Comunicazioni orali

Carotid interventions

C1

IMPACT OF ANATOMICAL FEATURES OF AORTIC ARCH AND CULPRIT CAROTID ARTERY ASSESSED BY MACDONALD' SCORE ON THE SHORT-TERM OUTCOME OF CAROTID ANGIOPLASTY AND STENTING

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Background. Management of extracranial carotid stenosis is considered an important line in prevention of cerebrovascular stroke. Carotid angioplasty and stenting (CAS) has become a reasonable alternative to surgical carotid endarterectomy with comparable outcome. Anatomical features of aortic arch and culprit carotid artery represent a corner stone in CAS procedures. Many score systems have been proposed to identify complex anatomical features that may increase procedural difficulty and risk of complication. Macdonald S et al. (2009) have demonstrated score system based on anatomical features of aortic arch and culprit carotid vessel and have classified CAS procedures into 4 levels of difficulty. The aim of our study was to validate the impact of anatomical features of aortic arch and culprit carotid artery assessed by Macdonald' score on the short-term adverse outcome of CAS procedures.

Methods. The study included asymptomatic patients with 70% stenosis of ICA or symptomatic patients with 50% stenosis of ICA who presented to the catheterization labs in Ferrarotto-Catania and Ragusa hospitals, Italy, during the period from October 2009 to May 2011. Patients were considered symptomatic when they had symptoms related to the culprit ICA stenosis within the last 3 months (transient ischemic attack, stroke or amaurosis fugax). Degree of ICA stenosis was assessed according to NASCET method (ICA distal to the lesion is a reference diameter). Procedures were divided into 4 groups based on the anatomical variables of Macdonald' score; group I represented the least anatomical complexity while group IV represented the most complex anatomical features. Data of CAS procedures and short-term outcome including intraprocedural and during the first month after the procedures were collected and analyzed.

Results. The study included 104 ICA lesions in 100 consecutive eligible patients. 4 patients had CAS procedures on both sides in separate sessions. Patients were 71 males and 29 females with mean age 71.9±7.85 years and 21 patients were 80 years old (octogenarians). Asymptomatic ICA stenosis represented 76% of patients while symptomatic ICA stenosis represented 24%. Technical success was achieved in 103 procedures (99%), failed one procedure due to extreme complex anatomical features. Combined cerebrovascular (CV) adverse events had occurred in 5 patients (1 major stroke, 1 minor stroke and 3 transient ischemic attacks) with estimated rate 4.8%. No cases of amaurosis fugax, myocardial infarction or death had occurred. Group I included 49 procedures and had no CV events, Group II included 44 procedures and 1of them had CV event, group III included 9 procedures with 3 of them had CV events and group IV included 2 procedures with 1 of them had CV event. The study showed a significant difference in the number of CV events in relation to Macdonald's risk group with increased number of events in higher risk groups (χ^2=28.02, p<0.001).

Conclusion. Anatomical features of aortic arch and culprit carotid artery assessed by Macdonald's risk score have a significant impact on the short-term adverse outcome of CAS procedures.

C2

SETTING UP A MULTIDISCIPLINARY PROGRAM OF CAROTID ARTERY STENTING IN A COMMUNITY HOSPITAL: FEASIBILITY AND RESULTS IN A CONSECUTIVE SERIES OF 277 PATIENTS

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Aims. Recent trials comparing carotid artery stenting (CAS) with carotid endarterectomy (CEA) demonstrated controversial results but, the increase of the experience of the operators, the improvement of the stents and of the embolic protection devices and the high demand of a less invasive alternative has made CAS a highly competitive procedure.

Methods. We collected data about all consecutive patients with symptomatic or asymptomatic carotid artery stenosis who underwent CAS and analyzed clinical and procedural characteristics as well as immediate and long-term outcomes. From November 2007 to March 2014, 277 patients (mean age 72±7 years, 75.1% male) underwent CAS at our catheterization laboratory. Of these 129 (46.6%) were symptomatic. The procedures were performed after discussion of the cases and after reviewing imaging examination results with neurologists. Neurologic visits and duplex scans were scheduled 24 hours and 1 month after the procedure.

Results. From November 2007 to March 2014, 277 underwent CAS. The population was at high cardiovascular risk: 51.9% of the patients had known coronary artery disease, 5.8% congestive heart failure, 41.9% aged ≥75 years. Many patients (48.7%) had a complex plaque (soft, ulcerated, with thrombus). All procedures were performed with embolic protection devices: 69.7% distal, 20.9% proximal and 9.4% both. The stent implanted were closed-cell in 64.6%, hybrid in 23.5% and open cell in 11.9%. The primary success was achieved in all but 1 patient (99.6%). The rate of major complications at 30 days was 2.5%: 2 death (0.7%), 2 major strokes (0.7%), 3 minor strokes (1.1%) and 3 vascular complication (1.1%).

Conclusions. In our experience CAS was feasible and efficacy with a low rate of major complications, in agreement with randomized trials and registries, provided that a rigorous learning curve was followed and a CAS volume caseload was maintained.

C3

APPROCCIO BRACHIALE DESTRO PER PTA CAROTIDEE IN SITUAZIONI ANATOMICHE COMPLESSE

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Background. L'approccio attualmente più utilizzato per le procedure di PTA carotidea è sicuramente quello femorale, grazie alla versatilità nelle diverse varianti anatomiche e con i diversi dispositivi per la protezione dall'embolizzazione a disposizione. In presenza di condizioni che controindichino la manipolazione dell'arco aortico, tuttavia, è necessario cercare approcci alternativi.

Case report. Un uomo di 80 anni affetto da una stenosi critica della carotide sinistra si è rivolto al nostro centro nel marzo 2014. Il paziente era stato colpito da un ictus ischemico 3 mesi prima; in tale occasione un intervento di TEA era stato considerato gravato da un rischio operatorio eccessivo per la presenza di BPCO severa (stadio GOLD IV), e il paziente era stato dimesso in terapia medica. In anamnesi venivano segnalati inoltre un IMA nel 1998, trattato con PCI, e l'impianto di un PM per blocco AV completo. Durante il ricovero veniva effettuata una angio-TC, che mostrava una stenosi carotidea bilaterale: 60% ICA destra, near-occlusion di ICA sinistra. L'arco aortico, di tipo I, appariva affetto da diffusa ateromasia calcifica coinvolgente l'origine dei TSA e presentava un grosso trombo aggettante nel lume, distalmente all'ostio della succlavia sinistra. All'analisi del circolo cerebrale si riscontrava inoltre una ipoplasia del tratto A1-ACA sinistro, mentre entrambe le comunicanti posteriori non erano visibili. Per evitare la manipolazione dell'arco aortico ed il conseguente rischio di dislocazione del trombo, si effettuava un approccio dall'arteria brachiale destra con un introduttore 8F. Confermati all'angiografia i dati TC, si avanzava nell'ECA un sistema coassiale (guida JR 6F + catetere MP 4F) montato su un filo idrofilico Terumo da 0.035". Una volta in posizione, il catetere MP 4F veniva rimosso e il filo Terumo sostituito con un filo stiff 0,035". Non riuscendo tuttavia ad avanzare il sistema di protezione prossimale Mo.Ma 8F nella carotide comune, si cercava di aumentarne la rigidità posizionando un secondo filo standard 0.035" nell'ECA e rimuovendo il mandrino; il sistema, caricato sui due fili, veniva così posizionato con successo. La tollerabilità del sistema da parte del paziente, date le anomalie del circolo di Willis, veniva monitorata mediante Doppler trans-cranico. La lesione dell'ICA veniva predilatata con un pallone 2.5 x 30 mm; si procedeva poi ad impianto di uno stent Precise 8 x 40 mm, postdilatato ad alte pressioni. La procedura si concludeva con ottimo risultato finale e in assenza di complicanze; si otteneva emostasi con compressione manuale. Nel corso della successiva degenza il paziente si manteneva asintomatico e veniva dimesso in terza giornata post-procedurale.

Conclusioni. L'approccio brachiale destro costituisce una valida alternativa all'approccio femorale qualora sia necessario evitare la manipolazione dell'arco aortico e sia bensì indispensabile posizionare un sistema di protezione prossimale dell'embolizzazione distale 8F Mo.Ma (come nel caso di "near-occlusion lesions"). In presenza di anomalie del circolo intracranico, la monitorizzazione del flusso col Doppler TC permette di operare in condizioni di sicurezza.

C4

RANDOMIZED COMPARISON OF FLOW REVERSAL VS DISTAL FILTER FOR CEREBRAL PROTECTION DURING CAROTID ARTERY STENTING IN PATIENTS WITH STABLE CAROTID DISEASE

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Hypothesis. Previous studies revealed high incidence (up to 80%) of new asymptomatic cerebral lesion after CAS, with conflicting results comparing proximal protection with filter. Heterogeneity in patient selection, CAS techniques and operators' experience could have biased previous results.
Objectives. To establish if proximal protection with flow reversal, performed by experienced operators in a high volume center, may be more effective than filters in preventing cerebral embolization during CAS in patients with stable carotid disease.
Design and methodology. Patients with internal carotid artery stenosis >70%, without recent (<6 months) ischemic cerebral event, were randomly assigned to CAS with flow reversal (FR) or filter protection (FP)as cerebral embolic protection. Primary endpoint was the incidence of new cerebral ischemic lesions assessed by diffusion-weighted magnetic resonance imaging (MRI). Secondary endpoints were: number and diameter of new ischemic lesions; number of microembolic signals (MES) assessed by bilateral transcranial Doppler monitoring during all phases of the procedure. Major cardiovascular and cerebral events (MACCE) at 30 days were recorded. Expected rate of new cerebral lesion was 50% in FP, 17% in FR (as reported in previous studies); with α 5% and 1-β 80%, sample size was 30 patients per group.
Results. 60 consecutive patients were randomized. No difference in baseline and procedural characteristics were present. Incidence, number and diameter of new cerebral ischemic lesions, as number of MES and 30 days MACCEs were not significantly reduced by FR compared to FP (Table).
Conclusions. This randomized trial of patients with stable severe carotid disease undergoing CAS showed a very low incidence of new ischemic lesions in both groups. FR protection did not significantly reduce cerebral embolization.

	Filter (n=30)	Proximal protection (n=30)	p
Baseline characteristics			
Age (years) (mean±SD)	71.2±1.24	72.1±0.9	0.56
Females, n (%)	6 (20%)	8 (26.6%)	0.76
Coronary artery disease, n (%)	11 (36.6%)	15 (50%)	0.43
High surgical risk, n (%)	10 (33.3%)	12 (40%)	0.78
Target ICA left, n (%)	17 (56.6%)	14 (46.6%)	0.6
Type III arch, n (%)	6 (20%)	9 (30%)	0.55
Target ICA stenosis (mean±SD)	84.4±1.8	85.5±1.6	0.63
Results			
Patients with at least 1 new lesion, n (%)	5 (16.6%)	3 (10%)	0.7
No. new lesions (mean±SEM)	0.4±0.26	0.16±0.1	0.41
Diameter (mean±SEM)	4.83±0.5	6.6±1.6	0.18
New contralateral lesions, n (%)	1 (3.3%)	0	
MES, median (interquartile range)	125 (91-161)	103 (87-185)	0.6
MACCE at 30 days, n (%)	1 (3.3%)	1	1

C5

CAROTID ARTERY STENTING WITH DOUBLE CEREBRAL EMBOLIC PROTECTION IN SYMPTOMATIC PATIENTS

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Aims. Previous trials comparing carotid artery stenting (CAS) with carotid endarterectomy (CEA) demonstrated controversial results, mainly in symptomatic patients, because of higher stroke rate. However, the increase of the experience of the operators, the improvement of the stents and of the embolic protection devices (EPD) has made CAS a highly competitive procedure. In this study we tried to assess the feasibility and the safety of using double EPD (proximal and distal) in high-risk patients.
Methods. We collected data about all consecutive patients with symptomatic or asymptomatic carotid artery stenosis who underwent CAS and analyzed clinical and procedural characteristics as well as immediate and 30-day outcomes. All the procedures were performed after discussion of the cases and after reviewing imaging examination results with neurologists. Neurologic visits and duplex scans were scheduled 24 hours and 1 month after the procedure.
Results. From November 2007 to March 2014, 277 underwent CAS. In 26 of them (9.4%) double EPD was used (distal filter + MoMa, Medtronic, Minneapolis, MN). The whole population was at high cardiovascular risk: 51.9% of the patients had known coronary artery disease, 5.8% congestive heart failure, 41.9% aged ≥75 years. Many patients (48.7%) had a complex plaque (soft, ulcerated, with thrombus). The stent implanted were closed-cell in 64.6%, hybrid in 23.5% and open cell in 11.9%. In comparison with the patients treated with single EPD, those with double EPD presented with a higher rate of complex plaque (100% vs 43.4%, p<0.0001). There was no difference between the 2 groups in primary success (100% vs 96.4%, p=0.16) and in the rate of major complications at 30 days: death (0% vs 0.7%, p=0.45), major stroke (0% vs 0.8%, p=0.45), and minor stroke (0% vs 1.2%, p=0.66).
Conclusions. In our experience, in symptomatic patients with high-risk lesions, the use of double EPD (proximal and distal) is safe and effective in minimizing the risk of cerebral embolization

C6

RISULTATI A LUNGO TERMINE DELLA PTA CON IMPIANTO DI STENT PER IL TRATTAMENTO DELLA STENOSI SINTOMATICA DELL'ARTERIA SUCCLAVIA

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Obiettivo. Obiettivo dello studio è stato quello di valutare i risultati a lungo termine della terapia endovascolare per la stenosi sintomatica dell'arteria succlavia.
Background. È noto dai dati della letteratura che il trattamento delle stenosi sintomatiche dell'arteria succlavia ha un successo sovrapponibile a quello della chirurgia tradizionale ma la pervietà a lungo termine dei vasi trattati con la terapia percutanea non è ancora ben conosciuta.
Metodi. Abbiamo studiato retrospettivamente 90 pazienti (67 uomini ed 33 donne) con 90 lesioni. L'età media dei pazienti era 67 anni. I sintomi clinici erano rappresentati da insufficienza vertebro-basilare (77 pazienti, 85%), claudicatio dell'arto superiore (10 pazienti, 11%), angina pectoris (2 pazienti, 2.2%), severa ischemia dell'arto (1 paziente, 1.1%). Sono stati impiantati un totale di 82 stent e tutti i pazienti sono stati sottoposti a controllo eco-color Doppler con un follow-up medio di 50 mesi.
Risultati. La percentuale di successo tecnico immediato è stata del 95.6%. Il 91.2% dei pazienti trattati ha ricevuto l'impianto di un unico stent e in 4 pazienti (8,8%) è stata eseguita PTA semplice per presenza di gradiente transtenotico <10 mmHg post-dilatazione. Ci sono stati 4 insuccessi dovuti alla impossibilità di ricanalizzare l'arteria cronicamente occlusa (4.4%). Non ci sono state morti legate alla procedura. Non ci sono stati stroke, un TIA (1.1%), nessun evento embolico distale. La pervietà al follow-up a lungo termine è stata del 93.2%, 3 pazienti sono stati sottoposti a re-PTA per restenosi significativa (3.4%) e 3 pazienti sono andati incontro ad occlusione dello stent non più ricanalizzabile per via percutanea (3.4%).
Conclusioni. Il trattamento endovascolare per la malattia steno-occlusiva sintomatica dell'arteria succlavia è un trattamento efficace per quanto riguarda il successo immediato, l'efficacia clinica e la pervietà a distanza del vaso trattato. Questa procedura minimamente invasiva deve essere considerata come trattamento di prima scelta per la malattia ostruttiva sintomatica dell'arteria succlavia.

Mitral valve intervention 1

C7

EXTENDED USE OF PERCUTANEOUS EDGE-TO-EDGE MITRAL VALVE REPAIR BEYOND EVEREST CRITERIA: 30-DAY AND 12-MONTH CLINICAL AND ECHOCARDIOGRAPHIC OUTCOMES FROM THE GRASP REGISTRY

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Objectives. To compare, in high-risk patients with 3+ to 4+ mitral regurgitation (MR) dichotomized by baseline echocardiographic features, acute, 30-day, and 12-month outcomes following percutaneous mitral valve repair utilizing the MitraClip.
Background. The feasibility and mid-term outcomes after MitraClip implantation in patients with echocardiographic features different from the EVEREST (Endovascular Valve Edge-to-Edge Repair) I and II trials have been scarcely studied.
Methods. Clinical and echocardiographic outcomes through 12-month follow-up of consecutive patients whom underwent MitraClip implantation were obtained from an ongoing prospective registry. Two different groups, divided according to baseline echocardiographic criteria [investigational group ($EVEREST_{OFF}$) and control group ($EVEREST_{ON}$)], were compared.
Results. Seventy-eight patients were included in $EVEREST_{OFF}$- and 93 patients in $EVEREST_{ON}$-group. Important and comparable acute reductions in MR and no clip-related complications were revealed. The primary safety endpoint at 30-day was comparable between groups (2.6% vs 6.5%, respectively, p=0.204); in addition, MR reduction was mostly sustained, while equivalent

improvement in NYHA functional class were demonstrated. Kaplan-Meier freedom from death, surgery for mitral valve dysfunction, or grade ≥ 3+ MR at 12 months was demonstrated in 71.4% and 76.2%, respectively in the EVEREST$_{OFF}$ and EVEREST$_{ON}$ groups (log rank p=0.378). Significant improvements in ejection fraction and reduction in left ventricle volumes were demonstrated in both groups over time, but the baseline between-group differences were sustained.

Conclusions. MitraClip implantation in patients with expanded baseline echocardiographic features was associated with similar rates of safety and efficacy through 12-month compared with the control group. Further validation of our findings is warranted.

C8

HISTORY OF ATRIAL FIBRILLATION IN PATIENTS UNDERGOING TRANSCATHETER MITRAL VALVE REPAIR WITH MITRACLIP FOR SIGNIFICANT REGURGITATION: DOES IT MATTER?

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Background. Atrial fibrillation (AF) may impact adversely on mitral valve function. Transcatheter mitral valve repair (TMVR) with MitraClip is considered an acceptable alternative to surgical repair, and the EVEREST II trial has suggested that this holds true even in patients with AF. However, there is uncertainty on the outlook of real-world patients with AF undergoing TMVR.

Methods. We analyzed retrospectively collected data on patients undergoing TMVR at 3 tertiary care centers. Baseline, procedural, and outcome details were systematically sought. Patients were followed after discharge for clinical events and echocardiographic changes.

Results. A total of 74 subjects were included: 38 without AF and 36 with AF (8 paroxysmal, 7 persistent, 21 longstanding or permanent). Patients with AF were similar in baseline, echocardiographic and procedural characteristics, with the notable exception of worse overall functional class (p=0.020). Similarly favorable acute results were obtained in patients with AF and those without AF. However, mid-term follow-up showed that the risk of death or rehospitalizations after successful discharge was higher in patients with AF (33% vs 11%, p=0.023), as well as persistently worse average functional class (p=0.023). Differences were especially pronounced when focusing on patients with longstanding or permanent AF.

Conclusions. Despite similar baseline, echocardiographic and procedural features, patients with AF undergoing TMVR with MitraClip face a higher risk of adverse events during follow-up. Careful follow-up and medical management are thus mandatory in such patients, especially when AF is longstanding or permanent.

C9

PERCUTANEOUS MITRAL VALVE REPAIR WITH THE MITRACLIP SYSTEM FOR SEVERE MITRAL REGURGITATION IN PATIENTS WITH SURGICAL MITRAL VALVE REPAIR FAILURE

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Background. Surgical mitral valve repair (SMVR) is the preferred intervention for patients with either symptomatic severe mitral regurgitation (MR) or with asymptomatic severe MR and left ventricular dysfunction. The rates of freedom from severe MR 10 years after SMVR, however, are reported to be 70%, leading to considerable amount of mitral valve re-interventions, which carry substantial risk, particularly in elderly patients and in those with significant comorbidities. Percutaneous mitral valve repair (PMVR) with the MitraClip system due to its reduced invasiveness compared with conventional surgery, could as well function as a potential alternative to reoperation in patients with SMVR failure.

Objectives. We report, therefore, our initial experience with MitraClip implantation in patients with SMVR (i.e., annuloplasty) failure.

Methods. Between August 2008 and June 2014, a total of 207 consecutive patients who underwent PMVR at our institution were prospectively included in our Getting Reduction of Mitral Insufficiency by Percutaneous Clip Implantation (GRASP) registry. During the study period, PMVR was performed in 7 patients (3.6%) with surgical mitral valve annuloplasty failure. Median interval between SMVR and PMVR was 8 years (range: 5-12 years). One case was performed, though, 7 days after SMVR as a "bail out" procedure for acute surgical failure.

Results. Device success (residual MR ≤2+), was achieved in all patients. Post-procedural MR grade, mean pressure gradient of mitral valve (4.9±0.9 mmHg), and mitral valve area (2.1±0.4 cm^2) were satisfactory. No cases of procedural death, stroke, myocardial infarction, or urgent cardiovascular surgery occurred. Only one patient, in whom PMVR was performed in the acute phase (i.e., 7 days after SMVR), died due to multi-organ failure during hospital stay, thus imparting all-cause and cardiovascular mortality rates of 16.7% and 0%, respectively. Follow-up was available in all the remaining 6 patients (median follow-up period 12 months, range: 3-31 months). All patients but one experienced an improvement of NYHA functional class compared with baseline and maintenance or improvement of MR status compared with post-procedure at follow-up. When our findings are put in perspective with the overall population from the GRASP registry, the mean age and logistic EuroSCORE were significantly higher in patients with vs. without prior SMVR group (74.8±2.8 years versus 71.6±10.2 years, p=0.041, and 19.6±11.7 versus 10.4±10.9, p=0.046, respectively), whereas no significant differences were observed in terms of baseline NYHA functional class and left ventricle ejection fraction (37.0±7.3% vs 36.8±13.2%, p=0.942). All the patients with prior SMVR achieved successful procedures with the implantation of only one clip, which was significantly lower compared to those without prior SMVR (p=0.027). No significant differences were documented regarding device implantation and total fluoroscopy time, as well as length of hospital stay between the groups.

Conclusion. We were able to demonstrate in a preliminary experience the safety and efficacy of PMVR with MitraClip therapy in patients with surgical mitral valve annuloplasty failure.

C10

EFFECTIVENESS OF MITRACLIP THERAPY IN PATIENTS WITH REFRACTORY HEART FAILURE

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Aims. To assess effectiveness of MitraClip therapy in patients with refractory heart failure (HF) and severe mitral regurgitation (MR).

Methods and results. The study population (16 patients, mean age 69±13 years, 75% male) consisted of two groups: 8 patients who were dependent on diuretics and/or inotropic drug infusion and/or IABP (group A) with a mean hospitalization length before the MitraClip procedure of 53±33 days and 8 patients (group B) who were on labile haemodynamic compensation (mean rate of hospitalization, in the last 50 days before the index procedure, of 25±4 days). Acute procedural success was observed in 94% of patients. 86% of group A patients were quickly weaned from pharmacologic and/or mechanical supports (5±3 days from the index procedure) and discharged at 20±10 days. All patients of group B were discharged after 10±8 days from the MitraClip procedure. At 1 year: a) cumulative survival rate was 83%; b) all patients were in NYHA functional class ≤II; c) residual MR ≤2 was observed in 89%; d) systolic pulmonary arterial pressure was significantly reduced compared to the baseline (from 54±10 to 39±8 mmHg; p=0.008); e) a significant reduction in cumulative HF hospitalization days in the post-procedure year (10 days) compared to the pre-implantation year (248 days; p<0.001) was observed.

Conclusions. In patients with refractory HF and severe MR, successful MitraClip implantation resulted in acute and persistent clinical benefit and net reduction in HF rehospitalization.

C11

A MULTICENTER REGISTRY ON THE RISK-BENEFIT BALANCE OF AVANTGARDE CARBOFILM-COATED STENT IN REAL-WORLD PATIENTS AT HIGH RISK FOR EARLY DISCONTINUATION OF DUAL ANTIPLATELET THERAPY UNDERGOING PERCUTANEOUS CORONARY INTERVENTION: FOCUS ON DIABETIC STATUS

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Objective. We aimed to appraise the risk benefit-balance of the Avantgarde Carbofilm-coated stent in patients undergoing percutaneous coronary intervention (PCI) at high risk for premature dual antiplatelet therapy (DAPT) discontinuation.

Background. Carbofilm coating may increase the biocompatibility of coronary stents, but their risk-benefit balance according to diabetic status remains unclear.

Methods. Patients underwent PCI with the Avantgarde Carbofilm-coated stent and judged by the caring physician at high risk of premature DAPT interruption were retrospectively identified. Subjects were distinguished in 3 groups: non-diabetic (ND), non-insulin-dependent diabetic (NIDDM), and insulin-dependent diabetic (IDDM). Outcomes of interest were major adverse cardiac events (MACE), and their individual components.

Results. A total of 619 patients were included: 490 (79.2%) in the ND group, 95 (15.3%) in the NIDDM group, and 33 (5.3%) IDDM group. After 15±7 months, MACE occurred in 6.9% in the ND group, 17.9% in the NIDDM group, and 21.2% in the IDDM group (p<0.001), with similarly trends for death and cardiac death (all p<0.05). Multivariable analysis confirmed that those in the ND group were at lower risk than those in the NIDDM group for MACE and death (p=0.020 and p=0.005, respectively).
Conclusion. The Avantgarde Carbofilm-coated stent appears associated with favorable results in patients undergoing PCI and judged at high risk of premature DAPT withdrawal, especially those without diabetes mellitus.

C12

COMPARISON OF MEN VERSUS WOMEN WITH SIGNIFICANT MITRAL REGURGITATION UNDERGOING TRANSCATHETER MITRAL VALVE REPAIR WITH MITRACLIP

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Transcatheter mitral valve repair (TMVR) with MitraClip is being used with increasing popularity for significant mitral regurgitation and suitable valve anatomy. Whether there are differences in baseline, procedural, or outcome data in men versus women undergoing this procedure is uncertain. We thus analyzed retrospectively collected data on patients undergoing TMVR at 3 tertiary care centers. Baseline, procedural, and outcome details were systematically sought. Patients were followed after discharge for clinical events and echocardiographic changes. A total of 84 subjects were included: 39 (46%) males and 45 (54%) females. Women and men had significant differences in age, height, body surface area, prevalence of coronary artery disease, chronic obstructive pulmonary disease, receipt of implantable cardioverter-defibrillators, and systolic dysfunction. Despite this, procedural success was similarly high in both genders, with only one procedural failure in a man. Echocardiographic follow-up showed persistent improvement in mitral regurgitation in 38 (98%) males and 45 females (100%, p=0.464), with similarly significant reductions in vena contracta (within-subject p<0.001, between-subject p=0.728), effective regurgitant orifice area (within-subject p<0.001, between-subject p=0.884), and systolic pulmonary artery pressure (within-subject p<0.001, between-subject p=0.282). Clinical outcomes at 12-month follow-up were also not different in males versus females, with 4 (10%) deaths in men and 11 (24%) in women (p=0.152). Sensitivity analyses limited to propensity score matched pairs confirmed the similar procedural, echocardiographic and clinical outlook in men and women (all p>0.05). In conclusion, males and females with significant mitral regurgitation and established indications to TMVR with MitraClip appear to equally benefit from this procedure.

PCI – Patient subsets

C13

NEI PAZIENTI CON SINDROME CORONARICA ACUTA SOTTOPOSTI A PCI L'ANEMIA ACQUISITA HA UN VALORE PROGNOSTICO?

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Background. Nell'ambito delle sindromi coronariche acute oltre alla trombocitopenia anche l'anemia, sia di base che post-procedurale, è stata correlata ad un aumento della mortalità, oltre che di eventi avversi (MACE), quindi con l'ischemia miocardica. Tuttavia ad oggi non esiste una definizione univoca di anemia. L'anemia post-PCI (PPA) è stata definita da Sattur come nadir di emoglobina (Hb) ≤10 g/dl dopo PCI, in linea con la pratica clinica di trasfondere con questi valori. Nel recente lavoro di Schiariti et al. che ha analizzato il ruolo della trombocitopenia (TC) post-PCI sugli outcome ischemici a lungo termine si è visto che il contropulsatore aortico (IABP) potrebbe svolgere un ruolo da protagonista nascosto. Pertanto lo scopo di questo studio è valutare l'effetto sugli outcome ischemici a lungo termine di un altro parametro laboratoristico, ovvero dell'anemia.
Metodi. Prima di tutto la PPA è stata definita come la riduzione in termini relativi del numero di globuli rossi (GR) ≥15% rispetto al valore basale e la TC acquisita come il calo relativo ≥25% del numero di piastrine rispetto al basale. Sono stati esaminati 873 pazienti, un sottogruppo del SANTISS (Sant'Anna Tirofiban Safety Study, www.clinicaltrials.gov Identifier: NCT00566892) e suddivisi in quattro gruppi: Gruppo 1= pazienti non anemici e non trombocitopenici (n=641; 73.68%); Gruppo 2= non trombocitopenici e anemici (n=121; 13.91%); Gruppo 3= trombocitopenici e non anemici (n= 47; 5.40%); Gruppo 4= trombocitopenici ed anemici (n= 61; 7.01%). L'analisi univariata inter-gruppo ha esaminato la correlazione tra le due variabili ed il rischio di eventi avversi. Sono state inoltre effettuate le curve di Kaplan-Meier. Infine con la Cox forzata è stato analizzato il valore predittivo di outcome ischemici delle diverse variabili.
Risultati. L'analisi univariata ha mostrato l'importanza dell'anemia in quanto l'incidenza di MACE ad un anno era significativamente aumentata non solo nei pazienti anemici e trombocitopenici rispetto ai non anemici e non trombocitopenici [Gruppo 1 vs Gruppo 4 hazard ratio (HR)=3.45 con intervallo di confidenza (IC)= 1.46-8.15 e Gruppo 4 vs Gruppo 1 HR=0.29 con IC=0.23-0.68], ma anche nei pazienti anemici rispetto ai non-anemici e non-trombocitopenici (Gruppo 1 vs Gruppo 2 HR=2.47 con IC= 1.33-4.59 and Gruppo 2 vs Gruppo 1 HR=0.40 con IC=0.22-0.75). Volendo esaminare quale variabile fosse realmente predittiva di eventi avversi è stata effettuata una Cox forzata includendo sia l'anemia che le trombocitopenia post-PCI: solo l'anemia correlava significativamente con gli outcome ischemici. Inoltre analogamente ai risultati di Schiariti lo IABP aveva un ruolo prognostico predittivo (p=0.0015), così come l'età (p=0.0036) e l'ipertensione.
Conclusioni. Sembra che l'anemia "assorba" completamente il valore predittivo di outcome ischemici della trombocitopenia. Questo è il primo studio che definisce l'anemia post-PCI in termini relativi, assumendo un cut-off matematicamente calcolato pari al 15%. Questi risultati potrebbero essere di una certa rilevanza clinica nell'individuazione, all'interno delle sindromi coronariche acute, di una popolazione ad alto rischio.

C14

COMPARISON OF RISK OF ACUTE KIDNEY INJURY FOLLOWING PRIMARY PERCUTANEOUS CORONARY INTERVENTIONS WITH THE TRANSRADIAL APPROACH VS THE TRANSFEMORAL APPROACH (FROM THE PRIPITENA URBAN REGISTRY)

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The risk of acute kidney injury (AKI) is a major issue after percutaneous coronary interventions (PCI), especially in the setting of ST-elevation myocardial infarction. Preliminary data from large retrospective registries seem to show a reduction of AKI when a transradial (TR) approach for PCI is adopted. Little is known about the relation between vascular access and AKI after emergent PCI. We here report the results of the PRIPITENA, a retrospective database of primary PCI performed at high volume centers in the urban areas of Rome and Milan. Primary endpoint of this study was the occurrence of AKI in the TR and transfemoral (TF) access site groups. Secondary endpoints were major adverse cardiovascular events (MACE), stent thrombosis and Thrombolysis in Myocardial Infarction (TIMI) major and minor bleedings. The database included 1330 patients, 836 treated with a TR and 494 with a TF approach. After a propensity matched analysis performed to exclude possible confounders, we identified 450 matched patients (225 TR and 225 TF). The incidence of AKI in the 2 matched groups was lower in patients treated with TR primary PCI (8.4% vs 16.9%, p=0.007). MACE and stent thrombosis were not different among study groups, whereas major bleedings were more often seen in the TF group. At multivariate analysis, femoral access was an independent predictor of AKI (OR 1.654, 95% CI 1.084-2.524, p=0.042). In conclusion, in this database of primary PCI, the risk of AKI was lower with a TR approach and the TF approach was an independent predictor for the occurrence of this complication.

C15

REMOTE ISCHEMIC PRECONDITIONING AND RISK OF CONTRAST-INDUCED NEPHROPATHY AFTER PERCUTANEOUS CORONARY INTERVENTION: THE EURO-ASIA CRIPS RANDOMIZED CONTROLLED TRIAL

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Aims. The potential protective effect of remote ischemic preconditioning (RIPC) on contrast-induced nephropathy (CIN) after percutaneous coronary intervention (PCI) remains to be defined.
Methods. A double-blind, randomized, placebo controlled multicenter study was performed. Patients were allocated 1: 1 to RIPC or standard therapy if they are younger than 85 years old, with a renal clearance in the interval 30-60 ml/min/1.73 m^2 and candidate to PCI for all clinical indications except for primary PCI in ST segment elevation myocardial infarction (STEMI). Incidence

of CIN was the primary endpoint, whilst incidence of periprocedural myocardial infarction the secondary one. Diabetes mellitus was the only pre-specified analysis.
Results. From February 2013 to April 2014, a total of 3108 patients scheduled for angiography were screened. 442 fulfilled the inclusion criteria, 223 received PCI and were randomized to sham RIPC (n=107) or treatment group (n=116). The only pre-specified subgroup of diabetic patients presented 88 (38%) cases. RIPC significantly reduced AKI incidence in the overall population (12.1% vs 26.1%, p=0.01, with a number needed to treat 9), in non diabetic patients (9.2% vs 25.0%, p=0.02) whilst diabetic subgroup showed no benefit (16.7% vs 28.2%, p=0.21). A trend, although not significant, was reported for periprocedural myocardial infarction (8.4% vs 16.4%, p=0.07).
Conclusions. Remote ischemic preconditioning significantly reduces the incidence of CIN in non diabetic patients undergoing PCI. Larger studies are needed for patients with diabetes mellitus.

C16

IL VALORE PROGNOSTICO A LUNGO TERMINE DELLA TROMBOCITOPENIA POST-PCI NEGLI OTTUAGENARI

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Background. La trombocitopenia post-PCI è un ormai noto fattore predittivo di eventi avversi ischemici ed emorragici. Si comprendono quindi le cautele in pratica clinica non solo nell'impiego di nuovi farmaci ma anche di strategie invasive precoci negli anziani, che di per sé hanno valori di piastrine più bassi. Infatti se da un lato l'eparina, gli inibitori delle glicoproteine e il contropulsatore aortico migliorano gli outcome, dall'altro possono essere essi stessi causa della riduzione del numero di piastrine. Il fine di questo studio è di definire il ruolo della trombocitopenia post-PCI negli ottuagenari e di determinare se questa stessa influisca sull'incidenza di eventi avversi ad un anno così come nella popolazione più giovane.
Metodi. In questo studio sono stati presi in considerazione 873 pazienti, un sottogruppo del SANTISS (Sant'Anna Tirofiban Safety Study, www.clinicaltrials.gov Identifier: NCT00566892). Questi sono stati divisi prima di tutto in due gruppi: ottuagenari (n=55) e non ottuagenari (n=818) ed è stata effettuata un'analisi di varianza (ANOVA) per definire le differenze tra i gruppi. In base alla presenza o meno di trombocitopenia post-PCI (riduzione relativa del numero di piastrine ≥25%) sono stati ottenuti quattro gruppi: Gruppo 1= pazienti non trombocitopenici e non ottuagenari (n=718); Gruppo 2= pazienti trombocitopenici e non ottuagenari (n=100); Gruppo 3= pazienti non trombocitopenici e ottuagenari (n=47); Gruppo 4= pazienti trombocitopenici ed ottuagenari (n=8). Infine con un approccio univariato sono state effettuate le curve di Kaplan-Meier per la valutazione della diversa incidenza inter-gruppo di eventi ischemici compositi ad un anno, definiti come morte cardiaca, angina, trombosi acuta dello stent o necessità di ripetere la PCI o di effettuare intervento cardiochirurgico.
Risultati. Gli ottuagenari erano più frequentemente donne con insufficienza renale cronica e diabete mellito insulino-dipendente, livelli più bassi di globuli rossi ed emoglobina. Meno frequentemente erano sottoposti a PCI rescue, somministrazione di trombolitici e di inibitori della GPIIb/IIIa. Inoltre questo gruppo presentava un esordio significativamente più precoce ed una maggiore incidenza di morte (10.90% vs 2.32%; p=0.001), eventi ischemici (23.63% vs 9.41%; p=0.001) ed emorragici (7.27% vs 2.32%; p=0.05). L'analisi univariata ha evidenziato che la trombocitopenia correlava con l'incidenza di eventi ischemici solo nella popolazione di non ottuagenari [Gruppo 1 vs Gruppo 2 hazard ratio (HR)=1.36 intervallo di confidenza (IC)=1.21-4.61]. D'altra parte l'età era un fattore predittivo di eventi ischemici nel setting della popolazione di non trombocitopenici [Gruppo 1 vs Gruppo 3 HR=3.09 con IC= 1.20-7.98].
Conclusioni. A differenza della popolazione più giovane la trombocitopenia post-PCI non sembra essere correlata agli outcome ischemici a lungo termine negli ottuagenari. Non è chiaro se ciò possa essere riconducibile alla presenza di fattori maggiormente influenti sul più elevato tasso di mortalità, ovvero le comorbidità, oppure sia dovuto al trattamento meno aggressivo di questi pazienti nell'ambito delle sindromi coronariche acute.

C17

ESPOSIZIONE RADIOLOGICA NELLE PROCEDURE DIAGNOSTICHE ED INTERVENTISTICHE CORONARICHE: CONFRONTO TRA ACCESSO RADIALE DESTRO E SINISTRO

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Introduzione. Rispetto all'accesso femorale (AF), l'accesso radiale (AR) è caratterizzato da una minore incidenza di complicanze vascolari e di sanguinamenti. La maggiore difficoltà nella manipolazione dei cateteri può tuttavia tradursi in un incremento dei tempi di fluoroscopia e, di conseguenza, della dose di radiazioni. Benché l'AR destro sia di gran lunga il più diffuso, in quanto giudicato più comodo dalla maggior parte degli operatori, nell'AR sinistro il decorso dei cateteri è più simile all'AF, consentendo una manipolazione più semplice dei cateteri che potrebbe tradursi in una riduzione dei tempi di fluoroscopia. Obiettivo di questo studio è stato confrontare l'esposizione alle radiazioni, misurata con il Dose Area Product (DAP), in procedure eseguite tramite AR destro e sinistro in un Laboratorio a prevalente impiego di AR.
Metodi. Abbiamo retrospettivamente selezionato le procedure coronariche diagnostiche ed interventistiche (PCI) eseguite nel nostro Laboratorio nell'arco di cinque anni (2009-2014), includendo nell'analisi solo le procedure in cui fossero disponibili l'indice di massa corporea (BMI) del paziente, il tempo di fluoroscopia (TF) ed il DAP; abbiamo escluso gli studi di bypass, che generalmente eseguiamo con AR sinistro per lo studio dei bypass in arteria mammaria omolaterale. Abbiamo eseguito sia un propensity score matching che un'analisi multivariata allo scopo di aggiustare per i fattori confondenti clinici e procedurali, prendendo in considerazione età, BMI, genere, presentazione clinica (sindrome coronarica acuta o meno), tipo di PCI (primaria, *ad hoc*, multivasale), numero di stents impiantati, utilizzo di contropulsatore aortico ed operatore che eseguiva la procedura.
Risultati. Sono state analizzate 1464 procedure, 1175 delle quali eseguite tramite AR destro (Dx: 80.2%) e le rimanenti 289 tramite AR sinistro (Sx: 19.8%). I pazienti del gruppo Sx erano più anziani (68.5±12.1 vs 64.7±11.9; p<0.01) e sono stati più spesso sottoposti a PCI (53.6 vs 45.8; p<0.05), anche se meno spesso a PCI primaria (8.7 vs 14.5; p<0.01) rispetto ai pazienti del gruppo Dx. I valori mediani di DAP erano significativamente più elevati nel gruppo Dx rispetto al gruppo Sx sia per le procedure diagnostiche che per le procedure interventistiche (4482 vs 3540 cGy.cm^2 and 11523 vs 10086 cGy.cm^2, rispettivamente; p<0.05); non abbiamo invece osservato differenze significative nel TF e nel volume di contrasto. Tuttavia, nella popolazione matched, costituita da 269 procedure per ciascun gruppo, non abbiamo osservato differenze significative nei valori di DAP tra Dx e Sx (3990 vs 3542 cGy.cm^2 and 9964 vs 10216 cGy.cm^2, rispettivamente; p=NS). All'analisi multivariata abbiamo identificato i seguenti predittori indipendenti di DAP: età, BMI, genere maschile, procedura di PCI, numero di stent impiantati, operatore e diagnosi di sindrome coronarica acuta; il lato dell'AR, invece, non è risultato essere associato alla DAP.
Conclusioni. In un centro radiale a prevalenza di AR destro, l'AR sinistro non risulta associato ad una riduzione dell'esposizione alle radiazioni, del tempo di fluoroscopia o del volume di contrasto se paragonato all'AR destro.

C18

ADVANCED AGE AND RENAL DYSFUNCTION IN INTERVENTIONAL CARDIOLOGY: WHAT SHOULD WE DO?

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Background. Coronary angiography is often complicated by contrast media induced nephropathy (CIN) resulting in permanent renal dysfunction or restoration of normal renal function. This problem is more relevant in elderly patients with severe renal dysfunction.
Purpose. The aim of the study was to evaluate the incidence of CIN in patients with age over 80 years, with estimated glomerular filtration rate (eGFR) of less than 60 ml/min/1.73 m^2, undergoing coronary angiography or angioplasty with iobitridol, a water-soluble, non-ionic, monomeric, low-osmolar, iodine-based contrast medium.
Materials and methods. 260 consecutive patients with eGFR <60 ml/min have been enrolled; 48% were males, mean age 81.8 years and incidence of diabetes mellitus was 59%. All the pts were hydrated with 1 ml/kg/h of saline (0.45%) or 0.5 ml/kg/h for pts with left ventricular ejection fraction <45% before and after contrast media administration (mean volume was 111.11 ml). CIN was defined as an increase in serum creatinine level >25% after 48 hours. One way ANOVA test was used to determine differences between variables.
Results. Baseline eGFR was 38.9±9.57 ml/min/1.73 m^2, after 24 hour was 39.85±9.4 ml/min/1.73 m^2 (p=NS), after 48 hours was 37.17±9.25 ml/min/1.73 m^2 (p=NS); the incidence of CIN was significantly higher in those patients (42, 16.15%) with eGFR <40 ml/min/1.73 m^2 (p<0.001), but none of these pts was treated with hemodialysis.
Conclusion. In high risk patients with advanced age and renal dysfunction, the incidence of CIN after iobitridol administration was low, but always without need of hemodialytic treatment. The incidence of CIN in patients over 80 supports the use of hydration and the use of a low-osmolality contrast medium as a preventive measure in this high risk patients. Caution in administration of contrast medium is necessary in elderly pts with eGFR <40 ml/min/1.73 m^2, particularly during interventional procedures.

C19

HIGH PREVALENCE AT COMPUTED CORONARY TOMOGRAPHY OF NON-CALCIFIED PLAQUES IN ASYMPTOMATIC HIV PATIENTS TREATED WITH HAART

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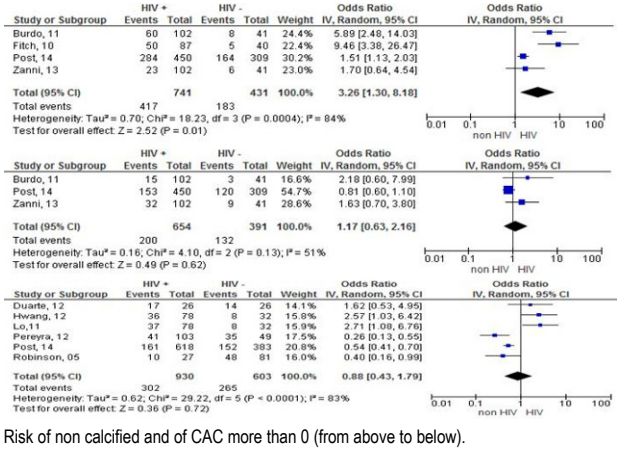
Introduction. Prevalence and features of coronary plaques in HIV asymptomatic patients remain to be determined.

Methods. PubMed, Cochrane and Google Scholar were searched for articles evaluating asymptomatic HIV patients evaluated with coronary computed tomography. The primary end point was prevalence of coronary stenosis (more than 30%), while prevalence of coronary stenosis (more than 50%), of calcified coronary (CCP), non-calcified coronary plaques (NCP) and of Coronary Artery Calcification Score (CAC) more than 0 were the secondary ones.

Results. 9 studies with 1229 HIV patients and 1029 controls were included. HIV patients were more frequently of male gender, with higher rates of diabetes mellitus and of hypertension (although not significant). Prevalence of significant coronary stenosis (>30%) did not differ between HIV+ and HIV- patients [42% (37-44) and 46% (35-52) with an odds ratio (OR) of 1.38 (0.86-2.20)]. Similarly prevalence of coronary stenosis above 50% (15% 9-21 and 14% 7-22 with an OR of 1.11 [0.81-1.52]), of CCP (31% 24-32 and 21% 14-30 with an OR of 1.17 [0.63-2.16] and of CAC above zero (43% 39-48 and 46 26-56 with an OR of 0.88 [0.43-1.79] did not differ among HIV+ and HIV- patients. On the contrary rates of NCP were significantly higher in HIV-positive patients [58% (48-60) and 17% (14-27) with an OR of 3.26 (1-30-8.18)], with an inverse relationship with Cd4 cell count at meta-regression (Beta -0.20, -0.35-0.18, p=0.04).

Conclusion. Asymptomatic HIV patients present with higher rates of non-calcific coronary plaques at computed tomography, especially those with low CD4 cell counts.



Risk of non calcified and of CAC more than 0 (from above to below).

C20

CONFRONTO TRA ACCESSO RADIALE E ACCESSO FEMORALE CON UTILIZZO SISTEMATICO DEL DISPOSITIVO DI EMOSTASI FEMOSEAL™ NELL'ANGIOPLASTICA PRIMARIA

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Introduzione. L'accesso radiale (AR) è in grado di ridurre i sanguinamenti legati al sito di puntura rispetto all'accesso femorale (AF). Nonostante il rischio di sanguinamento femorale possa essere ridotto dall'utilizzo di dispositivi di emostasi (VCD), esistono limitati dati di confronto tra AR e AF con VCD, soprattutto in pazienti ad alto rischio di sanguinamento come quelli sottoposti ad angioplastica primaria (pPCI). Il FemoSeal™ è un dispositivo composto da due dischi di polimero riassorbibile il cui utilizzo è associato ad una ridotta incidenza di sanguinamenti legati all'accesso e di complicanze vascolari. Scopo del nostro studio è stato paragonare l'incidenza di sanguinamenti, definiti secondo la classificazione TIMI, e di eventi cardiovascolari maggiori (MACCE) intraospedalieri in una popolazione di pazienti sottoposti a pPCI tramite AR o AF con FemoSeal™.

Metodi. In questo studio osservazionale, retrospettivo, abbiamo arruolato 777 pazienti sottoposti a pPCI presso due Centri ad alto volume nel quadriennio 2010-2013. Abbiamo escluso i pazienti sottoposti anche ad impianto di contropulsatore aortico e quelli in cui l'emostasi femorale era ottenuta con sistemi diversi dal FemoSeal™. La popolazione è stata divisa in pazienti trattati mediante AR, arruolati nel Centro A (Gruppo 1, n=511) e pazienti trattati mediante AF, arruolati nel Centro B (Gruppo 2, n=266). Abbiamo eseguito un'analisi multivariata ed un propensity-score matching allo scopo di correggere per i fattori confondenti clinici e procedurali.

Risultati. I due gruppi sono risultati sovrapponibili per le caratteristiche cliniche di base, ad eccezione di una maggiore prevalenza di dislipidemia e storia familiare nel Gruppo 2. Abbiamo riscontrato una maggior percentuale di flusso TIMI 3 finale e di stenting diretto nel gruppo 2 (96.2% vs 90.6% e 60.6% vs 30.1%, rispettivamente; p<0.05); abbiamo invece osservato un maggior utilizzo di tromboaspirazione e di bivalirudina nel Gruppo 1 (42.3% vs 30.5% e 27.4% vs 0.0%; p<0.01). L'incidenza complessiva di sanguinamenti è risultata maggiore nel Gruppo 2 (5.6% vs 2.1%; p<0.05) ed era dovuta ad una differenza nei TIMI major (2.3% vs 0.2%; p<0.01). Non abbiamo, invece, osservato differenze significative nell'incidenza di MACCE (3.4% vs 3.5%; p=0.9). Risultati analoghi sono stati osservati anche nella popolazione "propensity-matched", costituita da 229 pazienti per gruppo; l'incidenza complessiva di sanguinamenti è risultata maggiore nel Gruppo 2 (6.6% vs 1.3%; p<0.05), anche in questo caso dovuta ad una differenza nei TIMI major (2.6% vs 0.0%; p<0.05), mentre l'incidenza di MACCE era paragonabile nei due gruppi (2.6% vs 4.4%; p=0.44). All'analisi multivariata abbiamo identificato i seguenti predittori di sanguinamento: accesso femorale (OR 3.2, 95% CI 1.3-7.5), utilizzo di inibitori del recettore GP IIb/IIIa (OR 3.6, 95% CI 1.5-8.7) e frequenza cardiaca alla presentazione (OR 1.04, 95% CI 1.02-1.07).

Conclusioni. Nella pPCI il tasso di sanguinamenti TIMI major è risultato più elevato nell'AF con emostasi mediante FemoSeal™ rispetto all'AR, mentre il tasso di sanguinamenti TIMI minor e di MACCE è risultato simile.

C21

ONE YEAR FOLLOW-UP AFTER PERCUTANEOUS CORONARY INTERVENTION WITH RADIAL APPROACH IN A POPULATION OLDER THAN 84 YEARS HOSPITALIZED FOR ACUTE CORONARY SYNDROME: A SINGLE CENTER EXPERIENCE

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Aims. The proportion of elderly population in the pts admitted for ACS is growing. There is evidence that the age is one of the most predictors of adverse outcomes. The benefit of percutaneous coronary revascularization in very old pts has been poorly investigated.

Methods and results**.** 133 pts ≥84 years with ACS underwent PCI (10% of the ACS population admitted). 57.1% were female. The mean age was 87.2 years (SD 2.3 years); 10.5% were ≥90 years old. 63.2% of the pts were admitted for STEMI, 36.8% for NSTEMI. The radial access was performed in 60.9% of the pts, with a percentage increase from year to year (2007: 0.0%, 2008: 7.1%, 2009: 35.7%, 2010: 56.5%, 2011: 69.6%, 2012: 87.0%, 2013: 92.9%). No radial access site complications occurred. The success rate of the procedure was 95%. The arterial shift from radial to femoral was 2%. The culprit vessel was: 3% unprotected LM, 44% LAD, 31% RCA, 20% circumflex, 1% intermediate, 1% SVG. In 10.5% of pts we performed a PCI without stent. The number of stent per pt was 1.27. The percentage of DES was 7.4%. The use of glycoprotein IIb/IIIa inhibitors was 2%. Major bleeding, major stroke, and need for dialysis were respectively <2%, <1%, <1%. The in-hospital mortality was 14.3% (21.4% for STEMI and 2.0% for NSTEMI). The cumulative 6 month mortality was 22.6% (32.1% for STEMI and 6.1% for NSTEMI); after hospital discharge (n=114) was 9.6%. The cumulative 1-year mortality was 33.8% (44.1% for STEMI and 16.3% for NSTEMI); after hospital discharge (n=114) was 22.8%. Pts treated on LAD showed a higher mortality proportion (32.8% vs 14.7%, χ^2=6.1, p<0.05).

Conclusions. In our experience the percutaneous coronary revascularization strategy in elderly pts is feasible. The transradial artery approach for treatment of elderly patients ≥84 years with ACS are safe with high success rate. This approach can improve safety and patient comfort. The cumulative mortality at 6 and 12 months was 22.6% and 33.8%, respectively.

Structural interventions

C22

EFFECTIVENESS OF PERCUTANEOUS PFO CLOSURE ON RECURRENCE OF CEREBRAL ISCHEMIC EVENTS IN HIGH SELECTED PATIENTS: A LONG-TERM OUTCOME MULTICENTRE STUDY

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Objectives. To determine long-term outcomes in a population underwent percutaneous closure of patent foramen ovale (PFO) for secondary prevention of ischemic cryptogenic stroke (CS).

Background. Despite a clear superiority of percutaneous closure of PFO versus lifelong medical therapy, demonstrated in several series, randomised controlled trials (RCTs) and the subsequent meta-analyses showed conflicting results.

Materials and methods. From January 2000 to December 2013, 457 consecutive patients underwent percutaneous PFO closure were prospectively

registered. Primary outcome were recurrent ischemic cerebral accidents (CVAs).

Results. All patients with a mean age or 49 years, presented with at least one ischemic cerebral lesion MRI/CT documented, more frequently with strokes (55.3%), followed by TIAs (39.8%) and a small percentage of silent brain ischemia (4.8%); 23.7% of them were recurrent events. 56% of patients had a severe basal shunt, 76% had none or one cardiovascular risk factors, 37% had atrial septal aneurism (ASA) and 23% embryonic residua associated with PFO. Prevalent PFO morphology was tunnel PFO, with long tunnelisation (15.4±4 mm). Percutaneous closure of PFO was immediately successful in 99.3% of patients. After long term follow-up (mean 5 years, from 6 months to 14 years), recurrent CVAs occurred in 7 patients (1.5%): 5 strokes and 2 TIAs. Three deaths (0.6%) occurred, not for cardiovascular causes. 0.6% patients were lost at follow-up. 12 (2.6%) patients developed AF at follow-up.

Conclusions. Percutaneous closure of PFO is a safe and effective procedure in secondary stroke prevention in a high selected population presenting with high risk characteristics.

C23

TRANSCATHETER LEFT ATRIAL APPENDAGE CLOSURE WITH THE AMPLATZER CARDIAC PLUG DEVICE FOR ISCHEMIC STROKE PREVENTION IN PATIENTS WITH ATRIAL FIBRILLATION: A SINGLE CENTER EXPERIENCE

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Background. Stroke prevention in patients with atrial fibrillation (AF) is largely based on the use of oral anticoagulants. A significant proportion of patients with atrial fibrillation do not receive anticoagulation due to relative or absolute contraindications, oral anticoagulants failure in stroke prevention or patient reluctance. The left atrial appendage (LAA) percutaneous closure has been demonstrated to be a safe and feasible approach for those patients. The aim of our study is to evaluate the clinical and procedural outcomes in patients undergoing percutaneous LAA closure with the Amplatzer Cardiac Plug (ACP) device.

Methods. This was a prospective single-center study of consecutive patients undergoing percutaneous LAA closure with the ACP device. All patients had a high risk for stroke and bleedings. Stroke risk assessment was performed with the CHA_2DS_2-VASc score and the bleeding risk was estimated with the HAS-BLED score. The procedure was performed through a transseptal access under fluoroscopic and trans-esophageal echocardiography guidance. Clinical and imaging (transthoracic or transesophageal echocardiography, or CT scan) follow-up was performed at 1, 6 and 12 months.

Results. Between May 2011 and May 2014, LAA occlusion was attempted in 22 patients (13 males, median age 75 [range 71-79]) with AF. All patients were at high risk for cardioembolic stroke (median CHA_2DS_2-VASc score 5 [range 3-6]) and for bleeding (median HAS-BLED 4 [range 3-4]). The APC was successfully implanted in all patients. The anatomical features of the LAA included a LAA median diameter of 21 mm [range 18.5-23] and a median landing zone length of 21 mm [range 19-24]. The ACP size most frequently used was 24 mm. The median procedural duration was 75 minutes [range 60-91] with a median fluoroscopic time of 15 min [range 13-19]. The median length of stay after the procedure was 2 days [range 2-3]. There were two in-hospital events: a cardiac tamponade successfully treated with pericardiocentesis the day after the procedure and a peri-procedural ischemic stroke (the second patient undergoing LAA percutaneous closure in our experience). The median follow-up was of 252 days [range 60-465]. Two patients died for heart failure not related to the device implantation. The estimated annual stroke risk based on the CHA_2DS_2-VASc score was 6.7% while the observed rate of ischemic stroke was 4.5% at the follow-up. In regards to major bleeding: TIMI rate was 0%, BARC 3a rate was 9%, HAS-BLED rate was 9%.

Conclusions. Percutaneous closure of LAA with ACP seems to be safe and effective to prevent stroke in patients with AF at high risk for stroke and bleeding, who do not receive oral anticoagulant therapy. The observed stroke rate after percutaneous LAA closure in this series seems to be lower than predicted by baseline CHA_2DS_2-VASc.

C24

ARE LEFT ATRIAL APPENDAGE (LAA) DIMENSIONS OR DEVICE OVERSIZE PREDICTORS OF LEAK AFTER PERCUTANEOUS LAA CLOSURE?

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Purpose. Percutaneous left atrial appendage (LAA) closure is recently emerging as an interesting tool in preventive embolic risk in patients with atrial fibrillation and contraindication or at high risk for anticoagulation therapy. Incomplete LAA occlusion may occur in up to 40% of cases during follow-up but its clinical impact is still debated. Aim of this study is to evaluate the possible correlation between the LAA dimension and the presence of follow-up leaks.

Methods. Between August 2010 and January 2014, consecutive patients that underwent LAA closure procedure in our Institute were enrolled. At baseline, all the patients were evaluated clinically, as well as with transthoracic and transesophageal echocardiography: in order to guide the correct device sizing, LAA diameter and depth have been assessed by TEE measurements, taken in the mid-esophageal views at 0-30°, 45-60°, 90° and 120°. Two months after the procedure outpatient transesophageal examination was planned in order to identify peri-device leaks. Primary end point was to determine whether the size of the LAA ostium or the device oversize were predictors of leaks.

Results. 52 consecutive patients were enrolled (65% male; mean age 70.5±8.7 years; mean LVEF 50±8%; mean CHA_2DS_2-VASc and HAS-BLED scores 3±1.6 and 3±1.1, respectively). Mean LAA ostium diameter and depth were 19.9±3.4 mm and 28.8±5.4 mm, respectively; both available devices were used: chosen devices had a median size of 24 mm, with a mean oversize of 4.2±3 mm in relation to the largest TEE diameter. Out of 52 patients, we analysed 39 TEE follow-up: 16 (41%) peri-device leaks were detected: three type 1, six type 2, five type 3; two type 4. The total procedural success, defined as the presence of a leak <3 mm, was achieved in 30 (77%) cases. No statistical significant difference was noted in mean LAA maximum diameter, mean device dimension, mean device oversizing between patients with follow-up leaks and patients without (20.9 vs 19.6 mm, 24 vs 24 mm, 3.4 vs 4.5 mm, respectively) or in chosen device type.

Conclusions. LAA closure procedure is becoming an interesting procedure, safe and effective, for thromboembolic prevention in atrial fibrillation patients. The rate of follow-up leaks in our Institute is comparable with previous data and it seems not to be related to LAA dimensions or device oversizing. Possible predictors may be the shape of the landing zone or other technical aspects that must be further investigated.

C25

THE LEVEL OF RIGHT-TO-LEFT SHUNT IS CORRELATED WITH MIGRAINE SEVERITY AND PREDICTS RELIEF OF SYMPTOMS BY ANTIPLATELET THERAPY IN PATIENTS UNDERGOING PERCUTANEOUS PATENT FORAMEN OVALE CLOSURE

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It is known that there is a relationship between migraine with aura (MWA) and patent foramen ovale (PFO). A definite mechanism has never been demonstrated. However, a hypothetical link between paradoxical embolism in the arterial circulation and both MWA and PFO-related stroke has been proposed.

Methods. 60 patients affected from migraine and candidate to percutaneous PFO closure because of at least two cerebral ischemic events, were included in the study (mean age 39.6±3.1 years). PFO was diagnosed by transcranial Doppler (TCD) and transthoracic echocardiography (TTE) with an agitated saline test. Patients were divided into three subgroups according to right to left shunt (RLS) severity: mild, moderate or severe. Migraine severity was evaluated by the Migraine Disability Assessment Score (MIDAS). All patients received acetylsalicylic acid (ASA) 100 mg/die for 3 months before undergoing percutaneous PFO closure. After the intervention all patients received clopidogrel 75 mg/die for 1 month and ASA 100 mg/die for 6 months. A 3 month, 6 month and 9 month follow-up after percutaneous PFO closure was performed as well.

Results. RLS grade at TCD was proportional to MIDAS (mean MIDAS 29.2±4.3 in severe RLS; 20±2.4 in moderate RLS; 9.6±2.3 in mild RLS). ASA 100 mg/die for 3 months induced a significant migraine improvement in patients with moderate or severe RLS when compared to patients with mild RLS (MIDAS 15.5±2.8 in severe RLS, $p<0.05$; 11.4±2.3 in moderate RLS, $p<0.05$; 8.1±2.1 in mild RLS, $p=0.15$). 3 months after PFO closure MIDAS significantly reduced in all groups studied (MIDAS 9.2±1.9 in severe RLS, $p<0.05$; 8.4±2 in moderate RLS, $p<0.05$; 6.1±1.6 in mild RLS, $p<0.05$). The result was completely confirmed at 6 and 9 month follow-up. Furthermore, we demonstrated that the residual RLS, 6 months after PFO closure, is connected to MIDAS significantly increased with respect to patients without residual shunt (MIDAS 9±1.2 in moderate residual RLS, 10.75±2.5 in mild residual RLS, 7.1±1.8 in absence of residual RLS; moderate residual RLS vs no residual shunt $p=0.05$; mild residual RLS vs no residual shunt $p<0.05$). Presence of interatrial septal aneurysm (ISA) is connected to major risk of residual RLS and is correlated to increased MIDAS at time 0 and 9 months after PFO closure.

Conclusions. RLS severity is proportional to MIDAS, and predicts migraine improvement after pharmacological therapy with ASA 100 mg/die, especially in moderate and severe RLS in patients who had also experienced multiple cryptogenic cerebrovascular events. Subsequent PFO closure was able to ameliorate migraine symptoms also in those patients with mild RLS. The migraine improvement is independent of antiplatelet therapy because the reduction of MIDAS is confirmed at 9 months follow up. Presence of ISA is connected to major risk of residual RLS and predicts reduced migraine improvement after PFO closure.

C26

LA TROMBECTOMIA REOLITICA NEL TRATTAMENTO DELL'EMBOLIA POLMONARE: RISULTATI INIZIALI DELL'ATTIVITÀ DEI CENTRI OPERATIVI NELLA REGIONE LOMBARDIA

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Introduzione. La tromboembolia polmonare acuta (TEP), in particolare quando ad alto rischio, ovvero associata a instabilità emodinamica, rappresenta una patologia gravata da elevata mortalità e morbilità nonostante gli sforzi che si stanno compiendo sia in termini di diagnosi precoce che di trattamento intensivo. In letteratura sono riportate esperienze di singoli centri circa l'efficacia e la sicurezza della trombectomia reolitica mediante catetere (TR) nel trattamento della TEP ad alto rischio.

Scopo. Valutare retrospettivamente l'andamento clinico a breve termine di pazienti con TEP trattati con TR nei centri della regione Lombardia.

Metodi e risultati. Tra giugno 2011 e gennaio 2014, 26 pazienti affetti da TEP per la maggior parte con profilo ad alto rischio, diagnosticata mediante angio-TAC, sono stati sottoposti in urgenza a TR mediante l'utilizzo del catetere Angiojet Xpeedior 6F (Bayer Medical Care Inc, Pittsburgh, Pennsylvania). Il successo tecnico e procedurale, definito dalla capacità di fare avanzare il sistema attraverso le arterie polmonari e di ridurre significativamente il burden trombotico, stimato mediante Miller index, migliorando il quadro emodinamico dei pazienti, è stato raggiunto in 25 casi (96.15%). La trombolisi loco-regionale con rTPA alla dose massima di 20 mg è stata somministrata in 17 pazienti (65.38%). Un sanguinamento maggiore secondo la classificazione TIMI si è verificato in 4 pazienti (15.38%), in 1 caso da pseudoaneurisma femorale secondario a puntura arteriosa accidentale, in 2 casi da emorragia del tratto gastro-enterico e nell'ultimo caso da emorragia del tratto genito-urinario. Durante il decorso intra-ospedaliero si sono verificati 3 decessi (11.53%) di cui uno peri-procedurale in paziente anziana giunta con quadro di shock refrattario e 2 per cause non cardiopolmonari. I restanti 23 pazienti sono stati dimessi a domicilio dopo una degenza mediana di 10 giorni. Il follow-up mediano a 3 mesi è al momento disponibile per 15 pazienti (65.21%); un paziente è deceduto per cause non cardiopolmonari, i restanti pazienti sono asintomatici senza evidenza di ipertensione polmonare residua all'ecocardiogramma.

Conclusioni. La nostra esperienza multicentrica iniziale, seppur limitata, conferma la sicurezza e l'efficacia a breve termine della TR nel trattamento della TEP ad alto rischio, suggerendo che tale metodica possa essere adottata in modo particolare in pazienti con quadro di severa instabilità emodinamica e con controindicazione o inefficacia della trombolisi sistemica.

C27

CHIUSURA PERCUTANEA DEL FORAME OVALE PERVIO CON DISPOSITIVO CERAFLEX: INIZIALE ESPERIENZA DI UN SINGOLO CENTRO

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Il forame ovale pervio (FOP) è una condizione anatomica predisponente ad embolia paradossa con possibili manifestazioni neurologiche nella popolazione generale. Diversi dispositivi sono utilizzati nella pratica clinica. Recentemente è stato introdotto un nuovo device (Ceraflex, Lifetech). Ceraflex è un dispositivo di chiusura ricoperto di Nitride di Titanio che accelera l'endotelizzazione e previene il rilascio di nickel, presenta un basso profilo strutturale ed un'ampia flessibilità.

Obiettivo. Valutare il successo procedurale e le possibili complicanze maggiori periprocedurali (embolia, erosioni, infarti del miocardio, sanguinamenti, infezioni del device, dislocazione del dispositivo) nella iniziale esperienza dell'uso del dispositivo in un singolo centro e valutarne il follow-up a breve termine.

Materiali e metodi. Otto pazienti (età 42±9 anni; 5 donne e 8 maschi) sono stati arruolati presso il nostro centro per essere sottoposti a chiusura percutanea con dispositivo Ceraflex dal marzo al giugno 2014. Tutti i pazienti riportavano in anamnesi uno o più episodi i TIA/ictus con evidenza di lesioni focali di tipo embolico alla RMN cerebrale ed in 5 casi (62.5%) era presente una trombofilia. Tutti i pazienti sono stati dimessi con doppia antiaggregazione (ASA 75 mg + clopidogrel 75 mg) per 3 mesi e nei pazienti con trombofilia è stata data indicazione a proseguire con ASA 75 mg.

Risultati. Gli otto pazienti sono stati sottoposti a chiusura percutanea secondo la tecnica standard. In 7 degli 8 pazienti (87.5%) la chiusura percutanea con Ceraflex è stata eseguita con successo, mentre in una paziente la procedura è stata sospesa per il sospetto di una fistola tra l'arteria e vena della femorale destra. In 3 casi (47%) dei 7 pazienti è stato utilizzato un dispositivo Ceraflex 18 mm e negli altri 4 (53%) un device 25 mm. In una paziente in cui è stato usato un dispositivo 25 mm è stato evidenziato un setto multifenestrato all'ecotransesofageo intraoperatorio eseguito prima della chiusura, trattato efficacemente. In una paziente (12.5%) dopo posizionamento del dispositivo si è osservata importante emissione di bolle dal catetere Mullins con sopraslivellamento del tratto ST durante la procedura, regredito spontaneamente e senza dismissione enzimatica nelle ore successive. In nessun paziente sono state evidenziate complicanze maggiori periprocedurali. I 7 pazienti sottoposti a chiusura percutanea sono stati valutati con un Follow-up clinico-strumentale a 1 e in 4 casi (57%) a 3 mesi. In tutti i pazienti sono state escluse complicanze maggiori e all'ecosalino non è stato evidenziato passaggio di bolle né di base, né dopo manovra di Valsalva. Nella paziente non sottoposta a chiusura gli accertamenti strumentali successivi hanno escluso la fistola artero-venoso dell'arteria femorale, ma si è evidenziato una opposizione trombotica della vena, pertanto dopo 2 mesi di trattamento con anticoagulante la paziente è stata nuovamente sottoposta efficacemente a chiusura percutanea del FOP ma con un altro tipo di device.

Conclusione. Il dispositivo Ceraflex (Lifetech) è stato utilizzato nel nostro centro con alta percentuale di successo procedurale e senza complicanze periprocedurali maggiori. Al follow-up a 1 mese in tutti i pazienti non era evidente passaggio di bolle all'ecosalino.

C28

ULTRASOUND-GUIDED BALLOON ANGIOPLASTY OF ARTERIOVENOUS FISTULAS FOR HEMODIALYSIS IN A DAY-HOSPITAL SETTING

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Introduction. Many arteriovenous fistulas (AVFs) for dialysis access fail to mature or develop stenosis while in use. There is growing experience in treating these immature or failing AVFs with percutaneous balloon angioplasty (PTA). This procedure, however, involves exposure to radiation and to potentially nephrotoxic intravenous contrast in patients who are often not yet on dialysis. We report our experience with ultrasound-guided PTA of AVFs, without utilization of radiation and intravenous contrast, in a day-hospital setting.

Methods. All patients undergoing ultrasound-guided PTA of AVFs in our center from April 2013 to June 2014, entered into an observational, prospective study. The indication for PTA was given in all cases by a dedicated working group, consisting of a nephrologist, angiologist, vascular surgeon and interventional cardiologist. The procedures were performed in a day-hospital setting. All procedures were performed in the catheterization laboratory, under local anesthesia, without use of fluoroscopy and contrast medium. In all cases the interventional cardiologist was responsible for vascular access, advancement of the wire and performance of PTA under echo color Doppler guidance by the angiologist. In all cases a 4 French, 10 cm-long introducer has been used; unfractionated heparin was administered as a bolus at a dose of 80 IU/kg; immediately after the end of the procedure the introducer was removed and hemostasis was performed by manual compression. Procedural success was defined as an in increase in the cross sectional area of the vessel and a reduction of focal acceleration at pulsed-wave Doppler in correspondence of the stenosis.

Results. Twenty-two procedures were performed in 19 patients (16 males, 72%, mean age 62±14 years), suffering from end-stage chronic renal failure. The indication to PTA was: malfunctioning AVF for development of stenosis in 16 cases (84%), immature AVF in 3 cases (16%). In all cases, the failure to maturation/malfunctioning was the result of hypoplasia/stenosis of veins or prosthetic venous conduits, downstream to the arteriovenous anastomosis. Vessels treated were: 8 cephalic veins of the forearm, 5 prosthetic conduits of the forearm, 3 cephalic veins of the arm, 3 basilic veins of the arm, 3 median cubital veins. Semi-compliant balloons (diameter 4.5±0.6 mm, 5±1 inflations), for a total time of inflation of 200±46 seconds, were used in all procedures. In 2 cases a drug-eluting balloon was used too. Mean duration of the procedures was 26 ± 8 minutes. In all cases procedural success was obtained. The complications observed were: a case of acute occlusive thrombosis of the vein, efficaciously treated by local administration of urokinase, followed by PTA; a small subcutaneous hematoma, around the site of entry of the introducer.

Conclusions. Ultrasound-guided PTA is a safe and effective strategy for the treatment of immature or malfunctioning AVFs. The procedure may be executed in a day-hospital setting, it is very well tolerated by the patient and eliminates the disadvantages represented by radiological exposure and contrast medium hazard.

C29

PERCUTANEOUS LEFT ATRIAL APPENDAGE CLOSURE AFTER TAVI IN AN ELDERLY PATIENT WITH ATRIAL FIBRILLATION NOT RECEIVING ORAL ANTICOAGULATION THERAPY

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Introduction. The prevalence of atrial fibrillation (AF) in the general population is 1-2%, increasing with age up to 15% in very elderly patients. The prevention

of cardioembolic stroke is essential to maintain good quality of life and to decrease the incidence of hospitalizations. The left atrial appendage percutaneous closure is a safe approach to treat selected patients with AF, who do not receive oral anticoagulants. Aortic valve stenosis is also frequently diagnosed in elderly patients. Transcatheter aortic valve implantation (TAVI) is a therapeutic alternative to surgical aortic valve replacement for patients with symptomatic severe aortic stenosis and high surgical risk or inoperable patients. The association of these strategies may allow to avoid long-time oral anticoagulation therapy in patients with high risk of stroke and bleeding complications. Both these percutaneous therapeutic approaches permit to maintain quality of life, reducing hospitalization and complications in very elderly patients.

Case report. An 89-year-old female patient with history of hypertension, hypercholesterolemia, myelodysplasia syndrome with thrombocytopenia for as long as twenty years and paroxysmal AF not treated with anticoagulation therapy. In 2012, a moderate aortic valve stenosis was detected. On November 2013, the patient became symptomatic for chest pain with a rise of hs-troponin I up to 4 ug/L. Cardiac catheterization revealed a severe aortic stenosis (valve area of 0.92 cm^2, AVAi 0,5 cm^2/m^2, peak to peak gradient across the aortic valve of 30 mmHg), ejection fraction 60% and no significant coronary artery disease. Patient was excluded from surgical valve replacement because of high surgical risk. Thereby, transfemoral TAVI with the implantation of Edwards Sapien XT 26 mm was performed on February 2014. As procedure-related complication, a focal dissection of the right common femoral artery was observed, confirmed by angio-CT imaging with a false lumen extended for 1 cm, with no indication to surgical repair. The stability of dissection was assessed by vascular Doppler after 5 days. In the post-procedure period, the patients developed new onset paroxysmal AF. Anticoagulation therapy was not administered because of her comorbidities, while dual antiplatelet therapy was maintained. On March 2014, a vascular Doppler confirmed the previous vascular complication of the right common femoral artery without evidence of persistent dissection. On April 2014 a complete clinical assessment including transthoracic echocardiography was repeated. In view of the thromboembolic risk score (CHA_2DS_2-VASc =4), the bleeding risk score (HAS-BLED =3), the high risk of fall and the patient's propensity, we did not indicate oral anticoagulant therapy, and left atrial appendage closure was planned. On May 2014, under trans-esophageal echocardiography guidance, the percutaneous closure of the left atrial appendage with Amplatzer Cardiac Plug 26 mm was successfully performed. Neither pericardial effusion nor device related complications were detected by the transthoracic echocardiography during the in-hospital follow-up. 24 hours after the procedure, the patient was discharged with dual antiplatelet therapy, in addition to antihypertensive and statin therapy and antiarrhythmic drugs. At 1-month clinical and echocardiographic follow-up, no adverse events occurred and correct placement of both devices was observed.

C30

FATTIBILITÀ ED EFFICACIA DI PTA IN FAV

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La fistola artero-venosa [FAV] è un presidio utilissimo per eseguire cronicamente le dialisi. Al confezionamento della FAV vi è un limite legato al numero di queste per braccio. L'obiettivo del nostro studio è valutare la fattibilità e la pervietà nel tempo di PTA e/o re-PTA di FAV malfunzionanti di pazienti emodializzati al fine di prolungarne la loro naturale emivita.

Dal gennaio 2012 al giugno 2014, 35 pazienti consecutivi sono stati sottoposti ad angiografia di FAV disfunzionanti. Dei pazienti in esame, 29 (83%) erano maschi, l'età media era 67,5 anni ed erano stati sottoposti in precedenza a 428 punture di media della fistola per dialisi. Quattro pazienti non sono stati considerati eleggibili per la PTA e quindi rinviati al chirurgo vascolare per il riconfezionamento di una nuova fistola.

Sono state eseguite 31 PTA, 27 (87%) efficaci. Nel 62% è stata utilizzata come sede di accesso l'arteria omerale, nei restanti casi la vena efferente della fistola. Nel 91% dei casi il trattamento è stato eseguito nella porzione venosa della fistola. In 6 (22.2%) pazienti è stato posizionato uno stent. Al follow-up, attualmente medio di 8.6 mesi, la restenosi è stata del 16.1% a 6 mesi, trattata efficacemente con POBA.

In conclusione, riteniamo che per prolungare l'emivita di una FAV l'intervento di PTA con o senza stent sia una tecnica valida e sicura; ulteriori dati potranno essere ottenuti dal nostro campione con il progredire del follow-up.

Primary PCI strategies and logistics

C31

IMMEDIATE AND MID-TERM OUTCOMES FOLLOWING PRIMARY PCI WITH BIORESORBABLE VASCULAR SCAFFOLD IMPLANTATION IN PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION: INSIGHTS FROM THE MULTICENTER "REGISTRO ABSORB ITALIANO" (RAI REGISTRY)

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Aims. Bioresorbable vascular scaffold (BVS) has been designed to overcome the limitations of metallic stents. Although BVS has been tested firstly in patients with stable angina and simple lesions, its role in ST-segment elevation myocardial infarction (STEMI) is intriguing, but to date limited data are available on its performance in this setting. This multicenter prospective study assessed mid-term clinical outcomes following single or multiple overlapping BVS implantation in the STEMI setting.

Methods and results. A prospective cohort analysis was performed on all STEMI patients that underwent primary percutaneous coronary intervention (PCI) with BVS implantation. Between December 2012 and February 2014, 1232 STEMI patients underwent primary PCI at the participating Centers. Of these, 74 (6.0%) received a BVS, 18 (24.3%) of them were multiple and overlapping. Procedural success was obtained in 72 (97.3%) cases without differences between the groups (overlapping BVS 100% vs non-overlapping 96.4%, p=0.5). One patient experienced a re-infarction due to sub-acute BVS thrombosis which was successfully managed with balloon only PCI while the other patient had a "slow-flow" phenomenon (final TIMI flow 1). At a median of 6 month (IQR 2-16) follow-up, 2 non fatal MI (2.7%), 3 (4.1%) target lesion revascularization and 1 sub-acute BVS thrombosis (18 days after PPCI) were reported in 3 patients (2 single BVS [3.6%] and 1 [5.6%] overlapping BVS, p=0.5). All the events were successfully managed.

Conclusions. Despite the limited number of patients, this experience suggests that BVS implantation in STEMI patients can be successfully performed with interesting immediate and mid-term outcomes. Larger studies of head-to-head comparison versus contemporary standard of care and longer follow-up are needed to fully assess the clinical benefit of BVS in this subset of patients.

C32

INCIDENCE, PREDICTORS AND IMPACT OF STENT MALAPPOSITION IN PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION TREATED WITH EVEROLIMUS-ELUTING STENTS

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Aims. To investigate the incidence, mechanisms and clinical impact of incomplete stent apposition (ISA), in patients with ST-segment elevation myocardial infarction (STEMI) treated with with everolimus-eluting stent (EES).

Methods. From January 2011 to January 2012, 114 STEMI patients (114 culprit lesions) undergoing primary EES implantation were prospectively evaluated. The impact of culprit plaque morphology and atherothrombotic components on ISA was assessed with a comprehensive OCT, histopathological and inflammatory blood biomarker analysis. Serial OCT imaging of the infarct-related artery was obtained after thrombus aspiration, immediately after EES implantation and at 9-month follow-up. Thrombus aspirates and inflammatory serum biomarkers were additionally analyzed. Clinical outcomes, defined as major adverse cardiac and cerebrovascular events (MACCEs), a composite of cardiac death, recurrent myocardial infarction, stroke, and ischemia-driven target-lesion revascularization, were determined at 2 years.

Results. Acute ISA occurred in 82 (71.9%) of cases. Lesion length, vessel lumen volume and thrombus presence at the pre-stent OCT assessment were identified as independent predictors of acute ISA. At follow-up acute ISA resolved in 36 (43.9%) lesions. Conversely, persistent ISA was observed in 46 lesions (56.1%) with a whole malapposition area that decreased from 0.26 mm^2 at stent implant to 0.10 mm^2 at follow-up. Receiver-operating curve analyses indicated a volume of acute malapposition >2.82 mm^3 as a better

separator of persistent versus resolved ISA (area under the curve 0.726, p<0.001; 95% CI 0.62-0.84, sensitivity 80.4%, specificity 52.8%). At 9-month late acquired ISA (LAISA) was observed in 39 lesions (34.2%). Whereas persistent ISA was located at the stent edges (78.0%), LAISA preferentially occurred at the stent body (82%) (p>0.001). LAISA lesions were also less post-dilated (17.0% vs 49.0%, p=0.021) as compared with non-LAISA lesions. Notably, LAISA lesions had longer underlying thin cap fibroatheroma (TCFA),(3.20 mm vs.1.80 mm, p=0.032) in the entire target vessel and less white thrombus before stent implantation (25.6% vs 46.7%, p=0.021) as compared with non-LAISA lesions. Moreover, the absolute reduction of myeloperoxidase values between the STEMI procedure and the 9-month follow-up was significant lower in patients with LAISA (539.4 vs 265.5, p=0.019) as compared with non-LAISA patients. Independent predictors of LAISA were a longer ruptured TCFA [OR 1.8, (95% CI 1.2-3.3), p=0.04] and the presence of IL5 [OR 6.5, (95% CI 1.3-32.3), p=0.02] in aspirates. There was no difference in MACCEs between patients with or without ISA at 2-year clinical follow-up.

Conclusions. In STEMI patients treated with EES OCT-detected ISA is a frequent finding, but limited in extension. Acute ISA mainly depends on anatomical factors and ISA persistency is dictated from its baseline magnitude. Conversely, atherothrombotic culprit plaque components play a major role in LAISA. ISA development was not associated with increased risk of clinical events at 2 year. Larger studies at longer clinical follow-up are warranted to evaluate its clinical impact.

C33

FOLLOW-UP SCINTIGRAFICO E CLINICO DI PAZIENTI CON STEMI RANDOMIZZATI AL TRATTAMENTO CON TROMBOASPIRAZIONE MANUALE O MECCANICA: RISULTATI A MEDIO TERMINE DELLO STUDIO COCOTH

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Background. L'impiego dei dispositivi di tromboaspirazione in corso di angioplastica primaria in pazienti con infarto miocardico acuto e sopralivellamento del tratto ST (STEMI) è risultato in grado di migliorare la riperfusione miocardica. Per valutare l'estensione dell'area infartuale e la funzione ventricolare sinistra, sia in acuto che durante il follow-up, viene utilizzata la scintigrafia miocardica di perfusione.

Scopo. Confrontare i dati relativi al follow-up scintigrafico e clinico di 185 pazienti con STEMI arruolati nello studio COCOTH, trattati con tromboaspirazione in corso di angioplastica primaria e randomizzati al trattamento con il catetere manuale Export® (n=95) o con il dispositivo meccanico Angiojet® (n=90).

Metodi e risultati. La scintigrafia miocardica di perfusione è stata eseguita 24-48 ore dopo l'angioplastica primaria e dopo 6 mesi dall'evento acuto in 147 pazienti (79.5%). Alla scintigrafia al follow-up rispetto a quella basale è stato osservato nei due gruppi trattati con Export® e Angiojet® una riduzione significativa dell'infarct size (Δ 14.5±60.1 e 12.1±80.1, rispettivamente; p<0.001) ed un aumento significativo della frazione di eiezione del ventricolo sinistro (Δ 13.4±19.6 e 12.8±31.7, rispettivamente; p<0.001) ma, nella scintigrafia al follow-up, non sono state osservate differenze significative tra i pazienti trattati con Export® o Angiojet® in termini di infarct size (14.9±11.4 vs 15.7±14.7, p=0.747), infarct severity (0.51±0.14 vs 0.52±0.16, p=0.691) e frazione di eiezione del ventricolo sinistro (51.8±11.4 vs 50.0±12.4, p=0.360). Al follow-up clinico con durata mediana di 237 giorni (181-481), eseguito su 169 pazienti (91.4%), 9 sono deceduti (5.3%), senza differenze significative tra i due gruppi di trattamento.

Conclusioni. I risultati osservati nella presente analisi dimostrano che i pazienti di ambedue i gruppi di trattamento hanno presentato una riduzione significativa dell'estensione dell'area infartuale ed un aumento della funzione sistolica ventricolare sinistra; inoltre, i presenti dati confermano l'assenza di differenze significative tra le due metodiche di tromboaspirazione analizzate, considerando sia alcuni indicatori scintigrafici dell'area di necrosi che la mortalità al follow-up. Questo studio avvalora pertanto l'ipotesi che il sistema di tromboaspirazione manuale andrebbe utilizzato in prima battuta nella maggior parte dei casi, riservando l'utilizzo del dispositivo meccanico in presenza di trombosi persistente o massiva oppure in caso di fallimento del primo, permettendo così un miglioramento del rapporto costo-efficacia.

C34

RESIDUAL INTRASTENT THROMBUS AFTER PRIMARY ANGIOPLASTY IS ASSOCIATED WITH MACE AT FOLLOW-UP. INSIGHTS FROM THE COCTAIL II STUDY

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Background. Patients with ST-elevation myocardial infarction (STEMI) treated with primary angioplasty tend to have worse procedural results due to the presence of larger amount of residual intrastent thrombus. However little is known about the relationship between residual intrastent thrombus and clinical outcome. Aim of the present study was to explore the correlation between the amount of residual intrastent thrombus burden and the clinical outcome in patients enrolled in the randomized COCTAIL II trial.

Methods. The study population consisted of 128 STEMI patients which underwent primary PCI within 6 h from onset of chest pain and randomized to one of the following four treatments: local infusion of abciximab delivered by the ClearWay with (group 1) or without thrombectomy (group 2), intracoronary abciximab with (group 3) or without thrombectomy (group 4). Residual intrastent thrombus burden at OCT assessment was defined as: number of cross section with residual thrombus area >10% and mean thrombus area % (average of % thrombus area in all stented cross sections). All patients had a clinical assessment at a mean follow-up of 12 months.

Results. OCT assessment was available in 119 patients. Nine had a MACE (periprocedural myocardial infarction, myocardial infarction during follow-up or cardiac death), while110 had no complications (control group). The control group showed a smaller number of cross section with residual thrombus area >10% than the MACE group (8.26±9.49 vs 16.00±12.25; p=0.02) and a smaller mean thrombus area % (4.71±2.639 vs 6.33±2.94, p=0.08).

Conclusion. Residual intrastent thrombus is associated with higher incidence of cardiac events during follow-up in STEMI patients treated with primary angioplasty despite the adoption of aggressive strategy for thrombus removal.

C35

USE OF A MECHANICAL THROMBUS ASPIRATION SYSTEM WITH RADIAL APPROACH IN PATIENTS WITH ACS: A SINGLE CENTER EXPERIENCE

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Aims. There are different strategies to optimize the final results and outcomes during primary PCI in patients with STEMI. The use of a thrombus aspiration system represents an appropriate strategy revascularization before stent implantation.

Methods and results. Retrospective analysis of consecutive patients admitted to our hospital for ACS (STEMI/NSTEMI) and treated with thrombus aspiration device during PCI between Jan 2008 and Dec 2013. Baseline characteristics of the patients, ACS data, procedural information, need of access shift, vascular complications were recorded. 487 patients were treated with thrombus aspiration device during STEMI (34% of STEMI population of our database); 38 patients during NSTEMI (1% of NSTEMI population who underwent PCI). In 96% of cases we used a manual thrombus aspiration system (Export). In 27 patients (5.5%) we used a mechanical thrombus aspiration system (Angiojet): 25 patients (93%) presented with STEMI (7% of the patients with cardiogenic shock), 2 patients (7%) with NSTEMI. We used the Angiojet system as second choice (manual system failure) in 26/27 cases (96%). 93% of the "Angiojet" population was male. The mean age was 67.3 years. The radial access was performed in 75% of the patients. No radial access site complications occurred. The success rate of the procedure was 93%. In 2 cases we recorded mechanical system failure (in one case due to severe tortuosity of the vessel). The treated vessel was: 18% left anterior descending, 4% circumflex, 60% right coronary artery, 18% saphenous vein graft bypass. The minimum luminal diameter of the vessel was 2.5 mm. In 4 patients we use Angiojet during in-stent thrombosis: 3 subacute (2 BMS, 1 DES) and 1 late thrombosis (BMS). In 12 patients (45%) we performed only thrombus aspiration without stent; in 15 patients (55%) we implanted a stent after thrombus aspiration (20% with DES). In 1 case we use the Angiojet for evidence of distal thrombus embolization after stent implantation. The TIMI flow before thrombus aspiration was 0 in 95% of the cases; after the procedure was: 3 in the 53%, 2 in the 24%, 1 in 23% of the patients. The use of glycoprotein IIb/IIIa inhibitors was 60%. Temporary pacemaker was used in 15% of the procedures. Scheduled control angiography was performed after primary PCI (mean time 5.2 days) in 14 patients (52%), showed coronary artery patency in all patients: in 10 patients (71%) the TIMI flow was 3, in 4 (29%) was 2. In 3 cases we performed a PCI with DES during the second procedure. In 6 patients (22%) we repeated coronary angiography after discharge (mean time 85 days): we found 3 patients (50%) with TIMI 3 flow, 1 patient with TIMI 2 and 2 patients with vessel occlusion (1 intrastent occlusion).

Conclusions. In STEMI, especially with angiographic evidence of thrombus burden and high risk of distal embolization, thrombus aspiration is recommended. In case of manual device failure due to the massive thrombus burden, the use of a more complex technique such as mechanical thrombectomy appears safe, effective and provides a low use of stents. The use of the mechanical device together with radial approach is feasible and can reduce the risk of bleeding related to aggressive antithrombotic therapy.

C36

GESTIONE DEI PAZIENTI CON SINDROME CORONARICA ACUTA CON SOPRASLIVELLAMENTO DEL TRATTO ST: ESPERIENZA DELLA RETE PROVINCIALE DI VITERBO

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Obiettivo. Raggiungimento degli standard di cura per i pazienti con sindrome coronarica acuta con sopraslivellamento del tratto ST (SCA-STEMI) previsti dalle linee guida europee.

Background. La rete ospedaliera della provincia di Viterbo (circa 350.000 abitanti) è costituita da un Hub centrale, fornito di UTIC ed emodinamica h24, e 5 Spoke zonali con un eterogeneo livello di profilo tecnologico che impedisce il trasferimento bilaterale dei pazienti con sindrome coronarica acuta.

Metodi. A partire dal 2010 è stato istituito un protocollo di gestione intra ed extra-ospedaliero dello STEMI che tiene conto della logistica e delle caratteristiche territoriali in cui opera la rete Provinciale. Tale protocollo prevede un diverso iter terapeutico condizionato da 4 elementi fondamentali: tempo di insorgenza dei sintomi, profilo di rischio ischemico (es. shock), profilo di rischio emorragico (es. controindicazioni alla trombolisi), tempo di trasferimento presso il centro Hub.

Risultati. Da aprile 2010 a luglio 2014 sono stati diagnosticati e trattati 552 pazienti con diagnosi di SCA-STEMI. Di questi 429 sono stati trattati mediante angioplastica primaria, 57 sono stati trattati mediante angioplastica rescue, 66 sono stati sottoposti a trombolisi e successiva rivascolarizzazione percutanea (staged). Il tempo pre-coronarico medio è stato di 5.2±3.4 ore con un tempo door-to-balloon medio di 1.1±0.3 ore. In base a tali risultati la maggioranza dei pazienti con SCA-STEMI è stato trattato secondo il protocollo instaurato in conformità con gli standard di qualità previsti dalle attuali linee guida. Il tasso cumulativo di eventi cardiaci maggiori avversi (MACCE) a 30 giorni è stato di 5.1%. La descrizione dettagliata degli eventi insieme con un follow-up ad 1 anno sarà disponibile per la data del congresso.

Conclusioni. La creazione di un apposito protocollo condiviso di gestione ha reso possibile l'attuazione delle linee guida europee per il trattamento dei pazienti con SCA-STEMI nella provincia di Viterbo. In particolare la creazione di un'adeguata rete organizzativa tra i vari ospedali territoriali che consenta il corretto inquadramento del profilo di rischio del paziente e la scelta dell'iter terapeutico più adeguato è risultata efficace per superamento delle barriere logistico-territoriali.

Miscellaneous 1

C37

STRATIFICARE IL RISCHIO NEI PAZIENTI AFFETTI DA ANGINA STABILE: QUANDO INTENSIFICARE LE CURE? RISULTATI DI UNA META-ANALISI OSSERVAZIONALE

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Background. Negli anni, un gran numero di marcatori clinici e di laboratorio sono stati valutati in differenti contesti clinici per predire la prognosi nei pazienti con angina stabile ma, mancano dati precisi su quali dati valutabili durante i controlli ambulatoriali possano maggiormente influenzare la prognosi.

Metodi. Sono state eseguite ricerche sistematiche su Medline e PubMed per ricercare gli studi sull'argomento pubblicati fino al 2013, cioè che riportassero predittori di eventi cardiovascolari (morte, infarto miocardico acuto, ictus e necessità di rivascolarizzazione) nei pazienti con angina stabile. L'end-point primario sono stati i MACE (major cardiovascular events) intesi come composito di morte, infarto miocardico e rivascolarizzazione. I singoli componenti sono stati invece analizzati come end-point secondari.

Risultati. Al termine della selezione sono stati inclusi 38 studi (101 551 pazienti). Dopo un follow-up mediano di 57 mesi, i MACE si sono verificati nel 7.8% (95% CI 6.0-9.6), con l'infarto miocardio nel 6.20% (IC 95% 4.2-9), e la necessità di ripetere la rivascolarizzazione (sia chirurgica o percutanea) nel 19.5% (95% CI 14.25-24.95). Il sesso maschile (OR 1.28, 95% CI 1.13-3.40), la frazione d'eiezione ridotta (OR 8.53, IC 95% 1.90-16.84), il diabete mellito (OR 1.93, IC 95% 1.10-11.20), il precedente infarto miocardico (OR 2.06, 95% CI 1.40-5.64) e il riscontro di valori elevati di proteina C-reattiva (OR 1.67. 95% CI 1.21-6.41) sono stati i più potenti predittori di eventi cardiovascolari.

Conclusioni. Questa meta-analisi dimostra che alcune caratteristiche cliniche, semplici da ottenere anche in ambulatorio e a basso costo, possono aiutare i medici a identificare gli approcci diagnostici e terapeutici più appropriati all'interno della vasta gamma di pazienti con malattia coronarica stabile.

C38

PROSTHESIS CHOICE FOR TRANSCATHETER AORTIC VALVE REPLACEMENT: IMPROVED OUTCOMES WITH THE ADOPTION OF A PATIENT-SPECIFIC TRANSCATHETER HEART VALVE SELECTION ALGORITHM

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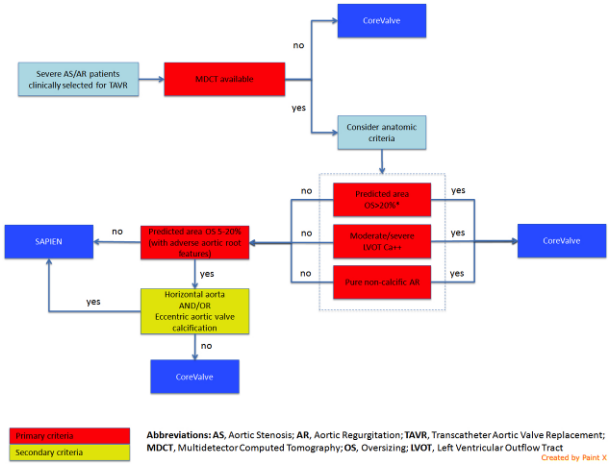
Background. Transcatheter aortic valve replacement (TAVR) is routinely performed by using either self-expanding or balloon-expandable prostheses, which are the most widely used TAVR devices. No specific indications for these two valves have been adopted so far. This study prospectively investigated the impact of a patient-specific transcatheter heart valve (THV) selection algorithm on TAVR outcomes.

Methods and results. Consecutive patients who underwent TAVR using the selection algorithm since April 2012 (n=184) were compared with earlier consecutive patients in whom the algorithm was not applied (n=193). The primary endpoints were: 1) VARC-defined device success, and 2) paravalvular regurgitation (PVR) ≥ moderate. Patients in the study group were more likely to have diabetes mellitus (35.3% vs 24.9%, p=0.027), whereas COPD was more frequent among the control group (28.4% vs 39.3%, p=0.027). Device success was obtained in 87.0% of patients included in the study group and in 77.2% of those included in the control group (adjusted OR: 1.85, 95%CI 1.03-3.31, p=0.039). On echo, PVR ≥ moderate was present in 5.6% of the study group and in 17.4% of the control group (adjusted OR: 0.35, 95%CI 0.16-0.76, p=0.008).

Conclusions. The implementation of a patient-specific THV selection algorithm for TAVR, which entails a specific THV implantation (CoreValve or SAPIEN XT) for specific aortic root anatomies, may improve clinical outcomes after TAVR by allowing higher device success and reducing the incidence of more than mild PVR.



C39

TRATTAMENTO DEI GRAFT VENOSI DEGENERATI CON STENT MEDICATI AUTOESPANDIBILI: LA NOSTRA ESPERIENZA

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Introduzione. I by-pass venosi (SVG) presentano un'importante degenerazione nel corso del tempo. Il 50% di SVG non sono pervi entro 10 anni. La malattia dei gafts venosi è caratterizzata da importante degenerazione con elevata stratificazione trombotica.

Razionale e scopo. Trattare i SVG degenerati utilizzando stent autoespandibili in quanto la caratteristica di autoepandibilità permetterebbe agli stent di adattarsi meglio alle irregolarità di parete ed alle variazioni di calibro presenti nei by-pass venosi permettendo quindi una migliore apposizione alle pareti del vaso rispetto agli stent balloon expandable. La possibilità di evitare eccessive postdatazioni dello stent (grazie alla loro struttura in nitinolo) potrebbe ridurre l'embolizzazione distale. La struttura in nitinolo permette agli stent autoespandibili di continuare ad espandersi nel corso del tempo in caso di vasodilatazione, risoluzione del trombo o rimodellamento positivo ed il meccanismo di rilascio degli stent autoespandibili (da distale a prossimale) potrebbe risultare in una minore embolizzazione distale e restenosi grazie al minore stiramento sulle pareti del vaso.

Risultati. Da settembre 2012 a maggio 2014 abbiamo trattato con stent autoespandibili 18 pazienti con un follow-up di 6 mesi in 13 casi. 12 pazienti presentavano un quadro di sindrome coronarica acuta con evidenza angiografica di placca soft e trombosi endoluminale. L'età media dei graft è di 12 anni (range: 4-21 anni). In 8 casi è stato utilizzato un filtro di protezione embolica distale. 4 pazienti presentavano dilatazione aneurismatica del graft

(diametro massimo del vaso tra 6 e 7 mm). Non si sono verificate complicanze maggiori. In un caso abbiamo impiantato uno stent balloon expandable a valle dello stent autoespandibile per dissezione distale del vaso con buon risultato finale. In tutti i casi abbiamo ottenuto un buon risultato angiografico (flusso finale TIMI III). A tre mesi dalla procedura abbiamo eseguito un controllo angio-TC (13 pazienti) che ha confermato la pervietà degli stent. Tutti i pazienti sono rimasti asintomatici durante il follow-up.

Conclusioni. Il trattamento dei graft venosi degenerati con stents autoespandibili e mediante tecnica "soft touch" (dilatazione solo delle porzioni stenotiche con palloni sottodimensionati) comporterebbe un minor rischio di embolizzazione distale e quindi di infarto periprocedurale. Tale tecnica implicando un minor trauma parietale ridurrebbe inoltre l'incidenza di restenosi e potrebbe risolvere il problema del mismatch di calibro in quanto tali stent possono essere utilizzati sino a 6.5 mm di diametro.

Prospettive. I dati disponibili sui drug-eluting stent (DES) riportano che i DES non offrono vantaggi evidenti sulla mortalità e infarto del miocardio dopo 1 anno. Le lesioni dei SVG sono state escluse o scarsamente rappresentate nei trial sui DES. Tutti gli studi sono stati effettuati solo con stent balloon expandable. Studi per valutare l'efficacia di uno stent autoespandibile bare metal (BMS) o DES nella malattia dei SVG potrebbero fornire risultati significativi e portare a un miglioramento del trattamento di SVG.

C40

ESPOSIZIONE DEI PAZIENTI ALLE RADIAZIONI IONIZZANTI NELLE PROCEDURE DI EMODINAMICA: DATI DI UN SINGOLO CENTRO

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Introduzione. È ormai a tutti noto il danno delle radiazioni ionizzanti ai pazienti sottoposti a procedure di emodinamica, danni che si verificano quando tali radiazioni superano il livello di riferimento (LDR).

Obiettivi. Gli obiettivi dello studio sono i medesimi dello studio Healthy Cat Lab del GISE, cioè determinare il valore medio, la deviazione standard e il 75° percentile (3 quartile) della distribuzione dei valori delle DAP e dei tempi di fluoroscopia (fluoroscopy time) registrati nel database Estensa (Database dell'Emodinamica di Parma), relativi a pazienti sottoposti a coronarografia (CA) e angioplastica (PTCA) negli ultimi due anni (dal 1/3/2012 al 1/3/2014) e confrontare questi valori con i valori di riferimento internazionali e della letteratura.

Metodi. Dal 1° marzo 2012 al 1° marzo 2014 per ogni procedura dal Database Estensa, sono stati estrapolati la DAPtotale, DAPscopia, DAPgrafia, tempo di scopia, indice di massa corporea (BMI) del paziente e l'operatore medico che ha eseguito l'esame. Le procedure sono state classificate in 3 sottogruppi principali: solo coronarografia (CA), solo angioplastica (PTCA), coronarografia seguita da angioplastica (CA+PTCA). Sono state analizzate 2252 CA (746 femmine, 1506 maschi), 692 PTCA (194 femmine, 498 maschi) e 1128 CA+PTCA (317 femmine, 811 maschi). L'età media era 69.8 anni (72.3 per le femmine, 68.7 per i maschi), il peso medio era 76.7 kg (80.8 per i maschi, 76.7 per le femmine) e il BMI medio era 26.9 (26.2 per le femmine e 27.2 per i maschi).

Tabella 1. DAP totale.

	N.	Mean	Median	25th percentile	75th percentile	IQR
CA	1740	38.1	30.2	18.4	47.1	28.7
PTCA	548	78.0	63.1	35.6	103.3	67.6
CA+PTCA	827	81.9	71.5	47.1	103.5	56.3

Tabella 2. Fluoro time (min).

	N.	Mean	Median	25th percentile	75th percentile	IQR
CA	1740	7.03	5.6	4.1	8.4	4.3
PTCA	548	13.6	12.1	8.0	18.1	10.1
CA+PTCA	827	14.1	12.4	9.2	17.0	7.8

Tabella 3. CA, PTCA, CA+PTCA.

	N.	Cumulative DAP (Gy cm^2)	Fluoro time (min)
CA			
Noi	1740	47.1	8.4
GISE 2012	609	67.8	7.1
Diamond 2008	672	45	6.5
PTCA, CA+PTCA			
Noi	1375	103.4	17.3
GISE 2012	505	160.6	18.8
Diamond 2008	662	85.0	15.5

Risultati. Le Tabelle 1, 2 e 3 mostrano rispettivamente i dati della DAP totale, del tempo di scopia, della CA, PTCA, CA+PTCA.

Come si evince dalle tabelle il valore di DAP delle CA (47.1 Gy cm^2) è sotto quello della media nazionale (67.8 Gy cm^2) e leggermente superiore a quello di Diamond 2008 (45 Gy cm^2) che è la più grande survey europea che ha coinvolto 8 paesi per 1 anno; per il tempo di fluoroscopia nelle CA il Centro di Parma è leggermente superiore sia alla media nazionale che a Diamond 2008, mentre considerando PTCA e CA+PTCA (come vengono considerate insieme in letteratura) il Centro di Parma è leggermente superiore a Diamod 2008 ma ampiamente sotto la media nazionale; lo stesso andamento si verifica in questo gruppo per il tempo di fluoroscopia.

Conclusioni. Il Centro di Parma sta lavorando bene per la CA; per la PTCA siamo a circa un 20% in più come valore della DAP rispetto alla media europea ma comunque nettamente al di sotto del LDR "nazionale". Per i pochissimi casi (<1%) che hanno superato la DAP trigger proponiamo un follow-up dei pazienti.

C41

TIMI FRAME COUNT COME ALTERNATIVA ALL'IMR NELLA VALUTAZIONE FUNZIONALE DEL MICROCIRCOLO CORONARICO IN PAZIENTI CON ANGINA STABILE E CORONARIE ANGIOGRAFICAMENTE NORMALI

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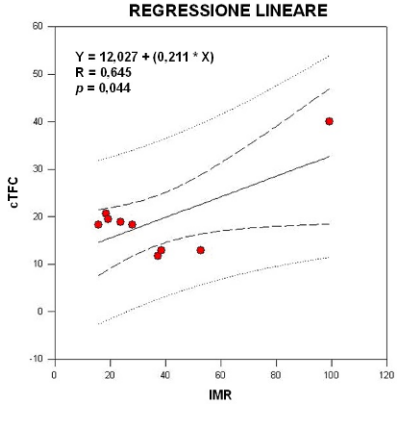
Background. L'evidenza angiografica di vasi epicardici "normali" o lievemente ateromasici è un riscontro comune, documentato in circa il 20-30% dei pazienti sottoposti a coronarografia. Nell'angina stabile a coronarie "normali", o più correttamente nell'angina in assenza di CAD ostruttiva, l'ischemia miocardica riconosce diverse entità patogenetiche che coinvolgono le arterie epicardiche, il microcircolo coronarico, o entrambi. L'impatto prognostico dell'angina a coronarie "normali" differisce a seconda del meccanismo fisiopatologico sottostante. Numerosi studi hanno dimostrato che i pazienti che ne sono affetti, pur potendo beneficiare delle nuove terapie antianginose, non ricevono una terapia farmacologica specifica e vanno incontro a frequenti re-ospedalizzazioni, cateterismi cardiaci ripetuti e quindi ad una peggiore qualità della vita. La corretta diagnosi di angina microvascolare, basata sull'evidenza di una disfunzione del microcircolo coronarico, consentirebbe di intraprendere una terapia anti-ischemica mirata. Attualmente il gold standard per la valutazione del microcircolo coronarico è rappresentato dal l'Index of Microvascular Resistance (IMR) (St. Jude Medical).

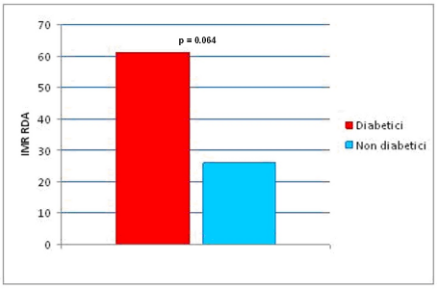
Obiettivi. L'obiettivo principale dello studio è stato verificare l'esistenza di una correlazione statisticamente significativa tra l'IMR ed il TIMI Frame Count (TFC), al fine di validare il TFC come metodica alternativa per lo studio del microcircolo coronarico. Il TFC è caratterizzato da minore invasività e più facile determinazione.

Obiettivo secondario è stata la valutazione, mediante IMR, della disfunzione microcircolatoria coronarica nel sottogruppo di pazienti diabetici.

Materiali e metodi. Dal maggio 2012 al maggio 2014, sono stati valutati con metodica IMR ed inclusi nello studio 10 pazienti consecutivi che soddisfacevano i seguenti criteri di inclusione: angina stabile, coronarie epicardiche angiograficamente prive di stenosi significative. Per la correlazione tra i valori di TFC ed IMR è stato utilizzato un test di regressione lineare per variabili indipendenti. Per il confronto dei valori di IMR del gruppo dei pazienti diabetici vs il resto della popolazione arruolata è stato utilizzato un test di confronto non parametrico (Mann-Whitney Rank Sum Test).

Risultati. La regressione lineare tra le due variabili IMR e TFC ha prodotto la retta di regressione: Y = 12.027 + (0.211 * X), con R=0.645 ed una p=0.044; si evidenzia una correlazione significativa tra le due variabili (Figura 1). Lo studio ha inoltre evidenziato una mediana dei valori di IMR più alta nei pazienti affetti da diabete mellito (3) rispetto alla rimanente popolazione; la differenza è risultata ai limiti della significatività statistica, confermando il possibile ruolo patogenetico del diabete nella disfunzione del microcircolo coronarico (p=0.064) (Figura 2).





Conclusioni. Lo studio del microcircolo coronarico in assenza di patologia a carico dei vasi epicardici ha importanti implicazioni prognostiche e terapeutiche; l'IMR rappresenta il gold standard per la valutazione del microcircolo coronarico ma presenta alcuni limiti: è invasivo, costoso ed allunga i tempi della procedura diagnostica. Il nostro studio ha dimostrato come il TFC, calcolato dopo un semplice esame angiografico, può fornire una valutazione rapida, sicura, economica ed affidabile della funzione del microcircolo in soggetti con angina stabile e coronarie angiograficamente normali. Inoltre nella sottopolazione dei pazienti diabetici con angina stabile e assenza di CAD ostruttiva, la disfunzione microvascolare è di più frequente riscontro. A supporto dei dati preliminari ottenuti, sono necessari ulteriori studi su più ampie casistiche anche al fine di ricercare un validato cut-off di TFC che consenta di porre diagnosi di disfunzione del microcircolo coronarico.

C42

OPTICAL COHERENCE TOMOGRAPHY FOR CHARACTERIZATION OF CARDIAC ALLOGRAFT VASCULOPATHY IN YOUNG RECIPIENTS WITH A LONG FOLLOW-UP TIME AFTER HEART TRANSPLANTATION

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Background. Cardiac allograft vasculopathy (CAV), the leading cause of late morbidity and mortality in heart transplant (HTx) recipients, is usually detected by coronary angiography and intravascular ultrasound. However, optical coherence tomography (OCT) has been shown to enable detection of CAV more clearly both quantitatively and qualitatively. Indeed, in recent studies performed in adult HTx recipients, OCT allowed to identify features typical of atherosclerosis, thus challenging the current pathophysiological concept of CAV. Thus, aim of our study was to characterize CAV by OCT in a young population of HTx recipients.

Methods. We prospectively enrolled 21 consecutive young HTx recipients without significant stenoses at annual CAV screening by coronary angiography. In all patients, the left anterior descending coronary artery (LAD) was imaged with OCT (St Jude Medical, Westford, MA, USA). OCT images were analyzed off-line by two independent investigators in a validated core lab. A qualitative OCT analysis was carried on along the proximal 30 mm of the LAD, divided into three segments of 10 mm each (N= 63). Quantitative OCT analysis was performed at the site of maximal intimal thickness.

Results. Patients were 27 years old and 9 (43%) were male; mean time from HTx was 11.8±6.6 years and mean donor age was 20.9±8.6 years. No patient had a diagnosis of diabetes mellitus, only one patient was smoker, 38% had hypertension and 9.5% hyperlipidemia. The prevalence of atherosclerotic characteristics by OCT per segment analysis was: eccentric plaque 38%, calcification 6.3%, lipid pools 23.8%, microchannels 4.7%, layered complex plaque 1.5%, respectively. Features of vulnerable plaque or complicated lesions, including thin-cap fibroatheroma, macrophages, intimal laceration or intraluminal thrombus, were not detected. Quantitative OCT findings are shown in the Table. Of note, all patients had intimal hyperplasia with an abnormal (>1) intima-to-media ratio. Intimal plus media thickness was indicative of CAV (≥0.3 mm) in 20 (95%) patients and resulted correlated with time after transplantation (p=0.04).

Mean intima thickness, mm	0.62±0.29
Mean media thickness, mm	0.12±0.05
Intima area, mm^2	3.17±1.31
Internal elastic lamina area, mm^2	11.8±3.6
External elastic lamina area, mm^2	13.1±3.9
Lumen area, mm^2	8.6±3.2

Conclusions. In contrast to what has been recently observed in adult HTx recipients, coronary atherosclerosis with vulnerable plaque and complicated lesions is not frequent in young HTx recipients, despite a long follow-up time after HTx and a relevant intimal hyperplasia. This is likely due to the low prevalence of atherosclerotic risk factors and young donor age in our unique population and suggests different pathophysiological and therapeutic implications.

Restenosis, DEB and new coronary stents

C43

15 MESI DI IMPIANTO DI SCAFFOLD BIORIASSORBIBILE. ESPERIENZA DI UN SINGOLO CENTRO

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Introduzione. Lo scaffold bioriassorbibile (BVS) è entrato nel repertorio del nostro laboratorio di emodinamica nel febbraio 2013 e da allora è parte integrante del repertorio a nostra disposizione, di devices coronarici impiantabili. Lo scopo di questo lavoro è di osservare in modo retrospettivo la casistica dei pazienti sottoposti ad impianto di BVS.

Materiali e metodo. Sono stati analizzati tutti i pazienti sottoposti ad impianto di BVS, con particolare attenzione per la diagnosi di ingresso, la predilatazione, la postdilatazione in rapporto al diametro del BVS impiantato e il successo procedurale.

Risultati. Da febbraio 2013 a maggio 2014 sono stati trattatati presso il nostro centro 73 pazienti (55 M e 18 F) con età media di 54.3±9.3 anni. Familiarità per cardiopatia ischemica nel 19%, fumo di sigaretta nel 41%, diabete nel 13.6%, dislipidemici nel 15%, ipertesi nel 37% dei casi. I pazienti trattati avevano nel 39.7% STEMI, nel 23.2% NSTEMI, nel 17.8% UA e nel 12.3% angina stabile (87.7% di sindromi coronariche acute). Il 50.7% aveva una malattia coronarica monovascolare, il 32.8% bi vascolare ed il 6.8% trivascolare. Nei 73 pazienti sono stati impiantati complessivamente 98 BVS. Il 54% dei BVS è stato impiantato sulla discendente anteriore, il 16,3% sulla circonflessa, il 20.4% sulla coronaria di destra ed il 9.2% su altri rami coronarici. La predilatazione è stata effettuata nel 100% dei casi, media di diametro 2.8±0.4 mm e lunghezza media 14.5±2.7 mm, il diametro medio dei BVS è stato di 2.9±0.4 mm e lunghezza media 20.3±5.4 mm, con rapporto diametro pallone predilatazione/diametro BVS di 0.96. La postdilatazione è stata effettuata nel 41% dei casi con media di diametro 3.2±0.4 mm e lunghezza media 14.3±1.5 mm con rapporto diametro pallone postdilatazione/diametro BVS di 1.1. Nel 41% dei casi è stata eseguita la tromboaspirazione manuale mentre l'IVUS è stata eseguita nel 19.1% dei pazienti. Nel 5.4% dei pazienti è stata praticata l'aterectomia rotazionale. FFR nel 10.8% dei pazienti. In nessuna caso l'OCT (non presente attualmente nel nostro laboratorio). Un solo BVS è stato aperto e poi non impiantato per mancata progressione dello stesso su un vaso tortuoso. Nessun decesso tra i pazienti che hanno ricevuto un BVS, nessuna trombosi acuta o subacuta. 21 pazienti (28.7%) sono seguiti con follow-up non invasivo della discendente anteriore tramite CFR eseguita con eco-Doppler transtoracico.

Conclusioni. La nostra casistica evidenzia che i BVS sono stati impiantati in soggetti relativamente giovani con sindrome coronarica acuta (STEMI, NSTEMI, UA), prevalentemente affetti da malattia coronarica monovascolare dell'arteria discendente anteriore, rivelandosi un device efficace e sicuro.

C44

CLINICAL OUTCOME IN ACUTE CORONARY SYNDROME PATIENTS TREATED WITH A 2ND GENERATION DRUG-ELUTING STENT: THE ROLE OF DIABETES MELLITUS IN TERMS OF LESION- AND PATIENT-RELATED OUTCOME

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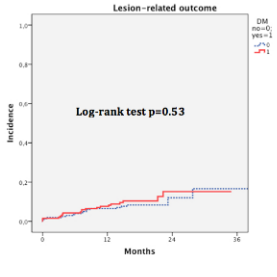
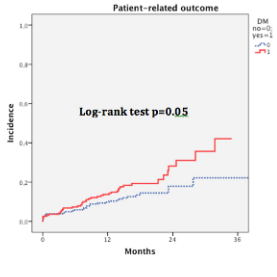
Background. Drug-eluting stents (DES) have shown promising clinical results in the treatment of acute coronary syndrome (ACS) patients. However, diabetes mellitus (DM) is a predictor of poor outcome after percutaneous coronary intervention. There are limited data on ACS patients treated with 2nd generation DES according to diabetic status.

Methods. This prospective study included 452 ACS patients (78% male, mean age 65.6±11.6 years) treated with a 2nd generation DES. We evaluate the clinical outcomes in terms of lesion-related events (including target lesion revascularization, cardiac death and target vessel myocardial infarction) and patient-related events (including all-cause death, any myocardial infarction and any revascularization).





Results. From January 2009 to March 2013, 210 DM patients and 242 non DM patients with ACS were enrolled. DM patients were older, more frequently of male sex and suffering more often of hypertension, hypercholesterolemia and chronic renal failure. DM was statistically associated with multi-vessel CAD and incomplete revascularization. Lesion-related outcomes were comparable between the two groups (10.4% for DM vs 8.8% for non DM, p=0.61) while patient-related outcome show a statistical trend against DM population (21.4% for DM vs 14.6% for non DM, p=0.08). Kaplan-Meier survival curves show a statistical significance for patient-related outcome (Figure).
Conclusion. There is a significant gap in patient-related outcome compared to lesion-related outcome among DM patients in ACS population, mainly driven by the rate of repeated revascularization of the non-culprit lesions due to the chronic background of diabetic coronary artery disease.

C45

DRUG ELUTING BALLOON: ESPERIENZA MONOCENTRICA "REAL WORLD"

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Introduzione. L'utilizzo dei palloni medicati (DEB) rappresenta un'emergente alternativa nel trattamento delle lesioni coronariche semplici e complesse. Diversi studi randomizzati e registri hanno, di fatto, dimostrato una buona efficacia e sicurezza di questi devices sia a breve che a lungo termine.
Obiettivi. Esperienza monocentrica, real world, sull'utilizzo dei DEB nel trattamento della re-stenosi intrastent (ISR) e nei vasi nativi.
Materiali e metodi. Nel nostro studio sono stati valutati retrospettivamente tutti Pazienti consecutivi trattati con almeno un pallone In.Pact Falcon™ (Medtronic Inc., Minneapolis, MN, USA) a rilascio di paclitaxel tra gennaio 2012 e maggio 2014. I principali end-points valutati sono stati morte cardiovascolare, infarto miocardico (MI), target vessel revascularization (TVR) e target lesion revascularization (TLR) clinicamente indicata. End-point principale è stato l'occorrenza di MACE definiti come composito di morte cardiovascolare, MI e TLR.
Risultati. 34 pazienti consecutivi (38 lesioni) sono stati complessivamente analizzati. L'età media è stata di 69.4±9.1 anni e l'82.1% erano di sesso maschile. I principali fattori di rischio erano rappresentati da ipertensione arteriosa e dislipidemia. La maggior parte dei soggetti (82.4%) erano già stati sottoposti ad angioplastica, mentre l'indicazione clinica è risultata essere ugualmente distribuita tra pazienti stabili (47.1%) ed instabili (47.1%). Tuttavia due pazienti sono stati trattati in corso di STEMI (5.8%). La principale indicazione all'utilizzo è stata la ISR (74.4%) principalmente di tipo II (46.6%). Sono state trattate 1.12±0.47 lesioni per paziente, di cui il 46.2% di tipo C, di lunghezza media 18.49±9.1 mm, coinvolgenti una biforcazione coronarica nel 10.3% dei casi. Sono stati utilizzati 1.32±0.68 palloni per paziente senza successiva necessità di impianto di stent. Non si sono verificati MACE sia intraospedalieri che a 30 giorni. Il follow-up a medio termine è stato disponibile nel 76.5% dei pazienti (mediano 349 giorni [IQ 172-479]) con occorrenza di MACE dell'11.5%.
Conclusioni. La nostra esperienza conferma la buona performance dei DEB sia a breve che a medio termine in lesioni complesse.

C46

SAFETY AND EFFICACY OF TREATMENTS FOR IN-STENT RESTENOSIS: A NETWORK META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS

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Aims. The optimal treatment for patients presenting with in-stent restenosis remains to be defined, given the large spectrum of alternative strategies. We performed a network meta-analysis of randomized controlled trials to compare safety and efficacy of the different treatments for in-stent restenosis.
Methods and results. All randomized controlled trials investigating different treatments for patients presenting with in-stent restenosis were included. Major adverse cardiac events (a composite endpoint of death, myocardial infarction, target lesion revascularization, myocardial infarction and stent thrombosis) were the primary endpoint, while its components the secondary ones and where appraised within a hierarchical Bayesian model computing odds ratios. Non compliant/semi compliant balloons were evaluated in 11 studies with 1149 patients, bare metal stent in one study with 224 patients, rotablator in one study with 146 patients, sirolimus eluting stent in 9 with 1017 patients, paclitaxel eluting stent in 7 with 1048 patients, paclitaxel coated balloon in 4 studies with 282 patients, everolimus eluting stent in 1 study with 32 patients, and brachytherapy in 5 with 716 patients. After a median of 12 months (10-14), paclitaxel coated balloon performed not inferior to sirolimus eluting stent, paclitaxel eluting stent and everolimus eluting stent, all of them being superior to non compliant and cutting balloon. This reduction in major adverse cardiac events was mainly driven by reduction in target lesion revascularization obtained by paclitaxel coated balloon, paclitaxel eluting stent, sirolimus eluting stent when compared to other strategies. Rates of myocardial infarction did not differ between various treatments, as those of stent thrombosis, apart from a reduction of stent thrombosis offered by paclitaxel coated balloon when compared to cutting balloon (odds ratio 0.28: 0.02-0.9, all confidence interval 95%).
Conclusions. Paclitaxel coated balloon performed similar to first generation drug eluting stent for treatment of in-stent restenosis, being superior to cutting and non compliant balloon.

C47

RESTENOSI DI STENT MEDICATI: USO DEI PALLONI A RILASCIO DI FARMACO (DRUG-ELUTING BALLOON, DEB)

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Introduzione. Nonostante l'uso degli stent medicati (DES) abbia drammaticamente ridotto la restenosi intra-stent (ISR), tale fenomeno è tuttora presente, senza che sia del tutto chiara la migliore opzione terapeutica. I drug-eluting balloon (DEB) possono rappresentare una buona scelta di trattamento, ma non sono ancora disponibili in letteratura dati sul follow-up. Lo scopo del nostro studio è stato valutare l'efficacia e la sicurezza dei DEB nel trattamento della restenosi degli stent medicati in pazienti ad alto rischio in un follow-up medio.
Metodi. Abbiamo condotto uno studio prospettico sui pazienti con evidenza angiografica di restenosi intra-stent medicato da maggio 2010 a ottobre 2013. I pazienti con lesioni focali o proliferative diffuse sono stati esclusi. L'endpoint primario è stato il tasso di restenosi post-procedura con DEB. L'endpoint secondario era un endpoint composito di MACE, quali morte cardiaca, infarto miocardico e rivascolarizzazione del vaso e della lesione target. Tutti i pazienti hanno ricevuto un pretrattamento con aspirina e carico di clopidogrel di 300 mg, seguiti da doppia antiaggregazione piastrinica per 3 mesi e singola in cronico. Una visita ambulatoriale associata a test d'ischemia è stata effettuata a 6 e 12 mesi, seguita da un follow-up telefonico semestrale.
Risultati. Sono stati arruolati 78 pazienti con restenosi intra-stent medicato, per un totale di 85 DES-ISR, poiché 7 pazienti presentavano una doppia restenosi del DES, su due diversi vasi coronarici. I pazienti selezionati avevano un'età media di 67 anni. L'86% era maschio, il 41% diabetico, il 72% dislipidemico. I pazienti erano giunti alla nostra osservazione con sindrome coronarica acuta nel 40% dei casi. Il DEB è stato gonfiato per un tempo medio di 60 secondi, previo pre-trattamento della lesione con cutting balloon o pallone non compliante. Non ci sono stati eventi avversi peri-procedurali ed in nessun caso è stato necessario l'impianto addizionale di uno stent. Durante il follow-up (medio di 14.8±10.5 mesi), non si sono verificate morti né stroke. Nessun paziente è stato ricoverato per scompenso cardiaco. Sedici pazienti sono stati sottoposti a una coronarografia di controllo, 12 dei quali per sindrome coronarica acuta, mentre 4 per ischemia strumentale. Tra questi 16 pazienti, 11 hanno mostrato una restenosi post-DEB. Gli altri 5 avevano una progressione di malattia su altri vasi o presentavano una coronaropatia stabile. La restenosi del DEB è avvenuta nel 13% dei casi. La presentazione clinica più frequente della restenosi post-DEB è stata la sindrome coronarica acuta (73%). I pazienti con restenosi di DEB sono stati trattati in 7 casi con impianto di nuovo DES, un caso è stato trattato con bypass, un caso mediante ottimizzazione della terapia medica e 2 pazienti sono stati candidati a terapia con shock-waves.
Conclusioni. La nostra esperienza ha confermato la sicurezza e l'efficacia del trattamento della DES-ISR con palloni medicati, mostrando un tasso di restenosi (13%) perfettamente in linea con la letteratura.

C48

AG-READY (AGRIGENTO-REAL WORLD DRUG ELUTING BALLOON REGISTRY) 2014

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Aims. This real world observational registry aims to highlight our experience with drug eluting balloons in the treatment of drug-eluting stent restenosis and de novo lesions in vessel smaller than 3 mm. We enrolled unselected and consecutive patients referred to our center for coronary angiography with indication to coronary revascularization and coronary subsets suitable for drug eluting balloon use, according to the German Consensus Group recommendations.
Methods and results. Our study was conducted in a single center by five resident operators. All patients presenting to our institution from October 2011 to October 2012 with significant drug-eluting in-stent restenosis and/or de novo lesion in vessel smaller than 3 mm, who were eligible to receive drug eluting balloon treatment, were included in the registry. Clinical and angiographic characteristics were obtained. 12 months clinical\angiographic follow up was scheduled for all patients after discharge. After 1 and 6 months a clinical examination and ECG was performed in all patients. Post-procedural and follow-up endpoints included in the analysis were: cardiac death, myocardial infarction and target lesion revascularization (TLR). A total of 116 patients received treatment with drug eluting balloon in the study period; significant number having major risk factors for coronary artery disease, 40% diabetics; 82% hypertensive; 61% hyperlipemic). 58% of the patients had multivessel disease. Target vessel was most commonly First Obtuse Marginal branch (26.2%). 36% of the patients have in stent restenosis (ISR). Only 2.9% of the procedures was switched on stenting. The "SeQuent® Please" paclitaxel-eluting balloon (B. Braun Melsungen AG) was used for

revascularization. Patients were angiographically/clinically followed for a median of 12 months. No patients died or was re-admitted for acute myocardial infarction during this period, 16% received TLR and successfully performed a re-PCI with DES (11 patients), BMS (5 patients) or DEB (2 patients); re-admission diagnosis were unstable angina in 40% of the cases and stable angina in 30%, 30% of TLR was performed after angiographic evidence of significant ISR at follow-up; In TLR group 8 patients had performed re-PCI for ISR, 4 patients after small vessel treatment and 3 patients after bifurcation treatment. The worst result for ISR treatment with DEB were observed in coronary venous graft (11 patients treated), with 75% of restenosis after DEB treatment.

Conclusions. Our experience highlight the safety and efficacy of drug eluting balloons in the treatment of drug-eluting ISR and de novo lesion in vessel smaller than 3.0 mm, for patients having significant risk factors for coronary artery diseases. Nevertheless poor results were observed in the treatment of ISR on coronary venous graft, although our data derived from a relatively small number of patients. This registry continuing to enroll patients currently, hoping to make more meaningful our experience. However, further studies are needed to define the real drug eluting balloons indications and limitations in the coronary artery disease treatment.

C49

SAFETY AND EFFICACY OF DRUG ELUTING STENT FOR SMALL VESSEL DISEASE: PRELIMINARY RESULTS OF A SINGLE-CENTRE EXPERIENCE

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Background. Balloon angioplasty with use of coronary stents is the treatment of choice for small vessels coronary artery disease. The challenge of this procedure is restenosis phenomenon, which potentially leads to target lesion revascularization (TLR) and target vessel revascularization (TVR). It is known that small vessel disease (diameter <3 mm) is an independent predictor of restenosis. From the literature we know that use of drug eluting stents (DES) reduces the incidence of restenosis, compared to bare metal stents, reducing global major adverse cardiac events (MACE) at follow-up.

Aims. The aim of this study is to evaluate DES performance in the treatment of small vessel lesions.

Methods. Our study is a prospective observational single-centre registry that was approved by our local Ethic Committee. Patients were eligible for the study if they had small vessel coronary disease (vessel diameter between 2.25 and 2.75 mm) and were indicated to PCI, but also if they signed the informed consent form, were adult and willing to participate in all follow-up assessments. Clinical follow-up were performed at 6 and 12 months after procedure. Primary endpoint is the MACE, composed by death, myocardial infarction and clinically driven-TLR. Secondary endpoints were clinical and device success, MACE and TLR at 6 months, TVR and sent thrombosis (ST) at 6 and 12 months. Patients were indicated to dual antiplatelet therapy (DAPT) for 12 months.

Results. Between May 2013 and January 2014, 50 consecutive patients with small vessel lesions were treated with DES and were enrolled in our study. Mean age of the cohort was 73.6 years, 86% of the patients had hypertension, 54% hyperlipidemia, 30% diabetes (14% insulin dependent), 50% had history of smoking, 40% had previous PCI. Acute coronary syndrome was treated in 74% of the patients. During the procedure 95% of cases were pre-dilated, 43% were post-dilated and 6% were thrombus aspirated. Major vessel treated were LAD (24%), circumflex coronary artery (20%) and RCA (16%). Vessel diameter was on average 2.6±0.3 mm, 23.5±10.6 mm is the average lesion length and 92.4±5.8% the value of stenosis. Six month follow-up was completed for 100% of patients. DAPT was assumed by 100% of patients. Device success was achieved in 100% of cases, clinical success in 98%; 1 patient (2%) had periprocedural myocardial infarction. TVR occurred in 1 patient (2%); any stent thrombosis was recorded. Primary endpoint was achieved by 100%, secondary endpoint by 96%.

Conclusion. Preliminary results (6 month follow-up) of our single centre experience show that treatment of small vessel coronary artery disease with DES seems to be safe and effective in different clinical settings.

C50

A REAL-WORLD SINGLE CENTRE EXPERIENCE USING THE SELF-EXPANDING CORONARY STENT

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Background. A coronary self-expanding stent (Stentys S.A., Paris, France) may overcome the drawback of difficult stent sizing and avoid stent malapposition with subsequent risk of restenosis and thrombosis. This feature should be particularly useful in case of primary percutaneous coronary interventions (PCI) in patients with ST-elevation myocardial infarction (STEMI) or in the presence of complex coronary anatomy like coronary ectasia (a segment of artery >1.5 times the diameter of adjacent segments) or bifurcations.

Methods. We tasted the efficacy and safety of this stent in consecutive patients undergoing PCI in our centre. The decision to use a self-expanding stent was at discretion of the operator. The primary endpoint was the composite of the following major adverse cardiac and cerebrovascular events (MACCE) at 12 months: death, recurrence of myocardial infarction, target vessel revascularization (TVR) and stroke.

Results. 82 patients (mean age: 64±15; men: 83%; diabetes: 22%) treated with a self-expanding stent were enrolled. The indications for PCI were STEMI in 62%, non ST-elevation myocardial infarction (NSTEMI)/unstable angina in 21%, and stable angina in 17%. 40% of patients had ectatic coronary arteries (with a vessel diameter >4.5 mm) and 18% coronary bifurcated lesions. DES/BMS ratio was 56/26. Two patients (2.4%) experienced MACCE at 12 months. In both of them a geographic miss during stent deployment with non complete coverage of the lesion led to TVR after few months.

Conclusion. The self-expanding stent showed a low rate of clinical events in routine clinical practice. This stent is particularly useful in case of difficult stent sizing like STEMI, coronary ectasia or bifurcations. Self-expanding stent deployment is different compared to traditional stents and a learning curve is needed in order to avoid geographic miss and achieve a good result of the procedure.

C51

UTILIZZO DI BIORESORBABLE VASCULAR SCAFFOLD (BVS) NELLA VASCULOPATIA DEL CARDIOTRAPIANTATO: FOLLOW-UP A BREVE E MEDIO TERMINE

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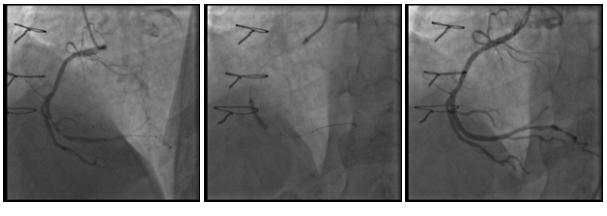
La vasculopatia del cardiotrapiantato (cardiac allograft vasculopathy, CAV) è una forma specifica di aterosclerosi coronarica accelerata e rappresenta la principale causa di mortalità e morbilità del paziente sottoposto a trapianto cardiaco, raggiungendo il 30% delle morti totali dei pazienti sopravvissuti a 5 anni. La presenza di inspessimento medio-intimale, dimostrato nei principali studi con tecniche di imaging quali IVUS o OCT ha permesso di predefinire lo sviluppo della CAV a medio e lungo termine. L'angioplastica coronarica percutanea con successivo impianto di stent metallici (bare metal stent, BMS) o medicati (drug eluting stent, DES) non ha mostrato grandi risultati a medio e lungo termine, dovuti principalmente agli alti tassi di restenosi e rapida progressione di malattia in questa specifica popolazione. Il recente utilizzo di scaffold vascolari totalmente bioassorbibili (BVS) – Absorb, Abbott Vascular – ha portato notevoli vantaggi, soprattutto in termini di completo restoring del vaso, recupero della vosomotilità e bassa incidenza di restenosi. Nella CAV tale utilizzo potrebbe essere particolarmente interessante in considerazione del fatto che la malattia coronarica può essere maggiormente evolutiva, richiedere utilizzo di stent multipli e coinvolgere nel tempo più segmenti coronarici.

Da gennaio 2013 ad oggi sono stati impiantati presso la nostre Divisione 6 BVS Absorb in 5 pazienti cardiotrapiantati affetti da CAV, documentata all'esame angiografico e/o IVUS. L'età media della popolazione era di anni 49 anni, 3 maschi e 2 femmine. Le cause di trapianto cardiaco erano le seguenti: 1 cardiopatia dilatativa idiopatica, 1 cardiopatia dilatativa post miocardite 3 cardiopatia dilatativa post-ischemica. Le lesioni responsabili erano in 2 casi IVA; 1 CX e 3 CDx. Il diametro medio dei BVS era 2.9 mm e 21,3 mm di lunghezza media. Stenosi pre-impianto calcolata con QCA in 4 lesioni e IVUS in 2 lesioni. Successo procedurale avvenuto nel 100% dei casi, in un paziente si è osservato una occlusione di un side branch di esile calibro (small side branch occlusion <2 mm) con minimo incremento post-PCI dei valori di troponina e CK-MB senza tuttavia raggiungere criteri per diagnosi di IMA periprocedurale. Il follow-up medio è stato di 6 mesi. Abbiamo riscontrato 1 exitus dovuto a cause non cardiache (quadro di severo distress respiratorio associato a sepsi). Non vi sono stati casi di restenosi, trombosi di BVS, target lesion revascularization o IMA nell'osservazione al FU.

Nella popolazione in esame l'impianto di BVS per il trattamento della CAV ha mostrato buon profilo di sicurezza ed efficacia nel follow-up a breve e medio termine. Attualmente in letteratura è descritto 1 solo caso di impianto di BVS nella CAV che ha mostrato buon risultato anche a controllo IVUS a distanza. Ulteriori studi clinici e realizzazione di un registro multicentrico potranno fornire maggiori informazioni sull'utilizzo di questa tecnologia in un setting specifico di aterosclerosi coronarica particolarmente aggressiva come nella CAV.



Bioresorbable vascular scaffold

C52

CLINICAL OUTCOME IN A REAL WORLD SINGLE CENTER EXPERIENCE USING A NEW BIOABSORBABLE POLYMER DES

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Background. Bioabsorbable polymer drug eluting stents (DES) represent a very promising new category of DES. Bioflow III, a multicenter international registry of all-comers patients treated with Orsiro DES (sirolimus eluting and bioabsorbable polymer DES) showed 4.7% of target lesion failure (TLF) and 0.5% of stent thrombosis (ST, definite and probable) at 12 month follow-up. However, data about their extensive utilization in real world and longer follow-up are lacking.

Objective. The aim of this registry is to evaluate the clinical outcome at 6, 12 and 18 months of a bioabsorbable polymer DES in all-comers fashion.

Method. In the period starting from April 17, 2012 to October 16, 2013, 117 patients were treated with Orsiro DES. Patients were followed up at 6, 12 and 18 months post procedure, to determine the incidence of major adverse cardiac events (MACE): cardiac death, target vessel myocardial infarction or clinical driven target vessel revascularization, stent thrombosis (ST). Dual antiplatelet therapy (DAPT) was recommended for all patient at least for 12 months.

Results. The mean age of the cohort was 65.3±10.3 (75% male, 25% diabetes, 5% severe renal disease), acute coronary syndrome (ACS) was present in 70% of patients (23% primary PTCA, 19% unstable angina, 28% NSTEMI). A total of 120 procedures and 153 lesions were analyzed (71% single vessel disease, 25% double vessel disease and 4% triple vessel disease, LAD involved in 31%, CDX in 27% and Cx in 20%) with 39 bifurcations (55% of these were Medina 1,1,1). Lesions were type B2/C in 66% of cases, 4% were restenosis. In 15% of lesions TIMI flow pre-procedure was 0; thrombus was clearly present in 9% of cases. Patients were pretreated with aspirin, heparin and a second antiplatelet drug (plavix 58%, prasugrel 11%, ticagrelor 12%). Clinical device success was 99.3%. At the moment the first follow-up was completed, 82% compliance. Successive follow-up are in progress: 75% and 38% of compliance were reached at 12 and 18 months, respectively. A total of five deaths were observed: 3 non cardiac deaths caused by neoplasia and cerebral accident one year after procedure and 2 cardiac related (one sudden death 3 weeks after implantation in a 82 year with very low ejection fraction and one in-hospital death in a patient with anterior STEMI, cardiogenic shock and >12 hours symptom onset). One patient had subacute stent thrombosis (7th day), treated with a new PTCA. No target lesion revascularization or target vessel revascularization was observed. At 6 months, patients maintaining DAPT were 96%, while at the second and third follow-up, 57% and 27%, respectively.

Conclusions. Orsiro is a new bioabsorbable polymer stent that performed very well in our unselected experience, despite the high number of patients with SCA (in particular treated with primary PTCA) and despite the long follow-up. The incidence of global follow-up events was very low (MACE <3.5% per patients and <2% per stents), similar to Bioflow III results and better compared to literature patients presented with SCA.

C53

AGRIGENTO SINGLE CENTER EXPERIENCE WITH 180 BVS IN DAILY CLINICAL PRACTICE: 6 TO 12 MONTH FOLLOW-UP

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Scopo. I DES convenzionali modificano il flusso coronarico, riducono la funzionalità della parete coronarica e inducono disfunzione endoteliale. Grazie allo sviluppo di device totalmente bioriassorbibili (Bio Vascular Scaffold, BVS), che forniscono supporto meccanico ed eluizione di farmaci antiproliferativi, si prefigura la possibilità di trattamento delle stenosi coronariche con una "restitutio ad integrum" del vaso ponendo le basi per una reale "terapia riparativa vascolare". Il BVS offre una valida chance per superare molte limitazioni dei DES convenzionali, con conseguenti vantaggi: ripristinata vasomotilità, late lumen gain, ridotta infiammazione, ridotta trombosi tardiva, possibile riduzione della doppia antiaggregazione, maggiore spazio per successiva rivascolarizzazione chirurgica, compatibilità con TAC. Abbiamo analizzato il BVS Absorb in un registro prospettico osservazionale, fornendo il nostro parere su sicurezza, performance e risultati clinici a medio/lungo termine del BVS.

Metodi e risultati. 120 pazienti con 152 lesioni hanno richiesto 180 BVS dal settembre 2012 al gennaio 2014. Età media 52.6 anni, 59% diabetici, 81% ipertesi, 56% ipercolesterolemici, 30% fumatori, 53% con familiarità per cardiopatia ischemica. Tutti i pazienti sono stati seguiti clinicamente per 6 mesi; imaging coronarico invasivo è stato eseguito in casi selezionati. Per pazienti con stenosi coronariche oltre il Tipo A è stata programmata coronarografia a 6 mesi. 1, 3, 9 and 12 mesi di follow-up telefonico sono stati programmati per tutti i pazienti. Gli endpoint includevano morte cardiaca, infarto miocardico e clinically driven target lesion revascularization (TLR) a 6 mesi. Doppia antiaggregazione è stata prescritta per 12 mesi. Lesioni lunghe (≥20 mm) sono state trattate nel 76% delle PCI totali, biforcazioni nel 10%, occlusioni croniche totali nel 5.5%. I BVS sono stati impiantati per NSTEMI, STEMI, Angina stabile ed instabile. 97.3% di successo procedurale; dissezioni maggiori sono state riscontrate nel 2.7% delle PCI. A 6 mesi, non ci sono state morti cardiache; si è osservata solo una TLR causata da una trombosi su un lungo tratto di overlapping tra due BVS esordita con STEMI. L'angiografia a 6 mesi su 67 pazienti ha mostrato late lume loss 0.29±0.03 mm, nessuna significativa ristenosi e 3 aneurismi post BVS. OCT a 6 mesi su 8 pazienti confermano buona apposizione dello stent e completa endotelizzazione delle maglie; OCT a 3 mesi su 4 pazienti ha mostrato precoce e completa endotelizzazione delle maglie con un risultato "BMS-like". IVUS a 6 mesi su 12 pazienti ha rivelato una tendenza all'undersizing degli stent. 30 pazienti hanno follow-up clinico ad 1 anno; nessuno ha riferito sintomi ischemici, con assenza di re-PCI e/o morti cardiache.

Conclusioni. La nostra esperienza suggerisce, sicurezza e buona performance del BVS in differenti quadri angiografici e clinici a 6 mesi. OCT an IVUS hanno evidenziato buona apposizione e precoce endotelizzazione con una tendenza all'undersizing nei primi impianti, risolta con l'acquisizione di maggior esperienza con le tecniche d'impianto. Un piccolo gruppo di 30 pazienti con follow-up a 12 mesi fornisce dati rassicuranti sull'outcome clinico a lungo termine. Abbiamo osservato inoltre risultati sovrapponibili su lesioni tipo A e su lesioni lunghe, che incoraggiano il trattamento di queste ultime con BVS con possibilità reale di restitutio ad integrum di vasi affetti da severa patologia ateromasica. Il nostro registro continua ad arruolare pazienti per rendere più significativa la nostra esperienza e chiarire quando e come il BVS potrebbe rappresentare un valida alternativa ai DES convenzionali.

C54

EARLY AND MID-TERM OUTCOME IN A "REAL-WORLD" POPULATION TREATED WITH BIORESORBABLE VASCULAR SCAFFOLD

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Objectives. The aim of the study was to evaluate procedural, short and mild-term safety and efficacy of Bioresorbable Vascular Scaffold (BVS) implantation in a real-world setting.

Background. Data associated with the real-world use of BVS in unselected lesions are lacking.

Method and results. A total of 289 unselected patients were treated with BVS in a single center, from March to May 2014. In 63 (21.8%) patients a metallic stent was also implanted. Clinical and angiographic characteristics of evaluated patients are summarized in Tables 1 and 2, respectively. Two third of patients were ≤65 years old. Fifty percent presented an acute coronary syndrome and in all of these patients BVS were implanted in the culprit lesion. The left anterior descending was the vessel most frequently treated (49.6%). In one case (0.3%) saphenous vein graft was treated and in 8 (2.2%) cases left main was treated. Fifty-eight (15.8%) of the lesions treated with BVS were located at site of bifurcation; 33 cases (9.0%) involved total coronary occlusions and 21 (5.7%) of the treated lesions were in-stent restenosis. In 65 (17.7%) cases, overlap of one or more BVS was observed. Dissections due to BVS implantation was detected in 28 (7.6%) of lesions and all were successfully treated. At 1 month, 2 patients died, only one death was defined as CV death (probable subacute scaffold thrombosis at day 26). One acute scaffold thrombosis due dissection of proximal scaffold's edge occurred during hospitalization and a TLR due dual antiplatelet therapy discontinuation occurred at day 25. At mid-term follow-up the rate of device-oriented events was 1.8% and just 4 TLR occurred after 6 months.

Conclusions. This study showed that BVS use in unselected lesions was associated with good procedural and mid-term safety and efficacy outcomes. Longer follow-up and larger samples are needed to confirm these promising results.

Table 1. Clinical characteristics.

No. patients	289
Age (years) (mean±SD)	60.6±9.5
Age ≤65	238 (82.3)
Male, n (%)	248 (85.8)
Hypertension, n (%)	199 (68.8)
Diabetes, n (%)	71 (24.5)
Insulin-dependent, n (%)	31 (10.7)
Smoking, n (%)	106 (36.6)
Dyslipidemia, n (%)	171 (59.1)
Family history, n (%)	135 (46.7)
Prior PCI, n (%)	89 (30.7)
Prior CABG, n (%)	8 (2.7)
CKD (eGFR <60 ml), n (%)	21 (7.3)
Stable angina, n (%)	144 (49.8)
UA/STEMI, n (%)	91 (31.5)
STEMI, n (%)	54 (14.5)

Table 2. Angiographic characteristics.

No. patients	367
Treated vessel, n (%)	
Left anterior descending	182 (49.6)
Left circumflex	79 (21.5)
Right coronary artery	97 (26.4)
Total no. BVS	545
No. BVS per lesion	1.48
Lesion type (ACC/AHA), n (%)	
Type A	56 (15.3)
Type B_1	129 (35.1)
Type B_2	73 (19.9)
Type C	109 (29.7)
Bifurcation, n (%)	58 815.8)
Chronic total occlusion, n (%)	33 (9.0)
Planned overlap, n (%)	65 (17.7)
In-stent restenosis, n (%)	21 (5.7)
Lesion length (mean±SD) (mm)	21.6±16.9
Proximal RVD (mean±SD) (mm)	3.1±0.6
Distal RVD (mean±SD) (mm)	2.9±0.5
BVS length (mean±SD) (mm)	33.6±23.0
BVS diameter (mean±SD) (mm)	3.12±0.4

RVD, reference vessel diameter.

C55

TECHNICAL AND PROCEDURAL SUCCESS OF PERCUTANEOUS CORONARY INTERVENTION OF CHRONIC TOTAL OCCLUSION WITH BIORESORBABLE VASCULAR SCAFFOLD IMPLANTATION: INSIGHTS FROM THE GHOST-CTO REGISTRY

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Purpose. Implantation of bioresorbable vascular scaffolds (BVSs) holds several theoretical advantages after successful percutaneous recanalization of chronic total occlusions (CTOs), including vasomotion restoration and the possibility to reconstruct long coronary segments with the scaffolds dissolving in approximately two years. However, there is a lack of knowledge on the feasibility and early safety of percutaneous coronary intervention (PCI) with the systematic use of BVSs in CTO lesions.

Methods. Technical and procedural success of BVS implantation in CTO PCIs performed at a single center between June 2013 and January 2014 were prospectively evaluated. Technical success was defined as 1) successful CTO recanalization; 2) successful BVS delivery and implantation; 3) post-procedural residual diameter stenosis <30% within the treated segment; 4) restoration of TIMI grade 3 antegrade flow. Procedural success was defined as technical success with no in-hospital major adverse cardiac events (MACE).

Results. A total of 23 CTO lesions were successfully recanalized in 23 patients (mean J-CTO score 1.65±1.09, length of occlusion 36.0±24.0 mm, anterograde Werner class 0.91±0.83, retrograde Werner class 1.22±0.93). Most of the procedures (21/23) were performed via the default antegrade approach, whereas switching to a retrograde approach was needed in two cases (8.7%). At least one BVS was successfully implanted in all patients (total scaffold number 69; mean number per patient 3.00±1.41; mean scaffold length 52.67±4.71). Four patients (17.4%) received both BVSs and drug-eluting stents (due to shelf unavailability in three cases and delivery failure in one case). Post-procedure residual diameter stenosis was <30% in all cases but one. Technical success was 21/23 (91.3%). Optical coherence tomography assessment was performed at post-procedure in 19 of 23 patients (82.6%). Edge dissections were detected in 2 of 19 patients (10.5%). Scaffold under-expansion was noted in 11 of 53 scaffolds analyzed (21%). BVS fracture was observed in 1 of 25 overlap sites analyzed (4%). No incomplete stent apposition was observed. In hospital stay was uneventful in all cases, with no MACE (procedural success 91.3%).

Conclusions. The use of BVSs in PCI of CTO lesions appears feasible and associated with high rates of technical and procedural success. While the early results are promising, long-term follow-up is needed to ascertain the true potential of BVSs in this setting.

C56

30-DAY CLINICAL OUTCOMES OF OVERLAPPING ABSORB BVS FOR THE TREATMENT OF LONG CORONARY LESIONS: DATA FROM THE ITALIAN MULTICENTER RAI REGISTRY

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Aims. Data on the clinical outcome of patients with long coronary lesions requiring treatment with overlapping everolimus-eluting bioresorbable vascular scaffold (Absorb BVS) are scant. It is currently uncertain whether the relatively high profile of BVS might impair endothelization at sites of overlap leading for increased risk of acute and mid-term complications, e.g. stent thrombosis. We report the procedural and short-term clinical outcomes in a cohort of patients having at least one vessel treated with at least 2 overlapped Absorb BVS.

Methods and results. Consecutive patients included in a multicenter registry at 9 centers in Italy were systematically followed for major adverse cardiac events. Clinical data were obtained for 61 patients (mean age 56.2 years, 75.8% males) with a total of 64 lesions treated with overlapping Absorb BVS. Diabetic patients were 13.6%. Multivessel disease was present in 62.1% of patients. Mean length covered by overlapping BVS was 54.54 (±16 mm). On 64 lesions, only 3 lesions were ≤28 mm, being the shortest lesion 22 mm. The mean number of implanted Absorb BVS was 2.3 scaffolds per lesion and 2.64 scaffolds per patient. At one month, no stent thromboses occurred. The only observed adverse event was a peri-procedural myocardial infarction (asymptomatic rise of troponin-I which did not require coronary angiography).

Conclusions. Our findings suggest that treatment of long lesions by means of overlapped Absorb BVS appears to be safe at one month.

C57

BIORESORBABLE VASCULAR SCAFFOLD IN COMPLEX LESIONS: ACUTE AND MID-TERM FOLLOW-UP CLINICAL OUTCOMES

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Objectives. The aim of this single-center study, which is part of an ongoing prospective "real-world" registry, was to assess the feasibility and mid-term clinical outcomes of bioresorbable vascular scaffold (BVS) implantation in complex coronary lesions.

Background. Clinical data associated with the real-world use of BVS in unselected and complex lesions are lacking.

Methods and results. Among a total of 244 patients treated with BVS included in the GHOST registry, 154 (63.1%) patients underwent PCI with BVS in 172 complex lesions. These include 75 (43.6%) long lesions (≥25 mm); 49 (38.5%) bifurcations lesions; 7 (4.1%) left main lesions; 20 (11.6%) in-stent restenosis (ISR); 29 (16.9%) chronic total occlusions (CTO); one (0.6%) saphenous vein graft lesion and 52 (30.3%) STEMI. A total of 314 BVS were implanted and left anterior descending (LAD) was most treated vessel (45.3%). Intra-coronary imaging was performed to confirm good apposition of scaffolds. Bailout stenting was needed in 19 (11%) lesions, mostly due to dissection (8.1%) that was successfully treated. No in-hospital adverse events were observed. At 1-month follow-up a sudden death at day 26 occurred, being classified as cardiovascular death and, according to ARC definitions, defined as probable sub-acute stent thrombosis. The other adverse events included 5 TLRs as follows: 1 occurred at about 6 months and 4 occurred over 6 months follow-up.

Conclusions. This preliminary experience suggested that BVS implantation for complex lesions treatment is feasible and associated with promising acute and short-term clinical outcomes. However, larger studies with a larger population and a longer follow-up are needed to adequately address the safety and efficacy of BVS use in this setting.

C58

USE OF THE ABSORB BIORESORBABLE VASCULAR SCAFFOLD FOR SUPERFICIAL FEMORAL OR POPLITEAL ARTERY REVASCULARIZATION: PROOF OF CONCEPT FROM A CASE SERIES

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Background. Despite a plethora of device that can be used to optimize the results of superficial femoral artery (SFA) or popliteal artery endovascular therapy, the ideal device is still missing. Very favorable data are accruing on

the Absorb coronary bioresorbable vascular scaffold. We hypothesized that the Absorb bioresorbable vascular scaffold could prove beneficial also for SFA and popliteal artery revascularization.
Methods. We retrospectively collected from our administrative database baseline, procedural, and outcome data on patients undergoing lower limb Absorb implantation, which was carried out according to typical coronary techniques, and ≤0.5 mm oversizing for balloon post-dilation. Follow-up is clinical and with duplex ultrasound at 1, 3, 6 and 12 months as per our standard of practice.
Results. A total of 22 patients (25 limbs) underwent Absorb-supported revascularization between December 2013 and June 2014. Average age was 67±12 years, with 7 (32%) women, and most commonly Fontaine 2b at admission (20 [91%]). The target vessel was the SFA in 20 (80%) cases and the popliteal artery in 5 (20%) cases, with an average lesion length of 84±62 mm, and 10 (60%) total occlusions. Multiple Absorbs were required in 18 (72%) cases, with a total Absorb length per limb of 85±62 mm (minimum 18 mm, maximum 252 mm). Angiographic success was obtained in all procedures, in the absence of procedural complications. Clinical and duplex ultrasound follow-up at 1 and 3 months have shown so far favorable results, without any repeat revascularization or loss of patency, but further follow-up is ongoing.
Conclusions. The present case series, reporting on the novel use of the Absorb bioresorbable vascular scaffold for SFA and popliteal artery revascularization, suggest that this device can prove useful and safe also in the lower limbs. Further follow-up and larger series are however needed before a more widespread adoption of this approach.

TAVI clinical outcome and complications

C59

EARLY AND MID-TERM OUTCOMES OF 1904 PATIENTS UNDERGOING TRANSCATHETER BALLOON-EXPANDABLE VALVE IMPLANTATION: RESULTS FROM THE ITER REGISTRY

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Background. Transcatheter aortic valve implantation (TAVI) has been proposed as a therapeutic option for high risk or inoperable patients with severe symptomatic aortic valve stenosis. Aim of this retrospective multicenter study is to report early and mid-term clinical and echocardiographic outcomes of patients undergoing TAVI with a balloon-expandable device in Italy.
Methods. From 2007 to 2012, 1904 patients were enrolled at 33 centers in the Italian Transcatheter balloon-Expandable valve Registry (ITER). The study device is the SAPIEN/SAPIEN XT (Edwards Lifesciences, Irvine, USA). A minimum follow-up of one-year was required to be part of the Registry. Outcomes were assigned according to the updated Valve Academic Research Consortium (VARC-2) definitions.
Results. Mean age was 81.6±6.2 and 1147 (60.2%) patients were female. Out of 352 (18.5%) patients who had at least one previous cardiac intervention, 49 (2.6%) underwent valve-in-valve TAVI. Mean Logistic EuroSCORE, EuroSCORE II and STS Score were 22.4±14.6%, 7.3±6.7% and 9.2±7.6%, respectively. The procedural accesses were: transfemoral, 1252; transapical, 629; transaortic, 19; transaxillary, 4. The reported 30-day mortality was 7.2% (137 patients). The most significant VARC-2 outcomes are summarized in the Table. At discharge mean transprosthetic gradient was 10.7±4.5 mmHg. Incidence of post-operative mild, moderate or severe paravalvular leaks were respectively: 32.1%, 5.0% and 0.4%. Overall 1, 2 and 3 years survival were 84.5%, 76.4% and 68.2%.

N.	1904
Device failure	221 (11.6%)
>1 valve implanted	14 (0.7%)
Aortic valve replacement	9 (0.5%)
Operative mortality (within 24h)	47 (2.5%)
Aortic regurgitation ≥ moderate	100 (5.2%)
Mean aortic gradient ≥20 mmHg	64 (3.4%)
Acute myocardial infarction (≤72h)	26 (1.4%)
Stroke (non disabling)	36 (1.9%)
Stroke (disabling)	18 (1.0%)
Life threatening bleeding	186 (9.9%)
Major bleeding	200 (10.6%)
Major vascular complication	177 (9.3%)
Acute kidney injury (AKIN) grade 2-3	155 (8.1%)
PM implantation (before discharge)	116 (6.1%)

Conclusions. According to our data, patients undergoing TAVI with a balloon expandable device show good early and mid-term clinical and hemodynamic results. In particular the incidence of post-operative pacemaker implantation as well as moderate/severe regurgitations seems reasonable. The incidence of mild regurgitation is still a matter of concern.

C60

OUTCOME A 3 ANNI IN PAZIENTI CONSIDERATI "OFF-LABEL" SOTTOPOSTI AD IMPIANTO DI COREVALVE: ESPERIENZA DI UN SINGOLO CENTRO

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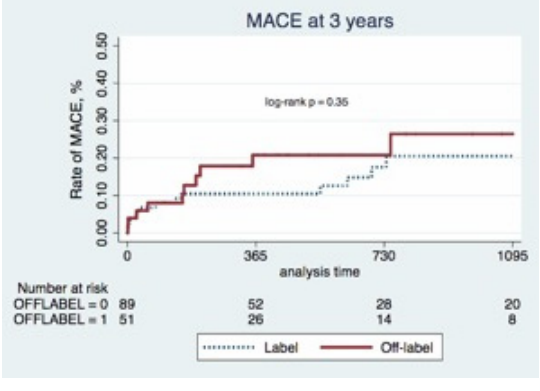
Background. Alcune condizioni anatomiche cardiache sono considerate sfavorevoli per l'impianto di CoreValve e ne escluderebbero l'uso secondo le indicazioni approvate.
Scopo. Determinare l'impatto della presenza di condizioni controindicanti l'impianto di CoreValve ad un follow-up di 3 anni.
Metodo. Abbiamo seguito 154 pazienti consecutivi sottoposti ad impianto di CoreValve nel nostro Ospedale Universitario. Abbiamo confrontato i pazienti che sonostati sottoposti ad impianto "off-label" verso i pazienti con nessuna controindicazione all'impianto. Lo status "off-label" è stato definito, secondo le indicazioni della casa produttrice, con la presenza di almeno uno fra: frazione d'eiezione ventricolare sinistra severamente depressa (FEVS <30%), severa ipertrofia del VS (setto interventricolare ≥17 mm) o insufficienza mitralica (IM) severa (≥3+/4+). Il confronto è stato eseguito per le caratteristiche cliniche basali, e per l'outcome a 30 giorni e a 3 anni dall'impianto valvolare. L'outcome è stato valutato secondo le definizioni VARC-2 a 30 giorni e in termini di eventi avversi cardiaci e cerebrali maggiori (MACCE) a 3 anni, definiti come morte, infarto e stroke.
Risultati. Un impianto "off-label" è stato eseguito in 53 (34%) pazienti. Le caratteristiche basali in termini di età, sesso, classe NYHA di presentazione, presenza di fibrillazione atriale, malattia vascolare periferica ed insufficienza renale cronica sono risultati simili tra i due gruppi. I pazienti con status "off-label" hanno avuto un maggior rischio all'intervento cardiochirurgico (Logistic EuroSCORE 28±15% vs 23±14%, p=0.03) alla presentazione. A 30 giorni i due gruppi sono risultati comprabili in termini di successo procedurale, complicanze vascolari maggiori, sanguinamenti maggiori o a rischio di vita, e mortalità. I MACCE a 3 anni sono stati simili tra i 2 gruppi ["label" 21% (IC 12-34%) vs "off-label" 26% (IC 14-46%), log-rank p=0.35).
Conclusioni. Nell'esperienza del nostro centro l'impiego "off-label" di CoreValve si è dimostrato fattibile ed efficace in termini di outcome procedurale a medio termine.



C61

FOUR-YEAR DURABILITY OF CLINICAL AND HEMODYNAMIC OUTCOMES OF TRANSCATHETER AORTIC VALVE IMPLANTATION WITH SELF EXPANDING COREVALVE: A SINGLE CENTER EXPERIENCE

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Background. Long-term data on durability of currently available transcatheter heart valves are limited. We sought to assess 4-year clinical and echocardiographic outcomes in patients undergoing transcatheter aortic valve implantation (TAVI) with CoreValve prosthesis.

Methods. Between June 2007 and February 2014, 450 consecutive patients with symptomatic severe aortic stenosis underwent TAVI using both CoreValve, Edwards-SAPIEN, and Lotus valves. For the purposes of this study we included only those patients undergoing successful TAVI with CoreValve prosthesis who had a minimum follow-up of 4 years (n=125). All outcomes were defined according to the Valve Academic Research Consortium (VARC 2).

Results. Survival rates at 1, 2, 3 and 4 years were 83.2, 76.8, 73.6 and 66.3%, respectively. Survival from cardiovascular mortality rates at 1, 2, 3 and 4 years were 88.0, 84.0, 83.2 and 80.8%, respectively. No deaths were directly related to valvular dysfunction. Freedom from reoperation was 98.5%. We reported satisfactory long-term valve performance in terms of mean pressure gradients and aortic valve area (AVA). Aortic regurgitation was a common finding after the procedure, especially due to PVR, which was observed in the majority of patients (71.5%), mostly mild (52.0%). All patients with mild PVR were either unchanged or slightly improved over time. Progression from mild acute PVR to moderate PVR at 4-year follow-up was reported in three patients. No cases of severe PVR were noticed. Prosthetic valve failure was reported in 4 patients (3.2%). Valve thrombosis or late valve embolization were not reported.

Conclusions. Our study demonstrated that favorable outcomes after successful TAVI are associated with sustained clinical and functional cardiovascular benefits up to 4-year follow-up. Signs of moderate prosthetic valve failure are present only in a small percentage of patients.

C62

SIX-YEAR CLINICAL AND HEMODYNAMIC OUTCOMES FOLLOWING TRANSCATHETER AORTIC "BALLOON-EXPANDABLE" VALVE IMPLANTATION

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Background. Transcatheter aortic valve implantation (TAVI) is a therapeutic option in high-risk or inoperable patients suffering from severe symptomatic aortic valve stenosis (SSAVS). Concerns still exist regarding long-term results and freedom from adverse events.

Aim. Our single-center prospective study assessed long-term clinical and hemodynamic outcomes in patients undergoing TAVI with "balloon-expandable" prosthesis.

Methods. From 2007 to 2014, 361 consecutive patients underwent TAVI at our institution. Data were prospectively collected in our TAVI database and retrospectively analyzed selecting patients treated with "balloon-expandable" device. Variables were defined according to the EuroSCORE definitions and outcomes were reported according to the VARC-2 definitions. Patients underwent clinical and echocardiographic follow-up at our "TAVI-dedicated" out-patient clinic. Multivariate logistic regression analysis was performed in order to identify independent predictors of mortality at follow-up.

Results. We included 254 patients treated with balloon-expandable device (23.8% with Edwards Sapien, 72.5% with Edwards Sapien XT and 3.7% with Edwards SAPIEN 3; Edwards Lifesciences Irvine, CA). The mean age was 80±7 years, 47% was male and trans-femoral (TF), trans-aortic (TAo) and trans-apical (TA) TAVI were performed in 144 (56.7%), 6 (2.4%) and 104 (4.08) patients, respectively. Mean follow-up was 22.0±14.3 months (range: 0.1-56). At 30-day total mortality was 4.6%, cardiovascular death 3.8%, stroke 2.5% and myocardial infarction 2.1%. Moreover, 1-year and long term total mortality were 15.2% and 19.3%, cardiovascular death 7.8% and 9.7%, stroke 2.9% and 3.3 and myocardial infarction 2.9% and 3.5%, respectively. The rate of pace maker implantation was 10.5%. Independent predictors of all-cause mortality at follow-up were reported in Table. Mean gradient and effective orifice area at follow-up were: 10.5±5.9 and 1.9±0.6 cm^2/m^2, respectively.

Table. Predictors of all-cause mortality.

	OR	95% CI	p
Creatinine clearance pre-TAVI	1.1	1.0-1.3	0.03
EuroSCORE II	1.1	1.0-1.2	0.05
Cardiac heart failure pre-TAVI	2.9	1.3-6.6	0.01
Aortic regurgitation ≥2+/4 pre-TAVI	2.9	1.2-6.9	0.01
Device type (SAPIEN)	4.0	2.5-14.5	0.001
Paravalvular leak ≥2+/4	1.6	1.1-4.6	0.02
Vascular complications	4.1	1.8-9.7	0.001
Acute kidney injury	2.9	1.1-7.7	0.04
Sepsis	6.9	1.3-15.3	0.03

Conclusions. Our data show that TAVI has good early and long-term clinical and hemodynamic outcomes in high risk or inoperable patients with SSAVS.

C63

A SINGLE-CENTER EXPERIENCE WITH TRANSCATHETER AORTIC VALVE IMPLANTATION USING SOLELY THE COREVALVE DEVICE

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Background. Transcatheter aortic valve implantation (TAVI) has clearly emerged as a promising alternative to surgery in high-risk patients with severe aortic stenosis as well as to medical therapy plus valvuloplasty in those with prohibitive risk. There is currently uncertainty, however, on the best device to perform TAVI safely and durably in the real-world setting. We hereby report on our ongoing experience based on the sole use of the CoreValve device.

Methods. We retrospectively collected from our administrative database baseline, procedural and outcome data for all patients in whom TAVI had been attempted in our center. The CoreValve device was used in all cases, whereas preprocedural computed tomography was performed only in case of equivocal findings at transthoracic echocardiography. Patients were followed after the procedure clinically and with transthoracic echocardiography 1, 6, and 12 months after the index procedure, and then yearly.

Results. A total of 245 patients were included, with 157 (64%) females and average age 80±5 years. Operative risk was very high, with an average logistic EuroSCORE of 37±13%, whereas aortic valve area was 0.82±0.36 cm^2, and left ventricular ejection fraction 51±9%. A 31 mm device had been used in 19 (8%) of cases, a 29 mm device in 134 (55%), and a 26 mm device in 86 (35%), but no 23 mm device had been used. Technical success was obtained in all cases, with only 1 (0.4%) exhibiting ≥3+/4+ post-TAVI aortic regurgitation. Permanent pacing as a result of TAVI was instead required in 39 (16%) of patients. Clinical follow-up at ≥12 months after TAVI confirmed the satisfactory outlook of these patients, notwithstanding their high surgical risk, with overall survival of 93% (95% confidence interval 88% to 96%).

Conclusions. The CoreValve device, when used by experienced operators well versed in its peculiar features and patient selection requirements, can yield satisfactory short- and long-term clinical results in high-risk patients with aortic stenosis undergoing TAVI.

C64

EARLY, INTERMEDIATE AND LATE INFECTIOUS COMPLICATIONS AFTER TRANSCATHETER OR SURGICAL AORTIC-VALVE REPLACEMENT: A PROSPECTIVE COHORT STUDY

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Background. Transcatheter aortic valve implantation (TAVI) has been proposed to treat older surgical high-risk or inoperable patients with severe symptomatic aortic stenosis. There are limited data regarding short-term and long-term infectious complications in these patients.

Aim. The objective of this study was to define the incidence, aetiology and outcome of early and late infectious complications following TAVI compared with patients >65 years old undergoing traditional surgical aortic replacement (SAR).

Methods. This was a prospective observational study evaluating all consecutive patients who underwent TAVI or SAR in our center from November 2009 to November 2012. Both commercially available devices, the Edwards SAPIEN XT balloon-expandable prosthesis and the Medtronic Core-Valve self-expanding device were included. Only transfemoral TAVI procedures were analysed. The following parameters were collected for each patient: demographics, clinical and laboratory findings, comorbidities, microbiological data, duration of intensive care unit stay and hospital stay, incidence of infections during hospitalization and 6 and 12 months after valve replacement, side-effects and outcome (overall mortality and mortality attributable to infection). To compare TAVI with SAR we included consecutive patients with an age ≥65 years undergoing SAR during the same study period, with a 1:2 ratio. Bloodstream infections, respiratory infections, urinary tract infections and skin or soft tissue infections were defined according to the standard definitions of the Centers for Disease Control and Prevention (CDC). Follow-up was performed up to 1 year after the procedure of valve implantation.

Results. Fifty-one patients underwent TAVI and were compared with 102 patients who underwent SAR. Compared with SAR patients, those who underwent TAVI had lower incidence of early post-operative (11.7% vs 26.4%, p 0.04), intermediate (5.9% vs 17.6%, p 0.01) and late (7.8% vs 11.7%, p 0.03) infections. Among SAR patients the most common infections were bloodstream infections, pneumonias, urinary tract infections and sternal wound infections. Patients who underwent TAVI had a longer survival without infection (358 days vs 312.9, p 0.006). There were no significant differences in 12-month crude survival between the two study populations.
Conclusion. Despite a high frequency of coexisting illnesses, patients undergoing TAVI develop few infectious complications. TAVI appears to be a reasonable and safe option in high-risk patients with severe symptomatic aortic stenosis.

C65

TAVI AS A SUSTAINABLE OPTION FOR HIGH-RISK AND INOPERABLE AORTIC STENOSIS PATIENTS. A SINGLE-CENTER MICROECONOMIC COST ANALYSIS

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Aims. The treatment of high-risk and inoperable aortic stenosis (AS) patients with TAVI has already been demonstrated, with a solid evidence of clinical effectiveness. Nevertheless, the thresholds of economic sustainability for such a therapeutic approach are still under discussion, with discrepant results, especially in lower-risk cohorts of patients. The aim of this study was to analyze the direct and general cost from the hospital perspective of a consecutive cohort of patients treated with TAVI from May 2010 to December 2013 in an Italian center.
Methods. A micro-economic cost analysis of 65 consecutive AS patients treated with Edwards SAPIEN and SAPIEN XT transcatheter valve has been performed. The direct cost of single-patient utilization of devices, the length of stay and the treatment of major complications have been collected, while remaining costs of other items have also been estimated, based on standard treatment protocols (e.g. operating room use, general costs, ancillary devices, etc.). General costs have been separately analyzed and presented, since they accounted for 17% of direct measured costs. An inter-quartile cohort analysis of direct costs and an analysis of the correlation of the direct costs with the key parameters (e.g. age, logistic EuroSCORE [logES], presence of major comorbidities and post-operative complications) have been performed.
Results. In the whole population, 42 patients were treated by transfemoral approach, while 23 were transapical procedures. The mean age was 80±6 years and the mean logES 27.5±16.8% without significant differences between patients treated with transfemoral or transapical approach. In-hospital mortality was 6.1% (4/65). The total mean direct cost for each patient was €31 398±5331. 70% of direct costs were related to the procedure (devices and personnel involved in the procedure), while 16% were related to in-hospital stay (Intensive Care Unit, Cardiology/Cardiac Surgery Ward) and cost of health care personnel, and remaining 14% were related to General costs. Inter-quartile analysis of direct costs (1st quartile: €27 789; 2nd quartile €29 378; 3rd quartile €32 994) showed that the cost of the procedure is quite predictable for the majority of the patients. Only a weak correlation with logES and no correlation with age were found with the direct costs of the procedures. No significant difference in terms of procedural costs between patients treated with transfemoral and transapical approach were found. However, TA procedures showed higher direct and total costs than TF (€34.088 vs. €29.989 for direct cost, €39.800 vs. €34.817 for total cost), essentially due to higher daily cost of cardiac surgery and Post-operative intensive care stay. All presented results are substantially aligned with evidence recently published on cost of TAVI procedure in Italy and France (Bartoli et al. 2012, Chevreul 2013).
Conclusion. TAVI is still considered an expensive procedure; however, the high predictability of costs can help to conduct a transcatheter program in a sustainable way and to plan a correct allocation of resources. It is likely that further improvements in the different steps of the pathway (patients selection, team skill, reduction of in-hospital stay), as well as a decrease in the cost of the device, will strongly contribute to reduce the global expenditure of a TAVI program.

C66

COMPARISON BETWEEN SELF EXPANDABLE VS BALLOON EXPANDABLE VALVE DEVICE IN ALL-COMERS HIGH RISK PATIENTS

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Background. Transcatheter aortic valve implantation (TAVI) is an effective treatment option for high-risk patients with severe aortic stenosis.
Aim. It was to compare the safety and the efficacy of balloon-expandable device and the self-expandable device in terms of device success, correct position of the device with paravalvular leaks (PVL). Secondary end points included clinical outcomes (cardiovascular mortality, bleeding, vascular complications and postprocedural pacemaker placement) at 30 days and 12 months.
Methods. We included in our registry all consecutive high-risk patients with severe and symptomatic aortic stenosis. 220 pts were screened and 105 were considered eligible to TAVI. All procedure was transfemoral TAVI with a balloon-expandable or self-expandable device. Clinical follow-up was performed at 1 and 12 months.
Results. From November 2009 to June 2014, 220 consecutive pts with severe and symptomatic AS were evaluated; 105 pts were considered eligible to TAVI. Mean age was 81.6±6.75 years old and 57.14% were women. Mean AVA was 0.6±0.2 cm^2 and in both groups the logistic EuroSCORE was >20 (mean value 26.3±16.9%). 55 pts implanted CoreValve and 50 pts implanted Edwards Sapien. No differences were found in clinical baseline characteristic between two groups. Total procedural success was 90.5% (95/105 pts) and it was higher with Edwards Sapien (83.6% vs 98% p=0.017). Only in CoreValve Group 7 pts underwent valve in valve implantation. Post-dilatation rate was higher in CoreValve Groups (21.8% vs 6% p=0.026). The incidence of aortic regurgitation (AR) was grade I: 39.6% vs 65.3% pts p=0.018; grade II-III 39.6% vs 16.3% p=0.014, respectively in CoreValve and Edwards group. PVL were divided in mitro-aortic and septo-aortic on the basis of anatomical localization. Severe PVL were higher with CoreValve (40.4% vs 16.1%, p=0.014) and mitro-aortic localization was more represented if compared with Edwards group. No significant differences in terms of MACCE and complications at 48h follow-up were found. 30-day follow-up did not show significant differences in terms of mortality, bleeding, vascular complication and PM implantation. All pts improved symptoms and NYHA class and this data was related to PVL severity. In 60% of pts with NYHA class >3 there was a moderate to severe PVL. Long-term follow-up (mean FU 13±10 months) showed a significant difference between groups in terms of global mortality (CoreValve 50% vs 26.5% Edwards, p=0.01) while no significant difference in terms of cardiac mortality (CoreValve 8.1% vs 4.9% Edwards, p=0.25).
Conclusions. In high risk patients with severe and symptomatic aortic stenosis the TAVI is safe with both device and the self-expandable valve showed a higher procedural success rate and a lower PVL incidence. Similar short and long term outcomes were achieved with either valves.

C67

LONG TERM FOLLOW-UP OF PATIENTS UNDERGOING VALVULOPLASTY IN TAVI ERA: A MULTICENTRE RETROSPECTIVE STUDY

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Aims. The introduction of transcatheter aortic valve implantation (TAVI) has generated a renewed interest in the treatment of high risk patients with severe aortic stenosis and serious contraindication for aortic valve replacement. This study describes the indications and long-term outcomes of balloon aortic valvuloplasty (BAV) in recent years.
Methods. All patients undergoing BAV in our centres from 2005 to 2013 were enrolled. All cause death at follow-up were the primary end-point, while need of re-intervention, myocardial infarction and stroke the secondary ones, along with BAV periprocedural complications according to VARC criteria (death, bleeding, vascular complications, acute kidney injury).
Results. Among 586 consecutive patients, BAV as bridge to TAVI was performed in 277 (47.3%), as bridge to surgical aortic valve replacement (SAVR) in 71 (12.1%) and as destination therapy in 238 (40.6%). Median age was of 82.1±7.4, 54.1% of them being female, with a median ejection fraction of 48.3±15.8%. In-hospital mortality was 8.5%, 5.2% after excluding patients presenting with cardiogenic shock, being acute kidney injury (10.7%) the most frequent complication. Cardiogenic shock and a renal clearance <60 $ml/min/m^2$ were independent predictors of all-cause death in a multivariate analysis. After a median follow-up of 240 days, 31.4% of patients died, 5.6% were rehospitalized for heart failure and 33.8% performed a new intervention (10.1% BAV, 71.2% TAVI, 18.7% SAVR). Echocardiography showed that the medium and peak transaortic gradients decreased after valvuloplasty from 46 (CI 44.3-48.2) to 39 mmHg (CI 37.8-44), and from 78 (CI 74.8-81.5) to 59 mmHg (CI 53-64), respectively. After 6 months medium gradient was 36 mmHg (CI 28.7-38.1) and peak gradient 54.mmHg (CI 46.4-62.9), showing durability of the valvuloplasty. Aortic valve area (AVA) increased after valvuloplasty from 0.67 (CI 0.64-0.69) to 1.50 cm^2 (CI 1-1.9) and 0.95 cm^2 (CI 0.8-1) after 6 months.
Conclusion. BAV is nowadays safe and effective, with a durable effect in the reduction of transaortic valve gradient. Clinically, after 10 month follow-up, no reintervention is needed in most patients.

PCI in STEMI

C68

ST-SEGMENT RESOLUTION IN STEMI TREATED BY PRIMARY PCI AND SECOND-GENERATION STENTS: PREDICTORS AND IMPLICATIONS IN LONG-TERM CLINICAL OUTCOME FROM THE EXAMINATION TRIAL

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Aims. Presence of ST-segment resolution within 1 or 2 hours after first-generation DES implantation during primary PCI has shown to be highly predictive of infarct-related artery patency and of the degree of effective microvasculature perfusion. However, those studies on ST-segment resolution and primary PCI employed first-generation DES and very low rate of thrombus aspiration devices use. Indeed, prognostic significance of ST-segment resolution in second-generation DES era in primary PCI is unknown. We sought therefore to evaluate the predictors of ST-segment resolution and its impact of 2-year outcome in the EXAMINATION population.

Methods and results. The EXAMINATION trial design was a prospective, randomized, multicenter trial that enrolled all-comer patients with STEMI, from 12 to 48 hours after the onset of symptoms. The primary endpoint of this sub-analysis was the endpoint of all-cause death, any myocardial infarction or any revascularization at 2 years. We also evaluated its individual components together with the following stent-derived endpoints: target vessel myocardial infarction, target vessel and target lesion revascularization and stent thrombosis according to the Academic Research Consortium definition. The final cohort of the study was represented by 1351 patients (90%) of the 1504 EXAMINATION enrolled patients. Out of these, 851 (63%) exhibited ST-segment resolution (Group 1) whereas remaining 500 patients (37%) did not (Group 2). Group 2 was older (62.5±12 vs 59.6±12, p<0.001) and had more likely diabetes (22% vs 13%, p<0.001) and hypertension (52% vs 47%, p=0.04) compared to Group 1. However, Group 1 had more frequently dyslipidemia (47% vs 41%, p=0.016) than other group. Group 2 showed higher rate of multivessel disease (15% vs 10%, p=0.005) and lower ejection fraction (48±10% vs 53±9%, p<0.001) as compared to Group 1. On the other hand, Group 1 was characterized for higher TIMI flow pre-PCI (TIMI flow 3: 22% vs 16%, p=0.034) with higher use of direct stenting (65% vs 56%, p=0.011), less number of stent implanted (1.3±1 vs 1.4±1), which were also shorter (27±14 vs 29±15 mm, p=0.009) and smaller (3.1±1 vs 3.2±1 mm, p=0.04) as compared to Group 2. By multivariable analysis, the independent predictors of ST-segment resolution were absence of diabetes (HR 0.514, 95%CI: 0.357-0.739; p<0.001], hyperlipidemia (HR 1.525, 95% CI: 1.525-2.011, p=0.004), Killip class I (HR 1.633, 95% CI: 1.073-2.487, p=0.022) and ejection fraction (HR 1.044, 95% CI: 1.029-1.059, p<0.001). The 2-year rate of primary endpoint was higher in Group 2 compared to Group 1 (20% vs 14%, p=0.001), driven namely by higher rate of myocardial infarction attributed to target vessel (3% vs 1%, p=0.029) and revascularization (14% vs 10%, p=0.014). In addition, a higher rate of definite and definite/probable stent thrombosis was present in patients without ST-segment resolution as compared to those with (3% vs 1%, p=0.005 and 4% vs 1%, p=0.001).

Conclusions. ST-segment resolution in STEMI patients is predicted by absence of diabetes, hyperlipidemia, low Killip class and high ejection fraction. Furthermore, at 2-year clinical follow-up, patients without ST-segment resolution exhibit a higher rate of myocardial infarction, revascularization and stent thrombosis in comparison with patient with ST-segment resolution.

C69

PROGNOSTIC IMPACT OF NON-INFARCT-RELATED-ARTERY CHRONIC TOTAL OCCLUSION REVASCULARIZATION IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION TREATED BY PRIMARY ANGIOPLASTY

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Background. Registries and randomized trials have shown that non-infarct-related-artery (IRA) chronic total occlusion (CTO) carries a poor early and late outcome in patients with acute myocardial infarction (AMI) treated with primary percutaneous coronary intervention (PCI). We sought to investigate the prognostic impact of a staged successful CTO-PCI in patients with AMI treated with primary PCI.

Methods. From 2003 to 2011, 1756 patients underwent primary PCI. Out of these, 212 (12%) had a concurrent non-IRA CTO; in 70 patients (33%) a staged CTO-PCI attempt was performed and was successful in 53 (76%). The 6-month cardiovascular mortality in the successful revascularization of CTO (s-CTO; n=53) group was compared with the persistently occluded CTO (o-CTO; n=159) group. Multivariable analysis was performed to identify independent predictors of mortality.

Results. The mean age was lower in s-CTO than o-CTO (64±11 vs 69±13; p=0.010) and left anterior descending artery (LAD) CTO rate was higher in s-CTO (32% vs 18%; p=0.034). There were no differences between groups in the incidence of diabetes (17% vs 15%), anterior AMI (45% vs 40%) and Killip class 3-4 on admission (23% vs 26%). All patients with successful CTO-PCI received DES in CTO lesions. In the s-CTO group a complete coronary revascularization was achieved in 92% of the patients. The 6-month clinical follow-up rate was 100%. The cardiovascular mortality rate was 1.9% in the s-CTO group and 16.4% in the o-CTO group (p=0.006). At multivariate analysis s-CTO (HR 0.06; p=0.008), LAD-CTO (HR 4.9; p<0.001) and Killip class 3-4 on admission (HR 14; p<0.001) resulted independent predictors of mortality.

Conclusions. In the setting of high risk patients with AMI and a concurrent non-IRA CTO, the successful CTO-PCI after primary angioplasty was associated with an improvement in survival. These data support the benefit of a complete coronary revascularization in this subset of patients with AMI.

C70

LONG-TERM OUTCOME IN VERY OLD PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION

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Purpose. Although octogenarians constitute a fast growing portion of cardiovascular patients, few data are available on the long-term outcomes of very old patients (age ≥85 years) with ST-elevation myocardial infarction (STEMI) undergoing emergent coronary angiography.

Methods. A total of 126 very old patients (age 88±2 years, 42% males) undergoing emergent coronary angiography (within 12 hours from symptoms onset) because of STEMI, who presented at our institution between January 2007 and December 2013, were consecutively enrolled. All 126 patients underwent primary percutaneous coronary intervention (PCI). 24 (19%) patients died during the index hospitalization. Long-term follow-up (median 898 days, interquartile range 1019 days) was obtained for the remaining 102 patients.

Results. During the first year of follow-up, 14 (14%) patients died; in 10 cases (71%), death was due to cardiac causes. 31 (30%) patients died after a median follow-up of 496 (205-1005) days; among them, 17 (55%) died because of cardiac causes. 52 patients (51%) had re-hospitalization due to cardiovascular causes: heart failure was observed in 30 patients, recurrent myocardial ischemic events (including unstable angina or myocardial infarction) in 17 patients, cerebrovascular accidents in 4 patients and aborted sudden dead in 1 patient. At univariate analysis, chronic renal failure was the only variable significantly associated with mortality (p=0,001) while anterior myocardial infarction was significantly related with the combined end-point of mortality and re-hospitalization (p=0.02). Multivessel disease and moderate-to-severe mitral regurgitation or aortic stenosis at baseline were not significantly related to overall mortality.

Conclusions. In the population of the oldest-old patients with STEMI surviving after the index hospitalization, primary PCI is associated with a good long-term survival, despite a non-negligible incidence of re-hospitalization due to cardiovascular events.

C71

SOS-CAMPANIA (STUDIO OSSERVAZIONALE SULLO STEMI IN CAMPANIA): ANALISI DELLA GESTIONE ASSISTENZIALE DELLO STEMI IN CAMPANIA IN ASSENZA DI RETE

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La Campania è stata individuata nel programma Stent for Life come area regionale per l'implementazione dell'assistenza dello STEMI in rete. La regione ha promulgato nel 2013 il decreto di istituzione del protocollo clinico organizzativo della rete per l'infarto miocardico. Allo stato attuale lo scenario è caratterizzato da un numero adeguato di UTIC e di emodinamiche in rapporto alla popolazione residente ma dalla presenza di accordi non strutturali tra singoli ospedali per il trattamento dello STEMI. Lo scopo dello studio è analizzare i percorsi e i tempi inter e intraospedalieri del trattamento dei pazienti con STEMI in Campania, nonché le scelte terapeutiche adottate.

La survey ha raccolto le informazioni relative ai casi consecutivi di STEMI occorsi sul territorio della Campania dal 10 maggio al 10 giugno 2013. Dei 44 centri con UTIC censiti i dati sono stati raccolti e trasmessi da parte di 32, di cui 9 Hub h24, 6 Hub non h24 e 17 Spoke. I centri Hub h24 hanno trattato 219 pazienti, di cui 120 provenienti dal proprio DEA e 99 trasferiti dai centri Spoke. I centri Hub non-h24 hanno trattato 52 pazienti, di cui 44 provenienti dal proprio DEA e

8 trasferiti dai centri Spoke. La Tabella 1 registra nel dettaglio, in relazione alla tipologia del centro, le strategie riperfusive e i tempi. Nella Tabella 2 sono riportati le percentuali di impiego dei farmaci antiaggreganti e anticoagulanti in relazione alla struttura accettante e al tipo di strategia riperfusiva.
Dallo studio emerge come in epoca anteriore all'attuazione della legge istitutiva della rete per l'emergenza cardiologica in Campania la scelta della strategia riperfusiva e della terapia antitrombotica associata è principalmente legata alle caratteristiche del Centro. Differenze sono state evidenziate anche nei tempi di riperfusione sia per il door to needle che per il door to balloon.

	Hub h24 (n=9) 219 pazienti		Hub non h24 (n=6) 52 pazienti	
	Pz dal proprio DEA (n=120)	Pz dai centri Spoke (n=99)	Pz dal proprio DEA (n=44)	Pz dai centri Spoke (n=8)
Trombolisi	2	41	16	6
PCI primaria	110	53	25	0
PCI rescue	0	15	3	2
Farmaco-inv <24h	1	12	3	4
Farmaco-inv >24h	1	15	8	0
Non riperfuso	8	3	2	2
FMC-rip. (min)	77±67	161±137	94±86	ND
D2N (min)	NA	41±58	23±14	ND
D2B (min)	56±52	147±144	80±71	ND

	Hub h24	Hub non h24		Spoke	
		P-PCI	Th	P-PCI	Th
N. pazienti	164	25	18	44	42
ASA	162 (98%)	25 (100%)	17 (95%)	42 (95%)	41 (98%)
Clopidogrel 300 mg	29 (18%)	5 (20%)	13 (72%)	19 (43%)	30 (71%)
Clopidogrel 600 mg	12 (7%)	3 (12%)	2 (11%)	1 (2%)	4 (9%)
Prasugrel	59 (36%)	2 (8%)	0	6 (14%)	1 (2%)
Ticagrelor	49 (30%)	13 (52%)	0	8 (18%)	3 (7%)
UFH	71 (43%)	5 (20%)	18 (83%)	23 (52%)	22 (52%)
LMWH	22 (13%)	18 (72%)	2 (11%)	10 (23%)	11 (26%)
Bivalirudina	32 (19%)	0	0	0	0
Fondaparinux	9 (5%)	1 (4%)	0	4 (9%)	8 (19%)
Anti-IIb/IIIa upstream	3 (2%)	1 (4%)	0	1 (2%)	2 (5%)
Anti-IIb/IIIa downstream	17 (10%)	2 (8%)	0	8 (18%)	2 (5%)

C72

POLYMER FREE AMPHILIMUS-ELUTING STENT IN STEMI PATIENTS: ONE-YEAR FOLLOW-UP

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Background. Since permanent polymer is implicated in adverse events associated with delayed vessel healing after drug eluting stents (DES) implantation, great efforts have been made to develop more biocompatible DES with biodegradable polymer or without polymer. Recently a new cobalt chromium alloy coated with Carbofilm polymer free Amphilimus-eluting stents (PF-AES) has been proposed (CRE8® AlviMedica). Due to these characteristics, the stent provides a better bio- and haemo-compatible characteristics. Limited data are currently available on the use of PF-AES in patients with STEMI.
Aims. The present registry aimed to evaluate the safety and efficacy of PF-AES in patients with ST elevation myocardial infarction.
Methods and results. This prospective registry includes 70 unselected STEMI patients with a high cardiovascular risk profile undergoing primary PCI (pPCI) for ≥1 significant lesion in a major epicardial coronary vessel treated with PF-AES. Only patients with contraindications for DES use were excluded. The end-point of the registry was the rate of major adverse cardiac events (MACE): all death (AD), death of cardiac or procedure-related origin (CD), stent thrombosis (ST), myocardial infarction (MI), target lesion revascularization (TLR). Clinical follow-up at 12 months showed: AD 6 (8.5%), CD 2 (2.8%), MI, ST and TLR (0).
Conclusions. In a real-world cohort of STEMI patients undergoing pPCI, the use of PF-AES has been proven safe and effective in terms of cardiac death, new revascularization and stent thrombosis. These results confirm and expand previous findings showing the efficacy and safety of PF-AES.

C73

CULPRIT VESSEL IN STEMI PATIENTS WITH PREVIOUS CORONARY ARTERY BYPASS GRAFT

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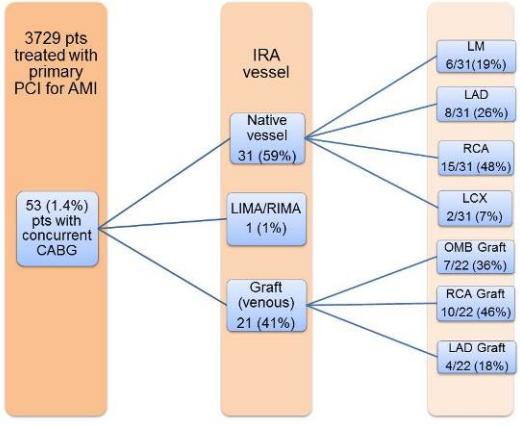
Background. The number of patients presenting with acute ST-segment elevation myocardial infarction (STEMI) and prior coronary artery bypass grafting (CABG) is increasing. These patients have been poorly studied.
Aim. The aim of this study was to assess the clinical and angiographic characteristics and outcomes of STEMI patients with prior CABG.
Methods and results. From 1995 to 2013, patients admitted with the diagnosis of STEMI and treated with PPCI were prospectively included in the STEMI-Florence Registry. Out of 3933 STEMI patients, only 53 (1.3%) had a prior CABG. Non CABG patients presented with electrocardiographic diagnosis of anterior STEMI in 1841 cases (47%), inferior in 1818 (47%) and lateral in 222 (6%), while CABG group patients presented with an electrocardiographic diagnosis of inferior STEMI in 36 cases (66%), anterior in 16 (30%) and lateral in 2 (4%; p=0.044). The mean time from CABG to myocardial infarction was 11±6 years. The infarct related artery of CABG patients was a native vessel in 31 patients (59%), a saphenous graft in 21 patients (40%) and an internal thoracic artery (left mammary artery) in 1 patient (1%). Native vessel involved left main in 6 patients (19%), left anterior descendent artery in 8 (26%), right coronary artery in 15 (48%) and circumflex artery in 2 patients (7%). Saphenous graft occlusion involved right coronary artery in 10 (46%), obtuse marginal graft in 7 patients (36%), and left anterior descendent artery in 4 (18%; Figure 1). CABG patients were older, less frequently smokers but more frequently dyslipidemic and with previous myocardial infarction, and more frequent three vessel disease than patients without CABG. Procedural characteristics showed more complex revascularization in CABG group (Rx time of 19±9 vs 10±9 in non CABG, p=0.0001), but similar angiographic results (final coronary TIMI flow grade III 94% vs 97% in non CABG, p=0.134). No differences between the two groups were observed regarding in-hospital and 6-month death.
Conclusions. Patients with prior CABG represent a trivial proportion of STEMI patients treated with PPCI, and inferior STEMI is the more frequent ECG pattern at presentation. Culprit lesion was mainly due to native vessel thrombosis, or less frequently to saphenous graft disease. Internal thoracic artery occlusion is an exceptionally rare occurrence.



Miscellaneous 2

C74

IMPACT OF GENDER ON URIC ACID LEVELS AND ITS RELATIONSHIP WITH THE EXTENT OF CORONARY ARTERY DISEASE: A SINGLE CENTRE COHORT STUDY

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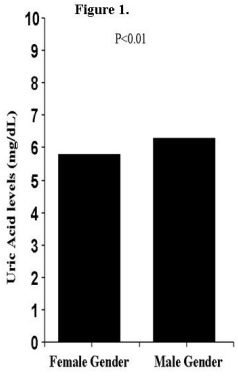
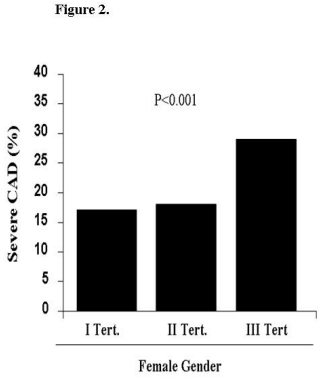
Background. Serum uric acid (SUA) elevation has been largely addressed as a possible risk factor for cardiovascular disease. However, uric acid has not clearly emerged as independent risk factor for coronary artery disease (CAD). Several studies in literature have assessed gender-related differences in the association between elevated SUA levels and cardiovascular events with conflicting results. Therefore, aim of the current study was to evaluate the impact of gender on SUA and its relationship with the extent of coronary artery disease.
Methods. Our population is represented by 3520 consecutive patients undergoing coronary angiography from March 2007 to October 2012. Both males and females were subsequently divided according to tertiles of SUA. Fasting samples were collected for uric acid levels assessment. Coronary disease was defined for at least 1 vessel stenosis >50% as evaluated by QCA. Severe coronary disease was defined as three-vessel disease and/or left main disease.
Results. Among 3520 patients, we identified 2442 men (69.4%) and 1078 women (30.6%). Males had higher levels of uric acid (6.33±1.7 vs 5.8±1.9, p<0.001, Figure 1) and displayed a significantly higher prevalence and extent of CAD (p<0.001) and more complex coronary lesions (p<0.001). Interestingly, males with elevated SUA had a tendentially lower prevalence of CAD (p=0.052). On the other side no relationship was found between SUA levels and the presence of severe CAD (p=0.76). Among females higher SUA

levels were significantly associated with higher prevalence of severe CAD (p<0.001) (Figure 2) (adjusted OR [95%CI] 1.29 [1.03-1.62], p=0.03). On the other side no relationship was found between SUA and the prevalence of CAD (p=0.10).

Conclusion. Our study showed that even though uric acid levels are significantly higher in men, high uric acid levels are associated with severe CAD only in women. Future large studies are certainly needed to confirm our findings and to evaluate the effects of SUA lowering therapies on cardiovascular prevention and outcome.





C75

EFFICACY OF CONTRAST MEDIUM INDUCED PD/PA RATIO IN PREDICTING FUNCTIONAL SIGNIFICANCE OF INTERMEDIATE CORONARY ARTERY STENOSIS ASSESSED BY FRACTIONAL FLOW RESERVE: THE RAPIDA INIEZIONE DI MEZZO DI CONTRASTO VS NITROPRUSSIATO O ADENOSINA NELLE STENOSI CORONARICHE INTERMEDIE (RINASCI) STUDY

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Background. A critical prerequisite for the assessment of the functional significance of coronary stenosis by Fractional Flow Reserve (FFR) is the achievement of maximal hyperemia using adenosine. Nevertheless, both the intra-venous (i.v.) and the intra-coronary (i.c.) routes have several drawbacks that limit the widespread application of FFR in the real world. Radiographic contrast medium induces sub-maximal reactive hyperemia. We hypothesized that Pd/Pa ratio registered during sub-maximal reactive hyperemia induced by i.c. injection of conventional non-ionic radiographic contrast medium (contrast medium induced Pd/Pa ratio: CMR) can be sufficient for the assessment of physiological severity of stenosis in the vast majority of cases. The aim of the present study was to test the accuracy of CMR in comparison to FFR.

Methods. 104 intermediate coronary stenoses were prospectively and consecutively enrolled. CMR was obtained after i.c. injection of 6 ml of radiographic contrast medium, while FFR was measured after i.c. (600 µg) or i.v. (140 µg/kg/min) administration of adenosine.

Results. Despite CMR values were significantly higher than FFR values (0.88 [IR 0.80-0.92] vs 0.87 [IR 0.83-0.94], p<0.001), a strong correlation between CMR and FFR values was observed (r=0.94, p<0.001) with an excellent agreement at Bland Altman analysis (95% CI of disagreement: -0.029 to 0.072). ROC curve analysis showed an excellent accuracy of CMR cut-off of ≤0.83 in predicting FFR value ≤0.80 (AUC 0.97 [CI 95%, 0.91-0.99, specificity 96.1, sensitivity 85.7]. Moreover, no FFR value ≤0.80 corresponded to a CMR ≥0.88.

Conclusion. CMR, a novel index obtained during sub-maximal hyperemia induced by conventional radiographic contrast medium, is accurate in predicting the functional significance of a coronary stenosis evaluated by FFR. This could allow limiting use of adenosine to obtain FFR to doubtful cases. In particular, we suggest to consider significant a CMR value ≤0.83, not significant a CMR value ≥0.88 and to induce maximal hyperemia using adenosine for FFR assessment when CMR is between 0.84 and 0.87.

C76

AXXESS - BIFURCATION DEDICATED SELF-EXPANDABLE DRUG ELUTING STENT - IN ACUTE ST ELEVATION MYOCARDIAL INFARCTION

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Background. One probable cause of stent malapposition during primary STEMI PTCA can be attributed to the vessel vasoconstriction and thrombus burden. On the other site an over-expansion of the stent can cause distal embolization. On the other hand when the acute occlusion involves the bifurcation of major epicardial arteries provisional stenting may cause shifting of the thrombus to the side branch and if two stent strategy is used then the amount of metal at the carina site and the presence of residual thrombus may cause early thrombosis.

Objective. To evaluate if the bifurcation can be treated in the setting of acute myocardial infarction with bifurcation dedicated self-expandable drug eluting stent.

Methods. In the period January-December 2013, 10 non-consecutive patients (6 males, 3 females, mean age 69±15 years) with angiographically evidence of acute artery occlusion involving the bifurcation where treated with placement of bifurcation dedicated self-expandable drug eluting stent (AXXESS, Biosensors). In all patients intracoronary bolus followed by intravenous infusion of Angiox (The Medicines Company) was performed. The coronary artery distribution was as follows: right coronary (occlusion at the bifurcation posterior descending and posterior-lateral branch) in 3 patients, circumflex artery (occlusion at the bifurcation with first or second marginal branches) in other 3 patients and left anterior descending artery (occlusion at the site first diagonal branch) in the rest 4 patients. In all patients aggressive and repetitive thrombus aspiration was performed. Preparation for stent placement at the bifurcation was achieved with repetitive pre-dilatation of both main and site branch. Once achieved a TIMI flow III even with the use of intracoronary adenosine and sodium nitroprusside the dedicated self-expandable drug eluting stent (AXXESS, Biosensors) was placed. Types of Axxess stent were: 3/11 mm in 3 patients, 3/14 mm in 3 patients; 3,5/14 mm in other 4 patients. No post-dilatation and no other stent either on main or site branch was placed. In all patients the final TIMI flow was 3 and blush grade was also 3. No complications were observed during the hospital stay.

Conclusions. The combination of self-expandable and dedicated for bifurcations makes Axxess stent suitable solution in case of acute ST-elevation myocardial infarction when the thrombotic occlusion involves the bifurcation of major coronary arteries. Our cases are first in the literature demonstrating its safe placement and good immediate result regarding vessel patency, TIMI flow and good vessel wall apposition.

C77

DURATION OF BALLOON INFLATION IS CRITICAL DURING BVS IMPLANTATION

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Background. Adequate expansion is critical to achieve optimal scaffold apposition to the vessel wall, key issue for success of the percutaneous coronary intervention (PCI). However, compared to metallic stents BVS present different mechanical properties. Hence, slow deployment and maintenance of balloon inflation for at least 30" is recommended for BVS implantation. However, since no evidences are available demonstrating the superiority of a longer balloon dilatation time, the implantation technique is highly variable among different centers.

Methods. Consecutive lesions, treated with a second generation BVS at a single center, were included in the present analysis. A total of 24 BVS-treated lesions were included in the present analysis. After BVS deployment at 12 ATM the balloon was rapidly deflated and scaffold expansion was documented with an angiogram. The same balloon was then inflated again and kept at 12 atm for 30". Finally, a further angiogram was obtained to evaluate BVS expansion. Quantitative coronary angiography (QCA) was performed at each step.

Results. A significant increase of MLD-to-reference scaffold diameter (RSD) ratio (MR-ratio) from 0.70±0.10 after initial stent deployment to 0.79±0.10 after the 30"-long balloon dilation was observed (p<0.001). Of note, this result was consistent across all sub-segments, as well as across almost all lesion subgroups. A substantial reduction in the prevalence of residual stenosis from 29% to 17% was registered after the 30"-long dilation.

Conclusions. Our results strongly support the importance of 30"-post dilation during BVS deployment to achieve optimal scaffold apposition and minimize residual stenosis.

C78

DUE ANNI DI ESPERIENZA DI ATERECTOMIA ROTAZIONALE IN UN SINGOLO CENTRO

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Introduzione. In epoca di drug eluting stent (DES) si è reso necessario un ottimale impianto degli stent per evitare la trombosi degli stessi. L'aterectomia rotazionale (AR), in caso di lesioni coronariche complesse calcifiche, è in grado preparare bene la stenosi affinché lo stent possa essere impiantato in modo corretto, con il giusto diametro e con geometria endoluminale ottimale.

Materiale e metodo. È uno studio osservazionale retrospettivo. Da maggio 2012 a giugno 2014 sono stati trattati presso il nostro centro 67 pazienti con AR. Presentazione della casistica.

Risultati. *Pazienti trattati:* 67 (11 F, 56 M); età media 71.58±10; cardiopatia ischemica nota 40.3%; pregresso BPAC 10.4%; vasculopatia 19.4%; diabete 24%; ipertensione arteriosa 49%; ipercolesterolemia 27%; fumo 15%; IRC

9%. *Presentazione clinica dei pazienti:* angina stabile 46%, angina instabile 12%, NSTEMI 27%, STEMI 4.4% (AR eseguita in acuto in un solo caso, gli altri due AR delle non *culprit lesions*), shock cardiogeno 4.4%. Frazione di eiezione media 52±10%. Nel 79% dei casi l'AR è stata eseguita per via transradiale. Alla coronarografia i pazienti presentavano: malattia monovascolare nel 13.4% dei casi, monovaso + tronco comune 1.5%, bivascolare nel 30%, bivascolare + TC 1.5%, trivascolare nel 25%, tre vasi + graft venosi 4.4%, tre vasi + tronco comune 8.9%. I vasi trattati sono stati: la discendente anteriore nel 28.3%, la circonflessa nel 9%, la coronaria destra nel 24% ed il tronco comune nel 4.4% dei casi. In 50 casi è stata utilizzata la tecnica con singola *burr* (diametro 1.33±0.1) ed in 17 casi la tecnica con doppia *burr* (diametro max 1.66±0.1). Il rapporto *burr*/vaso trattato è risultato 0.51±0.06). 111 i DES impiantati. 2 perforazioni coronariche avvenute nel secondo anno, dopo aver dilatato con il pallone, mai direttamente con l'AR. 2 casi di intrappolamento delle *burr* risolti. Nessun decesso.

Conclusioni. Nella nostra casistica si evidenzia che i pazienti trattati con AR sono anziani, con molte comorbidità e con malattia coronarica complessa. Si è rivelata nel tempo una metodica sicura ed efficace, eseguita con un rapporto *burr*/vaso trattato ben al di sotto del limite consigliato.

C79

DIFFERENTI CUT-OFF PER IFR ED FFR NELLA VALUTAZIONE DI STENOSI CORONARICHE INTERMEDIE: ESPERIENZA PROSPETTICA, MONOCENTRICA, ITALIANA

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Presupposti. La presenza di una finestra temporale diastolica del ciclo cardiaco con resistenze vascolari coronariche minime e costanti ha consentito il recente sviluppo della metodica instantaneous wave-free ratio (iFR) per la valutazione funzionale senza adenosina delle stenosi intermedie. Alcuni studi che consideravano la sua accuratezza diagnostica rispetto alla oramai validata fractional flow reserve (FFR) hanno mostrato risultati discordanti.

Obiettivo. Lo scopo di questo studio è quello di confrontare l'accuratezza diagnostica dei diversi valori di cut-off sia per IFR che FFR, valutati nella pratica clinica.

Materiali e metodi. Tutti i pazienti hanno eseguito sia valutazione iFR che FFR nella stessa seduta, previa infusione di 300 mcg di nitrato intracoronarico prima della valutazione funzionale. Per ogni misurazione FFR venivano inoltre somministrati preventivamente 120 mcg di adenosina per via selettiva endocoronarica. Sono state utilizzate le curve ROC per valutare l'accuratezza diagnostica dei diversi cut-off iFR (0.86 e 0.89) rispetto quelli della FFR (0.80 FAME e 0.75 DEFER). Sensibilità, specificità, valore predittivo positivo (VPP), valore predittivo negativo (VPN) sono stati determinati. I pazienti sono stati trattati secondo i risultati FFR (cut-off <0.80).

Risultati. 54 pazienti (77% maschi) con stenosi intermedie (50-70%) sono stati inclusi (89 lesioni). L'età media era di 68±11 anni. La presentazione clinica era angina stabile (63%) o angina instabile/NSTEMI (37%). La maggior parte dei pazienti (89%) presentava una malattia multivasale. All'analisi coronarica quantitativa (QCA) offline la stenosi percentuale media era del 62±9%. I migliori valori di cut-off per IFR e FFR, tra quelli testati, sono risultati 0.89 per IFR e 0,80 per FFR, con sensibilità e VPN del 100%; specificità 87% e VPP 78%. Sulla base di questi cut-off 43 lesioni (48%) avevano IFR positivo e solo 7 tra queste presentavano una discordante valutazione FFR. Una significativa correlazione tra le due tecniche è stata rilevata all'analisi di regressione lineare (R=0.84, p<0.0001). All'analisi ROC l'area sotto la curva approssimava l'unità (0.96). Il grafico di Bland-Altman chiarisce questi risultati, mostrando una differenza media tra valori di FFR ed IFR di 0.02±0.11. Considerando FFR come gold standard per il decision making, la rivascolarizzazione è stata eseguita in 23 pazienti (43%), e differita nei rimanenti 31 (67%). Al follow-up clinico (da 3 a 12 mesi), tutti i pazienti sono rimasti asintomatici per angina pectoris e nessuno di loro ha presentato eventi avversi cardiovascolari maggiori.

Conclusione. Questa esperienza monocentrica italiana conferma che 0.89 è il cut-off IFR ottimale rispetto al valore soglia per FFR di 0.80. Si identifica così una stenosi coronarica funzionalmente critica con una sensibilità del 100% e specificità del 87%. Questo valore conferma così quello adottato dall'ADVISE-Registry. Ampi studi clinici randomizzati già avviati saranno essenziali per supportare il suo uso quotidiano nel processo decisionale nei nostri laboratori di emodinamica.

Mitral valve intervention 2

C80

SPECKLE-TRACKING ECHOCARDIOGRAPHY IN THE EVALUATION OF LEFT AND RIGHT VENTRICULAR FUNCTION AFTER MITRACLIP IMPLANTATION IN FUNCTIONAL MITRAL REGURGITATION

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Purpose. Our aim was to assess the changes of left (LV) and right (RV) ventricular function with two-dimensional (2DSTE) and three-dimensional speckle-tracking echocardiography (3DSTE) after percutaneous mitral valve repair with the MitraClip system (Abbott, Abbott Park, IL) in high-risk surgical patients with severe functional mitral regurgitation (MR).

Methods. Patients underwent 2D and 3D transthoracic echocardiography before MitraClip implantation and after 6 months of follow-up. Longitudinal, circumferential, radial strains, and global area strain (GAS) were calculated by 2DSTE and 3DSTE. Data analysis was performed offline.

Results. Fifteen patients with moderate-to-severe or severe MR undergoing MitraClip were prospectively included. Device success was achieved in 14 patients. New York Heart Association functional class improved acutely at discharge (p<0.005) and continued to improve progressively during follow-up (p<0.001). Echocardiography was performed at discharge and at six months. The primary efficacy end point (MR reduction of at least 1.0 grade or reduction of regurgitant orifice area by 0.1 cm2 or LV end-diastolic volume by 10% compared with baseline) was obtained in 11 patients. A significant improvement was shown in 3D LV ejection fraction (p<0.005), LV end-diastolic volume (p<0.001), LV end-systolic volume (p<0.001), left atrial volume (p<0.005), 2D global longitudinal strain (p<0.005), 3D global longitudinal strain (p<0.001), and GAS (p<0.001). A significant improvement was also shown in 3D RV ejection fraction (from 42.2±8.1 to 53.1±7.6%, p<0.005) and global free wall RV strain (-18.1±4.5 vs -23.3±4.8%, p<0.001).

Conclusions. These results show a significant improvement of LV and RV function and deformation and clinical parameters 6 months after MitraClip. Compared with 2D LV strain imaging, 3D echocardiography allowed faster image acquisition and more comprehensive analysis of multidirectional strain.

C81

PERCUTANEOUS MITRAL VALVE REPAIR WITH THE MITRACLIP® SYSTEM IN PATIENTS ALREADY TREATED WITH MITRACLIP

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Background and aim. Percutaneous mitral valve repair with the MitraClip® System (Abbott Vascular, Abbott Park, IL, USA) is an emerging alternative of treatment in patients with severe mitral regurgitation (MR) at high risk for conventional surgical therapy. We report a single center experience about the feasibility and efficacy of this novel procedure in patients with prior MitraClip implantation and severe MR recurrence.

Materials and methods . From October 2008 to June 2014, 207 consecutive patients underwent mitral valve repair with the MitraClip® System in our Department. Because of worsened clinical conditions and recurrence of ≥3+ MR at follow-up, 9 of them (age 74±7 years old, male 55%, EuroSCORE II (7.9±4.8%), STS risk score for mortality 10.6±8.7%, STS risk score for morbidity or mortality 42±19%) have undergone a second procedure of MitraClip implant (REDO). Six patients (66%) had suffered from functional mitral valve disease and three patients (34%) from degenerative valvular disease. In selecting the patients for the procedure, TTE and TEE played a major role. The feasibility of the implant was assessed by considering the position of the previously implanted clip(s), the shape of the two orifices, the origin, the direction and the degree of the regurgitant jet(s), deciding in advance the position of the future clip(s), and finally assessing the mean transvalvular gradient and the mitral valve area [anatomical and by PHT], excluding the presence of mitral stenosis.

Results. The REDO was performed after a mean of 20±12 months from the first procedure. One patient was re-treated within one month of the first procedure, and these cases we would like to underline, because the final degree of MR at the end of the first procedure was ≤2+, in stable hemodynamic conditions. MR recurrence is usually due to progressive left ventricle and mitral annulus dilation, although in these cases it could be due to mechanisms of leaflets' progressive stretching. One clip was implanted in 6 patients (66%), while 2 patients (34%) were treated with two clips. Mean anesthesia time was 137±42 minutes; mean device time, defined as the time from guide insertion until delivery catheter removal, was 38±24 minutes. For 8 patients (88%), a significant MR reduction (≤2) was observed at the end of the procedure and at discharge, in the absence of both significant mitral stenosis and intraprocedural complications. The fifth patient, who already had pericardial effusion at the beginning of the procedure, experienced cardiac tamponade during the implant. Pericardiocentesis was performed, but the puncture of a coronary caused the patient to be immediately transferred to Cardiac Surgery. She died during her hospital stay in ICU, two days after surgery. Another patient died for acute kidney injury and right heart failure 30 days after the REDO. A mean follow-up of 150±54 days is available for the remaining three patients, who are in the lowest NYHA functional classes (NYHA II) and present a low degree of MR (≤2+).

Conclusions. In our experience, a REDO procedure of percutaneous mitral valve repair with the MitraClip System is feasible and effective, but a complete echocardiographic assessment has to be previously performed. A higher number of REDO procedures is essential to confirm its real usefulness, effectiveness and feasibility.

C82

IMPACT OF TRICUSPID REGURGITATION ON CLINICAL AND ECHOCARDIOGRAPHIC OUTCOMES AFTER PERCUTANEOUS EDGE-TO-EDGE MITRAL VALVE REPAIR: INSIGHTS FROM THE GRASP REGISTRY

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Aims. To evaluate the association of baseline tricuspid regurgitation (TR) on the outcomes after percutaneous mitral valve repair (PMVR) with the MitraClip system.

Methods and results. Data from 146 consecutive patients with functional mitral regurgitation (MR) were obtained. Two different groups, dichotomized according to the degree of pre-procedural TR (moderate/severe, n=47 and none/mild, n=99), had their clinical and echocardiographic outcomes through 12 months compared. At 30 days, the primary safety endpoint was significantly higher in moderate/severe TR compared with none/mild TR (10.6% vs 2.0%, p=0.035). Marked reduction in MR grades observed post-procedure were maintained through 12 months. While NYHA functional class significantly improved in both groups compared with baseline, it was impaired in moderate/severe TR compared with none/mild TR group (NYHA >II at 30 days: 33.3% vs 9.2%, p<0.001; at 1 year: 38.5% vs 12.3%, respectively, p=0.006). Left ventricle reverse remodeling and ejection fraction improvement were revealed in both groups. The primary efficacy endpoint at 12 months determined by freedom from death, surgery for mitral valve dysfunction, or grade ≥3+ MR was comparable between groups, but combined death and re-hospitalization for heart failure rates were higher in moderate/severe TR group. Multivariable Cox regression analysis demonstrated that baseline moderate/severe TR and renal failure were independent predictors of this combined endpoint.

Conclusions. Although PMVR with MitraClip led to improvement in MR, TR, and NYHA functional class in patients with baseline moderate/severe TR, the primary safety endpoint at 30 days was impaired, while moderate/severe TR independently predicted death and re-hospitalization for heart failure at 12 months.

C83

MITRACLIP IMPLANTATION FOR HIGH RISK PATIENTS WITH SEVERE MITRAL REGURGITATION: FIRST YEAR EXPERIENCE

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Background. Mitral regurgitation is a common valvular disease with a huge impact on morbidity and mortality. Current guidelines recommend surgical repair or replacement of the mitral valve in patients with severe MR1 and symptoms of heart failure or left ventricular dysfunction. However, despite improvements in surgical technique, perioperative morbidity and mortality continue to be a significant problem in high risk patients with advanced age, multiple comorbidities and advanced heart failure. Percutaneous edge-to-edge mitral valve repair using the MitraClip system has evolved as a new tool in the treatment of mitral regurgitation (MR) in high risk patient.

Aim. This study sought to evaluate in-hospital and 30 days clinical outcomes of percutaneous mitral valve repair.

Methods. Twenty high surgical risk patients with symptomatic significant MR were evaluated for MitraClip implantation. Clinical and echocardiographic parameters were recorded at baseline and at follow-up. Patients were followed for at least 48 hours post-clip implantation in the cardiology department. On a follow-up visit patients were evaluated for functional class and echocardiographic features including MR severity, LV dimensions and function, and pulmonary pressure.

Results. The patients' mean age was 74.8±6.7 years and 38% were male. We screened 20 patients from June 2013 to May 2014 and 90% (18/20) were submitted to MitraClip implantation with 100% successful. Mean left ventricular ejection fraction was 36.3±11.7%. Grade III-IV MR was present in all patients with the vast majority suffering from functional MR secondary to ventricular remodeling. New York Heart Association (NYHA) class was III-IV in all patients. Vena contracta was 0.71±0.14 cm; regurgitant volume was 82.2±36.7 ml, end-systolic and end-diastolic volumes were 115±42.4 ml and 175±43.8 ml, respectively. E-wave velocity was 124.11±50.75 cm/s. Mean PAPs value was 45.2±15.6 mmHg. Post MitraClip implantation all patients were submitted at echocardiographic control within 48 hours. Acute reduction of MR grade to ≤2 was accomplished in 17 patients (94.4%) with a 30 day mortality of 11.1% (2/18), one of these for non-cardiac death. EF increased to 37.3±11.5%, NYHA class improved of one or two class in all patients. End-systolic and end-diastolic volumes were 105.75±18.9 ml and 161.5±18 ml, respectively. E wave velocity was 137±37.6 cm/s and PAPs value was 39.5±14.1 mmHg.

Conclusions. MitraClip implantation is feasible and safe in high risk highly symptomatic patients with significant MR. Acute and mid-term results are comparable to similar high risk patient cohorts in the literature. Continued surveillance and longer follow-up are needed to elucidate which patients are most likely to benefit from the procedure.

C84

ONE- AND TWO-YEAR SAFETY AND EFFICACY OUTCOMES OF PATIENTS UNDERGOING EDGE-TO-EDGE PERCUTANEOUS MITRAL VALVE REPAIR (FROM THE GRASP REGISTRY)

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The aim of this study was to report on the one- and two-year outcomes of percutaneous mitral valve repair with the MitraClip technique in patients with grade ≥3+ mitral regurgitation (MR) at high risk for conventional surgical therapy enrolled in the prospective GRASP (Getting Reduction of mitrAl inSufficiency by Percutaneous clip implantation) registry. Acute device success was defined as residual MR ≤2+ after clip implantation. The primary safety endpoint was the rate of major adverse events (MAEs) at 30 days. The primary efficacy endpoint was freedom from death, surgery for mitral valve dysfunction, or grade ≥3+ MR at 1 and 2 years. A total of 207 patients were treated.

One hundred and sixty-two patients (78%) presented with functional MR and 45 patients (22%) with organic MR. Acute device success was observed in 206 patients (99.5%). Device implantation time significantly diminished with experience and varied significantly between cases with one versus ≥2 clips. No procedural mortality was recorded. MAEs occurred in 7 patients at 30 days (4.6%). No surgery for mitral valve dysfunction occurred within 2 years. Freedom from death, surgery for mitral valve dysfunction, or grade ≥3+ MR was 77.6% and 61.8% at 1 and 2 years, respectively. No significant differences were noted in the primary efficacy endpoint between patients with degenerative MR and those with functional MR.

In conclusion, percutaneous mitral valve repair with the MitraClip technique was shown to be safe and reasonably effective in 207 patients from a real-world setting.

C85

GENDER-RELATED CLINICAL AND ECHOCARDIOGRAPHIC OUTCOMES AT 30-DAY AND 12-MONTH FOLLOW-UP AFTER MITRACLIP IMPLANTATION

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Gender-related differences have been demonstrated in patients with moderate to severe (3+) and severe (4+) mitral regurgitation (MR) who undergo surgical mitral valve (MV) intervention. Percutaneous edge-to-edge MV repair utilizing the MitraClip system has recently demonstrated promising results in the treatment of either degenerative or functional 3+ to 4+ MR, but the impact of gender in the outcomes of this novel intervention is currently unknown. Clinical and echocardiographic outcome data through 12-month follow-up obtained from GRASP registry of 171 consecutive patients whom underwent MitraClip implantation were dichotomized by the gender (106 males and 65 females). The primary safety end point (incidence of major adverse events at 30 days) was observed in 4 males (3.8%) and 4 females (6.2%) (p=0.358), while the primary efficacy end point (freedom from death, surgery for mitral valve dysfunction, or grade ≥3+ MR at 12-month follow-up after clip implantation obtained by Kaplan-Meier estimates) was revealed in 76.3% and 70.2%, respectively (log rank p=0.231). Remarkable reduction in MR post-procedure was revealed in both groups and these results were mostly sustained over time. Furthermore, left ventricle reverse remodeling coupled with improvement in New York Heart Association functional class was demonstrated in both groups. In conclusion, MitraClip intervention is safe and efficacious until mid-term follow-up, regardless of patients' gender. Further validation of our findings is warranted.

C86

TWENTY-YEAR FOLLOW-UP AFTER SUCCESSFUL PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY IN A LARGE CONTEMPORARY SERIES OF PATIENTS WITH MITRAL STENOSIS

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Background. Percutaneous balloon mitral valvuloplasty (PMV) is currently considered the standard of care for suitable patients with rheumatic mitral stenosis.

Aim. To report very long-term results up to 20 years, in a large series of patients treated by PMV.

Methods. Between 1991 and 2010, 527 consecutive patients underwent PMV in a single centre. Procedural success was defined as post-procedural valve area ≥1.5 cm^2 and regurgitation moderate or less, without in-hospital major adverse cardiac and cerebro-vascular events. The primary endpoint was 20-year incidence of major adverse cardiac events (MACE), including cardiovascular death and need for mitral surgery or repeat PMV.

Results. Long-term follow-up (mean 11.6±4.9 years; range 0.5 to 20) was completed in 441 patients (91.5% of eligible). The incidence of the primary endpoint was 41.9% (95% confidence interval [CI]: 37.3 to 46.7%). The rate of cardiovascular death, need for mitral surgery or repeat PMV was 9.1% (95% CI: 6.6 to 12.1), 27% (95% CI: 22.9 to 31.4), and 5.9% (95% CI: 3.9 to 8.5), respectively. Cumulative MACE-free survival at 20 years was 35.9±4.7%. At multivariate analysis, male gender (hazard ratio [HR]: 1.99; 95% CI: 1.4-2.8, p<0.001), echocardiographic score >8 (HR: 2.19; 95% CI: 1.6-2.9, p<0.001), atrial fibrillation (HR: 1.54; 95% CI: 1.2-2.1, p=0.003) and valve area ≤1.75 cm^2 after PMV (HR: 3.1; 95% CI: 2.3-4.2, p<0.001) were identified as independent predictors of the primary endpoint.
Conclusions. Up to 20 years after successful PMV, a sizeable proportion of patients still exhibit a good clinical result.

PCI pharmacology

C87

IMPACT OF BASELINE HAEMORRHAGIC RISK ON THE BENEFIT OF BIVALIRUDIN VERSUS UNFRACTIONATED HEPARIN IN PATIENTS TREATED WITH CORONARY ANGIOPLASTY: A META-REGRESSION ANALYSIS OF RANDOMIZED TRIALS. FOCUS ON STENT THROMBOSIS

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Background. Bivalirudin significantly reduces 30-day major and minor bleeding compared with unfractionated heparin (UFH), while resulting in similar or lower rates of ischemic events in both patients with stable and unstable coronary disease undergoing percutaneous coronary intervention. Available data show increased rates of acute stent thrombosis (ST) in bivalirudin treated patients. We performed a meta-analysis of randomized trials to evaluate the impact of bivalirudin compared with UFH, with or without glycoprotein IIb/IIIa receptor inhibitors (GPI), on the rates of mortality, myocardial infarction (MI), ST and major bleeding.
Methods. We searched electronic databases for randomized controlled trials with >100 patients comparing bivalirudin (±provisional GPI) with UFH with either routine or provisional GPI in patients undergoing percutaneous coronary intervention. The principal efficacy end points were mortality, MI and definite ST within 30 day, whereas major bleeding was the principal safety end point. We assessed the benefit of bivalirudin for each efficacy end point relative to the baseline bleeding risk, using the control (UFH) major bleeding rate as proxy for that risk.
Results. A total of 16 randomized trials that enrolled 38,676 patients were included. Overall, there was no significant difference in mortality (1.24% vs 1.26%, OR [95% CI] 0.99 [0.82-1.18], p=0.888) and MI (4.87% vs 4.58%, OR [95% CI] 1.07 [0.94-1.21], p=0.298) between bivalirudin monotherapy and UFH (±GPI), whereas major bleeding was significantly lower with bivalirudin (1.6% vs 3.0%, OR [95% CI] 0.57 [0.46-0.70], p<0.001), as well as minor bleeding (3.3% vs 5.5%, OR [95% CI] 0.6 [0.5-0.71], p<0.001). Bivalirudin reduced major and minor bleeding across the entire bleeding risk spectrum. Data on ST were available for 11 out of 16 trials: we found a significant difference in definite ST (1.03% vs 0.65%, OR [95% CI] 1.54 [1.14-2.08], p=0.0046) which was less frequent in UFH (±GPI) patients. This was confirmed when restricting the analysis to STEMI patients (1.92% vs 0.90%, OR [95% CI] 2.17 [1.15-4.09], p=0.0164).
Conclusions. Bivalirudin significantly reduces major and minor bleeding regardless of the estimated baseline hemorrhagic risk. No significant benefit was found in terms of the overall rate of 30-day death or MI, but more definite ST were found in bivalirudin monotherapy patients, probably reflecting the shorter half-life of such anticoagulant.

C88

PERCUTANEOUS CORONARY INTERVENTIONS IN PATIENTS WITH ELEVATED INR VALUES: A SUB-ANALYSIS OF THE WARFARIN AND CORONARY STENTING (WAR-STENT) REGISTRY

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Introduction. In patients treated with oral anticoagulant therapy with vitamin K-antagonists (OAC) who are referred for percutaneous coronary interventions (PCI), the optimal peri-procedural management of OAC (to stop it or not) is still unclear. Maintaining OAC might be associated with increased bleeding risk, whereas interrupting it might increase thrombotic complications. The aim of our study was to evaluate the in-hospital outcome of OAC patients undergoing PCI and included in the WARfarin and Coronary STENTing (WAR-STENT) registry, according to the pre-procedural International Normalized Ratio (INR) value.
Methods. The WAR-STENT registry (NCT 00722319) is a prospective, multicenter, observational study including consecutive patients on OAC undergoing PCI with stenting. The in-hospital occurrence of bleeding and thrombotic complications for those in whom pre-procedural INR value was known were evaluated. Patients have been analyzed in two groups based on INR values ≥1.8 (Group 1) or <1.8 (Group 2).
Results. Out of the 411 patients, 157 had an available pre-procedural INR value and were included in our analysis: 106 patients (75±11 years, 26% male) in Group 1 and 51 patients (74±11 years; 35% male, p=NS) in Group 2. There were no significant differences between the two groups as in term of major cardiovascular risk factors and peri-procedural antiplatelet therapy. The mean pre-procedural INR value was 2.3±0.4 in Group 1 and 1.5±0.2 in Group 2 (p<0.001). There was no significant difference in the intra-procedural heparin dose between the two groups (4515±1818 U in Group 1 and 4977±1435 U in Group 2, p=0.15). The use of transradial approach was significantly higher in Group 1 (76 cases, 72%) compared with Group 2 (23 cases, 45%, p=0.002). No significant differences in in-hospital major (3.8% in Group 1 and 3.9 % in Group 2, p=1.00) or minor bleeding (6.6% in Group 1 and 2% in Group 2, p=0.44) were observed. Most of the bleeding events were non access site major bleedings with only 1 case of access site bleeding. Death rate (4% in Group 1 and 0% in Group 2, p=0.31) and peripheral embolism (0% in Group 1 and 2% in Group 2, p=0.32) did not differ between the two groups.
Conclusions. In a non-selected population of patients treated with OAC who underwent PCI with stent, maintaining peri-procedural OAC with a INR value ≥1.8 appears to be safe, being not associated with increased bleeding events compared to a strategy of OAC interruption.

C89

BIVALIRUDIN VERSUS HEPARIN IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION: A META-ANALYSIS OF RANDOMIZED TRIALS

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Background. There is uncertainty about the impact of bivalirudin, as compared to unfractionated heparin, on clinical outcomes in patients with ST-segment elevation myocardial infarction (STEMI).
Methods. A meta-analysis of randomised trials comparing bivalirudin versus heparin in patients with STEMI undergoing primary percutaneous coronary intervention was performed. Three randomised trials enrolling 7612 patients were included. Analysis was by intention to treat.
Results. At 30 days, bivalirudin, as compared to heparin, was associated with a similar risk of all-cause mortality (3.03% vs 3.38%, odds ratio (OR) 0.90, 95% confidence intervals (CI) [0.63 to 1.29], p=0.57). Bivalirudin significantly increased the risk of definite (1.98% vs 0.86%, OR 2.53, 95% CI [1.31 to 4.87], p=0.006); definite or probable (2.11% vs 1.10%, OR 2.30, 95% CI [1.08 to 4.90], p=0.03); and acute stent thrombosis (1.39% vs 0.31%, OR 4.41, 95% CI [2.34 to 8.29], p<0.001); leading to nonsignificantly higher reinfarction rates (2.0% vs 1.31%, OR 1.72, 95% CI [0.89 to 3.35], p=0.11), and to a significantly increased risk of ischemia driven revascularization (2.50% vs 1.52%, OR 1.80, 95% CI [1.02 to 3.18], p=0.04) at 30 days. No firm evidence for a reduction in major bleeding associated with bivalirudin use was found (3.93% vs 6.39%, OR 0.63, 95% CI [0.39 to 1.04], p=0.07).
Conclusions. In patients with STEMI, bivalirudin use, as compared to heparin, is associated with similar all-cause mortality at 30 days. However, bivalirudin increases the risk of stent thrombosis and ischemia driven repeat revascularization, while no strong evidence that it significantly reduces major bleeding at 30 days is present.

C90

EFFICACIA DELLA TROMBOLISI INTRATROMBO IN PAZIENTI CON STEMI SOTTOPOSTI A PCI PRIMARIA PREVIA TROMBECTOMIA

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Background. Nello STEMI un'immediata riperfusione del vaso culprit mediante PCI consente di ottenere il salvataggio del tessuto miocardico e, quindi, un miglioramento dei risultati clinici. L'introduzione della tromboaspirazione, conseguente alla notevole incidenza del fenomeno del "no-reflow", ha consentito un miglioramento del flusso epicardico e della perfusione miocardica, tuttavia restano da chiarire ancora diversi punti.
Scopo. Il nostro trial, denominato DISSOLUTION, si è posto l'obiettivo di valutare, in pazienti con STEMI sottoposti a PCI primaria, l'utilità del rilascio locale, direttamente nello spessore del trombo, di una bassa dose di trombolitici, nell'aumentare l'efficacia della tromboaspirazione.
Metodi. 102 pazienti con STEMI ed evidenza angiografica di trombosi occlusiva della coronaria culprit sono stati randomizzati in due gruppi, che hanno ricevuto, rispettivamente, un bolo locale, intratrombo di 200 000 unità di urochinasi (n=51) o soluzione salina (n=51), seguita da tromboaspirazione manuale (Pronto TM, Vascular Solution, Inc.,

Minneapolis, Minnesota) e PCI. Entrambi i gruppi hanno ricevuto abciximab (bolo e.v. + infusione per 12h). Gli endpoint comprendevano il TIMI flow grade e frame count finale, il myocardial blush grade (MBG), la risoluzione del tratto ST in 60 minuti (STR) >70%, ed i MACCE, definiti come morte, reinfarto, ictus, o target clinicamente guidato di rivascolarizzazione del vaso a 6 mesi. Inoltre, tutti i pazienti hanno effettuato un controllo ecocardiografico per la valutazione della frazione di eiezione ventricolare sinistra (LVEF) e del wall motion score (WMS).

Risultati. Le caratteristiche cliniche ed angiografiche dei due gruppi erano sovrapponibili. I pazienti sottoposti ad urochinasi intratrombo hanno mostrato un flusso TIMI 3 significativamente maggiore (90% vs 66%, p=0.008), un TIMI frame count post-PCI inferiore (19±15 vs 25±17, p=0.033), una perfusione miocardica post-procedurale significativamente aumentata (MBG 2 o 3: 68% vs 45%, p=0.028) ed una migliore STR >70% (82% vs 55%, p=0.006). Il controllo ecocardiografico al terzo giorno non ha mostrato differenze tra i due gruppi né nella frazione d'eiezione ventricolare sinistra (51±12 vs 49±10%, p=0.363) né nel wall motion score index (1.81±0.36 vs 1.60±0.49; p=0.907). Nel follow-up clinico a 6 mesi, il gruppo di pazienti trattato con urochinasi intratrombo ha mostrato una migliore sopravvivenza libera da MACE (6% vs 21%; long-rank p=0.044) e, nel follow-up ecocardiografico, ha presentato una frazione d'eiezione ventricolare sinistra maggiore (57±13 vs 52±17%, p=0.098) ed un wall motion score index più basso (1.76±0.44 vs 1.91±0.39; p=0.071), indicativi di una migliore cinesi regionale miocardica a 6 mesi in questi pazienti. È stato altresì predisposto un sottogruppo di 25 pazienti, il cui materiale trombotico aspirato è stato sottoposto ad esame istologico. Il materiale aspirato dai pazienti trattati con urochinasi è risultato decisamente maggiore (4 vs 2 mm^3), ed inoltre, si presentava più soffice, frammentato in minuscole sferule diffuse, anziché compatto come nel gruppo che aveva ricevuto soluzione salina.

Conclusioni. Il nostro studio ha dimostrato che, in pazienti con STEMI sottoposti a PCI primaria, il rilascio locale, intratrombo di basse dosi di agenti trombolitici prima della trombectomia manuale è associato ad un miglioramento del flusso coronarico post-procedurale e della perfusione miocardica, nonché dell'esito clinico a 6 mesi.

C91

INTRACORONARY ADENOSINE ADMINISTRATION REDUCES MACE AND HEART FAILURE IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION UNDERGOING PRIMARY PERCUTANEOUS CORONARY INTERVENTION: A META-ANALYSIS OF RCTS

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Background. Primary percutaneous coronary intervention (PPCI) is the preferred reperfusion strategy in patients with STEMI. It has been constantly observed that, despite restoring a good epicardial flow with PCI, myocardial perfusion at the cellular level remains impaired in nearly 50% of STEMI patients. Many molecules and drugs have been studied to improve myocardial perfusion, one of the most promising is adenosine. However, clinical trials comparing intracoronary (IC) adenosine with placebo have shown conflicting results, with some studies being underpowered to evaluate clinical hard endpoints. Thus, the aim of the current study was to perform a meta-analysis of all available randomized controlled trials (RCTs) comparing the effect of intracoronary adenosine versus placebo on clinical outcomes in patients undergoing primary percutaneous coronary intervention.

Methods. PubMed MEDLINE, the Cochrane Library and ISI Web of Knowledge electronic databases were scanned up to April 23rd 2014. The following search syntax was used in the search: ("intracoronary adenosine") AND ("primary percutaneous coronary intervention" OR "ST elevation myocardial infarction" OR "primary pci" OR "acute myocardial infarction" OR "no reflow"). The meta-analysis included ten RCTs.

Results. At short-term analysis, incidence of MACEs was significantly lower in the IC adenosine group than in the placebo group (Fig. 1) (RR=0.64; 95% CI 0.46-0.89; p=0.008). Similarly, long-term incidence of MACEs was significantly lower in the IC adenosine group than in the placebo group (Fig. 2) (RR=0.62; 95% CI 0.39-0.96; p<0.03). In addition, the incidence of heart failure was also lower in the IC adenosine group than in the placebo group (RR=0.47; 95% CI 0.26-0.84; p=0.01).

Conclusions. This meta-analysis shows for the first time that intracoronary adenosine adjunctive therapy does improve MACEs and HF in patients with ACS-STEMI treated with P-PCI.

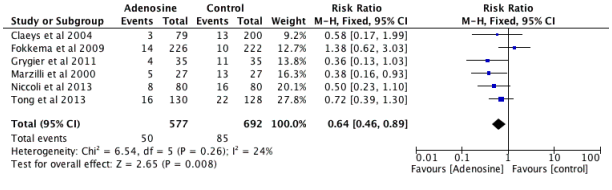

Figure 1. Short-term follow-up (<1 month) – MACEs.

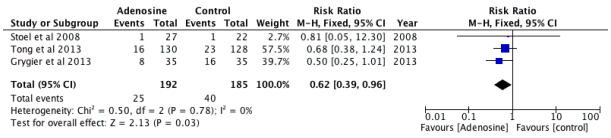

Figure 2. Long-term follow-up (6-12 months) – MACEs.

C92

BIVALIRUDIN AS COMPARED TO UNFRACTIONATED HEPARIN IN PATIENTS UNDERGOING PERCUTANEOUS CORONARY REVASCULARIZATION: A META-ANALYSIS OF 16 RANDOMIZED TRIALS

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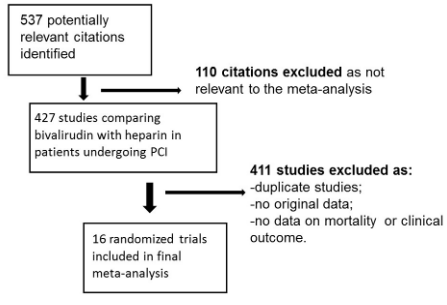
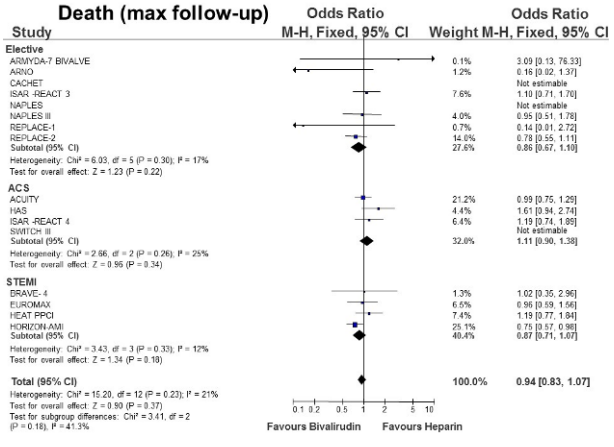
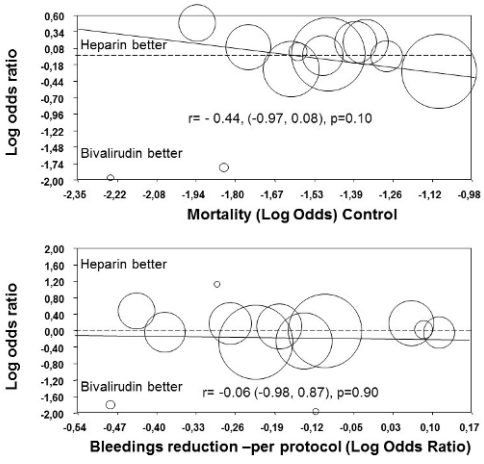
Background. Bivalirudin is nowadays a largely used anticoagulation strategy for percutaneous coronary revascularization procedures (PCI), due to a reported better safety profile as compared with unfractionated heparin (UFH). However, is still questioned whether bivalirudin may provide advantages in clinical outcome beyond the known benefits in major bleeding complications. In current study we performed a comprehensive meta-analysis of randomized trials evaluating efficacy and safety of bivalirudin as compared with UFH in patients undergoing PCI.

Methods and study outcomes. Literature archives and main scientific sessions abstracts were scanned for randomized trials comparing bivalirudin with UFH in patients undergoing PCI. Primary efficacy endpoint was overall mortality. Secondary endpoints were: 1) mortality within 30 days; 2) overall non fatal myocardial infarction and non fatal myocardial infarction within 30 days. Safety endpoint were the rate of major bleedings according to a per protocol definition or TIMI classification. A prespecified analysis was conducted according to clinical presentation (elective, ACS, STEMI).

Results. A total of 16 randomized clinical trials, 36303 patients, were finally included, 54% randomized to bivalirudin and 46% to heparin. Death occurred in 1042 (2.9%) of patients, with no difference in mortality between bivalirudin and UFH (2.9%, vs 3% OR [95%CI] 0.94 [0.83-1.07], p=0.37, p_{het}=0.23). The results did not change according to clinical presentation (elective, ACS, STEMI). By meta-regression analysis no significant relationship was observed between benefits in mortality with bivalirudin as compared to UFH and risk profile (r=-0.44 [-0.97, 0.08], p=0.10) or reduction in major bleeding complications (r=-0.06 [-0.98, 0.87], p=0.9). No difference was observed for death within 30 days (OR [95%C] 0.98 [0.81-1.20], p=0.88, p_{het}=0.27), myocardial infarction within 30 days (OR [95%CI] 1.08 [0.96-1.20], p=0.21, p_{het}= 0.12) and overall myocardial infarction (OR [95%C] 1.06 [0.97-1.15], p=0.20, p_{het}=0.03). However, bivalirudin was associated with a significant reduction in bleedings according to both study protocol definition (OR [95%CI] 0.63 [0.57-0.70], p<0.00001; p_{het}<0.0001) or TIMI major criteria (OR [95%CI] 0.65 [0.53-0.79], p<0.00001; p_{het}= 0.95).







Conclusions. Present meta-analysis shows that in patients undergoing PCI, bivalirudin, as compared with UFH, is associated with a significant reduction in major bleeding complications that, however, did not translate into mortality benefits, independently from the type of presentation. Among STEMI patients bivalirudin is associated with higher 30-day recurrent MI.

C93

FRAILTY AND END-OF-LIFE IN ACS PATIENTS: IDENTIFICATION AND PROGNOSTIC IMPACT

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Introduction. The role of frailty and end of life (EoL) in patients with acute coronary syndrome (ACS) remain to be determined.

Methods. All consecutive unselected patients admitted to the Emergency Department (ED) of two European hospital with a diagnosis of ACS during three different periods among 2011 and 2013 were included. Patients were divided according to positive or negative GSF (The Gold Standards Framework), which was calculated together with traditional cardiovascular risk scores (GRACE, ACEF, New York PCI risk score) and the Clinical Frailty Scale. All-cause death at one year follow-up was the primary outcome; cardiac and non cardiac death, all cardiovascular and all non-cardiovascular events at one year were the co-primary end points.

Results. 430 ACS patients were enrolled and 427 had a complete one year follow-up. 36 (8.4%) had a positive GSF: they were older (77.6±12.7 vs 68.9±11.8; p<0.001), with a lower BMI (23.18±4.1 vs 26.3±4.5; p=0.003), more frequently women (52.8% vs 31.5%; p=0.015), less dyslipidemic (22.2% vs 56.9%; p<0.001) and had more comorbidities. They were also less angiographically studied (66.7% vs 92.9%; p<0.001) and received less interventional procedures (47.2% vs 72.8%; p=0.002). At 12-month follow-up a positive GSF was associated with higher rate of all-cause death (47.2% vs 4.3%; p<0.001), cardiac death (13.9% vs 2.6%; p=0.005), non cardiac death (33.3% vs 1.8%; p<0.001) and all non-cardiovascular events (47.2% vs 15.3%; p<0.001). The AUC for the ROC curve for all-cause death was 0.803 (95% CI 0.635-0.970). In the correlation analysis GSF had good correlation only with the Clinical Frailty Scale (Pearson's correlation 0.499; p<0.001).

Conclusion. The prognostic indicator GSF can be a useful tool to identify EoL ACS patients, being independently related to one year death and non cardiovascular events.

TAVI

C94

PROCEDURAL AND CLINICAL OUTCOMES OF SUBCLAVIAN VERSUS TRANSAORTIC APPROACH FOR TRANSCATHETER AORTIC VALVE REPLACEMENT WITH SELF-EXPANDABLE COREVALVE: AN ITALIAN MULTICENTER EXPERIENCE

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Background. Transfemoral approach represents the first choice of vascular access for transcatheter aortic valve replacement (TAVR). When not feasible, alternative approaches such as subclavian or direct ascending aorta (transaortic rout) are used for self-expandable CoreValve implantation. Aim of this work was to compare the safety of TAVR with self-expandable valve through these alternative vascular approaches.

Methods. All consecutive patients underwent TAVR with self-expandable CoreValve prosthesis treated through alternative approach in 4 high volume Italian Centre. Devices success and combined safety endpoint according to VARC-2 criteria were evaluated.

Results. Among 1049 patients undergoing CoreValve implantation between September 2007 and February 2014, 242 (23%) have been treated through alternative access: subclavian (147/242, 61%) and transaortic (95/242, 39%) route because of peripheral artery disease. Demographic features were quite similar in both groups except for a higher clinical risk profile [median STS: 10% (IQR 6-14%) vs 6% (IQR 4-12%), p<0.001] and previous CABG (20% vs 10%, p=0.021) in transaortic group compared to subclavian one. Device success was similar in two groups (87% vs 80%, respectively; p=0.164). The subclavian group showed higher rate of fluoro time [22 min (IQR 16-28) vs 17 min (IQR 13-20), p=0.05] and contrast used (192±81 ml vs 148±63 ml, p<0.001). The transaortic group showed a higher incidence of combined safety end point (27% vs 16%, p=0.04) mostly driven by a higher rate of acute kidney injury/stage 2-3 (10% vs 2%, p=0.01) as well as the length of hospital stay [10 days (IQR 8-14) vs 8 days (IQR 7-12), p<0.001]. Compared to subclavian group, the transaortic had a similar cumulative incidence of survival rate at 30-day (94.6% vs 90%, respectively; p=0.21).

Conclusion. Compared to subclavian, the transaortic group had higher clinical risk profile with a higher incidence of combined safety endpoint mostly due to acute kidney injury/stage 2-3. However, no differences were observed in the device success and survival rate at 30 days.

C95

DEGENERATION OF TRANSCATHETER IMPLANTED AORTIC BIOPROSTHESIS: A SINGLE CENTER EXPERIENCE

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Purpose. Transcatheter aortic valve implantation (TAVI) is emerging as an effective alternative to surgical aortic valve replacement in inoperable and high-risk patients. No definitive data are available on long term durability of transcatheter-implanted aortic bioprosthesis (TIAB). We describe the different management in two cases of TIAB degeneration.

Methods and results. 336 TAVI (297 Medtronic CoreValve®) were performed in our center since 2007. Main demographic, clinical and echocardiographic data are shown in Table 1. Median follow-up was 13 months.

Age, years	81.6±6.4
Female	178 (53.2%)
Logistic EuroSCORE	20 (13-30)
NYHA functional class III/IV	243 (72.4%)
Diabetes mellitus	97 (29.1%)
Serum creatinine, mg/dl	1.1 (0.9-1.5)
Prior myocardial infarction	60 (18.1%)
Peripheral vascular disease	99 (29.5%)
Left ventricular ejection fraction, %	50.8±12.4
Mean aortic gradient, mmHg	51.7±15.4
Aortic valve area index, cm^2/m^2	0.4±0.2

In our experience we met two cases (0.59%) of CoreValve early degeneration. Median degeneration time was 5.5 years. The first case was a 91-year-old female, with worsening dyspnea and echocardiographic evidence of calcific degeneration of the CoreValve 26 mm bioprosthesis causing severe stenosis (mean pressure gradient: 53 mmHg; AVA: 0.5cm^2/m^2). After heart team discussion, considering age, frailty and comorbidities (mild cognitive impairment, stage 3 chronic kidney disease), very-high surgical risk, we opted for a conservative strategy, optimizing medical therapy with progressive improvement of patient clinical status till the discharge. The second patient was a 67-year-old man with end-stage kidney failure on dyalisis, complicated by tertiary hyperparathyroidism, already treated by subtotal parathyroidectomy; he was admitted to our intensive care unit for acute pulmonary edema. Echocardiography showed calcific degeneration of CoreValve bioprosthesis causing severe stenosis (mean pressure gradient: 52 mmHg; AVA: 0.4 cm^2/m^2) with preserved left ventricular function (EF 53%). We performed a successful valve-in-valve implantation with a CoreValve 29 mm and progressive improvement of patient clinical status in the follow-up.

Conclusions. In scientific literature, few cases of degenerated porcine CoreValve and bovine Sapien XT valve have been described. The pathogenesis of calcification of bioprosthetic heart valves is poorly understood even though it is probably multifactorial. In our experience the common predictive factor of early degeneration was chronic kidney disease.

C96

EXPANDABLE SHEATH FOR TRANSFEMORAL TRANSCATHETER AORTIC VALVE REPLACEMENT: PROCEDURAL OUTCOMES AND COMPLICATIONS

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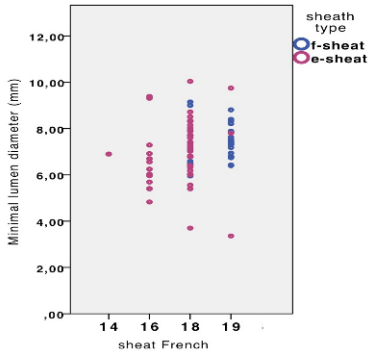
Aims. Among transfemoral Edwards transcatheter aortic valve implantation (TF TAVI), the expandable sheath (e-sheath) has been described to present a lower rate of access complications, compared to the fixed size sheath (f-sheath). Our aim was to compare the incidence of periprocedural complications when using f-sheath vs e-sheath during TAVI.

Methods. From September 2009 to May 2014, we included 141patients undergoing TF TAVI in our center with the Edwards SAPIEN(TM)/SAPIEN XT/SAPIEN 3 balloon-expandable prosthesis (Edwards Lifesciences, Irvine, CA) utilizing the Novaflex, Novaflex+ and Commander delivery systems; access closure was obtained with the Prostar system in all cases. E-sheath (18/19/16/14 F) was used in 91 patients (64.5%), whereas f-sheath (18/19 F) was utilized in 50 patients. The crossover technique was performed in 108 patients (79.4%). All complications were defined according to Valvular Academic Research Consortium 2 (VARC-2) consensus.

Results. Out of 305 patients who underwent TAVI, 76 (54.7%) was female, mean age was 80.5±6.5 years and logistic EuroSCORE was 20.7±12.2%. Mean minimal femoral artery diameter was 6.9±1.4 in e-sheath group and 7.4±0.8 mm f-sheath group (p=0.06). Mean outer diameter was 6.9 ± 0.4 in e-sheath and 7.4±0.1 in f-sheath group (p<0.001). Outer sheath diameter/artery ratio was 1.054±0.275 in e-sheath group and 1.10±0.104 in f-sheath group (p=0.4). VARC major vascular complications rate were similar in the 2 groups: e- sheath 14 (15.6%) vs f-sheath 6 (12.2%) (p=0.62), as well as minor vascular complications: 28 (31.5%) vs 14 (29.2%) (p=0.84). Similarly, bleeding complications were comparable between e-sheath and f-sheath groups: life-threatening bleeding 2 (4.2%) vs 2 (2.2%), major bleeding 19 (21.3%) vs 13 (27.9%), and minor bleeding 29 (32.3%) vs 9 (18.8%) (p=0.35). By logistic regression analysis, no association was found between vascular complication and sheath type, outer, minimal lumen diameter, or ratio of out of diameter to minimal lumen ratio.

Conclusions. The use of expandable sheath did not reduce vascular and bleeding complications in TF-TAVI. However the introduction of this approach allowed transfemoral TAVI in patients with smaller femoral arteries (Figure) probably limiting its potential benefits.



C97

MORTALITÀ PRECOCE POST-INTERVENTO DI TAVI: CORRELAZIONE CON LE CARATTERISTICHE DEI PAZIENTI E LE COMPLICANZE PERIPROCEDURALI

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Background. La TAVI (transcatheter aortic valve implantation) è un'importante opzione terapeutica nella stenosi aortica severa per pazienti inoperabili o a elevato rischio chirurgico. Gli endpoint, per valutare con uniformità la sicurezza e l'efficacia della TAVI, stabiliti dai documenti di consenso VARC e VARC-2, sono: mortalità, infarto miocardico, stroke, complicanze vascolari ed emorragiche, insufficienza renale acuta, disturbi di conduzione, aritmie, altre complicanze procedurali e valutazione della funzione valvolare. L'obiettivo del nostro studio, pertanto, è valutare le caratteristiche preoperatorie, le complicanze periprocedurali e a 1 mese dei pazienti sottoposti a TAVI presso il nostro centro per cercare elementi predittivi di mortalità.

Metodi. Da novembre 2009 ad aprile 2014 sono state eseguite presso il nostro centro 206 TAVI, impiantando 160 protesi Edwards SAPIEN e 46 CoreValve con approccio transfemorale (88.8%), transapicale (6.8%) e transucclavio (4.4%). A maggio 2014 63 pazienti (30.6% di cui 59% donne) risultano deceduti. La mortalità è stata valutata in acuto (intra-procedurale e a 1 mese) e entro 1 anno dall'intervento (mortalità precoce) utilizzando la curva di Kaplan-Meier, dividendo la mortalità per cause cardiovascolari (CV) e non CV.

Risultati. Le principali caratteristiche della nostra popolazione sono riassunte in Tabella.

Età (anni)	83.5±3.9
Maschi	37.4%
Logistic EuroSCORE	18.9±8.7
STS	8.8±4.6
NYHA ≥3	77.2%
BPCO	24.3%
Diabete	26.2%
Coronaropatia	41.7%
Pregressa valvuloplastica	15,5%
Fibrillazione atriale	34%
IRC	25.7%
NT-proBNP pre	9654.0±10558.5

Dei 206 pazienti, 70 (34.0%) sono andati incontro a complicanze: 58.6% periprocedurali e 41.4% entro 1 mese. Di questi 70 pazienti 20 sono deceduti al follow-up. Le principali complicanze sono state: vascolari (maggiori e minori) 41.4%, tamponamento cardiaco (12.9%), impianto di PM 17.1%, stroke 1.4% e altre (scompenso cardiaco, aritmie e disturbi della conduzione, arresto cardiaco, 21.4%). La mortalità acuta è stata 8.7% e la mortalità precoce 21.7%. All'analisi multivariata la mortalità intraricovero è risultata correlata (p<0.05) con BPCO, insufficienza aortica (IAo) pre-TAVI, incremento di troponina (TnI) post-TAVI e il verificarsi di complicanze periprocedurali; la mortalità a 1 mese con le complicanze periprocedurali e l'incremento di TnI; la mortalità a 1 anno con la pregressa valvuloplastica, il proBNP pre, l'anemizzazione post, l'incremento di TnI e il logistic EuroSCORE. Nella nostra casistica l'IAo residua era presente nel 68.4% dei casi, di cui solo nel 11.3% era almeno moderata e non è risultata correlata con la mortalità. La mortalità per cause CV è risultata maggiore (p<0.001) a 1 mese e a 1 anno dalla TAVI rispetto alla non CV. L'85% dei decessi per cause non CV si è verificato nei primi 2 anni della nostra esperienza.

Conclusioni. Dall'analisi del nostro studio si evince che alcune caratteristiche cliniche e le complicanze periprocedurali correlano con la mortalità acuta e precoce. La mortalità per cause CV è maggiore entro 1 anno dalla TAVI. Una migliore selezione dei pazienti, possibile mediante curva di apprendimento, ha consentito la riduzione delle morti non CV precoci.

C98

CLINICAL OUTCOMES OF PATIENTS WITH LOW-FLOW, LOW-GRADIENT SEVERE AORTIC STENOSIS ACCORDING TO TREATMENT MODALITY

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Objective. We aimed to compare clinical outcomes among patients presenting with "classical" low-flow, low-gradient severe aortic stenosis according to the assigned treatment modality.

Methods. Between April 2005 and December 2012, 210 patients with low-flow, low-gradient severe aortic stenosis (indexed aortic valve area [AVA] ≤0.6 $cm^2.m^{-2}$, left ventricular ejection fraction [LVEF] <50% and mean gradient (MG) <40 mmHg) underwent treatment allocation to either medical therapy (MT) (n=47) surgical aortic valve replacement (SAVR) (n=52) or transcatheter aortic valve implantation (TAVI) (n=111). Pre-procedural non-invasive and invasive hemodynamic indices, coronary artery disease (CAD) complexity and procedural characteristics were compared between groups. Primary end-point was all-cause mortality at 1 year.

Results. Baseline characteristics were similar between patients allocated to MT and TAVI, whereas SAVR patients were younger (MT 82.47±5.03 vs SAVR 78.43±54.10 vs TAVI 82.04±5.08 years, p<0.0001) and lower risk (STS score MT 10.82±7.25 vs SAVR 4.85±2.95 vs TAVI 7.88±4.80%, p<0.001). CAD complexity was significantly greater among MT patients (SYNTAX score MT 29.2±17.9 vs SAVR 20.4±12.5 vs TAVI 21.6±14.1, p=0.036). Pre-procedural AVA (MT 0.69±022, SAVR 0.73±0.23, TAVI 0.74±0.21cm^2, p=0.40) and MG (MT 25.23±9.33 vs SAVR 29.26±9.54 vs TAVI 28.54±10.30 mmHg, p=0.09) were similar between groups, but patients undergoing SAVR had a higher baseline LVEF (MT 30.28±9.72 vs SAVR 38.90±11.94 vs TAVI 34.35±11.32%, p=0.001) and lower prevalence of moderate/severe mitral regurgitation (MT 52.3% vs SAVR 30.0% vs TAVI 52.8%, p=0.02). SAVR patients also had lower pulmonary artery systolic pressures (MT: 59.71±15.29 vs SAVR 50.63±16.15 vs TAVI 58.17±14.72 mmHg, p=0.023) on pre-procedural right heart catheterization. Contractile reserve was present in 68.8% of patients undergoing dobutamine stress echocardiography. At 12 months, the primary endpoint was significantly lower among both SAVR (13.5% vs 57.4%, HR 0.17, 95% confidence interval [CI] 0.076-0.40, p<0.001) and TAVI (20.7% vs 57.4%, HR 0.28, 95% CI 0.16-0.49, p<0.001) as compared with MT patients. No significant differences in the primary endpoint were observed between SAVR and TAVI patients (p=0.27).

Conclusions. Among patients with low-flow, low-gradient severe aortic stenosis, SAVR and TAVI improved survival compared with MT. Clinical outcomes of TAVI and SAVR appeared similar among appropriately selected patients with low-flow, low-gradient severe aortic stenosis.

C99

IL PROFILO EMODINAMICO DELLE BIOPROTESI AORTICHE NEL PAZIENTE ANZIANO: TAVI ED EDWARDS INTUITY A CONFRONTO

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Background. Oltre alla TAVI, un'alternativa per i pazienti ad alto rischio chirurgico è l'impianto di protesi biologiche "sutureless". Il loro impianto, spesso mininvasivo, ha soprattutto il vantaggio di ridurre il tempo di clampaggio aortico, e quindi di ischemia cardiaca, e di conseguenza la durata complessiva dell'intervento. Una di queste è la Edwards Intuity™, ossia un modello a rilascio rapido posizionabile tramite 3 suture "guida", e costituito da uno stent in nitinol balloon-expandable.

Materiali e metodi. La ricerca è stata condotta su un campione di ultrasettantacinquenni affetti da stenosi aortica (SA) severa con indicazione a trattamento. Di tali pazienti, 129 sono stati sottoposti a procedura trans-catetere negli ultimi 4 anni, mentre a 34 è stata impiantata una Edwards Intuity negli ultimi 2 anni. La popolazione studiata, prevalentemente di sesso femminile (61.8 vs 55.9%), presentava un EuroSCORE logistico >20% (26.616 vs 20.483%). Nell'80.4% dei pazienti TAVI è stata utilizzato l'accesso trans-femorale, nel 13.1% quello trans-apicale e nel 6.5% quello trans-aortico; sempre in questo gruppo è abbastanza scontato che l'entità della concomitante insufficienza mitralica (IM) sia più grave (p<0.001). Obiettivo dello studio è stato quello di confrontare le bioprotesi in termini di performance emodinamica, sulla base dei dati raccolti in occasione dei controlli ETT eseguiti entro la dimissione e a 6-12 mesi dall'impianto.

Risultati. Nonostante nell'immediato post-impianto, i pazienti TAVI presentino gradienti massimo (18.368 vs 20.3 mmHg) e medio (9.765 vs 11.433 mmHg), se pur di poco, ma inferiori rispetto a quelli dei pazienti Intuity, tale situazione si ribalta al follow-up quando, una volta superato lo stress chirurgico, tali gradienti risultano rispettivamente circa 6 (p<0.002) e 4 mmHg (p<0.001) superiori. Allo stesso modo molto significativa (p<0.001) è risultata la differenza in termini di mismatch protesi-paziente (PPM): è evidente come un PPM non significativo (EOAi >0.85 cm^2/m^2) sia nettamente prevalente tra i pazienti Intuity (91.7 vs 41.4%), mentre un PPM severo (EOAi <0.65 cm^2/m^2) tra quelli trattati per via trans-catetere (27.6 vs 4.2%). Inoltre, come prevedibile, al follow-up i rigurgiti protesici sono largamente prevalenti nei pazienti TAVI (p<0.001). A differenza dei loro coetanei trattati per via chirurgica che miglioravano significativamente (p<0.03) la loro FEVS solo al follow-up, i pazienti sottoposti a TAVI miglioravano notevolmente la loro FEVS così come la PAPs anche e già nell'immediato post-operatorio (rispettivamente p<0.001 e p<0.03), presentando per giunta una riduzione significativa (p<0.03) dell'entità dell'IM al follow-up.

Conclusioni. Quello appena descritto è il primo studio di confronto tra la Edwards Intuity e le protesi trans-catetere, che considera il fattore fragilità. Visto che le protesi sutureless rappresentano ormai una realtà nel trattamento della SA severa nei pazienti ad alto rischio, la TAVI potrebbe essere eventualmente riservata a pazienti ancora più fragili e che necessitino di un miglioramento immediato della loro performance cardiaca, indipendentemente dalla concomitanza di IM.

C100

TRANSCATHETER AORTIC VALVE IMPLANTATION WITHOUT BALLOON PREDILATION: A NON-RANDOMIZED SINGLE CENTRE EXPERIENCE

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Background. Balloon pre-dilation (BAV) is considered an essential step of transcatheter valve implantation procedure (TAVI), to facilitate the crossing of the aortic bioprostheses; however there is not clear evidence supporting this policy in all patients. Moreover balloon pre-dilation might be responsible in part of atrioventricular conduction disturbances and cerebrovascular embolizations during TAVI procedures. Recent evidence showed that without balloon predilation, an implantation success could be achieved in the vast majority of patients, but few data are available on the safety and efficacy of this approach. Aim of this study is to evaluate the safety of TAVI without pre-BAV compared with the standard implantation technique.

Methods and results. A total of 72 consecutive patients (pts) with symptomatic severe aortic stenosis and contraindication to surgical replacement or at very high surgical risk underwent TAVI at Carlo Poma Hospital (Mantova, Italy). Femoral percutaneous approach was used in 60 pts (83%), femoral surgical cut-down in 5 (7%), subclavian surgical cut-down in 4 (5%) and surgical direct aortic approach in 3 (4%). Self-expandable prostheses (Corevalve Medtronic Ltd) were used in all patients. 40 pts underwent TAVI procedure without BAV. With the exception of patients with severe left ventricular dysfunction in which no BAV technique was routinely used, the choice of the procedure technique (pre-dilation of the valve or not) was left at operator discretion. Demographics and procedural data of the whole cohort as well as the two subgroups are listed in Table 1 and expressed as mean and standard deviation. Procedural and in-hospital results are summarized in Table 2.

Table 1. Demographics and procedural data.

	Overall (n=72)	BAV (n=32)	No BAV (n=40)	p
Age (years)	84±5	83.5±5	84.6±5	0.4
Female gender	32 (44%)	15 (47%)	17 (42.5%)	0.8
Log. EuroSCORE	22.9±10	20.8±10	24.2±10	0.07
EF (%)	50±11	55±6	43±11	0.05
Mean grad. (mmHg)	47±10	52±9	44±11	0.09
AVA (cm^2)	0.7±0.12	0.7±0.15	0.7±0.1	1
Echo calcium score (3-4)	65 (90%)	29 (92%)	36 (90%)	1

Table 2. Results.

	Overall (n=72)	BAV (n=32)	No BAV (n=40)	p
Procedural success	72 (100%)	2 (100%)	40 (100%)	1
In-hospital death	3 (4.2%)	2 (6.2%)	1 (2.5%)	0.6
TIA/stroke	2 (2.8%)	1 (3.1%)	1 (2.5%)	1
Definitive PM	11/63 (17.5%)	5/28 (18%)	6/35 (17%)	1
LV perforation	1 (1.5%)	1 (3.1%)	0	1
Vasc. complications	7 (10%)	3 (9%)	4 (10%)	1
Post-dilation	14 (19%)	6 (16%)	8 (22%)	1
Post-TAVI AR >2	3 (4.3%)	2 (6.2%)	1 (2.5%)	0.6

Conclusions. In this non-randomized single centre experience TAVI without pre-dilation is feasible and safe compared with the standard implantation technique. Larger series are needed to evaluate the efficacy of this simplified technique and to determine which patients are more likely to benefit from this approach.

C101

IMPACT OF MITRAL REGURGITATION ON SURVIVAL AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION

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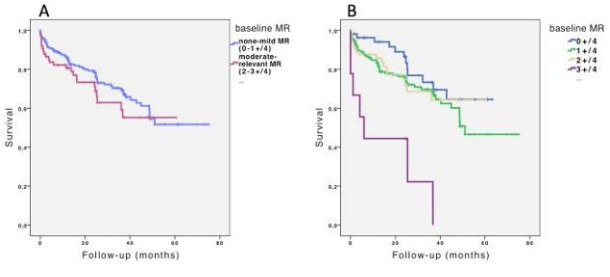
Background. Transcatheter aortic valve implantation (TAVI) has recently been consolidated as an alternative for patients at high or prohibitive surgical risk. However, concomitant significant mitral regurgitation (MR) in this setting is frequent. Some studies have identified the presence of concomitant moderate-to-severe MR as a predictor of early and late mortality after TAVI, nevertheless impact of MR on late survival remains challenging. The aim of our study was to evaluate the presence of MR as a prognostic marker after TAVI.

Methods. Monocentric study enrolling 333 consecutive patients treated by TAVI between June 2007 and December 2013. Baseline echocardiographic severity of MR was classified in 4 grades (0 none or trivial, 1 mild, 2 moderate, 3 relevant, 4 severe). Kaplan-Meier survival analysis evaluated impact of MR on survival after TAVI. Mean follow-up duration was of 23±18 months.

Results. Study population presented mean age of 80±6, 176 patients were females (53%), mean logistic EuroSCORE was of 20.4±12.2. Eighty-eight patients were treated by CoreValve (26%), 245 patients (74%) were treated by Edwards TAVI. Among study population, baseline MR was defined absent or trivial in 61 patients (18%), mild in 192 patients (58%), moderate in 70 patients (21%), relevant in 10 patients (3%). None patient presented severe MR. Baseline moderate or relevant MR (2-3+/4) was a predictor of 30-day mortality (p=0.048, OR 2.88, 95%CI 1.01-8.23). TAVI patients with moderate or relevant MR (2-3+/4) had similar late mortality compared to patients with mild or less MR (0-1+/4) (Log Rank p=0.27; Figure A). However, specific degrees of baseline MR severity presented different survival curves (Log Rank



p=0.015; Figure B). In fact, relevant MR (3+/4) was associated to increase in overall mortality at long-term follow-up (p<0.001, OR 4.75, 95%CI 2.18-10.36).
Conclusions. Baseline moderate or relevant MR was associated to an increase in early mortality; late mortality after TAVI was related to relevant MR.

PCI pharmacology: oral treatment

C102

MALE VS FEMALE COMPARISON OF HIGH ROSUVASTATIN AND ATORVASTATIN PRETREATMENT IN PATIENTS UNDERGOING ELECTIVE PCI TO REDUCE THE INCIDENCE OF MYOCARDIAL PERIPROCEDURAL NECROSIS. THE ROMA GENDER DIFFERENCES TRIAL

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Background. In ROMA and ROMA II trials we showed that the administration of high loading dose of rosuvastatin/atorvastatin within 24 hr before non urgent percutaneous coronary intervention (PCI) seems to decrease the incidence of periprocedural myocardial necrosis (pMN) and that the reloading of statin, in stable patients on chronic statin treatment, improves procedural and long term clinical outcomes compared to the standard treatment.
Objectives. The aim of this study is to assess the sex differences between male and female in terms of efficacy of high-dose statin (rosuvastatin/atorvastatin) to reduce the pMN and major adverse cardiovascular and cerebrovascular events (MACCE) in patients undergoing elective PCI.
Methods. The associations between sex subgroup and the primary and secondary endpoints as well as interaction of sex subgroup with treatment effects were analyzed. In brief, patients who underwent elective PCI were randomly assigned to receive a pre-procedural loading dose of rosuvastatin (40 mg) or atorvastatin (80 mg) and a control group. The primary end-point was pMN and the occurrence of MACCE at long term follow-up.
Results. Twelve and 24-hour post-PCI troponin T (TnT) elevation N5× frequency, did not show significant differences between men and women treated with a reloading dose of atorvastatin/rosuvastatin 24h before PCI (respectively, at 12-h: 11.3% vs 8.3% 1; p=0.22 and at 24-h: 16.7% vs 17.9%; p=0.97) and between Men and Women untreated (respectively, at 12-h: 33.3% vs 36.3%; p = 0.66 and at 24-h 50% vs 52.6%; p = 0.65), confirming, however, the higher incidence observed in untreated groups, as already published in Roma II trial. At 12-month follow-up the incidence of cumulative MACCE did not show significant differences between men and women treated with reloading dose of atorvastatin/rosuvastatin 24 h before PCI (respectively, 5% vs 4%, p=0.62, Log-rank test), and between men and women untreated (respectively, 44% vs 43.7%, p=0.47, Log-rank test).
Conclusions. Female sex is not an independent risk factor for periprocedural myocardial necrosis and adverse clinical outcomes at long term follow-up in patients underwent elective PCI. As well rosuvastatin as atorvastatin showed similar beneficial effects in both sexes on procedural and long-term outcomes.

C103

TIME-RELATED EFFECT OF P2Y12 INHIBITORS PRE-TREATMENT IN PATIENTS WITH ACUTE ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION UNDERGOING PRIMARY PERCUTANEOUS CORONARY INTERVENTION

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The goal of ST-segment elevation myocardial infarction (STEMI) treatment is early reperfusion. Clopidogrel and new P2Y12 inhibitors, ticagrelor and prasugrel, demonstrated to improve angiographic results of primary PCI (pPCI) and 30-days MACE. Conversely antiplatelet inhibition increases bleeding; immediate CABG amounts for 3-4% of STEMI population with a not negligible major bleeding rate of 19%. Cause P2Y12 inhibitors has a delayed effect due to intestinal absorption, our observational study was aimed to define the ideal time course for P2Y12 inhibitors administration to get the best efficacy/safety balance.
A total of 42 consecutive patients with STEMI (81% males, 65±11.3 years, CRUSADE score 25.9±15.6, diabetes 45.2%) addressed to pPCI were enrolled. We divided our population into two groups: the "pre-treatment" group (n=17) included patients receiving a loading dose of P2Y12 inhibitor at least 30 min before pPCI while the "peri-interventional" group (n=25) received a loading dose of P2Y12 inhibitor after coronary angiography. Angiographic, clinical and biochemical parameters were evaluated.
The pre-treatment group showed a significantly higher post-pPCI TIMI-flow grade (r=0.33; p=0.003). Including in a multivariate analysis several treatment options, P2Y12 loading dose pre-treatment at least 30 minutes before remained the only independent predictor of post-pPCI TIMI-flow grade. Pre-treatment with P2Y12 inhibitors at any time before pPCI did not show a significant correlation with pPCI success. Bleeding did not differ between the groups.
Though current guidelines recommend rapid initiation of antiplatelet therapy, our findings suggest 30 minutes before the procedure as the minimum time window for thienopyridines administration to improve pPCI performance. Further studies are needed to define the best time point (related to the angiography time) for thienopyridines administration and to clarify if it can be tailored on patient features such as bleeding risk or predictable CABG indication.

C104

CORRELATION BETWEEN HIGH ON-TREATMENT PLATELET REACTIVITY AND PERIPROCEDURAL MYOCARDIAL INFARCTION: JUST A MATTER OF DEFINITIONS?

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Background. Previous studies have established the role of high platelet reactivity (HPR) as a predictor of peri-procedural myocardial infarction (PMI) after percutaneous coronary intervention (PCI). We aimed to verify the correlation between HPR and PMI in the light of the several available definitions.
Methods. We enrolled 502 consecutive patients undergoing PCI on aspirin and clopidogrel. Pre-PCI platelet reactivity was measured using the VerifyNow P2Y12 assay (results expressed in P2Y12 reaction units, PRU). Primary endpoint was the incidence of PMI according to the presence of HPR. PMI was defined according to the 2007 and 2012 universal definitions of myocardial infarction (UDMI), and the 2013 Society for Cardiovascular Angiography and Interventions (SCAI) definition. HPR was defined as PRU >208, PRU >235 and PRU ≥240.
Results. The incidence of PMI was 41.0% (206 patients) according to the 2007 UDMI, 6.6% (33 patients) according to the 2013 UDMI and 2.6% (13 patients) according to the 2013 SCAI definition. The incidence of HPR was in 53.4% (268 patients) according to the PRU >208 criterion, 38.6% (194 patients) according to the PRU >235 criterion, and 37.1% (186 patients) according to the PRU≥240 criterion. The incidence of PMI was consistently higher in patients with HPR according to all definitions (Table).
Conclusion. In patients on aspirin and clopidogrel undergoing PCI, HPR is consistently associated with the occurrence of PMI, independently of the criteria used for the definition of these two variables.

PMI	PRU >208 (n=268)	PRU ≤208 (n=234)	p	PRU >235 (n=194)	PRU ≤235 (n=308)	p	PRU ≥240 (n=186)	PRU <240 (n=316)	p
2007 UDMI	122 (45.5%)	84 (35.8%)	0.029	91 (46.9%)	115 (37.3%)	0.034	88 (47.3%)	118 (37.3%)	0.028
2012 UDMI	27 (10.1%)	6 (2.6%)	0.001	21 (10.8%)	12 (3.9%)	0.002	21 (11.3%)	12 (3.8%)	0.001
2013 SCAI	10 (3.7%)	3 (1.3%)	0.098	9 (4.6%)	4 (1.3%)	0.039	9 (4.8%)	4 (1.3%)	0.020

C105

SHORT-TERM VERSUS STANDARD 12-MONTH DUAL ANTIPLATELET THERAPY DURATION AFTER DRUG-ELUTING STENT IMPLANTATION

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Background. Current guidelines recommend up to 12 months dual antiplatelet therapy (DAPT) after percutaneous coronary interventions (PCI) with drug-eluting stents (DES) implantation. However, optimal DAPT duration is still a matter of debate. We aimed to evaluate clinical outcomes with short-term (≤6 months) DAPT as compared to standard guideline-recommended 12-month DAPT in patients treated with DES.
Methods. In May 2014, we searched PubMed, Embase, and Cochrane Clinical Trials for randomized trials directly comparing short-term (≤6 months) versus 12-month DAPT after PCI with DES implantation. Risk ratios (RR) were used as the metric of choice for treatment effects by using random- and fixed-effects models. I-squared index was used to assess heterogeneity across trials. The primary safety and efficacy outcomes were any bleeding and the composite of cardiac death and myocardial infarction, respectively. The secondary efficacy outcome was definite or probable stent thrombosis.
Results. We identified 3 trials: EXCELLENT (6-month vs 12-month DAPT, n=1443), RESET (3-month vs 12-month DAPT, n=2117), and OPTIMIZE (3-month vs 12-month DAPT, n=3119) – including a total of 6,679 patients with 12-month follow-up. At 12 months, short-term DAPT was associated with a reduced risk of any bleeding as compared to 12-month DAPT (RR 0.67, 95% CI 0.46-0.99). Risks of cardiac death or myocardial infarction (RR 1.09, 95% CI 0.82-1.46) and stent thrombosis (RR 1.31, 95% CI 0.68-2.50) did not differ between short-term DAPT compared with 12-month DAPT. Noteworthy, landmark analyses at the time of DAPT interruption showed that risks of

cardiac death or myocardial infarction (RR 0.97, 95% CI 0.60-1.56) as well as stent thrombosis (RR 1.20, 95% CI 0.37-3.92) did not differ between the two groups after DAPT interruption up to 12-month follow-up. No evidence of heterogeneity was observed across trials.
Conclusions. This meta-analysis indicates that short-term DAPT is associated with a reduced risk of bleeding but preserved antithrombotic efficacy compared with standard guideline-recommended 12-month DAPT after DES implantation.

C106

COMPLIANCE TO BID TICAGRELOR VERSUS SINGLE DOSE PRASUGREL IN PATIENTS DISCHARGED WITH AN INDICATION TO DAPT FOR CORONARY ARTERY DISEASE: A PROPENSITY MATCHED STUDY

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Background. Head-to-head comparisons for newer P2Y12 inhibitors (prasugrel and ticagrelor) are not currently available. In patients requiring dual antiplatelet therapy (DAPT) due to coronary artery disease, the bid administration required for ticagrelor is a concern for many clinicians – as compared with single administration of prasugrel – in light of possible complications related to premature withdrawal of the drug.
Aim. To assess differences in compliance to ticagrelor and prasugrel, and implications of this on outcomes, in real-life patients discharged with an indication to DAPT for coronary artery disease.
Methods. All patients discharged at our Institution in the period from December 2012 to April 2014 with an indication to ticagrelor were included in this study and compared with a matched control group of patients discharged with indication to prasugrel in the same period. After 1:1 matching for 4 main clinical variables (age, gender, clinical presentation [UA/NSTEMI, STEMI, stable coronary artery disease], type of revascularization [PCI vs surgical vs medical treatment]), the two populations were retrospectively analyzed and compared in terms of compliance (evaluated in terms of mean number of pills avoided per week of treatment) and adverse events.
Results. 176 patients were included in the study (88 per group). Mean age was 63.98±9.49 years in the prasugrel group and 66.88±11.64 years in the ticagrelor group, males were 73.8% and 72.7% respectively, UA/NSTEMI were 71.5% and 68.1% and STEMI were 17.0% and 11.3% respectively. At discharge, the indication was to 12-months DAPT in 97.7% and 93.1% of patients respectively, and less than 12 months in the remaining patients. After a median follow up of 237 days (range 27-365), patients who referred complete adherence to therapy (less than 1 pill avoided per week) were 95.4% and 88.6% (p=0.030) in the prasugrel and ticagrelor group respectively. 3.4% and 5.6% patients (p=ns) reported approximately 1 pill avoided per week in the prasugrel and ticagrelor group respectively. No patients in the prasugrel group referred 2 or more pills avoided per week, while in the ticagrelor group 3 patients (3.4%) reported approximately 2 pills avoided per week and 2 patients (2.2%) reported severely reduced compliance (approximately 8 pills avoided per week) due to dyspnoea (p=0.001). Four patients (4.5%) withdrew completely the P2Y12 inhibitor in the prasugrel group due to bleeding (3 patients) or to the need for starting warfarin therapy (1 patient). In the ticagrelor group, two patients withdrew the drug due to dyspnoea (p=NS). At follow up 3 MACEs occurred in the prasugrel group (1 CV-death, 2 TVR) and 2 MACEs in the ticagrelor group (1 CV death, 1 TVR) (p=NS). One TIMI major bleeding occurred in the prasugrel group and none in the ticagrelor group (p=NS). 3 TIMI minor bleedings in each group were observed (p=NS).
Conclusion. Compliance to P2Y12 therapy was high in both groups, but significantly lower in of patients who were administered ticagrelor compared to those taking prasugrel. Notably, this difference in compliance did not translate in differences of outcomes at follow-up.

C107

ALTERNATIVE STRATEGIES TO ASPIRIN AND CLOPIDOGREL FOR PATIENTS PRESENTING WITH ACUTE CORONARY SYNDROME: A NETWORK META-ANALYSIS

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Introduction. Alternative strategies to aspirin and clopidogrel for patients presenting with acute coronary syndrome (ACS) have been recently evaluated, with studies investigating both new antiplatelet drugs and new oral anticoagulation therapy.
Methods. Suitable randomized trials focusing on different choices of antiplatelet and anticoagulant therapy were systematically searched and abstracted. The risks of MACE (a composite end point of death, myocardial infarction and repeated revascularization), death and major bleeding were appraised within a hierarchical Bayesian model computing absolute rates (AR) and odds ratios (OR), with 95% confidence intervals.
Results. 10 studies with 53513 patients were included. Ticagrelor, prasugrel and rivaroxaban significantly reduced risk of MACE (HR 0.8 0.01-0.85; HR 0.9 0.03-0.95 and HR 0.8 0.02-0.9) when compared with aspirin and clopidogrel, while ticagrelor and rivaroxaban reduced risk of death (HR 0.8 0.7-0.9; HR 0.8 0.7-0.9). Ticagrelor had a reduced rate of major bleeding when compared to prasugrel (HR 0.8 0.6-0.9) and to rivaroxaban (HR 0.4 0.1-0.5; all CI 95%).
Conclusions. Ticagrelor and rivaroxaban reduced mortality when compared to aspirin and clopidogrel, while ticagrelor decreased the risk of bleeding when compared to prasugrel and rivaroxaban.

Bifurcation and CTO interventions

C108

PERCUTANEOUS CORONARY INTERVENTION VERSUS MEDICAL THERAPY FOR CORONARY CHRONIC TOTAL OCCLUSION: RESULTS FROM THE ITALIAN REGISTRY OF CHRONIC TOTAL OCCLUSION (IRCTO)

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Background. Chronic total occlusion (CTO) represents one of the most challenging lesion subset in interventional cardiology. The Italian Registry of Chronic Total Occlusion (IRCTO) aims to provide current data on CTO prevalence, and on clinical and angiographic characteristics and management of CTO patients. Moreover, it reports the effect of CTO treatment strategy on long-term prognosis.
Methods. The IRCTO is a prospective real world multicentre registry, which enrolled patients showing at least 1 CTO at coronary angiography in thirteen high volume catheterization labs across Italy. Clinical and angiographic data of all CTO patients, regardless of chosen treatment strategy (medical therapy [MT], percutaneous coronary intervention [PCI], or coronary artery bypass grafting [CABG]), were collected into a web database. In order to compare outcomes of patients undergoing different treatment strategies, while minimizing the impact of treatment selection bias and potential confounding, a rigorous adjustment by propensity score matching (PSM) was performed.
Results. A total of 1777 patients were enrolled, among these 826 (46.5%) patients were managed by MT, 776 (43.7%) by PCI and the last 175 (9.8%) were referred to CABG. At one year, patients undergoing successful PCI showed lower rate of MACCE and cardiovascular death in comparison with patients treated with MT and CABG (2.6% vs 8.2% and vs 6.9%, p<0.001 and p<0.01, and 1.4% vs 4.7% and vs 6.3%, p<0.001 and p<0.001 respectively). After PSM analysis patients treated with PCI showed lower incidence of death, acute myocardial infarction and re-hospitalization rate in comparison with MT (4.4% vs 1.5% p<0.001, 2.9% vs 1.1% p=0.03 and 4.4% vs 2.3% p=0.04, respectively).
Conclusions. The present study provides current data on prevalence, characteristics and management of CTO patients. More importantly, our data showed as percutaneous revascularization of a CTO leads to a significantly improved survival rate and a reduction in MACCE at 1-year follow-up in comparison with MT and/or CABG management.

C109

RETROGRADE RECANALIZATION OF CHRONIC TOTAL OCCLUSIONS IN EUROPE: PROCEDURAL AND IN-HOSPITAL OUTCOMES FROM THE MULTICENTER ERCTO REGISTRY

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Background. The aim of this study was to describe the five-year European experience of retrograde percutaneous coronary interventions (PCI) revascularization for complex chronic total occlusions (CTOs) of coronary arteries.
Methods. Demographic data, procedural outcomes and in-hospital clinical events were collected on 1582 consecutive lesions of 1395 patients enrolled between January 2008 and December 2012 having retrograde CTO PCI at 44 European medical centers by 45 experienced interventionalist operators. A J-CTO score was used to better describe success according to lesion difficulty. Data about clinical follow-up were collected.
Results. Patients mean age was 62.0±10.4 years. During the procedure the retrograde approach was used as first line strategy in 76.2% of cases, while immediately after antegrade failed approach in 23.8% of cases. Procedural

success was achieved in 75.3% of cases. A major complication occurred in 16 patients (1.0%). In multivariable analysis, age of the patient (per 10-year increase) (OR: 1.19, 95%CI: 1.03-1.34; p=0.02), lower operator volume (OR: 3.00, 95%CI: 2.41-4.21; p< 0.001) and increased retrograde J-CTO score (OR: 0.42, 95%CI: 0.24-0.74; p<0.001) were recognized as independent predictors of procedural failure. The mean follow-up period was 24.7±15.0 months. Major adverse cardiac and cerebral events (MACCE) occurred in 13.6% of cases (cardiac death 1.9%, myocardial infarction 3.2%, stroke 0.6% and target vessel revascularization 13%). By multivariate Cox regression, the independent predictors of MACCE were: male gender (HR: 0.47, 95%CI: 0.30-0.74; p=0.01); prior myocardial infarction (HR: 1.45, 95%CI: 1.01-2.09; p=0.04); number of previous attempts (HR: 1.63, 95%CI: 1.36-1.95; p<0.001); CTO length (HR: 1.01, 95%CI: 1.00-1.02; p=0.004); and total stent length (HR: 0.98, 95%CI: 0.97-0.98; p<0.001).

Conclusions. In Europe among selected centers dedicated to CTO revascularization, retrograde approach was performed over a 5-year period in 16.5% of these patients. The number of retrograde procedures was exponentially increasing during the last 2 years and was associated with high success, low major complications rates and good outcome.

C110

PERCUTANEOUS TREATMENT OF CORONARY BIFURCATION: A NETWORK META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS

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Introduction. The optimal percutaneous management of patients presenting with coronary bifurcation lesions remains to be defined.

Methods. Randomized controlled trials comparing different treatments for bifurcation lesions were included. Major Adverse Cardiovascular Events (MACE, a composite end point of death, myocardial infarction, target lesion revascularization [TLR]) was the primary end point, while each single event of the MACE composite endpoint was evaluated separately as well as Stent Thrombosis (ST). Main analysis included studies evaluating different kinds of treatment (provisional, T stenting, crush, culotte and double kissing double crush [DK crush]) along with type of implanted stents (BMS, sirolimus and paclitaxel stents defined as first generation DES and everolimus eluting stent [EES]) with or without final kissing balloon (FKB).

Results. Provisional strategy was evaluated in eleven studies with first generation DES and FKB (1819 patients) and without FKB in one RCT with 239, in two studies with BMS and FKB (67 patients), in one RCT with BMS and drug eluting balloon (40 patients) and in three studies with EES (408 patients). Crush stenting with first generation DES and FKB was appraised in three studies with 601 patients, T stenting with first generation DES and FKB in one RCT (101 patients), DK crush with first generation DES in 101 patients in one study and with EES in 2 studies with 395 patients and culotte into two studies (215 patients with first generation DES and 209 with EES). Provisional with EES did not result inferior to DK crush with EES (OR 0.58:0.29-1.1), to culotte with EES (OR 1.8: 0.7-4.1) and to crush and T stenting with first generation DES (OR 1.1: 0.4-1.9 and OR 1.2: 0.03-5 respectively). DK crush presented the highest probability of performing bests. About target lesion revascularization, provisional strategy was not inferior to two stent techniques, apart from DK crush which resulted superior (OR 0.42: 0.21-0.87), with the highest probability of performing bests. About stent thrombosis, no strategies performed superior to the others, with provisional with EES with the highest probability of performing bests.

Conclusion. Provisional strategy did not perform inferior to two stent techniques, apart from DK crush which resulted more efficacious for target lesion revascularization. Provisional strategy performed best for reducing ST.

C111

PERCUTANEOUS CORONARY INTERVENTION FOR CORONARY BIFURCATION LESIONS. FOLLOW-UP RESULTS OF 63 PATIENTS TREATED WITH TRYTON SIDE BRANCH STENT

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Background. Bifurcation lesions (BL) account for 15 to 20% of percutaneous coronary interventions (PCIs). BL PCI is associated with procedural difficulties, periprocedural complications and suboptimal long term results when compared with PCI of a non-BL. Tryton Side Branch (Tryton Medical, Inc., Newton, MA) is one of the dedicated bifurcation stents developed to simplify treatment and improve outcomes.

Objective. To report the procedural results and clinical outcomes of Tryton Side Branch treated BLs in 63 patients.

Methods and results. Sixty-three consecutive patients with true BLs (Medina 1,1,1; 1,0,1; 0,1,1), treated with the dedicated Tryton bifurcation stent, (median follow-up of 15.9±9.6 months), were included in our analysis. All angiographic images and adverse events were evaluated. Technical success was achieved in 60 patients (95%) and procedural success in 59 patients (93.6%). Mean main branch reference diameter was 3.04±0.33 mm, mean side branch reference diameter 2.35±0.25 mm with the final kissing balloon post-dilatation performed in 50 patients (79%). The median procedure time was 82±38 min, median fluoroscopy time 25.1±12.7 min, median X ray dose 550±5775 Gy/cm^2 and median contrast media volume administered 300±123 ml. In-hospital MACE rate was 6.3 %: 2 acute in-stent thrombosis in patients admitted for primary PCI, 1 type 4a myocardial infarction and 1 cardiac death due to progressive heart failure in a patient with severe left ventricular dysfunction. A follow-up longer than 6 months was available in 52 patients (88%). At 6-month follow-up MACE rate was 5% (3 target lesion revascularizations [TLR] in the side branch). Events occurred in patients with a small side branch diameter (2.1 mm mean reference diameter) and a very narrow-angle of bifurcation (<30°). The angiographic review of the cases, raised the suspicion of an inadequate implantation of the Tryton stent, with the distal marker of the transition zone positioned beyond the carina, as a result of a challenging assessment of the precise take off of the side branch.

Conclusion. Our data confirm that true bifurcation stenting with the Tryton dedicated stent is associated with a high technical and procedural success rate. However, a small side branch diameter, and a narrow angle of bifurcation still hamper the long-term success. An accurate selection of the lesions and a rigorous implantation technique, using multiple projections to better assess the side branch origin, may avoid technical failures and future adverse events.

C112

CORONARY RECANALIZATION OF CHRONIC TOTAL OCCLUSIONS: A SYSTEMATIC USE OF ANTEGRADE APPROACH WITH THE STEP-UP TECHNIQUE. A SINGLE CENTER EXPERIENCE

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Background. Chronic total coronary occlusions (CTOs) are a frequent finding in patients with coronary disease and remain one of the most challenging target lesion subset for intervention. Indeed, CTO percutaneous interventions (PCIs) are associated with lower rates of procedural success, higher complication rates, greater radiation exposure, and longer procedure times compared with non-CTO PCI. However, planned, standardized antegrade or retrograde approaches have recently improved outcomes of these procedures.

Aim. To assess in-hospital and long-term outcomes of a consecutive series of planned CTO-PCIs performed with a standardized approach by trained operators.

Methods. Between January and December 2013, 43 consecutive patients with a CTO and demonstration of myocardial viability and/or anginal symptoms, underwent planned PCI with a systematic use of antegrade approach and the step-up technique, always starting with the same soft, 0.09" tip, polymeric guide-wire (ASAHI Fielder XTA).

Results. Mean age was 62.6±9.36 years; 95% were males, 83% had hypertension, 23.2% diabetes and 57% dyslipidemia. Femoral and radial approaches were utilized in 32 (74%) and 11 (26%) of patients, respectively. Contralateral coronary angiography (from radial artery in 40 patients) was used in 21% of patients and a step-up wiring with an over-the-wire balloon or a micro-catheter in all patients. Procedural success was obtained in 36 patients (84%); specifically, in 29 (80%) with a single wire (Fielder XTA), in 7 (20%) with additional wires (ASHAI Miracle 3 and 6, Medtronic Provia 6). In the remaining 7 (16%) patients, the procedure was unsuccessful, despite the use of multiple wires (in all), a retrograde approach (in one) and an antegrade dissection/reentry system (Cross-boss, Boston Scientific) (in one), without any clinical event. The mean procedure time and fluoroscopy time were 66±55 min, 25±23 min, respectively. Mean quantity of contrast medium was 268±99 ml; radiation exposure (air kerma) was 4.6±2.1 Gray. In-hospital outcome was free of major events in all patients (moderate and transient rise of creatinine levels was detected in 4 patients). Follow-up was completed in all patients undergoing successful procedure. Among these patients, at a mean follow-up time of 8.3±5.4 months, only one patient (3%) had recurrent angina and underwent PCI of the target vessel.

Conclusions. Planned and standardized approach of CTO-PCI is associated with a good in-hospital and 1-year outcomes.

C113

COMPARISON OF A STRATEGY USING A DEDICATED SELF-EXPANDING BIOLIMUS A9-ELUTING STENT VERSUS STANDARD BIFURCATION STRATEGIES WITH A DRUG-ELUTING STENT (DES): AN OBSERVATIONAL RETROSPECTIVE STUDY

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Background. Percutaneous revascularization of bifurcation lesions continues to be a challenge. With the advent of dedicated bifurcation stents, it is necessary to compare them with the standard bifurcation techniques.

Aim. To compare a strategy using a dedicated self-expanding Biolimus A9-eluting stent (AXXESS stent) versus standard bifurcation strategies using a DES.
Methods. 166 patients undergoing PCI with bifurcation lesions from May 2010 to May 2014 were included in our analysis. 64 patients were enrolled in the AXXESS Group (AG) and 102 patients in the Standard Bifurcation Strategies Group (SG). Inclusion criteria: angiographic bifurcation lesion treated with Axxess stent or other bifurcation strategies. Exclusion criteria: thrombotic lesions and EF<30%. Primary end point: periprocedural outcomes, incidence of MACCE (cardiac-death, TVR, Stent Thrombosis, Stroke, MI) and bleeding events at 1, 6, 12 and 24 months.
Results. At baseline, no significant differences in terms of clinical and angiographic characteristics were observed except for STEMI pts (15.63% in AG vs 31.37% in SG, p=0.03) and for left main rate (0 in AG vs 9.18% in RG, p=0.01). Bifurcation technique used: Provisional (42.16%), Crush (29.41%), Culotte (9.8%), Stopper (5.8%) and other (12.83%). In the periprocedural outcomes we found statistical significance for residual stenosis (0 in AG vs 7.84% in SG, p=0.024) and not for other outcomes (acute stent thrombosis, dissection, coronary occlusion, coronary perforation). At 30 days no significant differences was observed in the two groups. At 6 moths, FU was performed in 44 pts in AG and 83 in SG. The overall incidence of MACCE was 6.82 in AG and 6.02% in SG (p=NS); MI rate was 4.55% in AG and 2.41% in SG (p=0.61); TVR was 2.27% in AG and 3.61% in SG (p=NS). Stroke rate was 2.27% in AG vs 0 in SG (p=0.35). Minimal bleeding was 4.55% in AG and 6.02% in SG (p=NS). No cardiac death occurred in the two groups. At 12 months, FU was performed in 33 pts in AG and 72 in SG. The overall incidence of MACCE was 24.24% in AG and 18.06 in SG (p=0.59); MI occurred in 6.06% in AG and 4.17% in SG (p=0.65); TVR rate was 12.12% in AG and 13.89% in SG (p=NS) while stroke occurred in 6.06% in AG and 0 in SG (p=0.1). Minimal bleeding was 12.12% in AG and 11.1 in SG (p=NS) while minor bleeding was 6.06% in AG and 0 in SG (p=0.1). No cardiac death occurred in the two groups. At 24 months, FU was performed in 15 pts in AG and 54 in SG. Statistical significance was found only in stroke rate (13.33% in AG vs 0 in SG, p=0.045). The overall incidence of MACCE was 26.66% in AG and 14.81% in SG (p=0.28); MI rate was 6.67% in AG and 3.7% in SG (p=0.53); TVR was 6.67% in AG and 11.1% in SG (p=NS). Minimal bleeding was 6.67% in AG and 9.26% in SG (p=NS). No cardiac death occurred in the two groups.
Conclusion. Our data show that AXXESS stent is safe and efficacy in the treatment of bifurcations and it is a valid alternative to standard bifurcation strategies. It showed better performance in periprocedural outcomes and no significant differences were observed during the follow up at 1, 6, 12 and 24 months. Further studies are required to confirm our findings.

C114

INCIDENCE, TREATMENT AND IN-HOSPITAL CLINICAL OUTCOME OF BIFURCATION LESIONS IN PATIENTS UNDERGOING PERCUTANEOUS CORONARY CHRONIC TOTAL OCCLUSION CORONARY INTERVENTIONS

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Background. Bifurcations lesions (BFLs) represent a distinct lesion subset associated with an increased risk of procedure related complications. Data about incidence, treatment and clinical outcome of BFLs associated with chronic total occlusions (CTO) are limited.
Methods. This study is a retrospective analysis of CTO PCI cases performed by a single CTO experienced operator. Patients with a BFL, within CTO vessel and a side branch with a reference diameter greater ≥ 2 mm were enrolled.
Results. A total of 905 patients (mean age 61.1±9.5 years, males 89.4%) were treated for 922 CTO lesions. Among them, 244 BFLs within the CTO vessels were observed (26.5%). Patients with and without BFLs had similar baseline clinical characteristics except for gender. Furthermore, BFLs were more often observed in left anterior descending CTO (48.4%) while right coronary artery was the most commonly involved vessel in non BFLs group (56.6%) (p<0.001). An angiographic success was achieved in 91.1% of cases with higher rate in non BFLs (92.5% vs 87.3%; p=0.04). Procedural time was significantly longer in BFLs than in non BFLs (139±67 min vs 124±68 min, respectively; p=0.003) with a greater use of contrast load (470±193 vs 436±227 ml, respectively; p=0.04) and higher number of stents (3.1±1.5 vs 2.9±1.4, respectively; p=0.035). Coronary perforation were more often observed in BFLs (4.9% vs 1.7%; p<0.001) resulting in more tamponades (2.4% vs 0.2%; p<0.001). True BFLs were encountered in the majority of cases (86.8%) and required more 2-stent technique than false BFLs (50% vs 18.8%; p=0.001).
Conclusion. The incidence of BFLs in CTO lesions is higher than generally reported in continuous coronary artery disease patients. The presence of BFLs in a CTO vessel remains a challenging situation for interventional cardiologists that increases the complexity of CTO procedure and may lead to less angiographic success and more peri-procedural complications.

Structural heart interventions

C115

COMBINED PERCUTANEOUS CLOSURE OF PARAVALVULAR LEAKS AND INTRAPROSTHETIC REGURGITATION AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION

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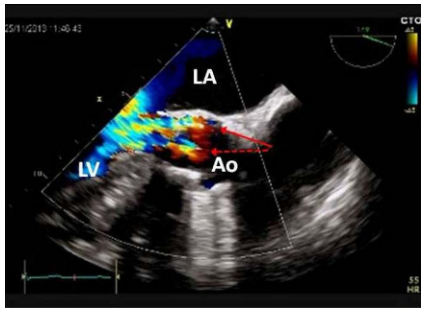
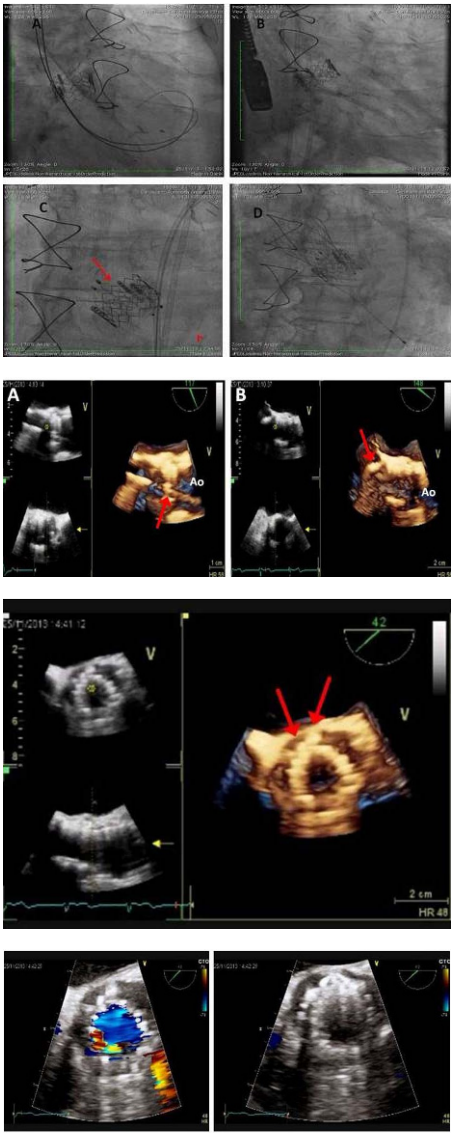
Introduction. It is well known that the occurrence of moderate to severe PVL negatively impacts prognosis after TAVI, with a two- to four-fold increase in mortality risk at one year compared to patients without significant PVL (1). In the reported case, severe aortic root calcification was assumed to be the cause of PVL after implantation of the Edwards Sapien XT prosthesis. Although several methods to establish objective parameters of PVL severity have been attempted, echocardiographic quantification remains challenging.
Description. A 71-year-old man was referred to our institution for increasing effort dyspnea. His past medical history consisted of systemic hypertension, type 2 diabetes mellitus, dyslipidemia, chronic obstructive pulmonary disease, and smoking. In 1996, he underwent bypass surgery for unstable angina secondary to multivessel coronary artery disease. Afterwards, in 2009, he developed severe aortic stenosis (mean gradient 46 mmHg, aortic valve area 0.7 cm^2). Owing to the coexistence of left ventricular systolic dysfunction, several comorbidities and history of prior bypass surgery, he was considered at high surgical risk and was treated by transcatheter aortic valve implantation (TAVI) using a 23-mm Edwards Sapien XT bioprosthesis (Edwards Lifesciences, Irvine, CA). The patient was admitted in NYHA class III, with blood pressure of 150/80 mmHg and heart rate of 75 bpm. The electrocardiogram showed atrial fibrillation and left bundle branch block. Transthoracic echocardiography (TTE) displayed left ventricular enlargement with preserved ejection fraction. Aortic regurgitation (AR) with multiple jets despite normal transprosthetic gradients and elevated pulmonary artery systolic pressure were detected. A transesophageal echocardiographic (TEE) examination was performed to identify the origin and severity of regurgitant jets. Color flow mapping of the aortic valve in the midesophageal long-axis view (159°) demonstrated posterior paravalvular leak (PVL) with holodiastolic flow reversal and central intraprosthetic regurgitation (Fig. 1). The circumferential extent of PVL (used as a semiquantitative measure of regurgitation severity) was approximately 20% of the entire valve. According to the Valve Academic Research Consortium (VARC) criteria, PVL was considered as at least moderate in severity (1). However, the sum of the two regurgitant jets resulted in severe regurgitant volume, as confirmed by the detection of diastolic flow reversal in the descending aorta (an index of AR severity) on pulsed-wave Doppler recording. The case was discussed by a multidisciplinary heart team. Based on the clinical and echocardiographic findings, TEE-guided closure of both PVL and intraprosthetic regurgitation under general anesthesia was planned. The left posterior leak was visualized in the left anterior oblique projection. Severe AR was confirmed by aortography. The left coronary margin of the Edwards Sapien XT prosthesis was retrogradely approached via common femoral artery using a 6F right coronary bypass diagnostic catheter (Cordis Corp., Miami, FL). A 260 cm 0.035" Terumo wire (Terumo Corp., Somerset, NJ) was advanced through the prosthetic valve struts and the native valve leaflets above the annular level, and the paraprosthetic leak was easily crossed. The Terumo wire was then removed and replaced with two Amplatzer superstiff 260 cm guidewires (Boston Scientific, Natick, MA) advanced into the left ventricle. A 10 x 5 mm Amplatzer Vascular Plug III device and a 8 x 7 mm Amplatzer Vascular Plug II device (St. Jude Medical, St. Paul, MN) were passed through two sheathless AL 7.5F catheters (Ashai, Tokyo, Japan) and were deployed along the length of PVL (Figs. 2, 3). Afterwards, the intraprosthetic leak was successfully treated with "valve-in-valve" implantation of a 26-mm CoreValve (Medtronic, Minneapolis, MN). Good device position as well as absence of regurgitation were confirmed by TEE (Figs. 4, 5). After the procedure, TTE showed the valve-in-valve prosthesis in position with normal excursions, no evidence of periprosthetic leak, and normal transprosthetic gradients (mean gradient 8 mmHg; max gradient 17 mmHg). The postoperative course was uneventful, and the patient was discharged on the fifth postoperative day.





Discussion. PVLs due to prosthesis under-expansion are usually treated successfully with balloon postdilatation. In our case, the coexistence of a significant central jet along with aortic root calcification discouraged this option. We preferred to perform a staged procedure with device closure of the paravalvular defect followed by valve-in-valve implantation for correction of the central AR jet. The Amplatzer Vascular Plugs were first designed for intravascular use, but subsequently they proved suitable for PVL closure after TAVI. To the best of our knowledge, this is the first case reporting the use of two Amplatzer Vascular Plugs for PVL closure, followed by successful valve-in-valve implantation of the CoreValve bioprosthesis.
Conclusion. Although TAVI has been established as a valid option for the treatment of high-risk patients with severe aortic stenosis, post-procedural AR remains a frequent occurrence. A minimally invasive strategy for PVL closure combined with the valve-in-valve technique may be considered a valuable alternative for the treatment of severe AR to avoid conventional surgical aortic valve repair or replacement.

C116

FOLLOW-UP A LUNGO TERMINE DELLA CHIUSURA DI FORAME OVALE PERVIO CON L'UTILIZZO DI DUE DIFFERENTI SISTEMI PERCUTANEI

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Introduzione. Molti studi dimostrano una associazione tra persistenza del forame ovale pervio (PFO) e stroke criptogenetico (SC). In precedenza era già stata evidenziata una relazione tra ricorrenza di eventi tromboembolici, PFO e SC. La chiusura percutanea di PFO, risulta una potenziale strategia terapeutica per la prevenzione secondaria dello stroke da embolia paradossa. Cinque trials osservazionali hanno evidenziato che la chiusura percutanea di PFO, rispetto alla terapia medica convenzionale, riduce il rischio relativo di recidiva di eventi cerebrovascolari dell'80%. È stato dimostrato che la procedura di chiusura percutanea di PFO è sicura e fattibile ed attualmente sono disponibili molteplici differenti dispositivi di chiusura.
Scopo. Realizzare un follow-up a lungo termine dei pazienti sottoposti a chiusura percutanea di PFO mediante due differenti tipi di dispositivo occlusivo, come prevenzione secondaria dopo SC. Il follow-up ha monitorato sopravvivenza, complicanze, ricorrenza di stroke ed altre eventuali patologie concomitanti significative.
Metodi. Tra il 2004 ed il 2012, 101 pazienti consecutivi (35 di sesso maschile e 66 femminile) sono stati sottoposti a chiusura percutanea di PFO. Tutti i pazienti presentavano anamnesi positiva per SC o attacco ischemico transitorio (TIA), associato a positività del quadro RM encefalo. Per le procedure percutanee, sempre guidate da ecocardiografia transesofagea, sono stati utilizzati due tipi di devices, l'Amplatzer® PFO Occluder (St. Jude Medical, St. Paul, MN, USA) oppure il Figulla Flex (Occlutech, Helsingborg, Sweden), posizionati rispettivamente in 52 (51.5%) e 49 (48.5%) dei pazienti trattati. Durante il 2011 ed il 2013, tutti i pazienti sopravvissuti sono stati contattati per il follow-up e sottoposti ad una indagine anamnestica particolarmente incentrata su eventuali recidive di stroke/TIA e potenziali complicanze della procedura percutanea. Tutti i pazienti sono stati sottoposti ad eco-color Doppler transtoracico con soluzione fisiologica agitata (BTTE) per la ricerca di shunt destro-sinistro, sia a riposo che durante manovra di Valsalva.
Risultati. Il follow-up medio dei pazienti è stato di 53 mesi. Un solo paziente (1.0%) ha manifestato un ulteriore nuovo evento cerebrovascolare, che attesta la quota di eventi neurologici attorno al 2.27 per 1000 pazienti/anno. Due pazienti sono deceduti per cause non cardiache. In 8 pazienti su 99 (8.0%), durante il follow-up, è stata documentata positività del BTTE; di questi pazienti, 5 erano stati trattati con Amplatzer (9,8%) e 3 con Figulla Flex (6.3%), (p=0.716). Un paziente ha sviluppato una recidiva clinica di TIA (0.9%) ed in particolare un solo paziente con positività del BTTE ha avuto una recidiva clinica di TIA (12.5%). Non è stata evidenziata alcuna relazione tra le dimensioni del device utilizzato e la presenza di positività di BTTE al follow-up (p=0.062) né maggiore incidenza di positività del BTTE in un device rispetto all'altro (p=0.716). L'esiguità del campione non ci ha permesso di valutare se esista o meno una differenza tra i due sistemi nell'incidenza di TIA al follow-up.
Conclusioni. In questo follow-up sul lungo periodo relativo a 101 pazienti consecutivi, la chiusura percutanea di PFO è associata ad un rischio molto ridotto di recidiva di stroke, ad assenza sia di mortalità legata ad accidenti cerebrovascolari sia di complicanze maggiori a breve e lungo termine relate al dispositivo posizionato. Pertanto la chiusura percutanea di PFO è un'opzione terapeutica sicura e fattibile; nessuna differenza statisticamente significativa è stata evidenziata tra i due sistemi di chiusura in relazione all'incidenza di positività del BTTE nel follow-up a lungo termine.

C117

PERCUTANEOUS LEFT ATRIAL APPENDAGE CLOSURE: SINGLE CENTRE EXPERIENCE

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Purpose. In the last few years, percutaneous left atrial appendage (LAA) closure is emerging as a preventive strategy in embolic risk reduction for atrial fibrillation patients. Aim of this study is to evaluate the safety and short term efficacy of this procedure, as well as to provide new information on antithrombotic protocol adopt after the procedure.
Methods. Between August 2010 and June 2014, consecutive patients that underwent LAA closure procedure in our Institute were enrolled. At the baseline, all the patients were evaluated clinically, as well as with a transthoracic and transesophageal echocardiography. After the procedure outpatient visits and transesophageal examinations were planned (the first of which after 2 months). All patients were dismissed with double anti-platelet therapy (cardioaspirin + clopidogrel); clopidogrel was interrupted if the device was well implanted after the first echocardiographic control. Primary end points were efficacy (occurrence of ischemic stroke or systemic embolism) and safety (procedural complications).
Results. 73 patients were enrolled (65% male; mean age 70.5±8.7 years; mean LVEF 50±8%; mean CHA_2DS_2-VASc and HAS-BLED scores 3±1.6 and 3±1.1, respectively). Indications for LAA closure were separated in two groups: hemorrhagic complications of anticoagulant therapy as gastrointestinal bleedings (50%), previous intracranial hemorrhage (13%), labile INR (9%) and anticoagulation failures, as ischemic stroke (15%) or LAA thrombosis during VKA therapy (13%). Both available devices were used; the median size was 24 mm. The procedure had a small rate of acute complications (1 pericardial effusion requiring pericardiocentesis, 2 vascular access site complications). The total procedural success, defined as the presence of a leak < 3 mm, was achieved in 30 (77%) cases. Until now, no ischemic events were found. 2 major bleedings (both on double antiplatelet therapy) and 2 minor bleedings occurred. Only 1 major cardiovascular event (other than bleedings) happened: a cardiovascular death for infective endocarditis.
Conclusions. LAA closure procedure is becoming an interesting tool for thromboembolic risk reduction in atrial fibrillation patients. In a high volume centre, it appears to be a safe and effective procedure. More data are needed to determine the best antithrombotic protocol.

C118

NEW ONSET ATRIAL FIBRILLATION AFTER PERCUTANEOUS PFO CLOSURE IN A LARGE POPULATION WITH LONG-TERM FOLLOW-UP

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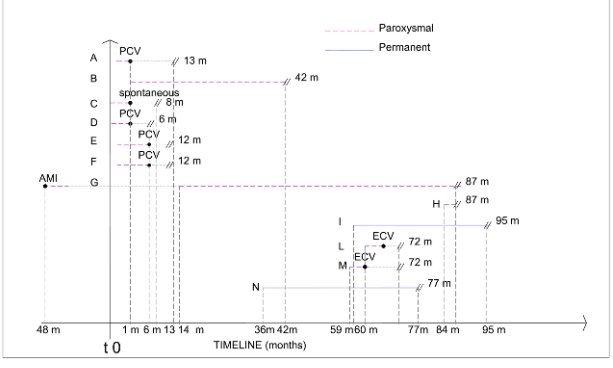
Objectives. To study new onset atrial fibrillation (AF) in a long-term follow-up population underwent percutaneous closure of PFO for secondary prevention of ischemic cerebrovascular events (CVAs).

Background. AF is the most criticized side effect of the interventional treatment versus lifelong medical therapy, in secondary prevention of recurrent CVAs, leading to chronic anticoagulation.

Materials and methods. From January 2000 to December 2013, 457 consecutive patients underwent percutaneous PFO closure were prospectively registered and regularly contacted at 6, 12, 18 24 months and every year after for a clinical instrumental evaluation. We reviewed all cases on new onset of AF.

Results. Of the 457 patients that underwent percutaneous closure of PFO, between January 2000 and December 2013, 12 (2.6%) developed AF, paroxysmal and permanent, during a mean follow-up of 5 years (from 6 months to 14 years). None of these patients had new CVAs. In the analysis of predisposing factors to AF, no correlation was found neither with PFO features (anatomy and embryonic residua) nor with types of closure devices. However, analysing type, onset and remission of AF, two homogeneous groups of patients were identified. First group patients, younger (mean age 38 years old), with none or one cardiovascular risk factors, had early onset of paroxysmal AF (<6 months), with quick remission after pharmacological cardioversion. Patients of the second group, older (mean age 65 years), with multiple risk factors and prior myocardial infarction, had a late onset (mean 53 months later) of persistent or permanent AF. Probably these patients would have developed AF, regardless percutaneous closure of PFO.

Conclusions. AF is not a common side effect of percutaneous closure of PFO. Not all cases of AF at follow-up should be attributed to the procedure. In our study, AF is not associated with new CVAs and procedure-related AF is a benign and transitory arrhythmia responsive to pharmacological cardioversion.



C119

GENDER-RELATED DIFFERENCES IN PATIENTS WITH PFO UNDERGOING PERCUTANEOUS CLOSURE

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Background. Gender-related differences are often observed and debated in several heart diseases. The influence of sex on patients with patent foramen ovale (PFO) undergoing percutaneous closure is poorly studied.

Aim. To evaluate the gender-related differences of patients with PFO undergoing transcatheter closure.

Methods. Between 2001 and 2014, all consecutive patients with PFO undergoing percutaneous closure to our institution were included in a prospective registry and analyzed according to gender. Transcatheter PFO closure was performed with the Amplatzer PFO Occluder or the Amplatzer Cribiform Septal Occluder (St Jude Medical, St Paul, MN). Clinical follow-up was collected at 30-days, 6, 12, 24 months and yearly thereafter.

Results. 140 patients were included in the study (40% men, 60% women). Most of the patients suffered for cryptogenic stroke or TIA. Females had more risk factors for ischemic events (89% vs 77%), more headache/migraine (40% vs 23%), more basal shunt (62% vs 40%), less multiple events (27% vs 46%) than males. PFO closure was successful in more than 98% of the cases and intraprocedural complications consisted in 1 major embolism, 1 transient ST elevation, 1 pericardial effusion needing pericardiocentesis and 2 new onset atrial fibrillations, without significant gender differences. No major in-hospital complications occurred with a mean length of stay of 4 days. At scheduled follow-up, outcome was favorable (overall major adverse events <7%) and did not differ between genders in terms of stroke, TIA and new atrial arrhythmias. Headache/migraine seemed to be more improved in women than in men.

Conclusions. In our prospective registry of patients undergoing PFO closure, females were more represented than men and few baseline gender-related differences were detected. The outcome was similar and favorable between groups but women seemed to benefit of PFO closure more than men in term of headache/migraine.

C120

RESIDUAL SHUNT AFTER PERCUTANEOUS CLOSURE OF PATENT FORAMEN OVALE WITH SIMPLE ANATOMY. A COMPARISON BETWEEN AMPLATZER AND NON-AMPLATZER DEVICES

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Aims. To evaluate the relationship between the percutaneous patent foramen ovale (PFO) occluder device type (Amplatzer vs non-Amplatzer) and residual right-to-left shunt (RLS) in patients with simple fossa ovalis anatomy (without septal aneurysm).

Methods and results. We enrolled 130 patients with large RLS at contrast-enhanced transcranial color Doppler (TCCD) undergoing percutaneous PFO closure with an Amplatzer device (n=73, 56.2%) or not (n=57, 43.8%; Table 1), all under rotational intracardiac echocardiography (ICE) guidance. Residual RLS was evaluated 3 and 12 months after the procedure by TCCD. PFO percutaneous closure was successful in all patients. At TCCD, a significant residual RLS (grade ≥2) was observed in 20 (15.4%) and 9 (6.9%) patients at 3 and 12 months, respectively. Larger baseline RLS, greater longitudinal and transverse fossa ovalis dimensions and use of non-Amplatzer devices were e associated with significant residual 12-month RLS (Table 2). Figures 1 and 2 show the procedural results according to the

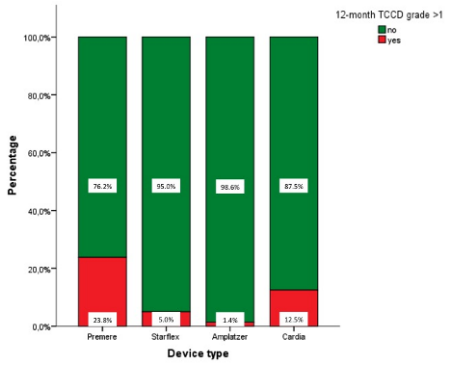
Table 1. Baseline characteristics of the study population.

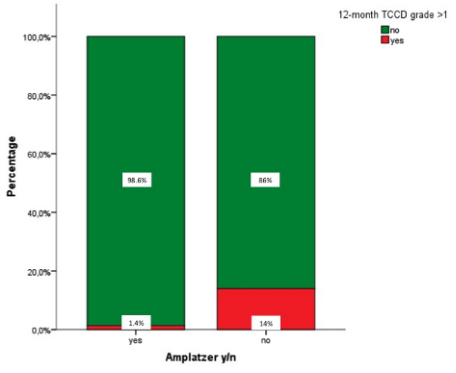
No. patients	130
Age (years)	42.2±12.8
Gender (M/F)	42 (32.3%) / 88 (67.7%)
>1 cardiovascular risk factor	7 (5.4%)
Grading of baseline RLS	
3	95 (73.1%)
4 or 5	35 (26.9%)
Prominent Eustachian valve or Chiari's network	20 (15.4%)
Clinical presentation	
Stroke	45 (34.6%)
Transient ischemic attack	48 (36.9%)
Peripheral embolism	4 (3.1%)
Migraine with subclinical brain lesions	33 (25.4%)
Device type	
Amplatzer	73 (56.2%)
Cardia	16 (12.3)
Premere	21 (16.1)
Starflex	20 (15.4)
Device size	
<25 mm	21 (16.1%)
≥25 mm	109 (83.9%)

Table 2. Demographic, intracardiac and device characteristics according to the presence of significant residual RLS at 12 months after percutaneous PFO closure.

	12-month RLS grade ≥2		p
	+ (n= 9)	- (n=121)	
Age (years)	40.1±16.4	42.3±12.5	0.57
Sex (M/F)	4 (44.4%) / 5 (55.6%)	38 (31.4%) / 83 (68.6%)	0.42
Baseline RLS grade 3 vs 4 or 5	4 (44.4%) vs 5 (55.6%)	91 (75.2%) vs 30 (24.8%)	**0.045**
Prominent EV/CN	1 (11.1%)	19 (15.7%)	0.71
Device type Amplatzer vs non-Amplatzer	1 (11.1%) vs 8 (88.9%)	72 (59.5%) vs 49 (40.5%)	**0.005**
Device size <25 mm vs ≥25 mm	0 (0%) vs 9 (100%)	21 (17.4) vs 100 (82.6%)	0.172
ICE-aorta FO dimensions (mm)	15.8±2.5	13±2.6	**0.005**
ICE-4chamber FO dimensions (mm)	21.1±2.1	16.1±2.9	**<0.0001**

Values are mean ± SD, or n (%).
PFO, patent foramen ovale; RLS, right-to-left shunt; EV/CV, Eustachian valve/Chiari's network; ICE, intracardiac echocardiography; FO, fossa ovalis.





device type. At multivariate analysis including propensity score, the longitudinal (4-chamber) fossa ovalis dimension >19.8 mm (OR 18.3; 95%CI 3.13-107.21; p=0.001) and the use of non-Amplatzer devices (OR 12.96; 95%CI 1.30-128.3; p=0.03) were confirmed as independent predictors of significant residual RLS at 12 months.

Conclusion. Our study suggests that the use of non-Amplatzer devices and a large fossa ovalis are independent predictors of persistent residual RLS after percutaneous closure of PFO with simple anatomy.

C121

LONG-TERM OUTCOMES FOLLOWING TRANSCATHETER PFO CLOSURE: IMPACT ON THROMBOEMBOLISM AND ON CHRONIC CEPHALALGIA

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Background. The clinical significance of patent foramen ovale (PFO) is not well defined. Even though transcatheter closure of PFO has been available for over 2 decades, it has remained controversial due to a paucity of evidence to guide patient and device selection.

Aim. To assess safety and efficacy of percutaneous PFO closure in a prospective single center registry.

Methods. Between July 2001 and March 2014, all consecutive patients undergoing transcatheter PFO closure in our institution using the Amplatzer PFO Occluder or the Amplatzer Cribiform Septal Occluder (St. Jude Medical, St. Paul, MN) were included. Clinical follow-up was collected at 30 days, 6, 12, 24 months and yearly thereafter.

Results. 150 patients were included in the study (60% female, mean age 48.9±12.9). Indications for closure were cryptogenic stroke (43.3%), TIA (46%), migraine with ischemic lesions at cerebral CT/MR (4%), decompression syndrome in scuba divers (1.3%), peripheral embolism (0.6%), primary prevention in patients with anatomical or clinical risk factors for thromboembolism (4.8%). 56 patients (37.3%) had a clinical history of recurrent cerebral ischemia, 58 patients (38.6%) had multiple ischemic lesions at cerebral CT/MR, 17 patients (11.3%) had a documented thrombophylia. PFO closure was successfully performed in 149 (99.3%) patients, with a mean procedural time of 33 minutes. Intraprocedural complications were 1 major air embolism, 1 isolated transient ST elevation, 1 pericardial effusion requiring pericardiocentesis, 2 new onset atrial fibrillations. There were no major in-hospital complications, and mean length of stay was 4.2 days. At median 50.5 months follow up (range 1-155 months), 4 TIA and 1 stroke were observed. New onset of atrial arrhythmias occurred in 5 patients. Among 50 patients (33.3%) who had previous history of chronic headache or migraine requiring medications, the majority (30 patients, 60%) referred substantial relief or total regression of symptoms after PFO closure.

Conclusions. In our experience, transcatheter PFO closure is a safe procedure, which may effectively prevent ischemic events in patients with history of TIA/stroke or other conditions at risk for paradoxical embolism. Among patients with previous history of migraine/headache, symptoms were substantially reduced or abolished in the majority of patients.

C122

FOLLOW-UP A MEDIO TERMINE DELL'IMPIANTO DI OCCLUSORE DELL'AURICOLA SINISTRA

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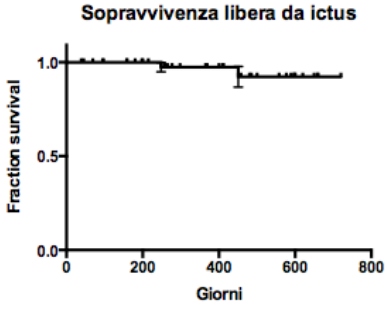
Premessa. Il posizionamento di occlusore nell'auricola sinistra per prevenire eventi tromboembolici in pazienti affetti da fibrillazione atriale non valvolare impossibilitati a seguire terapia anticoagulante orale per controindicazioni assolute o relative pare offrire una valida alternativa terapeutica. Di seguito descriviamo i risultati a medio termine nei pazienti trattati presso il nostro Laboratorio.

Materiale e metodi. Dal settembre 2009 a maggio 2014 sono stati trattati 51 pazienti, di età media 76±4 anni, con score CHA_2DS_2-VASc medio pari a 4.6±1.2, tutti con controindicazioni assolute ad inizio o prosecuzione di terapia anticoagulante orale. In tutti i casi è stato utilizzato l'Amplatzer Cardiac Plug (St. Jude Medical). La percentuale di successo è stata pari a 92%, definita come corretto posizionamento della protesi in assenza di leak periprotesici >2 mm e con osservanza dei criteri di stabilità. Si sono osservate due complicazioni periprocedurali (embolizzazione precoce della protesi in aorta addominale, recuperata per via percutanea, ed un versamento pericardico non tamponante). Tutti i pazienti sono stati dimessi con indicazione a doppia terapia antiaggregante per 3 mesi e successivamente a terapia con solo acido acetilsalicilico (ASA). Il follow-up ha compreso un ecocardiogramma transesofageo di controllo ad un mese, tre mesi e sei mesi e successivamente in caso di necessità clinica. Ad un follow-up di 435±128 giorni tre pazienti sono deceduti per cause non correlabili alla procedura (una polmonite, una morte cardiaca improvvisa ed una riacutizzazione di scompenso cardiaco). Due pazienti, pari a 1.02% hanno sofferto di un evento embolico cerebrale (un ictus ed un TIA). In uno di questi casi l'ecocardiogramma transesofageo, eseguito 30 giorni dopo l'evento acuto, ha mostrato una massiva trombosi apparentemente ad origine dal pin del dispositivo, che ha reso necessaria inizialmente terapia con eparina a basso peso molecolare e successivamente, in considerazione della persistenza della trombosi, con warfarin).

Se si considera il profilo di rischio della popolazione trattata nel medesimo periodo ci si sarebbero attesi 8.4 ictus in assenza di terapia e 6 ictus in terapia con ASA. L'impianto dell'occlusore sembra quindi essere terapia altamente efficace in questa popolazione.



Nursing

C123

EFFETTI DELLA RICANALIZZAZIONE PERCUTANEA DELLE OCCLUSIONI CORONARICHE CRONICHE TOTALI SULLA QUALITÀ DI VITA DELLA PERSONA

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Background. La rivascolarizzazione delle occlusioni coronariche croniche totali (CTO) ha rappresentato una delle maggiori sfide per il cardiologo interventista sin dall'introduzione dell'angioplastica coronarica percutanea. L'introduzione degli stent medicati, con l'abbattimento dei tassi di restenosi e di riocclusione, ha fornito la spinta decisiva al trattamento percutaneo di queste lesioni. Allo stato attuale, la logica che spinge al trattamento percutaneo delle CTO è costituita da migliori outcome a lungo termine, ridotta incidenza di bypass ed un miglior status clinico, con miglioramento della sintomatologia anginosa e della tolleranza all'esercizio e miglioramento e della qualità della vita. Numerosi studi sono orientati all'accertamento ed all'implementazione del self-care dei pazienti e l'infermiere è il professionista della salute che, attraverso le sue prestazioni, aumenta o ripristina l'autonomia delle persone che assiste; gli interventi infermieristici devono essere sempre mirati al miglioramento della salute intesa anche come benessere e soddisfazione del paziente.

Domande di ricerca. La QdV dei pazienti con CTO coronarica migliora dopo intervento di rivascolarizzazione.
Metodi e strumenti. *Disegno di studio*: osservazionale prospettico. *Popolazione*: la popolazione a cui si rivolge lo studio è quella composta dai pazienti afferenti al Laboratorio di Emodinamica del CCM. *Criteri di inclusione*: pazienti di età >18 anni che effettuano un intervento elettivo di rivascolarizzazione di CTO, sintomatici per angina da sforzo con documentazione di ischemia miocardica inducibile concordante con la sede dell'ostruzione o referti di esami diagnostici che documentino la presenza di CTO. *Criteri di esclusione*: pazienti che presenteranno deficit cognitivi da non permettere una corretta applicazione del protocollo di studio. Failure della procedura. *Raccolta e analisi dei dati*: la raccolta dati prevede una valutazione secondo i questionari validati scientificamente EuroQol-5D Seattle Angina Questionnarie e Rose Angina Questionnarie, che saranno somministrati da un infermiere in tre momenti diversi: a) all'ingresso in ospedale o comunque prima della procedura di rivascolarizzazione (T0); b) 1 mese dopo la procedura di rivascolarizzazione (T1); c) 6 mesi dopo la procedura di rivascolarizzazione (T2). La somministrazione dei questionari a 1 mese e ad 6 mesi, verrà effettuata mediante intervista telefonica, previa accettazione da parte dei pazienti arruolati del consenso informato.
Risultati attesi. Ci si aspetta un aumento del livello della Qdv nei pazienti che si sottopongono a rivascolarizzazione coronarica di CTO correlato con la diminuzione della sintomatologia anginosa nei pazienti e con lo stato di salute inteso come livello di benessere psico-fisico della persona.

C124

LA SALA OPERATORIA DEL FUTURO: SALA IBRIDA

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La sala ibrida è una struttura operatoria con caratteristiche tecnologiche molto avanzate che unisce i requisiti di una sala operatoria tradizionale per chirurgie ad elevata specializzazione (cardiochirurgia, chirurgia vascolare, neurochirurgia) con apparecchiature integrate di diagnostica radiologia molto sofisticata (come quelle impiegate in cardiologia interventistica, angioradiologia ecc.).L'angiografo Ibrido utilizza il primo sistema multi-asse che può essere posizionato nel modo desiderato e può essere controllato con maggiore facilità e precisione rispetto ad un sistema a pavimento o/a soffitto tradizionale, offre un'eccellente visualizzazione di strutture fini e consente di ingrandire l'immagine senza perdita di dettagli.
La sala ibrida offre la possibilità di "convertire" agevolmente interventi mininvasivi, che si dovessero complicare, in interventi chirurgici standard senza spostare il paziente, l'equipe e le attrezzature tecnologiche offrendo le condizioni di maggiore sicurezza sia per il paziente che per gli operatori. L'angiografo di nuova generazione o "ibrido" fornisce un'eccezionale flessibilità di posizionamento del paziente, consentendo più angolazioni e una completa copertura dalla testa ai piedi ed molteplici posizioni di lavoro. La C-braccio minore consente l'accesso ad entrambi i lati destro e sinistro del paziente, permette un migliore accesso al corpo con meno interferenza con l'anestesista rispetto ai sistemi convenzionali e la possibilità di effettuare una forma unica di angiografia rotazionale che utilizza algoritmi di ricostruzione speciali per generare immagini CT-come in meno di un minuto direttamente al tavolo.
La disponibilità di un ambiente protetto come quello di una sala operatoria consente di migliorare sia la gestione dei pazienti complessi che completare la filiera diagnostico-terapeutica che oggi diventa garanzia prerogativa della struttura ospedaliera di riferimento. Questa nuova combinazione tra l'atto diagnostico e l'atto chirurgico favorisce il concetto d'integrazione interdisciplinare che affronta criticità cliniche elevate con strumentazione ad elevato standard tecnologico.

C125

L'INFERMIERE COME ATTORE NELL'ALLEANZA TERAPEUTICA E ASPETTI PSICO-SOCIALI NELLE MALATTIE CARDIOVASCOLARI: DA UN'INDAGINE PRESSO IL DIPARTIMENTO DI MALATTIE CARDIOVASCOLARI DELL'ACO SAN FILIPPO NERI DI ROMA

Ciro Campanelli[1], Giulio Speciale[2], Adriana Roncella[2], Marinella Spaziani[2], Barbara Lirosi[1], Anna Rita Ottaviani[2], Maria Losacco[2]
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Per alleanza terapeutica intendiamo la relationship tra tutti gli attori sanitari e non, che si rapportano al paziente durante il soggiorno ospedaliero. L'infermiere è quindi uno degli attori protagonisti che interseca le relazioni tra il paziente, la malattia, l'ospedalizzazione e la famiglia.
Scopo. Fotografare i disagi psicofisici del paziente prima e durante il soggiorno in ospedale, in relazione alla famiglia, al personale ospedaliero e se e quali attori possano essere i più idonei a supportarli.
Metodologia. Sono stati randomizzati 100 pazienti, di cui 50 di cardiochirurgia e 50 di emodinamica. È stato utilizzato un questionario composto da 26 domande chiuse e per la valutazione è stata usata una scala quantitativa.
Risultati. Il paziente cardiologico è risultato più ansioso nella fase prima del ricovero, mentre il cardiochirurgico durante il ricovero. La depressione ha dato risultati diversi e contrastanti tali da renderla uno stato psichico indipendente. È risultata forte la presenza del supporto famigliare, che tuttavia ha mostrato uno stato ansioso rilevante. Il paziente riferisce un maggiore rapporto interpersonale con il medico in cardiologia, e con quello infermieristico in cardiochirurgia. Il supporto psicologico in ambiente ospedaliero è più richiesto dai pazienti cardiochirurgici.
Conclusioni. I pazienti esaminati, nonostante i diversi quadri clinici, hanno presentato numerose uniformità. La più evidente è la rilevanza data alla figura dell'Infermiere, inteso non solo come figura sanitaria rivolta all'assistenza, ma soprattutto come risorsa qualitativa nel supporto psico-sociale indispensabile per il paziente e la famiglia. Questo aspetto richiederebbe secondo noi un ulteriore approfondimento.

C126

MISURAZIONE DEL TEMPO DI COAGULAZIONE ATTIVATO DOPO SOMMINISTRAZIONE INTRA-VENOSA O INTRA-ARTERIOSA DI EPARINA IN PAZIENTI SOTTOPOSTI A CHIUSURA PERCUTANEA DI PERVIETÀ DEL FORAME OVALE

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Premesse. Nelle procedure di chiusura percutanea del forame ovale pervio (PFO) il mantenimento di un livello appropriato di anticoagulazione è di fondamentale importanza per la prevenzione di trombosi a livello del dispositivo e/o del sistema di rilascio. Attualmente non è noto se la somministrazione di eparina sodica per via intra-venosa (IV) o intra-arteriosa (IA) abbia effetti diversi sul tempo di coagulazione attivato (ACT), test che viene comunemente utilizzato in sala di emodinamica per valutare il livello di anticoagulazione.
Scopo. Valutare l'effetto della somministrazione IV o IA di eparina sull'ACT in una serie consecutiva di pazienti sottoposti a chiusura percutanea di PFO.
Metodi. Ventuno pazienti (11 donne; età 47±15 anni) sono stati consecutivamente sottoposti a chiusura percutanea di PFO. La somministrazione di eparina sodica (70 UI/Kg) è stata effettuata secondo uno schema precostituito di randomizzazione: IA (arteria femorale), IV centrale (vena femorale-IVC) e IV periferica (vena ante-cubitale-IVP). Il controllo dell'ACT è stato effettuato dopo 30 minuti dalla somministrazione su sangue prelevato dall'a. femorale, dalla v. femorale e da una vena anticubitale. Per annullare l'effetto del seppur minimo ritardo temporale del prelievo e della effettuazione del test è stato utilizzato uno schema precostituito di randomizzazione.
Risultati. I risultati sono riportati nelle Tabelle 1 e 2.

Tabella 1

	Vena periferica	Vena femorale	Arteria femorale	p
ACT basale (s)	134±10	130±12	126±17	0.10
ACT post (s)	193±40	212±48	199±60	0.28

Tabella 2

	Somministrazione eparina vena femorale (n=10)	Somministrazione eparina arteria femorale (n=11)	p
Prelievo v. periferica	195±41	191±41	0.86
Prelievo v. femorale	220±58	205±37	0.49
Prelievo a. femorale	188±28	210±79	0.40

Conclusioni. La somministrazione IV o IA di eparina sodica non determina differenze significative sull'ACT misurato nel sangue prelevato dall'a. femorale, dalla v. femorale e da una vena anti-cubitale. Pertanto entrambe le vie di somministrazioni possono essere utilizzate indistintamente durante le procedure di chiusura percutanea di PFO.

C127

MODELLI ORGANIZZATIVI IN RADIOLOGIA INTERVENTISTICA: REQUISITI, PROFESSIONALITÀ, STRUTTURE E TECNOLOGIA

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La relazione parte illustrando le attività di radiologia interventistica eseguibili nei centri di 1, 2 e 3 livello, secondo le indicazioni e le linee guida fornite dal "quaderno del ministero della salute" pubblicato nel novembre 2011 e titolato "Criteri di appropriatezza clinica, strutturale e tecnologica di radiologia interventistica", passando poi ad analizzare come una sala angiografica multidisciplinare debba modificare il suo assetto in base allo specialista che vi opera e dello spazio a disposizione.
Proprio la multidisciplinarietà delle nuove sale angiografiche "ibride" richiede una specifica preparazione del personale che vi opera sia tecnico che infermieristico, una profonda conoscenza del tipo di procedure che si eseguono e dei materiali che vengono utilizzati dai vari professionisti. Anche per questo la gestione del magazzino diventa di estrema importanza, ed è necessaria un'attenta valutazione del fabbisogno in base al numero di procedure eseguite.

Verrà infine ribadito come sia estremamente importante il lavoro di "squadra" all'interno di una sala di interventistica multidisciplinare e di quanto sia importante un continuo aggiornamento. Proprio per questo è stato creato ed attivato, nell'anno accademico 2013-2014, dall'Università degli Studi di Bologna in collaborazione con AITRI (Associazione Italiana Tecnici di Radiologia Interventistica), un master di 1 livello in "Radiologia vascolare, interventistica e neuroradiologia" aperto a tecnici di radiologia, infermieri e medici che si ripeterà anche nell'anno accademico 2014-2015.

C128

LA RIDUZIONE DI DOSE RADIANTE NELLE INDAGINI VASCOLARI CORONARICHE MEDIANTE TC. CONFRONTO TRA CORONAROGRAFIA E TAC CORONARICA

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Sin dalla sua introduzione nella pratica clinica l'angiografia coronarica viene considerata il gold standard diagnostico nella valutazione delle arterie coronarie, grazie alle sue elevate risoluzioni temporale, spaziale e di contrasto. Complessivamente ogni anno vengono effettuate alcuni milioni di procedure cardiologiche interventistiche e solo in Italia nel 2013 le coronarografie sono state 270.521.

Secondo alcuni studi, escludendo la radioterapia, in Emodinamica si utilizza la più alta dose di radiazioni e di ciò ne sono poco consapevoli anche i cardiologi che fanno ricorso alla coronarografia anche per una valutazione dei pazienti che potrebbe essere fatta diversamente. Negli ultimi 10 anni, però, si è assistito ad un continuo miglioramento della risoluzione temporale e spaziale delle apparecchiature di tomografia computerizzata multidetettore e ciò ha consentito una rapida espansione delle applicazioni cardiologiche di tali apparecchiature ed in particolare ha reso possibile l'imaging coronarico non invasivo. L'angiografia coronarica con tomografia computerizzata (CCTA) ha dimostrato di essere una metodica efficace ed economicamente sostenibili per giungere ad una diagnosi precoce nei pazienti con sospetto di malattia coronarica.

A partire dal 1997, le norme europee dell'Euratom, recepite in Italia nel 2000, hanno disposto la rilevazione delle dosi in ogni procedura e la registrazione del dato nelle informazioni fornite ai pazienti. Le dosi rilevate sono espresse in termini di DAP, DLP e Bequerel rispettivamente per le coronarografie, TAC coronariche e scintigrafie. Il DAP (Dose Area Product) è la dose di esposizione radiologica somministrata al paziente ed è calcolata in ogni procedura è rappresenta il prodotto della dose per l'area espressa in Gy cm2 mentre il DLP (Dose Lenght Product), espresso in mGy x cm, rappresenta il prodotto tra la dose e la lunghezza dell'esame.

Una coronarografia comporta mediamente un esposizione di almeno 10 mSv contro, ad esempio, i circa 3 mSv utilizzati in una tac coronarica; 1 mSv equivale a 50 radiografie standard del torace. Lo scopo del presente studio è la valutazione dei differenti risultati dosimetrici ottenuti all'acquisizione di TC cardiache con l'impiego di un protocollo di riduzione della dose radiante e la coronarografia come metodica diagnostica ponendo a confronto i dati ottenuti tra le due procedure.

Per la coronarografia i dati considerati sono stati il tempo totale di fluoroscopia, il numero totale di immagini prodotte e il prodotto dose per area (DAP) complessivo mentre per la CCTA i dati dosimetrici raccolti, comprendono il DLP dell'acquisizione nelle condizioni basali, il DLP dell'acquisizione con mezzo di contrasto ed il DLP totale dell'esame. Nell'ottica di ridurre quanto possibile l'evenienza di effetti lesivi nel corso degli anni si è posta sempre maggiore attenzione alla dose di radiazioni a cui viene esposto il paziente, adottando quello che gli anglosassoni definiscono "the ALARA (as low as reasonably achievable - quanto più bassa si possa ottenere in modo ragionevole).

C129

EFFICACIA DI UNO STRUMENTO DEDICATO (HEART PASS) NELLA GESTIONE DEL RISCHIO CLINICO DEI PAZIENTI DA SOTTOPORRE A PROCEDURE DI CARDIOLOGIA INTERVENTISTICA VERSUS UNO STRUMENTO STANDARD (BOARDING CARD AZIENDALE)

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Background. La complessità delle patologie trattate, l'invasività delle terapie, i presidi diagnostici sofisticati, la delicatezza delle dinamiche tra le UU.OO. di ambito cardiologico, e tra area cardiologica e UU. OO. afferenti, e le carenze nell'organico fanno emergere l'importanza di un'adeguata gestione del rischio clinico. In ottemperanza alle Raccomandazioni Ministeriali n. 7 e n. 9 sulla prevenzione dell'errore terapeutico e sulla prevenzione dell'evento avverso, e in osservanza alla Check List per la Sicurezza in Sala Operatoria abbiamo creato ex novo uno strumento cartaceo di supporto.

Scopo. Il presente studio osservazionale, prospettico si propone come obiettivo di verificare l'efficacia di un strumento operativo denominato "Heart Pass" che ha introdotto controlli specifici per l'attività dell'Unità di Cardiologia Interventistica cercando, così, di perseguire standard qualitativi più elevati e sicuri per il paziente in termini di riduzione dei rischi e contenimento della spesa economica.

Metodi. Elaborando il "Percorso Perioperatorio" specifico abbiamo creato un nuovo strumento denominato "Heart Pass" che, mutuando alcune parti della Boarding Card (B.C.) aziendale ha introdotto controlli specifici cercando, così, di perseguire standard qualitativi più elevati e sicuri per il paziente. Sono state esaminate tulle le HP dei pazienti sottoposti a procedure di cardiologia interventistica nel periodo dicembre 2013-febbraio 2014 (T_1), e attraverso una scheda di valutazione creata ad hoc sono stati verificati l'errore di terapia pre e post procedurale, l'errore di tecnica di chiusura e la non appropriata preparazione dei presidi da utilizzare in fase procedurale. I risultati così ottenuti sono stati confrontati con quelli derivanti dalla stessa analisi condotta sulle B.C. dei pazienti nel periodo luglio-ottobre 2013 (T_0).

Risultati. Da un'analisi preliminare è emerso che nel periodo T_1 sono state eseguite 128 procedure ripartite tra n. 90 coronarografie e n. 38 impianti di PM o IDC. L'errore di terapia si è prevenuto nell'89.3%, la prevenzione delle complicanze post operatorie è stato stimato nel 94.53% dei casi e l'errore di tecnica di chiusura e la non appropriata preparazione dei presidi da utilizzare in fase procedurale è risultato essere del 29.7%. Nel periodo T_0 sono state eseguite 109 procedure ripartite tra n. 76 coronarografie e n. 33 impianti di PM o IDC. L'errore di terapia si è prevenuto nel 55.47%, la prevenzione delle complicanze post operatorie è stato stimato nel 74.5% dei casi e l'errore di tecnica di chiusura e la non appropriata preparazione dei presidi da utilizzare è risultato essere del 47.65%.

Conclusioni. Le prime considerazioni evidenziano interessanti implicazioni per la pratica quali: una miglior gestione del rischio clinico stimato nella riduzione del 20.03% in termini di prevenzione delle complicanze post procedurali e conseguente riduzione della degenza media totale; l'analisi dell'errore di tecnica di chiusura e della non appropriata preparazione dei presidi procedurali ha evidenziato una diminuzione del 17.95%. Dal punto di vista economico il follow-up attuato costituisce una riduzione dei costi in termini di presidi utilizzati.

C130

QUANDO E COME È COINVOLTO IL PERSONALE INFERMIERISTICO NEL TRATTAMENTO DELLA CHIUSURA DELL'AURICOLA PER VIA PERCUTANEA

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La chiusura percutanea dell'auricola sinistra si è dimostrata una valida alternativa alla terapia anticoagulante orale (TAO) nei pazienti con fibrillazione atriale non valvolare (FANV) e con controindicazioni a quest'ultima per elevato rischio emorragico. Infatti, nei pazienti con FANV, la principale sede di formazione di trombi endocavitari è l'auricola sinistra, e la sua chiusura mediante dispositivi di occlusione percutanea ha dimostrato di garantire un'adeguata protezione da eventi tromboembolici in assenza di TAO.

La chiusura percutanea dell'auricola sinistra è eseguita da cardiologi interventisti, e prevede il rilascio dei dispositivi di occlusione mediante appositi sistemi di posizionamento percutanei, attraverso accesso venoso femorale e puntura transettale, sotto guida fluoroscopica e ecocardiografica transesofagea. Parallelamente all'attività medica durante la procedura assume fondamentale importanza la presenza di personale infermieristico esperto e addestrato alle esigenze di Sala, in modo da ottenere una precisa e affidabile preparazione del paziente e della strumentazione necessaria. Dopo la preparazione del campo sterile, degli introduttori e dei sistemi di rilascio, nel nostro Centro sono infatti compito dell'infermiere di Sala il rilievo e il monitoraggio continuo dei parametri vitali del paziente (comprensivi di pressione cruenta, saturazione di ossigeno e ECG), l'assistenza al paziente e al medico durante l'esecuzione dell'ecocardiogramma transesofageo, il pronto riconoscimento di eventuali complicanze, oltre le consuete mansioni di compilazione dei registri di Sala e di carico e scarico del materiale.

Nel nostro Centro sono stati sottoposti a chiusura per cutanea di auricola sinistra 33 pazienti, di cui 21 uomini e 12 donne, di età media di 67.6±8.2 anni, con elevato rischio tromboembolico (CHA_2DS_2-VASc medio 3.23±1.33) ed emorragico (HAS-BLED medio 3±1.09), e con controindicazione assoluta a TAO. I pazienti sono stati sottoposti a impianto di dispositivo Watchman in 27 casi, e nei restanti 6 a impianto di dispositivo Amplatzer Cardiac Plug. Tutte le procedure sono state concluse con successo e non si sono verificate complicanze acute: la durata media delle procedure è risultata 67.78±18 minuti, con tempi di scopia medi di 16.81±2.53 minuti.

Il ruolo dell'infermiere è fondamentale durante tutte le fasi della procedura di chiusura percutanea dell'auricola sinistra, in particolar modo per quanto riguarda l'assistenza al paziente e il riconoscimento di eventuali complicanze, e permette di completare le procedure in sicurezza.

C131

LA MULTIDISCIPLINARIETÀ NELLE SALE ANGIOGRAFICHE

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Nell'ultimo ventennio l'interventistica cardio vascolare ha avuto processi evolutivi esponenziali, facendo virare la metodica da procedura diagnostica a procedura quasi esclusivamente interventistica. A questa crescita hanno contribuito l'evoluzione delle apparecchiature angiografiche e lo sviluppo di

materiali sempre meno invasivi e tecnologicamente avanzati. A far progredire una metodica ormai acquisita come determinante nella cura dei pazienti aterosclerotici con patologie e/o complicanze vascolari di vario genere viene proposta la collaborazione di diverse strutture e diverse figure professionali che utilizzano la stessa metodica per il trattamento delle patologie aterosclerotiche dei diversi distretti anatomici. Il modello proposto e sostenuto come valido è quello di inglobare in un'unica struttura tre diverse metodiche quali: l'interventistica coronarica (emodinamica) la neuro interventistica e la radiologia vascolare interventistica del distretto arterioso "periferico" favorendo la formazione di personale tecnico infermieristico altamente specializzato e la collaborazione diretta e quotidiana di medici interventistici di culture diverse quali i cardiologi emodinamisti e i radiologi vascolari. Il tutto a vantaggio del paziente che in caso di patologia ateromasica polidistrettuale può vedere risolte le problematiche inerenti la sua patologia in un'unica seduta interventistica. Questa è la realtà della nostra struttura che vorremmo far conoscere ed esportare come modello valido di efficienza sanitaria.

C132

EFFICACIA DI UN PROGRAMMA INFERMIERISTICO REMINDER PER MIGLIORARE L'ADERENZA AGLI STILI DI VITA SANI NEI PAZIENTI A RISCHIO CARDIOVASCOLARE

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Background. L'ipertensione è un fattore di rischio predittivo di malattia cardiovascolare. Se il target pressorio non è raggiunto con la modifica dello stile di vita sono indicati trattamenti farmacologici, ma l'aderenza al trattamento è intorno al 50-70%. Questa scarsa aderenza può essere migliorata da strategie gestionali attraverso team multidisciplinari specifici. Inoltre l'ipertensione spesso coesiste con altri fattori di rischio cardiovascolari la cui modifica può ridurre l'incidenza di infarto miocardico e migliorare la qualità di vita. Tali raccomandazioni non sono sempre seguite dai pazienti. Tra i metodi proposti per migliorare la qualità della cura dell'ipertensione, è stato sperimentato l'inserimento della figura dell'infermiere case manager. Ad oggi, nessuno studio, ha condotto un intervento infermieristico di "reminder" attraverso l'utilizzo della posta elettronica per valutarne l'efficacia sull'aderenza agli stili di vita sani.

Scopo. Il presente studio ha lo scopo di indagare se la combinazione di un programma educativo associato ad un sistema "remainder" realizzato via e-mail e gestito da infermieri, migliori l'aderenza agli stili di vita sani dei pazienti a rischio cardiovascolare e qiuindi abbia un effetto terapeutico sul controllo della PA.

Metodi. Sono stati arruolati 200 pazienti con diagnosi di ipertensione arteriosa e/o con uno o più di uno dei seguenti fattori di rischio CV associati. Tali soggetti sono stati randomizzati in due gruppi utilizzando un generatore di numeri casuali computerizzato: gruppo A (n=100) e gruppo B (n=100). Il primo ha ricevuto un programma educativo iniziale, ed uno strutturato di contatti settimanali via e-mail, entrambi realizzati e monitorati dagli infermieri; il secondo ha ricevuto un programma informativo ed educativo iniziale gestito da infermieri ma senza il sistema remainder.

Risultati. Da un'analisi preliminare, relative alle caratteristiche cliniche di base, non si sono osservate sostanziali differenze fra i due gruppi; tuttavia i risultati riscontrati in tutto il trend, tra la prima visita (T0) e il terzo controllo (T3), sono risultati in decremento a conferma dell'efficacia del trattamento in questione. Nel complesso la riduzione dei valori di PAS e PAD osservata è stata nel gruppo A di circa 14.9 mmHg e 9.0 mmHg, mentre per il gruppo B il decremento risulta pari a 11.55 mmHg per la PAS e 7.45 mmHg per la PAD. Inoltre i risultati relativi all'aderenza alle indicazioni fornite ai pazienti per le modificazioni dello stile di vita mostrano come il Gruppo A abbia apportato maggiori variazioni alle abitudini di vita quotidiana rispetto ai componenti del Gruppo B.

Conclusioni. Le prime considerazioni evidenziano interessanti implicazioni per la pratica quali una miglior gestione del paziente iperteso a domicilio in termini di aderenza ai trattamenti e un incremento della compliance individuale e collettiva. Inoltre per l'attività infermieristica la gestione di tipo remainder costituisce un momento di innovazione e di slancio culturale. Dal punto di vista economico il follow-up remainder costituisce una notevole riduzione dei costi potendo seguire i pazienti al proprio domicilio.

C133

"EXIT ANGIOGRAPHY" DOPO CARDIOCHIRURGIA PER CARDIOPATIE CONGENITE COMPLESSE: UN NUOVO APPROCCIO ANGIOGRAFICO

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I difetti strutturali residui alla chirurgia correttiva e palliative delle cardiopatie congenite, possono complicare il decorso post operatorio delle cardiopatie medesime. La precocità della diagnosi è essenziale, il ritardo diagnostico infatti può avere effetti sul risultato del trattamento. I difetti inter-ventricolari, la funzione ventricolare o la patologia valvolare, possono essere diagnosticati con l'ecocardiografia trans-esofagea che però raramente è idonea a definire l'anatomia delle strutture extracardiache e in particolare quella dei rami dell'arteria polmonare. Riportiamo la nostra iniziale esperienza nell'utilizzo dell'angiografia intraoperatoria in un gruppo di pazienti affetti da sindrome del cuore ipoplasico, in occasione del comprensive I e II stadio. Dal febbraio 2012 a Giugno 2014 l'angiografia post operatoria è stata eseguita in 10 pazienti. L'angiografia è stata eseguita utilizzando l'angiografo portatile Siemens ARCADIS AVANTIC. Si è iniettato mezzo di contrasto in vena cava superiore o in vena anonima sinistra. La strategia terapeutica non è stata variata in 6/10 pazienti. La revisione chirurgica è stata effettuata sulla base degli elementi ottenuti in 4/10 e in 2 casi è stata effettuata terapia interventistica intraoperatoria con il posizionamento di stent all'origine dell'arteria polmonare destra e a livello dell'anastomosi tra la vena cava superiore e l'arteria polmonare.

C134

PRINCIPI TEORICI E APPLICAZIONI PRATICHE DELL'IFR: DAI RISULTATI DEL REGISTRO ADVISE ALLA PRATICA CLINICA NEL LABORATORIO DI MESTRE-VENEZIA

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Recentemente, nella pratica clinica, è stato introdotto con l'acronimo iFR (istantaneous wave free ratio) un indice riferibile al grado di criticità funzionale relativa ad una stenosi coronarica; tale rapporto è derivato da misurazioni di pressione intracoronarica e prodotto in maniera automatica attraverso un algoritmo.

L'indice iFR si differenzia dal noto sistema FFR (fractional flow reserve) per aspetti sostanziali, principalmente dati dall'assenza di somministrazione del farmaco vasodilatatore (adenosina) e dal fatto che la misurazione viene eseguita in particolari fasi del ciclo pressorio, quando cioè le microresistenze vascolari sono minimizzate e stabili. Nonostante il registro ADVISE abbia ben correlato le misure iFr ed FFR (94%), il valore di cut-off per le due metodiche risulta diverso; se nella FFR i valori al di sotto dello 0,80 indicano stenosi significativa, nell'iFR esiste una "zona grigia"(0.86 < iFR >0.93) dove la proporzionalità con la misura FFR è scarsa e la misurazione necessità dello stimolo iperemico farmacologico (come per FFR) per una valutazione efficace. Lo scopo di questo elaborato è il reporting dell'introduzione della metodica iFR nel nostro centro con alcuni consigli pratici.

Da gennaio a giugno 2014 sono stati valutati 34 pazienti con 46 stenosi coronariche intermedie che come parte della gestione clinica, hanno richiesto valutazione funzionale con guide di pressione; come prima scelta è stata utilizzata la metodica iFR. Nei pazienti con valore di iFR dubbio (zona grigia) è stata somministrata adenosina per via endovenosa o intracoronarica secondo protocolli interni al laboratorio.

Secondo l'esperienza riportata, iFR rappresenta un promettente ed innovativo metodo per la valutazione funzionale della patologia coronarica, attualmente l'utilizzo di questa tecnologia si deve affiancare alle misure FFR. Risulta importate che il personale tecnico e infermieristico coinvolto, conosca le procedure di utilizzo per assicurare misurazioni ad elevata affidabilità. È necessario saper riconoscere le principali problematiche che possono sorgere e le possibili fonti di errore nelle misurazioni.

C135

LA DENERVAZIONE RENALE TRANSCATETERE: RUOLO DELL'INFERMIERE DI EMODINAMICA

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L'ipertensione arteriosa resistente alla terapia farmacologica comporta un aumento fino ha tre volte della mortalità cardiovascolare rispetto all'ipertensione controllata farmacologicamente. L'iperattività del simpatico gioca un ruolo chiave in questi pazienti. Attualmente è possibile ottenere l'interruzione selettiva delle fibre simpatiche, che decorrono nell'avventizia delle arterie renali, con il calore trasmesso alla parete vasale mediante radiofrequenza, la fibrosi delle fibre che ne consegue riduce la pressione arteriosa.

I pazienti vengono portati in sala di Emodinamica per eseguire una procedura simile allo stenting renale, vengono pretrattati con cardioaspirina e clopidogrel e devono essere ben idratati. L'infermiere di sala rileva i parametri vitali, misura tre volte la pressione arteriosa (per eseguire una media finale) e verifica la pervietà dell'accesso venoso, poi posiziona l'elettrodo di ritorno sul fianco del paziente (vengono posizionati due elettrodi se il peso del paziente è superiore a 110 kg e/o il generatore registra un'elevata impedenza). La denervazione renale transcatetere (TRenD) viene effettuata con accesso femorale arterioso con introduttore 8F, previa anestesia locale con lidocaina. Si somministra eparina (5000 o 7500 UI a seconda del peso del paziente). Poiché l'ablazione delle fibre simpatiche provoca dolore viscerale importante durante l'erogazione dell'energia è necessario somministrare al paziente una terapia antalgica, il nostro protocollo prevede la somministrazione di fentanyl (al momento della puntura femorale e durante l'ablazione) e propofol (in infusione continua) con la supervisione dell'anestesista. In caso di ipotensione viene somministrata atropina, se si verifica uno spasmo dell'arteria renale si somministrano vasodilatatori (es nitrati).

Al termine della procedura viene eseguita l'emostasi (solitamente con Angioseal 8F). Il paziente viene tenuto in osservazione e monitorato in sala di

Emodinamica sino a completa ripresa dello stato di coscienza. Successivamente viene portato in reparto di degenza dove viene monitorata la diuresi, i parametri vitali e viene controllato il sito di puntura arteriosa.

C136

RADIOPROTEZIONE OPERATIVA IN CARDIOLOGIA INTERVENTISTICA

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Ai fini della radioprotezione degli operatori addetti alle sale di cardiologia interventistica molte azioni pratiche possono comportare una riduzione delle dosi assorbite dagli operatori stessi. Di fondamentale importanza risulta essere la collaborazione di tutte le figure professionali coinvolte nel processo di ottimizzazione delle procedure quali: tecnici di radiologia, medici specialisti, infermieri e esperto qualificato. Ogni figura deve collaborare secondo la propria mansione e confrontarsi con il gruppo di lavoro. Regole fondamentali sono l'osservazione delle norme di radioprotezione e la riduzione, quando possibile, del numero di persone presenti in sala, la distanza dalla sorgente di radiazione diffusa (il paziente), il tempo di permanenza in prossimità del paziente stesso, la posizione assunta nella sala e il corretto uso delle schermature e dei dispositivi di protezione individuale (DPI) prescritti dall'esperto qualificato. La valutazione delle dosi al personale viene eseguita utilizzando diverse modalità quali: la dosimetria personale e la dosimetria ambientale per mezzo di misure periodiche e, in punti fissi, con i dosimetri ambientali. La corretta gestione dei DPI e dei sistemi di dosimetria (corretta affissione dei dosimetri ambientali e utilizzo, come da prescrizione dell'esperto qualificato, dei dosimetri personali) permettono di monitorare, in modo continuativo, l'efficacia del programma operativo di radioprotezione messo in atto.

C137

LA RIABILITAZIONE CARDIOLOGICA NEL PAZIENTE CON SCOMPENSO CARDIACO

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Background. Lo scompenso cardiaco rappresenta tuttora la causa principale di ospedalizzazione e re-ospedalizzazione. I programmi di riabilitazione cardiologica hanno documentato la loro efficacia nel restituire al paziente e alla famiglia una migliore qualità di vita riducendo, anche, il numero delle ospedalizzazioni. Le linee guida internazionali raccomandano programmi di riabilitazione cardiologica e prevenzione secondaria in varie patologie cardiache: 1) pazienti con cardiopatia ischemica: post-infarto miocardico, post bypass aortocoronarico, post-angioplastica coronarica, cardiopatia ischemica stabile; 2) pazienti sottoposti ad intervento di chirurgia valvolare; 3) pazienti con scompenso cardiaco cronico; 4) pazienti con trapianto di cuore o cuore/polmone; 5) pazienti operati per cardiopatie congenite; 6) pazienti con arteriopatia cronica obliterante periferica; 7) pazienti portatori di pacemaker o di defibrillatori.
Obiettivi. Riduzione delle re-ospedalizzazioni; riduzione del rischio di successivi eventi cardiovascolari; miglioramento della qualità di vita.
Materiali e metodi. Nell'aprile 2011 è stata avviata presso il Presidio Ospedaliero Santa Croce di Fano dell'A.O. Ospedali Riuniti Marche Nord l'attività di Riabilitazione Cardiologica. Inizialmente sono stati presi in carico e trattati soggetti con cardiopatia ischemica e recente evento coronarico acuto, soggetti trattati con rivascolarizzazione meccanica o chirurgica. Dal febbraio 2014, a seguito dell'apertura, presso lo stesso presidio ospedaliero, di un ambulatorio per lo scompenso cardiaco, sono stati elaborati programmi di riabilitazione dedicati a questi pazienti. Nella nostra realtà la riabilitazione cardiologica è il risultato di una collaborazione ed integrazione di più figure professionali (cardiologi, medici fisiatri, infermieri, fisioterapisti, psicologhe, dietiste, endocrinologi, nefrologi, ecc.). I pazienti vengono avviati al programma di riabilitazione dopo attenta valutazione clinica, o dall'ambulatorio per lo scompenso, o in regime di ricovero. Il training (programma) prevede un allenamento personalizzato definito in base a parametri strumentali: test ergo spirometrico con individuazione dei valori di carico massimo, frequenza cardiaca e VO_2 picco o, in alternativa, 6 minute walk test, indicatori soggettivi, come la scala di Borg. Facendo riferimento al protocollo HF-ACTION il programma riabilitativo ha una durata complessiva più prolungata con un training fisico personalizzato.

C138

ITER ASSISTENZIALE NELLE DISOSTRUZIONI CORONARICHE

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La chronic total obstruction coronarica è l'occlusione cronica di un vaso coronarico, causata dalla presenza di placca ateromasica, presente da un tempo uguale o superiore a tre mesi, contraddistinta dall'evidenza angiografica di vasi collaterali che afferiscono al segmento distale della coronaria occlusa e dalla presenza di sintomatologia anginosa. Per tali motivi, pur essendo una procedura in elezione, si differenzia per: 1) complessità: conoscenza dei materiali e delle complicanze; 2) durata: assistenza mirata alla prevenzione del dolore e agli stati d'ansia; 3) utilizzo di una maggiore quantità di mezzo di contrasto: adeguata idratazione per la prevenzione del danno renale da mezzo di contrasto.
Come per l'esame coronarografico con possibilità di PCI, o PCI elettiva, la preparazione della persona assistita e della documentazione clinica è a carico del reparto afferente; all'arrivo in pre-sala si provvede alla check-list di tutti quegli elementi fondamentali per l'ammissione in sicurezza nel cath lab, per il tipo di procedura interessata.
Nell'ultimo decennio, l'avvento dei nuovi materiali, équipes con maggiore esperienza e la tecnica dell'approccio retrogrado, hanno contribuito a superare molte complessità tecniche.

C139

STENT RIASSORBIBILI: COSA CAMBIA PER L'INFERMIERE NELL'ASSISTENZA AL PAZIENTE NEL LABORATORIO DI EMODINAMICA?

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Introduzione. Dalla prima angioplastica coronarica nel 1977, il trattamento della cardiopatia ischemica può vantare l'introduzione di sempre più efficaci dispositivi per trattare le ostruzioni delle arterie coronarie: dai primi stent metallici, a quelli ricoperti da farmaco, sino ad arrivare agli stent riassorbibili (BVS). L'introduzione di questi nuovi stent modifica l'atteggiamento dell'infermiere di Laboratorio nei confronti del paziente?
Metodo e raccolta dati. Una ricerca retrospettiva e monocentrica effettuata nel nostro laboratorio di Emodinamica su 209 pazienti totali (110 DES Vs 99 BVS) con 450 stent impiantati (230 DES Vs 220 BVS) condotto dal 3 maggio 2013 al 13 maggio 2014, ci ha fornito lo spunto per alcune considerazioni e cambiamenti nell'assistenza durante le procedure. Abbiamo confrontato il tempo di scopia e grafia, la durata media della procedura, la quantità di contrasto somministrata ed il materiale utilizzato, considerando procedure relativamente complesse, senza raffrontare volontariamente il costo degli stent.
Considerazioni e conclusioni. Durante la ricerca abbiamo notato: a) un aumento del tempo sia di scopia che di grafia; b) un aumento della quantità di mezzo di contrasto somministrato; c) un aumento del tempo della procedura; d) maggiore materiale utilizzato. In effetti il posizionamento di questo stent richiede un maggiore tempo di scopia e grafia (fluoro time 31' DES vs 42' BVS/fluoro dose cumulativa 163 mGy cm^2 DES vs 163 mGy cm^2 BVS) in quanto radiologicamente poco visibile (se non dopo esperienza e con operatore molto attento), con possibilità, anche se in effetti remota, di complicanze per il paziente (soprattutto se la procedura deve essere ripetuta nel tempo). Parallelamente anche il quantitativo di mezzo di contrasto è aumentato, sempre per poter visionare la corretta posizione dello stent per il suo rilascio. A questo va aggiunta la possibilità di utilizzare anche OCT (optical coherence tomography) per controllo, con la necessità strumentale di ulteriore mezzo di contrasto (210ml DES vs 270 ml BVS). Si è inoltre visto che anche la durata della procedura è aumentata, con aumento del disagio per il paziente. Ed ultimo, ma non per importanza, anche il materiale e parallelamente il costo della procedura stessa (4-5 palloni DES vs 6-7 BVS/IVUS 70% DES vs 99% BVS). Come abbiamo ovviato a questo? Tempistica di scopia/grafia, durata procedura e quantitativo di materiale utilizzato, ovviamente è operatore-dipendente. Per prevenire l'insorgenza di CIN, il paziente viene preparato con N-acetilcisteina ed aumentata l'idratazione pre, durante e post-procedurale (durante la procedura di media vengono somministrate 1000/2000 ml di soluzione fisiologica). Inoltre, considerando la durata media della procedura, si cerca di ridurre al minimo il disturbo del paziente (dolore, ansia, ecc.) con utilizzo di sedativi ed antidolorifici di routine. L'introduzione di nuovi dispositivi comporta sempre mutamenti nell'assistenza al paziente, che deve rimanere sempre al centro della nostra attenzione, ricordando che … "Il primo requisito di un ospedale dovrebbe essere quello di non far del male ai propri pazienti." (Florence Nightingale).

C140

GESTIONE INFERMIERISTICA DURANTE PROCEDURA DI DENERVAZIONE DELLE ARTERIE RENALI PER IL TRATTAMENTO DELL'IPERTENSIONE ARTERIOSA RESISTENTE

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Introduzione. Negli ultimi anni si è progressivamente sviluppata una nuova metodica per il trattamento dell'ipertensione arteriosa resistente mediante denervazione delle arterie renali. Attualmente si utilizzano due tecnologie, radiofrequenza e ultrasuoni. La procedura, agendo sui nervi, genera un elevato stimolo doloroso viscerale.
Obiettivo. Illustrare la nostra esperienza in sala di emodinamica, nella gestione infermieristica, sia dal punto di vista assistenziale generale che di gestione anestesiologica della procedura.
Discussione. Nel periodo in esame (12 mesi) sono stati trattati 6 pazienti mediante denervazione con sistema ad ultrasuoni (Paradise, Recor Medical); le procedure sono state eseguite con accesso femorale 7F. La gestione infermieristica nella preparazione del paziente non si discosta dalle normali procedure diagnostiche ed interventistiche. Il sistema è composto dal

generatore ad ultrasuoni al quale viene connesso un catetere dedicato (pallone con all'interno trasduttore ad ultrasuoni), il priming del catetere è interamente automatico e prevede il riempimento del pallone con soluzione fisiologica al fine di raffreddare l'endotelio dell'arteria durante la procedura. Durante l'erogazione di ultrasuoni (10 secondi con sistemi di ultima generazione) si provoca algia intensa. La somministrazione di midazolam e morfinici è mandatoria, il nostro protocollo prevede che l'infermiere sorvegli l'attività respiratoria del paziente mediante saturazione periferica e intervenga, se necessario, con l'ausilio di unità respiratoria manuale in maschera. Nei casi in cui la procedura dovesse richiedere una sedazione più profonda, in sala è presente il medico anestesista che può intervenire con la somministrazione di ipnotici endovenosi ed anestetici di tipo inalatorio.
Conclusioni. Il lavoro illustra il comportamento delle unità infermieristiche in sala durante le procedure di denervazione, considerando soprattutto l'aspetto anestesiologico, nella gestione della sedazione superficiale e talora profonda in collaborazione con l'anestesista.

C141

LA GESTIONE INFERMIERISTICA DELL'ACCESSO RADIALE: CORRELAZIONE TRA OCCLUSIONE DELL'ARTERIA RADIALE (RAO) E FASCIATURA COMPRESSIVA

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Background. Nei pazienti sottoposti a coronarografia e ad angioplastica coronarica attraverso l'accesso arterioso radiale la letteratura riporta un'incidenza di RAO che va dal 2% al 18%. Tale dato è in realtà ampiamente sottostimato, soprattutto per la frequente assenza di sintomi da parte del paziente a cui la radiale si occlude. L'emostasi può essere effettuata attraverso devices dedicati oppure, come avviene nella nostra Unità Operativa, con la compressione attraverso fasciatura manuale.
Obiettivi. L'obiettivo primario dello studio è rilevare l'incidenza di occlusione dell'arteria radiale, sia acuta che tardiva, in pazienti trattati con fasciatura compressiva manuale. Obiettivo secondario è la rilevazione di complicanze quali ematomi, sanguinamenti, pseudoaneurismi e fistole artero-venose.
Materiali e metodi. È stato predisposto un Audit nell'Unità Operativa di Emodinamica e nel Reparto di Cardiologia della Clinica Cellini di Torino; sono stati arruolati pazienti sottoposti a coronarografia e ad angioplastica coronarica con accesso arterioso radiale. È stato creato uno specifico protocollo finalizzato all'emostasi ed alla prevenzione delle possibili complicanze associando la palpazione dell'arteria radiale al test di Barbeau modificato – cioè senza il pletismografo ma con utilizzo del saturimetro – ed al controllo con eco-color Doppler. È stata effettuata una raccolta dati che tiene conto dei fattori di rischio di occlusione riportati in letteratura. L'introduttore viene rimosso immediatamente al termine della procedura. Il protocollo prevede due fasciature compressive: una più stretta, esterna, che viene rimossa dopo 1 ora, una seconda, meno stretta, da rimuovere dopo 4 ore. Ogni paziente viene valutato in quattro diversi momenti: 1) alla rimozione dell'introduttore radiale ed al contestuale posizionamento della fasciatura compressiva, 2) dopo 4 ore, cioè alla rimozione della seconda fasciatura, 3) alla dimissione 4) trenta giorni dopo la procedura, con controllo clinico ed ecografico ambulatoriale. Lo studio è stato ideato e condotto da un team di infermieri formatisi nell'utilizzo dell'eco-Doppler, ponendo il focus sulla centralità del ruolo infermieristico in questa procedura.

C142

VALUTAZIONE DELLA RIDUZIONE DELLA DOSE AGLI OPERATORI TRAMITE L'UTILIZZO DI TELINI STERILI RADIOASSORBENTI IN PROCEDURE DI CARDIOLOGIA INTERVENTISTICA

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Nelle procedure interventistiche cardiologiche l'accesso radiale è sempre più utilizzato rispetto a quello femorale poiché gravato da minori complicanze vascolari, consente tempi di ricovero minori e da la possibilità al paziente di spostarsi dal letto in prima giornata. Questo comporta però un incremento dei tempi di scopia, una maggior vicinanza del primo operatore al paziente, cioè la sorgente di radiazione diffusa, e di conseguenza un aumento dell'esposizione a radiazioni ionizzanti dell'operatore stesso. Nonostante l'impiego dei dispositivi di protezione quali camice e occhiali piombati, paratiroide, schermi piombati pensili, le mani dell'operatore risultano essere tra le parti del corpo maggiormente esposte.
Per ridurre l'esposizione del primo operatore sono commercializzati telini sterili radioassorbenti realizzati con materiale non piombato (bismuto e antimonio), capaci di attenuare la radiazione diffusa, da apporre in prossimità dell'accesso direttamente sul campo sterile, con l'accorgimento di non intercettare il fascio X.
Scopo di questo lavoro è stato valutare l'effetto dell'impiego dei telini radioassorbenti Radpad (WIT) sull'esposizione degli arti del primo operatore durante procedure di Cardiologia Interventistica in angiosuite (angiografo Artis Zee, Siemens). I telini usati per questa valutazione sono di forma rettangolare e dotati di un taglio su uno dei due lati per facilitare il posizionamento in prossimità dell'accesso lungo l'arto superiore del paziente così da schermare la radiazione diffusa.
Le procedure valutate sono coronarografie, con eventuali successive ventricolografie, aortografie e procedure di angioplastica coronarica. La metodica di valutazione ha richiesto l'apporto di tutte le competenze professionali coinvolte nella procedura: tecnico di radiologia medica, fisico medico, cardiologo. Sono state valutate dal punto di vista dosimetrico le procedure di 20 pazienti di cui 10 effettuate senza l'ausilio del telino e 10 mediante il telino, in aggiunta ai normali sistemi di radioprotezione. L'esposizione agli arti è stata valutata mediante dosimetri a bracciale indossati dal primo operatore al polso più vicino all'accesso radiale. Per ogni caso sono stati annotati i dati anagrafici del paziente e i dati dosimetrici registrati dall'angiografo. Il report dosimetrico prodotto è stato inviato al Picture Archiving and Communication System (PACS) a cura del tecnico di radiologia. Particolare attenzione va posta, in misure di questo tipo, alla gestione dei dosimetri per la misura del fondo naturale di radiazione, alla distinzione fra dosimetri irraggiati e da irraggiare. Nel lavoro saranno descritte le metodiche messe in atto.
Lo studio ha dimostrato l'efficacia dell'utilizzo dei telini Radpad nella riduzione nell'esposizione a radiazione diffusa dal paziente verso l'operatore ed è stato di stimolo all'utilizzo routinario di questi dispositivi nell'ambito della Cardiologia Interventistica.

C143

IL RUOLO DEL TECNICO DI RADIOLOGIA NELL'UTILIZZO DELLA NUOVA METODICA DI VALUTAZIONE PER LE STENOSI CORONARICHE ANGIOGRAFICAMENTE INTERMEDIE

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Introduzione. Dall'analisi wave-intensity della curva di flusso coronarico ottenuta tramite una guida con sensore sia di pressione che doppler di flusso, è stato individuato un periodo del ciclo cardiaco nel quale le resistenze coronariche appaiono costanti e minime, similmente all'FFR (fractional flow reserve); il rapporto tra pressione di perfusione a monte e a valle di una stenosi, misurata all'interno di questa finestra temporale dovrebbe essere proporzionale alla severità emodinamica della stenosi stessa, questo rapporto costituisce il nuovo indice iFR (instant wave-free ratio o instant flow reserve).
Obiettivo. Illustrare la nostra esperienza nella sala di emodinamica di Latina descrivendo la gestione dell'apparecchiatura elettromedicale durante l'utilizzo della nuova metodica di valutazione delle stenosi angiograficamente intermedie.
Discussione. La valutazione funzionale delle stenosi coronariche angiograficamente intermedie rappresenta il principale campo di applicazione del FFR. Diversi studi hanno validato l'utilizzo del FFR come guida nella strategia di rivascolarizzazione. Recentemente lo studio ADVISE ha validato un nuovo indice di valutazione funzionale delle lesioni coronariche iFR. Questa valutazione funzionale della stenosi viene eseguita attraverso una guida dotata di sensore di pressione; è la stessa sonda che viene utilizzata per FFR, collegata con il connettore di pressione del PIM, dando una seconda linea di pressione rilevata dalla sonda. È fondamentale rendere due linee sovrapponibili: attendere che la sonda fuoriesca dal catetere guida per poi effettuare la normalizzazione rendendo le due linee di pressione sovrapponibili; dopo di chè la sonda viene portata a valla della stenosi dove noi registriamo un periodo (wave free-period: la durata di tale periodo è di 5 battiti consecutivi senza l'ausilio dell'adenosina) del ciclo cardiaco nel quale le resistenze coronariche appaiono costanti e minime.
Conclusioni. La metodica iFR è semplice ed immediata e non richiede la somministrazione dell'adenosina evitando i pur lievi effetti collaterali a breve del farmaco stesso; il vantaggio principale è il minor tempo di attesa per la valutazione funzionale della stenosi.

C144

EARLY NURSING TRASFER AFTER PPCI: THE SALENTO MODEL

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Introduction. The early transfer in ICU Spoke of STEMI affected patients, after coronary revascularization of "culprit" artery with PPCI in Hub centre, allows to eliminate the deeply rooted concept of therapy centralization. This also allows to highlight the role of ICU Spoke, with a strong acquisition of emergency management skills, above all for nursing team.
Material and methods. This work aims to give an overview about the early transfer (within 2 hours) into the Salento ICU Spoke centres of STEMI affected patients, who underwent PPCI revascularization. The data analyzed refer to 298 patients involved in the local coronary emergency network, called SalentIMA, from January 2012 to December 2013. The incidence of the early local transfer vs the hospital transfer has been analyzed in relation to adverse events (arrhythmia, slowflow, noreflow, intrastent thrombosis), the arterial access and the network itinerary covered by patients.

Results. From the analysis, it comes out that 72.7% of the 298 patients is male, with a medium age of 64.9±12.76 years. In 51.8% of the cases (152 patients) an early nursing transport has been used, whereas in the 71% of the 24 adverse events, a hospital transfer to the ICU Hub has been chosen as per guideline instructions. The arterial access used for PPCI procedure are the radial artery in 72.4% of the cases and the femoral one in 24.8%. In 2.7% of the cases a shift from the radial artery to the femoral one was needed. The 56% of the patients who had a femoral artery access, has been transferred to the Spoke centre, whereas for those with a radial access the percentage raises up to 58%. In case of shift just for 37% of patients the local early transfer has been chosen. As far as the itinerary is concerned, it comes out that 45.4% of patients who arrived to the centre Hub, through 118 → Cath Lab route, had an early transfer after PPCI. The percentage raises up to 68% in case of PS Spoke → Cath Lab route, and up to 70% in case of 118 → PS Spoke → Cath Lab route.

Conclusion. The early treatment network of SalentIMA, for STEMI affected patients on the territory of Lecce, gives nurses more autonomy and responsabilityfor local early transfer of stable revascularizated patients, through INDIA ambulances. Our results underline a significat use of the early transfer to ICU Spoke from the Hub centrefor patients, who hemodynamically and electrically stable. These organizzation leads to two important effects. On the one hand it provoks a useful reduction of ICU Hub crowding, that, in this way can concentrate on the real and complicated needs of the unstable patients. On the other hand, territory assistence acquires a co-star role in coronary emergency and acute cardiologic cases management, on the scene of an efficient network of STEMI cure.