mortality (OR 0.41, 95% CI 0.23-0.73) was found in patients undergoing complete revascularization; a trend toward a significant reduction in all-cause mortality (OR 0.78, 95% CI 0.53-1.15) was seen in this latter subgroup of patients. Also major adverse cardiovascular events (OR 0.51, 95% CI 0.34-0.75) and repeat revascularization (OR 0.32, 95% CI 0.22-0.43) were found significantly lower in patients treated with a complete revascularization approach. Results were confirmed when the Poisson regression models were developed to account for different duration of follow-up across included studies.

Conclusions. In STEMI patients with MVD a complete revascularization of non-IRA lesions led to significant reductions in cardiovascular mortality, overall events and repeat revascularization. Ongoing adequately powered studies will definitively address the optimal treatment management of MVD in the setting of STEMI.

C49

RETE LOCALE PER LO SHOCK CARDIOGENO REFRATTARIO

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Introduzione. L'ECMO veno-arterioso periferico (ECMO-VA) rappresenta un'opzione terapeutica nei pazienti con un quadro di shock cardiogeno refrattario (SCR). Non tutti gli ospedali hanno le capacità di gestire pazienti con SCR, pertanto è necessaria la creazione di una rete per centralizzare questi pazienti in ospedali di terzo livello, dove sia presente un laboratorio di emodinamica attivo 24h/24, un team di medici in grado di gestire device meccanici percutanei a breve e medio termine, una cardiochirurgia ed una terapia intensiva cardiologica dedicata ai cardiopatici critici.

Metodi. La nostra casistica è costituita da 19 pazienti con SCR supportati con ECMO-VA periferico, ricoverati consecutivamente presso la nostra UTIC. Nove pazienti sono stati ammessi direttamente presso il nostro ospedale (centro Hub), mentre 10 pazienti sono stati trasferiti da ospedali periferici (centri spoke). La nostra rete ECMO prevede un primo contatto telefonico e il successivo trasferimento dell'ECMO team al centro spoke, dove viene valutato, dal team multidisciplinare, se posizionare in loco l'ECMO o se trasferire il paziente al centro Hub.

Risultati. Le caratteristiche della popolazione del nostro studio sono riportate in Tabella. La causa prevalente di SCR era la sindrome coronarica acuta

Sesso	Età	Centri	Eziologia	Durata ECMO (giorni)	Ricovero UTIC (giorni)	Mortalità UTIC	Follow-up 6 mesi
F	74	Spoke	Takotsubo	7	22	No	Recupero
M	56	Hub	STEMI	21	21	Sì	
M	50	Hub	STEMI	2	2	No	Morte in attesa TC
F	66	Hub	Embolia polmonare	1	1	Sì	
F	58	Hub	STEMI	12	12	Sì	
F	57	Spoke	STEMI	3	27	No	Recupero
M	69	Hub	STEMI	8	8	Sì	
M	42	Spoke	STEMI	4	4	No	TC
F	32	Hub	Miocardite	9	47	No	Recupero
M	38	Hub	Intossicazione	4	49	No	Recupero
M	46	Hub	IM subacuto	1	62	No	Recupero
M	59	Spoke	STEMI	3	3	No	Morte in attesa TC
M	52	Spoke	STEMI	4	20	No	Recupero
M	33	Spoke	Storm elettrico	2	15	No	Recupero
F	49	Spoke	Storm tiroideo	3	17	No	Recupero
M	57	Spoke	NSTEMI	5	53	No	Recupero
M	72	Spoke	CMD	3	19	No	Recupero
M	62	Spoke	STEMI	4	38	No	Recupero
F	14	Hub	Miocardite	5	25	No	Recupero

UTIC, unità terapia intensiva cardiologica; NSTEMI, infarto miocardico senza sopraslivellamento del tratto ST; STEMI, infarto miocardico con sopraslivellamento del tratto ST; TC, trapianto cardiaco; CMD, cardiomiopatia dilatativa.

(57.8%). Cinque pazienti (26.3%) sono stati sottoposti ad impianto di ECMO-VA periferico nel centro spoke, 5 pazienti (26.3%) sono stati centralizzati presso il centro Hub con successivo impianto di ECMO-VA. Nei 9 pazienti ammessi direttamente all'ospedale Hub l'ECMO è stato posizionato nella quasi totalità dei casi dall'emodinamista nel laboratorio di emodinamica, per via percutanea, da accesso femoro-femorale con tecnica di Seldinger. Complessivamente 15 pazienti (78.9%) sono stati dimessi vivi dall'UTIC, in 12 di questi pazienti l'ECMO è stato usato come "bridge to recovery" e in 3 pazienti come "bridge to transplantation". Due pazienti sono deceduti per emorragia cerebrale mentre erano in attesa di trapianto cardiaco. La sopravvivenza a 6 mesi è stata del 68.4%, con ottimo recupero delle funzioni neurologiche (cerebral performance category scale 1-2).

C50

BIORESORBABLE VASCULAR SCAFFOLD TECHNOLOGY FOR SMALL VESSEL CORONARY ARTERY DISEASE: RESULTS FROM THE ITALIAN MULTICENTER RAI REGISTRY (CLINICALTRIALS.GOV IDENTIFIER: NCT02298413)

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Background. Early evidences on percutaneous coronary intervention with absorb bioresorbable scaffold (BRS) of small coronary vessels has been matter of concern. Accordingly, we aimed to assess the interplay between Absorb and small vessel disease (SVD) by the use of a large multicentre Italian registry.

Methods. The RAI (Registro Absorb Italiano) Registry is an investigator-driven, prospective registry that included consecutive patients treated with Absorb BRS (ABBOTT Vascular, Santa Clara, CA). Small vessel population included patients in which all the treated lesions had a reference vessel diameter (RVD) ≤2.75 mm at quantitative coronary analysis including patients with very small vessels (RVD ≤2.25 mm).

Results. Out of 1236 patients, 344 (mean age 59 years, 79% males) had SVD, 892 patients (mean age 58 years, 84% males) was the large vessel cohort. The SVD patients had a higher prevalence of diabetes (28% vs. 18%; p<0.001), stable coronary disease (42% vs. 36%; p=0.04) and a worse syntax score (13±8 vs. 11±8, p<0.001). A total of 1733 BRS were implanted in the overall population, 493 (28%) in SV patient population, 1240 (72%) in the large vessel cohort. The total average scaffold length was 32±11 mm in SVD and 27±14 mm in large vessel patients (p=0.02). In SVD group, 409 lesions were treated with scaffold 2.5 in 83% and 3.0 or 3.5 in 17% of the cases. At a median follow-up of 393 days (IQR 30-1120) there were no differences between the two studied groups both in device (4.7% vs. 4.2%; p=0.8) and patient-oriented (12.8% vs. 12.9%, p=0.9) composite endpoints. In the SVD group there was a numerically higher BRS definite scaffold thrombosis rate (2.1% vs. 0.9%; p=0.2). Restricting analysis to the 29 patients with treated very small vessels, we found a trend for increased device-oriented composite endpoint (10.3% vs 4.1, p=0.1) but not patient-oriented outcome (10.3% vs 12.9%), compared to patients with treated >2.25 mm RVD lesions. Definite scaffolds thrombosis rate was significantly higher in patients with treated very small vessels compared to controls (6.9% vs 1.1%, p=0.04).

Conclusions. Our analysis from RAI Registry showed that patients with SVD had similar 1-year device and patient-oriented outcomes with a large vessel patient population. Notwithstanding, they had a significantly higher rate of definite scaffold thrombosis mainly driven by patients with treated very small vessels.

C51

SMALL VESSEL CALIBER IN-STENT RESTENOSIS IN DIABETIC PATIENTS: DRUG COATED BALLOON AS TREATMENT OPTION IN THIS HIGH RISK POPULATION. A TWO-CENTER EXPERIENCE

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Background. In the last years, drug coated balloon (DCB) has achieved significant results in the treatment of ISR and last guidelines on myocardial revascularization suggest this device as the preferred choice. However, little is known about the safety and efficacy of small vessel caliber ISR treatment by DCB in diabetic patients.

Methods. Between June 2011 and January 2016 all diabetic patients with symptomatic ISR treated with DCB at 2 Italian centers expert in DCB-percutaneous coronary intervention (PCI) were analyzed. Primary endpoint was the assessment of target lesion failure (TLF), defined as composite of myocardial infarction (MI), cardiac-death and/or target lesion revascularization (TLR) and second endpoint was the incidence of major adverse cardiac events (MACE) during the available follow up.

Results. A total of 117 diabetic patients with ISR were enrolled and divided in two groups according to the vessel caliber: ≤2.75 mm (42 patients) vs >2.75 mm (75 patients). All patients were treated with 2 different types of second-generation DCB (In.Pact Falcon, Medtronic-Invatec, Frauenfeld, Switzerland; and Pantera Lux, Biotronik, Bulach, Switzerland). At the longest available clinical follow up (average 19.7±14.2 months), the occurrence of TLF was 11.9% in the small vessel caliber group vs 15.1% in the control group (p=0.86), with no significant differences in the incidence of MI (4.8% vs 6.8%; p= 0.92), TLR (7.14% vs 8.2%; p= 0.95) and there has been no cases of cardiac-death in both groups of patients. The incidence of target vessel revascularization (TVR) (11.9% vs 10.9%; p = 0.95) and MACE (11.9% vs 13.7%; p=0.86) were slightly different between the two groups of patients and there has been no cases of stent thrombosis.

Conclusions. Our study suggests that the use of a second generation DCB for the treatment of ISR in a population of diabetic patients with small vessel caliber disease might be associated with an optimal long-term clinical follow-up.

C52

PREVALENZA DI CATARATTA E OPACITÀ DEL CRISTALLINO NELLO STAFF DEL LABORATORIO DI CARDIOLOGIA INTERVENTISTICA: RISULTATI DELLO STUDIO HEALTHY CATH LAB

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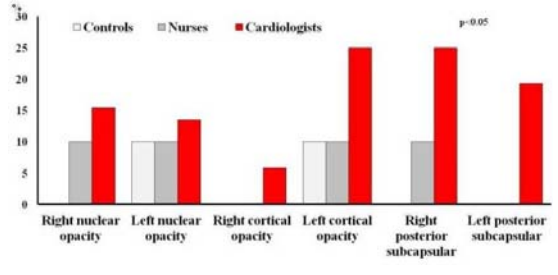
Background. Il progetto Italian Healthy Cath Lab si prefigge di indagare i diversi rischi biologici correlati all'esposizione cronica, occupazionale, a basse dosi di radiazioni ionizzanti. L'occhio é uno degli organi maggiormente esposto e il cristallino uno dei tessuti particolarmente sensibili alle radiazioni ionizzanti. Scopo del presente studio era la valutazione della prevalenza di cataratta e opacità del cristallino tra gli operatori del laboratorio di cardiologia interventistica.

Metodi. Lo studio comprendeva due bracci: A) una survey condotta attraverso la compilazione di un questionario da parte di 218 cardiologi interventisti [CI] (168 maschi, età 46±9 anni), 191 nurse [N] (76 maschi, età 42±7 anni), 57 tecnici di radiologia [T] (37 maschi, età 40±12 anni) e 280 controlli [C] appaiati per sesso e età (179 maschi, età 43±7 anni); e B) uno studio prospettico, di dimensioni ridotte che prevedeva una valutazione oculare, condotta durante l'ultimo congresso nazionale della Società Italiana di Cardiologia Interventistica in 49 CI (40 maschi, 48±11 anni), 10 N (10 maschi, 50±6 anni) and 10 C appaiati per sesso e età (8 maschi, 48±11 anni). Le opacità nucleari, corticali e subcapsulari del cristallino sono state classificate come di grado ≥2 secondo la scala LOCS III.

Risultati. A) La prevalenza di cataratta era significativamente maggiore tra i soggetti esposti (12±8 anni di lavoro) rispetto ai C (4.7% vs 0.7%, p=0.003), con un aumento di 7 volte del rischio (OR: 6.9, 95%CI: 1.6-29.5). L'incidenza di cataratta era significativamente superiore nei CI rispetto ai N e T (73% vs 18% e 9%, p=0.04, rispettivamente). B) La prevalenza dei diversi tipi di opacità del cristallino, in particolare quella subcapsulare posteriore, era superiore nei CI rispetto ai N e C (vedi Figura).



Conclusioni. I risultati dello studio Italian Healthy Cath Lab indicano che l'esposizione occupazionale a basse dosi di radiazioni ionizzanti rappresenta un significativo rischio per lo sviluppo di cataratta, in particolare nei cardiologi interventisti. Il monitoraggio delle dosi al cristallino e l'uso dei sistemi di protezione sono cruciali.

Coronary interventions

C53

OUTCOMES OF THE RETROGRADE APPROACH THROUGH EPICARDIAL VERSUS NON-EPICARDIAL COLLATERALS IN CHRONIC TOTAL OCCLUSION PERCUTANEOUS CORONARY INTERVENTION

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Background. The retrograde approach through epicardial collaterals for chronic total occlusion (CTO) percutaneous coronary intervention (PCI) is a challenging procedure. The aim of this study was to evaluate the outcomes of patients undergoing CTO PCI using a retrograde approach through epicardial versus non-epicardial collaterals.

Methods. We collected data from our single-center registry of consecutive patients undergoing retrograde CTO PCI, performed by an experienced operator through epicardial and non-epicardial (septals and bypasses) collaterals, between November 2012 and November 2015. Clinical, angiographic and procedural data were recorded. The primary endpoint (major adverse cardiac events, MACE) was a composite of cardiac death, target-vessel myocardial infarction (MI) and ischemia-driven target-vessel revascularization (TVR) on follow-up.

Results. During the study period, 228 CTO PCIs were performed. Of these, 77 procedures (31.6%) were performed retrogradely (n=38 epicardials, n=39 non-epicardials [n=33 septals and n=6 bypasses]) in 72 patients. Baseline clinical and angiographic characteristics were balanced between the epicardial and non-epicardial group. J-CTO score was 2.0±1.1 and 2.2±1.2, respectively (p=0.57). A septal collateral was the dominant collateral in 71.8% of the non-epicardial group and an epicardial collateral was the dominant source of collaterals in 90.9% of the epicardial group (p<0.001). Tip injection was performed in 95.8% overall, with no differences between groups (p=0.66). Procedural and technical success was achieved in 33.3% of the epicardial group and 71.8% of the non-epicardial group (p=0.001). Procedural complications were higher in the epicardial group (24.2% vs. 7.7%, p=0.05), driven by perforation. After a median follow-up of 447 (343-754) days, MACE were observed in 20.7% of epicardial patients vs. 5.3% in non-epicardial patients (p=0.05), driven by MI (acutely) and TVR (both acutely and throughout follow-up).

Conclusions. Retrograde CTO PCI through epicardial collaterals is associated with lower success rate, higher rate of complications and worse long-term outcomes, as compared with non-epicardial collaterals, even in the hands of an experienced operator.

C54

PROCEDURE DI ANGIOPLASTICA CORONARICA IN DAY SURGERY: ANALISI DI MICRO-COSTING

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Obiettivo. Ricostruire il costo virtuale delle procedure "semplici" di angioplastica coronarica (PTCA) con stent medicato eseguite in regime di day surgery e compararlo con il consumo di risorse normalmente associato alla procedura erogata, come da pratica clinica corrente, in regime di ricovero ordinario.

Metodi. L'analisi, condotta secondo la prospettiva ospedaliera, è stata realizzata in accordo con la metodologia dell'Activity Based Costing attraverso un approccio bottom-up basato sulla rilevazione delle tempistiche di impiego dei fattori produttivi diretti (personale, esami diagnostici, farmaci, materiali) e indiretti (permanenza in sala, assistenza in reparto) attraverso interviste ai professionisti coinvolti nell'intero percorso paziente durante la degenza. Protagonista virtuale dell'analisi è un paziente "standard" in termini di età, genere, morbilità, severità della patologia le cui condizioni cliniche generali potrebbero giustificare l'esecuzione della procedura di PTCA in regime di day surgery. I due differenti percorsi di cura ospedalieri – ricovero ordinario vs day surgery – sono stati analizzati e confrontati per ciascuna fase della degenza ospedaliera, ossia pre-ricovero, ricovero, intervento chirurgico, post-operatorio.

Risultati. La ricostruzione del percorso paziente durante l'ospedalizzazione e del relativo consumo di risorse ha evidenziato che la procedura erogata in regime di ricovero ordinario ha un costo di circa 2.230€ e che i fattori produttivi che incidono maggiormente sul costo totale riguardano i materiali e farmaci (52%) e la degenza ospedaliera (34%). La stessa procedura erogata in regime di day surgery ha un costo di circa 1.700€, supponendo che sia necessaria una sola notte di degenza. Tra quelle considerate, la voce di costo che incide maggiormente sul costo totale è quella relativa ai materiali e ai farmaci (68%), cui è associato un costo identico a quello previsto in regime di ricovero ordinario. La tariffa DRG associata alla PTCA in day surgery – nonostante sia più bassa del rimborso previsto per il ricovero ordinario – risulta comunque remunerativa rispetto ai costi effettivamente sostenuti dalla struttura ospedaliera, che rappresentano solo il 34% della tariffa.

Conclusioni. L'analisi consente di dimostrare che l'erogazione della PTCA in regime di day surgery, oltre ai comprovati benefici clinici e psicologici di cui può usufruire il paziente, garantisce considerevoli vantaggi di natura economica sia per la struttura ospedaliera - che potrebbe bilanciare la riduzione delle tariffe di rimborso corrispondenti con un incremento dei volumi - che per la regione – che andrebbe a rispondere in maniera più efficace al bisogno di salute della popolazione, senza sostenere costi aggiuntivi rispetto a quelli attuali, ma piuttosto ottenendo un risparmio significativo.

C55

IN-HOSPITAL OUTCOME AND MANAGEMENT OF PATIENTS WITH ACUTE CORONARY SYNDROME AND DIABETES IN LOMBARDIA: INSIGHTS FROM THE "ACS AND DIABETES REGISTRY"

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Background. Patients with acute coronary syndrome (ACS) and diabetes are at high risk of in-hospital adverse events. Diabetic patients usually have worse outcome compared to non-diabetics and a specific management is recommended.

Aim. To investigate diabetics management and in-hospital outcome in the population of the multicenter prospective "ACS and Diabetes Registry" carried out in Lombardia during a nine week period (March 4th to June 9th 2015).

Methods and Results. 559 consecutive ACS patients (mean age 68.7±11.3 years, 35% ≥75 years, 18.2% on chronic insulin therapy) with "known DM" (56%) or "hyperglicemia" (HG) (44%) defined as blood glucose value ≥126 mg/dl at admission, were included in the registry at 29 hospitals. Diabetes consulting was performed in 24.8% of the cases (known DM 33.4% vs HG 14.1%, p<0.001). Investigators claimed to follow an anti-diabetic protocol in the setting of ACS in 85.3%: in more than half of the cases insulin was not used, but if chosen the s.c. administration was preferred. 66 (11.8%) patients without anamnestic diagnosis of diabetes had a value of glycated hemoglobin above 6%. 89 (84.0%) nSTEMI diabetic patients interrupted metformin before angiography. 51 (66.2%) nSTEMI diabetic patients with chronic kidney disease (Cockcroft-Gault <60 ml/min) received contrast-induce nephropathy (CIN) prophylaxis. After a median hospital stay of 8 IQR (6-13) days, 9 (1.6%) patients died (known DM 2.3% vs HG 0.8%, p=0.170), 62 (11.2%) had a myocardial infarction (known DM 9.8% vs HG 12.9%, p=0.252), 7 (1.3%) had ischemic or hemorrhagic stroke (known DM 1.4% vs HG 1.2%, p=0.352), 13 (2.3%) had a TIMI major bleeding (known DM 2.9% vs HG 1.6%, p=0.304). At univariate analysis several factors were statistically associated to in-hospital adverse events (death, re-infarction, stroke and TIMI major bleeding): ECG at presentation (p=0.003), pre-hospital cardiac arrest (p=0.017), Killip Class (p<0.001), heart team valuation (p=0.03), SYNTAX score (p=0.044), insulin ev use (p=0.027), hypoglycemia (p<0.001), CIN prophylaxis (p=0.006); however at multivariate analysis none of them resulted as independent predictor.

Conclusion. In our registry, patients with "know DM" received a different and better management of glycemic status. More than 10% of patients had unknown diabetes. Diabetes by itself does not predict in-hospital outcome.

C56

EFFECTS OF STATINS ON PLAQUE RUPTURE ASSESSED BY OPTICAL COHERENCE TOMOGRAPHY IN PATIENTS PRESENTING WITH ACUTE CORONARY SYNDROMES: INSIGHTS FROM THE OCT-FORMIDABLE REGISTRY

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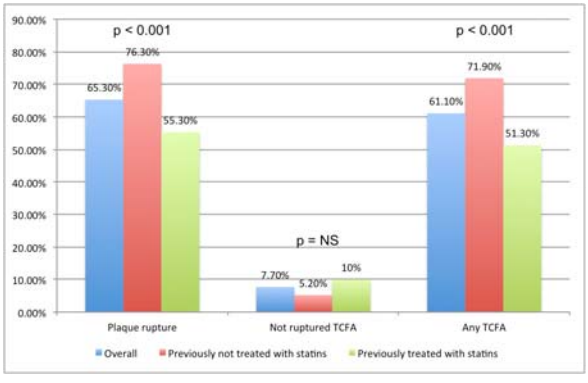
Aims. Chronic pre-treatment with statins may reduce mortality and morbidity in patients experiencing acute coronary syndromes (ACS), but mechanisms accounting for these findings are not completely understood.

Methods. The OCT-Formidable registry retrospectively enrolled 285 consecutive patients with ACS undergoing OCT in 9 European centers. Patients were stratified according to chronic prescription of statin before the ACS. The primary endpoint was the presence of ruptured plaques at OCT. Secondary end-points were the presence of non-ruptured thin-cap fibro-atheroma (TCFA) as the culprit lesion and TCFA at any site. Pre-specified sensitivity analysis was conducted according to the pattern of ACS (STEMI vs. NSTE-ACS).
Results. Mean age of enrolled patients was 60.4±12.8 years, 148 (51.9%) patients presented hyperlipemia, 45 (15.8with diabetes mellitus; diagnosis at presentation was STEMI in 142 (49.8%) cases. One hundred and fifty patients (52.6%) were on chronic pre-treatment with statins: they presented more probably NSTE-ACS at admission (111, 74%) rather than STEMI, while the opposite was encountered for patients not on statins. As shown in the figure, previous treatment with statins related significantly to a lower prevalence of ruptured plaques (55.3% vs. 76.3, p<0.001) and of TCFA at any site (51.3% vs. 71.9%, p<0.001) and did not show any relationship with non-ruptured TCFA at the culprit site. These results were confirmed for NSTE-ACS and not for STEMI patients.
Conclusions. Chronic pre-treatment with statins is associated with a reduced prevalence of ruptured plaques in patients presenting with ACS, particularly in those with NSTE-ACS. Statins bear the potential to reduce morbidity also when they fail to prevent ACS.



C57

OUTCOMES OF CHRONIC TOTAL OCCLUSION PERCUTANEOUS CORONARY INTERVENTION ACCORDING TO DISSECTION/RE-ENTRY VERSUS WIRE ESCALATION TECHNIQUES

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Background. Few studies have investigated the outcomes of patients with a chronic total occlusion (CTO) undergoing percutaneous coronary intervention (PCI) using dissection/re-entry (DR) vs. wire escalation (WE) techniques.
Methods. We combined consecutive patient data from 3 CTO PCI specialized centers. Only patients in whom successful CTO wiring was achieved were considered. Subjects were divided in DR (antegrade or retrograde) and WE (antegrade or retrograde). Major adverse cardiac events (MACE: cardiac death, target-vessel MI and target-vessel revascularization) on follow-up were the primary endpoint. Multivariable Cox regression analysis was performed to identify independent predictors of MACE.
Results. We included 792 patients (n=323 DR, n=469 WE). In the WE group, 83.6% were antegrade procedures, whereas 16.4% were retrograde cases. In DR, these figures were 43.0% and 57.0%, respectively. Among antegrade DR procedures, a wire-based technique was utilized in 58.3% and CrossBoss/Stingray (Boston Scientific, Marlborough, MA) in 41.7%; among retrograde DR cases, reverse CART was used in 84.2%. DR patients had a higher prevalence of prior MI, prior PCI and prior CABG, but a lower prevalence of severe chronic kidney disease. As compared with WE, DR was used more frequently on the right coronary artery (68.8% vs. 40.5%) and less frequently on the left anterior descending (15.9% vs. 36.4%, p<0.001). The J-CTO score was higher in DR (2.42±1.18 vs. 1.43±1.11, p<0.001). Total stent length was also higher in DR (89.7±42.1 vs. 57.7±36.7 mm, p<0.001). Procedural complications were more frequent in DR group (3.4% vs. 1.1%, p=0.02), driven by coronary perforation. After a median follow-up of 454 (354-822) days, MACE rates were similar (15.0% in DR vs. 10.8% in WE, p=0.10). On multivariable analysis, DR was not independently associated with MACE. Independent predictors of MACE were: prior CABG, worse renal function, lower ejection fraction, CTO PCI indicated for acute coronary syndrome, higher number of diseased vessels, in-stent CTO and higher J-CTO score.
Conclusions. Although CTO PCI with DR, as compared with WE, was used in more challenging clinical and angiographic scenarios, DR was not associated with adverse clinical outcomes on follow-up.

Antiplatelet therapy

C58

ORAL ANTIPLATELET THERAPY IN PATIENTS WITH ACUTE CORONARY SYNDROME AND DIABETES IN LOMBARDIA: INSIGHTS FROM THE "ACS AND DIABETES REGISTRY"

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Background. Patients with acute coronary syndrome (ACS) and diabetes mellitus (DM) are at higher risk of death compared to non-diabetics. New and more potent oral antiplatelet agents (prasugrel and ticagrelor) significantly reduced major cardiovascular events in the whole spectrum of ACS with a more pronounced effect in case of DM.
Aim. To investigate the use of oral antiplatelet agents in the population of the multicenter prospective "ACS and Diabetes Registry" carried out in Lombardia during a nine-week period between March and May 2015.
Methods and Results. 559 consecutive ACS patients (mean age 68.7±11.3 years, 35% ≥ 75 years, 50% STEMI), with "known DM" (56%) or "hyperglycemia" (HG) defined as blood glucose value ≥ 126 mg/dl at admission were included in the registry at 29 Hospitals. 460 patients (85%) received a myocardial revascularization. 55% of patients were pre-treated with at least one oral P2Y12 inhibitor (clopidogrel in more than half of the cases). Pretreatment with oral drug was more frequent in UA/NSTEMI compared with STEMI (63.3% vs 45.1%) but upstream administration of a new P2Y12 inhibitor was reported in 70% of STEMI and only in 40% of UA/NSTEMI patients. We found no difference between DM vs HG related to pretreatment (57% vs 50%, p=0.09), however among pre-treated patients with DM there was a wider use of clopidogrel rather than of prasugrel/ticagrelor (57% vs 43%, p=0.015). Upgrade from clopidogrel to a new P2Y12 inhibitors occurred in 13% of the cases. At discharge a DAPT was prescribed to 88% of the patients with ticagrelor or prasugrel in 60%; oral anticoagulant therapy (OAT) was indicated in 10% associated to DAPT in 83% of them. There was no significant difference between new P2Y12 vs clopidogrel in patients with known DM (49% vs 51%, p=0.78), while patients with HG had a higher prescription of prasugrel/ticagrelor (72% vs 28%, p<0.001). Among patients <75, STEMI were more frequently treated with new P2Y12 inhibitors (84% vs 16%, p<0.001) compared to UA/NSTEMI and so were those with known DM (58% vs 42%, p=0.023) and with HG (85% vs 15%, p<0.001). Differently, in patients aged ≥75, clopidogrel was significantly the most prescribed agent, and its use was not influenced by STEMI versus UA/NSTEMI clinical presentation or by diabetic history.
Conclusion. Based on data of the present real world prospective registry, a history of known DM does not affect the choice of a more intensive and consistent oral antiplatelet therapy.

C59

CONFRONTO TRA DIFFERENTI STRATEGIE ANTICOAGULANTI IN PAZIENTI CON SCA-NSTE: RISULTATI A 12 MESI DEL REGISTRO CORDAS (COMPARATIVE RESEARCH OF DIFFERENT ANTITHROMBOTIC STRATEGIES IN PATIENTS WITH ACUTE CORONARY SYNDROME UNDERGOING CORONARY REVASCULARIZATION)

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Background. La terapia antitrombotica anticoagulante rappresenta il cardine nel trattamento dei pazienti con SCA-NSTE. Come più volte ribadito nelle linee guida internazionali, momento fondamentale nella gestione di tali pazienti è la stratificazione del rischio ischemico ed emorragico con l'utilizzo di score di rischio validati (GRACE score e CRUSADE score). Il corretto inquadramento del paziente con SCA deve infatti tener conto del fatto che il rischio di eventi ischemici e quello di complicanze emorragiche spesso vanno di pari passo: i pazienti ad elevato rischio ischemico presentano una probabilità più elevata di sanguinamenti maggiori e il verificarsi di episodi emorragici risulta associato ad una prognosi peggiore.
Metodi. Il progetto CORDAS (COmparative Research of Different Antithrombotic Strategies in patients with acute coronary syndrome undergoing coronary revascularization), registro osservazionale monocentrico, è nato dall'esigenza di raccogliere prospetticamente i dati di sicurezza ed efficacia relativi alla scelta dei farmaci antitrombotici nei pazienti con diagnosi di sindrome coronarica acuta NSTE candidati a

trattamento invasivo di rivascolarizzazione miocardica e fornire una stima affidabile dell'incidenza di eventi ischemici ed emorragici in questa popolazione di pazienti (follow-up medio di 11.2 mesi). L'end-point principale è un endpoint composito costituito da mortalità per cause cardiovascolari e non, infarto miocardico non fatale, stroke e sanguinamenti maggiori definiti dalla classificazione BARC. End-point secondario è composto invece da trombosi di stent ed incidenza di sanguinamenti minori secondo la classificazione BARC. Il Registro, regolarmente approvato dal Comitato Etico, ha arruolato 229 pazienti (156 uomini, 71% e 64 donne, 29% con età media rispettivamente di 68±12 anni e 75±14 anni) a partire da novembre 2013 fino a novembre 2015. La scelta del tipo di farmaco anticoagulante all'ingresso in Unità Coronarica è stata decisa in base alla valutazione del rischio emorragico utilizzando il CRUSADE score (rischio emorragico basso, CRUSADE score <30, somministrata enoxaparina, rischio emorragico moderato-elevato, CRUSADE score ≥30, somministrato fondaparinux, pazienti portatori di protesi valvolari meccaniche ed insufficienza renale avanzata (clearance creatinina<20 ml/min) somministrata UFH. Questo ha permesso quindi di personalizzare la terapia anticoagulante in base al rischio emorragico individuale.

Risultati. I pazienti con un GRACE score>140 hanno avuto un incremento significativo di eventi emorragici maggiori e totali rispetto a coloro con GRACE score ≤140 (14.8% vs 2%). La scelta dell'accesso radiale rispetto a quello femorale ha ridotto significativamente le complicanze emorragiche totali (10.1% vs 36.4%). Durante il follow-up a 11.2 mesi, completato in 220 pazienti, si sono verificati 26 eventi avversi maggiori appartenenti all'end-point principale. L'analisi multivariata ha mostrato che la sopravvivenza libera da eventi è risultata significativamente maggiore nei pazienti con accesso radiale rispetto all'accesso femorale (p<0.0001). Tale analisi ha inoltre dimostrato che l'incidenza di eventi maggiori è risultata statisticamente significativa (p<0.0001) in pazienti con stroke e nei pazienti sottoposti a coronarografia dopo un intervallo di tempo >72 ore dall'ingresso in Unità Coronarica. Non abbiamo osservato differenze statisticamente significative sull'incidenza di sanguinamenti maggiori tra i pazienti che presentavano CRUSADE score ≤30 e >30, nonostante questi ultimi abbiamo un rischio emorragico intrinseco più elevato. Riteniamo possibile che questo sia il risultato di una terapia anticoagulante personalizzata sul rischio emorragico individuale. All'analisi univariata un CRUSADE score >30 è risultato associato ad una prognosi peggiore a breve e lungo termine, ovvero ad una maggiore incidenza di eventi maggiori (p<0.05). L'analisi multivariata non ha invece confermato tale associazione statisticamente significativa.

Conclusioni. L'analisi effettuata sul database CORDAS ci ha consentito di osservare che: 1) il sanguinamento maggiore intraospedaliero rimane vincolato ad un elevato rischio ischemico (GRACE score >140); 2) il CRUSADE score potrebbe diventare uno strumento per individuare i pazienti con prognosi peggiore; 3) la valutazione in toto del rischio emorragico, dei sanguinamenti e della prognosi non dovrebbe prescindere dall'impiego contemporaneo del CRUSADE score e GRACE score; 4) l'accesso radiale ha confermato correlarsi con una minore incidenza di sanguinamenti totali ma anche con una sopravvivenza libera da eventi significativamente maggiore rispetto all'accesso femorale.

C60

MANAGEMENT OF ASPIRIN INTOLERANCE IN PATIENTS UNDERGOING PCI: THE ROLE OF MONO-ANTIPLATELET THERAPY – A RETROSPECTIVE, MULTICENTER, CASE SERIES

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Background. The optimal management of patients with aspirin intolerance who underwent a percutaneous coronary intervention remains to be assessed. The management with a P2Y12 inhibitor alone is a quite common choice despite a lack of data on safety and efficacy in particular for prasugrel and ticagrelor. Aim of our study is to retrospectively evaluate the safety and efficacy of mono-antiplatelet therapy in patients with aspirin intolerance who underwent a PCI.

Methods. We systematically searched inside hospital's electronic archives of the Interventional Cardiology Unit, Infermi Hospital, Rivoli and San Luigi Gonzaga University Hospital, Orbassano, Italy, the Cardiovascular Institute of the University of Ferrara and the Interventional Cardiology Unit of the Hospital Clinico San Carlos, Madrid for patients who underwent a PCI and were discharged with a diagnosis of: "aspirin intolerance", "aspirin hypersensitivity" or "aspirin allergy" from January 2006 to June 2016. We included in the study only those treated with a mono-antiplatelet therapy at discharge. All the patients identified were reassessed with a follow-up visit. Data about the coronary artery disease, the aspirin intolerance and about major acute cardiovascular events (MACE) in hospital and at follow-up collected. Moreover, we compared the safety and efficacy on clopidogrel monotherapy with that one of new P2Y12 inhibitors.

Results. We collected 70 patients, 25 (35%) women and 45 (65%) men, with a medium age of 72±10 years. An acute coronary syndrome was the clinical presentation in 47 (67%) patients with an NSTEMI in 19 (27%) of them. By contrast a stable CAD was present in 23 (33%) patients. Of those, 46 (65%) were treated with clopidogrel and 24 (35%) with a new P2Y12 inhibitor (15 patients with ticagrelor and 9 with prasugrel). The average ejection fraction at admittance was 56±11%. The most common manifestations of aspirin intolerance were skin reactions in 15 (25%) patients and asthma in 6 (10%) patients. All the patients were treated with a PCI except one treated with CABG. The most used stents were DES in 49 cases (70%) with an average length of 25±16 mm. After a follow-up of 41.4±28.8 months, 28 (40%) suffered a new MACE, 6 (8.6%) died, 5 (7.1%) required a target vessel revascularization and 9 (12.9%) patients a target lesion revascularization. Most of the MACE, 24 (86%) occurred in the first 12 months after the index event. No significant differences were found between patients treated with clopidogrel monotherapy and new P2Y12 inhibitor monotherapy except for age (74.3±10 vs. 67.2±10.5 years, p=0.008), follow-up duration (54±26 vs. 17±14 months, p=0.01) and target lesion revascularization (9 vs 0, p=0.02). Finally, after 12 months of therapy with a new P2Y12 inhibitor 5 patients downgrade anti-platelet therapy to clopidogrel.

Conclusion. To the best of our knowledge this is the first study evaluating the safety and efficacy of a mono anti-platelets therapy regimen in patients with aspirin intolerance who underwent a stent implantation. Despite the study limitations, the monotherapy with an anti-platelet medication seems weighted by a high number of MACE. Additional data must be collected to deeply evaluate the safety and efficacy of prasugrel and ticagrelor. In the meantime the published data on the safety and efficacy of aspirin desensitization represent a solid and evidence based strategy to manage aspirin intolerance in patients undergoing PCI.

C61

SAFETY AND FEASIBILITY OF ASPIRIN DESENSITIZATION IN PATIENTS WITH CORONARY ARTERY DISEASE UNDERGOING CORONARY ANGIOGRAPHY: INSIGHTS OF A MULTICENTER REGISTRY

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Background. Aspirin therapy is the cornerstone of treatment in patients with coronary artery disease (CAD). Aspirin sensitivity not only limits patients to benefit from the long-term use of this antiplatelet agent but is also often an impediment percutaneous coronary interventions with stent implantation. The present study aimed to assess safety and feasibility of a standard desensitization protocol in patients with aspirin sensitivity and CAD, undergoing coronary angiography and to identify those patients at the highest risk of developing adverse reactions.

Methods. This is a prospective, multicenter, observational study. A total of 6 centers in Italy participated in this registry. Patients with a history of aspirin hypersensitivity, admitted with acute coronary syndrome or with stable known or suspected CAD, before coronary angiography were identified and submitted to the desensitization protocol. A history of aspirin sensitivity was reported in 303 patients (mean age 67±11 y, 78% presenting with acute coronary syndrome). The most common history of reaction to aspirin was urticaria (n=139, 52%), followed by angioedema (n=87, 22%), asthma (n=64, 21%), and anaphylactic reaction (n=13, 5%). Of note, among patients with urticaria/angioedema 13 patients (4%) had a history of idiopathic chronic urticaria. All patients underwent the desensitization procedure: six sequential doses of aspirin (1, 5, 10, 20, 40, and 100 mg) administered orally at predefined intervals, with the procedure lasting 5.5 hours. None received pretreatment with antihistamines or corticosteroids. Blood pressure, pulse, cutaneous, nasoocular, or pulmonary reactions were monitored until 4 hours after the procedure. Patients were followed-up for 24±11 months.

Results. The desensitization procedure was performed before cardiac catheterization in all patients, but 59 (21%) who presented ST-elevation myocardial infarctions and in whom urgent reperfusion was required. Drug eluting stents were implanted in 59% of patients. The desensitization procedure was successful in 287 pts (95%), and in all patients with a history of anaphylactic reaction. Out of the 13 patients with a history of idiopathic chronic urticaria, only in two patients the desensitization failed. No serious adverse reactions occurred in patients with a failure of the protocol: 7 patients developed cutaneous reactions, 3 had mucosae reactions, and 5 had a asthma-reactions. All reactions were immediately resolved with corticosteroids and antihistamines. At long follow-up term, 43 (14%) of patients had aspirin discontinuation, which was never due to sensitivity reactions.

Conclusion. This standard desensitization protocol is safe and effective in patients with coronary artery disease, irrespective of the type of sensitivity.

C62

SINGLE ANTIPLATELET THERAPY IN PATIENTS WITH CONTRAINDICATION TO DUAL ANTIPLATELET THERAPY AFTER TAVI: A SAFE ALTERNATIVE?

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Aims. There is limited evidence to support decision making regarding discharge antiplatelet therapy following transcatheter aortic valve implantation (TAVI). Our aim was to assess the outcome of patients discharged on single antiplatelet (SAPT) or dual antiplatelet therapy (DAPT) following TAVI.

Methods. Consecutive patients were identified by retrospective review of a dedicated TAVI database of a single high volume center in Milan, Italy between January 2009 and December 2014. Our primary endpoint was the rate of net adverse clinical events (NACE) defined as a composite of all-cause mortality, major bleeding requiring hospitalization, cerebrovascular accidents, redo-TAVI or surgical aortic valve replacement and valve thrombosis.

Results. A total of 458 patients were included in the final analysis; 118 patients were discharged on SAPTand 340 on DAPT. Reasons for discharge SAPT included: high risk of bleeding (n= 34; 29%), post procedural bleeding (n=37; 31%), thrombocytopenia (n=23; 19%), vascular complications (n=16; 14%) and high-risk vascular access (n=8; 7%). The mean length of DAPT therapy was 5.1±2.4 months. Patients discharged on DAPT had a higher burden of coronary artery disease (48.4% vs. SAPT 38.9%; p=0.015). At follow-up, no differences were observed in the incidence of NACE, all-cause or cardiovascular mortality and cerebrovascular events. NYHA class III-IV was an independent predictor of NACE.

Conclusions. Prescribing only SAPT after TAVI in selected patients was not associated with an increased risk of events and may be an acceptable alternative to DAPT in elderly patients at high-risk of bleeding. However, the results of randomized controlled trials are awaited to understand the impact of different anti-thrombotic strategies on long-term outcomes.

Primary angioplasty

C63

CLINICAL AND ANGIOGRAPHIC PERFORMANCE OF POLYMER-FREE BIOLIMUS-ELUTING STENT IN PATIENTS WITH ST-SEGMENT ELEVATION ACUTE MYOCARDIAL INFARCTION IN METROPOLITAN PUBLIC HOSPITALS: THE BESAMI MUCHO STUDY

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Introduction. Early-generation drug-eluting stents were more effective than bare-metal stents, although their polymers components have been implicated in the pathogenesis of delayed arterial healing, vessel remodelling and delayed stent thrombosis. Recently, a novel polymer-free drug-coated stent has shown excellent clinical performance in clinical trial setting. This study aimed to assess the efficacy and safety of a new generation polymer-free biolimus-eluting stent in real world patients with ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention.

Methods. Consecutive patients treated with a new-generation polymer-free biolimus-eluting stent (BioFreedom, Biosensors Europe, Morges, Switzerland) because of ST-segment elevation myocardial infarction were included in this study. Patients with cardiogenic shock were excluded from enrolment. The primary endpoint of the study was the rate of major adverse cardiac events (MACE), a composite of cardiac death, recurrent myocardial infarction and ischemia-driven target vessel revascularization at one-year follow-up. Secondary endpoints were single components of the primary endpoint and stent thrombosis. In a subgroup of patients, baseline, post-procedural and follow-up coronary angiograms were digitally recorded and assessed off-line by quantitative coronary angiography.

Results. Overall, 175 patients (64±14 years, 141 men) were included in this study. Diabetes mellitus was present in 27% of cases, 21% were active smokers and 8% had previously undergone a coronary revascularization procedure. At one-year follow-up, the cumulative rate of MACE was 4.6%. Three (1.7%) patients have died of non-cardiac cause and one (0.6%) had an arrhythmic cardiac death, five (2.9%) patients had ischemia-driven target vessel revascularization, although only three (1.7%) had target lesion revascularization. Two (1.1%) patients had acute stent thrombosis yielding non-fatal myocardial infarction. Six-month angiographic follow-up was performed in 70 patients (63±14 years, 61 men). At baseline, a TIMI 3 flow was observed in 79% of patients, reference vessel diameter was 2.84±0.65 mm whereas diameter stenosis and minimal lumen diameter just after opening the culprit lesion was 75.4±14.1% and 0.69±0.39 mm, respectively. Post-procedural diameter stenosis and post-procedural minimal lumen diameter were 13.5±8.9% and 2.63±0.58 mm, respectively. At follow-up, quantitative coronary angiography revealed diameter stenosis of 24.1±13.7% and minimal lumen diameter of 2.29±0.56 mm, thus yielding a late lumen loss of 0.13±0.14 mm.

Conclusions. In a real-world setting, implantation of a new-generation polymer-free biolimus-eluting stent during ST-segment myocardial infarction is associated with favourable clinical and angiographic results, pointing toward the overall efficacy and safety of the device in complex clinical scenarios.

C64

SAFETY AND EFFICACY OF INTRACORONARY RTPA ON TOP OF TIROFIBAN FOR THE RESTORATION OF MYOCARDIAL PERFUSION IN PATIENTS WITH HIGH RESIDUAL THROMBUS BURDEN AFTER FAILED MANUAL THROMBECTOMY

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Background. Acute myocardial Infarction (AMI) is characterized by thrombotic occlusion of a major coronary artery. Early and complete recanalization of the infarct-related artery (IRA) 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.

Purpose. The aim of this study 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 16 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 ever 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 dismission) was 49± 5.

Conclusions. This preliminary experience shows that in patients with high residual thrombus burden after failed manual trombectomy 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.

C65

MANAGEMENT AND CLINICAL OUTCOME OF PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION AND CORONARY ANEURYSMS

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Background. Coronary arterial aneurysms (CAAs) are dilatations of coronary artery segments exceeding 50% of the reference vessel diameter. The incidence of CAAs ranges from 0.3% to 5.3% according to several angiographic studies. Until now only few case reports have described CAAs in the clinical setting of ST elevation myocardial infarction (STEMI).

Purpose. The aim of the present study is to describe the management and the clinical outcome of a single center STEMI population undergoing primary percutaneous coronary intervention (pPCI) presenting CAAs at angiography.

Methods. From our database including 2300 STEMI in the last ten years (2005-2015), we retrospectively collected data about patients with CAAs as target lesion (Group A) or in at least one non-target vessel (Group B) and patients without CAAs at angiography (Group C). We report the interventional and medical management of group A and the clinical outcome of all the three groups using the composite endpoint death and MI (D-MI) and stent thrombosis (ST).

Results. 43 patients (1.9%) were included in the analysis: mean age 64.9 (SD 11.4 years), 80% male, 19% with diabetes and 49% with anterior MI. Group A included 20 cases (47%) and Group B 23 cases (53%). In Group A thrombus aspiration was performed in half of the cases (rheolytic in one third); at least one stent was implanted at CAAs site in 70% of cases with a prevalent use of drug eluting stents; in one case the aneurysm was excluded with a covered stent. In most cases (85%) a final TIMI 2-3 flow was obtained. Intraprocedural glycoprotein IIb/IIIa inhibitor was used in 65% of cases. Therapy at discharge included aspirin and a dual antiplatelet therapy (DAPT) in all the cases; vitamin K antagonist oral anticoagulant therapy was prescribed to two patients in association to DAPT. In Group A ST occurred in 15%, in group B in 8% and in Group C in 2% of the cases. In Group A, at a median follow-up of 256 (IQR 9-470) days, D-MI occurred in 30% of the patients. The same rate (30%) occurred in the population of Group B at a median follow up of 385 (IQR 30-1086) days. In both groups D-MI occurred early after the index event (median follow up of 16 days). In Group C the rate of D-MI was 16% at a median follow-up of 507 IQR (168-1007) days. In this group the median time to event was 53 days.

Conclusions. In our STEMI population, patients with CAAs as culprit lesions were mainly treated with thrombus aspiration and DES use. The presence of

CAAs is associated with a high rate of stent thrombosis, mortality and myocardial infarction occurring early after the index event. Large registries are warranted to best clarify optimal interventional and medical management.

C66

PRASUGREL VERSUS CLOPIDOGREL IN PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION UNDERGOING PERCUTANEOUS CORONARY INTERVENTION: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Background. Prasugrel is recommended over clopidogrel in patients with ST elevation myocardial infarction (STEMI) undergoing percutaneous coronary intervention (PCI)

Objective. To evaluate the association of prasugrel vs clopidogrel assignment with mortality reduction in STEMI patients treated with PCI.

Methods and Results. An extensive literature search for full-text articles published in 2007-2014 obtained 8 studies: 2 randomized controlled trials (RCTs) and 6 non-randomized studies (non-RSs). Primary analysis included only of RCTs. A secondary only explorative analysis of non-RSs was however performed. A total of 14912 patients were included in the meta-analysis, 4082 in RCTs and 10830 in non-RSs. Death from any cause at longest available follow-up was considered as the primary end point. In the primary analysis prasugrel showed a no significant all-cause of death reduction at longest available follow-up (RR 0.78, 95% 0.57-1.08, p=0.13) and at 30 days (RR 0.68, 95% CI 0.44-1.03 p=0.07) with no increase of bleeding risk (RR 1.1, 95% CI 0.85-1.42, p=0.46) In non-RSs, prasugrel assignment was associated with a significant mortality reduction both at longest and at 30 days follow up (unadjusted RR respectively 0.56, 95% CI 0.41-0.77, p=0.0002 and 0.56, 95% CI 0.43-0.73, p=0.0001).

Conclusion. In STEMI patients treated with PCI, prasugrel compared to clopidogrel appeared to be safe but had no effect on mortality.

C67

CARDIAC MAGNETIC RESONANCE VALIDATION OF THE AGE-THROMBUS-INDEX OF MICROCIRCULATORY OBSTRUCTION (ATI) SCORE IN PATIENTS WITH ST ELEVATION MYOCARDIAL INFARCTION

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Aim. Identification of patients with ST elevation myocardial infarction (STEMI) at high risk of no reflow during primary percutaneous coronary intervention (PPCI) is desirable in order to provide, early in the cath-lab, adjunctive or additional therapeutic strategy to the conventional approach with stenting. The ATI score has been recently proposed as possible diagnostic tool able to predict early in the cath-lab, before stenting, an unfavourable final IMR >40 at the end of the procedure. We aimed to validate the ATI score against the presence of microvascular obstruction and final infarct size, measured by cardiac magnetic resonance imaging (MRI).

Methods. In STEMI patients undergoing PPCI, thrombus score was assessed after guidewire passage and IMR was measured using a pressure wire (Certus, St. Jude Medical, St. Paul, Minnesota) immediately before stenting. The ATI score was calculated [Age (>50 = 1 point); pre-stenting IMR (>40 and <100 = 1 point; ≥100 = 2 points); Thrombus score (4=1 point; 5=3 points)]. MRI scan was performed within 48 hours from admission and at 6 month follow-up to assess the extent of infarct size (IS%) and microvascular obstruction (MVO%).

Results. ATI score was prospectively calculated in 69 consecutive STEMI patients. All patients underwent acute MRI scanning within 48 hours. 6 month follow-up MRI scan was available in 41/69 patients. At the acute MRI scan ATI score was significantly related to both IS% (ATI score 0-1: 27.0 (13.3-32.9), ATI score 2-3: 34.9 (18.0-44.3) and ATI score 4-5-6: 41.0 (28.9-54.0) p=0.001) and to MVO% (ATI score 0-1: 0.0 (0.0-1.0), ATI score 2-3: 0.5 (0.0-2.2) and ATI score 4-5-6: 3.0 (1.0-13.0) p=0.001). Furthermore, a correlation between ATI score and final IS% at 6 months follow up was also observed (ATI score 0-1: 15.0 (3.0-22.0) ATI score 2-3: 22.0 (6.8-30.2) and ATI score 4-5-6: 34.0 (24.8-37.5), p=0.008)

Conclusions. ATI score calculated during PPCI predicts early microvascular obstruction and infarct size both acutely and at 6 months, supporting the clinical application of ATI score as a tool to identify high-risk patients who may benefit from additional or alternative therapeutic interventions.

Miscellaneous

C68

CONFRONTO TRA 3D ANGIO QFR NON INVASIVA ED FFR NELLA VALUTAZIONE FUNZIONALE DELLE STENOSI CORONARICHE IN PAZIENTI CON ANGINA STABILE: RISULTATI PRELIMINARI

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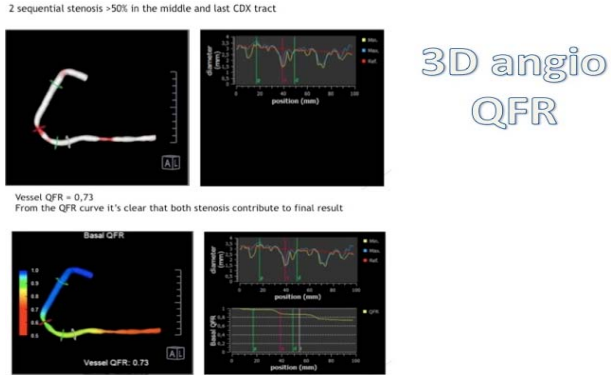
Scopo. Confrontare un nuovo metodo non invasivo di valutazione del significato funzionale delle stenosi coronariche basato sull'angiografia coronarica con ricostruzione 3D (3d Angio QFR della Medis) con l'FFR tradizionale in un gruppo di pazienti con angina stabile.

Premesse. L'FFR è uno strumento riconosciuto di studio della riserva coronarica; tuttavia richiede tempo, hardware dedicato, è invasiva e abbastanza costosa e spesso richiede la somministrazione di Adenosina (ADO) con aumento dei costi e possibili effetti collaterali. Recentemente molte ricerche si sono concentrate sull'uso di metodiche non invasive in grado di ottenere le stesse informazioni e due di esse sono disponibili per l'uso clinico: Heartflow® basata sulla CT multislice e 3DAngio QFR® (MEDIS NL marchio CE a luglio prossimo). Tutti questi metodi si basano su sofisticati algoritmi di fluido dinamica insieme con la ricostruzione 3D della coronaria e la misura del frame count. Un esempio è indicato nella Figura 1. I risultati preliminari sono molto promettenti con una forte correlazione con l'FFR.



Casistica e metodi. Da maggio al 15 giugno 2016 15 pazienti con angina stabile e con stenosi coronariche ≥ 50% in almeno un vaso sono stati valutati con FFR in accordo con le linee guida correnti. Sono stati valutati 30 vasi con stenosi variabili dal 52 al 74%. 3D Angio QFR è stata valutata su una workstation Medis dedicata da un operatore non a conoscenza dei dati dell'FFR; l'analisi statistica (correlazioni, ROC curve) è stata eseguita utilizzando il software MedCalc.

Risultati. Sono state ottenute 44 coppie di confronto QFR/FFR, di base e dopo ADO; queste coppie sono state divise per l'analisi in 3 gruppi: 1=tutte le coppie; 2=ADO QFR versus ADO FFR; 3=QFR basale versus ADO FFR. Correlazioni e curve ROC con cutoff a 0.8 per i 3 gruppi sono mostrate nella Tabella.

Group	r	ROC curve				
		Sensitivity	Specificity	PPV	NPV	AUC
1*	0.8	84	81	82	89	0.926
2**	0.88	85	92	88	90	0.962
3***	0.94	80	100	88	90	0.962

*All QFR- FFR matches (44 pairs)
**QFR ADO versus FFR ADO matches (23 pairs)
***QFR basal versus FFR ADO matches (22 pairs)

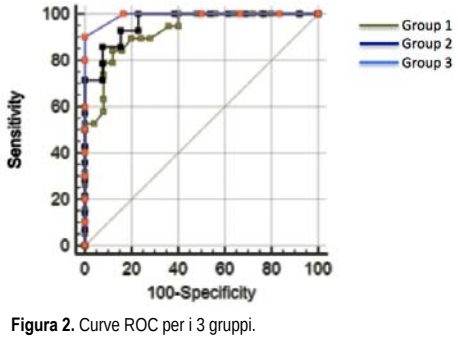


Figura 2. Curve ROC per i 3 gruppi.

Conclusioni. La nostra esperienza preliminare mostra che la 3D Angio QFR è una metodica affidabile per la valutazione del significato funzionale delle stenosi coronariche. I nostri risultati sono sovrapponibili a quelli riportati in letteratura, mostrando una buona riproducibilità. Ci sono tuttavia alcune

differenze tra QFR e FFR, la prima secondo noi più dipendente dalla conformazione del vaso e dal flusso, la seconda più basata sulla risposta del microcircolo e sullo stato del miocardio sottostante. La correlazione pressoché perfetta tra QFR basale e ADO FFR deve essere validata da numeri più ampi e, se confermata, renderebbe la QFR uno strumento semplice, economico e facilmente implementabile nel cathlab per lo studio ed il trattamento dei pazienti con angina stabile. Infatti, essendo la QFR basale ottenibile dalla semplice angiografia, consentirebbe di definire lo stato funzionale nella grande maggioranza dei pazienti già di base, selezionando inoltre i pochi casi dubbi da valutare con metodica invasiva.

C69

SIMPLIFIED HYBRID ALGORITHMS FOR PRESSURE WIRE INTERROGATION EXPLOITING ADVANTAGES OF A COMBINED INSTANTANEOUS WAVE-FREE RATIO AND CONTRAST MEDIUM INDUCED PD/PA RATIO APPROACH: INSIGHT FROM THE SPARE MULTICENTER PROSPECTIVE STUDY

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Background. Achieving a maximal hyperaemia by means of adenosine still remains a limiting factor for a widespread adoption of fractional flow reserve (FFR). Hence, novel adenosine-free indexes of stenosis severity as instantaneous wave-Free Ratio (iFR) and contrast medium induced Pd/Pa ratio: (CMR) along with different hybrid decision-making strategies were proposed aiming to circumvent these limitations. IN this study we evaluate the merits of combining hybrid algorithms for pressure wire interrogation in a prospective multicenter cohort of patients.

Methods and Results. Eighty-six patients with 108 de novo intermediate coronary stenoses were prospectively enrolled. A significant correlation with FFR was documented for iFR ($r=0.75$, $r^2=0.57$; $p<0.0001$) and CMR ($r=0.85$, $r^2=0.73$; $p<0.0001$), although CMR demonstrated a strong correlation with a close agreement at Bland-Altman analysis (0.03±0.05, 95% CI of disagreement: -0.12 to 0.05). Adopting a Hybrid iFR-CMR-FFR strategy up to 90% of cases (n=97) would be free from adenosine while 57% of cases (n=64) would be free from both adenosine and additional medium-contrast requirement.

Conclusions. A hybrid iFR-FFR-CMR decision-making strategy for revascularization could increase adoption of physiology-guided PCI drastically reducing the need for vasodilator administration, whilst maintaining high classification agreement with an FFR-only strategy. Combining together advantages of different physiologic indexes could be an attractive option waiting definitive data exploring adenosine-free indexes as a sole guide for revascularization.

C70

PREDICTIVE VALUE OF A BI-DIMENSIONAL TRANSTHORACIC ECHOCARDIOGRAPHIC SIGN TO IDENTIFY THE ANOMALOUS ORIGIN OF THE LEFT CIRCUMFLEX CORONARY ARTERY FROM THE RIGHT CORONARY SINUS

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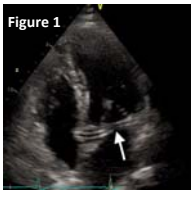
Background. It has been reported a "binary image" projecting into the left atrium above the mitral annulus in apical 4-chamber view using two-dimensional transthoracic echocardiography (TTE) (Figure 1, arrow) corresponding to an anomalous left circumflex coronary artery (LCX) originating from the right coronary sinus (Figure 2) or the right coronary artery (RCA, Figure 3) with retro-aortic course (Figure 2). This anomaly has a prevalence of 0.18 to 0.67% and is usually considered a "benign" variant. However, rarely these patients may develop symptoms due to kinking, narrowing or compression due to its retro-aortic course and a case of sudden death was also described. For interventional cardiologists the anticipation of an anomalous coronary origin is of great relevance either in elective or in acute settings to reduce the time of fluoroscopy during the diagnostic phase. Therefore a correct identification before coronary angiography of this anomaly is useful. However, to date, only sporadic case reports of this echocardiographic sign are present in the literature and there are no prospective data of the diagnostic accuracy of this sign in predicting the presence of this anomaly.

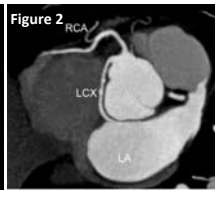
Purpose. We sought to prospectively determine the sensibility, specificity, positive (PPV) and negative (NPV) predictive value and the diagnostic accuracy of this sign on TTE in diagnosing the anomalous LCX using coronary angiography (CA) as reference method to detect the presence or absence of this coronary anomaly.

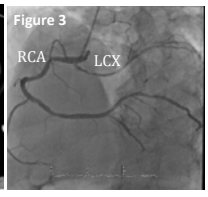
Methods. We enrolled all consecutive patients (aged >18 years) referred to our center for CA from November 2014 until April 2016 for various pathological conditions (ischemic, valvular, dilated cardiomyopathy). All these patients underwent a complete TTE before CA.

Results. 1372 adult patient were studied. The anomalous LCX was found in 9 patients on CA with a prevalence of 0.64%. The "binary image" was present in 8 subjects on TTE and in all these patients the diagnosis was confirmed by CA. The only patient in which TTE failed to reveal the sign had a very poor acoustic window in the apical projections. The sensibility, specificity, PPV and NPV of this echocardiographic sign were 90.0%, 99.9%, 100% and 99.9% respectively in diagnosing the anomalous LCX with a diagnostic accuracy of 99.9%.

Conclusions. This prospective study demonstrates for the first time that in an adult population the presence of this particular TTE sign of "binary image" above the mitral annulus is typical for this anatomic variant of LCX and shows a high diagnostic accuracy.







C71

SHOCK EMORRAGICO IN PAZIENTE CON CARCINOMA DELLA LARINGE: TRATTAMENTO PERCUTANEO DI UNA COMPLICANZA NON COMUNE

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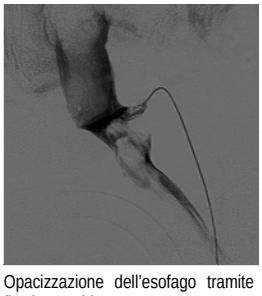
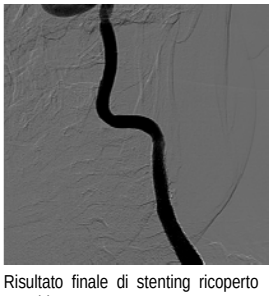
Paziente di 65 anni, affetto da diabete mellito tipo 2 ed esiti di laringectomia con tracheo-stomia chirurgica per carcinoma della laringe, resistente a chemio- e radio-terapia, già complicato da fistola faringo-cutanea trattata con protesi salivare, recentemente rimossa.

Il paziente giungeva in pronto soccorso a seguito di episodio di ematemesi e sincope. All'ingresso si presentava ipoteso, tachicardico, soporoso ma risvegliabile alla chiamata. Gli esami di laboratorio mostravano anemia severa (emoglobina 4.5 g/dl). Veniva posizionato sondino naso-gastrico con aspirazione di 300 cc di materiale ematico e si iniziava espansione volemica. Durante le manovre iniziali si assisteva a nuovo episodio di ematemesi con arresto cardiaco da bradi-asistolia, sottoposto a manovre rianimatorie efficaci. Si procedeva dunque a stabilizzazione emodinamica con noradrenalina in infusione continua e.v. e trasfusione di 8 sacche di emazie concentrate e 4 sacche di piastrine. Il paziente veniva quindi ricoverato presso la rianimazione. Dopo valutazione da parte dell'Otorinolaringoiatra e del Chirurgo Vascolare, che escludevano possibilità di trattamento chirurgico per la severità del quadro clinico e per la presenza di vasto ematoma del collo che impediva l'accesso chirurgico, il paziente giungeva alla nostra osservazione per studio angiografico per eventuale procedura di embolizzazione arteriosa. L'indagine, eseguita tramite accesso arterioso femorale destro, mostrava vistoso passaggio di mezzo di contrasto dal tratto distale del bulbo carotideo dell'arteria carotide comune sinistra verso l'esofago. Posta diagnosi di shock emorragico da fistola carotido-esofagea, si procedeva pertanto in emergenza al trattamento percutaneo con posizionamento di stent ricoperto. Nei giorni successivi si assisteva ad una graduale stabilizzazione emodinamica con svezzamento dal supporto aminico e ad un progressivo recupero neurologico. La successiva degenza veniva complicata da infezione urinaria intercorrente. Il paziente veniva dimesso in trentaquattresima giornata post-operatoria. Al follow-up si segnala nuovo ricovero in Neurologia circa 5 mesi dopo, a causa di un attacco ischemico transitorio in corso di stato settico da Enterococco fecale. Per il riscontro ecografico ed angiografico di restenosi critica dello stent ricoperto recentemente posizionato sull'arteria carotide interna sinistra, è stata eseguita angioplastica con stenting intrastent, con buon risultato.



Opacizzazione dell'esofago tramite fistola carotidea sn.



Risultato finale di stenting ricoperto carotide sn.

C72

EARLY PREDICTORS OF CONTRAST-INDUCED ACUTE KIDNEY INJURY AFTER CORONARY ANGIOGRAPHY AND INTERVENTION IN A LARGE UNSELECTED POPULATION

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Background. Contrast-Induced Acute Kidney Injury (CI-AKI) is conventionally defined as an acute impairment of the renal function after iodinated contrast medium (CM) administration in the absence of other related causes and increases morbidity and mortality. We aimed at evaluating incidence and predictors of CI-AKI in a large unselected population and also describe the incidence of persistent renal damage (PRD).

Methods. This is a retrospective observational study that screened all the consecutive patients that underwent coronary angiography or interventions at the university hospital of Verona between January 2010 and December 2012. Either iso-osmolar or low-osmolarity CM were used. We excluded patients without available serum creatinine (SCr) determination at baseline, 12-24 or 48-72hours. Standard measures to prevent CI-AKI, such as hydration and Metformin interruption, were adopted according to our institutional protocols. The primary endpoint was the detection of CI-AKI defined as a relative increase in SCr concentration of at least 25% and/or an absolute increase in SCr concentration of at least 0.3 mg/dl as measured 48-72 hours. The secondary endpoint was the assessment of PRD (defined as a persistent CI-AKI condition at 20-40 days). Long-term renal function impairment was instead defined as an eGFR reduction of more than 25% at 12-24 months compared with baseline.

Results. Of 3997 screened patients, 1020 had all the needed data to be included. Renal function information at 20-40 days and 12-24 months were available in 795 and 731 cases, respectively. The mean age was 66.37±11.82 years, 74.5% were men, 31.1% had preexisting CKD, defined by a basal eGFR <60 ml/min/1.73 m^2, and 29.4% had diabetes mellitus. CI-AKI occurred in 130 cases (12.7%).Patients who developed CI-AKI were significantly older (69.89±10.38 vs 65.86±11.95, p<0.001), had lower LVEF (42.96 ± 11.99 vs 50.34 ± 11.58, p=0.003), higher basal SCr (1.30±1.19 vs 1.12±0.80, p=0.028), lower basal eGFR (73.20 ± 34.94 vs 79.83 ± 31.68, p=0.032) and preexisting CKD (44.4% vs 29.1%, p=0.001).As previously suggested by our group, early (12-24h) increments of SCr (5-10% from baseline) is the only independent predictor of CI-AKI at multivariate logistic regression (OR=1.16, 95%CI 1.008-1.36, p=0.04). CI-AKI was significantly associated with increased SCr values at 20-40 days compared with the baseline (OR= 4.97, 95% CI 4.38-11.1, p<0.001). Moreover, CI-AKI was associated with a significant worsening of the renal function at long-term follow-up (OR=3.39, 95% CI 2.1-5.49, p<0.001). PRD occurred in 40 out of 130 (30.7%) patients who developed CI-AKI.At long-term follow up the eGFR was significantly reduced in PRD patients compared with transient CI-AKI (-24.3±21.8 vs -12.5±16.6, p=0.009) and they had higher rate of dialysis initiation(14.6% vs 2.2%, p=0.012).

Conclusions. In this large unselected sample CI-AKI after coronary angiography or interventions occurred in 12.7% of cases and 20-40 days PRD in 30.7% of CI-AKI patients. Patients developing PRD are at higher risk of long-term renal impairment and dialytic therapy. We also confirm that slight, early increments of SCr (5-12% from the baseline at 12-24 hours) independently predict CI-AKI occurrence

Non-coronary interventions – 2

C73

PREDICTORS OF PERMANENT PACEMAKER IMPLANTATION AFTER TRANSCATHETER AORTIC VALVE REPLACEMENT

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Background. Permanent pacemaker (PPM) requirement is a known complication after transcatheter aortic valve implantation (TAVI) and it is still a challenge in severely calcified aortic valves. The aim of the study was to determine predictors of PPM implantation after TAVI.

Methods. A total of 168 patients at high surgical risk and without PPM at baseline underwent TAVI using Edwards SAPIEN valve (Edwards Lifesciences, California) (n=100), Direct Flow Medical valve (Direct Flow Medical, California) (n=44), Lotus valve (Boston Scientific, Massachusetts) (n=20) and ACURATE neo valve (Symetis, Switzerland) (n=4). Volumetric quantification of calcification of the aortic valve complex including left ventricular outflow tract (LVOT) and aortic root (AR) (from annulus to the ostia of the coronary arteries) and the distribution of calcification within this area (non coronary cusp (NCC), left coronary cusp (LCC) or right coronary cusp (RCC)) were assessed from preoperative contrast-enhanced multi-slice computed tomography.

Results. Out of 168 patients (mean age 83 ± 6 years; 50% male), 27 (16%) had a PPM implantation in-hospital. Binary logistic regression analysis identified as independent predictors of PPM implantation the presence of COPD (p=0.001) and the type of the valve (p=0.009), with a lower incidence of PPM with the balloon expandable valve (13%) and a higher incidence with the retrievable and repositionable aortic valves (20,6%), in particular with the Lotus valve (45%). In addition LCC calcification (p=0.002) and also LVOT calcification under the LCC (p=0.010) were significant predictors. The amount and distribution of calcification were similar between patients treated with the balloon expandable valve and those treated with retrievable and repositionable aortic valves (p=0.889). Only patients treated with the Lotus valve had a significantly more severe calcification of the LVOT (p<0.001), but not of the aortic root (p=0.399).

Conclusions. Not only the type of the valve prosthesis, but also the distribution of calcification should be considered as predictors of PPM implantation.

C74

SELF-EXPANDABLE TRANS-CATHETER AORTIC VALVE IMPLANTATION FOR THE TREATMENT OF FAILED MITROFLOW PROSTHESIS: A SINGLE CENTRE EXPERIENCE

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Background. Valve-in valve (ViV) trans-catheter aortic valve implantation (TAVI) is an alternative treatment option for patients with failed aortic bio-prosthesis and high or prohibitive surgical risk. We aim at reporting our experience regarding self-expandable TAVI in stented Mitroflow bio-prosthesis, which is known to be at high risk of coronary occlusion.

Methods and Results. Between September 2010 and June 2016, 29 patients with degenerated aortic bio-prosthesis underwent trans-catheter valve-in-valve (ViV) procedure at our institution. Seventeen out of them (58.6%) had a failed stented Mitroflow (MF) bio-prosthesis. Among these patients, 8 were males and mean age was 80±5. They were severely symptomatic (NYHA functional class ≥III) and at high surgical risk with median STS and EuroSCORE II of 9 (5-29) and 18 (13-32) respectively. Four patients had patent bypass to the left coronary system. Degenerated MF valve induced aortic stenosis in 4 patients, aortic insufficiency in 5 cases and combined failure in 8 subjects. MF sized 19, 21 or 23 mm in 2, 7 and 8 patients, respectively. Through femoral (88.2%) or trans-aortic (11.8%) approach, CoreValve or Evolut R 23 mm was deployed in all but 2 subjects who received CoreValve 26 mm when 23mm version had not yet been marketed. No patients received pre-dilatation, whereas post-dilatation was performed in 9 patients. Stand-by for cardiopulmonary bypass (CPB) was available in 9 patients and used in 2 cases because of cardiac arrest occurrence as consequence of acute or sub-acute left main (LM) occlusion that was successfully treated with percutaneous coronary stenting. In one patient a "preventive" LM stenting was performed with a final "kissing balloon" (simultaneous balloon inflation in LM and aortic bio-prosthesis). No stroke, procedural death or major vascular complication occurred. A new pacemaker was implanted needed in 3 patients. Of note, the procedure was considered "off-label" in more than 50% of cases. At 30-day follow-up only one patient died due to cardiovascular cause. A significant NYHA functional class reduction was detected. Median gradient was 8 mmHg (IQR 5-15) with only two patients who showed a value ≥20mmHg, without clinical impact. All patients had none or mild aortic regurgitation.

Conclusions. Trans-catheter aortic valve-in-valve implantation using self-expandable device in failed Mitroflow bio-prosthesis is a feasible procedure that may be safe and effectiveness acutely and at early-term follow-up. Coronary occlusion can be prevented or quickly treated with favourable outcome providing CPB availability. Increased post-procedural gradient does not seem to be frequent or clinically influent. Further investigations are needed to confirm our results.

C75

ATHEROSCLEROTIC DISEASE BURDEN AND OUTCOME IN PATIENTS WITH CRITICAL LIMB ISCHAEMIA: THE EXPERIENCE OF A LARGE VOLUME DIABETIC FOOT CENTRE

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Background. Critical limb ischaemia (CLI) is a challenging clinical issue accounting for a progressively increasing rate of hospitalizations and major amputations in diabetic patients. Although atherosclerotic burden is supposed to be higher in these patients, current evidence is poor and coming from small unselected populations.

Methods. 503 diabetic patients (age 72±11, 69% males) admitted to Diabetic Foot Unit and treated with peripheral angioplasty for CLI were included in the study (reference period: 2014). CLI was diagnosed in presence of ischaemic leg pain at rest or worsening arterial ulcers in the foot. Revascularization procedure was performed with the aim of restoring a direct flow to the foot independently of the 'angiosome' concept.

Demographics of all patients, angiographic characteristics and procedural data were prospectively collected in a dedicated database. Clinical follow-up was performed through medical records review and planned outpatient clinic at 12 months.

Results. All patients were in Rutherford class V-VI, whereas a TUC >3 class was present in 327 patients (65%). Superficial femoral artery (SFA) was diseased in 46.3% of patients, of note a concomitant SFA and two below-the-knee (BTK) vessels disease was present in 212 patients (42.1%). 157 patients (31.2%) had a severe 3 BTK vessels disease. Procedural success was 94.4% for SFA lesions while it ranged from 79.8% to 82.7% for each BTK vessel. A drug-eluting balloon was used in 108 patients, while a stent was deployed only in 5% of cases. An average of 206 mm of disease per patient was successfully treated, which corresponded with 47.7% of the entire extension of the disease. Major amputations at 12 months occurred in 4.1% of patients, with 2.7% performed below the knee.
Conclusions. Peripheral atherosclerotic disease in diabetic patients with CLI is often a complex scenario involving both SFA lesions and BTK disease. A reasonable strategy consisting of restoring a direct flow to the foot, even without unblocking all BTK vessels, is effective in achieving a reasonably low rate of major amputations in a high-risk population.

C76

IL RUOLO DELL'ECOCARDIOGRAFISTA STRUTTURALE NELLA DIAGNOSI E GESTIONE DELLE COMPLICANZE PROCEDURALI DURANTE CHIUSURA PERCUTANEA DELL'AURICOLA SINISTRA

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Introduzione. L'esclusione transcatetere dell'auricola sinistra è una valida alternativa alla terapia cronica con anticoagulanti in pazienti selezionati, con fibrillazione atriale, per la prevenzione dello stroke. Le complicanze procedurali come l'embolizzazione del device, il versamento pericardico con tamponamento cardiaco e la formazione acuta di trombi sono eventi non infrequenti; la conoscenza della causa, la prevenzione e il trattamento della complicanze sono fondamentali per il successo della procedura. Il monitoraggio transesofageo 2D/3D ha un ruolo mandatorio nel riscontro e trattamento delle eventuali complicanze.
Metodi. Nel nostro istituto sono state effettuate 55 procedure di esclusione percutanea dell'auricola sinistra in un periodo di tre anni e la percentuale di complicanze maggiori è stata del 5% (3 pazienti).
Caso 1. Paziente di 81 anni, CHA_2DS_2-VASc: 4, HAS-BLED: 3. È stata impiantato dopo numerosi rilasci un device Watchman n. 24. Le misure della compressione, valutate secondo le sezioni standard al transesofageo rientravano nei parametri idonei al rilascio come pure l'assenza di leak residui al termine della procedura. Dopo poche ore il paziente accusa improvvisa paraparesi degli arti arti inferiori e la TAC dimostra la presenza del device a livello del carrefour aortico. Il device è stato ricatturato per via percutanea.
Caso 2. Paziente di 76 anni, CHA_2DS_2-VASc: 3, HAS.BLED:4. Immediatamente dopo il rilascio di una protesi di Watchman n.27, il monitoraggio ecocardiografico evidenziava versamento pericardico ematico di circa 3 cm circondante l'intero viscere cardiaco responsabile di tamponamento cardiaco risolto con pericardiocentesi. Il transesofageo nel frattempo, mostrava la posizione troppo profonda e distale della protesi in auricola responsabile della perforazione.
Caso 3. Paziente di 61 anni, CHA_2DS_2-VASc:3, HAS.BLED:4. Durante la procedura, dopo l'impianto di device Amulet n.25, il controllo transesofageo dimostrava la presenza di una formazione trombotica a livello del disco sul versante atriale. La formazione trombotica, estremamente mobile raddoppiava le sue dimensioni nel giro di pochi secondi e sembrava adesa al sistema di rilascio della protesi. La stessa formazione veniva osservata all'esterno del paziente una volta rimosso il delivery system originante dallo stesso (FIG.1). Il paziente non ha avuto problemi neurologici acuti. Al controllo transesofageo a distanza (45 giorni) veniva evidenziata una formazione trombotica di notevoli dimensioni sul versante atriale del disco.
Conclusioni. Le complicanze legate alla delicata procedura di chiusura percutanea dell'auricola sinistra tendono a diminuire con la progressiva esperienza degli operatori. Queste possono avvenire in ogni stadio della procedura stessa (relate alla puntura transettale o all'impianto del device) e la loro immediata scoperta e trattamento sono fondamentali per la sicurezza del paziente e la buona riuscita della procedura. La sorveglianza ecocardiografica è quindi necessaria in ogni step della procedura.

Figura 1. Formazione trombotica adesa al delivery system relativa al caso 3.

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COMPARISON OF THE FULLY REPOSITIONABLE AND RETRIEVABLE LOTUS VALVE AND DIRECT FLOW MEDICAL VALVE FOR THE TREATMENT OF SEVERE AORTIC STENOSIS: A HIGH-VOLUME SINGLE CENTER EXPERIENCE

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Aims. A limitation of first generation transcatheter aortic valve replacement (TAVR) devices was the occurrence of paravalvular leak (PVL) that when greater than mild has been demonstrated to a predictor of mortality. Second generation devices have been designed to reduce this. One technological advance has been the ability to reposition devices to facilitate optimal implantation depth to reduce the likelihood of PVL. In this study we compare procedural and 30-day outcomes according to the Valve Academic Research Consortium (VARC)-criteria following TAVI with the fully repositionable and retrievable Lotus and Direct Flow Medical (DFM) devices.
Methods. Baseline characteristics, procedural and follow-up data from consecutive patients with severe aortic stenosis (AS) who underwent transfemoral (TF) TAVR with Lotus valve and DFM valve at a highly experienced high-volume center between March 2012 and May 2016 were retrospectively analyzed. Severe AS was defined by echocardiographic criteria including an aortic valve area (AVA) of <1 cm^2 or an indexed AVA of <0.6 cm^2/m^2 in combination with clinical symptoms. Patients treated for aortic regurgitation or for bioprosthesis failure were excluded.
Results. A total of 175 patients with severe AS underwent TF TAVR with the Lotus (n=60) and DFM (n=115) valves. Baseline characteristics and perimeter derived annulus diameters did not differ between the two groups. Device success rates (95% vs 96.5%, p=0.63) and VARC-defined combined safety (90% vs 93%, p=0.48) and clinical efficacy (86.7% vs 90.4%, p=0.45) endpoints 30 days were similar between Lotus and DFM groups. One case of valve embolization was reported in the Lotus group. There were no severe cases of PVL; one patient in the Lotus group and two patients in the DFM developed moderate PVL. The rate of mild PVL was low in both groups (10% in Lotus and 15% in DFM group, p=0.46). The Lotus valve was associated with a higher rate of new pacemaker implantation (37.3% vs. 11.2%, p<0.001) and a lower mean aortic gradient (9.4±5 vs 12.3±5, p<0.001) at 30-days compared to the DFM valve.
Conclusions. In this single-center, retrospective analysis, both Lotus and DFM devices showed excellent device success, safety and efficacy at 30 day follow-up. The DFM valve was associated with higher transvalvular gradients but lower new pacemaker implantation rate when compared to the Lotus valve.