

# Poster

## CORONARY: ACUTE CORONARY SYNDROME, GENERAL

### P1

#### SURGICAL TREATMENT OF CORONARY ARTERY TO PULMONARY ARTERY FISTULA WITH A SACCULAR ANEURYSM

Gerardo Musuraca<sup>1,2</sup>, Remo Albiero<sup>3</sup>, Carlo Angheben<sup>2</sup>, Cristiana Giovanelli<sup>2</sup>, Clotilde Terraneo<sup>4</sup>, Nicola Martinelli<sup>5</sup>

<sup>1</sup>Cath Lab, Division of Cardiology, Santa Maria del Carmine Hospital, Rovereto, <sup>2</sup>Cardiologia, Santa Maria del Carmine Hospital, Rovereto,

<sup>3</sup>Cath Lab, UOC Cardiologia, Sondrio, <sup>4</sup>UOC Cardiologia, ASST Lariana, Mariano Comense (CO), <sup>5</sup>Medicina, Università di Verona, Verona

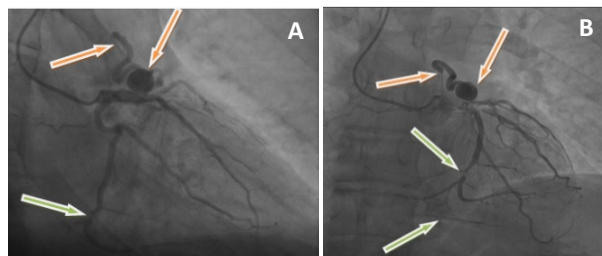
**Introduction.** A 60-year-old man with hypercholesterolemia and hypertension presented with acute coronary syndrome (ACS). The electrocardiogram (ECG) showed T wave inversion in V4-V6 D1 and aVL while the transthoracic echocardiogram was normal, without left ventricular (LV) wall motion abnormalities. Coronary angiography showed critical atherosclerotic lesions in the distal part of left circumflex coronary artery (LCx, culprit lesion), chronic total occlusion of the right coronary artery (RCA), critical stenosis of the left anterior descending (LAD), and a coronary artery fistula (CAF) originating from the proximal LAD and emptying into the pulmonary artery (PA) via a coronary saccular aneurysm (12x12x10 mm). A multi-detector row computed angiography (MDCT) confirmed the presence of the coronary saccular aneurysm with an indication for surgical treatment. The patient was operated on by use of aneurysmorrhaphy, closure of the fistula and coronary artery bypass grafting (CABG) on RCA and LCx. The postoperative course was uneventful and the patient was discharged on postoperative day 14. MDCT was useful for understanding the spatial relation between the CAF and the connection with PA.

**Methods.** CAF is an abnormal direct connection between a coronary artery and either a cardiac chamber (coronary-cameral fistula), a vein (coronary arterio-venous fistula) or, most rarely, the PA. The reported incidence of CAF is ranging from 0.1% to 0.8% of adult population. The reported occurrence of CAA combined with CAF to the PA is very rare and its clinical manifestations have not been fully understood. Most CAF are small and asymptomatic. The clinical presentation depends mainly on the extent of the left to right shunt. However, symptoms can develop with advancing age and shunting of the blood flow. Symptoms include angina pectoris, resulting in a coronary steal phenomenon or, as occurred in this case, an ACS. It is widely accepted that all symptomatic CAF patients should be treated surgically. However, surgical treatment for asymptomatic patients is still controversial. A PubMed search was performed for articles between 2000 and 2010 to describe the current characteristics of congenital CAFs in adults collecting a group of 304 adults. With regard to CAF origin, the subjects were tabulated into unilateral, bilateral or multilateral fistulas and compared. Fistula-related major complications are described as: aneurysm formation, infective endocarditis, myocardial infarction, rupture, pericardial effusion and tamponade. In this group of 304 patients, dyspnea (31%), chest pain (23%) and angina pectoris (21%) were the prevalent clinical presentations. Continuous cardiac murmur was heard in 82% of the subjects. Depending upon the size and location of the fistulae, epicardial and endocardial surgical ligation or percutaneous endoluminal procedures (embolization) can be performed. Surgical correction can be difficult or impossible when the CAF are diffuse. Transcatheter closure approaches have emerged as a less invasive strategy (with CAF closure by coils) and are nowadays considered a valuable alternative to surgical correction with similar effectiveness, morbidity and mortality.

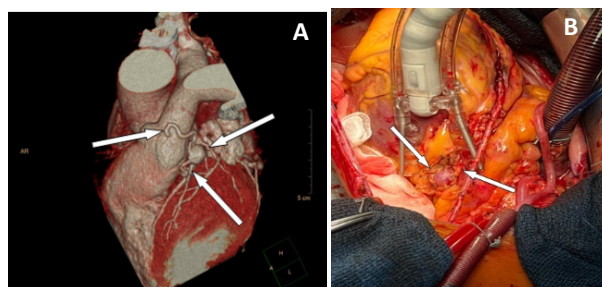
**Results.** The percutaneous management, however, is mainly limited by the individual anatomic features of the CAF and an appropriate patient's selection is considered as a key determining factor to achieve complete occlusion. Therapeutic approaches are designed to reduce myocardial oxygen demand and thereby ameliorate the demand-supply mismatch. Symptomatic relief has been achieved with  $\beta$ -blockers or with calcium-channel blockers. In our case, the origin of the CAF from proximal LAD and the drainage into the PA was identified by CAG and confirmed by MDCT (Figure 1). In particular, showing a diastolic blood flow from the proximal LAD through a complex fistula resulting in a very important PA contrast opacification (Figure 2A). The coronary steal phenomenon associated with a CAF can cause itself angina pectoris but CAF, in association with coronary aneurysm, in case of rupture, can cause sudden death, pericardial tamponade, compression of surrounding structures, and congestive heart failure. Considering the risk of rupture or subsequent myocardial ischemia and thrombotic events, our patient was scheduled for surgical correction of the CAF and CAA, associated with

CABG to RCA, LAD and LCx. Median sternotomy was performed and inspection showed a fistulous vessel from LAD to PA via saccular aneurysm. Cardiopulmonary bypass was established. The ascending aorta was clamped and cardioplegic arrest was obtained via antegrade coronary perfusion, and then retrograde perfusion through the coronary sinus was used intermittently. The fistula was ligated and the outflow vessel in the PA was closed with a 4-0 Prolene polypropylene running suture. The CAA was subsequently incised and completion of aneurysmectomy was done (Figure 2B); triple bypass grafting was performed (left internal mammary artery to distal LAD, SVG to OM and to PDA). The ascending aorta was declamped, and the heart resumed beating spontaneously.

**Conclusions.** We report a very rare case of a patient who presented with ACS and evidence of a CAF to the PA associated with a saccular CAA and critical 3-vessel coronary artery disease. The patient underwent successful surgical correction of all the aforementioned abnormalities with direct closure by suture of the CAF inflow segment, aneurysmectomy, direct closure of the CAF's outflow segment into PA, and 3-vessel CABG.



**Figure 1.** (A) CAG showing saccular aneurysm originating from the proximal portion of the LAD and the connection with PA (orange arrows). On the lower part, the culprit lesion on the circumflex coronary artery (green arrows). (B) Another view showing saccular aneurysm originating from the proximal portion of the LAD, the connection with PA (orange arrows). On the lower part, the culprit lesion on the circumflex coronary artery and the opacification of a posterior interventricular branch of RCA (green arrows).



**Figure 2.** (A) Computed tomography coronary angiography showing a fistula from the LAD to the PA and in the middle part a saccular aneurysm and the outflow tract of vessel from aneurysm to PA (arrows). (B) Intraoperative image: fistula from the LAD was visualized before the incision of the aneurysm (white arrow).

### P2

#### SPONTANEOUS LEFT MAIN CORONARY ARTERY DISSECTION: CLINICAL FEATURES, MANAGEMENT AND OUTCOMES

Carlo Gasparone<sup>1</sup>, Michele Morosato<sup>1</sup>, Davide Romagnolo<sup>1</sup>, Francesco Federico<sup>1</sup>, Francesco Moroni<sup>2</sup>, Cosmo Godino<sup>1</sup>, Matteo Pagnesi<sup>3</sup>, Luca Baldetti<sup>1</sup>, Alessandro Beneduce<sup>1</sup>

<sup>1</sup>IRCCS San Raffaele Scientific Institute, Milan, <sup>2</sup>Pauley Heart Center, Virginia Commonwealth University, Richmond, USA, <sup>3</sup>ASST Spedali Civili and Department of Medical and Surgical Specialties, Radiologic Sciences, and Public Health, University of Brescia, Cardiology Unit, Brescia

**Introduction.** Spontaneous coronary artery dissection (SCAD) is a significant cause of myocardial infarction (MI), particularly in young women, and is linked to an increased risk of long-term major adverse cardiovascular events (MACE). Dissection involving the left main coronary artery (LM) is rare and lacks specific data. The aim of this study is to investigate clinical features, management, and outcomes of patients suffering from LM SCAD.

**Methods.** We conducted a systematic review and patient-level pooled analysis of literature published between 1990 and 2022 using "left main" and "dissection" as search keywords.

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**Results.** The analysis included 125 patients diagnosed with LM SCAD. The mean patient age was 40±10 years, with women accounting for 80% of the cases. Cardiovascular risk factors were minimally prevalent. Remarkably, 36% of cases occurred during pregnancy. Most patients (75%) presented with flow-limited dissection and 97% manifested acute coronary syndrome: 63% ST-segment-elevation MI, 28% with non-ST-segment-elevation MI, and 9% with unstable angina. Cardiogenic shock (CS) at presentation was documented in 21% of patients, while serious ventricular arrhythmias in 8% of cases. In 76% of patients, dissections spread to other vessels, most frequently affecting the left anterior descending artery (LAD) (in 68% of cases), and less commonly extending to both the LAD and left circumflex artery (in 40% of cases). In-hospital death occurred in 7% of the cohort. Invasive management was chosen for most of the patients, with percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) carried out in 24% and 37% of cases, respectively. Revascularization was associated with lower rates of the primary composite endpoint of in-hospital death, MI, and need for urgent myocardial revascularization (OR 0.16, 95% CI 0.06-0.40, p<0.001), both in hemodynamically stable patients and in those presenting with CS. The advantages of revascularization remained evident during the follow-up period, leading to a reduction in the primary composite endpoint (HR 0.23, 95% CI 0.08-0.64, p=0.005).

**Conclusions.** Our analysis of the most extensive collection of LM SCAD patients showed considerable in-hospital mortality and post-discharge MACE. Revascularization significantly improved clinical outcomes regardless patient's hemodynamic condition.

### P3

#### EFFECTS OF SARS-CoV-2 LOCKDOWN ON CLINICAL CHARACTERISTICS OF ACUTE CORONARY SYNDROMES: ARE YOUNGER PATIENTS MORE FREQUENTLY HIT?

Tommaso Capobianco, Walther Iannotti, Riccardo Agostini, Luca Persiani, Marco Chiostrì, Giorgio Iacopo Baldereschi, Carlo Di Mario, Francesco Meucci, Renato Valenti, Niccolò Marchionni, Emanuele Cecchi

Dipartimento Cardio-Toraco-Vascolare, Azienda Ospedaliero-Universitaria Careggi, Firenze

**Introduction.** In 2019, the SARS-Cov-2 pandemic outbreak required restrictive measures to limit virus spread. Our study aims to assess how changes in dietary habits and lifestyle associated with such measures have affected the characteristics of patients with acute coronary syndromes (ACS) in the post-lockdown period. In particular, we evaluated if ACS incidence was higher in younger patients, who were more negatively affected by lockdown measures.

**Methods.** We analysed 609 ACS patients and compared the clinical, laboratory and angiographic characteristics of those admitted 6 months before lockdown (n=312) and those admitted in the same 6 months period after lockdown. Moreover, we compared several anthropometric and laboratory data between pre- and post-lockdown either in younger (≤55 years old) and older patients.

**Results.** The incidence of ACS in young adults (≤55 years) resulted significantly higher in the post- vs. pre-lockdown period (17.5% vs. 10.9%, p=0.019). A trend to a higher percentage of ST-elevation myocardial infarction (STEMI) was observed in the post-lockdown period together with a significant lower incidence of non-STEMI (p=0.033). Moreover, in the post-lockdown period we observed in younger patients a significant increase in weight, body mass index, admission glycemia and triglycerides while in older patients these parameters resulted significantly reduced.

**Conclusions.** Lockdown may have negatively affected cardiovascular risk thus increasing the incidence of ACS, particularly in younger patients who probably underwent more relevant lifestyle changes, with several consequent anthropometric and metabolic alterations. Such evidences should be considered to take preventive measures in case a new state of emergency occur.

### P4

#### SICUREZZA E FATTIBILITÀ DELLA RIVASCOLARIZZAZIONE MIocardica PERCUTANEA STAGED SISTEMATICA NEL PAZIENTE CON CORONAROPATIA MULTIVASALE

Giuseppe Verolino, Dario Calderone, Davide Sala, Paolo Ghiso Basile, Roberto Latini, Paolo Sganzerla

IRCCS, Istituto Auxologico Italiano, Ospedale San Luca, Milano

**Introduzione.** Oltre il 50% dei pazienti che si presenta per una sindrome coronarica acuta (ACS) con soprasslivellamento del tratto ST (STEMI) sono affetti da una coronaropatia plurivasale. Questa ha una prevalenza ancora più elevata nei soggetti con ACS senza soprasslivellamento di ST (NSTEMI) e non è di infrequente riscontro nei soggetti che giungono a coronarografia nel quadro di una sindrome coronarica cronica (CCS). In tutte le situazioni cliniche sopramenzionate, una rivascularizzazione miocardica completa, anatomica e/o funzionale, è garanzia di una riduzione dei futuri eventi avversi cardiaci maggiori rispetto ad una rivascularizzazione parziale seguita da follow-up clinico. A tutt'oggi non

sono perfettamente chiari i migliori criteri temporali per completare la rivascularizzazione miocardica una volta stabilizzata la lesione colpevole, o quella a carico del vaso che sottende la maggior quantità di miocardio a rischio. Scopo del presente lavoro è l'illustrazione dell'esperienza di un singolo centro sull'esecuzione sistematica della rivascularizzazione staged nei pazienti affetti da coronaropatia multivasale.

**Metodi.** Nel 2022, 629 pazienti sono stati nel 2022 a coronarografia diagnostica presso l'ospedale San Luca di Milano; in caso di riscontro di malattia multivasale (>1 vaso con stenosi ≥75%) è stata adottata sistematicamente una strategia di staging della rivascularizzazione mediante una seconda procedura a distanza, effettuata in un secondo ricovero. In caso di presentazione clinica STEMI o UA/NSTEMI, nella prima procedura è stata trattata la lesione colpevole o con caratteristiche angiografiche di alto rischio (placca ulcerata e/o soft, presenza di trombo) e/o il vaso che sottendeva la maggior quantità di miocardio a rischio, rispettivamente.

**Risultati.** Nell'anno in esame sono state effettuate 799 procedure di PCI su 625 pazienti (299 con ACS, 326 con CCS). Di questi, sono risultati portatori di coronaropatia multivasale 175 pazienti (109 bivaso e 66 trivaso) che sono stati consecutivamente avviati ad una rivascularizzazione stadiata. Il 100% dei pazienti è stato dimesso dopo la prima procedura con duplice terapia antiaggregante e statina ad alto dosaggio. La seconda procedura di rivascularizzazione è stata effettuata ad una distanza mediana di 54 giorni. Durante questo intervallo di tempo non si è registrato alcun caso di morte né di stroke. 6 pazienti (3,6%), tutti con iniziale presentazione ACS, sono stati anticipatamente trattati (n.3 per NSTEMI, n.3 per angina instabile) rispetto alla data prevista per la PCI stadiata, a distanza mediana di 7 giorni dalla prima procedura. Tutti hanno ricevuto con successo il completamento di rivascularizzazione con buon risultato angiografico e senza alcuna sequela clinica negativa immediata.

**Conclusioni.** Una strategia di staging a distanza del completamento della rivascularizzazione miocardica percutanea in questa popolazione di soggetti si è dimostrata fattibile e sicura, consentendo anche il controllo dell'efficacia del primo trattamento in termini di pervietà del vaso e del suo effetto sulla funzione ventricolare (recupero o meno) e permettendo la valutazione degli effetti della terapia farmacologica ipolipemizzante di fondamentale importanza per la riduzione degli ulteriori eventi avversi futuri.

### P5

#### VARIABILITY OF TIME TO HEALING OF SPONTANEOUS CORONARY ARTERY DISSECTION ASSESSED THROUGH CORONARY COMPUTED TOMOGRAPHY ANGIOGRAPHY

Filippo Zilio, Marianna Mochen, Simone Muraglia, Marco Borghesi, Federico Zucchelli, Daniel Todaro, Eleonora Bonvicini, Fabiola Morat, Davide Giovannini, Michele Dallago, Giulia Casagrande, Roberto Bonmassari

Ospedale Santa Chiara, Trento

**Introduction.** Spontaneous coronary artery dissection (SCAD) results from a spontaneous, non-traumatic, and non-iatrogenic separation of the coronary arterial wall by intramural hematoma caused by intimal tear or spontaneous haemorrhage that is unrelated to atherosclerosis. SCAD is an important cause of myocardial infarction particularly in young to middle-aged women. Natural history of this condition is poorly understood: spontaneous healing has been demonstrated through coronary angiography in the vast majority of patients at long term follow-up, but the timing of healing is still not clear. Nowadays, coronary CT angiography (CCTA) is emerging as a noninvasive option to evaluate SCAD healing at least for coronary arteries with diameter ≥2 mm and could help in understanding the natural history of this condition.

**Methods.** In this single-centre, retrospective study, patients affected by SCAD between 2017 and 2022 were included. Patients with SCAD involving coronary arteries with diameter ≥2 mm who did not undergo percutaneous coronary intervention (PCI) and underwent to at least one CCTA during follow-up were evaluated with regard to evolution of SCAD and time to healing.

**Results.** Among 93 patients for whom diagnosis of SCAD was posed by coronary angiography, 33 conservatively managed patients (84.8% female, mean age 51.8±12.3 years) underwent to at least one CCTA during follow-up. At a median time of 49 days (IQR 13 to 82 days), a complete healing of SCAD was demonstrated in 6 patients (18.2%), while most of the patients showed a stability or partial healing and 1 patient (3.0%) an extension of SCAD. During further follow-up, of 10 patients who did not show a significant healing at the first CCTA, 4 patients showed a complete healing, while 6 patients showed a stability of SCAD extension or only partial healing at the longest available CCTA follow up (median follow-up 191 days, IQR 96 to 249 days). As regards clinical events, no death, myocardial infarctions, or target vessel PCIs were reported during follow-up.

**Conclusions.** Spontaneous healing is commonly seen in SCAD and can be demonstrated by CCTA. However, the timing of complete healing is largely variable between individuals: therefore, studies focusing factors impacting natural history of SCAD are needed.

## P6

### RIVAROXABAN AFTER TRANS-RADIAL CORONARY PROCEDURES: THE NUDGE THEORY APPLIED TO THE PREVENTION OF RADIAL ARTERY OCCLUSION?

Renzo Laborante<sup>1</sup>, Mattia Galli<sup>1</sup>, Emiliano Bianchini<sup>1</sup>, Marco Giovanni Mennuni<sup>1</sup>, Giuseppe Patti<sup>2</sup>, Domenico D'Amario<sup>2</sup>  
<sup>1</sup>Università Cattolica del Sacro Cuore, Roma, <sup>2</sup>Università del Piemonte Orientale, Novara

**Introduction.** Radial artery occlusion (RAO) represents the most common post-procedural complication after trans-radial access (TRA). We conducted a meta-analysis of all randomized controlled trials (RCTs), evaluating the postoperative use of rivaroxaban to prevent RAO after trans-radial coronary procedures.

**Methods.** PubMed and Scopus were searched from inception until April 24<sup>th</sup>, 2023. Studies were included if: 1) they were RCTs, 2) anticoagulant therapy was used after the coronary procedure, and 3) the rate of RAO was reported. The efficacy endpoint consisted of the incidence of RAO at 1 month, assessed by ultrasound examination of the wrist. Safety endpoints were: 1) the rate of hemorrhagic events at 1 month [defined according to the Bleeding Academic Research Consortium (BARC) criteria], and 2) the incidence of local complications on the puncture site (aneurysm, hematoma, arteriovenous fistula, and compartment syndrome).

**Results.** Out of 193 articles initially screened, 2 were included in the meta-analysis, with a total population of 903 patients. The drug investigated in both RCTs was rivaroxaban 10 mg once daily for 7 days after the coronary procedure. The rivaroxaban-treated group had a lower incidence of RAO at 1 month compared to the control group [risk ratio (RR) 0.50, 95% confidence interval (CI) 0.31-0.80, P<0.01; I<sup>2</sup>=0%], without a significant increase in both the incidence of bleeding (total and divided according to BARC criteria) and local complications.

**Conclusions.** Short-term use of rivaroxaban after a trans-radial coronary procedure may represent a hopeful approach to reduce the incidence of RAO, without evident safety issues. Further RCTs are needed to confirm these results.

## P7

### STEMI: ECG TRANSMISSION AND DOOR TO BALLOON

Yasser Odeh

Cardiologia, Ospedale degli Infermi di Rivoli, Rivoli

**Introduzione.** In Piemonte dal mese di Dicembre 2021 le unità operative del 118 hanno iniziato a trasmettere in telemedicina tramite il sistema Life Net gli elettrocardiogrammi (ECG) dei pazienti con sospetta sindrome coronarica acuta (SCA) direttamente alle unità di terapia intensiva coronarica (UTIC) dotate di Emodinamica. In letteratura vi è solida evidenza che la riduzione del tempo "door-to-balloon" abbia un impatto sulla mortalità e la prognosi dei pazienti. Lo scopo della medicina territoriale e degli ospedali dovrebbe basarsi su una stretta collaborazione per favorire un tempo "door-to-balloon" più limitato possibile. Abbiamo pertanto valutato l'impatto della teletrasmissione degli ECG nella riduzione delle tempistiche di rivascolarizzazione nell'infarto miocardico con soprasslivellamento del tratto ST (STEMI) ed il conseguente impatto clinico e prognostico.

**Metodi.** L'endpoint primario dello studio era il tempo "door-to-balloon" dei pazienti con sospetto STEMI in cui l'ECG è stato teletraspresso (T-STEMI), che quindi accedevano direttamente al laboratorio di emodinamica (LE) senza transitare dal Dipartimento di Emergenza e Accettazione (DEA), rispetto al tempo "door-to-balloon" dei pazienti in cui la diagnosi di STEMI veniva fatta in DEA e che solo successivamente accedevano in emodinamica (Non-T-STEMI). L'endpoint secondario era il grado di risoluzione del tratto ST dopo angioplastica primaria rispetto all'ECG di presentazione.

**Risultati.** Nel periodo compreso dal 01/12/2021 al 01/05/2023 sono stati retrospettivamente arruolati i pazienti che accedevano alla Sala di Emodinamica di due Centri (Ospedale degli Infermi di Rivoli e Ospedale Mauriziano Umberto I di Torino) per STEMI. In totale 142 pazienti sono stati arruolati nel gruppo T-STEMI e 268 pazienti sono stati arruolati nel gruppo Non-T-STEMI. L'endpoint primario di tempo "door-to-balloon" medio è stato di 37 minuti nel gruppo T-STEMI e 71 minuti nel gruppo non T-STEMI (p<0.001). Per quanto riguarda l'endpoint secondario, il gruppo T-STEMI ha avuto una regressione media del soprasslivellamento del tratto ST del 66% rispetto al 58% del gruppo Non-T-STEMI (p=0.2).

**Conclusioni.** La nostra esperienza dimostra la fattibilità e l'efficacia di un sistema di teletrasmissione nella riduzione del tempo "door-to-balloon" in pazienti con diagnosi di infarto miocardico acuto sul territorio; notiamo percentuali maggiori di regressione del tratto ST sempre nei pazienti il cui ECG è stato teletraspresso che però non raggiungono una significatività statistica data anche l'esiguità del campione preso in esame. Il nostro studio evidenzia l'importanza della stretta collaborazione tra emergenza territoriale ed ospedaliera ed allo stesso tempo anche l'ampio margine di lavoro che va fatto per implementare il sistema di teletrasmissione.

## P8

### COMPARISON OF SUTURE-BASED AND PLUG-BASED VASCULAR CLOSURE DEVICES FOR DELAYED HEMOSTASIS OF LARGE BORE ACCESS AFTER IMPELLA CP REMOVAL: A RETROSPECTIVE OBSERVATIONAL STUDY

Elisa Nicolini, Alessandro Maolo, Margherita Mariottini, Tommaso Piva  
SOSD Emodinamica Interventistica, Strutturale e Pediatrica, Ospedali Riuniti Ancona, Ancona

**Introduction.** P-VAD Impella CP is a valuable treatment option for patients in cardiogenic shock, but it is associated with a substantial risk of vascular and bleeding complications, during insertion, maintenance and, most of all, during removal and hemostasis achievement. Therefore, the aim of this study was to compare the efficacy and safety of suture-based to plug-based vascular closure device for delayed hemostasis of large bore access after Impella CP removal.

**Methods.** In this retrospective study, the procedural and intra-hospital outcome of 40 patients with suture-based devices, Prostar XL and Perclose Proglide, was compared to 25 patients with MANTA plug-based closure devices. Technical success was defined as access-site hemostasis in absence of major BARC bleeding (Bleeding Academic Research Consortium) or major and minor vascular complications (according to VARC3 criteria) and not requiring any additional intervention within 30 days of the index procedure.

**Results.** In 58 patients the Impella CP device was placed for cardiogenic shock (CS), 12 patients were in pre-shock and acute heart failure at admission and 2 patients with acute heart failure underwent elective placement for a high-risk PCI. Most of the patients (n=60) received an Impella CP, 5 an Impella 2.5 and 9 required an escalation to ECMO support. Coronary angiography (65/65) and subsequent PCI (55/65) was performed in the majority of patients; 3 patients received concomitant aortic balloon valvuloplasty. The Impella device was implanted before PCI in 79.5%. The median duration of Impella support was 138 hours (interquartile range 69-213). Overall, the rate of in-hospital mortality was 21%. Median in-hospital stay was 27 days (IQR: 22-40 days). Rate of technically correct placement of closure devices was 82% in the suture-based group and 100% in the plug-based group (p<0.05). There was a significant reduction of severe bleeding complications (p=0.039) and significant shorter time to hemostasis (p=0.002) in plug-based vs suture-based system. No ischemic complications occurred in both group nor significant vessel stenosis. A Doppler ultrasonography exam was performed routinely before discharge in all patients and confirmed vessel integrity. Two major vascular complications related to VCD failure occurred in suture-based group: in one case a covered stent was successfully implanted, in the other one switch to vascular surgery was deemed necessary due to VCD failure and femoral artery injury in a patient in whom Impella device was left in place for 8 days.

**Conclusions.** Delayed hemostasis of large bore access with percutaneous vascular closure devices after Impella CP removal appears feasible. In this single center experience, the use of plug-based VCD devices appears to be safer and more effective compared to suture-based devices to achieve hemostasis. This hypothesis should be further tested in a randomized trial.

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## P9

### ANGIOGrafo SIEMENS ARTIS VD11 ED IL PROTOCOLLO CLEARstent NELL'ESECUZIONE DI ANGIOPLASTICA CORONARICA PERCUTANEA: ESPERIENZE DI PRESIDIO LUCANIA (SA)

Nicola Ragosa, Antonio Aloia, Antonio Di Lascio, Filippo Marco Tambasco, Antonio Carmine Elia, Antonietta Sacco, Lucio Carotenuto, Gianfranco Lerro, Martina Mautone, Gianluca Di Sevo, Giovanni Manganiello  
U.O.C Cardiologia, P.O San Luca Vallo della Lucania-ASL Salerno, Vallo della Lucania

**Obiettivi.** L'utilizzo delle funzioni di immagine CLEARstent consente di evidenziare strutture fini, ad esempio l'espansione di uno stent. Vengono create immagini composite eseguendo la media di diversi fotogrammi di una scena e considerando l'allineamento dei marker di uno stent. Se è disponibile un segnale ECG, viene considerata anche la fase cardiaca. L'utilizzo della funzione CLEARstent consente di creare speciali immagini di riferimento da qualsiasi scena o da scena fluoroscopica acquisita nativamente. L'obiettivo delle immagini CLEARstent vuole essere quello di ottimizzare il risultato procedurale di una rivascolarizzazione cardiaca meccanica e di migliorare gli outcome dei pazienti trattati.

**Metodi.** L'utilizzo dell'angiografo Siemens Artis VD11 richiede specifiche conoscenze e competenze tecniche e mediche riguardanti, almeno, protezione dalle radiazioni, procedure di sicurezza e sicurezza del paziente. Le persone che lavorano con il sistema, che lo utilizzano e che lo spostano devono aver acquisito tali conoscenze e competenze nella loro vita lavorativa. L'addestramento applicativo è stato fornito al personale medico-tecnico-infermieristico dell'U.O di Emodinamica del P.O

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"San Luca" di Vallo della Lucania da personale Siemens qualificato. L'addestramento applicativo offerto da Siemens è vincolante prima di qualsiasi utilizzo del sistema.

**Risultati.** Sono state eseguite, presso la nostra U.O di Emodinamica, nel periodo che va dal 27-11-2021 al 21-12-2022, periodo di utilizzo di suddetto angiografo, 604 procedure di angiografia coronarica e 101 rivascularizzazioni in regime urgenza (STEMI-NSTEMI ad alto rischio). In tutte le procedure di rivascularizzazione miocardica meccanica l'apertura ed il posizionamento ottimale degli stent coronarici sono stati verificati con il sistema CLEARstent. Non si è registrata nessuna complicanza periprocedurale.

**Conclusioni.** Il sistema CLEARstent dell'angiografo Siemens Artis VD11 consente di evidenziare strutture fini, ad esempio stent ipoespansi creando speciali immagini di riferimento da qualsiasi scena fluoroscopica acquisita negativamente consentendo, di conseguenza, un ottimale posizionamento ed apertura di uno stent coronarico. Si inserisce, pertanto, insieme alle tecniche di imaging intracoronarico (IVUS, OCT) come ausilio ulteriore per guidare gli interventi percutanei al fine ultimo di ottimizzare il risultato procedurale acuto della PCI e nel migliorare gli outcome clinici dei pazienti trattati.

### P10

#### RIVASCARIZZAZIONE MIOCARDICA PERCUTANEA GUIDATA DALLA VALUTAZIONE FUNZIONALE MEDIANTE FFR: ESPERIENZA DI PRESIDIO

Nicola Ragosa, Antonio Aloia, Antonio Di Lascio, Aniello Carbone, Antonio Carmine Elia, Antonietta Sacco, Lucio Carotenuto, Filippo Marco Tambasco, Gianfranco Lerro, Martina Mautone, Gianluca Di Sevo, Giovanni Manganiello

<sup>1</sup>U.O.C Cardiologia, P.O San Luca Vallo della Lucania-ASL Salerno, Vallo della Lucania

**Obiettivi.** La presenza di ischemia miocardica influenza significativamente la prognosi dei pazienti affetti da malattia aterosclerotica coronarica. La riserva frazionale di flusso coronarico (FFR) fornisce ai cardiologi interventisti la possibilità di identificare le stenosi coronariche associate alla presenza di ischemia inducibile e, quindi, di valutarne il trattamento più appropriato. Le informazioni ottenibili con l'indagine FFR, in molti contesti clinici ed angiografici, sono cruciali nella pianificazione di una procedura di rivascularizzazione percutanea coronarica. Questo strumento permette di identificare immediatamente la criticità funzionale di una lesione evitando di dover ricorrere all'esecuzione di test non invasivi (scintigrafia miocardica, ecocardiografia da stress, test ergometrico) per la ricerca di ischemia miocardica inducibile/ridotta riserva coronarica. Il trattamento dei sintomi (angina) e la riduzione della quota di ischemia miocardica inducibile sono gli obiettivi principali della procedura coronarica percutanea (PCI) nei pazienti affetti da coronaropatia.

**Metodi.** L'utilizzo della valutazione funzionale mediante FFR richiede specifiche conoscenze e competenze tecniche e mediche. Le persone che lavorano con il sistema, che lo utilizzano devono aver acquisito tali conoscenze e competenze nella loro vita lavorativa. L'addestramento applicativo è stato fornito al personale medico-tecnico-infermieristico dell'U.O di Emodinamica del P.O "San Luca" di Vallo della Lucania da personale Boston Scientific ed Abbott qualificato. L'addestramento applicativo è vincolante prima di qualsiasi utilizzo del sistema.

**Risultati.** Sono state eseguite, presso la nostra U.O di Emodinamica, nel periodo che va dal 01-01-2022 al 01-06-2023, 827 procedure di angiografia coronarica e 383 rivascularizzazioni. In 103 procedure di rivascularizzazione miocardica è stata utilizzata la valutazione funzionale (FFR, RFR Boston Scientific e/o FFR, DFR Abbott). Non si è registrata nessuna complicanza periprocedurale. Nessuno dei 103 pazienti andati incontro a rivascularizzazione miocardica percutanea guidata dalla valutazione funzionale ad oggi è stato riospedalizzato per sindrome coronarica acuta (STEMI, NSTEMI, Angina instabile).

**Conclusioni.** La FFR è la principale metodica validata che fornisce un dato funzionale nella valutazione delle stenosi coronariche all'interno del laboratorio di emodinamica. Nei pazienti con coronaropatia stabile permette di identificare con sicurezza e riproducibilità le lesioni che necessitano una rivascularizzazione meccanica da quelle che possono essere trattate con la sola terapia medica. Con opportuni accorgimenti la metodica FFR può essere utilizzata per valutare qualsiasi tipo di lesione coronarica sia essa isolata o associata ad altre stenosi in vasi diversi, o nello stesso vaso. Da un punto di vista scientifico, la FFR ha dimostrato di essere sicura, efficace nella diagnosi e di garantire efficienza del percorso del paziente nel periodo di follow-up. Un utilizzo della FFR secondo le indicazioni delle linee guida internazionali assicura il trattamento ottimale per i pazienti con coronaropatia multi vasale.

### P11

#### INTRACORONARY LITHOTRIPSY IN PRIMARY PCI

Ciro Mauro, Davide D'Andrea, Fulvio Furbatto, Federica Serino, Gerardo Carpinella, Fulvio La Rocca, Fabio Massimo Esposito, Crescenzo Materazzi

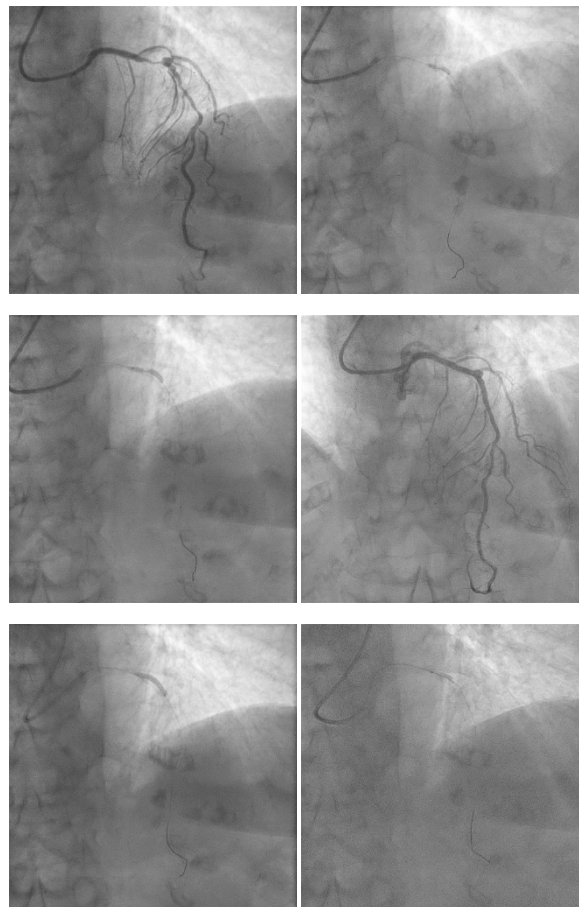
AORN A Cardarelli, Cardiologia - UTIC, Napoli

**Razionale.** Con l'allungamento dell'aspettativa di vita ed il progredire delle terapie di prevenzione e trattamento dei fattori di rischio cardiovascolare e dello scompenso cardiaco è in aumento la popolazione di ultraottantenni che vanno incontro a sindromi coronariche acute che necessitano del tempestivo trattamento percutaneo. In questa popolazione la patologia coronarica può assumere maggiore complessità.

**Risoluzione tecnica.** Il caso in questione si riferisce ad una donna, 93 anni, che accede presso la ns Emodinamica per STEMI anteriore. L'angiografia mostra una subocclusione trombotica di IVA, nel contesto di una severa patologia calcifica, indilatabile con palloni semicomplianti e non complianti di calibri crescenti. Solo il trattamento con litotrissia intracoronarica con catetere a palloncino Shockwave permette una corretta preparazione della lesione e il successivo ed efficace impianto di DES.

**Implicazioni cliniche.** Il ricovero è decorso in assenza di complicanze fino alla dimissione dopo 6 giorni dall'angioplastica primaria. Al follow-up ad un mese si registra un miglioramento della funzione sistolica globale, FE 50%, con acinesia del segmento apicale anteriore e settale.

**Prospettive.** Nel setting dello STEMI l'utilizzo di devices di debulking di lesioni calcifiche è previsto nell'1-2% dei casi. In alcuni pazienti e specialmente negli anziani o nei dializzati la sindrome coronarica acuta si iscrive su un quadro di severa patologia cronica calcifica. Considerando il progressivo aumento dell'età dei pazienti si prevede un aumento dell'utilizzo di questi sistemi, al fine di ottimizzare il risultato immediato e l'efficacia a lungo termine dell'angioplastica.



### P12

#### LEFT MAIN ANGIOPLASTY IN AN ELDERLY WOMAN

Elvira Verrengia

Ospedale Civile Santo Spirito, Pescara

**Introduzione.** La SCA-NSTEMI nel paziente molto anziano è frequente causa di mortalità soprattutto con il coinvolgimento del tronco comune. L'angioplastica del TC è mandatoria nel paziente in corso di sindrome coronarica acuta quando la chirurgia diventa proibitiva

**Metodi.** Il caso in questione riguarda una paziente anziana con sindrome coronarica acuta. Il quadro coronarografico ha evidenziato occlusione cronica dell'iva ostiale riabilitata da circolo eterocoronario dalla coronaria destra. Stenosi severa della circonflessa e del corpo del TC.

**Risultati.** Considerando l'età della paziente si è posto indicazione ad angioplastica TC-CX considerando il circolo collaterale proveniente da destra. Inaspettatamente in seguito a predilatazione sull'asse TC-CX si è determinato ripristino del flusso su ramo IVA (open sesame technique) pertanto è stata eseguita PTCA+stent sull'asse TC-IVA previo debulking con litotrixisia intracoronarica.

**Conclusioni.** L'angioplastica del TC è una procedura eseguibile anche nel paziente anziano. L'utilizzo di tecniche da CTO possono essere utili anche in condizioni ordinarie.

### CORONARY: ACUTE CORONARY SYNDROME, PHARMACOLOGY

#### P13

##### DANNO RENALE ACUTO DA MEZZO DI CONTRASTO: STUDIO OSSERVAZIONALE RETROSPETTIVO. IL FARMACISTA OSPEDALIERO IN COLLABORAZIONE CON L'EMODINAMICA

Caterina Fiazza<sup>1</sup>, Daniela Aschieri<sup>2</sup>, Guido Rusticali<sup>3</sup>, Alberto Monello<sup>2</sup>, Laura Donà<sup>1</sup>, Elena Siviero<sup>4</sup>

<sup>1</sup>Direzione Tecnica di Farmacia- Farmacia Ospedaliera, AUSL Piacenza, Piacenza, <sup>2</sup>UOC Cardiologia, AUSL Piacenza, Piacenza, <sup>3</sup>UOS Cardiologia Interventistica, AUSL Piacenza, Piacenza, <sup>4</sup>Scienze del Farmaco, Università di Pavia, Pavia

**Introduzione.** Le procedure interventistiche, che utilizzano lo iodio, sono un eccellente modello terapeutico per il trattamento delle malattie arteriose e coronariche. Dal momento che il numero di pazienti sottoposti a tali procedure sono in crescita, aumenta di conseguenza il rischio di danno renale acuto da mezzo di contrasto (contrast-induced acute kidney injury, CI-AKI). L'aumento dell'incidenza di tale fenomeno coinvolge anche il farmacista ospedaliero, in quanto esperto del farmaco e della farmacovigilanza.

**Metodi.** Tale studio osservazionale retrospettivo monocentrico ha preso in esame 159 pazienti ricoverati presso l'U.O. di Cardiologia dell'Ospedale Guglielmo da Saliceto. I pazienti arruolati sono di ambo i sessi, di età ≥18 anni, con consenso informato e con infarto miocardico acuto con sopraslivellamento del tratto ST (STEMI), dal 1° Gennaio 2021 al 31 Dicembre 2021. Lo studio verte intorno alla descrizione dello sviluppo di CI-AKI in una situazione di STEMI dopo somministrazione di mezzo di contrasto iodato (MCI). Per ogni paziente sono stati raccolti i seguenti dati: sesso, età, comorbidità, valori di creatinina, azotemia e velocità di filtrazione glomerulare pre e post procedura, tipo e volume di mezzo di contrasto, e la presenza di fattori di rischio. Sono state valutate le comorbidità pregresse e i fattori di rischio di ogni paziente in modo da individuare le cause che maggiormente hanno inciso sulla gravità della malattia, in aggiunta all'azione primaria.

**Risultati.** Sono stati considerati 159 pazienti di ambo i sessi con un'età media di 65 anni, di cui 8 sono deceduti e 10 non presentavano nessun fattore di rischio. I parametri analizzati dopo MCI sono creatinina sierica, azotemia, velocità di filtrazione glomerulare e fattori di rischio, come patologie pregresse. Alla luce dei dati raccolti, i pazienti che dopo 48 ore hanno mostrato danno renale acuto sono 19. L'analisi ha riscontrato una prevalenza di pazienti ipertesi (n=104), fumatori (n=71), affetti da dislipidemia (n=51), diabetici (n=34), obesi (n=30) e con insufficienza renale cronica (n=8).

**Conclusioni.** I fattori predisponenti che determinano una maggior incidenza nello sviluppo della patologia sono ipertensione, diabete e dislipidemia, e non fattori legati alla procedura o al farmaco. Non è stata visualizzata nessuna correlazione tra l'incidenza di CI-AKI e la dose di farmaco; la differenza è data dallo stato di salute del paziente.



#### P14

##### GLUTATHIONE INFUSION FOR COUNTERACTING CONTRAST-ASSOCIATED ACUTE KIDNEY INJURY IN PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION UNDERGOING PRIMARY PCI

Alessio Arrivi<sup>1</sup>, Amalia Morgantini<sup>2</sup>, Riccardo Rosati<sup>2</sup>, Giacomo Pucci<sup>3</sup>, Attilio Placanica<sup>4</sup>, Martina Sordi<sup>5</sup>, Carlo Bock<sup>1</sup>, Matteo Casavecchia<sup>1</sup>, Marco Bazzucchi<sup>1</sup>, Marcello Dominici<sup>1</sup>, Enrico Mangieri<sup>2</sup>, Gaetano Tanzilli<sup>2</sup>

<sup>1</sup>Interventional Cardiology Unit, S. Maria University Hospital, Terni, <sup>2</sup>Department of Clinical, Internal Medicine, Anesthesiology and Cardiovascular Sciences, Sapienza University of Rome, Policlinico Umberto I, Rome, <sup>3</sup>Unit of Internal Medicine, S. Maria University Hospital, Terni, <sup>4</sup>San Giovanni Evangelista Hospital, Tivoli, <sup>5</sup>S. Maria University Hospital, Terni

**Background.** Contrast-associated acute kidney injury (CA-AKI) is still a major concern for referring physicians, especially in the setting of ST-elevation myocardial infarction (STEMI) patients undergoing primary PCI (pPCI). To evaluate whether glutathione sodium salt (GSS) infusion impacts favorably on CA-AKI, an unplanned exploratory data analysis of the GSH 2014 trial was performed.

**Methods.** 100 patients with STEMI were assigned at random to an experimental group (n=50) or to a placebo group (n=50). Treatment consisted of an intravenous infusion of GSS lasting over 10 min before pPCI. The placebo group received the same quantity of normal saline solution. After the interventions, glutathione was administered in the same doses to both groups at 24, 48 and 72 hours.

**Results.** CA-AKI occurred in 5 out of 50 patients (10%) allocated to the experimental group (GSS infusion) and in 19 out of 50 patients (38%) allocated to the placebo group (p between groups <0.001). No patients in either group required renal replacement therapy. After allowing for multiple confounders, GSS administration (OR 0.17, 95% CI 0.04-0.61) and door-to-balloon time (in hours) (OR 1.61, 95% CI 1.01-2.58) have been the only independent predictors of CA-AKI.

**Conclusions.** The results of this sub-study, which show a significant trend towards an improved nephroprotection in the experimental group, led to the hypothesis of a possible new prophylactic approach to counteract CA-AKI using repeated GSS infusion. Subsequent studies with specific clinical outcomes would be necessary to confirm this data.

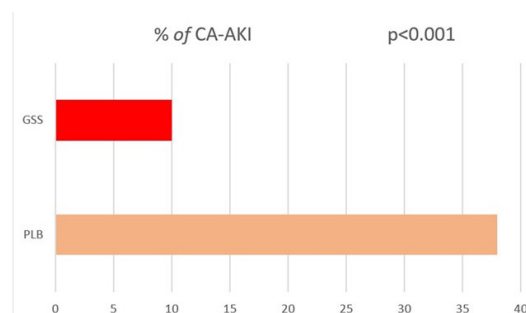


Figure 1. Proportion of contrast-associated acute kidney injury (CA-AKI) diagnosed among patients randomized to placebo (PLB) or glutathione sodium salt (GSL) infusion.

#### P15

##### SAFETY AND EFFICACY OF BEMPEDOIC ACID: A SYSTEMATIC REVIEW OF RANDOMIZED CONTROLLED TRIALS

Marco Nebiolo<sup>1,2</sup>, Ovidio De Filippo<sup>2</sup>, Federico Giacobbe<sup>1,2</sup>, Ilaria Pagliassotto<sup>1,2</sup>, Irene Borzillo<sup>1,2</sup>, Andrea Solano<sup>1,2</sup>, Emanuele Ravetti<sup>1,2</sup>, Mario Iannaccone<sup>3</sup>, Maurizio Bertaina<sup>3</sup>, Attilio Leone<sup>4</sup>, Silvia Monticone<sup>1</sup>, Maria Felice Brizzi<sup>5</sup>, Gaetano Maria De Ferrari<sup>1,2</sup>, Fabrizio D'Ascenzo<sup>1,2</sup>

<sup>1</sup>Department of Medical Sciences, University of Turin, Turin, <sup>2</sup>Division of Cardiology, Cardiovascular and Thoracic Department, Città della Salute e della Scienza Hospital, Turin, <sup>3</sup>Division of Cardiology, San Giovanni Bosco Hospital, ASL Città di Torino, Turin, <sup>4</sup>Department of Advanced Biomedical Sciences, University of Naples "Federico II", Naples, <sup>5</sup>Division of Internal Medicine and Hypertension, Department of Medical Sciences, University of Turin, Turin

**Introduction** Bempedoic acid (BA) is a novel lipid-lowering therapy (LLT). We performed a systematic review and meta-analysis to assess the efficacy and safety of BA in patients with hypercholesterolemia.

**Methods.** PubMed, Scopus, and Cochrane library databases were searched for randomised controlled trials evaluating the efficacy and/or safety of BA compared with placebo. Trials investigating dosages other than 180 mg/die were excluded. Major adverse cardiovascular events (MACE) were the primary efficacy endpoint. LDL-cholesterol reduction was the primary laboratory endpoint. Pre-specified safety endpoints included muscle-related adverse events, new-onset diabetes, and gout. The protocol was registered on PROSPERO (temporary ID:399867).

**Results.** Study search identified 275 deduplicated results. 11 studies, encompassing 18315 patients (9854 on BA vs 8461 on placebo/no treatment) were included. BA was associated with a reduced risk of MACE (OR 0.86, 95%CI 0.79-0.95), myocardial infarction (OR 0.76, 95% CI 0.64-0.88) and unstable angina (OR 0.69, 95% CI 0.54-0.88) compared to control, over a median follow up of 87 (15-162) weeks. BA was associated with a reduction of LDL-Cholesterol (mean difference [MD] -22.42, 95% CI -24.02% to -20.82%), total cholesterol (-16.50%, 95% CI -19.21% to -13.79%), Apo-B lipoprotein (-19.55%, 95% CI -22.68% to -16.42%) and high-sensitivity CRP (-27.83%, 95% CI -31.71% to -23.96%) at 12 weeks. BA was associated with a higher risk of gout (OR 1.55, 95%CI 1.27-1.90) as compared with placebo. Efficacy on laboratory endpoints was confirmed, with a variable extent, across patients on statin or ezetimibe background therapy.

**Conclusions.** The improved cholesterol control achieved with BA translates into a reduced risk of MACE, including myocardial infarction and coronary revascularisation. The drug has a satisfactory safety profile except for an increased risk of gout.

**CORONARY: CHRONIC CORONARY SYNDROME, PCI**

**P16**

**FULL ROBOTIC ENHANCEMENT FOR HYBRID CORONARY REVASCLARIZATION**

Giulia Botti<sup>1,2</sup>, Dario Bertolone<sup>2,3</sup>, Konstantinos Bermpeis<sup>2</sup>, Marta Belmonte<sup>2,3</sup>, Michele Mattia Viscusi<sup>2,3</sup>, Jeroen Sonck<sup>2</sup>, Bernard De Bruyne<sup>2,4</sup>, Alaide Chieffo<sup>1,5</sup>, Emanuele Barbato<sup>6</sup>, Frank Van Praet<sup>2</sup>, Eric Wyffels<sup>2</sup>

<sup>1</sup>Università Vita-Salute San Raffaele, Milano, <sup>2</sup>Cardiovascular Center Aalst, OLV-Clinic, Aalst, Belgium, <sup>3</sup>Università di Napoli Federico II, Napoli, <sup>4</sup>Lausanne University Hospital, Lausanne, Switzerland, <sup>5</sup>IRCCS Ospedale San Raffaele, Milano, <sup>6</sup>Università La Sapienza, Roma

**Introduction.** Hybrid coronary revascularization is an established approach to achieve a complete and durable treatment in multivessel coronary artery disease. Robotic enhancement (RE) or assistance (RA) both for minimally invasive direct coronary artery bypass (MIDCAB) and percutaneous coronary intervention (PCI) are emerging as feasible and reliable options to furtherly reduce surgical invasiveness on the one side, and potentially increase precision while minimizing professional radiation exposure on the other. The aim of this series is to assess the feasibility, in-hospital outcomes and 30-day outcomes of full robotic enhancement for hybrid coronary revascularization.

**Methods.** All patients who underwent RE-MIDCAB (robotically harvested and manually anastomosed left internal mammary artery - LIMA on the left anterior descending artery - LAD) + RA-PCI at our center were prospectively enrolled in an internal registry. Patients were considered eligible if undergoing RE-MIDCAB and RA-PCI within the same hospital stay or if RA-PCI was staged and performed through admission to the day-clinic. The primary objective was the evaluation of in-hospital outcomes; 30-day composite clinical and vessel-specific outcomes were also investigated.

**Table 1.** Procedural characteristics.

RE-MIDCAB	n=13
Operative time (min)	156 (IQR 130-167)
Need for cardiopulmonary bypass	-
Need for intraoperative inotropes	-
Conversion to manual	-
R-PCI	n=13
Procedural time (min)	52 ± 21.0
Radiation Dose (cGym2)	197 ± 169.44
Contrast (ml)	258±136.37
Conversion to manual or need for manual assistance	-
Any robotic malfunction	-
Multivessel PCI	3 (23.1)
Vessels treated	N = 18
LAD	-
LCX	8 (61.5)
Marginal	5 (38.5)
RCA	5 (38.5)
Bifurcation	4 (30.8)
Total stent number	1.62 ± 0.74
Total stent length	45 ± 33.2

**Table 2.** Outcomes.

In-hospital outcomes	n=13
Length of stay	
ICU stay (days)	1 (IQR 1-2)
Days between CABG and PCI	4 (IQR 3-9)
Hospital stay (days)	8 (IQR 6-10)
Same-day discharge (day of PCI)	4 (30.8)
Staged R-PCI	4 (30.8)
Death	-
Bleeding	1
Periprocedural MI	-
Stroke	-
Stent thrombosis	-
Medications at discharge	n=13
DAPT	13 (100)
Warfarin / NOAC	-
30-Day outcomes	n=13
Death, Bleeding, MI, Stroke,	-
Rehospitalization for angina	-
TVR, TLR, Stent thrombosis/ISR	-

**Results.** 13 patients underwent RE-MIDCAB + RA-PCI at our center from July 2021 to March 2023; 92% were male and the mean age was 67. Diagnostic angiography displayed a median of two diseased vessels per patient, a mean Syntax Score of 21.0, a mean fractional flow reserve (FFR) on the LAD of 0.75 and mean pullback pressure gradient (PPG) on the LAD of 0.46. Neither the RE-MIDCAB nor the RA-PCI required conversion to manual procedure, and no robotic malfunction was detected (Table 1). Median length of hospital stay was 8 days (IQR 6-10); median ICU stay was 1 day (IQR 1-2) and RA-PCI was performed 4 days after RE-MIDCAB, on average. PCI was staged in 30.8% of patients, for whom same day discharge was possible after PCI in all cases. The only reported complication during hospital stay was one access site bleeding requiring surgical revision. At 30-day follow-up no clinical nor vessel-specific complications were reported (Table 2).

**Conclusions.** Full robotic enhancement for hybrid coronary revascularization consistently proved to be a safe, reproducible and effective approach to achieve optimal complete revascularization in patients with multivessel coronary artery disease.

**P17**

**VALUE OF COLLATERAL GRADING SYSTEMS IN RETROGRADE PERCUTANEOUS CORONARY INTERVENTION OF CHRONIC TOTAL OCCLUSIONS: A COMPARISON OF THE J-CHANNEL SCORE, RENTROP CLASSIFICATION AND WERNER GRADE**

Rocco Giunta<sup>1</sup>, Mario Lombardi<sup>1</sup>, Alex Nap<sup>2</sup>, Yvemarie Somsen<sup>2</sup>, Gentian Gjermeni<sup>1</sup>, Martina Bongiovanni<sup>1</sup>, Giuseppe Migliore<sup>1</sup>, Paul Knaapen<sup>2</sup>, Alfredo Ruggero Galassi<sup>3</sup>, Carlo Cicerone<sup>1</sup>  
<sup>1</sup>Cardiologia, Ospedale Villa Sofia, Palermo, <sup>2</sup>Department of Cardiology Heart Center, Amsterdam UMC, Location Vrije Universiteit Amsterdam, Amsterdam, Netherlands, <sup>3</sup>AOU P. Giaccone, Palermo

**Introduction.** The Japanese Channel (J-Channel) score was introduced to aid in retrograde percutaneous coronary intervention (PCI) of chronic total coronary occlusions (CTOs). The predictive value of the J-Channel score has not been compared to other collateral grading systems such as the Rentrop classification and Werner grade. The aim of the study is to investigate the predictive value of the J-Channel score, Rentrop classification and Werner grade for successful collateral channel (CC) guidewire crossing and technical CTO PCI success.

**Methods.** A total of 600 prospectively recruited patients underwent single-vessel CTO PCI. All grading systems were assessed under dual catheter injection. CC guidewire crossing was considered successful if the guidewire reached the distal segment of the CTO vessel through a retrograde approach. Technical CTO PCI success was defined as Thrombolysis in Myocardial Infarction flow grade 3 and residual stenosis <30%.

**Results.** Of 600 patients, 262 (44%) underwent CTO PCI through a retrograde approach. Successful CC guidewire crossing was achieved in 211 (81%) patients. The J-Channel score showed a superior predictive value for CC guidewire crossing (AUC 0.735) compared to the Rentrop classification (0.674, p=0.04) and Werner grade (0.650, p=0.03). Technical CTO PCI success was reported in 236 (90%) subjects. The Rentrop classification exhibited a numerically higher discriminatory ability (0.699) compared to the J-Channel score (0.672) and Werner grade (0.583).

**Conclusions.** The J-Channel score aids in strategic collateral channel selection during retrograde CTO PCI. However, the J-Channel score, Rentrop classification and Werner grade have limited value in predicting technical CTO PCI success.

## CORONARY: DEB

## P18

## SAFETY AND EFFICACY OF DRUG-COATED BALLOONS FOR CORONARY BIFURCATION LESIONS: A SINGLE CENTER EXPERIENCE

Luigi Alberto Iossa<sup>1,2</sup>, Gabriele Venturi<sup>1</sup>, Margherita Fabroni<sup>1,2</sup>, Antonio Mugnolo<sup>1</sup>, Francesco Bacchion<sup>1</sup>, Alberto Zamboni<sup>1</sup>, Giorgio Morando<sup>1</sup>

<sup>1</sup>Dipartimento di Scienza Cardiovascolari, Ospedale Mater Salutaris, Legnago, <sup>2</sup>Dipartimento di Scienze Cardiovascolari, AOUI Verona, Verona

**Introduction.** Drug-coated balloons (DCB) represent an alternative to drug-eluting stents (DES). Their potential advantage has been advocated in particular for coronary sites where neointimal proliferation may limit the long-term benefit of angioplasty with stent implantation, such as in small vessels and bifurcations. However, evidence regarding their safety and efficacy for coronary bifurcation lesions (CBL) setting is still scarce.

**Methods.** In the present study, we present our experience with the use of DCB to treat CBL. We retrospectively analyzed our internal registry to retrieve all patients undergone to DCB angioplasty for CBL. We collected procedural and clinical as well as last available follow-up data. Our primary endpoint was procedural success defined as final TIMI flow 3, absence of residual stenosis >30% after DCB angioplasty and absence of bailout stent implantation. Our secondary endpoint was defined as MACCEs (death from any cause, nonfatal myocardial infarction, stroke or revascularization on lesion treated with DCB during index procedure) free survival at last available follow-up. Endpoint were analyzed separately for in-stent restenosis (ISR) and de novo lesions.

**Results.** From June 2017 to April 2023, 29 patients with CBL underwent DCB angioplasty addressing to 13 true bifurcations (Medina 1,1,1) and 16 non-true bifurcations. Fifteen CBL were ISR and 14 de novo lesions. Among non-true bifurcations, 2 patients presented Medina 1,1,0 and 2 patients Medina 1,0,0, 11 Medina 0,0,1 and 1 patient Medina 1,0,1. All DCB used were paclitaxel-coated balloon, and were applied only if lesion preparation was considered acceptable. In 4 cases cutting balloon to prepare the lesion was needed. The DCB ranged in diameter from 1.25 to 3.5 mm and varied in length between 15 to 30 mm. The minimum time of inflation was 60 s. Mean age was 66 years. Thirteen out of 29 patients underwent a revascularization procedure with the indication of myocardial infarction and 4 of those had ST-elevation myocardial infarction. In 2 cases, DCB did not guarantee an adequate TIMI flow, and implantation of DES was needed. In all other cases, we obtained a complete success with the restoration of TIMI 3 flow on all vessels treated (procedural success 93.1%). Excluding these 2 patients, we collected data at the follow-up from 21 patients, ranging from 1 month to 63 months and with a mean follow-up time of 25 months. Coronary angiography control was performed only if deemed by clinical indications. We could collect follow-up data for 11 out of 15 patients with ISR, with a mean follow-up time of 31 months. Two patients (18%) received myocardial revascularization for stable angina with a mean time of presentation of 11 months. All other patients presented event free survival (82% rate). Follow-up data were retrievable for 8 out of 14 patients with de novo lesions, with a mean follow-up time of 12 months. No patient received myocardial revascularization on segments treated with DCB during the index procedure. Events free survival for this group was 100%.

**Conclusions.** Our data support DCBs as valid alternative to DES in setting of CBL in terms of procedural efficacy and clinical follow-up, both in the case of ISR and de novo lesions. We acknowledge as limitation the simple size of our sample and the absence of follow-up data for a non-negligible portion of the patients.

## P19

## SINGLE CENTER EXPERIENCE WITH DRUG COATED-BALLOON IN STEMI PATIENT

Andrea Bottardi<sup>1</sup>, Gabriele Facci<sup>1</sup>, Gabriele Venturi<sup>2</sup>, Antonio Mugnolo<sup>2</sup>, Alberto Zamboni<sup>2</sup>, Francesco Bacchion<sup>2</sup>, Luigi Alberto Iossa<sup>1</sup>, Margherita Fabroni<sup>1</sup>, Giorgio Morando<sup>2</sup>

<sup>1</sup>University of Verona, Verona, <sup>2</sup>Mater Salutaris Hospital of Legnago, Legnago

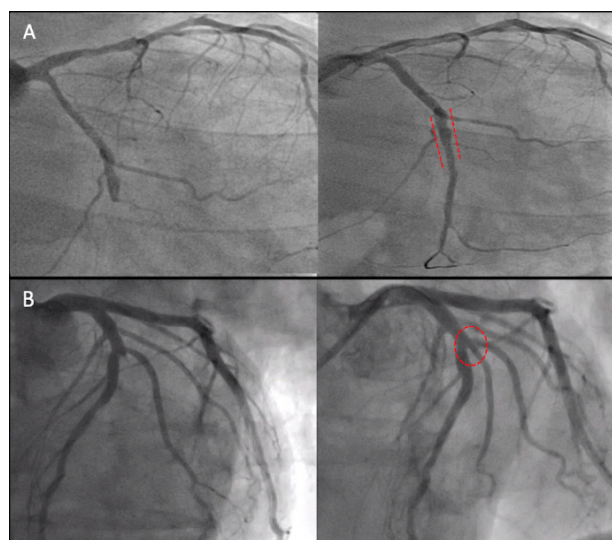
**Background.** Percutaneous coronary intervention (PCI) with drug-eluting stents (DES) is currently recommended as first choice in patients with AMI. However, bleeding risk due to dual antiplatelet therapy and increased by acute setting and the risk for early and late in stent restenosis (ISR) still raise some concerns in some particular settings. Drug-coated balloons (DCB), represent a possible alternative which could overcome these concerns and have gained discrete popularity in ISR, small vessel disease and bifurcation lesions. The aim of the present abstract was to show safety and outcome of DCB in the treatment of acute coronary syndrome with particular focus on STEMI patients.

**Methods.** We retrospectively investigated our internal registry between February 2019 and January 2023 to retrieve data about STEMI treated with DCB. Indication to DCB instead of stent depended on operators' preferences, based mostly on vessel diameter or anatomy complexity.

Culprit lesions were prepared with thromboaspiration when thrombus was visible after lesion crossing, followed by adequate predilatation. The aim of the study was to show procedural success and 6-month outcome in terms of major cardiac adverse events, target vessel revascularization, target lesion revascularization and target lesion thrombolysis.

**Results.** Between May 2018 and May 2023 11 patients with myocardial infarction and ST elevation were treated with primary PCI and DCB: four de novo lesions and six ISR. One patient with de novo lesion shifted to a stenting bailout strategy due to coronary dissection, leading to an overall procedural success rate of 90.9%. For all the remaining patients final angiography showed good result or DCB angioplasty with 3 TIMI flow. In-hospital survival was obtained by 10 out of 11 patients (90.9%): death occurred in only one patient with ISR and complex past medical history with three vessel coronary artery disease for cardiogenic shock the day after procedure. No MACCEs occurred at last available follow-up for the 10 patients (90.9% MACCEs free survival). No target lesion revascularization and no target vessel revascularization was reported.

**Conclusions.** Among our single center experience, DCB proved to be an effective strategy for AMI culprit lesion revascularization, with overall good procedural success and mid-term outcome. However, when applied in the context of de novo lesion, dissection and late restenosis can occur. This register presents the limitations of a small sample and a short period of follow-up, therefore needing further validation.



**Figure 1.** Two cases of pPCI treated with DCB strategy and their good angiography results. (A) Thrombotic occlusion of the circumflex coronary artery. (B) Occlusion of diagonal branch in the left anterior descending trifurcation.

## P20

## TO CUT OR NOT TO CUT: CUTTING BALLOON FOR LESION PREPARATION BEFORE DRUG-COATED BALLOON ANGIOPLASTY

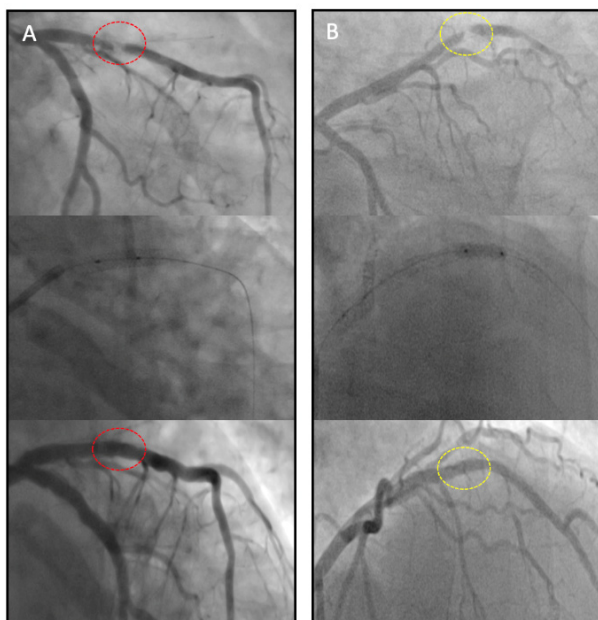
Gabriele Facci<sup>1</sup>, Andrea Bottardi<sup>1</sup>, Gabriele Venturi<sup>2</sup>, Antonio Mugnolo<sup>2</sup>, Francesco Bacchion<sup>2</sup>, Alberto Zamboni<sup>2</sup>, Giorgio Morando<sup>2</sup>

<sup>1</sup>Division of Cardiology, Department of Medicine, Verona University Hospital, Verona, <sup>2</sup>Division of Cardiology, Mater Salutaris Hospital, Legnago

**Introduction.** There are limited data on the use of drug-coated balloon (DCB) in calcified lesions. In particular, evidence regarding the use of cutting balloon before DCB angioplasty is scarce.

**Methods.** We retrospectively analyzed our internal registry between May 2017 and May 2023 to retrieve intrastent restenosis (ISR) angioplasty performed with DCB. We divided our population according to the use of cutting balloon as debulking technique before DCB. The objective of the study was to compare the two population in term of procedural success (primary endpoint defined as absence of flow-limiting dissection or residual stenosis >30% or bail-out to stent strategy) and 6 months target lesion revascularization (TLR) (secondary endpoint).

**Results** Between May 2017 and May 2023, 106 ISR were treated with DCB-angioplasty at our center: 24 were prepared with cutting-balloon, mostly because of high calcification burden, while 82 only with conventional NC balloon before DCB strategy. Procedural success was achieved in all patients analyzed (100%). Therefore, there were no differences in procedural success between the two groups. In the cutting balloon group, mainly for unstable angina, a new angiography was performed for 4 patients: one underwent target vessel revascularization (4.1%) while three target lesion revascularizations (12.5%). In the second group, 7 out of 82 presented stable angina and needed new angiography resulting in target lesion revascularization (9.1%) due to severe ISR (2 underwent surgical revascularization, 5 percutaneous with DCB). Therefore, cutting balloon was not associated with increased target lesion revascularization (TLR) (HR 2.7; 95% CI 0.70-10.52; p=0.147).



**Figure 1.** (A) A series showing focal ISR of proximal LAD resulting into subocclusive disease, a lesion successfully prepared with cutting balloon and treated with DCB delivery. The last frame shows an optimal angiographic result. (B) Another LAD mid ISR successfully treated with cutting balloon, followed by DCB delivery.

**Conclusions.** Lesion preparation with cutting balloon represents a valid strategy in the setting of in-stent restenosis before DCB angioplasty in terms of procedural success and 6-month risk for target lesion revascularization. Our single-center registry presents the limitation of a small number which did not allow for any adjustment and a short follow-up period but provides an overview of a real-world experience.

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**P21**

**CORONARY IMAGING IN PERCUTANEOUS CORONARY INTERVENTIONS WITH DRUG-COATED BALLOONS: TEMPORAL TRENDS AND OUTCOMES IMPLICATIONS FROM A SINGLE CENTER EXPERIENCE**

Alessandro Carli<sup>1,2</sup>, Rocco Gioscia<sup>3</sup>, Monica Verdoia<sup>3</sup>, Andrea Rognoni<sup>3</sup>, Giuseppe Patti<sup>1,2</sup>  
<sup>1</sup>Cardiologia, AOU Maggiore della Carità, Novara, <sup>2</sup>Università del Piemonte Orientale, Novara, <sup>3</sup>Cardiologia, Ospedale degli Infermi - ASL Biella, Biella

**Introduction.** Percutaneous coronary intervention (PCI) is the most used technique to treat coronary disease so far. Despite technological improvements, thrombotic and restenotic complications caused by the continuous insult on the endothelium from the foreign stent body still burden long term prognosis. Drug eluting balloons (DEB) have been proposed as safe and effective alternative to drug-eluting stents, especially in particular coronary anatomies and lesions, progressively expanding their indications. While the usefulness of intracoronary imaging to optimize stent implantation has been extensively demonstrated, few data are available with DEB. The aim of this paper was to investigate the temporal trends and utilization of intracoronary imaging in consecutive patients undergoing PCI with DEB; and their impact on the outcomes.

**Methods.** We extracted data from our multicentric, real-life, observational registry of all patients undergoing coronary angiography from 2015 to 2021 including consecutive patients undergoing PCI with DEB for de-novo lesions or in-stent restenosis. Patients were analyzed according to the use of intracoronary imaging. Primary outcome endpoint was the occurrence of major cardiovascular ischemic events (MACE). Secondary endpoints were overall death and target vessel revascularization (TVR).

**Results.** We included 379 patients treated with drug-eluting balloons, among them 25 (6.59%) had an imaging-guided PCI. No clinical difference was observed according to imaging use, whereas lower rates of calcifications (p=0.02), higher use of post-dilatation (p=0.02) and higher percentage of stenosis (p=0.04) were observed in the imaging group. A progressive increase in the utilization of imaging was observed up to 2018, therefore reaching a plateau, reflecting the proportion between PCI

on restenosis or de-novo lesions. At a median follow-up of 670 days, MACE were observed in 77 (22.3%) of the patients. A trend for higher rate of MACE (25% vs 22%) and a significant increase in TVR (29% vs 19%) were observed in patients treated with imaging-guided PCI, that were confirmed after correction for baseline differences (adjusted OR [95%CI] 2.24 [0.95-5.29], p=0.07 and adjusted OR [95%CI] 3[1.34-6.8], p=0.01). Similar results were observed for de-novo lesions and restenosis.

**Conclusions.** The present study shows that among patients treated with DEB for de-novo or restenotic lesions, the use of intracoronary imaging is still low, and mainly reflects the type of treated lesion. A negative prognostic impact was associated with the use of intracoronary imaging, probably reflecting a higher lesion complexity. However, future randomized trials should evaluate the role of imaging in PCI with DEB.

**P22**

**IMPACT OF BAIL-OUT STENTING AFTER DRUG-COATED BALLOON IN DE NOVO SMALL VESSELS PERCUTANEOUS CORONARY ANGIOPLASTY: A SINGLE CENTER EXPERIENCE**

Francesco Palermo, Alessandro Mazzapicchi, Gabriele Ghetti  
 Sant'Orsola, Bologna

**Introduction.** De novo drug-coating balloon (DCB) percutaneous coronary angioplasty (PCI) is comparable to drug eluting stent (DES) PCI and it seems superior in terms of major adverse cardiac events (MACE) in small vessels disease. Nevertheless de novo DCB PCI is affected by a not negligible bail-out stent (BOS) rate. In randomized controlled trials, BOS in small vessels PCI showed two times more MACE in confront of DCB only PCI or DES only PCI arm, without a significant difference probably due to the small amount of case. The aim of this registry is to investigate if the BOS technique is associated to higher risk of 1-year target vessel failure (TVF).

**Methods.** All consecutive de novo DCB PCI patients have been included from January 2020 and December 2022. BOS was done according international consensus statement. The rate of bail-out stent was 15% for all lesion. In case of BOS in at least one lesion the patient was allocated in BOS arm, otherwise in DCB only group. The primary endpoint was 1-year TVF; this is a composite endpoint of cardiac death, target vessel myocardial infarction (TV-MI), clinically driven target vessel revascularization, angiographic restenosis.

**Results.** A total of 233 patient were included; 192 patients in DCB only group and 41 patients in BOS group. Table 1 shows baseline clinical and laboratory features. On multivariate analysis, the only independent predictor of 1-year TVF is bail-out DES implantation (OR 3.35, 95% CI 1.18-9.50, p=0.02) (Table 2).

**Table 1.** Clinical and laboratory features.

	no BOS	BOS	p
Age	72,0 ± 11,8	69,6 ± 10,8	0.22
BMI	26,9 ± 4,1	27,6 ± 3,7	0.05
Gender (male) n (%)	47 (24,5)	6 (14,6)	0.17
Hypertension, n (%)	154 (81,0)	30 (73,2)	0.26
Dyslipidemia, n (%)	142 (74,7)	34 (82,9)	0.26
Current or ex smoker, n (%)	98 (51,5)	25 (60,9)	0.36
Diabetes, n (%)	72 (38)	14 (34)	0.65
Family history, n (%)	35 (18)	8 (20)	0.87
Clinical presentation, n (%)			0.33
stable CAD	62 (33)	12 (29)	
Unstable Angina	24 (13)	7 (17)	
NSTEMI	63 (33)	18 (44)	
STEMI	41 (21)	4 (10)	
Subacute myocardial infarction	2 (1)	0 (0)	
Severe valvular disease, n (%)			0.42
Aortic stenosis	11 (5,7)	0 (0)	
Mitral regurgitation	9 (4,7)	1 (2,4)	
Any others	4 (2,1)	1 (2,4)	
EF (%)	53 ± 12	53 ± 12	0.94
Syntax score	19 ± 11	19 ± 12	0.72
Number vessels disease, n (%)			0.65
1	53 (28)	9 (22)	
2	68 (35)	14 (34)	
3	71 (37)	18 (44)	
Number of treated vessels, n (%)			0.79

1	143 (75)	33 (81)	
2	38 (20)	6 (15)	
3	11 (6)	2 (5)	
Lesion type according to ACC/AHA classification, n (%)			
A	30 (16)	3 (7)	
B1	78 (41)	12 (29)	
B2	69 (36)	18 (44)	
C	15 (8)	8 (20)	
CTO lesions, n (%)	9 (5)	3 (7)	0.49
Bi-trifurcation, n (%)	95 (50)	20 (49)	0.94
DES in other vessel, n (%)	143 (75)	37 (90)	0.03
Hb (g/dL)	12.8 ± 1.8	13.2 ± 2.1	0.10
Creatinin (mg/dL)	1.3 ± 1.4	1.3 ± 1.0	0.43
DAPT, n (%)			
Clopidogrel	120 (64)	23 (56)	
another P2Y12	46 (25)	11 (27)	
Triple therapy	21 (11)	7 (17)	
Beta-blocker, n (%)	156 (83)	35 (85)	0.71
Lipid lowering drugs, n (%)	184 (98)	39 (95)	0.46
RAAS inhibitor drugs, n (%)	147 (78)	35 (86)	0.37
Glyphosine, n (%)	13 (7)	2 (5)	0.63

BOS: bail-out stenting, BMI: body mass index, CAD: chronic artery disease, NSTEMI: no ST elevation myocardial infarction, STEMI: ST elevation myocardial infarction, EF: ejection fraction, ACC/AHA = american college of cardiology/american heart association, CTO = chronic total occlusion, DES = drug eluting stent, Hb = Hemoglobin, DAPT = dual antiplatelet therapy, RAAS renin-angiotensin aldosterone system.

Table 2. Multivariate analysis.

	OR	CI 95%	P
BOS	3.35	1.18 – 9.50	0.02
DES in other vessel	1.04	0.26 – 4.13	0.95
BMI	0.99	0.88 – 1.12	0.87
ACC/AHA Classification			
A	0.67	0.11 – 4.04	0.66
B	1.18	0.21 – 6.47	0.85
C	3.32	0.53 – 20.62	0.20

OR = odds ratio, CI: confidence interval, BOS = bail-out stenting, DES: drug eluting stent, BMI = body mass index, ACC/AHA = american college of cardiology/american heart association

**Conclusion.** Bail-out stenting in de novo DCB PCI is an independent predictor of target vessel failure at 1 year from the index procedure.

## P23

### DATI DA 5 ANNI DI ESPERIENZA DEL REGISTRO SCOUT (SIROLIMUS COATED BALLOON USE IN TRAPANI)

Dario Buccheri, Luigi Priolo, Stefano Cangemi, Daniele Vinci  
UOS Emodinamica, PO Sant'Antonio Abate di Trapani, Trapani

**Introduzione.** L'angioplastica coronarica con impiego di pallone medicato ha guadagnato crescente interesse negli ultimi anni, rappresentando classicamente una possibile strategia per il trattamento della restenosi o delle lesioni di piccoli vasi, oppure come di recente proposto in alcuni trial per il trattamento di lesioni coronariche de novo non solo di piccoli vasi.

**Metodi.** Si presenta la casistica monocentrico dell'U.O.S. di Emodinamica del P.O. "Sant'Antonio Abate" di Trapani relativa ad angioplastica coronarica con impiego di pallone medicato al sirolimus, coinvolgente pazienti arruolati nel registro osservazionale "Eastbourne" e nel trial clinico randomizzato "TRANSFORM II".

**Risultati.** In un totale di 56 pazienti sono state trattate lesioni coronariche da restenosi intrastent, lesioni coronariche de novo su piccoli vasi, lesioni coronariche de novo su vasi di medio calibro nell'ambito del trial clinico randomizzato "TRANSFORM II". Non si sono verificate complicanze procedurali maggiori; in circa il 10% dei casi si è reso necessario ultimare la procedura con impianto di stent, ottenendo il successo angiografico finale nella totalità delle procedure. Si è svolto regolarmente il follow-up (per lo più clinico) dei pazienti coinvolti, registrando risultati in linea con i dati di letteratura. In particolare l'eventuale dissezione non flusso limitante della lesione trattata con pallone medicato ha dimostrato stabilità clinica ed angiografica nei casi controllati con coronarografia.

**Conclusioni.** La nostra casistica di angioplastica coronarica con impiego di pallone medicato al sirolimus mostra buoni risultati procedurali ed al

follow-up, in linea con i dati di letteratura; nella nostra esperienza tali risultati favorevoli, non solo nelle lesioni coronariche da restenosi, motivano il crescente impiego di tale device nell'interventistica coronarica.

## CORONARY: DES

### P24

#### RUOLO DEGLI STENT MEDICATI SENZA POLIMERO NEI PAZIENTI DIABETICI INSULINO-DIPENDENTI SOTTOPOSTI A RIVASCOLARIZZAZIONE CORONARICA PERCUTANEA: UNO STUDIO OSSERVAZIONALE MONOCENTRICO

Filippo Luca Gurgoglione<sup>1</sup>, Giorgio Benatti<sup>1</sup>, Luigi Vignali<sup>1</sup>, Iacopo Tadonio<sup>1</sup>, Emilia Solinas<sup>1</sup>, Andrea Denegri<sup>1</sup>, Marco Covani<sup>1</sup>, Mattia De Gregorio<sup>1</sup>, Diego Ardisino<sup>1</sup>, Francesco Nicolini<sup>2</sup>, Giampaolo Niccoli<sup>1</sup>

<sup>1</sup>UOC Cardiologia, Azienda Ospedaliero-Universitaria di Parma, Parma, <sup>2</sup>UOC Cardiocirurgia, Azienda Ospedaliero-Universitaria di Parma, Parma

**Introduzione.** I pazienti affetti da diabete mellito (DM), in particolare insulino-dipendente, e malattia aterosclerotica coronarica (CAD), presentano una maggior necessità di rivascularizzazione coronarica percutanea (PCI) e una maggior incidenza a distanza di failure di PCI. Recentemente, gli stent medicati senza polimero (PF-DES) hanno dimostrato fornire vantaggi in termini meccanistici comparati ai DES con polimero permanente (PP-DES) o biodegradabile (BP-DES). Tuttavia, studi di outcome hanno fornito risultati contrastanti nei pazienti privi di DM e nella popolazione con DM. Obiettivo del presente studio è comparare l'efficacia dei PF-DES vs PP/BP-DES, in una coorte di pazienti affetti da DM insulino-dipendente, ovvero la coorte di pazienti a maggior rischio di failure di PCI.

**Metodi.** Abbiamo condotto uno studio osservazionale monocentrico retrospettivo-prospettivo, includendo tutti i pazienti consecutivi affetti da DM insulino-dipendente e concomitante CAD e sottoposti a PCI con impianto di DES presso il Laboratorio di Emodinamica dell'Azienda Ospedaliero-Universitaria di Parma da gennaio 2018 a marzo 2023. La popolazione in studio è stata suddivisa in due gruppi a seconda del tipo di DES adoperato: PF-DES vs PP/BP-DES. Di tutti i pazienti sono stati raccolti i dati clinico-laboratoristici, angiografici e l'anamnesi farmacologica al momento dell'ospedalizzazione ed è stato effettuato un follow-up tramite colloquio telefonico e/o controllo clinico. L'endpoint primario è stato l'incidenza di target vessel failure (TVF), endpoint composito che comprendeva le morti per cause cardiovascolari (CV), l'occorrenza di infarto miocardico (IMA) non fatale e le rivascularizzazioni nel vaso target (TVR).

**Risultati.** Abbiamo incluso un totale di 132 pazienti, di cui 44 (33.3%) pazienti sono stati inclusi nel gruppo PF-DES, 88 (66.7%) nel gruppo PP/BP-DES. Al follow-up mediano di 34 mesi, il TVF è stato riscontrato in 24 [18.2%] pazienti. Nel dettaglio, si sono verificate 8 [6,1%] morti per cause CV, 14 [10.6%] IMA non fatali e 16 [12.1%] TVR. Non sono state riscontrate differenze riguardo l'endpoint primario di TVF nei due gruppi in studio (11.4% nel gruppo PF-DES vs 21.6% nel gruppo PP/BP-DES; p=0.151), mentre il gruppo PF-DES si associava ad un minor incidenza di TVR (4.5% nel gruppo PF-DES vs 15.9% nel gruppo PP/BP-DES; p=0.047) (Figura 1). Infine, la comparazione delle curve di Kaplan-Meier mediante log-rank test ha mostrato che il gruppo PF-DES presentava un trend verso una maggior libertà da TVF (p=0.055) rispetto al gruppo PP/BP-DES e una maggior libertà da TVR (p=0.025) rispetto al gruppo PP/BP-DES.

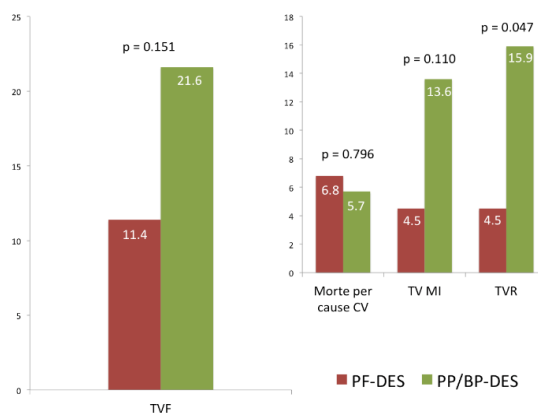


Figura 1. Dati di outcome al follow-up nei due gruppi di studio.

CV, Cardiovascolare; MI, infarto miocardico; PF/PP/BP-DES, stent medicato senza polimero/con polimero permanente/con polimero biodegradabile; TVF, failure nel vaso target; TVR, rivascularizzazione del vaso target.

**Conclusioni.** Il nostro studio ha dimostrato che, all'interno di una coorte di pazienti affetti da DM insulino-dipendente e concomitante CAD sottoposti a PCI, la strategia PF-DES, comparata con i PP/BP-DES, si associa ad una riduzione della TVR al follow-up e ad un trend verso una riduzione del TVF.

**CORONARY: IMAGING**

**P25**

**OPTICAL COHERENCE TOMOGRAPHY FOR GUIDING IN-STENT RESTENOSIS AND STENT THROMBOSIS MANAGEMENT**

Francesca Ciliberti<sup>1</sup>, Livio Giuliani<sup>2</sup>

<sup>1</sup>Cardiologia-UTIC, Università degli Studi "G. d'Annunzio" Chieti-Pescara, Chieti, <sup>2</sup>UOC Emodinamica, Ospedale "SS. Annunziata", Chieti

**Introduction.** Optical coherence tomography (OCT) has been increasingly utilized to guide revascularization of in-stent restenosis (ISR). There are different underlying pathological mechanisms that contribute to the development of the ISR, like stent under-expansion, non-overlapping stents, stent fracture, edge dissection and increased plaque at the stent edge. With the high resolution (10-15 μm) of OCT, mechanical abnormalities that aims to the stent thrombosis can be assessed and managed. Current ESC/EACTS-guidelines give class IIA recommendation for diagnostic intracoronary imaging with OCT for stent failure assessment. However, this method has not been used in large-scale multi-center prospective studies.

**Methods.** By a network meta-analysis, it has been possible to synthesis both direct and indirect evidence from relevant trials. Sources include PubMed, Cochrane Library Central Register of Controlled Trials and Embase for trials about the use of optical coherence tomography in the ISR.

**Results.** To understand the clinical impact of OCT findings during percutaneous coronary intervention, different trials like CLI-OPCI I and II both reported post-stent optimization in 35 – 31% of cases respectively. In the ILLUMIEN I, OCT changed PCI strategy in 27% of cases. In the trial CLI-OPCI the reported post-stent optimization was in 35% of cases. However, to understand the power of OCT to explore the stent thrombosis characteristics and mechanisms we deemed different trials, such as the national PESTO French registry; in this study, the underlying morphological abnormality was identified in 96.7% of patients with OCT and struts malapposition was the most frequent cause. Before OCT, the mechanisms of stent restenosis was completely identified in 12% of patients, this increased to 41% after OCT. The percentage of patients with 'unidentified' mechanisms was reduced from 48% without OCT to 13% with OCT. These differences were statistically significant (P<0.001). In the PRESTIGE registry (Prevention of Late Stent Thrombosis by and Interdisciplinary Global European Effort) a cause of stent restenosis was identified in all the cases. In the Bern registry the management of the patient was impacted by OCT-findings in 66% of cases (n=810). OCT findings in the diagnostic setting influenced patient management in 74%. In 52% of OCT-guided cases, post-stent OCT revealed presumably significant findings triggering additional intervention for stent optimization or change in medical therapy.

**Conclusions.** These findings suggest that lesions with ISR should universally undergo intracoronary imaging assessment to determine the cause and to manage them in the best way.

**CORONARY: PCI LESION/PATIENT SUBSETS**

**P26**

**PERCUTANEOUS CORONARY INTERVENTION FOR LEFT MAIN DISEASE IN HIGH BLEEDING RISK: OUTCOMES FROM A SUBANALYSIS OF THE DELTA 2 REGISTRY**

Giulia Botti<sup>1,2</sup>, Francesco Federico<sup>1</sup>, Emanuele Meliga<sup>3</sup>, Joost Daemen<sup>4</sup>, Fabrizio D'Ascenzo<sup>5</sup>, Davide Capodanno<sup>6</sup>, Didier Tchétché<sup>7</sup>, Nicolas Van Mieghem<sup>4</sup>, Sunao Nakamura<sup>8</sup>, Corrado Tamburino<sup>6</sup>, Roxana Mehran<sup>9</sup>, Matteo Montorfano<sup>1,2</sup>, Alaide Chieffo<sup>1,2</sup>

<sup>1</sup>Università Vita-Salute San Raffaele, Milano, <sup>2</sup>Interventional Cardiology Unit, IRCCS Ospedale San Raffaele, Milano, <sup>3</sup>Interventional Cardiology Unit, Cardinal Massaia Hospital, Asti, <sup>4</sup>Erasmus University Medical Center, Rotterdam, Netherlands, <sup>5</sup>A.O.U. Città della Salute e della Scienza, Torino, <sup>6</sup>Azienda Ospedaliero Universitaria Policlinico "G. Rodolico - San Marco", Division of Cardiology, University of Catania, Catania, <sup>7</sup>Clinique Pasteur, Toulouse, France, <sup>8</sup>New Tokyo Hospital, Matsudo, Japan, <sup>9</sup>Icahn School of Medicine at Mount Sinai, The Zena and Michael A. Wiener Cardiovascular Institute, New York, USA

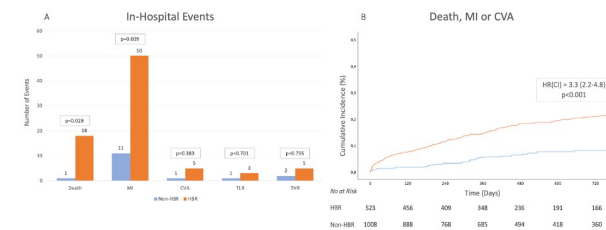
**Introduction.** High bleeding risk (HBR) can represent a challenge, especially in patients with complex coronary lesions undergoing PCI. This study aims at investigating the prevalence of HBR in a wide and

comprehensive cohort of patients undergoing left main (LM) PCI, describing their clinical phenotype, and reporting their procedural outcomes.

**Methods.** The analysis was performed on data from the DELTA (Drug Eluting Stent for Left Main Coronary Artery) 2 Registry, which prospectively included patients who underwent LM PCI at 19 centers worldwide. The patients were defined to be at HBR if ≥1 Major Criteria or ≥2 Minor Criteria from the Academic Research Consortium (ARC) were met. The primary endpoint was a composite of all-cause death, myocardial infarction (MI) or stroke at median follow-up.

**Results.** A total of 1531 patients were included, the rate of HBR was 65.8%. Besides the different clinical characteristics embedded in the ARC definition, HBR had higher prevalence of acute coronary syndrome (ACS) at presentation (49.2% vs 26.8%, p<0.001), and experienced higher in hospital mortality (1.8% vs 0.2%; p=0.029) and MI (5.0% vs 2.1%, p=0.009) (Figure, panel A). The median follow-up was 473 days. The rate of the primary endpoint was more than three times higher in HBR patients (20.8% vs 6.1%; HR 3.3; 95% CI 2.2-4.8) (Figure, panel B), and significantly driven by all cause death (16.2% vs 4.6%; HR 3.3; 95% CI 2.2-5.1) and MI (5.8% vs 1.9%; HR 2.9; 95% CI 1.5-5.7). Conversely no significant difference was reported in terms of target lesion revascularization (TLR) probable or defined stent thrombosis.

**Conclusions.** HBR patients undergoing LM PCI experienced higher rates of all cause death and MI at follow-up; similar outcomes were also reported in-hospital.



**P27**

**PREDICTORS AND IMPACT OF CARDIOGENIC SHOCK IN OLDEST OLD STEMI PATIENTS UNDERGOING INVASIVE MANAGEMENT**

Alessandro Ruzzarin<sup>1</sup>, Enrico Fabris<sup>2</sup>, Simone Muraglia<sup>3</sup>, Giorgio Caretta<sup>4</sup>, Andrea Pezzato<sup>5</sup>, Filippo Zilio<sup>6</sup>, Matthias Unterhuber<sup>1</sup>, Gianluca Campo<sup>5</sup>, Luca Donazzan<sup>1</sup>

<sup>1</sup>Cardiologia, Ospedale Centrale di Bolzano, Bolzano, <sup>2</sup>Cardiologia, Azienda Ospedaliero Universitaria Ospedali Riuniti di Trieste, Trieste, <sup>3</sup>Cardiologia, APSS Trento, Trento, <sup>4</sup>Cardiologia, Ospedale Civile Sant'Andrea, La Spezia, <sup>5</sup>Cardiologia, Azienda Ospedaliero Universitaria di Ferrara, Ferrara

**Introduction.** Data about cardiogenic shock (CS) in very elderly (age ≥85 years) ST-elevation myocardial infarction (STEMI) patients are scarce. We sought to assess the prognostic factors and the short-term impact of CS in this population.

**Methods.** Consecutive very elderly STEMI patients undergoing invasive treatment were included in a retrospective multicenter real-world registry of 5 Hub hospitals in Northern Italy. CS was defined according to clinical criteria. Multiple logistic regression modeling was performed to assess the independent factors associated with CS. A Cox regression analysis was performed to predict early mortality for patients with CS.

**Results.** Among 623 STEMI patients consecutively enrolled (mean age 88.7 [2.9] years, 52.6% females), 80 (12.8%) presented with CS. Baseline characteristics and procedural characteristics are presented in Table 1 and Table 2, respectively. At the multiple logistic regression, a previous acute myocardial infarction (AMI) was the only predictor of CS (OR 2.41,

**Table 1.** Clinical characteristics of the very elderly STEMI population.

Characteristics	Overall (N=623)	Cardiogenic Shock (n=80, 12.8%)	Non Cardiogenic Shock (n=543, 87.2%)	P - value
Age (years)	88.7 (2.9)	89.1 (3.4)	88.6 (2.9)	0.14
Female Gender	328/623 (52.6%)	48/80 (60%)	280/543 (51.6%)	0.35
BMI, (kg/m <sup>2</sup> )	24.7 (3.4)	24.6 (3.1)	24.75 (3.4)	0.78
Hypertension	485/616 (77.8%)	60/75 (80.0%)	425/541 (78.6%)	0.88
Dyslipidemia	244/615 (39.2%)	32/74 (43.2%)	212/541 (39.2%)	0.53
Diabetes Mellitus	133/615 (21.3%)	14/74 (18.9%)	119/541 (22.0%)	0.65
Known CAD	119/615 (19.1%)	23/74 (31.1%)	96/541 (17.7%)	0.01
Previous AMI	89/615 (14.3%)	19/74 (25.7%)	70/541 (12.9%)	<0.01
Known PAD	158/615 (25.4%)	31/74 (41.9%)	127/541 (23.5%)	<0.01
CKD	176/615 (28.3%)	24/74 (36.5%)	149/541 (27.5%)	0.13

Values presented as n (%) unless stated otherwise. SD, standard deviation. AMI: acute myocardial infarction; BMI: body mass index; CAD: coronary artery disease; CKD: chronic kidney disease; PAD: peripheral arterial disease.

**Table 2.** Procedural characteristics of very elderly STEMI patients undergoing invasive management.

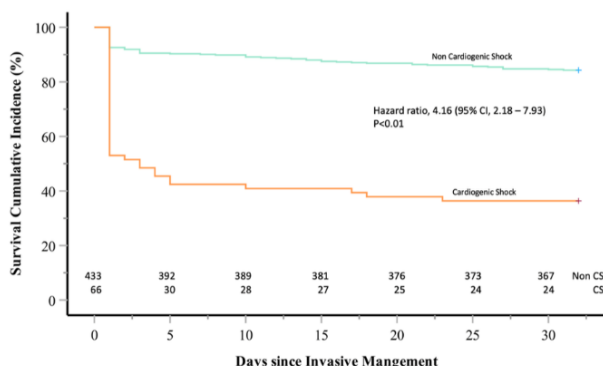
Characteristics	Overall (N=523)	Cardiogenic Shock (n=68, 13.0%)	Non Cardiogenic Shock (n=455, 87.0%)	P - value
LAD culprit	259/523 (49.5%)	31/68 (45.6%)	228/455 (50.1%)	0.51
Anemia	110/503 (21.0%)	17/63 (27.0%)	93/440 (21.1%)	0.33
WBC	10.42 (4.5)	10.9 (4.3)	10.3 (4.5)	0.31
NLR	8.66 (6.4)	10.9 (9.5)	8.4 (5.8)	0.13
Radial Access	360/433 (83.1%)	32/60 (53.3%)	328/433 (75.8%)	<0.01
MCS device	14/523 (2.7%)	11/68 (16.2%)	3/455 (0.7%)	<0.01
Culprit-only	500/515 (98.5%)	63/66 (95.5%)	437/449 (97.3%)	0.42
Strategy				

Values presented as n (%) unless stated otherwise. SD, standard deviation.  
LAD: left anterior descending artery; MCS: mechanical circulatory support; NLR: Neutrophil-Lymphocyte Ratio; STEMI: ST-elevation myocardial infarction; WBC white blood cells.

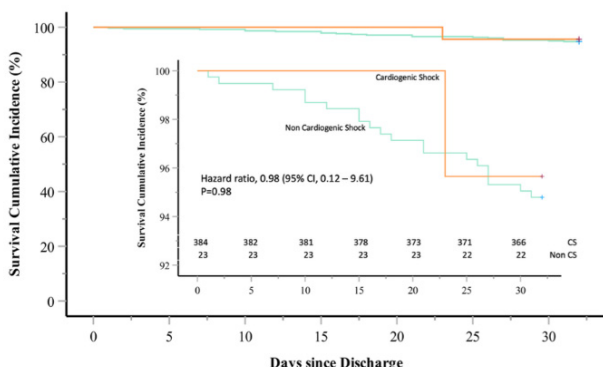
**Table 3.** Multiple logistic regression model performed to assess predictors of cardiogenic shock.

Variable	Odds Ratio	(95% CI)	P - value
Age	1.02	0.93 – 1.12	0.68
BMI	1.00	0.92 – 1.08	0.97
Female Sex	1.73	0.99 – 3.04	0.06
Arterial Hypertension	0.83	0.43 – 1.61	0.58
Dyslipidemia	1.04	0.59 – 1.85	0.88
Diabetes Mellitus	0.82	0.41 – 1.63	0.57
COPD	0.72	0.29 – 1.81	0.49
Chronic Kidney Disease	1.33	0.75 – 2.37	0.34
Previous AMI	2.41	1.26 – 4.64	0.01
Previous Stroke	1.53	0.67 – 3.45	0.31
LAD Culprit	1.04	0.60 – 1.80	0.90

AMI: acute myocardial infarction; BMI: body mass index; COPD: chronic obstructive pulmonary disease coronary artery disease; LAD: left anterior descending artery.



**Figure 1.** One-month survival rate after STEMI complicated by cardiogenic shock in very elderly patients undergoing invasive management.



**Figure 2.** One-month survival rate after discharge.

95% CI 1.26-4.64, p=0.01), other data are presented in Table 3. The rate of in-hospital mortality was significantly higher in patients presenting with CS compared to non-CS (64.9% vs 13.7%, p<0.01). In regard to 30-day mortality, CS was associated with a higher risk of mortality at 30 days (adjusted HR 4.16, 95% CI 2.18-7.93, p<0.01) despite invasive management (Figure 1). Among patients who survived hospitalization, CS at presentation was not associated with higher risk of mortality at one-month follow up (Figure 2).

**Conclusions.** Cardiogenic shock is an ominous complication of acute myocardial infarction. At one-month follow up, very elderly STEMI patients presenting with CS had a higher risk of mortality when compared to non-CS patients. Among survivors of hospitalization, this risk seems not to remain during the first month after discharge.

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**ECHOCARDIOGRAPHIC CHARACTERISTICS OF WRIST ARTERIAL VESSELS AFTER PRIMARY TRANS-RADIAL ACCESS FAILURE**

Simona Minardi<sup>1</sup>, Alessandro Sciahbasi<sup>2</sup>, Alessio Gensano<sup>3</sup>, Ludovica De Fazio<sup>3</sup>, Francesco Starnazzi<sup>1</sup>, Alessandro Bocci<sup>3</sup>, Martina Renda<sup>1</sup>, Nicolò Salvi<sup>2</sup>, Cristian Di Russo<sup>2</sup>, Roberto Patrizi<sup>2</sup>, Maria Cera<sup>2</sup>, Silvio Fedele<sup>2</sup>, Antonino Granatelli<sup>2</sup>  
<sup>1</sup>Università degli Studi di L'Aquila, L'Aquila, <sup>2</sup>Ospedale Sandro Pertini, ASL Roma 2, Roma, <sup>3</sup>Division of Cardiology, Department of Clinical and Molecular Medicine, Faculty of Medicine and Psychology, Sant'Andrea Hospital, Sapienza University, Roma

**Introduction.** Trans-radial approach (TRA) is recommended by international guidelines as the default vascular access for percutaneous coronary intervention (PCI), due to the lower risk of vascular complications and higher patient comfort compared to transfemoral approach. However, TRA is associated to a rate of failure and crossover to a different access accounting up to 10% of procedures. Few data exist about clinical factors predisposing to crossover, moreover, information about anatomical features of failed access is lacking. Aim of our study is to evaluate echographic characteristics of wrist arterial vessels after primary TRA and to compare anatomical features, doppler parameters and complication rates of patients who underwent crossover or non-crossover procedures.

**Methods.** All patients who underwent in a single center to percutaneous coronary diagnostic or interventional procedures through TRA who necessitated of vascular crossover after TRA failure were included in this prospective observational study. A control group of consecutive patients with TRA performed by the same operators, without crossover was included (with a 2:1 rate compared to crossover group to avoid possible selection bias). All patients were checked 24-hour post procedure to perform wrist vessels ultrasound (US) and to evaluate possible vascular complications and bleeding. US measurements were performed 1-3 cm proximal to the radial styloid process or the pisiform bone. Diameter, perimeter, area, intimal thickness and distance from the subcutaneous were measured in short axis, doppler parameters such as peak systolic velocity (PSV), end-diastolic velocity (EDV), resistance index (RI= (PSV-EDV)/PSV) were measured in long axis.

**Results.** A total of 136 patients were enrolled in the study, 48 crossover (69% right TRA failure, 31% left TRA failure) and 88 controls. After failure of right TRA, the crossover was performed to left TRA 55% (n=18), to right trans-femoral access (TFA) 36% (n=12), to right trans-ulnar access (TUA) 6% (n=2) and to left TFA 3% (n=1). After left TRA failure, the crossover was performed to right TFA 67% (n=10), right TRA 27% (n=4) and left TFA 7% (n=1). Crossovers were significantly older than the cases (71±11 years vs 67±11 years, p=0.02) and significantly shorter in stature (165±11 mm vs 170±8 mm, p=0.004) while there were no significant differences in weight and BMI between the two groups. In the crossover group there were more females (48% vs 33%), although the difference with the control group was not statistically significant (p=0.09). Comparing ultrasound data, diameter and area of the failed TRA were smaller than the control TRA although statistical significance was narrowly missed (2.9±0.09 mm vs 2.5±1 mm, p=0.06 and 0.09±0.14 cm<sup>2</sup> vs 0.06±0.03 cm<sup>2</sup>, p=0.09), maybe due to the small sample size. Perimeter of the failed TRA was significantly smaller than the corresponding TRA in the control group (10±0.1 mm vs 8±0.13 mm, p<0.001). No significant differences were found in doppler parameters. Radial dissections were the only vascular complications observed and were more frequent among crossovers than controls although the difference was nearly not significant (6% [n=3] vs 0, p=0.07). No major bleeding was observed. Vascular access hematoma rate was double in crossovers (15% [n=7] vs 6% [n=5], p=0.159).

**Conclusions.** In our study, radial US evaluation after TRA failure showed a smaller calibre of the artery associated with patients' older age and shorter height compared to controls. Larger sample size is necessary to confirm our results and to evaluate possible differences in vascular complications.

## P29

### ESPERIENZA MONOCENTRICA SULLO SCAFFOLD RIASSORBIBILE MAGMARIS: DATI DAL REGISTRO MADIT (MAGMARIS DEVICE REGISTRY IN TRAPANI)

Dario Buccheri, Luigi Priolo, Stefano Cangemi, Daniele Vinci  
*UOS Emodinamica, PO Sant'Antonio Abate di Trapani, Trapani*  
**Introduzione.** Nell'ambito dell'interventistica coronarica l'impiego dello scaffold riassorbibile Magmaris è attualmente riservato ai centri partecipanti a registri osservazionali dedicati a tale device, così da garantire adeguata selezione dei pazienti e delle lesioni coronariche da sottoporre all'impianto dello scaffold, nonché stabilire a priori un preciso programma di follow-up.

**Metodi.** Si presenta la casistica monocentrica dell'U.O.S. di Emodinamica del P.O. "Sant'Antonio Abate" di Trapani relativa ad angioplastica coronarica con impiego di scaffold riassorbibile Magmaris, che data circa 3 anni (dal luglio 2020 ad oggi), coinvolgente 28 pazienti, reclutati nei registri osservazionali "IT MASTERS" e "SHERPA-MAGIC", rispettando i criteri di inclusione ed esclusione di tali registri ed i relativi programmi di follow-up.

**Risultati.** Sono state trattate quasi esclusivamente lesioni coronariche de novo, applicando una tecnica standardizzata di preparazione della lesione, impianto, postdilatazione e controllo del risultato con imaging intracoronarico, ottenendo successo procedurale nella totalità delle procedure. Come da programma, ad un anno dall'impianto è stato eseguito un follow-up coronarografico e per imaging intracoronarico; si sono registrati complessivamente 3 eventi di "target lesion failure" e 2 eventi di "target vessel failure", tutti in particolare in casi di lesioni non semplici; nessun decesso.

**Conclusioni.** La nostra casistica di angioplastica coronarica con impianto di scaffold riassorbibile Magmaris rivela buoni risultati procedurali ed al follow-up, nei casi ben selezionati per tale device, in particolare in caso di lesioni coronariche semplici. La conferma degli attuali risultati nel prosieguo del follow-up fornirà dati a supporto di una simile tecnologia riassorbibile per l'interventistica coronarica.

## CORONARY: PCI, COMPLICATIONS

## P30

### INCIDENCE OF COMPLICATIONS IN A CONTEMPORARY ALL COMERS POPULATION UNDERGOING CORONARY PROCEDURES

Andrea Pezzato, Andrea Lalaro, Giulia Gagno, Giancarlo Vitrella, Marco Anzini, Matteo Dal Ferro, Serena Rakar, Andrea Perkan, Gianfranco Sinagra, Enrico Fabris  
*Cardiothoracovascular Department, University of Trieste, Trieste*  
**Introduzione.** The current incidence of complications in patients undergoing coronary angiography (CA) and/or percutaneous coronary intervention (PCI) is poorly defined. Therefore we assessed the incidence of complications in a contemporary all comers population undergoing CA and/or PCI.

**Methods.** We included in a dedicated registry all patients who underwent CA and or PCI between January-2017 and December 2022 at the University Hospital of Trieste. Complications occurred in the cath lab were immediately registered, while for later complications the assessment was based each year on a critical reassessment of the discharge letters.

**Results.** A total of 9579 patients underwent CA and/or PCI (5876 only diagnostic CA and 3703 PCI). Median age was 70 (IQR 61-77) years, 71% were males. There were 2853 elective procedure (29.8%), 5142 urgent procedure (53.7%) and 1583 emergent procedure (16.5%). The incidence of overall complications were 6.8%, 12.3% vs 3.3% p<0.001 in CA and PCI groups respectively. This difference was driven by a higher incidence of allergic reaction to iodinated contrast media (2.9% vs 1.2% p<0.001), vascular complications (1.8% vs 0.9% p<0.001), cardiac complications (6.9% vs 0.6% p<0.001) and acute kidney injury (AKI) (0.7% vs 0.3%; p=0.02) complications. When considering subgroups, overall complications (8.5% vs 6.4%; p=0.002), cerebral complications (0.6% vs 0.2%; p=0.002) and AKI (1.3% vs 0.3%; p<0.001), were higher in patients older than 80-year. Interestingly vascular complications (1.8% vs 1.0%; p<0.001) and AKI (0.7% vs 0.4%; p=0.038), were higher in female compared to male patients. Acute stent thrombosis were higher in emergent patients compared to urgent patients (0.57% vs 0.04% p<0.001). Vascular complications were higher in femoral access compared to radial access (3.8% vs 1.0% p<0.001).

**Conclusions.** In a contemporary real-world all comers population undergoing CA and/or PCI, the incidence of overall complications is 6.8%. Some complications were higher in female, older patients and in emergency setting.

## P31

### EMBOLIZZAZIONE DISTALE

Gino Duronio, Elvira Verrengia  
*Cardiologia-UTIC, ASL Pescara, Pescara*

**Introduzione.** L'embolizzazione distale è una complicanza temibile in corso di angioplastica prevalentemente nelle sindromi coronariche acute, ma occasionalmente anche in corso di angioplastica nel paziente con angina stabile.

**Metodi.** Il caso in questione evidenzia un quadro di embolizzazione distale a seguito di traumatismo indotto dal passaggio dello stent in una coronaria tortuosa.

**Risultati.** Il trattamento dell'embolizzazione distale nel caso in questione è stato ottenuto grazie al supporto del microcatetere con l'utilizzo di diversi fili guida e il trattamento dei piccoli vasi distale mediante dilatazione con pallone. Un unico vaso distale è stato trattato con impianto di stent.

**Conclusioni.** L'embolizzazione distale è una complicanza temibile e piuttosto rara nel corso di una procedura di angioplastica coronarica. Farmaci antitrombotici ed un paziente avanzamento delle guide permettono la gestione della complicanza.

## CORONARY: PCI, LONG-TERM OUTCOMES

## P32

### ADVANTAGES OF STAGED MYOCARDIAL REVASCULARIZATION ON RENAL FUNCTION: FOCUS-ON

Giuseppe Verolino<sup>1</sup>, Dario Calderone<sup>1</sup>, Nicole Speziali<sup>2</sup>, Davide Stucchi<sup>2</sup>, Davide Sala<sup>1</sup>, Paolo Ghiso Basile<sup>1</sup>, Roberto Latini<sup>1</sup>, Paolo Sganzerla<sup>1</sup>  
*<sup>1</sup>Laboratorio di Emodinamica, IRCCS Istituto Auxologico Italiano - Ospedale San Luca, Milano, <sup>2</sup>Scuola di Specializzazione in Malattie dell'Apparato Cardiovascolare, Università degli Studi Milano Bicocca, Milano*

**Introduction.** The completeness of myocardial revascularization should be every time reached in patients with coronary artery multivessel disease (MVD) both in stable and acute settings. Nevertheless, the multivessel percutaneous coronary intervention (PCI) at the same time carries some concerns due to the contrast administration and procedural time. To date, the impact of delayed revascularization on renal function in patients with MVD with or without chronic kidney diseases (CKD) was investigated but not completely understood.

**Methods.** From January 2022 to December 2022, every patient with UA/NSTEMI, STEMI, or stable CAD undergone to coronary angiography, in the case of MVD, were treated with PCI of the culprit lesion only (or worst lesion based on angiographic morphology) and with a staged PCI in a different procedure and hospitalization. For each patient, the renal function with creatinine (Cr) and estimated glomerular filtration rate (eGFR), and contrast dye administered (ml) were reported.

**Results.** 166 patients with MVD were treated in two different procedures. The median time of staged PCI was 54 days (IQR 49-62). In the overall population, 62 patients have CKD (eGFR mean 45.7± 9.7 ml/min, Cr mean 1.34 ± 0.5 mg/dl) and 104 have a good renal function. A t-test for paired samples has shown that there are no clinically relevant differences in terms of renal function between the two procedures (Cr I stage - Cr II stage mean difference -0.04 mg/dl, 95% CI -0.07 to -0.01, p<0.05; eGFR I stage - eGFR II stage mean difference 3.59 ml/min, 95% CI 1.62-5.56, p<0.001). Interestingly, from the first to second procedure, the contrast dye administration was lower (mean difference 27.8 ml, 95% CI 17.1-38.4, p<0.001). A Cox-regression to evaluate the risk of acute kidney injury (AKI) has shown no impact of contrast dye volume administered on the outcome, regardless of the CKD presence at baseline (HR 1, 95% CI 0.99-1.01, p=0.63).

**Conclusions.** In patients with CKD and MVD, a careful evaluation of the global risk of AKI should be done in consideration of potential harm due to contrast administration. A preliminary strategy of the culprit or culprit-like only PCI with a staged PCI away from the first may represent a safe approach to ensure a complete revascularization with renal function sparing.

## P33

### LONG-TERM RESULTS AFTER BVS ABSORB IMPLANTATION IN A REAL-WORLD POPULATION: THE AG-SORB REGISTRY

Salvatore Geraci, Gerlando Pilato, Giovanni Vaccaro, Ilenia Alessandra Di Liberto, Dario Savarino, Marco Martello, Michele Giusti, Davide Diana, Giuseppe Caramanno  
*Cardiologia, Ospedale San Giovanni di Dio, Agrigento*

**Introduzione.** Il principio della "vascular reparative therapy", secondo cui è possibile trattare lesioni coronariche con device che si dissolvono nel tempo portando ad una potenziale "restitutio ad integrum" del vaso, è stato diffuso e condiviso tra i cardiologi interventisti. Nonostante il "first in men trial" sul BVS (bioresorbable everolimus-eluting vascular scaffold) Absorb e i primi registri abbiano fornito dati su come a due anni si possa

avere il completo riassorbimento dello scaffold impiantato in lesioni coronariche semplici e su pazienti selezionati, con un basso tasso di trombosi, i risultati clinici a lungo termine riguardo sicurezza ed efficacia hanno portato al ritiro dal mercato del suddetto device. Noi riportiamo i dati sull'outcome a lungo termine, dai 9 fino a 10 anni, dopo impianto di BVS Absorb dal nostro registro monocentrico AG-SORB.

**Metodi.** AG-SORB è un registro prospettico, monocentrico e open-label, che arruolava pazienti sottoposti a impianto di BVS Absorb con tecnica standardizzata dal Settembre del 2012 fino alla data ultima in cui fu possibile impiantare il device, presso l'Ospedale San Giovanni di Dio di Agrigento. La scelta dell'impianto di BVS era lasciata all'operatore, senza criteri di inclusione/esclusione pre-specificati. Tutti i pazienti del registro dopo l'impianto dello scaffold sono sottoposti a follow up clinico ogni 6 mesi e dopo 1 5 anni ogni 12 mesi. L'outcome primario è rappresentato dalla TLF (target lesion failure), definito come combinazione di morte cardiaca, infarto del vaso target e ID-TLR (ischemia-driven target lesion revascularization). Nel registro è stata utilizzata tecnica standardizzata per l'impianto degli scaffold, il 100% dei pazienti ha eseguito predilatazione con pallone di rapporto 1:1 rispetto al vaso target o 1 mm più piccolo rispetto a questo, il 98% dei pazienti ha eseguito postdilatazione mediante palloni non compliant con rapporto in diametro 1:1 rispetto allo scaffold o con diametro 0.5 mm superiore a quest'ultimo.

**Risultati.** Ad oggi 97 pazienti del registro sono eleggibili per follow up a lungo termine, fino ad un massimo di oltre 120 mesi. Il follow-up clinico è stato eseguito a 5 anni nel 98% dei pazienti, oltre i 9 anni nel 70% circa, oltre il 50% dei pazienti ha eseguito angiografia nel corso dei 10 anni dall'impianto di BVS Absorb. Tutti i pazienti hanno ricevuto prescrizione per doppia terapia antiaggregante (DAPT) di durata non inferiore a 12 mesi, 3 pazienti (3%) hanno discontinuato la DAPT tra 6 e 12 mesi per patologie intercorrenti. L'età media dei pazienti era di  $59.8 \pm 9.5$  anni, maschi 78%, sindromi coronariche acute 67%, angina stabile 33%. Le lesioni tipo B2/C, secondo la classificazione ACC AHA, hanno rappresentato il 20% del totale, lesioni tipo B1 il 58%, lesioni tipo A il 22%. Il SYNTAX score medio era  $11.9 \pm 5.7$ . 133 scaffold sono stati impiantati in 97 pazienti. La lunghezza media degli scaffold impiantati è stata di circa 29 mm con overlap nel 20% dei pazienti. LAD ha rappresentato il vaso target in circa il 48% dei casi.

**Conclusioni.** Nella popolazione real world del registro AG-SORB sottoposta a follow up la frequenza dell'outcome primario (TLF) a lungo termine, oltre i 9 anni e fino a 10 anni, risulta del 14% circa, con 1 morte cardiaca direttamente correlata alla lesione target (device-related thrombosis). Nel complesso, in base alla nostra personale esperienza, un utilizzo maggiormente oculato, con condivisione di tecniche ottimizzate di impianto e attenta selezione dei pazienti per lungo periodo di doppia antiaggregazione, avrebbe forse potuto portare a migliori outcome con il suddetto device, fin linea con i dati in letteratura sui DES. AG-SORB risulta ovviamente gravato dai limiti oggettivi di un registro monocentrico.

## CORONARY: PHYSIOLOGY

### P34

#### QUANTITATIVE FLOW RATIO-BASED OUTCOMES IN PATIENTS UNDERGOING TRANSCATHETER AORTIC VALVE IMPLANTATION. QUAESTIO STUDY

Pierluigi Demola<sup>1</sup>, Iginio Colaiori<sup>1</sup>, Davide Bosi<sup>1</sup>, Sergio Musto D'Amore<sup>1</sup>, Marco Vitolo<sup>2,3</sup>, Giorgio Benatti<sup>4</sup>, Luigi Vignali<sup>4</sup>, Iacopo Tadonico<sup>4</sup>, Davide Gabbieri<sup>5</sup>, Luciano Losi<sup>6</sup>, Paolo Magnavacchi<sup>7</sup>, Fabio Alfredo Sgura<sup>2</sup>, Giuseppe Boriani<sup>2</sup>, Vincenzo Guiducci<sup>1</sup>

<sup>1</sup>Cardiology Unit, Azienda USL - IRCCS di Reggio Emilia, Reggio Emilia, <sup>2</sup>Cardiology Division, Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Policlinico di Modena, Modena, <sup>3</sup>Clinical and Experimental Medicine PhD Program, University of Modena and Reggio Emilia, Modena, <sup>4</sup>Cardiology Department, Azienda Ospedaliero-Universitaria di Parma, Parma, <sup>5</sup>Cardiac Surgery Division, Hesperia Hospital, Modena, <sup>6</sup>U.O. Cardiologia, Ospedale "Guglielmo da Saliceto", Piacenza, <sup>7</sup>Cardiology Division, Baggiovara Hospital, Modena

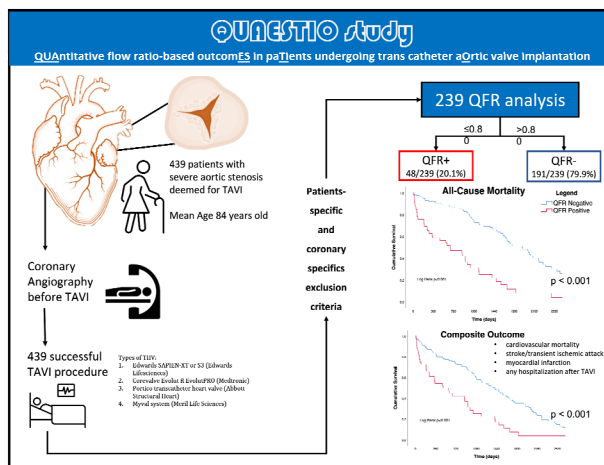
**Background.** Coronary artery disease (CAD) is common in patients with aortic valve stenosis (AS) ranging from 60 to 80%. The clinical and prognostic role of coronary artery lesions in patients undergoing transcatheter aortic valve implantation (TAVI) remains unclear. The aim of the present observational study was to estimate long-term clinical outcomes by quantitative flow ratio (QFR) characterization of CAD in a well-represented cohort of patients affected by severe AS treated by TAVI.

**Methods.** A total of 439 invasive coronary angiographies of patients deemed eligible for TAVI by local Heart Teams with symptomatic severe AS were retrospectively screened for QFR analysis. The primary endpoint of the study was all-cause mortality. The secondary endpoint was a composite of cardiovascular mortality, stroke/transient ischemic attack (TIA), acute myocardial infarction (AMI), and any hospitalization after TAVI.

**Results.** After exclusion of patients with no follow-up data, coronary

angiography not feasible for QFR analysis and previous surgical myocardial revascularization (CABG) 48/239 (20.1%) patients had a QFR value lower or equal to 0.80 (QFR+ value), while the remaining 191/239 (79.9%) did not present any vessel with a QFR positive value. In the adjusted Cox regression analysis, patients with positive QFR were independently associated with an increased risk of all-cause mortality (Model 1, HR 3.47, 95% CI 2.35-5.12; Model 2, HR 5.01, 95% CI 3.17-7.90). In the adjusted covariate analysis, QFR+ involving LAD (37/48, 77.1%) was associated with the higher risk of the composite outcome compared to patients without any positive value of QFR or non-LAD QFR positive value (11/48, 22.9%).

**Conclusions.** Pre-TAVI QFR analysis can be used for a safe, simple, wireless functional assessment of CAD. QFR permits to identify patients at high risk of cardiovascular mortality or MACE, and it could be considered by local Heart Teams.



### P35

#### FEASIBILITY, SAFETY, AND PROGNOSTIC IMPLICATIONS OF ACETYLCHOLINE PROVOCATIVE TEST IN PATIENTS WITH MYOCARDIAL BRIDGE

Giuseppe Ciliberti<sup>1</sup>, Renzo Laborante<sup>1</sup>, Attilio Restivo<sup>1</sup>, Fabio Casamassima<sup>1</sup>, Gaetano Rizzo<sup>1</sup>, Antonio Maria Leone<sup>1</sup>, Francesco Burzotta<sup>1</sup>, Carlo Trani<sup>1</sup>, Filippo Crea<sup>1</sup>, Domenico D'Amario<sup>2</sup>

<sup>1</sup>Fondazione Policlinico Universitario Agostino Gemelli IRCSS, Roma, <sup>2</sup>Dipartimento Medicina Translazionale, Università del Piemonte Orientale, Azienda Ospedaliero-Universitaria Maggiore della Carità, Novara

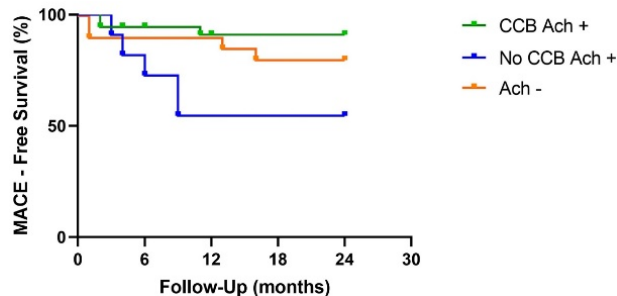
**Introduction.** Among several pathophysiological mechanisms underlying myocardial bridge (MB)-related ischemia, coronary artery spasm (CAS) may play a pivotal role in promoting anginal symptoms and adverse cardiac events. Invasive acetylcholine (Ach) provocative test may unmask CAS and implement personalized therapies. However, evidence supporting the safety and relevance of this test is still lacking in MB patients. Therefore, the aim of our study was to assess the feasibility, safety, and prognostic implications of invasive Ach test in MB patients.

**Methods.** This study is a pre-specified subgroup analysis of the "RIALTO", an ambispective and observational registry (ClinicalTrials.gov Identifier: NCT05111418) of patients with angiographic evidence of MB. Among 444 patients enrolled in the registry, 73 underwent intracoronary Ach test and were considered in this study. Ach test was considered positive for epicardial CAS in the presence of focal or diffuse epicardial coronary diameter reduction  $\geq 90\%$ , associated with the occurrence of anginal symptoms and ischemic ECG shifts. Microvascular CAS was diagnosed when anginal symptoms and typical ischemic ST-segment changes developed in the absence of epicardial coronary constriction. The incidence of major and minor complications was considered as a safety endpoint. Primary and secondary endpoints were, respectively, the incidence of major adverse cardiac events (MACE), defined as the composite of cardiac death, myocardial infarction and cardiac hospitalization, and the rate of significant angina, defined as Seattle Angina Questionnaire (SAQ) Angina Summary Score  $\leq 70$  in patients with and without CAS, up to 24 months follow-up.

**Results.** CAS was diagnosed in 65.8% of MB patients. The most common type and site of spasm was a focal constriction of the mid left anterior descending (LAD) coronary artery (41.9%), which was also the most common location of MB (82.2%). No fatal or major complications were reported, while 12.3% of patients experienced minor complications (transient episodes of brady- and tachyarrhythmia). The rate of MACE was significantly higher in patients with a positive Ach test (Ach+ patients) without calcium channel blocker (CCB) prescription at discharge, compared with patients with a negative Ach test (Ach- patients) and compared with Ach+ patients receiving CCBs (5% vs. 20% and 9%,

respectively,  $p < 0.01$ ) (Figure). The rate of patients with significant angina (SAQ  $\leq 7$ ) was significantly higher in the Ach+ group compared with the Ach- group (47.7% vs. 25%, log-rank = 0.04).

**Conclusions.** CAS may be frequently detected in patients with MB. Invasive Ach provocative test may unmask CAS, one of the pivotal pathophysiological mechanisms underlying MB-related ischemia (impaired endothelium-dependent vasodilatation). This assessment proved to be safe and feasible, and it was able to identify a subgroup of patients with a higher angular burden, for whom a targeted therapy with CCBs may reduce the incidence of MACE.



**P36**

**PROGNOSTIC RELEVANCE OF QUANTITATIVE FLOW RATIO IN PATIENTS WITH AORTIC STENOSIS UNDERGOING TRANSCATHETER AORTIC VALVE IMPLANTATION**

Iginio Colaiori<sup>1</sup>, Fabio Mangiacapra<sup>2</sup>, Luca Paolucci<sup>2</sup>, Pierluigi Demola<sup>3</sup>, Marco Vitolo<sup>4</sup>, Giorgio Benatti<sup>5</sup>, Luigi Vignali<sup>5</sup>, Luciano Losi<sup>6</sup>, Fabio Sgura<sup>4</sup>, Giuseppe Boriani<sup>4</sup>, Vincenzo Guiducci<sup>3</sup>

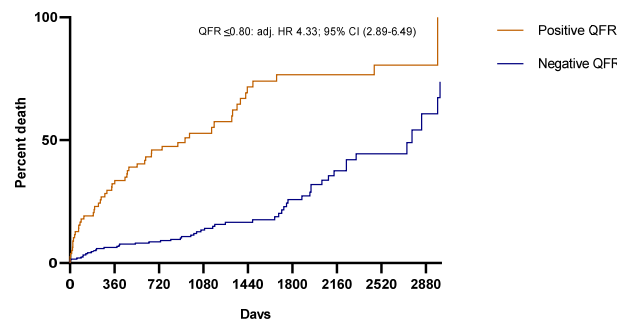
<sup>1</sup>Ospedale Santa Maria Goretti, Latina, <sup>2</sup>Università Campus Biomedico, Roma, <sup>3</sup>Arcispedale Santa Maria Nuova, Reggio Emilia, <sup>4</sup>Policlinico di Modena, Modena, <sup>5</sup>AOU Parma, Parma, <sup>6</sup>Ospedale Guglielmo da Saliceto, Piacenza

**Introduction.** No definitive data are available regarding the effectiveness of quantitative flow ratio (QFR) in defining clinical outcomes in patients with coronary artery disease (CAD) treated with medical therapy and aortic stenosis undergoing transcatheter aortic valve replacement (TAVR). The objective is to stratify clinical outcomes in patients treated with TAVR according to the presence of significant CAD as defined by QFR not undergoing coronary revascularization.

**Methods.** We prospectively enrolled 318 patients. All patients underwent coronary angiography with QFR evaluation. Percutaneous coronary interventions (PCI) were routinely deferred. Patients were stratified according to the presence of a positive QFR ( $< 0.80$ ) and according to QFR tertiles. Primary outcome was all cause death at 5-year follow-up.

**Results.** Overall, 105 (33.0%) patients died. At ROC analysis, global QFR showed a significantly higher effectiveness in discriminating patients actually experiencing the outcome compared to the global %DS (respective AUCs: 0.706 vs 0.596,  $p < 0.001$ ). Patients showing low QFR values experienced a higher frequency of the outcome during follow-up when stratified in tertiles or according to the presence of at least one QFR  $< 0.80$  (low QFR: 55.2%; medium QFR: 29.8%; high QFR: 14.7%; QFR  $< 0.80$ : 65.4%; QFR  $> 0.80$ : 22.5%). In a multivariate model, the presence of QFR positive lesions was associated with an independently increased risk of all-cause death during follow-up [HR 4.33, 95% CI (2.89-6.49)].

**Conclusions.** Patients with significant CAD as defined using QFR not undergoing revascularization show an increased risk of death following TAVR. Further studies investigating QFR-guided PCI are mostly needed to address this issue.



**P37**

**FRACTIONAL FLOW RESERVE-GUIDED DRUG COATED BALLOON-BASED TREATMENT OF BIFURCATION LESION – A CASE REPORT**

Alessandro Appetecchia<sup>1</sup>, Fabio Mangiacapra<sup>1</sup>, Annunziata Nusca<sup>1</sup>, Elisabetta Ricottini<sup>1</sup>, Rosetta Melfi<sup>1</sup>, Paolo Gallo<sup>1</sup>, Raffaele Rinaldi<sup>1</sup>, Simone Circhetta<sup>1</sup>, Federica Coletti<sup>1</sup>, Giuseppe Migliaro<sup>1</sup>, Francesco Grigioni<sup>1</sup>, Gian Paolo Ussia<sup>1</sup>

<sup>1</sup>Department of Medicine, Università Campus Bio-Medico di Roma, Roma

**Rationale.** Several techniques have been developed for percutaneous treatment of bifurcation lesions. In the absence of significant stenosis at the ostium of the side branch, provisional stenting is currently recommended as the strategy of choice after stenting of the main branch. However, the implantation of two stents for bifurcation lesions implies an increased thrombotic risk, potentially requiring prolonged dual antiplatelet therapy also in the setting of chronic coronary syndrome.

**Technical resolution.** A 63-year-old male patient with a history of anaphylactic reaction to aspirin and head surgery for oligodendroglioma removal, presented with chest pain on effort. Coronary CT showed a 60% stenosis in the mid LAD. Coronary angiography confirmed a bifurcation lesion (Medina 1,0,0) of the mid LAD, which was functionally significant at fractional flow reserve (FFR - 0.76). After zotarolimus-eluting stent implantation in the LAD, post-dilatation, and proximal optimization technique (POT), angiography showed an ostial stenosis of the diagonal branch. Functional assessment was repeated and showed an FFR of 0.92 in the LAD and of 0.77 in the diagonal branch. After predilatation of the diagonal branch with a semi-compliant balloon, a sirolimus coated-balloon was inflated at the ostium on the side branch and also used for a kissing-balloon dilatation. Following final POT, FFR was 0.92 in the LAD and 0.88 in the diagonal branch. The patient was therefore treated with clopidogrel and indobufen for one month, and with clopidogrel alone thereafter. Three-month follow-up was uneventful.

**Clinical implications.** The use of coronary physiology to assess the involvement of side branches after stenting of the main branch may be helpful in guiding treatment strategies in bifurcation lesions. A minimalistic approach with DCB could be helpful in the treatment of side branches in high-risk patients to reduce the exposure to antiplatelet drugs.

**Perspectives.** Randomized trials are warranted to investigate the use of DCB in the treatment of bifurcation lesion.

**P38**

**ROLE OF CORONARY MICROVASCULAR DYSFUNCTION IN PATIENTS AFFECTED BY ARRHYTHMIA-INDUCED CARDIOMYOPATHY**

Alice Benedetti, Gianluca Castaldi, Enrico Poletti, Benjamin Scott, Carl Convens, Stefan Verheye, Pierfrancesco Agostoni, Paul Vermeersch, Carlo Zivelonghi

Hart Centrum, Ziekenhuis Netwerk Antwerpen (ZNA) Middelheim, Antwerpen, Belgium

**Background.** Arrhythmia-induced cardiomyopathy (AIC) is a condition in which arrhythmias determine left ventricular ejection fraction (LVEF) impairment. In patients with atrial fibrillation (AF), several pathophysiological mechanisms may contribute to LVEF reduction. However, underlying patient features that might increase vulnerability to AIC remain unclear. We hypothesise that coronary microvascular dysfunction (CMD) may play a role in the development of AIC.

**Methods.** In this prospective observational study, we included all consecutive patients with recent onset of AF ( $< 2$  months) and preserved LVEF or suspected AIC undergoing coronary angiography and invasive coronary physiology assessment. Significant coronary artery disease (defined as  $> 50\%$  stenosis on coronary angiography and/or FFR  $< 0.80$ ) and severe valvular heart disease were considered exclusion criteria. A cohort of consecutive patients affected by idiopathic dilated cardiomyopathy (DCM) and without AF was also analyzed as a control group. Invasive coronary physiology assessment was performed with a pressure and temperature sensor-tipped wire (PressureWire X) and data were analyzed by a dedicated software (Coroventis System). The presence of CMD was defined by CFR values  $< 2.0$  and/or IMR  $> 25$ .

**Results.** Among 65 patients enrolled: 30 were in the preserved LVEF group, 25 in the AIC group and 10 in the DCM group. Baseline characteristics were comparable between each group, except for persistent AF which was more frequent in the AIC group, and LVEF which was reduced in AIC and DCM groups by definition. Invasive coronary physiology assessment showed a significantly higher prevalence of CMD in the AIC group compared to preserved LVEF and DCM groups (76% vs 20%,  $p < 0.001$  and 76% vs 20%,  $p = 0.01$  respectively). This was represented by lower coronary flow reserve (CFR) in the AIC group compared to preserved LVEF and DCM groups [1.9 (IQR: 1.1, 2.5) vs 3.3 (IQR: 2.1, 4.3),  $p < 0.001$  and 1.9 (IQR: 1.1, 2.5) vs 3.0 (IQR: 2.9, 3.8),  $p = 0.03$  respectively] and higher index of microcirculatory resistance (IMR) [28 (IQR: 22, 47) vs 16 (IQR: 10, 23),  $p = 0.001$  and 28 (IQR: 22, 47) vs 16 (IQR: 9, 24),  $p = 0.03$  respectively]. Moreover, among patients with AF, we

observed a significant correlation between CFR and LVEF (coefficient beta: 3.14, 95% CI: 0.63, 5.64,  $p=0.015$ ) and between IMR and LVEF (coefficient beta: -0.30, 95% CI: -0.48, -0.11,  $p=0.002$ ).

**Conclusions.** Our study suggests that CMD might be involved in the pathogenesis of AIC development in patients with recent onset of AF.

**P39**

**IMPACT OF CORONARY MICROVASCULAR DYSFUNCTION ON THE DIAGNOSTIC PERFORMANCE OF QUANTITATIVE FLOW RATIO IN PREDICTING INVASIVE FRACTIONAL FLOW RESERVE**

Michele Mattia Viscusi<sup>1</sup>, Dario Bertolone<sup>1</sup>, Marta Belmonte<sup>1</sup>, Giulia Botti<sup>1</sup>, Monika Shumkova<sup>1</sup>, Angelo Ratti<sup>1</sup>, Pasquale Paolisso<sup>1</sup>, Bernard De Bruyne<sup>1</sup>, Emanuele Barbato<sup>1</sup>, Marc Vanderheyden<sup>1</sup>, Emanuele Gallinoro<sup>1</sup>

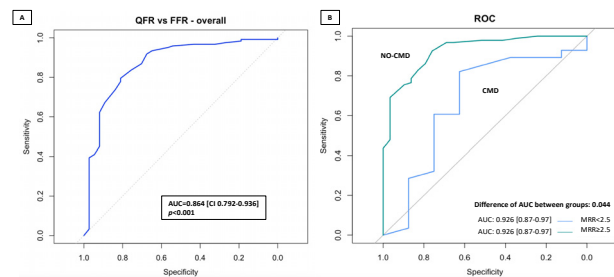
<sup>1</sup>OLV Cardiovascular Center, Aalst, Belgium

**Introduction.** Quantitative flow ratio (QFR) is a novel wire-free technique developed to assess the functional significance of coronary stenoses by utilizing 3-dimensional quantitative angiography (3D-QCA) and frame counting. However, since QFR is derived from computational analysis of angiographic data and thus requiring fixed reproducible standardized conditions to precisely predict invasive fractional flow reserve (FFR), the presence of coronary microvascular dysfunction (CMD), as defined accordingly by an abnormal microvascular resistance reserve (MRR), may alter this prespecified hemodynamic profile. As a consequence, potential discrepancies between the QFR and FFR may be attributed to the status of the subtended coronary microcirculation. Therefore, we aimed to evaluate the impact of CMD on the diagnostic accuracy of QFR.

**Methods.** This is an observational, single-center, study involving 169 patients with both obstructive and non-obstructive coronary artery disease undergoing FFR measurement and a comprehensive microvascular assessment of absolute flow (Q) and resistance (R) with continuous thermodilution. The study population has been grouped according to the underlying microcirculatory status defined by MRR. Particularly, the presence of CMD has been defined by an abnormal MRR (<2.5). The impact of CMD on the diagnostic performance of QFR has been assessed using FFR as reference.

**Results.** In the overall cohort, the diagnostic efficiency of QFR (area under the receiver-operating characteristic curve [AUC]) were high (AUC: 0.864 [95% confidence interval (CI): 0.792-0.936]). However, when assessed according to microcirculatory status, a significantly lower AUC of QFR were found in the CMD group as compared with the non-CMD group (AUC: 0.67 [95% CI: 0.43-0.89] vs. 0.93 [95% CI: 0.87-0.97];  $p<0.05$ ). According to the multivariate analysis, independent predictors of disagreement between QFR and FFR were MRR <2.5 and the (% diameter stenosis ( $p=0.042$  and  $p=0.011$ , respectively).

**Conclusions.** CMD decrease the diagnostic performance of QFR in predicting FFR and represent an independent predictor of disagreement between the two techniques.



**P40**

**PROGNOSTIC ROLE OF POST PERCUTANEOUS CORONARY INTERVENTION PHYSIOLOGICAL ASSESSMENT IN PATIENTS WITH DIABETES MELLITUS**

Domenico Galante<sup>1</sup>, Stefano Migliaro<sup>2</sup>, Gianluca Anastasia<sup>3</sup>, Federico Di Giusto<sup>3</sup>, Edoardo Petrolati<sup>3</sup>, Andrea Vicere<sup>3</sup>, Chiara Giuliana<sup>3</sup>, Ciro Pollio Benvenuto<sup>3</sup>, Vincenzo Viccaro<sup>3</sup>, Alessandro Conte<sup>3</sup>, Cristina Aurigemma<sup>3</sup>, Enrico Romagnoli<sup>3</sup>, Francesco Burzotta<sup>3</sup>, Carlo Trani<sup>3</sup>, Filippo Crea<sup>3</sup>, Antonio Maria Leone<sup>1</sup>

<sup>1</sup>Ospedale Fatebenefratelli Isola Tiberina, Gemelli Isola Roma, Rome,

<sup>2</sup>Aurelia Hospital, Rome, <sup>3</sup>Università Cattolica del Sacro Cuore-

Fondazione Policlinico Gemelli, Rome

**Background.** Emerging data showed that Physio-guided PCI (which incorporates functional assessment before and after the procedure) is associated with a reduced risk of adverse cardiovascular events. However, its role to predict outcome in patients with diabetes mellitus is not well established.

**Aims.** We investigated the prognostic ability of Physio-guided PCI to predict outcomes in patients with or without diabetes mellitus.

**Methods.** This is a sub-study of the PROPHET-FFR registry. Patients were divided in two groups according to the presence of diabetes mellitus; each subgroup was then stratified into three groups based on the results of invasive physiological assessment (IPA): Control group comprising patients for whom PCI was deferred based on a IPA; Angio-Guided PCI group comprising patients undergoing PCI based on a IPA but without a post-PCI IPA; Physio-guided PCI group comprising patients undergoing PCI based on a IPA and an IPA after PCI; The primary endpoint was the rate of major adverse cardiac events (MACEs), defined as a composite of death from any cause (AD), myocardial infarction (MI) and target vessel revascularization (TVR) at 36-months.

**Results.** A total of 1322 patients and 1591 lesions were available for the analysis. At Kaplan-Meier analysis with log-rank test the rate of MACEs was significantly higher in the Angio-guided PCI Group both in non-diabetic (8.9% in Control Group, 16.2% in Angio-guided PCI Group, 9.0% Physio-guided PCI Group,  $p<0.01$ ) and diabetic patients (11.9% in Control Group, 27.1% in Angio-guided PCI Group, 7.2% Physio-guided PCI Group,  $p<0.01$ ). A significant benefit of Physio-guided PCI over Angio-guided PCI was observed in patients with diabetes mellitus (MACEs, 27.1 Angio-guided PCI Group, 7.2% Physio-guided PCI Group  $p<0.01$ ), driven principally by TVR (12.9 Angio-guided PCI Group, 4.3% Physio-guided PCI Group  $p=0.07$ ) and AD (14.3 Angio-guided PCI Group, 1.4% Physio-guided PCI Group  $p<0.01$ ). This was less evident in non-diabetic patients (MACEs, 16.2 Angio-guided PCI Group, 9.0% Physio-guided PCI Group  $p=0.105$ ).

**Conclusions.** Physio-guided PCI confirmed its ability to predict outcomes in patients with or without diabetes mellitus. This benefit was consistently observed when compared to Angio-guided PCI only among patients with diabetes mellitus. These findings support the potential clinical utility of physio-guided PCI, particularly in patients with diabetes mellitus.

**P41**

**SEX-RELATED DIFFERENCES IN ABSOLUTE CORONARY FLOW AND MICROVASCULAR RESISTANCE IN PATIENTS WITH ANGINA AND NON-OBSTRUCTED CORONARY ARTERIES (ANOCA)**

Marta Belmonte<sup>1</sup>, Emanuele Gallinoro<sup>2</sup>, Dario Bertolone<sup>1</sup>, Pasquale Paolisso<sup>1</sup>, Michele Mattia Viscusi<sup>1</sup>, Tatyana Storozhenko<sup>1</sup>, Koshiro Sakai<sup>1</sup>, Giulia Botti<sup>1</sup>, Emanuele Barbato<sup>3</sup>, Marc Vanderheyden<sup>1</sup>, Carlos Collet<sup>1</sup>, Bernard De Bruyne<sup>1</sup>

<sup>1</sup>Cardiovascular Center OLV Aalst, Belgium, <sup>2</sup>IRCCS Ospedale Galeazzi

Sant'Ambrogio, Department of Biomedical and Clinical Sciences,

University of Milan, Milano, <sup>3</sup>Università La Sapienza, Roma

**Introduction.** Women with angina more often have non-obstructive coronary artery disease (ANOCA) compared to males. Coronary microvascular dysfunction (CMD) is responsible for angina in a sizable proportion of ANOCA patients. Intracoronary continuous thermodilution allows direct quantification of absolute coronary flow (Q) and microvascular resistance ( $R_{\mu}$ ). Our aim was to evaluate gender-related differences in the prevalence and pattern of CMD assessed with intracoronary continuous thermodilution in ANOCA patients. Specifically, we assessed resting and hyperemic Q ( $Q_{rest}$  and  $Q_{hyper}$ ),  $R_{\mu}$  ( $R_{\mu,rest}$  and  $R_{\mu,hyper}$ ), coronary flow reserve (CFR), and microvascular resistance reserve (MRR) in ANOCA patients stratified by gender.

**Methods.** Single-center, prospective study of patients with ANOCA. CMD was invasively assessed by intracoronary continuous thermodilution in the left anterior descending artery (LAD) and defined as CFR <2.5.

**Results.** A total of 118 patients (n=49 females and n= 69 males) were enrolled. The mean patient age was 65 years. The mean fractional flow reserve (FFR) was  $0.85\pm 0.04$ , with no difference between the 2 genders. There was no difference in  $R_{\mu,rest}$ ,  $Q_{rest}$  and  $Q_{hyper}$  between the two genders. However,  $R_{\mu,hyper}$  were higher in females compared to males ( $p=0.003$ ). Among patients with ANOCA, CMD was more prevalent in females (28% vs 22%,  $p=0.014$ ). Yet, in both females and males with CMD, a higher  $Q_{rest}$  was observed compared to patients without CMD. In male patients, also  $Q_{hyper}$  was lower in CMD patients versus those without CMD.

**Conclusions.** Among patients with ANOCA and investigated with intracoronary continuous thermodilution, CMD appeared more prevalent in females compared to males. Females had higher microvascular  $R_{\mu,hyper}$  compared to males. In both genders, CMD was characterized by higher  $Q_{rest}$ , suggestive of functional rather than structural CMD.

**P42**

**FEASIBILITY AND EFFICACY OF “PHYSIOLOGY-GUIDED PCI” USING PRESSURE CATHETER IN COMPARISON TO CONVENTIONAL PRESSURE WIRES: A MULTICENTRE STUDY**

Antonio Maria Leone<sup>1</sup>, Gianluca Anastasia<sup>2</sup>, Simone Biscaglia<sup>3</sup>, Domenico Galante<sup>1</sup>, Federico Di Giusto<sup>4</sup>, Stefano Migliaro<sup>2</sup>, Edoardo Petrolati<sup>6</sup>, Filippo Maria Verardi<sup>3</sup>, Davide Scancarello<sup>3</sup>, Rocco Vergallo<sup>2</sup>, Gianluca Campo<sup>3</sup>, Italo Porto<sup>2</sup>

<sup>1</sup>Ospedale Fatebenefratelli Isola Tiberina- Gemelli Isola, Roma, <sup>2</sup>Policlinico San Martino Genova, Genova, <sup>3</sup>Azienda Ospedaliera Universitaria di Ferrara, Ferrara, <sup>4</sup>Ospedale “C. e G. Mazzoni” AST Ascoli Piceno, Ascoli Piceno, <sup>5</sup>Aurelia Hospital, Roma, <sup>6</sup>Fondazione Policlinico Gemelli-Università Cattolica del Sacro Cuore, Roma

**Introduction.** Physiological assessment of intermediate coronary stenosis plays a key role for the selection of lesions susceptible to PCI. Growing evidence showed that invasive coronary functional assessment can also play a role in assessing the immediate outcome of PCI and also predict the clinical outcome of the patient. However the role of invasive physiological assessment in evaluating the immediate result of PCI, to optimize it and predict prognosis is less established. This also depends on the complexity of handling pressure wires, especially during the rewiring phase of the treated vessel. Furthermore, especially in the presence of diffuse disease and/or other untreated lesions in the target vessel, performing multiple rewires to check physiological result during PCI is considered risky. The monorail pressure catheter (Navvus Acist, USA), represents a valid alternative to this limitation because it works with a workhorse wire used for PCI.

**Methods.** This is a multicentre retrospective study involving patients who underwent invasive physiological assessment at the Policlinico Universitario A. Gemelli IRCCS in Rome (Italy) and at the Cardiology Department of the Azienda Ospedaliera Universitaria di Ferrara (Italy). Patients of Policlinico Universitario A. Gemelli IRCCS were selected by PROPHET-FFR study (NCT05056662). We compared patients who underwent PCI after an ischaemic FFR (or NHPR) value was obtained with the pressure catheter (PC group) with a similar patient population in whom functional assessment was performed with standard pressure wires (PW group).

**Results.** We enrolled 460 patients with 479 lesions undergoing PCI after the evidence of at least one hemodynamically significant stenosis. 143 patients with 150 lesions assessed using pressure catheter (PC) and 316 patients with 328 lesions assessed using conventional pressure wires (PW). After the achievement of a satisfactory angiographic result, post-PCI FFR assessment was performed in 127 cases (84.7%) using PC vs 134 cases (40.9%) using a PW (p<0.0001), without a significant difference in the post PCI FFR value (0.88±0.05 vs 0.87±0.05, p>0.05). A suboptimal post-PCI functional result (FFR/cFFR <0.90) was observed in 43 cases (33.9%) of the PC group vs 66 cases (49.3%) of PW group. An optimization was done with post-dilatation or further stenting in 23 cases (53.4%) of PC group vs 19 cases (28.8%) of PW group. This resulted in a higher final FFR result in the PC group than in the PW group (0.90±0.04 vs 0.88±0.04, p=0.056), despite a worse basal FFR value (0.75±0.08 vs 0.78±0.06, p<0.0001). A sub-analysis was performed selecting only the lesions on LAD (n=114 vs n=252 lesions respectively in PC and PW group). This showed a statistically significant difference in the post-PCI FFR value between the PC group and the PW group (0.90±0.04 vs 0.88±0.04, p=0.035). We also performed a propensity score analysis matching patients of both groups (PW n= 111; PC n=111) with similar clinical and angiographic baseline characteristics. This analysis confirms a higher rate of post-PCI functional evaluations (89.2% vs 38.7%, p<0.01), optimizations (53.8% vs 4.7%, p<0.01) and better final FFR value (0.90±0.04 vs 0.87±0.03, p=0.019) in PC group vs PW group with no significant difference of rate of suboptimal functional result post-PCI (39.4% vs 48.8%, p=0.295) and post-PCI FFR values (0.88±0.04 vs

**Table 1.** Baseline clinical characteristics.

	OVERALL	PRESSURE CATHETER	PRESSURE WIRES	p-value
N Patients	460	143	316	
N Lesions	479	150	328	
Male sex		97 (75.2%)	236 (77.6%)	>0.05
Age (years)		71.3	68.9	0.015
Ipertension		104 (83.9%)	224 (78.9%)	>0.05
Dyslipidemia		93 (75.6%)	219 (76.0%)	>0.05
Diabetes		54 (43.2%)	94 (34.2%)	0.083
Smoke		52 (40.6%)	131 (52.0%)	0.036
CAD family history		39 (33.3%)	76 (27.5%)	>0.05
LVEF (%)		52.2 ± 11.1	54.4 ± 11.3	0.074
MDRD (ml/min)		74.2 ± 24.7	80.7 ± 22.6	0.073
Previous MI/ACS		29 (23.6%)	89 (29.9%)	>0.05
Previous PCI		36 (28.0%)	143 (32.5%)	>0.05

**Table 2.** Baseline angiographic characteristics.

	PRESSURE CATHETER	PRESSURE WIRES	p-value
In tandem lesions	38 (25.5%)	105 (33.3%)	0.088
In-stent lesions	11 (7.3%)	32 (10.2%)	>0.05
Bifurcations	49 (33.3%)	34 (15.3%)	<0.0001
Angiographic evaluation (%)	67.4 ± 14.4	65.0 ± 11.2	0.081

**Table 3.** Functional evaluations and suboptimal results rate.

	OVERALL	PRESSURE CATHETER	PRESSURE WIRES	p-value
N functional evaluation post-PCI		127 (84.7%)	134 (40.9%)	<0.0001
N FFR post-PCI		103 (81.1%)	109 (81.3%)	>0.05
N suboptimal FFR post-PCI (FFR <0.81)		6 (8.5%)	5 (6.4%)	>0.05
N suboptimal FFR post-PCI (FFR <0.85)		15 (21.1%)	23 (29.5%)	>0.05
N suboptimal FFR post-PCI (FFR <0.90)		33 (46.5%)	51 (65.4%)	0.02
N suboptimal FFR/cFFR (<0.90)		43 (33.9%)	66 (49.3%)	0.012
N suboptimal FFR/cFFR (<0.85)		20 (15.7%)	28 (20.9%)	>0.05

**Table 4.** Overall functional assessment details.

	OVERALL	PRESSURE CATHETER	PRESSURE WIRES	p-value
Basal Pd/Pa		0.86 ± 0.10	0.91 ± 0.45	>0.05
Basal iFR/RFR/dPR		0.74 ± 0.17	0.84 ± 0.09	<0.0001
Basal cFFR		0.78 ± 0.17	0.81 ± 0.05	0.002
Basal FFR		0.75 ± 0.08	0.78 ± 0.06	<0.0001
Post-PCI Pd/Pa		0.94 ± 0.04	0.93 ± 0.03	>0.05
Post-PCI iFR/RFR/dPR		0.93 ± 0.06	0.91 ± 0.03	>0.05
Post-PCI cFFR		0.89 ± 0.05	0.89 ± 0.05	>0.05
Post-PCI FFR		0.88 ± 0.05	0.87 ± 0.05	>0.05
Post-Optimization Pd/Pa		0.94 ± 0.03	0.94 ± 0.03	>0.05
Post-Optimization iFR/RFR/dPR		0.92 ± 0.04	0.92 ± 0.02	>0.05
Post-Optimization cFFR		0.89 ± 0.05	0.90 ± 0.02	>0.05
Post-Optimization FFR		0.90 ± 0.06	0.90 ± 0.04	>0.05
Final cFFR		0.90 ± 0.04	0.89 ± 0.04	0.058
Final iFR/RFR/dPR		0.94 ± 0.04	0.92 ± 0.03	0.005
Final FFR		0.90 ± 0.04	0.88 ± 0.05	>0.05

**Table 5.** Functional assessment details on LAD.

	OVERALL	PRESSURE CATHETER	PRESSURE WIRES	p-value
Basal Pd/Pa		0.86 ± 0.09	0.91 ± 0.5	>0.05
Basal iFR/RFR/dPR		0.76 ± 0.18	0.83 ± 0.08	0.001
Basal cFFR		0.79 ± 0.06	0.81 ± 0.05	>0.05
Basal FFR		0.75 ± 0.08	0.78 ± 0.05	<0.0001
Post-PCI Pd/Pa		0.88 ± 0.04	0.86 ± 0.03	>0.05
Post-PCI iFR/RFR/dPR		0.93 ± 0.04	0.91 ± 0.03	0.04
Post-PCI cFFR		0.88 ± 0.04	0.88 ± 0.04	>0.05
Post-PCI FFR		0.88 ± 0.05	0.86 ± 0.05	>0.05
Post-Optimization Pd/Pa		0.94 ± 0.03	0.94 ± 0.03	>0.05
Post-Optimization iFR/RFR/dPR		0.92 ± 0.04	0.92 ± 0.02	>0.05
Post-Optimization cFFR		0.89 ± 0.05	0.89 ± 0.03	>0.05
Post-Optimization FFR		0.90 ± 0.06	0.91 ± 0.05	>0.05
Final cFFR		0.90 ± 0.04	0.89 ± 0.04	>0.05
Final iFR/RFR/dPR		0.93 ± 0.03	0.91 ± 0.03	0.011
Final FFR		0.90 ± 0.04	0.88 ± 0.04	0.035

**Table 6.** Propensity score matched population, baseline clinical characteristics (matched variables: age, male sex, diabetes, acute coronary syndromes, bifurcation, % stenoses).

Patients (n=222)	Pressure Catheter (n=111)	Pressure Wire (n=111)	p value
Age (mean±DS)	71.0±9.6	69.5±8.2	0.220
Hypertension %	84.6	77.9	0.210
Diabetes Mellitus %	44.1	37.8	0.339
Dyslipidemia %	77.3	83.6	0.234
Male sex %	76.6	69.4	0.226
Smoking %	40.9	32.9	0.258
Family History of CAD %	32.0	36.0	0.536
EF < 40%	12.6	9.1	0.387
MDRD (mean±DS)	73.6±24.8	84.7±24.5	0.076
Previous PCI %	29.7	28.4	0.833
ACS %	28.8	24.3	0.447

**Table 7.** Propensity score analysis, baseline lesions characteristics.

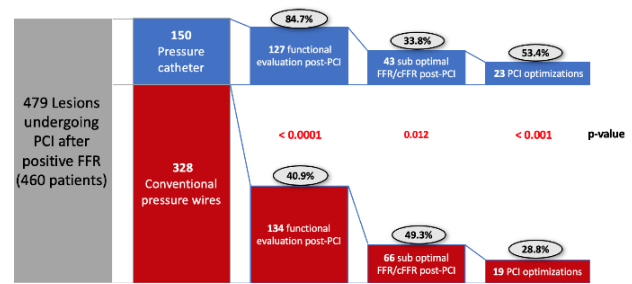
Lesions (n=222)	Pressure Catheter (n=111)	Pressure Wire (n=111)	p-value
% stenoses	67.8±13.5	68.1±9.3	0.837
In tandem lesions %	30.6	32.4	0.772
In stent-restenosis %	6.3	8.1	0.603
Bifurcation %	31.5	32.4	0.885
LAD %	81.1	81.9	0.862

**Table 8.** Propensity score analysis, functional evaluation and suboptimal results.

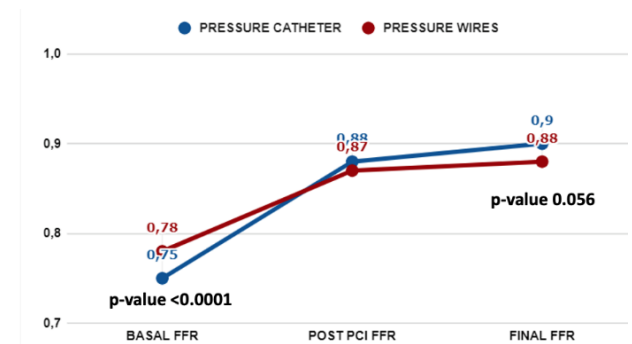
	Pressure Catheter (n=111)	Pressure wire (n=111)	p value
N° functional evaluation post PCI	99 (89.2%)	43 (38.7%)	<0.01*
N° FFR post PCI	59 (59.6%)	25 (58.1%)	0.871
N° FFR post PCI<0.80	5 (8.5%)	0 (0.0%)	0.133
N° FFR post PCI<0.85	14 (23.7%)	6 (24.0%)	0.978
N° FFR post PCI<0.90	28 (47.5%)	18 (72.0%)	0.04*
N° FFR/cFFR post PCI <0.85	18 (18.2%)	6 (14.0%)	0.536
N° FFR/cFFR post PCI <0.90	39 (39.4%)	21 (48.8%)	0.295
N° Optimizations	21	1	
N° Optimizations (% of N° FFR/cFFR post PCI <0.90)	53.8	4.7	<0.01*

**Table 9.** Propensity score analysis, functional assessment details.

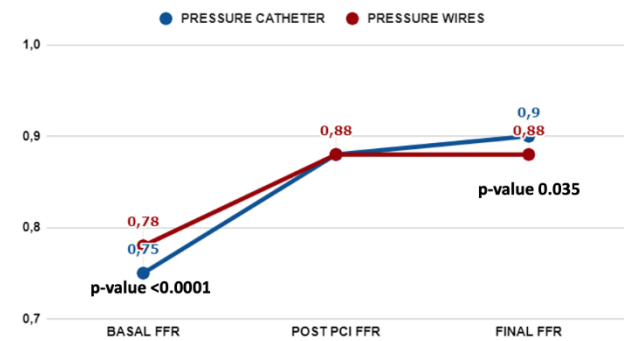
Lesions (n=222)	Pressure Catheter (n=111)	Pressure Wire (n=111)	p-value
Basal Pd/Pa	0.85±0.11	0.89±0.03	<0.01*
Basal NHIs	0.86±0.04	0.79±0.10	0.153
Basal cFFR	0.78±0.07	0.81±0.04	0.051
Basal FFR	0.75±0.09	0.76±0.03	0.490
post PCI Pd/Pa	0.93±0.03	0.94±0.03	0.172
post PCI NHIs	0.95±0.04	0.93±0.02	0.677
post PCI cFFR	0.86±0.04	0.89±0.03	0.091
post PCI FFR	0.88±0.04	0.87±0.03	0.263
Final NHIs	0.95±0.04	0.93±0.02	0.677
Final cFFR	0.90±0.03	0.92±0.01	0.500
Final FFR	0.90±0.04	0.87±0.03	0.019*
Δ (FFR post PCI - basal FFR)	0.13±0.09	0.11±0.06	0.374
Δ (Final FFR - FFR post PCI)	0.024±0.04	0.001±0.03	0.012*



**Figure 1.** Flow of functional assessment and treatment lesions-based



**Figure 2.** Overall FFR trend.



**Figure 3.** FFR trend on LAD.

0.87±0.03, p=0.263). A preliminary follow up analysis showed 14 MACE (composite endpoints of CV death, myocardial infarction, TVF and TVR) in PW group and 3 MACE in PW group with better survival trend (log-rank p=0.16, mean follow-up 14 months).

**Conclusions.** The use of the pressure catheter, using common workhorse wires, leads to greater procedural easiness and consequently more post-PCI functional re-evaluations, physiology guided optimizations and so higher final FFR values than traditional pressure wires. This could be associated with a better prognosis in patients treated with pressure catheter. Further larger prospective randomized trials are needed to obtain more data about clinical outcome.

## PERIPHERAL: ACUTE PULMONARY EMBOLISM

### P43

#### L'EMBOLIA POLMONARE ACUTA: NUOVI ORIZZONTI IN LABORATORIO DI EMOdinamica

Gioacchino Valenti, Guido Rusticali, Alberto Monello, Luciano Losi, Daniela Aschieri, Giovanni Nani, Francesco Passerini  
AUSL Piacenza, Piacenza

**Introduzione.** La TEP ha incidenza di 30-100 casi/100.000 abitanti/anno ed è una delle principali cause di mortalità cardiovascolare. Le linee guida ESC 2019 suggeriscono di trattare con eparina i pazienti a rischio intermedio-alto (non ipotensione, ventricolo destro alterato e alti valori di troponina), sconsigliando la trombolisi (rischio emorragico) e lasciando l'embolectomia a giudizio del clinico in caso di sopraggiunta instabilità emodinamica (limitatamente a quei centri in cui la tecnologia è

accessibile). Il caso descritto tratta di un paziente con TEP a rischio intermedio-alto e di come l'intuizione del cardiologo sia stata supportata dal lavoro del team multidisciplinare affinché il trattamento potesse essere effettuato in tempi utili.

**Caso clinico.** Femmina 75 anni affetta da ipertensione sistemica e recentemente dimessa con diagnosi di polmonite si presentava in PS lamentando dispnea. L'angio-TC mostrava TEP con trombo a cavaliere occupante gran parte delle arterie polmonari, severa dilatazione ventricolare destra (diametro basale 50 mm, 44 mm RVOT medio), vena cava dilatata; emodinamica stabile (PA 120/90 mmHg), troponina I lievemente aumentata (73.4 ng/L, v.n. <12 ng/L), che ponevano la paziente nella classe di rischio intermedio-alto, per cui veniva somministrata eparina e.v. come da linee guida. Successiva angio-TC svolta in quarta giornata non mostrava miglioramento del quadro radiologico. Perdurando la stabilità emodinamica che non poneva indicazione a trombolisi sistemica e l'ipossiemia con desaturazione periferica (pO<sub>2</sub> 60 mmHg, SO<sub>2</sub> <90%), veniva richiesta possibilità di utilizzo di tromboaspirazione polmonare. Nel rispetto delle linee guida ESC, il gruppo multidisciplinare (cardiologo clinico, emodinamista, farmacista) redigeva un documento per validarne. In quinta giornata veniva effettuata la procedura di embolectomia polmonare per via transfemorale (dispositivo Flowtriever). L'aspirazione del trombo (6cm lunghezza) migliorava fin da subito la PAPS: pre 67 mmHg, post 43 mmHg. All'angio-TC di controllo non più evidenziato trombo nei rami arteriosi principali (permanenza di trombi nelle segmentarie e subsegmentarie). All'ecocardiogramma pre-dimissione PAPS stimata 30 mmHg, TAPSE 19 mm.

**Conclusioni.** L'embolia polmonare acuta tutt'oggi rappresenta una realtà clinica per la quale non sono disponibili, in tutti i Centri, strategie terapeutiche efficaci sia nel trattamento del caso in acuto, sia per la prevenzione del quadro di ipertensione polmonare da tromboembolismo cronico. Il dispositivo Flowtriever da noi utilizzato si è dimostrato di facile e sicuro utilizzo, con risultato terapeutico immediato, sia dal punto di vista clinico che strumentale.

#### P44

##### THE FLOW MUST GO ON: LA TROMBECTOMIA MECCANICA PERCUTANEA NEL PAZIENTE CON TEP MASSIVA E INSTABILITÀ EMODINAMICA

Francesco Paolo Cancro, Francesco Vigorito, Amelia Ravera, Antongiulio Maione, Adele Pierri, Marco Di Maio, Gennaro Galasso, Tiziana Attisano, Cesare Baldi  
Azienda Ospedaliera Universitaria "San Giovanni di Dio e Ruggi d'Aragona", Salerno

Riportiamo il caso di una donna di 63 anni, con storia di recente intervento chirurgico per ulcera gastrica perforata complicato da peritonite, la quale accede presso il Pronto Soccorso (PS) della nostra Azienda Ospedaliera riferendo dispnea ingravescente ed episodio sincopeale. In PS riscontro di PA 80/50 mmHg, SpO<sub>2</sub> 87% in aria ambiente, all'emogasanalisi arteriosa riscontro di ipossia ipocapnica (O<sub>2</sub> 63 mmHg; pCO<sub>2</sub> 19 mmHg) e lattati 6.6 mmol/L, agli esami ematochimici riscontro di D-Dimero 6627. All'ecocardiogramma evidenza di ventricolo destro dilatato (RVD1 43 mm) con ridotta funzione contrattile (TAPSE 14 mm), e segni diretti e indiretti di ipertensione polmonare (PAPS 50 mmHg; D-shape del ventricolo sinistro; movimento paradossale del SIV). Nel sospetto di TEP veniva praticata angio-TC del torace in urgenza che documentava lungo i rami polmonari bilaterali multipli difetti di opacizzazione, in particolare a livello ilare e delle diramazioni dei lobi superiori e inferiori come da TEP massiva bilaterale; pertanto, la paziente veniva trasferita in unità di terapia intensiva cardiologica (UTIC). Per il persistere delle condizioni di instabilità emodinamica e per la controindicazione assoluta alla trombolisi (recente intervento chirurgico maggiore) veniva programmato intervento di trombectomia meccanica percutanea. Il controllo angiografico con catetere pig-tail documentava subocclusione tromboembolica di entrambi i rami polmonari principali con multipli difetti di riempimento dei rami lobari; pertanto, su guida "extra-stiff" si posizionava sistema FlowTriever® 24 Fr, effettuando multiple aspirazioni con rimozione di grosse quantità di materiale trombotico bilateralmente. Al termine della procedura si è verificato dimezzamento delle pressioni in arteria polmonare (da 50/25/30 mmHg a 30/10/15 mmHg), miglioramento degli indici ventricolari destri (RVD1 33 mm; TAPSE 20 mm; PAPS 27 mmHg) e miglioramento dell'emodinamica della paziente. Dopo 24 ore di monitoraggio in UTIC la paziente è stata trasferita nel reparto di Cardiologia dove per la persistenza di residui trombotici in vena safena è stata iniziata terapia anticoagulante orale con apixaban 5 mg bid. Dopo 5 giorni di degenza non complicata, la paziente è stata dimessa asintomatica e in buon compenso emodinamico.

La trombectomia meccanica percutanea per il trattamento della tromboembolia polmonare (TEP) è indicata nei pazienti con TEP ad alto rischio che presentano controindicazioni assolute alla trombolisi (IIa classe di evidenza C, secondo le linee guida ESC). Essa può essere praticata mediante diversi cateteri che possono provocare la frammentazione meccanica del trombo, l'aspirazione o anche, un approccio combinato meccanico e farmacologico con l'iniezione in-situ del

trombolitico. La maggior parte dei dati sulla trombectomia meccanica derivano da registri prospettici e trial con campioni ridotti, prevalentemente utilizzando la frammentazione ad ultrasuoni; da questi studi è emerso un notevole miglioramento della funzione ventricolare destra e della perfusione e pressione polmonare. Di recente lo studio FLARE che ha valutato l'efficacia e la sicurezza dell'utilizzo del sistema FlowTriever® in pazienti con TEP a rischio intermedio ha dimostrato un significativo miglioramento degli indici ventricolari destri, senza un significativo aumento delle complicanze emorragiche.

In conclusione, la trombectomia meccanica polmonare trova attualmente indicazione in pazienti con TEP ad alto rischio e controindicazione alla terapia trombolitica o lì dove la terapia trombolitica è stata utilizzata ma risultata inefficace. Il suo impiego come alternativa alla terapia trombolitica nei pazienti a rischio elevato o nei pazienti con TEP a rischio intermedio è in corso di valutazione.

## STRUCTURAL HEART DISEASE: GENERAL

#### P45

##### EFFICACY AND SAFETY OF VENOUS CLOSURE DEVICES USED FOR LEFT ATRIAL APPENDAGE OCCLUSION AND PATENT FORAMEN OVALE CLOSURE: A SINGLE CENTER EXPERIENCE

Gianluca Pillitteri, Pierluigi Merella, Giovanni Lorenzoni, Enrico Atzori, Cristiana Denurra, Giuseppe Talanas, Gavino Casu  
UOC Cardiologia Clinica e Interventistica, Ospedale AOU SS Annunziata, Sassari

**Introduction.** Vascular closure devices (VCDs) have demonstrated a significant reduction in post-procedural complications and a rapid recovery of ambulation, an early discharge and a reduced incidence of complications associated with vascular access site.

**Methods.** A prospective and observational study was carried out at our Interventional Cardiology Hub Center. Between January 2023 and June 2023, we enrolled 49 patients who underwent percutaneous closure of the left atrial appendage (LAAO) and patent foramen ovale (PFO) closure in our center. Venous vascular access was ultrasound guided and hemostasis was obtained using the Perclose Prostyle System. This system allows the execution of a percutaneous suture of the access site, leading to primary healing without presenting restrictions in case of need for new access to the same site, unlike devices with plug release.

**Results.** We enrolled 49 patients; mean age was 68.4 years (±16.4) with 63% of male patients. LAAO was performed in 36 patients (73%) with a mean age of 76.9 years (±7.3). In this group, 26 patients (72%) underwent LAAO for atrial fibrillation (AF) and high bleeding risk, 8 patients (22%) for AF and high thrombotic risk, 2 patients (6%) with AF and cerebral vascular malformations or amyloid angiopathy. Devices used were: Amplatzer Amulet (23 patients, 64%), Watchman FLX (8 patients, 22%) and LAmbré (5 patients, 14%). PFO closure was performed in 13 patients (26%), with a mean age of 44.9 (±10.1). In this group, 8 patients (62%) had ischemic stroke, while 5 patients (38%) experienced transient ischemic attack (TIA). VCDs were effective with achievement of immediate hemostasis in 43 patients (88%). In 12% of cases (6 patients) device failure was observed and manual compression was needed in 5 patients. In a single case, Z-suture was performed as bailout strategy. Ambulation was achieved within 12 hours of the procedure in 51% of cases (25 patients). In the remaining 49% (24 patients) it was obtained within the day following surgery. Complications potentially related to VCDs were found in only 3 cases (6%): a case of severe anemia with the need to blood transfusions, a case of vascular stenosis at the access site and a case of large femoral hematoma. The mean recovery days of patients undergoing these interventional procedures was 3.5 days. Hospitalization was only 2 days in 82% of cases (40 patients), corresponding to the time required to perform the procedure and subsequent 24-hour monitoring. Only in one case the hospital stay was lengthened due to a complication VDC-associated.

**Conclusions.** On the basis of our experience, using VCDs for venous vascular percutaneous procedures (LAAO and PFO closure) we had a quick achievement of hemostasis with a low rate of vascular complications.

	LAAO	PFO-Closure	Total
<b>Sex (M/F)</b>	23/13	8/5	31/18
<b>Age (years)</b>	76.9 (± 7.3)	44.9 (± 10.1)	68.4 (± 16.4)
<b>Success</b>	86%	92%	88%
<b>Complications</b>	8%	0%	6%
<b>Hospitalization (days)</b>	4	2.1	3.5

**P46**

**TRANSCATHETER CLOSURE OF MECHANICAL VERSUS BIOLOGICAL PROTHESIS MITRAL PARAVALVULAR LEAKS**

Alessandro Appetecchia, Annunziata Nusca, Fabio Mangiacapra, Rosetta Melfi, Elisabetta Ricottini, Paolo Gallo, Nino Cocco, Raffaele Rinaldi, Federica Coletti, Giuseppe Migliaro, Simone Circhetta, Francesco Grigioni, Gian Paolo Ussia

Department of Medicine, Università Campus Bio-Medico di Roma, Roma

**Rationale.** Paravalvular leak (PVL) is a severe but rare surgical mitral valve replacement complication. Most PVLs are asymptomatic and follow a benign clinical course due to their small size. When larger, the clinical presentation could be serious, including congestive heart failure or hemolytic anaemia. In this last setting, surgical redo could be a therapeutic option but associated with mortality rates approaching 16%. Therefore, percutaneous transcatheter closure procedures represent a valid alternative to surgery in these high-risk patients.

**Technical resolution.** We discuss two clinical cases undergoing percutaneous transcatheter closure of paravalvular leaks of a mechanical and biological mitral valve, respectively. The first clinical case concerns a 39-year-old female patient with a previous implant of a biological prosthesis and tricuspid plastic because of a severe mitral valve regurgitation (MVR), complicated after five months with bacterial endocarditis and subsequent partial detachment. Five years later, due to the evidence of recurrent severe MVR, she underwent another surgical valve repair with an SJM mechanical prosthesis n. 27, early complicated by partial prosthetic detachment with moderate PVL. For this reason, she underwent a first percutaneous closure of a medial periprosthetic leak following an acute decompensated heart failure episode. Five years later, another percutaneous closure of a lateral periprosthetic leak was carried out due to a new onset of dyspnoic symptoms and a decrease in functional capacity (NYHA Class III). The second clinical case involves a 45-year-old male patient with a previous history of ischemic heart disease treated with coronary bypass (LIMA to LAD, SVGs to MO and RCA) and MVR with Pericarbon More 29 mm biological prosthesis for severe MRV. After five years, he performed a re-intervention for posteromedial mitral prosthesis detachment and TAVI for contextual evidence of severe aortic stenosis. Following the recurrent evidence of a paravalvular leak with hemolytic anaemia (requiring several transfusions), the guy had another transcatheter closure of a mitral periprosthetic leak one year later.

**Clinical implication.** Patients had clinical and echocardiographic improvements after the procedure with excellent positioning of the devices, no interference with the adjacent valve leaflets, no significant residual regurgitation, relief of the dyspnea (NYHA Class II) and improvement of haemoglobin with reduction of hemolysis.

**Perspectives.** Although rare, severe PVL is an essential complication of surgical mitral valve replacement. Percutaneous paravalvular leak closure represents a small but important niche in structural interventions in the current era of interventional cardiology. An expert operator, an expert sonographer and an accurate preoperative patient evaluation by the heart team are required for the appropriate invasive management of this complication to obtain an excellent post-procedural result. Given the high rate of mortality and morbidity related to surgical redo, the percutaneous approach indeed represents a valid alternative with significant hemodynamic and clinical improvement that makes it an option to consider in high-risk patients.

**P47**

**AORTIC BALLOON VALVULOPLASTY EFFICACY AND SAFETY ACCORDING TO CALCIUM DISTRIBUTION AND VALVE GEOMETRY: THE ABCD STUDY**

Gianni Dall'Ara<sup>1</sup>, Carolina Moretti<sup>2</sup>, Caterina Cavazza<sup>3</sup>, Sara Picciocchi<sup>4</sup>, Miriam Compagnone<sup>1</sup>, Giuseppe Guerrieri<sup>5</sup>, Simone Grotti<sup>1</sup>, Daniela Sparta<sup>1</sup>, Elisabetta Fabbri<sup>6</sup>, Emanuela Giampalma<sup>4</sup>, Andrea Santarelli<sup>3</sup>, Marco Balducelli<sup>2</sup>, Marcello Galvani<sup>1</sup>, Fabio Felice Tarantino<sup>1</sup>

<sup>1</sup>UO Cardiologia, Ospedale Morgagni-Pierantoni, Forlì, <sup>2</sup>UO Cardiologia, Ospedale Santa Maria delle Croci, Ravenna, <sup>3</sup>UO Cardiologia, Ospedale Infermi, Rimini, <sup>4</sup>UO Radiologia, Ospedale Morgagni-Pierantoni, Forlì, <sup>5</sup>UO Cardiologia, Ospedale Bufalini, Cesena, <sup>6</sup>UO Ricerca Valutativa e Policy dei Servizi Sanitari, Forlì

**Introduction.** In patients with severe aortic valve stenosis, there are scarce data on the outcome of balloon aortic valvuloplasty (BAV) in relation to valve dimensions, and calcifications pattern. The procedure is not standardized, particularly the choice of the balloon size.

**Methods.** This retrospective multicentre study focused on efficacy and safety of BAV analysing the relationship between the balloon size, annulus geometry (i.e., diameters, perimeter, and area), and calcifications pattern (total burden, and calcium distribution over each individual leaflets). From March 2018 to March 2023, all consecutive patients undergoing BAV and ECG-gated multidetector computed tomography of the aorta were included, except those with a bicuspid valve. Calcium score was calculated on contrast-enhanced images according to a threshold given by luminal attenuation + 100 HU.

**Results.** One hundred and fifteen patients were enrolled. Procedural

success was 82.6%. The balloon-to-annulus ratio (BAR) relative to diameter, perimeter, and area was higher in patients with a successful BAV. In contrast, those who underwent unsuccessful BAV had a significantly higher aortic valve calcium burden, whereas its asymmetrical distribution did not correlate with procedural outcome. The complications rate was 4.3%, and no association with valve geometry or calcium burden was found. BAR minimum diameter was the best parameter to predict procedural success, with a cut-off at 0.85.

**Conclusions.** BAV efficacy is directly correlated with balloon size in relation to annulus dimension and inversely with total calcium burden. The minimum diameter of the valve may be adopted as a reference for the choice of the balloon size.

**STRUCTURAL HEART DISEASE: LAO**

**P48**

**LEFT ATRIAL APPENDAGE CLOSURE PERFORMED USING INTRACARDIAC ECHOCARDIOGRAPHY PROBE VIA ESOPHAGEAL ROUTE: FIRST RESULTS FROM A SINGLE CENTER, REAL-WORLD REGISTRY**

Giulia Laterra<sup>1</sup>, Claudia Artale<sup>2</sup>, Giombattista Barrano<sup>2</sup>, Giorgio Sacchetta<sup>2</sup>, Paolo Mazzone<sup>2</sup>, Maria Concetta Guarneri<sup>2</sup>, Marco Contarini<sup>2</sup>

<sup>1</sup>Cardiologia con UTIC, Umberto I, Enna, <sup>2</sup>Cardiologia con UTIC ed Emodinamica, Umberto I, Siracusa

**Introduction.** Left atrial appendage closure (LAAC) currently represents a standard option for patients with nonvalvular atrial fibrillation and existing contraindication to oral anticoagulation (OAC). Transesophageal echocardiography (TEE)-guided LAAC usually requires administration of anesthetic drugs to manage the discomfort of the probe during the procedure and avoid patient movements. Patients referred for LAAC procedure are usually old and they may have complications related to anesthesia (such as preoperative pulmonary complications, cognitive decline...). This is the premise to identify a "minimalist approach", without general anesthesia, in guiding LAAC. Intracardiac echocardiography (ICE) needs minimal sedation and for this reason it is the standard in some centres. Instead, the use of ICE via the esophageal route (ICE-TEE) is validated to identify the presence of LAA thrombi in patients with atrial fibrillation. We have used ICE TEE to guide the entire LAAC.

**Methods.** We enrolled 40 consecutive patients referred for LAAC. We performed this procedure using ICE-TEE. Procedural data and follow-up for midterm clinical outcomes were collected.

**Results.** According to mean CHA<sub>2</sub>DS<sub>2</sub>-VASc (5,9±1,6) and HAS-BLED (3,6±1,2) scores, the population included in this study was at high risk: 29% had a previous stroke and 57% a bleeding event. LAAC indications were gastrointestinal bleeding (41%), intracranial bleeding (16%), stroke despite anticoagulation therapy (20%), other like need for triple antithrombotic therapy (14%) and no compliance (9%). All LAAC procedures were guided using ICE-TEE, and switching to traditional TEE or traditional ICE was never required. In all patients we got good quality views if compared with the views obtained thanks to traditional TEE. Repositioning an FLX device was required in about 20% but ever the first selected device was delivered. This is probably correlated with the high experience of the operators who performed the procedure. No periprocedural complications were reported. Complications were related to the access site (5%): bleedings of the access site were reported and were resolved thanks to the compression of the puncture site. No other periprocedural complications were reported: major bleedings, in-hospital death, stroke, device embolization and pericardial effusion. At 45-day follow-up (visit and standard TEE were performed), no device complications occurred. Peridevice leaks (<5 mm) were found in 2%. No patient reported peridevice leaks >5 mm. No patient experienced stroke or major bleeding. At follow-up two patients died: one because of severe aortic stenosis and another one because of sepsis related to the genitourinary tract.

**Baseline characteristics.**

Age, years	75 ± 9
Male	72%
Arterial hypertension	65%
CKD	29%
Creatinine, mg/dl	1,2 ± 0,7
Diabetes mellitus	46%
Coronary artery disease	66%
Heart failure	28%
LVEF, %	48,8 ± 10
Precious stroke/TIA	26%
Previous bleeding	57%
CHA <sub>2</sub> DS <sub>2</sub> -VASc score	5,9 ± 1,6
HAS-BLED score	3,6 ± 1,2

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**LAAC indications.**

Bleeding with symptoms	57%
Gastrointestinal bleeding	41%
Intracranial bleeding	16%
Stroke despite OAC	20%
No compliance	9%
Other	14%

**Periprocedural/in-hospital outcomes.**

Procedural success	100%
Implant failure	0
Device embolization	0
Pericardial effusion	0
Access-site complication	2 (bleeding)
Bleedings major	0
Bleedings minor	2
Stroke	0
In-hospital death	0

**45-day follow-up.**

Device embolization	0
Stroke	0
Pericardial effusion	0
Bleeding major	0
Bleedings minor	0
Cardiac death related to procedure	0
Cardiac death not related to procedure	1
Non-cardiac death	1

**Conclusion.** Our registry showed a high procedural success rate of LAAC procedure using ICE-TEE. Switching to traditional TEE or traditional ICE was never required. In all patients the FLX device was successfully deployed. Only complications related access site occurred. At 45-day follow-up, no major bleeding, stroke and complication related to device were reported.

**P49**

**DIRECT ORAL ANTICOAGULANTS VERSUS PERCUTANEOUS LEFT ATRIAL APPENDAGE OCCLUSION IN ATRIAL FIBRILLATION: 5-YEAR OUTCOMES**

Francesco Melillo, Giulio Leo, Antonio Parlati, Carlo Gaspardone, Barbara Bellini, Paolo Della Bella, Matteo Montorfano, Patrizio Mazzone, Giulia Nemola, Gianmarco Cozzani, Stefano Stella, Francesco Ancona, Giacomo Ingallina, Anna Salerno, Michela Cera, Eustachio Agricola, Alberto Margonato, Cosmo Godino  
*Vita-Salute San Raffaele University, Milano*

**Background.** LAAO is an emerging option for thromboembolic event prevention in patients with NVAF. We previously reported data on comparison between LAAO and DOAC at two-year follow-up in NVAF patients at HBR (HAS-BLED  $\geq 3$ ). Limited data are available on long term follow-up. We aimed to evaluate the efficacy and safety of DOACs versus LAAO indication after 5 years.

**Methods.** We enrolled 193 HBR treated with LAAO and 189 HBR patients with DOACs. At baseline, LAAO group had higher HAS-BLED (4.2 vs 3.3,  $p < 0.001$ ) and lower CHADS-VASc (4.3 vs. 4.7,  $p = 0.005$ ). After 1:1 PSM, 192 patients were included (LAAO  $n = 96$ ; DOACs  $n = 96$ ).

bleeding events was similar ( $p = 0.221$ ). After PSM no significant difference in the primary effectiveness (LAAO 13.3% vs DOACs 9.5%,  $p = 0.357$ ) and safety endpoint (LAAO 7.5% vs DOACs 7.5%;  $p = 0.918$ ) were evident. Overall bleeding rate was significantly higher in DOACs group (25.0% vs 13.7%,  $p = 0.048$ ), while a non-significant higher number of TIA was reported in LAAO group (5.4% vs 1.1%,  $p = 0.098$ ). All-cause and cardiovascular mortality were higher in LAAO group at both unmatched and matched analysis.

**Conclusion.** We confirmed safety and effectiveness of both DOAC and LAAO in NVAF patients at HBR, with no significant differences in thromboembolic events or major bleeding were at 5-year follow-up. The observed increased mortality after LAAO warrants further investigations in RCTs.

**P50**

**CORRELAZIONE TRA ECOCONTRASTO SPONTANEO IN ATRIO SINISTRO ED EVENTI CEREBROVASCOLARI IN PAZIENTI CON FIBRILLAZIONE ATRIALE NON VALVOLARE SOTTOPOSTI A OCCLUSIONE PERCUTANEA DI AURICOLA SINISTRA: REGISTRO MONOMETRICO**

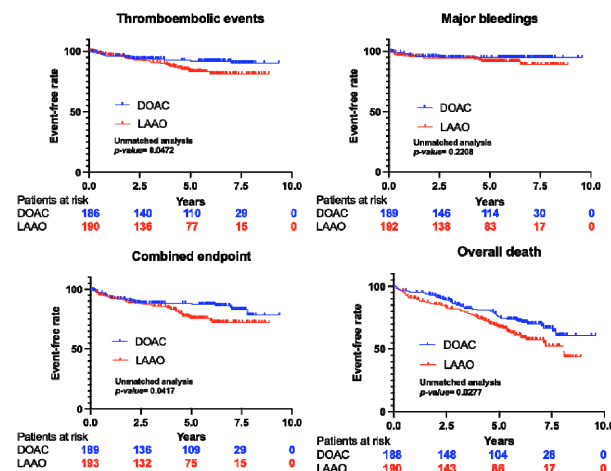
Salvatore Geraci, Michele Giusti, Gerlando Pilato, Marco Martello, Giovanni Diana, Davide Diana, Ilenia Alessandra Di Liberto, Dario Savarino, Giovanni Vaccaro, Giuseppe Caramanno  
*Cardiologia, Ospedale San Giovanni di Dio, Agrigento*

**Introduction.** Left atrial appendage occlusion (LAAO) represent an alternative to oral anticoagulation (OAC) for prophylaxis of thromboembolic events (TEs) in nonvalvular atrial fibrillation (NVAF) patients. Spontaneous echo contrast (SEC) is a known risk factor for atrial thrombus formation, is not yet clarify if this means an increased risk of device-related thrombus (DRT) or TEs during and following LAAO. We aimed to investigate both periprocedural and short-term stroke risks associated with LA SEC in patients undergoing LAAO.

**Methods.** A total of 46 consecutive NVAF patients treated with LAAO between May 2022 and May 2023 in our center by unique two operators equipe were divided into two groups based on preprocedural transesophageal echocardiography: the study group (LA more than moderate SEC;  $n = 20$ ) and the control group (none or mild LA SEC;  $n = 26$ ). The mean follow-up period was 3.5 months, the minimum was 45 days and the maximum was 6 months. All patients in the registry performed dual antiplatelet therapy (DAPT) with acetylsalicylic acid 100 mg and clopidogrel 75 mg for 45 days, single (SAPT) for at least 6 months.

**Results.** The study group patients had larger LA diameters and lower left ventricular ejection fraction. Procedural success was very high in both groups (98%). Periprocedural major adverse cardiac and cerebrovascular events and other major complications were 0% in both groups. After hospital discharge, and at follow-up, the number of TEs was 1 in study group vs. 0 in control. The incidence of device-related thrombus detected was 0% in both groups.

**Conclusions.** LA SEC did not show a significant relationship with periprocedural stroke events and DRT in patients undergoing percutaneous LAAO after 45 days DAPT in our registry, suggesting, with all limitations related to monocentric observational registry, that LA SEC can't identified as a clear predictor of stroke/TIA in patients with NVAF undergoing LAAO.



**Results.** At 5-year follow-up the rate of the combined safety and effectiveness endpoint (ISTH major bleeding and thromboembolic events) was significantly higher in LAAO group ( $p = 0.042$ ), driven by a higher number of thromboembolic events ( $p = 0.047$ ). The rate of ISTH-major

**STRUCTURAL HEART DISEASE: PFO CLOSURE**

**P51**

**LARGE PFO AREA IS ASSOCIATED WITH RESIDUAL POST NOBLESTITCH CLOSURE RIGHT-TO-LEFT SHUNT BUT NOT WITH CEREBRAL ISCHEMIC RECURRENCE**

Alessio Arrivi<sup>1</sup>, Riccardo Rosati<sup>2</sup>, Amalia Morgantini<sup>2</sup>, Giacomo Pucci<sup>3</sup>, Martina Sordi<sup>3</sup>, Marcella De Paolis<sup>3</sup>, Carlo Bock<sup>3</sup>, Matteo Casavecchia<sup>3</sup>, Marco Bazzucchi<sup>3</sup>, Marcello Dominici<sup>3</sup>  
<sup>1</sup>Interventional Cardiology Unit, S. Maria University Hospital, Terni, <sup>2</sup>Polinclinico Umberto 1, Rome, <sup>3</sup>S. Maria University Hospital, Terni

**Background.** Suture-mediated PFO closure using the NobleStitch EL system represents an innovative approach to treat patients with cryptogenic stroke and evidence of paradoxical embolism. The feasibility and safety of this approach have been demonstrated in the majority of septal anatomies. The association between residual post closure right-to-left shunt and cerebral ischemic recurrence is poorly investigated to date. We report data from a single center experience of patients treated with this technique.

**Methods.** We initially screened all patients with cryptogenic stroke and PFO during the period between January 2018 and December 2020, who satisfied criteria for percutaneous closure. We excluded those with carotid or aortic atherosclerotic plaques, left-sided cardiac embolic sources, repetitive supraventricular or ventricular arrhythmias at ECG-Holter monitoring, or multi-fenestrated septum at initial echocardiography. All the

remaining patients were treated with the NobleStitch ELsystem and subsequently followed up. Longitudinal follow-up visits were planned for each patient every 6 months from the day of procedure. After at least 1 year, all patients repeated contrast echocardiography and brain MRI in a day hospital regime.

**Results.** Twenty-three patients (mean age: 56±8 years, men 56%) were enrolled in the present study. Demographic, clinical, and echocardiographic characteristics of the population at baseline and at follow-up are shown in Table 1. The median follow-up duration was 16 months. None of the patients reported cerebral ischemic recurrence signs or symptoms at follow-up, or novel ischaemic lesions at brain MRI. Post-procedural residual grade 2 right-to-left shunt was found at the contrast echocardiography in 3 (13%) patients. The latter showed significantly greater PFO dimensions at baseline (PFO (length × width) (mm<sup>2</sup>) of 43 (24) in the no-residual shunt group vs 82 (62) in the residual shunt group; p=0.04].

**Conclusions.** Our data confirm a long-term good efficacy of the procedure and also that the initial characteristics of the PFO (tunnel area, calculated as the product of length × width) could predict the risk of residual inter-atrial shunt. The latter seems to be not related with the cerebral ischemia recurrence.

	No residual shunt	Residual shunt	P
N (%)	20 (87)	3 (13)	
Age, years	56 (8)	53 (12)	0.51
Male sex, n (%)	9 (45)	3 (100)	0.08
Hypertension, %	8 (40)	1 (33)	0.84
Follow-up length, months	23 (16)	16 (9)	0.42
Ejection fraction, %	62 (5)	63 (5)	0.75
PFO length, mm	13 (5)	24 (6)	0.04
PFO width, mm	3 (1)	4 (1)	0.24
PFO (length x width), mm <sup>2</sup>	43 (24)	82 (62)	0.04
ASA at follow-up, %	2 (10)	1 (33)	0.28

PFO: patent fossa ovalis; ASA: atrial septal aneurysm

## P52

### BEYOND THE DECADE: ASSESSING THE EXTENDED OUTCOMES OF TRANSCATHETER PFO CLOSURE

Carlo Gasparidone, Lorenzo Zaccaria, Paolo Costa, Anna Salerno, Daniele D'Atri, Andrea Tripoli, Davide Besana, Michele Tondo, Laura Vetrugno, Francesca Braccischi, Michele Morosato, Davide Morciano, Matteo Montorfano, Antonio Mangieri, Antonio Colombo, Cosmo Godino

IRCCS San Raffaele Scientific Institute, Milan

**Background.** Despite the rising employment of transcatheter device closure for patent foramen ovale (PFO) in the secondary prevention of cryptogenic stroke or transient ischemic attack (TIA), there remains a relative lack of data regarding its long-term outcomes. This study aims to describe long-term follow-up of patients undergoing device closure of PFO.

**Methods.** We conducted a retrospective analysis of consecutive adult patients who underwent PFO device closure from 2004 to 2012 at San Raffaele hospital. We obtained demographic, clinical, procedural, and follow-up data from electronic health records and telephone interviews.

**Results.** Our study included 432 patients (mean age 48±13 years; 45% female) with a mean follow-up duration of 13.6±1.5 years (all patients had at least ten years follow-up). Cryptogenic stroke was the most prevalent qualifying event for PFO closure, reported in 52% of patients, followed by TIA (41%). The most used device was the Amplatzer Septal Occluder (77%). Three cases of intra-procedural atrial fibrillation and one device embolization were reported, but no procedure-related deaths occurred. Recurrent stroke and/or TIA were reported in 5 patients, (4.2% of patients with follow-up data\*). Patients who experienced recurrent stroke/TIA were older and had a higher rate of cardiovascular risk factors than those who did not. The presence of residual shunt was not a predictor of recurrent events. Six new onset cases of atrial fibrillation were documented during follow-up, two of which occurred within three months post-procedure.

**Conclusions.** Transcatheter PFO closure is an effective strategy with high success rates, low complications, and favorable long-term outcomes for secondary prevention of recurrent embolic events.

\*Follow-up in progress: our present findings account for 119 patients (28% of the total cohort). The process of gathering complete follow-up data is ongoing, and we plan to present the full data set at the upcoming GISE 2023 Congress.

## STRUCTURAL HEART DISEASE: TAVI

### P53

#### ANGINA E STENOSI AORTICA SEVERA: PREVALENZA DI MALATTIA CORONARICA SIGNIFICATIVA NEI PAZIENTI SINTOMATICI

Gian Francesco Cucculliu<sup>1</sup>, Pierluigi Merella<sup>1</sup>, Giovanni Lorenzoni<sup>1</sup>, Giuseppe Talanas<sup>1</sup>, Cristiana Denurra<sup>1</sup>, Enrico Atzori<sup>1</sup>, Veronica Carboni<sup>2</sup>, Gavino Casu<sup>1</sup>

<sup>1</sup>SC Cardiologia Clinica ed Interventistica, Ospedale Civile Santissima Annunziata - AOU Sassari, Sassari, <sup>2</sup>Scienze Mediche, Chirurgiche e Sperimentali, Università degli Studi di Sassari, Sassari

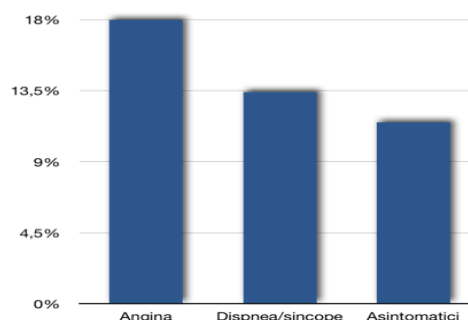
**Introduzione.** La stenosi valvolare aortica degenerativa è tra le più frequenti patologie strutturali cardiache, con una prevalenza che oscilla tra il 2% e il 7% nei pazienti oltre i 65 anni. Condizione frequentemente osservata in questi pazienti è la presenza di malattia coronarica. La fisiopatologia di entrambe queste condizioni è molto simile e l'aterosclerosi ne rappresenta un fattore di rischio comune. L'obiettivo del nostro studio è stato quello di valutare la presenza di ateromatosi coronarica nei pazienti con stenosi aortica e evidenziare se la presenza di angina fosse predittiva di malattia coronarica significativa.

**Metodi.** La nostra analisi è uno studio di coorte retrospettivo realizzato sui pazienti sottoposti a TAVI presso la Struttura Complessa di Cardiologia Clinica ed Interventistica e la Struttura Complessa di Cardiologia dell'A.O.U. di Sassari. Il periodo in esame è compreso tra gennaio 2021 e dicembre 2022. Tra le indagini preoperatorie in tutti i pazienti veniva eseguita la coronarografia di routine.

**Risultati.** Nel periodo in esame son stati trattati 200 pazienti (età media 81± 6 anni; sesso maschile 49%; FE 57%; gradiente medio 48,6 mmHg; nel 12% presenza di alterazioni distrettuali della cinetica segmentaria). Alla presentazione clinica i sintomi erano dispnea (80,5%), sincope (10,5%), angina (27,5%); mentre il 13% dei pazienti erano totalmente asintomatici. Una storia di SCA nei 12 mesi precedenti era presente nel 6%. Allo studio coronarografico il 30% del totale presentava malattia coronarica significativa. Il tasso di malattia coronarica significativa era 18% nei pazienti sintomatici per angina, 13,4% nei pazienti sintomatici esclusivamente per dispnea e/o sincope, 11,5% nei pazienti totalmente asintomatici (statisticamente la differenza era significativa, p=0,0015).

**Conclusioni.** La prevalenza di malattia coronarica nei pazienti sottoposti a TAVI nel biennio 2021-2022 è sovrapponibile a quella riscontrata nei più recenti trial clinici. La presenza di sintomatologia anginosa, pur risultando significativamente associata alla presenza di malattia coronarica, a causa del basso valore predittivo positivo, è poco utile clinicamente nella selezione di questi pazienti da destinare a studio coronarografico.

■ Prevalenza di malattia coronarica significativa in relazione alla sintomatologia



### P54

#### BALLOON EXPANDABLE VALVES IN PURE TRICUSPID AORTIC VALVE REGURGITATION – A SINGLE CENTRE EXPERIENCE

Marco Foroni, Mateusz Orzalkiewicz, Francesco Bendandi, Alessandro Mazzapicchi, Francesco Palermo, Antonio Giulio Bruno, Nevio Taglieri, Gabriele Ghetti, Cinzia Marrozzini, Nazzareno Galì, Tullio Palmerini, Francesco Saia

IRCCS Azienda Ospedaliero - Universitaria di Bologna, Policlinico Sant'Orsola Malpighi, Bologna

**Introduction.** Transcatheter aortic valve implantation (TAVI) in severe pure aortic valve regurgitation (AR) is challenging, as dedicated devices are not widely available. Self-expandable TAVI valves were mostly used in the published series (possibly due to perceived benefit of continuous radial pressure on the annulus facilitating anchorage of the oversized prosthesis). We analysed the oversizing and valve overexpansion achieved in inoperable pure AR patients who underwent TAVI with balloon-expandable valve (BEV) in our centre.

**Methods.** All consecutive severe AR patients with tricuspid aortic valve

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treated with BEV in our centre between Jan 2019 and April 2023 were enrolled in this prospective registry (n=11). The patients were divided into two groups: small annulus (area ≤500 mm<sup>2</sup>, n=5) and large annulus (>500 mm<sup>2</sup>, n=6). All patients underwent post-procedural CT scan to measure achieved oversizing with respect to the annulus and overexpansion of the prosthesis.

**Results.** The group comprised 63.6% (n=7) males with the mean age of 79.3 years. Pre-TAVI left ventricular ejection fraction (51.0 vs 36.8%, p=0.055) and mean aortic valve gradient (10.4 vs 7 mmHg, p=0.14) did not differ significantly between small and large annuli patients, respectively. Mean virtual basal ring area in small annuli patients was 388.0 ± 65.5 mm<sup>2</sup> and 620.2 ± 60.0 mm<sup>2</sup> in the large annuli patients. Overall 7 (63.6%) patients had no valvular calcifications, with the mean calcium volume being no different between small (mean=0 mm<sup>3</sup>) and large (mean=29mm<sup>3</sup>) annuli patients. All BEVs implanted were Sapien 3 or 3 Ultra with additional 1-8 ml of contrast where needed. Mean aortic valve gradient post-implantation was 9.0 mmHg vs 6.7 mmHg in the small and large annuli patients, respectively (p=0.12). No patients had a paravalvular leak and 1 patient in large annuli group had a mild central AR. No valve embolization occurred. One patient needed a new pacemaker implantation. Device success was 100% in both groups. The achieved oversizing with respect to the annulus ranged from 13 to 40%, in small annuli we achieved 31 ± 5.4% and in large annuli 25.2 ± 9.0%, not significantly different between the groups (p=0.41). Prosthesis overexpansion with respect to the nominal area ranged from 1 to 25%. It was significantly higher in large annulus (18.0 ± 6.2%) than in small annulus patients (9 ± 6.7%), p=0.045.

**Conclusions.** Our study confirms that BEV implantation in pure severe tricuspid AR is feasible with good procedural results and a wide range of oversizing sufficient for valve anchorage. No short-term complications occurred due to prosthesis over-inflation and significant oversizing but longer-term follow-up studies on larger groups of patients are needed.

**P55**

**CLINICAL AND ECHOCARDIOGRAPHY OUTCOMES OF PATIENTS WITH VERY-SEVERE AORTIC STENOSIS TREATED WITH TRANSCATHETER AORTIC VALVE IMPLANTATION**

Marco Angelillis<sup>1</sup>, Giulia Costa<sup>2</sup>, Marianna Adamo<sup>2</sup>, Alessandro Iadanza<sup>3</sup>, Marta Barletta<sup>4</sup>, Erica Ferrara<sup>5</sup>, Anna Sonia Petronio<sup>1</sup>

<sup>1</sup>Dipartimento Cardio-Toraco Vascolare, Azienda Ospedaliero Universitaria Pisana, Pisa, <sup>2</sup>Cardioracico, Spedali Civili Brescia, Brescia, <sup>3</sup>Cardiovascolare, Azienda Ospedaliero Universitaria Senese, Siena, <sup>4</sup>Policlinico San Donato, Milano, <sup>5</sup>Interventional Cardiology Unit, ASST Ovest Milanese, Legnano Hospital, Legnano

**Introduction.** Symptoms of aortic stenosis (AS) are not proportional to its severity and patients with very-severe AS (VSAS) remain asymptomatic for long time. Appropriate time for intervention in VSAS patients remains debated, as well as the effects of transcatheter aortic valve implantation (TAVI) on left ventricular hypertrophy (LVH). Aim of the study was to compare the procedural and 30-day outcomes of TAVI between patients with VSAS and patients with severe aortic stenosis (SAS), as well as the changes in LVH.

**Methods.** We selected patients with aortic peak velocity ≥5 m/s (VSAS), and those with aortic peak velocity 4-5 m/s (SAS) treated with TAVI. Patients with reduced left ventricular ejection fraction (LVEF <45%) were excluded. The primary endpoint was the incidence of all-cause death at 30 days. Secondary endpoints included the 30-day incidence of cardiac death, of cardiac re-hospitalization, and of stroke/transient ischemic attack and the changes in LVH from baseline to 30 days.

**Results.** 102 in the VSAS group and 535 in the SAS group were included. Patients in VSAS had a thicker septal wall (p<0.001), and a higher Agatston score (p<0.001) and calcium volume (p=0.007). No differences were observed regarding primary and secondary clinical endpoints. However, VSAS patients showed a significantly higher improvement in concentric LVH, although the prevalence of concentric LVH remained higher than in SAS patients.

**Conclusions.** TAVI in VSAS patients show similar procedural and clinical outcomes to SAS patients and experience a more pronounced improvement in the prevalence of concentric LVH.

**P56**

**DOUBLE VERSUS SINGLE SUTURE-BASED PLUS PLUG-BASED ENDOVASCULAR CLOSURE AFTER LARGE-BORE ARTERIOTOMY FOR TRANSCATHETER AORTIC VALVE IMPLANTATION**

Alessandro Comis<sup>1</sup>, Giuliano Costa<sup>2</sup>, Orazio Strazzieri<sup>1</sup>, Silvia Crescenza Motta<sup>1</sup>, Elena Dipietro<sup>1</sup>, Valentina Frittitta<sup>1</sup>, Sofia Sammartino<sup>1</sup>, Mariachiara Cali<sup>1</sup>, Luigi Ferrarotto<sup>1</sup>, Marco Barbanti<sup>3</sup>, Corrado Tamburino<sup>1</sup>

<sup>1</sup>Cardiology Department, University of Catania, Catania, <sup>2</sup>Cardiology Department, AOU "G. Rodolico - San Marco", Catania, <sup>3</sup>Cardiology Department, University of Kore, Enna

**Introduction.** Procedure-related vascular and bleeding complications after transcatheter aortic valve implantation still represents an important

issue that impact on patients' mortality and morbidity. The aim of this study was to compare single versus double suture-based devices plus a plug-based device after large bore arteriotomy for transfemoral (TF) TAVI.

**Methods.** A total of 517 patients with preprocedural computed tomography angiography (CTA) assessment and undergoing fully percutaneous TF-TAVI through a 14 Fr introducer from February 2018 to May 2023 at our Institution were considered. Matched pairs of patients were selected through a 1:1 propensity-score (PS) based adjustment. The primary outcomes were 30-day major vascular complications and major or life-threatening (LT) bleeding due to endovascular closure system failure.

**Results.** One hundred thirty-five PS matched pairs of patients were compared. At 30 days, there was no difference in major vascular complications (0.74% vs 2.20%, p=0.62) and in major/LT bleedings (2.96% vs 6.67%, p=0.25) between patients receiving single or double suture-based and a plug-based device for hemostasis after TF-TAVI. The use of a single suture-based device was associated with a lower risk of minor vascular complication (2.2% vs 10.3%, odds ratio [OR] 0.20, 95% confidence interval [CI]: 0.03-0.73; p=0.01) and a higher probability of next-day discharge (NDD) after TAVI (51.11% vs 37.78%, OR 1.72, CI: 1.03-2.88; p=0.04). No difference in all-cause death (0.74% vs 3.70%, p=0.21) was observed at 30 days.

**Conclusions.** A single, suture-based plus a plug-based device for endovascular hemostasis after TF-TAVI was associated with similar rates of major vascular complications and major/LT bleedings compared to the use of double, suture-based plus a plug-based device at 30 days.

**P57**

**SIMPLIFICATIONS IN TRANSCATHETER AORTIC VALVE REPLACEMENT**

Giulia Costa, Marco De Carlo, Cristina Giannini, Marco Angelillis, Matteo Mazzola, Paolo Spontoni, Laura Stazzoni, Chiara Primerano, Anna Sonia Petronio

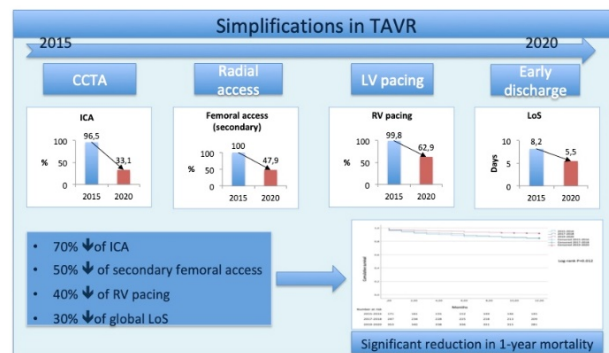
CardioToraco Vascolare-SD Emodinamica, Azienda Ospedaliero Universitaria Pisana, Pisa

**Introduction.** Given the expanding indications towards younger patients at lower surgical risk, transcatheter aortic valve replacement (TAVR) simplification and streamlining is gaining an increasing importance. The aim of the research is to examine the temporal trends towards procedural simplification of TAVR and to determine the outcomes of such strategies.

**Methods.** Patients undergoing TAVR from the year 2015 to 2020 were prospectively enrolled. The patients were divided in time tertiles according to the date of intervention. Data on pre-procedural planning including coronary computed tomography angiography (CCTA), procedures, and outcomes were compared between the time tertiles.

**Results.** A total of 771 consecutive patients from a single institution were enrolled. We observed a trend to use of a fully percutaneous vs. surgical approach for index access, left radial artery vs. contralateral femoral artery as the secondary access, and left ventricular pacing on the stiff guidewire vs. right ventricular pacing. Immediate device success significantly increased, whereas the length of hospital stay decreased. Overall, about 60% of the total study population underwent CCTA instead of coronary angiography, with no adverse events (Figure). One-year survival rates significantly improved over the time. A simplified TAVR approach was associated to better survival, whereas low baseline functional capacity, pre-existing coronary artery disease, renal impairment, peri-procedural blood transfusions, and paravalvular leak were related to worse outcomes.

**Conclusions.** Our study showed a constant tendency to procedure streamlining and to improved procedural success and one-year outcomes. A strategy based on CCTA allows sparing safely almost half of the pre-operative ICA.



**P58**

**LONG-TERM COMPARISON OF TRANSCATHETER AORTIC VALVE IMPLANTATION USING THREE DIFFERENT SECOND-GENERATION DEVICES**

Elena Dipietro<sup>1</sup>, Giuliano Costa<sup>1</sup>, Orazio Strazzieri<sup>1</sup>, Silvia Crescenza Motta<sup>1</sup>, Valentina Frittitta<sup>1</sup>, Alessandro Comis<sup>1</sup>, Carmelo Sgroi<sup>1</sup>, Corrado Tamburino<sup>1</sup>, Marco Barbanti<sup>2</sup>  
<sup>1</sup>Malattie dell'Apparato Cardiovascolare, AOU G.R. Policlinico-San Marco, Catania, <sup>2</sup>Cardiologia-UTIC, Università degli Studi di Enna "Kore", Enna

**Introduction.** Different studies demonstrated good long-term outcomes of transcatheter aortic valve implantation (TAVI) with first generation devices. Nevertheless, long-term outcomes of second-generation devices are currently lacking. The aim of the present study was to compare long-term clinical outcomes and bioprosthesis functioning of TAVI with Evolut R/PRO (Medtronic, Inc), Acurate Neo (Boston Scientific) or Sapien 3 (Edwards Lifesciences) transcatheter aortic valves.

**Methods.** We retrospectively analyzed clinical outcomes of patients undergoing TAVI with Evolut R/PRO, Acurate Neo and Sapien 3 from September 2014 to December 2018 at our Institution. Study endpoint were all-cause death, disabling stroke, re-hospitalization for heart failure (HF) and bioprosthetic valve failure (BVF) at 7 years.

**Results.** A total of 784 patients were analyzed with a median follow-up of 5.1 years. The median age was 81 years whereas the median estimated mortality risk according to Society of Thoracic Surgeons (STS) score was 4.5%. Four hundred twenty-two patients received the Evolut R/PRO, 215 the Sapien 3 and 147 the Acurate Neo device. At 7 years, the rates of overall survival (Evolut R/PRO 36.9% vs. Sapien 3 38.4% vs. Acurate Neo 35.3%, p=0.33), disabling stroke (Evolut R/PRO 8.4% vs. Sapien 3 8.2% vs. Acurate Neo 9.2%, p=0.20) and HF re-hospitalization (Evolut R/PRO 7.3% vs. Sapien 3 7.8% vs. Acurate Neo 8.5%, p=0.38) were similar among study devices. Finally, 7-year BVF rates were extremely low (0.9%) and comparable among Sapien 3 (4/215, 1.9%), Evolut R/PRO (1/422, 0.2%) and Acurate Neo (2/147, 1.4%) recipients.

**Conclusions.** Long-term clinical outcomes of patients undergoing TAVI with Evolut R/PRO, Sapien 3 and Acurate Neo devices were similar at 7 years. Rates of 7-year BVF were extremely low and comparable among the three transcatheter aortic valves.

**P59**

**IMPACT OF BURDEN AND DISTRIBUTION OF AORTIC VALVE CALCIFICATION ON THE HEMODYNAMIC PERFORMANCE AND PROCEDURAL OUTCOMES OF A SELF-EXPANDING, INFRA-ANNULAR TRANSCATHETER AORTIC VALVE SYSTEM**

Simone Circhetta, Annunziata Nusca, Michele Mattia Viscusi, Fabio Mangiacapra, Elisabetta Ricottini, Paolo Gallo, Rosetta Melfi, Nino Cocco, Raffaele Rinaldi, Valeria Cammalleri, Edoardo Nobile, Federico Bernardini, Federica Coletti, Agostino Spanò, Giuseppe Migliaro, Alessandro Appetecchia, Francesco Grigioni, Gian Paolo Ussia  
 Unità di Scienze Cardiologiche, Fondazione Policlinico Universitario Campus Bio-Medico di Roma, Roma

**Introduction.** Aortic valve calcification (AVC) has been investigated as a powerful predictor of procedural complications in patients undergoing transcatheter aortic valve implantation (TAVI). We focused on the impact of AVC burden and pattern of distribution on the occurrence of paravalvular leaks (PVL) and conduction abnormalities requiring permanent pacemaker implantation (PPI) in patients undergoing TAVI with the intra-annular, self-expandable Portico device. 30-day clinical outcomes according to AVC were also analyzed.

**Methods.** 103 patients were divided into tertiles according to AVC. Valve Academic Research Consortium (VARC)-3 definitions were used to classify procedural complications and 30-day outcomes.

**Results.** The occurrence of > mild PVL was significantly greater in the highest AVC tertile (89.5% versus 50% and 8.9% in the moderate and low AVC tertiles, respectively; p<0.001) and AVC tertiles were the only independent predictor of this complication (OR 7.321, 95%CI 3.101-17.284, p<0.001). Concordantly, AVC tertiles remained a predictor of post-TAVI conduction abnormalities (OR 3.734, 95%CI 1.315-10.607, p=0.013) but not PPI (OR 1.448, 95%CI 0.391-5.354, p=0.579). According to the calcium distribution, ROC analyses revealed that annular AVC but not left ventricle outflow tract (LVOT) calcium burden significantly indicated the development of PVL (AUC 0.863, 0.776-0.935, p<0.001) and conduction disorders/PPI (AUC 0.797, 0.700-0.894, p<0.001 and 0.723, 0.580-0.867, p=0.018, respectively). AVC tertiles were not an independent predictor of the composite 30-day outcomes (HR 1.556; 95%CI 0.896-2.702, p=0.117).

**Conclusions.** AVC significantly influences the Portico valve performance since a higher AVC is associated with increased PVL and conduction abnormalities needing PPI. Compared with other percutaneous TAVI systems, our findings suggest a minor role for LVOT calcification on the performance of this specific device.

**P60**

**PROGNOSTIC ROLE OF VISCERAL ADIPOSE TISSUE IN PATIENTS UNDERGOING TRANSCATHETER AORTIC VALVE REPLACEMENT**

Alberto Somaschini<sup>1</sup>, Amanda Casirati<sup>2</sup>, Luca Olivotti<sup>1</sup>, Stefano Cornara<sup>1</sup>, Veronica Giachello<sup>1</sup>, Matteo Astuti<sup>1</sup>, Matteo Ghione<sup>1</sup>, Marco Botta<sup>1</sup>, Marialaura Buscemi<sup>1</sup>, Riccardo Caccialanza<sup>2</sup>, Pietro Bellone<sup>1</sup>, Stefano Cordone<sup>1</sup>

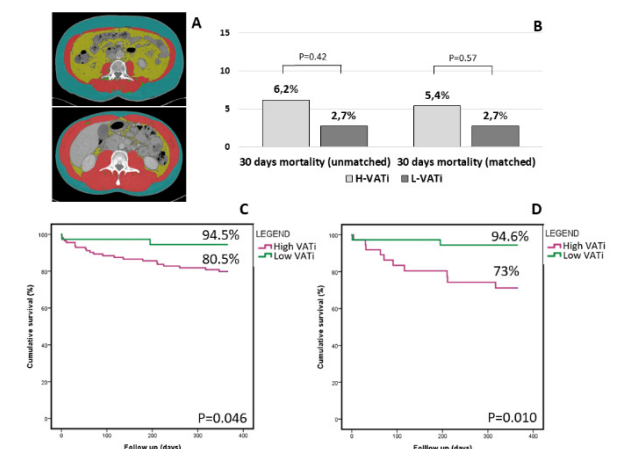
<sup>1</sup>S.C. di Cardiologia e UTIC, Ospedale San Paolo, Savona, <sup>2</sup>Clinical Nutrition and Dietetics Unit, Fondazione IRCCS Policlinico San Matteo, Pavia

**Introduction.** Computed tomography (CT) is a recognized method to assess body composition. The analysis of CT-scans at third lumbar vertebra level (L3-CT) allows to detect sarcopenia, which plays a negative prognostic role in patients undergoing Transcatheter Aortic Valve Implantation (TAVI). Conversely, the effect of visceral adipose tissue (VAT), a pro-inflammatory and metabolically active organ associated with unfavorable cardiovascular outcomes, is still poorly explored. We investigated the association between preoperative VAT and 30-day and 1-year mortality in patients undergoing TAVI.

**Methods.** Anamnestic, laboratory and clinical data of patients who underwent TAVI in 2010-2020 were collected. Preoperative CT exams were analyzed to measure VAT area (cm<sup>2</sup>) (Figure 1A), which was normalized for stature obtaining VAT index (VATi, expressed as cm<sup>2</sup>/m<sup>2</sup>). The sample was classified according to VATi values into two groups: low VATi [1<sup>st</sup> quartile] vs. high VATi [2<sup>nd</sup> to 4<sup>th</sup> quartiles]. The two groups were compared by T-test for continuous variables (expressed as mean ± SD) and Chi-square test for categorical variables (expressed as %). Mortality analyses were performed through Kaplan-Meier curves with log rank test. To address for potential confounding factors a propensity score (one to one matching with the nearest neighbor matching algorithm considering a caliper width of 0.2) based on STS mortality score and EuroSCORE II values was calculated in order to create two comparable groups.

**Results.** We enrolled 168 patients (45.8% males), 150 of whom had CT images available. Mean value of VATi was 58.6 ± 37.2 cm<sup>2</sup>/m<sup>2</sup> (range 1.7-172.3). Patients with higher VATi presented higher levels of glycemia (124 ± 40 vs. 111 ± 23 mg/dl, p=0.021), HbA1c (6 ± 0.8 vs. 5.6 ± 0.5%, p=0.001) and neutrophils (5.4 ± 2.7 vs. 4.5 ± 1.8 x 10<sup>3</sup>/μl, p=0.028). No differences were found between the two groups in terms of age, CKD (GFR <30 ml/min), previous stroke/myocardial infarction/surgical or percutaneous revascularization, intra-hospital complications and presence of comorbidities such as cancer, atrial fibrillation, diabetes, and COPD. Overall, 1-year and 30-day mortality were 16.1% and 5.4%, respectively. High VATi group [range 25.9-172.3 cm<sup>2</sup>/m<sup>2</sup>] presented higher 1-year mortality (19.5% vs. 5.5%, OR 4.2, p=0.046) as compared with low VATi group [range 1.7-25.7 cm<sup>2</sup>/m<sup>2</sup>], while no significant differences were found in 30-day mortality (6.2% vs. 2.7%, p=0.421). After propensity score creation, 37 pairs of patients were successfully matched; in the matched population, high VATi was significantly associated with a higher 1-year mortality (27% vs. 5.4%, p=0.010) but not with 30-day mortality (5.4% vs. 2.7%, p=0.421). Mortality analyses are shown in Figure 1B-D.

**Conclusions.** High levels of VATi are independently associated with a four-fold increased risk of 1-year mortality in patients treated by TAVI, whereas they show no significant impact on short-term mortality. Mortality increase could be mediated by enhanced inflammatory status and augmented incidence of metabolic complications related with abundant abdominal VAT. Adding VAT evaluation to the scores currently used in clinical practice could help to optimize pre-operative risk stratification in patients undergoing TAVI.



**Figure 1.** (A) Example of body composition segmentation through L3 CT-image analysis in a patient with High VAT (above) and Low VAT (below); yellow = visceral adipose tissue area; green = intramuscular adipose tissue area; light blue = subcutaneous adipose tissue area; red = skeletal muscle area. (B) Thirty-day mortality in the unmatched and in the matched population according to VATi. (C) Cumulative incidence of 1-year survival in the unmatched population according to VATi. (D) Cumulative incidence of 1-year survival in the matched population according to VATi.

## P61

### A CASE SERIES OF VALVE-IN-VALVE TRANSCATHETER AORTIC VALVE IMPLANTATION FOR TREATMENT OF DEGENERATED SURGICAL BIOPROSTHESES: ENSURING THE BEST CLINICAL OUTCOMES

Mihail Celeski, Annunziata Nusca, Agostino Spanò, Elisabetta Ricottini, Valeria Cammalleri, Fabio Mangiacapra, Rosetta Melfi, Nino Cocco, Paolo Gallo, Raffaele Rinaldi, Giuseppe Migliaro, Federica Coletti, Ylenia La Porta, Francesco Grigioni, Gian Paolo Ussia  
*Unit of Cardiovascular Science, Fondazione Policlinico Universitario Campus Bio-Medico, Roma, Roma*

**Introduction.** Valve-in-valve (ViV) transcatheter aortic valve implantation (TAVI) has emerged as a less-invasive alternative to conventional redo surgery for bioprosthetic valve dysfunction. However, its safety and effectiveness have not been widely described in the literature as for the native aortic stenosis treatment. In addition, valve migration, embolization, patient-prosthesis mismatch, and coronary obstruction remain potential serious complications of ViV-TAVI. We present a case series of seventeen patients with degenerated surgical aortic bioprostheses treated with valve-in-valve transfemoral TAVI.

**Methods.** From October 2020 to May 2023, seventeen patients with structural valve degeneration of surgical aortic bioprostheses undergoing ViV TAVI were included. The primary indication for ViV TAVI was intermediate to high operative risk (mean EuroSCORE II  $10.5 \pm 6\%$ ) or unfeasible redo surgery.

**Results.** The median age was  $76 \pm 11$  years, with one patient having ViV TAVI in a stentless bioprosthesis at 45 years. Trans-thoracic echocardiography was performed before and after the index procedure in all patients. The mean left-ventricular ejection fraction was  $39\%$  ( $\pm 19\%$ ), with an average mean gradient of  $39$  mmHg and concomitant prosthetic stenosis and regurgitation being the manifestations of the underlying structural degeneration in half of the patients. All the patients were carefully discussed by a heart team. Furthermore, most of them performed pre-procedural computed tomography angiography. Nearly 95% of the patients were previously treated with a stented bioprosthesis, with a median time to severe structural bioprosthesis degeneration (SBD) of 10 years ( $\pm 4$ ). However, more than half of the patients with SBD undergoing ViV TAVI had stented prostheses with externally mounted leaflets such as Trifecta and Mitroflow. All the procedures were performed without hemodynamic support using femoral access, and most prostheses were inserted retrograde under rapid pacing and fluoroscopic guidance. In nearly 60% of the patients, a self-expandable open-frame ACURATE Neo bioprosthesis was used, while Portico was used less frequently. Only one patient necessitated the use of the Triguard device for cerebral protection. There was 100% success with ViV TAVI according to VARC-3 criteria, with an immediate significant decrease of the trans-prosthetic peak-to-peak gradient and an average mean gradient reduction  $>35$  mmHg. There was 0% coronary obstruction, no valve embolization or migration, and no patient-prosthesis mismatch in any of the patients. Furthermore, there were not any major bleeding events related to TAVI, and a mild paraprosthetic leak was revealed in four of the patients. In addition, only one patient underwent pacemaker implantation due to post-procedural Mobitz 2 atrioventricular block. Thirty-day and 1-year mortality (1-year follow-up available for 13/17 patients) was 0%, and there were not any major adverse cardiac and cerebrovascular events (MACCE), including acute myocardial infarction and stroke. Almost all the patients reported a significant improvement in clinical symptoms and quality of life.

**Conclusions.** Our experiences suggest that transfemoral valve-in-valve TAVI is feasible and safe in intermediate-to-high-risk patients with degenerated surgical aortic bioprostheses. If conducted in experienced centers, ViV TAVI can be associated with low-risk mortality and a low MACCE rate. The self-expandable ACURATE Neo showed optimal results in this setting. Furthermore, multislice coronary computed tomography, together with assessment of clinical and anatomical factors and improvement in technical skills, can contribute to reducing the rate of adverse events, mortality, and morbidity after ViV TAVI. Future randomized studies on the current topic are therefore recommended.

## P62

### L'IMPATTO PROGNOSTICO DEL RAPPORTO TRA NEUTROFILI E PIASTRINE IN PAZIENTI SOTTOPOSTI A SOSTITUZIONE VALVOLARE AORTICA TRANSCATETERE

Stefano Cornara<sup>1</sup>, Alberto Somaschini<sup>1</sup>, Marco Ferlini<sup>2</sup>, Marco Aiello<sup>2</sup>, Marco Botta<sup>1</sup>, Fabrizio Gazzoli<sup>2</sup>, Matteo Ghione<sup>1</sup>, Veronica Giachello<sup>1</sup>, Giuseppe Lanzillo<sup>2</sup>, Luca Olivotti<sup>1</sup>, Stefano Ghio<sup>2</sup>, Stefano Pelenghi<sup>2</sup>, Stefano Cordone<sup>1</sup>

<sup>1</sup>Cardiologia, Ospedale San Paolo Savona, Savona, <sup>2</sup>IRCCS Policlinico San Matteo, Pavia

**Introduzione.** La selezione dei pazienti candidabili a sostituzione valvolare aortica transcattere (TAVR) è una delle sfide più difficili che ogni giorno viene affrontata in Heart Team. Al momento non sono disponibili risk score dedicati a pazienti TAVR, si utilizzano risk score derivati da pazienti sottoposti ad intervento cardiocirurgico tradizionale. Il rapporto tra granulociti neutrofili e piastrine (NPR) è un indice

infiammatorio con un dimostrato impatto prognostico in diversi contesti clinici, tra cui pazienti affetti da infarto miocardico acuto. Lo scopo di questo studio è valutare se NPR presenta un ruolo prognostico in pazienti sottoposti a TAVR.

**Metodi.** Nello studio sono stati arruolati presso l'IRCCS Policlinico San Matteo di Pavia e l'Ospedale San Paolo di Savona pazienti sottoposti a TAVR tra il 2010 e il 2020. NPR è stato calcolato dall'emocromo effettuato all'ingresso in ospedale per il ricovero in cui è stata eseguita la di TAVR, moltiplicando il valore ottenuto x1000. I valori di NPR sono stati stratificati in due gruppi in base al valore della mediana. Le differenze tra variabili continue sono state calcolate mediante Student t-test o Mann-Whitney U test ove appropriato. Le differenze tra variabili categoriche sono state calcolate utilizzando Fisher exact test o il test del chi quadro ove appropriato. Per correggere per eventuali valori confondenti è stata utilizzata un'analisi propensity matched (Caliper 0,02), correggendo per lo score STS mortality. Le analisi di mortalità sono state eseguite mediante curve di Kaplan-Meier e test del rango logaritmico.

**Risultati.** Sono stati arruolati in totale 300 pazienti nello studio. L'età media della popolazione era di  $82 \pm 5$  anni, il 54,3% erano donne, l'indice di massa corporea (BMI) medio era  $25,92 \pm 4,16$  kg/m<sup>2</sup>, nel 12% dei casi i pazienti erano affetti da fibrillazione atriale, nel 51% dei casi i pazienti presentavano una malattia coronarica e, nel 20,3% un pregresso infarto. Il valore di creatinina medio era  $1,22 \pm 0,95$  mg/dl, il valore di emoglobina  $11,96 \pm 1,67$  g/dl. Il 95% delle TAVR è stato eseguito con accesso femorale, l'STS mortality score medio era  $4,79 \pm 3,11$ . Il rapporto tra neutrofili e linfociti presentava una mediana di 226. I pazienti con un valore di NPR superiore alla mediana mostravano una mortalità ad 1 anno maggiore ( $16,2\%$  vs  $6,9\%$ ,  $p=0,01$ , OR 2.59, IC 95-95%  $1,18 - 5,66$ ; Figura 1A), mentre non erano presenti significative differenze nella mortalità a 30 giorni ( $4,4\%$  vs  $3,2\%$ ,  $p=0,14$ ). Sono state individuate mediante ad un'analisi propensity matched 133 coppie di pazienti. In questa popolazione NPR si è dimostrato un predittore indipendente di mortalità ad un anno ( $15,4\%$  vs  $6\%$ , OR 2.84, IC 5%-95%  $1,182 - 6,7$ ,  $p=0,01$ ; Figura 1B).

**Conclusioni.** Nel nostro studio NPR si è dimostrato un predittore indipendente di mortalità ad un anno in pazienti sottoposti a TAVR. In particolare, avere dei valori di NPR sopra la mediana è associato ad un rischio di mortalità 2.8 volte maggiore. NPR è un noto indice infiammatorio, facile da ottenere e costo-sostenibile che può aiutare a identificare i pazienti con un elevato rischio di mortalità prima di essere sottoposti a TAVR. Ulteriori studi sono necessari per confermare i nostri dati preliminari e valutare l'introduzione di NPR nella pratica clinica.

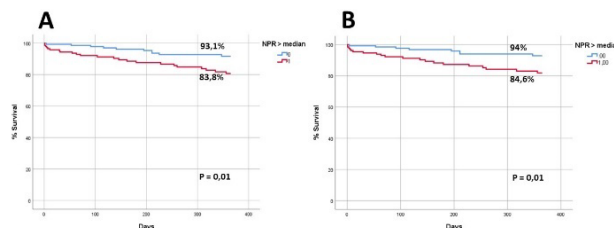


Figura 1. (A) Cumulative incidence of 1-year survival in the unmatched population. (B) Cumulative incidence of 1-year survival in the matched population.

## P63

### IMPACT OF TRANSCATHETER AORTIC VALVE IMPLANTATION WITH DEPLOYMENT OF SELF-EXPANDING VALVES IN CUSP OVERLAP VIEW ON POST-PROCEDURAL HIGH-DEGREE CONDUCTION DISTURBANCES IN A HIGH-VOLUME CENTRE

Silvia Crescenzia Motta<sup>1</sup>, Giuliano Costa<sup>1</sup>, Orazio Strazzieri<sup>1</sup>, Elena Dipietro<sup>1</sup>, Valentina Frittitta<sup>1</sup>, Alessandro Comis<sup>1</sup>, Sofia Sammartino<sup>1</sup>, Mariachiara Cali<sup>1</sup>, Marco Barbanti<sup>1,2</sup>, Corrado Tamburino<sup>1</sup>

<sup>1</sup>Cardiologia, A.O.U. Policlinico "G. Rodolico-San Marco", Catania, <sup>2</sup>Università degli Studi di Enna "Kore", Enna

**Introduction.** Recently, it has been demonstrated that the deployment of self-expanding Evolut transcatheter aortic valves yields better outcomes with a marked reduction of the need of permanent pacemaker implantation (PPI) after transcatheter aortic valve implantation (TAVI). Nevertheless, in this regard data from real-world practice are sparse.

**Methods.** We retrospectively analyzed 46 consecutive patients undergoing TAVI with Evolut platform deployed in cusp-overlap view at our Institution and undergoing post-procedural computed tomography angiography (CTA) assessment from September 2021 to July 2022. We assessed the length of membranous septum at pre-procedural CTA, and implantation depth at post-procedural CTA assessment. The angiographic valve implantation was measured at three-cusp view. Outcomes in terms of angiographic implantation depth and permanent pacemaker implantation were compared to 46 consecutive patients undergoing previously TAVI using the same platform with valve deployment in three-cusp view.

**Results.** Implantation depth in the cusp-overlap group was higher when measured at post-procedural CTA assessment compared to the three-

cuspid angiographic evaluation [5.4 mm (interquartile range (IQR) 4.0-7.0 mm) vs. 9.0 mm (IQR 6.5-10.0 mm)]. Implantation depth did not differ between patients who received TAVI implanted in three-cusp or cusp-overlap view [8.0 mm (IQR 4.9-9.3 mm) vs. 9.0 mm (IQR 6.5-10 mm),  $p=0.58$ ]. Similarly, rates of 30-day PPI did not differ between study groups (6.5% cusp-overlap vs. 4.3% three-cusp,  $p=0.646$ ). The length of membranous septum ( $p=0.65$ ), the implantation depth ( $p=0.75$ ) and the cusp calcium volume (right cusp,  $p=0.07$ ; left cusp,  $p=0.72$ ; non coronary cusp,  $p=0.98$ ) were not associated with 30-day PPI after TAVI. The only factor associated with 30 days PPI was pre-procedural right bundle branch block (odds ratio 7.43, 95% confidence interval 1.06-52.17,  $p=0.04$ ).

**Conclusions.** In a high-volume TAVI centre, the use of cusp-overlap view for self-expanding TAVI deployment did not impact on 30-day PPI after the procedure. The rates of 30-day PPI were extremely low implanting the devices in both cusp-overlap and three-cusp view. Larger, prospective, real-world studies involving patients treated by expert TAVI operators are required to confirm these findings.

## P64

### PREDICTORS AND LONG-TERM OUTCOME OF SEVERE PROSTHESIS-PATIENT MISMATCH AFTER SELF-EXPANDABLE SUPRA-ANNULAR TAVI IN DEGENERATED BIOPROSTHETIC SURGICAL VALVES

Francesco Bianchini<sup>1</sup>, Marco Lombardi<sup>1</sup>, Marco Busco<sup>1</sup>, Giulia Iannaccone<sup>1</sup>, Silvia Malara<sup>1</sup>, Cristina Aurigemma<sup>2</sup>, Enrico Romagnoli<sup>2</sup>, Lazzaro Paraggio<sup>2</sup>, Carlo Trani<sup>2</sup>, Francesco Burzotta<sup>2</sup>  
<sup>1</sup>Università Cattolica del Sacro Cuore, Roma, <sup>2</sup>Fondazione Policlinico Universitario Agostino Gemelli, Roma

**Introduction.** The valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) is increasing, and the occurrence of patient-prosthesis mismatch (PPM) post ViV-TAVI is associated with poor clinical outcomes. In our study we sought to: 1) assess the potential feasibility for assessing PPM following ViV-TAVI using multimodal imaging; 2) investigate the long-term outcomes and predictors of severe PPM.

**Methods.** 40 ViV-TAVI procedures between 2017-2023 using self-expandable supra-annular valves were included in our study. The effective orifice area (EOA) was calculated with the Gorlin equation combining echocardiographic data with invasive hemodynamic assessment. PPM was defined severe when the EOAI was  $\leq 0.65 \text{ cm}^2/\text{m}^2$  (if BMI  $<30 \text{ kg}/\text{m}^2$ ) or  $<0.55 \text{ cm}^2/\text{m}^2$  (if BMI  $\geq 30 \text{ kg}/\text{m}^2$ ). The primary clinical endpoint was defined as the composite of all-cause mortality and procedure-related or valve-related cardiovascular hospitalization.

**Results.** The presence of severe PPM was related to a higher incidence of the primary endpoint (9.1% vs. 44.4%;  $p = 0.023$ ) at a mean follow-up of 721 days. At the multivariate logistic analysis the pre-procedure ratio between inner area/area measured at CT, aortic regurgitation ( $\geq$  moderate) and lower renal function constituted independent predictors of severe PPM.

**Conclusion.** In ViV-TAVI using self-expandable supra-annular valves, a pre-procedural multimodal imaging assessment of incidence of PPM is feasible and a careful preprocedural assessment and planning could be helpful to avoid the onset of severe PPM which is associated with a major degree of clinical events at the long-term follow-up.

## P65

### LONG-TERM OUTCOMES AFTER VALVE-IN-VALVE TAVI ACCORDING TO DIFFERENT PATTERNS OF SURGICAL VALVE DEGENERATION

Mattia Lunardi, Luigi Alberto Iossa, Paolo Alberto Del Sole, Concetta Mammone, Gabriele Pesarini, Flavio Luciano Ribichini  
 AOUI Verona, Verona

**Aims.** Differences in long-term outcomes after valve-in-valve (ViV) transcatheter aortic valve implantation (TAVI) when treating aortic stenosis compared to aortic regurgitation, are not disclosed. The aim of this study is to compare clinical and hemodynamic outcomes at 24 months between different types of prosthesis degeneration underwent ViV-TAVI.

**Methods.** A total of 98 patients, who underwent ViV-TAVI at the University hospital of Verona were included in this study. Patients were classified into two groups according to type of prosthesis degeneration: group "AS" presenting pure or prevalent stenosis ( $n=53$ ) [mean gradient (MG)  $>34 \text{ mmHg}$  and aortic regurgitation (AR) less than moderate-to-severe]; group "AR" presenting pure or prevalent regurgitation ( $n=45$ ) (AR moderate-to-severe or severe, regardless of the magnitude of trans-aortic gradient). Adverse events were collected in hospital and up to 2 years of follow-up, including peri-procedural complications (major bleeding, major vascular complication, acute kidney injury, stroke and death) and a composite of major adverse cardiac events (MACEs: cardiac death, heart failure requiring hospitalization, stroke and endocarditis). The primary endpoint was the occurrence of MACEs at 2 years, while secondary endpoints included overall survival at 2 years, in-hospital complications, and hemodynamic performance of the bioprosthesis at 2 years, among the two groups.

**Results.** Mean age of the overall population was  $83.8 \pm 4.6$  years and 42.4% of patients were female. ViV-TAVI was performed for degeneration of a surgical previously implanted valve in 95% of cases, 3% were redo TAVI and 2% were homograft degenerations. Among surgical cases, the degenerated valve was a stentless prosthesis in 17.2% of cases and stented ones in 79.2%. Balloon expandable Valves were used in 44.8% of cases (49.5% "AS" group vs. 39.5% in "AR" group;  $p=0.243$ ). Post procedural gradient was  $13.74 \pm 6.74 \text{ mmHg}$  in the overall cohort with no differences between the two groups ( $14.6 \pm 6.33 \text{ mmHg}$  s.  $12.6 \pm 7.21 \text{ mmHg}$ ;  $p=0.265$ ). The composite of in-hospital complications amounted at 21.9% overall, mainly driven by acute kidney injury (AKI), that was the only adverse event occurring more likely in the AS group (20.8% vs. 2.3%;  $p=0.006$ ). At 24 months, MACEs occurred in 24.2% of cases, specifically 25.8% in the AS group and 23.9% in the AR group ( $p=0.537$ ). Overall survival at 2-year was 81.6%, without differences between the two groups. As regards hemodynamic parameters, LVEF at 2 years was  $57.08 \pm 13.32\%$  with no significant differences between the investigated cohorts ( $57.65 \pm 14.87\%$  vs.  $56.69 \pm 10.33\%$ ;  $p=0.360$ ). Similarly, MG was  $12.12 \pm 6.47 \text{ mmHg}$ , showing no differences according to the valve degeneration type ( $11.33 \pm 9.87 \text{ mmHg}$  vs.  $13.88 \pm 6.9 \text{ mmHg}$ ;  $p=0.308$ ).

**Conclusions.** The degeneration process of aortic bioprosthesis and their clinical presentation do not impact long-term outcomes after ViV-TAVI, both in terms of clinical events and hemodynamic performance of the transcatheter valve. Of note, when degeneration of the previous valve led to pure or prevalent aortic stenosis, the risk of acute renal failure after the procedure was higher, although this did not translate into late major adverse outcomes.

## P66

### COMMON FEMORAL INJURY AFTER TAVI

Mateusz Orzalkiewicz, Francesco Palermo, Marco Foroni, Francesco Chietera, Alessandro Mazzapicchi, Francesco Bendandi, Antonio Giulio Bruno, Gabriele Ghetti, Nevio Taglieri, Cinzia Marrozzini, Nazzareno Galì, Tullio Palmerini, Francesco Saia  
 Cardiologia, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna

**Introduction.** Routine angiographic control of the primary vascular access site following transcatheter aortic valve implantation (TAVI) from an accessory access is a common practice in many centres. At the level of the common femoral artery (CFA) puncture site it often shows the presence of injury (defined as a degree of stenosis and/or vessel wall dissection) after closure with a stitch-based vascular closure device (VCD). These lesions often are clinically silent and are regarded as a part of in the procedure and closure methodology. There is no consensus on classification, treatment and follow-up of these lesions. There is no data on the impact of the ultrasound (US) guidance on the occurrence of CFA injury. We reviewed the frequency and outcomes of CFA injury after TAVI.

**Methods.** We included all transfemoral TAVIs with percutaneous access from our centre between 2016 and 2021. We divided patients into non-US-guided and US-guided puncture groups. The CFA dissection was classified using a coronary dissection NHLBI classification (types A-F). The CFA injury was defined as the presence of any stenosis and/or dissection at the CFA puncture site. Severe injury was defined as  $>50\%$  stenosis and/or significant dissection (type  $>C$ ). The vascular complications were classified according to VARC 3 definitions. We analysed in-hospital and follow-up outcomes of these lesions.

**Results.** A total of 1192 consecutive transfemoral TAVIs with percutaneous femoral access (non-US guided  $n=466$ , US-guided  $n=726$ ) were included. Overall the number of primary access site related vascular complications (major and minor) was reduced with US guidance: 7.9% (37/466) vs 4.7% (34/726),  $p=0.0204$ . US guidance also reduced significantly the frequency of VCD failure with acute bleeding requiring prolonged balloon inflation, covered stent or surgery: non US-guided 1.7% (8/466) vs US-guided 0.3% (2/726),  $p=0.0171$ . The peripheral angiogram for review for CFA injury was available in 1080 patients. CFA injury occurred in 53% patients ( $n=577$ ), the occurrence of which was lower with US-guided (49.8%) vs non-US-guided (59.4%) access,  $p=0.0025$ . Severe CFA injury occurred in 8.4% (91/1080) of patients with no significant difference between US-guided and non US-guided groups: 7.9% (53/669) vs 9.2% (38/411), respectively ( $p=0.49$ ). Severe CFA injury with severe stenosis and/or flow-limiting dissection was treated after TAVI in 24 patients (22 PTA, 1 stent, 1 surgery). In the remainder 67 patients severe CFA injury was left untreated. Out of those patients the rate of in-hospital major and minor vascular complication rate was 4.4% (2 major haematomas requiring 2-4 units of blood transfused and 1 minor haematoma). In the median of 15.4 months follow-up 1 patient reported claudication that was treated medically. No acute vascular events occurred.

**Conclusions.** The US-guidance significantly reduced the rate of major and minor vascular complications of the primary access site and the overall rate of CFA injury. VCD failure was more common in non US-guided patients. The presence of severe CFA injury that is not flow-limiting is usually clinically silent and is not associated with vascular events in follow-up.

**P67**

**IMPACT OF CONTRAST MEDIA TYPE ON ACUTE KIDNEY INJURY AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION**

Luigi Ferrarotto<sup>1</sup>, Giuliano Costa<sup>1</sup>, Orazio Strazzeri<sup>1</sup>, Silvia Crescenzia Motta<sup>1</sup>, Elena Dipietro<sup>1</sup>, Valentina Frittitta<sup>1</sup>, Alessandro Comis<sup>1</sup>, Sofia Sammartino<sup>1</sup>, Mariachiara Cali<sup>1</sup>, Marco Barbanti<sup>2</sup>, Corrado Tamburino<sup>1</sup>  
<sup>1</sup>Cardiologia, A.O.U. Policlinico "G. Rodolico - San Marco", Catania,  
<sup>2</sup>Cardiologia, A.O. Umberto I, Enna

**Introduction.** Acute kidney injury (AKI) is a common complication after transcatheter aortic valve implantation (TAVI) that impacts on patients' morbidity, mortality as well as on public health expenses. Although it has been widely investigated that contrast media type impacts on the development of AKI after percutaneous coronary intervention, there is poor evidence in the setting of TAVI.

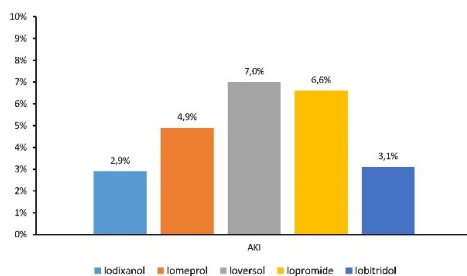
**Methods.** Consecutive patients undergoing TAVI between January 2020 and April 2023 at Policlinico di Catania were considered. The population was divided according to the specific contrast media type used for TAVI [iodixanol(n=105), iomeprol (n=164), ioversol (n=128), iopromide (n=212) and iobitridol (n=195)]. Moreover, the population was divided in 2 groups according to contrast media osmolarity: iso-osmolar contrast medium (IOCM, n=105) and low-osmolar contrast medium (LOCM, n=699).

**Results.** The incidence of AKI after TAVI was lower in patients receiving IOCM compared with those receiving LOCM, but did not meet statistical significance (2.9% vs. 5.3%, p=0.284). Analyzing the specific contrast media used, iodixanol had the numerically lower rate of post-TAVI AKI (2.9% vs. 4.9% iomeprol vs. 7.0% ioversol vs. 6.6% iopromide vs. 3.1% iobitridol, p=0.306). Age [odds ratio (OR) 0.92, 95% confidence interval (CI) 0.87-0.97, p=0.002] and CKD (OR 13.67, 95% CI 6.56-28.47, p<0.001) were independently associated with AKI after TAVI.

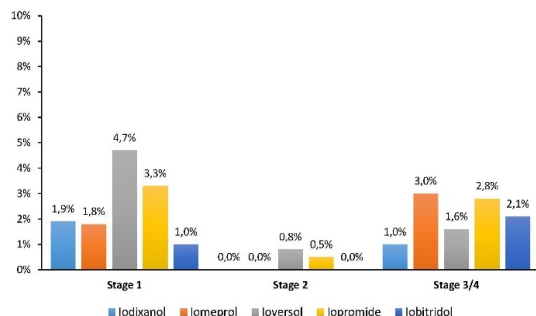
**Conclusions.** The use of IOCM yielded a lower rate of AKI after TAVI, but it did not reach statistical significance. IOCM should be used especially in patients affected by CKD, who have the higher risk to develop AKI after TAVI.

**Table 1.** Univariable and multivariable analyses of factors associated with acute kidney injury.

	Univariable analysis		Multivariable analysis	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Sex	0.72 (0.38-1.36)	0.311		
Age	0.96 (0.91-1.00)	0.107	0.92 (0.87-0.97)	0.002
Hypertension	1.07 (0.41-2.79)	0.888		
Diabetes	1.50 (0.79-2.84)	0.210		
Chronic kidney disease	10.34 (5.28-20.26)	<0.001	13.66 (6.56-28.47)	<0.001
PAD	2.07 (0.77-5.53)	0.144		
Prior MI	1.05 (0.43-2.53)	0.914		
Prior cardiac surgery	1.27 (0.43-3.70)	0.655		
NYHA class >III	1.32 (0.60-2.92)	0.487		
LVEF	0.97 (0.94-1.00)	0.060		
Anemia	2.79 (1.43-5.44)	0.003		
Loss of >3 g of Hb	1.89 (0.94-3.81)	0.074		
Vascular complication	1.09 (0.41-2.87)	0.850		
CMV	0.99 (0.99-1.00)	0.644		



**Figure 1.** Acute kidney injury incidence in patients undergoing TAVI according to the specific type of contrast media received.



**Figure 2.** Valve Academic Research Consortium-3 acute kidney injury stages according to the type of contrast media administered.

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**ROUTINE CEREBRAL EMBOLIC PROTECTION IN TRANSCATHETER AORTIC VALVE IMPLANTATION. A SINGLE-CENTRE EXPERIENCE**

Elisa Nicolini<sup>1</sup>, Alessandro Maolo<sup>1</sup>, Margherita Mariottini<sup>1</sup>, Roberto Manfredi<sup>2</sup>, Tommaso Piva<sup>1</sup>  
<sup>1</sup>SOSD Emodinamica Interventistica, Strutturale e Pediatrica, Ospedali Riuniti Ancona, Ancona, <sup>2</sup>Clinica di Cardiologia, Ospedali Riuniti Ancona, Ancona

**Introduction.** Despite technical improvement of devices, simplification of procedures and increased operators skills, TAVI procedures are still affected by ischemic cerebral events. Cerebral embolic protection devices (CEPD) during TAVI are effective in reducing cerebral embolization extent, but their role is largely debated as previous studies failed in demonstrating a clear clinical benefit. The aim of this study is to analyse our single centre experience with embolic protection during TAVI in an high-risk population.

**Methods.** The study has prospectively evaluated all patients underwent percutaneous transfemoral and transaxillary TAVI procedure between January 2018 and December 2022, in whom a cerebral embolic protection was planned to be used. Neurological assessment was routinely performed the day before and on the same day of the procedure; CT/MRI analysis were requested in case of clinically significant neurological event. We analyzed device deployment technical success, early and mid-term clinical outcomes in terms of periprocedural overt central nervous system injury, periprocedural and early mortality according to VARC-3 criteria.

**Results.** Between January 2018 and December 2022, 602 consecutive patients underwent percutaneous TAVI procedure with intention to use Sentinel cerebral embolic protection device (CEPD). An intermediate-high risk population was treated (STS 5.82). Sentinel device was successfully positioned in 586 of the 602 patients (97,3%); most of the failures happened during initial learning phase and mainly caused by significant tortuosity and calcifications of brachiocephalic trunk in type I arch (12/16). Mean deployment time was 3,55 min, no additional contrast dye was needed for device deployment. Macroscopic and discernible debris were harvested in 549/586 cases (93,7%). Patients receiving Evolute R/Pro presented with a greater number and size (>2000 micron) of particles captured compared to Sapien3 and Acurate Neo (p=0,01). There were 3 periprocedural overt Central nervous system injury (0,5%), occurred on the same day of procedure. One non-disabling stroke occurred in the unprotected left parieto-occipital brain region and the other one in the protected left fronto-insular region. In both cases, a large amount of debris was captured by the device. The third stroke happened because of severe haemodynamic instability at the end of a transaxillary TAVI performed in general anesthesia. CT-imaging showed a diffuse occipital lobe injury as a result of severe hypoperfusion, resulting in persisting hypoviscus at 90 day of follow-up. A low incidence of stroke/TIA was maintained at a follow-up of 1 and 12 months (1% and 2,4%) and this translates into low mortality for all cause (1,4% at 30 days and 4,9% at 1 year). 2 CEPD-related minor vascular complications occurred, consisting in brachial artery pseudoaneurysm.

**Conclusions.** Systematic cerebral protection in a real-world high risk population was safe, with high technical success and it is effective in preventing cerebral embolization, leading to low incidence of disabling stroke and mortality at 30 days up to 1-year follow-up.

**P69**

**BALLOON AORTIC VALVULOPLASTY PREDILATATION REDUCES THE RISK OF PARAVALVULAR LEAK IN PATIENTS WITH SEVERELY CALCIFIED AORTIC VALVES UNDERGOING TAVR WITH IMPLANTATION OF NEWER-GENERATION SELF-EXPANDABLE PROSTHESES**

Germano Junior Ferruzzi, Angelo Silverio, Michele Bellino, Mario Ferraioli, Cristina Sasso, Francesco Vigorito, Cesare Baldi, Gennaro Galasso, Tiziana Attisano

Dipartimento di Medicina, Chirurgia ed Odontoiatria, Università degli Studi di Salerno, Baronissi (Salerno); Unità di Cardiologia Interventistica, Dipartimento Cardio-Toraco-Vascolare, A.O.U. San Giovanni di Dio e Ruggi d'Aragona, Salerno

**Background.** The volume of calcium present at the native aortic valve (aortic calcium volume, ACV) has been associated with the risk of developing paravalvular leak (PVL) after transcatheter aortic valve replacement (TAVR). However, this evidence derives from studies on older generation prostheses. Also, the role of balloon aortic valvuloplasty predilatation (BAVp) on the mechanistic pathophysiological association between ACV and PVL is still poorly investigated.

**Aim.** To determine the association between ACV and the risk of significant PVL in patients with severe aortic stenosis undergoing TAVR using newer-generation self-expandable aortic prostheses, and to evaluate the potential influence of preliminary BAVp.

**Methods.** This study included consecutive patients with symptomatic severe aortic stenosis undergoing TAVR with newer-generation self-expandable aortic prosthesis from 2019 to 2023. The ACV was quantified from pre-procedural contrast enhanced multi-slice computed tomography (MSCT) images using the reading software OsiriX (OsiriX-MD v.2.8.2 64-

bit). PVL was quantified by transthoracic echocardiography and defined severe if  $\geq 2+/5+$ . Patients were divided into two groups: those who underwent BAVp and those who did not. The propensity score technique was employed to account for potential selection bias between patients undergoing or not BAVp.

**Results.** This study included 174 patients (median 81 years, 31.6% males); of them, 122 (70.1%) patients underwent BAVp. BAVp patients showed significantly higher values of left ventricular ejection fraction (LVEF,  $p=0.012$ ), mean aortic valve gradient ( $p<0.001$ ), and ACV ( $p<0.001$ ) than patients who did not undergo BAVp. Significant PVL after TAVR was reported in 28 (16%) patients. Overall, there was a significant association between ACV and the risk of developing significant PVL after TAVR both at unadjusted (OR: 1.001; 95% CI: 1.000-1.001,  $p=0.014$ ) and at propensity score adjusted logistic regression analysis (adjusted OR: 1.001; 95% CI: 1.000-1.001;  $p=0.033$ ; Table). Among the prespecified subgroups of interest, the association between ACV and the risk of developing PVL $\geq 2+$  after procedure was confirmed in patients who did not undergo preliminary BAVp (adjusted OR: 1.001; 95% CI: 1.000-1.001,  $p=0.035$ ) but not in the BAVp group (adjusted OR: 1.002; 95% CI: 1.000-1.003,  $p=0.635$ ).

**Conclusions.** This real-world study including patients with severe aortic stenosis undergoing TAVR using newer-generation self-expandable aortic prostheses, confirmed a strong significant association between ACV and the risk of developing significant PVL after procedure. Preliminary BAVp may mitigate the detrimental effect of ACV on the risk of developing PVL in this TAVR population.

**Table.** Unadjusted and adjusted logistic regression analysis for the association between ACV and PVL  $\geq 2+$ .

	Unadjusted		
	OR	95% CI	P
Overall	1.001	1.000-1.001	0.014
No BAVp	1.002	1.000-1.004	0.006
BAVp	1.001	1.000-1.001	0.250
	Adjusted*		
	aOR	95% CI	P
Overall	1.001	1.000-1.001	0.033
No BAVp	1.001	1.000-1.001	0.035
BAVp	1.002	1.000-1.003	0.635

ACV, aortic calcium volume; aOR, adjusted odd ratio; BAVp, balloon aortic valvuloplasty predilatation; CI, confidence interval; OR, odd ratio; PVL, paravalvular leak.

\*List of variables entered in the propensity score model: male sex, age, body mass index, diabetes, hypertension, dyslipidemia, chronic obstructive pulmonary disease, smoking, chronic coronary syndrome, prior myocardial infarction, prior percutaneous coronary intervention, atrial fibrillation, prior stroke, prior pacemaker implantation, prior implantable cardioverter-defibrillator, prior cardiac, resynchronization therapy, EuroScore II, baseline eGFR, baseline left ventricular ejection fraction, baseline mean aortic gradient, baseline aortic regurgitation, baseline mitral regurgitation, baseline tricuspid annular plane systolic excursion.

## STRUCTURAL HEART DISEASE: TRICUSPID INTERVENTIONS

### P70

#### SHAPING THE ANESTHETIC APPROACH TO TRICUSPID IMPLANTATION: INSIGHTS FROM A CASE SERIES

Sara Dormio<sup>1</sup>, Marina Pieri<sup>1</sup>, Alessandro Belletti<sup>1</sup>, Michele Morosato<sup>2</sup>, Dario Silvestri<sup>2</sup>, Matteo Montorfano<sup>2</sup>, Fabrizio Monaco<sup>1</sup>

<sup>1</sup>Anesthesia and Intensive Care, IRCCS San Raffaele Scientific Institute, Milano, <sup>2</sup>Department of Cardiology, IRCCS San Raffaele Scientific Institute, Milan

**Introduction.** The TricValve System presents a novel, minimally invasive strategy for managing severe tricuspid regurgitation (TR) in high-risk patients unsuitable for surgical or transcatheter orthotopic tricuspid valve (TV) repair or replacement. This case series aims to assess the anesthetic management challenges and outcomes associated with this procedure, seeking to generate insights that can inform and refine anesthetic protocols.

**Methods.** We conducted a retrospective review of patients who underwent TricValve implantation from December 2021 to March 2023 at San Raffaele Hospital, Milan. A systematic approach of pre-procedural planning and post-procedural debriefing was integrated to the management process (Table 1). Pre-anesthesia setup involved establishing two large-bore peripheral venous accesses and an invasive radial arterial line. A fast-track general anesthesia protocol, utilizing propofol or midazolam for induction and sevoflurane for maintenance was implemented. Intra-operative management involved anesthesia depth monitoring, real-time guidance via transesophageal echocardiography (TEE) and regular arterial blood gas analysis. Hemodynamic stability was maintained through an emphasis on adequate perfusion pressure, and additional anesthesia or neuromuscular blocking agents were administered when required. Pain management was achieved via intravenous paracetamol, with additional opioid analgesics administered as needed.

**Results.** Eight patients with of symptomatic severe TR successfully underwent TricValve implantation during the study period, with a mean procedure duration of 112 $\pm$ 44 minutes. Six patients had undergone previous cardiac procedures, and all had a history of atrial arrhythmia, including atrial fibrillation and atrial flutter. There were no anesthesia-related or implantation-related complications (Table 2). Median hospital stay was four days, whereas brief Intensive Care Unit (ICU) monitoring was needed for one patient. Intravenous paracetamol served as the primary analgesic except for one patient with allergy, in which tramadol was administered. Post-operative right shoulder pain was reported by 50% of the patients, which was managed with morphine bolus administration (average dose 4.75 $\pm$ 3.6 mg). Post-operative transthoracic echocardiograms confirmed correct device positioning in all patients. Upon discharge, none of the patients required outpatient analgesic therapy.

**Conclusions.** Our study demonstrates the potential of TricValve implantation in effectively managing severe tricuspid regurgitation, with no procedure-related complications and a 100% survival rate. A collaborative, interdisciplinary approach and targeted anesthesia management proved crucial for this success. Postoperative shoulder pain emerged as a frequent complication, whose pathogenesis is still not clear, and was successfully managed using targeted analgesic therapy.

**Table 1.** Anesthesiological management of TricValve implantation.

General Anesthesia induction	
Invasive hemodynamic pressure monitoring	
Two large bore peripheral venous accesses	
Central venous line not routinely placed	
Fast track protocol (propofol or midazolam for anesthesia induction + fentanyl 1mcg/kg + rocuronium 0.6 mg/kg)	
General Anesthesia maintenance	
Use of inhalation anesthetic agents (Sevoflurane)	
Real-time TEE monitoring	
Avoidance of opioids	
BIS monitoring	
Awakening and post-operative pain management	
Intravenous paracetamol 15 mg/kg	
Additional analgesia according to clinical need	

BIS, bispectral index; TEE, transesophageal echocardiography.

**Table 2.** Patients' baseline data, anesthesiological management and outcomes.

Patient	Age, years	Sex	Significant Comorbidities	Atrial arrhythmias	Previous cardiac procedures	Previous number of TAVR procedures	Hospital admission for TAVR severity	Procedure duration, min	Anesthesia protocol	Post-operative pain requirement (morphine)	Right shoulder pain	Stroke	Duration of ICU stay, h	Postoperative Duration of hospital stay, days	Hospital mortality	
1	79	M	CKD, OSAS, sinusoidal hypertension, hypertension <td>Permanent AF</td> <td>AF radio-frequency ablation</td> <td>no</td> <td>severe</td> <td>137</td> <td>Propofolated 17 mg/kg</td> <td>no</td> <td>no</td> <td>no</td> <td>0</td> <td>yes</td> <td>7</td>	Permanent AF	AF radio-frequency ablation	no	severe	137	Propofolated 17 mg/kg	no	no	no	0	yes	7	
2	44	F	HTN, T2DM, previous heart failure, hypertension	Permanent AF	SAVR	yes	severe	130	Propofolated 11 mg/kg	yes	yes	Morphine 10 mg	no	3	yes	6
3	67	F	OSAS, T2DM, hepatic sinusoidal, acute cholecystitis, Stage IV liver B-cell Non-Hodgkin's Lymphoma	Atrial Flutter	none	yes	severe	99	Propofolated 11 mg/kg	yes	yes	Morphine 1 mg	no	0	yes	3
4	69	F	HTN, T2DM, CKD	Permanent AF	Mitral valve replacement plus In Vivo-recapitulated mitral annuloplasty	no	severe	90	Propofolated 17 mg/kg	no	no	no	0	no	yes	4
5	79	F	HTN, CKD	Permanent AF	Mitral TEER	yes	severe	98	Propofolated 17 mg/kg	yes	yes	Morphine 3-2 mg	no	0	yes	5
6	83	F	HTN, T2DM, CKD	Atrial Flutter	TAVR	no	moderate	92	Propofolated 17 mg/kg	yes	yes	Morphine 1-2 mg	no	0	yes	5
7	75	F	T2DM	Permanent AF	Mitral valve replacement plus In Vivo-recapitulated mitral annuloplasty, TAVR	no	moderate	181	Propofolated 16 mg/kg	no	no	no	0	no	yes	7
8	63	F	HTN	Permanent AF	none	no	moderate	183	Propofolated 16 mg/kg	no	no	no	0	no	yes	4

AF, atrial fibrillation; CKD, chronic kidney disease; HTN, hypertension; OSAS, obstructive sleep apnea syndrome; SAVR, surgical aortic valve replacement; T2DM, type 2 diabetes mellitus; TAVR, transcatheter aortic valve replacement; TEER, transcatheter edge-to-edge repair.

### P71

#### TRANSCATHETER EDGE-TO-EDGE VALVE REPAIR FOR TRICUSPID REGURGITATION: COMPARATIVE ANALYSIS OF PROCEDURAL OUTCOMES BETWEEN PASCAL AND TRICLIP DEVICES

Valentina Ardizzone, Cristina Ferrari, Paolo Olivares, Marco Gennari, Carlo Maria Giacari, Federico De Marco  
Cardiologia Interventistica Valvolare e Strutturale, Centro Cardiologico Monzino, Milano

**Introduction.** The aim of this study was to compare the procedural outcomes of patients who underwent transcatheter tricuspid edge-to-edge valve repair (TEER) using the Pascal system versus the TriClip, Abbott

system, for significant (severe or greater) functional tricuspid regurgitation (TR) in a small patient cohort.

**Methods.** A retrospective analysis of tricuspid TEER procedures (Pascal versus TriClip, Abbott) performed at the Centro Cardiologico Monzino from May 2022 to May 2023 was conducted. Eighteen patients with significant functional TR symptomatic for dyspnea (NYHA III/IV) despite optimal medical therapy (OMT) and deemed to be at high surgical risk by institutional heart teams were included. Eleven patients were treated with the TriClip device system, while seven patients were treated with the Pascal system. The primary outcome measure was procedural success, defined as the implantation of at least one device with post-procedural TR grade  $\leq 2+$  without mortality or conversion to surgery. The secondary outcome measures included procedure time, fluoroscopy time, and length of hospital stay.

**Results.** The procedural success rate was 100% in both groups, with an average of  $1.9 \pm 0.2$  devices implanted per patient in the Pascal system group and  $1.8 \pm 0.3$  devices implanted per patient in the TriClip group. No intra-procedural complications were reported. Both groups showed a significant mean reduction in TR grade ( $p=0.001$ ), with the Pascal group at  $2.1 \pm 0.2$  and the TriClip group at  $1.8 \pm 0.1$ . The average procedure time for the Pascal group was  $81 \pm 25$  minutes, with  $16.4 \pm 5.0$  minutes of fluoroscopy, while the Abbott group had an average procedure time of  $80 \pm 24.5$  minutes, with  $15.6 \pm 4.5$  minutes of fluoroscopy. The mean length of hospitalization for both groups was  $2 \pm 0.6$  days. One case of single leaflet device attachment was observed in the Abbott group, which was successfully managed with the implantation of another device.

**Conclusions.** TEER on the tricuspid valve using both the Pascal system and the TriClip system demonstrated similar procedural success rates, safety profiles, and comparable procedure times. Larger prospective studies with long-term follow-up are necessary.

Table 1. Patient features.

Features	Pascal device	TriClip device
No. pts	7	11
Age, years	82±5	81±5
Arterial hypertension	5 (70%)	8 (73%)
Diabetes mellitus type 2	0 (0%)	2 (20%)
Dyslipidemia	2 (30%)	8 (73%)
CKD III/IV	3 (43%)	6 (55%)
CAD	2 (29%)	2 (18%)
Previous MI	0 (0%)	1 (9%)
Prior PCI	1 (14%)	2 (18%)
Prior CABG	1 (14%)	1 (9%)
Atrial fibrillation	7 (100%)	9 (82%)
Prior TIA/stroke	2 (29%)	0 (0%)
Pacemaker	0 (0%)	0 (0%)
Prior valve intervention	2 (29%)	6 (55%)
Hospitalization previous year	4 (57%)	6 (55%)
NYHA class III/IV	7 (100%)	11 (100%)
Diuretics	6 (86%)	11 (100%)
ACE inhibitors	3 (43%)	6 (55%)
Vasodilators	3 (43%)	1 (9%)
Beta-blockers	2 (29%)	7 (64%)

Table 2. Echocardiographic features.

Echocardiographic features	Pascal device	TriClip device
<b>Pre-procedure</b>		
Tricuspid regurgitation (severe or massive)	7	11
PAPs (mmHg)	39 ± 11	41 ± 10
Vena contracta (mm)	7.8 ± 0.6	7.9 ± 0.8
Septal-lateral annular diameter (mm)	43 ± 4	45 ± 5
Right ventricular FAC (%)	41 ± 8	42 ± 7
End-diastolic right ventricular area (cm <sup>2</sup> )	23 ± 9	25 ± 9
TAPSE (mm)	19 ± 4	19 ± 4
End-systolic right atrium area (cm <sup>2</sup> )	29 ± 5	30 ± 5
Inferior vena cava	22 ± 4	23 ± 5
Left ventricular ejection fraction (%)	60 ± 6	59 ± 7
<b>Post-procedure</b>		
Tricuspid regurgitation grade	0.9 ± 0.6	1.3 ± 0.4
Medium gradient (mmHg)	1.3 ± 0.4	1.4 ± 0.6
Reduction regurgitation grade	2.0 ± 0.6	1.8 ± 0.6

**P72**

**A REAL-WORLD COMPARATIVE ANALYSIS OF SURGICAL AND TRANSCATHETER APPROACHES TO TRICUSPID REGURGITATION**

Carlo Gasparдоне, Federica Gramegna, Michele Morosato, Laura Vetrugno, Gabriele Paci, Davide Morciano, Vincenzo Rizza, Caterina Mula, Alessandro Fuga, Giorgio Fiore, Francesco Ancona, Davide Margonato, Alberto Margonato, Paolo Denti, Nicola Buzzatti, Eustachio Agricola, Francesco Maisano, Cosmo Godino  
**IRCCS San Raffaele Scientific Institute, Milan**

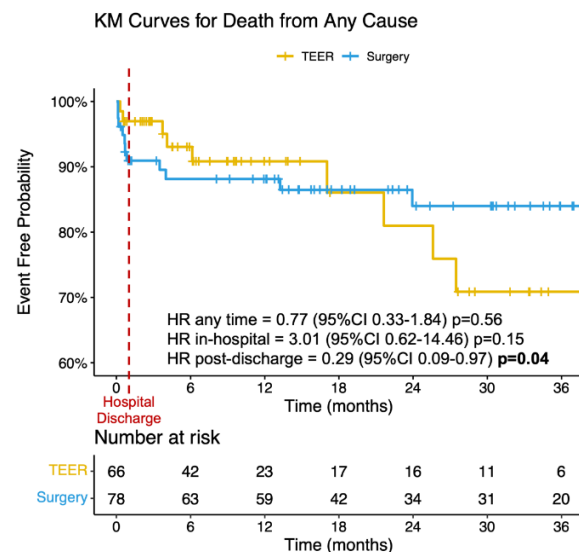
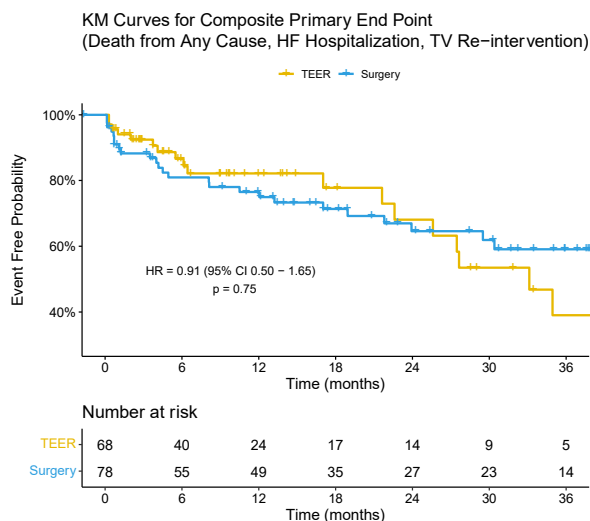
**Background.** The management of severe tricuspid regurgitation (TR) remains a challenge due to significant associated morbidity and mortality, compounded by limited treatment options. We aimed to compare the

demographic traits, echocardiographic features, and clinical outcomes of patients undergoing transcatheter tricuspid valve repair (TTVR) versus those undergoing isolated surgical tricuspid valve repair or replacement (STVR).

**Methods.** We conducted a retrospective analysis of consecutive adult patients treated for severe TR using TTVR or STVR at San Raffaele Hospital between 2017 and 2023. Baseline and follow-up data were obtained from electronic health records and through telephone interviews.

**Results.** Among the 79 TTVR patients and 80 STVR patients, the TTVR group was significantly older (76 vs. 65 years,  $p<0.001$ ), had higher prevalence of coronary artery disease (31% vs. 14%,  $p=0.02$ ) and atrial fibrillation (79% vs. 57%,  $p=0.007$ ), and were more symptomatic (NYHA class III/IV, 59% vs. 37%,  $p=0.01$ ). Moreover, a higher TRI-SCORE was observed in the TTVR group compared to the STVR group (5.03 vs. 3.04,  $p<0.007$ ). While there was no significant difference in baseline TR severity, functional TR etiology was more common in the TTVR group (86% vs. 63%,  $p=0.003$ ). This group also exhibited worsened right ventricle (RV) function and RV ventriculo-arterial coupling (TAPSE/PASP  $<0.36$ , 35% vs. 15%,  $p=0.01$ ). At a median follow-up of 1.14 years (IQR 0.41-1.50), the primary endpoint incidence (including death, TV surgery, or heart failure hospitalization) and mortality rates were similar in both groups (HR for primary endpoint 0.91; 95% CI, 0.50 to 1.65;  $p=0.75$ ) (HR for death 0.77; 95% CI, 0.33 to 1.84;  $p=0.56$ ). Nevertheless, when we employed a landmark analysis at the discharge time, STVR patients experienced a three-fold increase in in-hospital mortality rates (HR 3.01; 95% CI, 0.62 to 14.46;  $p=0.15$ ), but a three-fold decrease in post-discharge mortality rates (HR 0.29; 95% CI, 0.09 to 0.97;  $p=0.04$ ) when compared to TTVR patients.

**Conclusions.** This real-world retrospective study underscores the different characteristics of patients between TTVR and STVR. Despite a higher surgical risk and comorbidity burden among TTVR patients, mid-term clinical outcomes were similar to STVR. However, more extensive research within large-scale randomized control trials is required to validate these findings.



OTHER

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**BASELINE CHARACTERISTICS AND 3-YEAR OUTCOME OF NON-VALVULAR ATRIAL FIBRILLATION PATIENTS TREATED WITH THE FOUR DIRECT ORAL ANTICOAGULANTS**

Giulia Nemola<sup>1,2</sup>, Cosmo Godino<sup>2</sup>, Gianmarco Cozzani<sup>2</sup>, Anita Russi<sup>2</sup>, Carlo Gaspardone<sup>2</sup>, Anna Salerno<sup>2</sup>, Giulio Leo<sup>2</sup>, Michela Cera<sup>2</sup>, Alberto Zangrillo<sup>2</sup>, Alberto Margonato<sup>2</sup>, Francesco Maisano<sup>2</sup>, Matteo Montorfano<sup>2</sup>, Paolo Della Bella<sup>2</sup>

<sup>1</sup>Università di Milano, Milano <sup>2</sup>Università Vita-Salute San Raffaele, Milano

**Introduction.** Direct oral anticoagulants (DOACs) represent the cornerstone therapy for cardioembolic events prevention in patients with non-valvular atrial fibrillation (NVAF). In practice, the choice of one DOAC over another is guided by the physician's decision-making process, which considers specific patient and drug characteristics. This study aimed to evaluate the clinical features and long-term outcomes of a real-world population treated with DOACs.

**Methods.** We conducted a retrospective observational, single-center, multidisciplinary study enrolling consecutive NVAF patients treated with one of the four DOACs.

**Results.** From an initial number of 753 patients, we excluded 72 patients because of lost to follow-up, at the end we enrolled 681 patients: 174 (23%) treated with dabigatran, 175 (23%) with apixaban, 190 (25%) with rivaroxaban, and 214 (29%) with edoxaban. Patients treated with apixaban were significantly older, more women represented ( $p < 0.001$ ), and with a higher cardioembolic and bleeding risk ( $p < 0.001$ ). Dabigatran was preferred in patients with liver failure ( $p = 0.008$ ), while apixaban and edoxaban were chosen in chronic kidney disease ( $p = 0.002$ ). At 3-year follow-up, 20 patients (2.7%) experienced a systemic thromboembolic event without significant differences among the four DOACs. In the same period, an ISTH-major bleeding event occurred in 26 patients (3.6%), more statistically correlated to edoxaban (6.1%) ( $p = 0.038$ ). Thromboembolic events or major bleedings were higher in the edoxaban group (10%) compared to the others ( $p = 0.014$ ).

**Conclusions.** In our single-center real-world experience, the choice of the DOAC for a NVAF patient was tailored to specific patient's clinical features and drug pharmacokinetics. As a result, a small number of adverse events was observed.

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**PERFORMANCE EVALUATION OF A PORTABLE RADIATION SHIELDING SYSTEM FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

Emanuela Piccaluga<sup>1</sup>, Marco Felisi<sup>2</sup>, Davide Cicolari<sup>2</sup>, Gianfranco Martino<sup>1</sup>, Paola Enrica Colombo<sup>2</sup>, Jacopo Andrea Oreglia<sup>1</sup>

<sup>1</sup>Department of Interventional Cardiology, ASST Grande Ospedale Niguarda, Milano, <sup>2</sup>Department of Medical Physic, ASST Grande Ospedale Niguarda, Milano

**Introduction.** Interventional cardiology staff are among the categories with the highest occupational exposure to ionizing radiation; in this regard, as reported in the NCRP 184, the contribution to the collective effective dose from angiographic procedures is 12%, although their magnitude is only 1.2% of the total. For this reason, radiation protection of operators is an important issue, with several implementation strategies. Rampart system M1128 (Rampart ic, LLC) is a portable radiation shielding system that attenuates radiation scatter using a combination of lead-equivalent acrylic panels and soft shielding designed to protect the staff members. The purpose of this work is to evaluate its level of effectiveness in terms of reducing doses to operators, as well as its compatibility with the activity of the entire staff.

**Methods.** Rampart M1128 is a portable system composed of a couple of 1mm lead-equivalent acrylic panels; they can be rotated from 90° to 180° relative to each other, and they are adjustable in vertical direction, through electronic motor, in order to adapt the system to table heights and patient sizes. At the bottom of the panels additional 0.5 mm lead-equivalent soft shielding are assembled to increase the effectiveness of protection. In this way the system provides full-bodied radiation protection for physicians and staff. The device was tested by simulating realistic cath lab procedures, positioning on the angiographic table Alderson-Rando anthropomorphic phantom as patient. Dose rate ( $\mu\text{Sv/h}$ ) was measured with a X2 Survey sensor (RaySafe™) at four representative staff position in the room (first operator, second operator, radiology technician, nurse),

as shown in Fig. 1. For each position, the dose rate was evaluated for three different heights, 80-135-160 cm, corresponding to pelvis, chest, and lens, and for the four projections most commonly used in this type of procedure (RAO 20°/CAU 20°, RAO 30°/CRA 30°, LAO 55°/CAU 30°, LAO 90°). Each measurement was repeated twice: in the first case the usual clinical setup was simulated, in the second Rampart was added (Fig. 2). In this way, the effectiveness of the protection was assessed by evaluating the ratio of the measured dose rates in the different setups described, with and without the use of the shielding system. In addition, seven procedures (CA, PCI and TAVI) were performed with Rampart to prove its compatibility in the clinical routine.

**Results.** Phantom measurements demonstrated reduced doses to operators with Rampart. The position where this effect was most evident was definitely the first operator: considering the different simulated projections, for the height of 80 cm, the average reduction was -97.8%, ranging from -95.5% to -99.6%, while the values decreased for the heights of 135 cm and 160 cm, resulting respectively -79.4% (IQR -69.5/-89.0) and -77.2% (IQR -71.1/-83.1%). An important reduction in dose rate was also observed for the second operator; while at the lowest height similar reduction values to the first operator were found (88.6%, IQR -85.1%/-90.6%), for the highest positions (chest and lens) the reduction was less pronounced, amounting to -53.8% (IQR -32.2%/-74.4%) and -61.1% (IQR -48.1%/-77.2%), respectively, considering the different simulated projections. For the position occupied by the radiology technician, however, less attenuation was observed, evenly distributed across the three heights tested, with average values from -51.7% to -63.8%. It is important to emphasize that in this position the radiation field is significantly lower than in the stationary area of the first operator, going from a dose rate equal to few tens to several hundreds of  $\mu\text{Sv/h}$ . Finally, Rampart was also found to be effective for the position occupied by the nurse, with a reduction effect of more than 70%.

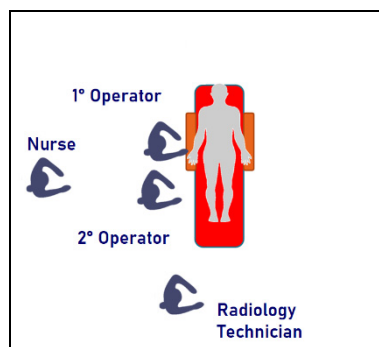


Figure 1. Four simulated representative staff position in the room.



Figure 2. Experimental setup with Rampart.

**Conclusion.** The data obtained in this study seem to indicate an important effectiveness of using the Rampart system for full-body shielding of different staff members in interventional cardiology procedures. In addition, the system does not interfere with clinical practice, even in the most complex procedures, and it can be easily transported to adjacent angiography rooms.