

# Poster

## Aortic valve disease

### P1

#### BALLOON EXPANDABLE MYVAL: SINGLE CENTER EXPERIENCE

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**Introduction.** Over the last 2 decades, transcatheter aortic valve implantation (TAVI) has emerged as a valuable alternative to surgery in an increasingly wide spectrum of patients affected by severe symptomatic aortic stenosis or degenerated bioprosthetic valve. We report our initial experience with MyVal THV (Meril Life Science, Vapi, India) implantation in native aortic valve and in aortic, mitral and tricuspid trans-catheter Valve-in-Valve (ViV), describing short-term patients' outcome.

**Methods.** The MyVal is a new CE mark TAVI device, it consists of a tri-leaflet valve of bovine pericardium mounted on a cobalt alloy frame with an internal polyester sealing cuff and an external polyester skirt. It's available in multiple size (from 20 mm to 32 mm in diameter, and half 21.5, 24.5 and 27.5 mm). MyVal THV is directly crimped on the delivery system balloon. To date, no data have proved MyVal safety and efficacy in the subset of ViV procedure, and in this scenario its use is still off-label.

**Results.** From November 2019 to May 2021 we use MyVal THV in 30 patients (mean age  $78.5 \pm 11.4$  years – range 28 to 91 years – 19 male). Main risk factors were severe renal failure in 23 pts (76.6%), coronary artery disease in 20 pts (66.6%), prior cardiac surgery in 8 pts (26.6%). Mean left ventricle ejection fraction was 50%, mean aortic valve gradient was 48 mmHg. Six patients were affected by stented biological prosthesis degeneration (2 in aortic, 3 mitral and 1 in tricuspid position). Twenty-three patients underwent trans-femoral arterial access for MyVal THV implant, one patient underwent distal trans-axillary approach. All mitral ViV were performed via femoral vein and trans-septal approach, the tricuspid case was performed via right jugular vein. MyVal THV size used were 24.5 in eight patients, 23 mm in seven and 27.5 mm in six patients. The procedure was successful in all cases. Mean post-procedure hemodynamic gradient in aortic position was 8 mmHg. No patients experienced vascular complications, acute kidney injury or stroke. Three patients underwent pace-maker implant. Median hospital stay was 5.5 days. At discharged mean aortic gradient was 11 mmHg, 22 patients (81%) had trivial or mild paravalvular leak, two patients (7.4%) had mild paravalvular leak.

**Conclusions.** Our experience demonstrated the safety and efficacy of the balloon-expandable MyVal THV both in native aortic valve and bioprosthetic degenerated setting in different anatomical positions. MyVal THV demonstrated also an excellent hemodynamic and extremely low rate of significant paravalvular leak.

### P2

#### A NOVEL SUPRA-ANNULAR SIZING METHOD OF TRANSCATHETER AORTIC VALVE PROSTHESES IN RAPHE-TYPE BICUSPID AORTIC VALVE DISEASE: THE LIRA METHOD

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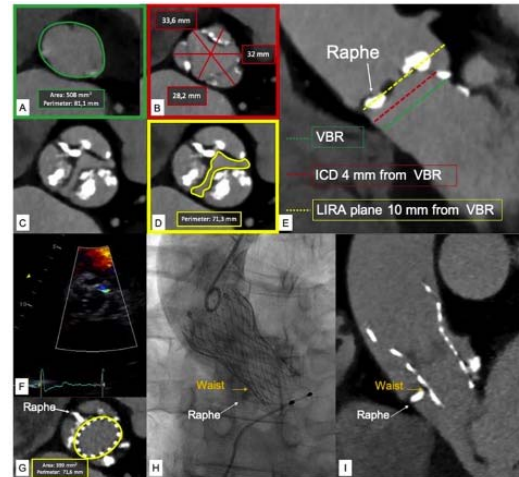
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**Background.** Recent evidence shows that transcatheter heart valve (THV) prostheses anchoring occurs at the raphe-level, known as Level of Implantation at the RAphe (LIRA) plane, in raphe-type bicuspid aortic valve (BAV) disease. The purpose of this study was to evaluate the application of a novel supra-annular sizing method, known as LIRA method, to optimize THV prosthesis sizing in raphe-type BAV disease.

**Methods and Results.** the LIRA method was applied to all consecutive patients with raphe-type BAV disease between November 2018 to January 2020 in our centre. THV prostheses were sized on the basis of baseline CT scan perimeters at the LIRA plane and at the virtual basal ring. In case of discrepancy between the two planes measurements, the plane with the smallest perimeter was considered the reference for prosthesis sizing. Post-procedural device success, defined according to Valve Academic Research Consortium-2 (VARC-2) criteria, was

evaluated in the overall cohort. 20 patients (mean patient age  $81 \pm 5.4$  years, 70% males) were identified as having a raphe-type BAV disease at pre-procedural CT scans and were implanted with different types of THV prostheses. The LIRA method appeared to be highly successful (100% VARC-2 device success) with no procedural mortality, no valve migration, no moderate-severe paravalvular leak and low transprosthetic gradient (residual mean gradient of  $8.2 \pm 2.9$  mmHg).

**Conclusions.** Supra-annular sizing according to the LIRA method appeared to be safe with a high device success. The application of the LIRA method might optimize THV prosthesis sizing in patients with raphe-type BAV disease.



**Figure 1.** Prosthesis sizing according to the LIRA method: A: VBR measurements; B: 4 mm above the VBR plane, three commissures can be visualized; C: BAV type 1 with calcific raphe between right and non coronary cusp; D: LIRA plane perimeter that traces the internal border of the leaflets; E: level of VBR (green dotted line), LIRA plane (yellow dotted line); F: doppler echocardiography showing a residual trivial leak; G: post-procedural prosthesis perimeter at the LIRA plane; H: fluoroscopy showing that Core Valve prosthesis waist (yellow arrow) coincides with the raphe level (white arrow); I: CT scan confirming that the prosthesis waist (yellow arrow) coincides with the raphe level (white arrow).

### P3

#### LONG TERM OUTCOMES OF CONCOMITANT PERCUTANEOUS CORONARY INTERVENTION AND TRANSCATHETER AORTIC VALVE IMPLANTATION

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**Introduction.** Severe aortic stenosis and coronary artery disease (CAD) frequently are present in the same patients and some of these may require percutaneous coronary intervention (PCI). The optimal timing of PCI in transcatheter aortic valve implantation (TAVI) setting is still highly debated. This study aimed to assess the safety and the effectiveness of TAVI and PCI performed in the same session compared with TAVI alone.

**Methods.** Patients with severe aortic stenosis (n = 1957) who underwent TAVI from June 2007 to April 2021 were divided into two groups: patients who underwent TAVI alone (n = 1804) and patients treated with TAVI and concomitant PCI (n = 153).

**Results.** The two study groups were comparable in terms of all baseline characteristics including age ( $81.0 \pm 5.7$  vs  $80.5 \pm 5.9$ ;  $p=0.362$ ) and STS score ( $4.3 \pm 3.2$  vs  $4.3 \pm 2.9$ ;  $p=0.891$ ). In hospital death (3.6% vs 4.6%,  $p=0.540$ ), stroke (1.1 vs 1.3,  $p=0.770$ ), major and life-threatening bleeding (15.6% vs 15.7%,  $p=0.974$ ), and acute kidney injury (7.4 vs 10.5,  $p=0.167$ ) were similar for both groups. At 3 years, the rates of all-cause death (2.6% vs 1.1%,  $p=0.687$ ) the composite endpoints of all-cause death and myocardial infarction (MI) (22.22% vs 22.28%;  $p=0.281$ ) and all-cause death, MI, and stroke (23.52% vs 23.4%;  $p=0.265$ ) were also comparable between the two groups.

**Conclusion.** Our study showed that that combined TAVI and PCI in the same session is a safe and effective strategy in patients undergoing TAVI with coexisting CAD requiring treatment.

**P4****RATE OF CARDIAC CONDUCTION DISORDERS AFTER TAVI: COMPARISON BETWEEN SAPIEN 3 AND SAPIEN 3 ULTRA BALLOON EXPANDABLE VALVES**

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**Introduction.** Conduction abnormalities are one of the most frequent complications in transcatheter aortic valve implantation (TAVI) present in about one third of patients post-procedure. New generation of prosthesis have been developed to better the procedural outcomes. Aim of our study was to compare the rate of new onset conduction abnormalities in patients undergoing TAVI with Edwards Sapien-3 versus Edwards Sapien-3-Ultra which has a bulkier PET outer skirt that could potentially provoke higher complications.

**Methods.** 329 patients undergoing heart-team-indicated TAVI with a balloon-expandable Edwards SAPIEN 3 (S-3) or Edwards SAPIEN 3 Ultra (S-Ultra) in a high-volume TAVI Center (Centro Cardiologico Monzino, Milan) between January 2018 and July 2020. 144 were S-Ultra recipients and 185 S-3 recipients. Standard ECGs were digitalized and reviewed by 2 cardiologists blinded to clinical data at baseline, early after procedure and at discharge. New onset of AV blocks, Bundle branch blocks, low-rate-A-Fib and pacemaker implantation were reported. Baseline characteristics, data on calcification, prosthesis ventricular position, and prosthesis over- or under-sizing were also reported to detect any bias or change in strategy that could explain different rate in conduction disorders new-onset. Continuous variables are reported as mean and standard deviation if normally distributed, and as median and interquartile range if not-normally distributed. For the comparison of categorical measures, the Chi-square test was used and for continuous values the Wilcoxon rank sum test was used.

**Results.** No significant differences in conduction abnormalities were found in S-3 group compared to S-Ultra immediately after procedure (S-3 43.8%; S-Ultra 45.1%;  $p=0.855$ ) nor at discharge (S-3 33.5%; S-Ultra 37.5%;  $p=0.852$ ). PM-implantation rate was comparable (S-3  $n=11$ , 5.9%; S-Ultra  $n=8$ , 5.6%;  $p=0.884$ ). No differences between groups were found for baseline characteristics, echography parameters and procedural data, but a difference was found in prosthesis ventricular position as S-3 valves were implanted lower into the outflow tract compared to S-Ultra (S-3  $4.8 \pm 1.57$  mm; S-Ultra  $4.4 \pm 1.36$  mm  $p=0.001$ ).

**Conclusions.** Our study shows no difference in rate of cardiac conduction abnormalities in patients undergoing balloon expandable TAVI with Edwards Sapien 3 compared to the new generation Edwards Sapien 3 Ultra. Even if bulkier, the presence of the new PET outer-skirt of the S-Ultra could raise the stability of the prosthesis making possible a "higher" positioning. Doing so major conduction disorders could be avoided because the valve can be implanted far from the structures of the conduction system.

**P5****MINIMALIST APPROACH TO TRANSAXILLARY TAVI: A SINGLE CENTER EXPERIENCE**

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**Introduzione.** La TAVI trans-ascellare rappresenta una valida alternativa all'approccio trans-femorale in presenza di severa arteriopatia obliterante agli arti inferiori. Originariamente l'accesso veniva ottenuto con isolamento chirurgico in anestesia totale. Ma l'obiettivo principale dell'avanzamento della tecnica e dei materiali è stato quello di ridurre le complicanze e di rendere tale procedura sempre più minimalista. Questo vale anche per l'accesso trans-ascellare per il quale un approccio totalmente percutaneo è ormai fattibile.

**Metodi.** Riportiamo la nostra casistica di TAVI trans-ascellare con tecnica totalmente percutanea. Tra luglio 2019 e maggio 2021, un totale di 13 pazienti (13/233) con stenosi aortica severa ad alto rischio sono stati sottoposti a TAVI trans-ascellare percutanea presso il nostro centro. È stato utilizzato un protocollo di analisi TC dedicato per tale accesso e valutati parametri dimensionali e qualitativi, compreso l'indice di tortuosità (IT), la distanza sito di accesso-piano valvolare, eventuali kinking e l'angolazione di entrata dell'arteria succlavia nell'arco aortico. In tutti i casi è stato utilizzata l'arteria femorale come accesso ancillare con duplice obiettivo: protezione dell'accesso principale mediante posizionamento di guida 0,018" e posizionamento di Pigtail in aorta ascendente. In arteria radiale sinistra è stata posizionata in 10 casi una cannula 18 Gauge, in 3 casi si è preferito creare un circuito femoro-radiale con guida 0,018". È stato utilizzato efficacemente il sistema di protezione embolica cerebrale Boston Sentinel. L'accesso ascellare sinistro è stato ottenuto mediante puntura eco-guidata; sono stati sempre predisposti 2 Proglide in preimpianto secondo la tecnica raccomandata. L'emostasi è stata ottenuta con la tecnica "dry-closure" avanzando un pallone da periferico 1:1 in arteria ascellare e gonfiato a basse atmosfere.

**Risultati.** Queste le caratteristiche salienti della popolazione: età media 84 anni (79,5-74,5), 10/13 uomini, BMI 23,9 kg/m<sup>2</sup>, FE 52,5% (39,7%-58,7%), Euroscore II 7 (5,6-20,6), STS-PROM 6 (3-7,93), tutti in classe

NYHA III-IV. Il diametro medio dell'arteria ascellare era  $7,4 \pm 1,5$ , il SAR (sheath to artery ratio) 1,68; l'indice di tortuosità 1,41; in soli 2 casi erano presenti calcificazioni posteriori in prossimità del sito di puntura mentre in 5 casi le calcificazioni erano moderate nel tratto prossimale dell'arteria succlavia ed in 1 caso severo tale da richiedere una PTA preventiva. Sono state impiantate prevalentemente protesi Edwards Sapien3/Ultra (10/13), 2 Medtronic Evolut Pro e 1 Abbott Portico. Il successo procedurale è stato del 100% (VARC3); non è stata necessaria alcuna conversione chirurgica; non si sono osservati leak moderati, in 2 casi leak lievi e in 11 casi assenza di leak. Non si sono verificate complicanze vascolari maggiori, sanguinamenti maggiori né lesioni del plesso brachiale; mentre si è osservata 1 complicanza vascolare minore dovuta al fallimento del sistema di emostasi che ha richiesto l'impianto di uno stent ricoperto con successiva trombosi dell'arteria brachiale risolta efficacemente con trombectomia reolitica (Angiojet 4 Fr) in assenza di reliquati funzionali. All'esplorazione del sistema di protezione cerebrale è stato raccolto in tutti i casi materiale embolico e in 7 casi le dimensioni erano >1000 micron. Si è verificato un evento cerebrale ischemico per-procedurale dovuto ad instabilità emodinamica durante l'estubazione, con disfunzione neurologica di grado moderato e completo recupero funzionale alla dimissione. La durata media della degenza è stata di 7 (7,5-10,7) giorni con dimissione diretta a domicilio. Al follow-up a 30 giorni la sopravvivenza è stata del 100%, non si sono verificate nuove ospedalizzazioni né eventi maggiori.

**Conclusioni.** Nella nostra esperienza l'approccio trans-ascellare totalmente percutaneo rappresenta l'accesso alternativo di riferimento in quanto fattibile e relativamente sicuro, considerando l'elevato profilo di rischio di tali pazienti per i quali una strategia mininvasiva è stata giudicata più appropriata.

**P6****STENT-ASSISTED COIL EMBOLIZATION FOR A GIANT EMBOLIC AORTIC PSEUDOANEURYSM**

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**Introduction.** Pseudo-aneurysm of the ascending aorta is an unusual and potentially fatal complication of cardiovascular surgery. The redo surgery is the treatment of choice, with significant perioperative morbidity and mortality rates. In this case report we propose a new technique that has allowed to obtain a perfect sealing of the pseudoaneurysm in a completely percutaneous way.

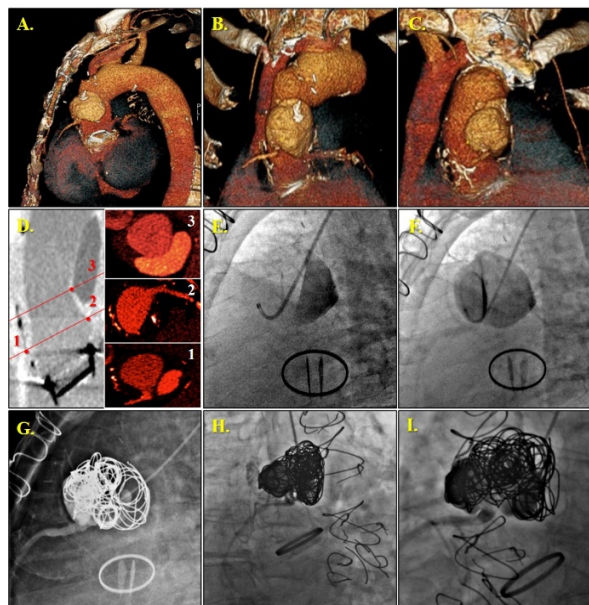
**Methods.** A 67-year-old male patient was hospitalized due to recurrent cerebrovascular events consisting of transient hemiplegia. He had a past medical history of arterial hypertension, chronic renal failure (GFR 45ml/min), insulin-dependent diabetes mellitus and bicuspid aortic valve disease. He underwent an initial surgical aortic valve replacement aged 27 years, followed by redo-surgery aged 57 with a Bentall procedure due to an aortic root aneurysm. He was established on long-term aspirin and warfarin therapy. CT head ruled out any acute or chronic hemorrhage and a trans-esophageal echocardiogram excluded potential cardio-embolic sources with the left atrial appendage being free of thrombus. Cardiac CT showed a giant pseudoaneurysm (3x4x5cm), which was in close proximity to the origin of the reimplanted right coronary artery arising between the native aorta and the Bentall vascular prosthesis. Furthermore, the CT demonstrated two sacs within the pseudo-aneurysm, in one of which sluggish flow was more evident). Diagnostic coronary angiography demonstrated a communication between the aortic pseudo-aneurysm and the roof of the origin of the right coronary artery (RCA). Given his previous multiple surgical procedures, a percutaneous interventional approach was proposed to seal the embolic source and prevent subsequent aortic rupture. The choice to use the coils compared to other devices depended on the priority of excluding the emboligenic source and on the proximity of the origin of the right coronary artery to the pseudoaneurysm. Initially the ostial RCA was stented with a 3.5 x 12 mm Supraflex stent, Sahajanand Medical Technologies Pvt Ltd. This was done in order to limit the communication with the pseudoaneurysm, avoid extrinsic compression of the RCA and to reduce the potential risk of embolization or migration of any subsequently implanted coils. Then, after selective catheterization with a 6 Fr mammary catheter, the separate sacs of the aneurysm were each sealed using numerous Interlock™ -18 Detachable Coils (Boston Scientific Corporation). A total of 14 coils were deployed, each of different lengths respectively with an excellent final angiographic result and patency of the right coronary artery.

**Results.** Six-month follow-up angiography and aortic CT confirmed the favourable clinical and radiological results with the pseudo-aneurysm dimensionally unchanged; the patient remained free from any cardiac or cerebrovascular events and was established on long-term warfarin therapy.

**Conclusions.** In patients presenting with recurrent cerebrovascular events who have undergone prior cardiovascular surgery, detailed multidisciplinary assessment and imaging is essential to identify potential



source of emboli. In our case, a high surgical risk patient was managed using a combined "stented-assisted coil embolization" strategy, which sealed the aortic pseudo-aneurysm and at the same time minimized the potential risk of rupture and future cardio-embolic events. Modern interventional techniques, together with imaging and a multidisciplinary clinical approach, allow us to diagnose and treat more and more complex cases with less invasive/surgical procedures.



## P7

### IMPACT OF RIGHT VENTRICULAR PACING IN PATIENTS WITH TAVI UNDERGOING PERMANENT PACEMAKER IMPLANTATION. THE PACE-TAVI INTERNATIONAL MULTICENTER STUDY

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**Background.** Permanent pacemaker implantation after Transcatheter Aortic Valve Implantation (TAVI) has emerged as a relevant issue, being more frequent than after surgery and the progressive shift towards low-risk patients stressed the importance to reduce the risk of complications that could impact patient's long-term prognosis. Long-term right ventricular pacing has been related to an increased risk of electromechanical asynchrony, negative left-ventricular remodeling, atrial fibrillation and heart failure, but there is a lack of evidence regarding the prognostic impact on TAVI patients. The aim of this international multicenter study is to assess the impact of right ventricular pacing on prognosis of TAVI patients undergone pacemaker implantation after the procedure due to conduction disorders.

**Methods.** All the consecutive patients with severe aortic stenosis treated with TAVI and subsequently underwent pacemaker implantation in each participating center were enrolled. Patients were divided into two subgroups according to the percentage of ventricular pacing (VP cut-off: 40%) at pacemaker interrogation. The primary endpoint was the composite of cardiovascular mortality and hospitalization for heart failure in subgroups based on the percentage of ventricular stimulation. All cause and cardiovascular mortality in the subgroups according to the percentage of ventricular pacing were the secondary endpoints.

**Results.** In total, 427 patients were enrolled, 153 patients with VP <40% and 274 with a with VP ≥40%. Patients with VP ≥40% were older (81,16 ± 6,4 years vs 80,51 ± 6,8 years), with higher NYHA class, a lower EF (55,26 ± 12,2 vs 57,99 ± 11,3 p=0.03), an increased end diastolic ventricular volume (112,11 ± 47,6 vs 96,60 ± 40,4 p=0.005) and diameter (48,89 ± 9,7 vs 45,84 ± 7,5 p=0.01). A higher incidence of moderate post-procedural paravalvular leak was observed in patients with VP ≥40% (37,5% vs 26,85% p=0.03). Ventricular pacing ≥40% was associated with a higher incidence of the composite primary endpoint of CV mortality and HF hospitalization (p at log rank test=0.006, adjusted HR 2.41; 95% CI 1.03-5.6; p=0,04). Patients with ventricular pacing ≥40% had also a higher risk of all-cause (p at log rank test =0.03, adjusted HR=1.57; 95% CI 1.03-2.38; p=0.03) and cardiovascular (p at log rank test =0.008, adjusted HR 3.77; CI 1.32-10.78; p=0.006) mortality compared to patients with a VP <40%.

**Conclusions.** TAVI patients underwent permanent pacemaker implantation after the procedure due to conduction disorders and with a VP ≥40% at follow up are at increased risk of cardiovascular death and HF hospitalizations and of all-cause mortality compared to patients with a VP <40%. It is mandatory to reduce the percentage of ventricular pacing at follow up when possible or consider left ventricular branch pacing and biventricular pacing in TAVI patients.

## P8

### CHANGES IN CLINICAL PRACTICE FOR TRANSCATHETER AORTIC VALVE IMPLANTATION DURING THE COVID-19 PANDEMIC: A SINGLE CENTER EXPERIENCE

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**Introduction.** The COVID-19 pandemic deeply affected healthcare systems activity all over the world. High request of intensive care and non-intensive in-hospital care for patients affected by COVID-19, brought to a reduced capability to provide healthcare to patients affected by a wide spectrum of disease. Especially during the first lockdown, beds availability in cardiovascular units was markedly reduced, and subjects affected by cardiovascular problems, including aortic stenosis, had less chances to be admitted and undergo elective interventional procedures. We present a single-center experience comparing TAVI procedures in number and features before and after the COVID-19 pandemic. Our purpose is to highlight how our activity was affected after the beginning of the first lockdown in March 9<sup>th</sup> 2020 and how patients features and clinical presentation changed in the same period.

**Methods.** Clinical data about consecutive patients who underwent TAVI from January 1<sup>st</sup> 2019 to March 8<sup>th</sup> 2020 and from March 9<sup>th</sup> 2020 to April 30<sup>th</sup> 2021 were collected. The database included clinical data of the patients undergoing TAVI, clinical outcomes and type of admission when TAVI was performed (elective admission vs Emergency Room (ER) admission). Moreover, for patients admitted in the ER, the reason for admission was included in the database.

**Results.** The comprehensive number of TAVI in the pre-COVID era from January 1<sup>st</sup> 2019 to March 8<sup>th</sup> 2020 was 153. From March 9<sup>th</sup> 2020 to April 30<sup>th</sup> 2021 the whole number of TAVI was 130. Despite a slightly higher proportion, no statistically significant difference was noted in the amount of patients presenting in the ER among TAVI candidates (15.7% vs 22.3%). Overall AHF occurrence in TAVI candidates was significantly higher during COVID-19 pandemic (8.5% vs 16.9%, p = 0.03). Other causes of admission in the ER in TAVI candidates included acute coronary syndrome (ACS), syncope and bradyarrhythmia. We found a statistically significant difference in STS (4.3±2.5 vs 5.4±4.1, CI 95%, p=0.039) and EuroSCORE II (5.7±5.3 vs 7.5±5.6, CI 95%, p=0.026). No significant difference was found in the rest of clinical features of patients undergoing TAVI except for eGFR (Table 1). Moreover, there was no statistically significant difference between groups for procedural mortality, ischemic events, bleedings, vascular complications and PMK implantation rate. A trend in reduction of in-hospital stay was also noted even though this difference was not statistically significant (Table 2).

**Table 1.** Clinical features of patients undergoing TAVI during the COVID-19 pandemic.

	Pre-COVID-19	COVID-19	p-value
Total TAVI	153	130	-
Age	81.6 ± 8.6	82.1 ± 4.9	n.s.
Female	80 (52.3)	76.8(59.1)	n.s.
STS	4.3 ± 2.5	5.4 ± 4.1	0.039
EuroSCORE II	5.7 ± 5.3	7.5 ± 5.6	0.026
EF	54.9 ± 10.7	56.2 ± 9.2	n.s.
eGFR	53.1 ± 23.2	64.6 ± 25.2	<0.001
ER admission n (%)	24 (15.7)	29 (22.3)	n.s.
AHF n (%)	13 (8.5)	22 (16.9)	0.03
ACS n (%)	6 (3.9)	3 (2.3)	n.s.
Syncope n (%)	4 (1.3)	4 (3.1)	n.s.
Other n (%)	1 (0.6)	0 (0.0)	n.s.

**Table 2.** Procedural and clinical outcomes in patients undergoing TAVI during the COVID-19 pandemic.

	Pre-COVID-19	COVID-19	p-value
Hospital stay (days)	10.4 ± 8.2	8.9 ± 5.1	n.s.
All-cause mortality n (%)	1 (0.6)	0 (0.0)	n.s.
Disabling stroke n (%)	1 (0.6)	0 (0.0)	n.s.
Non-disabling stroke n (%)	1 (0.6)	1 (0.8)	n.s.
LT bleeding n (%)	2 (1.3)	0 (0.0)	n.s.
Major bleeding n (%)	4 (2.6)	2 (1.5)	n.s.
Minor bleeding n (%)	7 (4.6)	6 (4.6)	n.s.
Access-related bleeding n (%)	0 (0.0)	2 (1.5)	n.s.
Major vascular complications n (%)	4 (2.6)	3 (2.3)	n.s.
Access-related major vascular complications n (%)	0 (0.0)	1 (0.8)	n.s.
Minor vascular complications n (%)	4 (2.6)	3 (2.3)	n.s.
Access-related minor vascular complications n (%)	2 (1.3)	4 (3.1)	n.s.
Acute kidney injury (AKI 3) n (%)	3 (1.9)	1 (0.8)	n.s.
PMK implantation	33 (21.6)	28 (21.5)	n.s.

**Conclusions.** The COVID-19 pandemic, significantly reduced the comprehensive number of TAVI in our center. The reduction was mostly during the first lockdown, during which providing healthcare for non-COVID patients was much harder. The amount of patients admitted in the ER and undergoing TAVI in the same admission was not significantly increased during the COVID-19 pandemic. However, AHF was the most frequent cause of admission in the ER and its overall occurrence in TAVI candidates was significantly higher during the COVID-19 pandemic. Fear for COVID-19 infection might have been a reason for patients to wait for unbearable symptoms and present with acute heart failure. Despite the proportion of patients undergoing urgent TAVI was increased and the pre-operative risk scores were higher, this approach didn't affect procedural outcomes.

## P9

### VOLUME OF CONTRAST TO CREATININE CLEARANCE RATIO PREDICTS EARLY MORTALITY AND AKI AFTER TAVI

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**Introduction.** The volume of contrast to creatinine clearance ratio (CV/CrCl) is a useful indicator of the risk of acute kidney injury (AKI) in patients undergoing percutaneous interventional procedures. Association between CV/CrCl and adverse outcome after transcatheter aortic valve implantation (TAVI) was suggested but it is not well established.

**Methods.** A large retrospective multicenter cohort of 1381 patients treated with TAVI was analyzed to assess the association between CV/CrCl and the risk of AKI and mortality at 90 days and one year after TAVI. Patients receiving renal replacement therapy at the time of TAVI were excluded.

**Results.** CV/CrCl was associated with the risk of AKI and 90 days mortality after TAVI after adjustment for age, sex, diabetes, baseline left ventricular function, baseline chronic kidney disease (CKD), previous myocardial infarction and peripheral vascular disease (HR 1.16, 95%CI 1.09-1.22, p<0.0001). Importantly, CV/CrCl was associated with the adverse outcome independently from the presence of baseline CKD (p for interaction=0.22). CV/CrCl was independently associated with the individual components of the composite primary outcome including AKI (OR 1.18, 95%CI 1.08-1.28, p<0.0001) and 90 days mortality (HR 1.90, 95%CI 1.01-3.60, p=0.047) after TAVI. AKI (HR 1.94, 95% CI 1.21-3.11, p=0.006) but not CV/CrCl was associated with the risk of 1-year mortality after TAVI.

**Conclusion.** CV/CrCl is associated with excess renal damage and early mortality after TAVI. Procedural strategies to minimize the CV/CrCl during TAVI may improve early clinical outcomes in patients undergoing TAVI.

## P10

### INCOMPLETE FUNCTIONAL REVASCULARIZATION IS ASSOCIATED WITH ADVERSE CLINICAL OUTCOMES AFTER TAVI

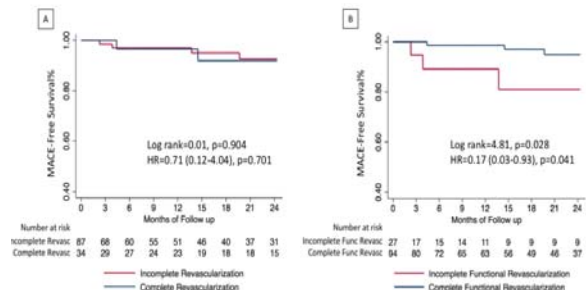
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**Introduction.** Whether incomplete functional revascularization has an impact on the clinical outcome of patients treated with transcatheter aortic valve implantation (TAVI) is still unknown. We aim to assess the prognostic value of residual functional Syntax score (rFSS) in a cohort of patients undergoing TAVI.

**Methods.** Patients with severe aortic stenosis and coronary artery disease (CAD) undergoing fractional flow reserve (FFR)-guided revascularization at University of Verona Hospital and John Radcliffe Hospital were analyzed. The primary endpoint of the study was the composite of cardiac death, myocardial infarction and revascularization at 2-year follow up after TAVI.

**Results.** One-hundred-twenty-one patients (226 lesions) were included. Median Syntax score (SS) and functional Syntax score (FSS) at baseline were 7 and 0. After revascularization or deferral according to FFR, residual SS (rSS) and rFSS were 5 and 0 respectively. At Cox regression analysis, angiographic incomplete revascularization (rSS=0) was not associated with the primary endpoint (HR 0.90, p=0.901), whereas functional incomplete revascularization was associated with better event-free survival at follow up (HR 5.03, p=0.048), even after adjusting for multiple confounders.

**Conclusion.** rFSS is associated with the clinical outcome at 2-year follow-up after TAVI. Complete functional revascularization may be regarded as a treatment goal for patients with CAD undergoing TAVI. Further studies are warranted to confirm our hypothesis.



**Figure.** Survival analysis of patients stratified according to complete vs incomplete revascularization assessed by means of anatomy (A) or physiology (B).

## P11

### PROTOCOLLO INTERAZIENDALE PER L'ESECUZIONE DI PROCEDURE TAVI IN UN CENTRO SPROVVISTO DI CARDIOCHIRURGIA. EVIDENZE DURANTE LA PANDEMIA COVID-19

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**Premessa.** Nell'ottica di fornire ai pazienti con stenosi aortica severa a rischio chirurgico elevato intermedio il miglior trattamento mediante procedura di TAVI, da circa 3 anni è attivo un protocollo di convenzione interaziendale tra la Cardiologia UTIC ed Emodinamica dell'AORN A. Cardarelli, centro sprovvisto di cardiocirurgia, ed il Laboratorio di Emodinamica dell'UOS di Angiologia del DAI Emergenze Cardiovascolari, Medicina Clinica e dell'Invecchiamento dell'AOU Federico II. Tale convenzione prevede l'effettuazione di procedure di TAVI per i pazienti dell'AORN Cardarelli mediante trasferimento in ambulanza rianimatoria presso l'emodinamica della Federico II con successivo rientro presso la struttura di provenienza dopo l'esecuzione della procedura interventistica sotto stretta sorveglianza medico infermieristica dell'equipe dell'AORN Cardarelli.

**Risultati.** Dall'avvio della convenzione nel fine aprile del 2018 a febbraio 2020 sono stati trattati con tale protocollo 36 pazienti con una età media di 81,1, il 72,2% rappresentato da sesso femminile. La casistica dal 2018 ad inizio 2020 mostrava un trend in netto aumento dei casi effettuati con un raddoppio dal 2018 al 2019. Il trend atteso nel 2020 era un incremento ulteriore, visti i numeri dopo il consolidamento del protocollo nella nostra realtà ospedaliera. Tuttavia la pandemia COVID 19 ha di fatto bruscamente rallentato la nostra attività TAVI. Nel periodo marzo 2020-maggio 2021 sono stati trattati 11 pazienti con età media 78,5 anni (sesso femminile 27,3%). Nell'anno di pandemia si è notato un peggioramento del quadro clinico di presentazione (Classe NYHA 4 nel 45,5% vs 24% dei primi anni) con quadri ecocardiografici più complessi nell'ultimo anno rispetto ai precedenti (FE media 42% vs 53% e gradiente aortico medio 49,2 vs 46,4). Tutti i pazienti sono stati dimessi al domicilio con una media di ricovero di circa 6 giorni (media di permanenza in UTIC 2,5 giorni) nel periodo pre-COVID, mentre si è riscontrato un netto aumento dei tempi di degenza durante la pandemia sia per i quadri clinici più complessi che per le procedure organizzative rese più difficoltose dal COVID. Tali difficoltà hanno incrementato in questo ultimo anno il tempo di degenza portandolo a circa 10 giorni (media degenza UTIC 4,2 giorni). Ulteriore evidenza delle difficoltà riscontrate è stata quella dei rifiuti incontrati da parte dei pazienti e familiari ad intraprendere il percorso TAVI durante la pandemia. Mentre negli anni precedenti il rifiuto alla procedura era assolutamente sporadico nell'ultimo anno abbiamo riscontrato su 11 pazienti trattati altri 5 pazienti che hanno rifiutato di sottoporsi al percorso TAVI preferendo la dimissione volontaria al domicilio motivandola con il timore del contagio ospedaliero, pur essendo presente nel nostro Ospedale percorsi nettamente separati tra i pazienti COVID e non.

**Conclusioni.** I risultati nei primi due anni di esperienza nel protocollo TAVI in questione evidenziano la fattibilità e la sicurezza di questa strategia nata al fine di estendere le procedure di TAVI anche nei centri

non dotati di cardiocirurgia. L'anno di pandemia COVID-19 ha purtroppo ridotto nettamente i casi trattati relegandoli di fatto ai pazienti più severi e complessi come dimostrato dai quadri clinici di presentazione e dalla maggiore durata dei tempi di ricovero.

## P12

### INITIAL EXPERIENCE OF A SINGLE CENTER JUST STARTING "ZERO CONTRAST" TAVI PROCEDURES

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**Introduction.** Acute kidney injury (AKI), after TAVI procedures, has been shown to be an independent predictor of worse outcomes; furthermore, even in most uneventful cases, renal impairment often leads to prolonged hospitalization, thus increasing the overall costs of procedures already considered very expensive. Main causes leading to AKI have been commonly found in contrast perioperative utilization, despite renal protection pre-treatment, and low cardiac output during or after the interventional procedure.

**Methods.** Since last January we started to avoid dye injection during peripheral vessel preparation, with a complete exclusion of contrast dye by using CO2 Angiodroid Injector, thus significantly reducing the amount of contrast previously used. This first step allowed a significant reduction of Creatinine raise after TAVI procedures. In patients with extremely impaired renal function, and extremely low glomerular filtration (<30 ml), we reckoned very high the risk of dialysis, which could severely affect the final outcome in old, sick patients referred for TAVI. In the last two months, we started implanting self-expanding percutaneous prosthetic valves by monitoring all the implant procedure with transesophageal echocardiography. Preoperative assessment considered "blank" contrast free CT scan. Five patients have been so far successfully treated with such technique, two of which treated with valve-in valve TAVI, certainly more favourable to determine the correct new valve position. One patient was preliminarily addressed to surgical femoral artery access due to extremely calcified peripheral vessels.

#### Results.

	Mean values
Age, years	83
Creatinine, mg/dl	1.8
GFR, ml/min/1.73 m <sup>2</sup>	30
Procedure duration, h	2.30
Fluoroscopy time, min	22
ICU stay, h	24
Overall hospital stay, days	5
Major complications	1 episode of TIA

**Conclusions.** AKI is a severe complication of interventional procedures and it's an independent predictor of worse prognosis. Despite renal protection treatment, the use of contrast often causes Renal impairment, worse when initial kidney conditions are already considered below normality. Beyond adequate hemodynamic stable conditions, the reduction or abolition of contrast dye has shown strict correlation with less AKI events. We have found noteworthy improvements soon after vascular access visualization with CO<sub>2</sub> instead of contrast. Patients with extremely compromised renal function found a further benefit as soon as a "zero contrast" strategy to deploy self expanding percutaneous aortic valves has been started in our Center. Transesophageal valve deployment monitoring is a feasible and safe opportunity, allowing the correct positioning and furthermore allowing immediate control of possible Anterior Mitral Leaflet and prosthesis unfavourable interaction.

## P13

### CEREBRAL EMBOLIC PROTECTION DURING TAVI: A SINGLE CENTER EXPERIENCE IN CONSECUTIVE PATIENTS

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**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 terms of procedural times, deployment success rate, and early clinical outcomes.

**Methods.** A total of 338 consecutive patients who underwent TAVI with Sentinel cerebral embolic protection were evaluated between January 2018 and February 2021. We analyzed device deployment technical success, size and amount of captured debris and periprocedural overt central nervous system injury, according to VARC-3 criteria.

**Results.** Between January 2018 and February 2021, 338 consecutive patients, mean age 82.6 years, mean STS score 5.2% underwent to TAVI with systematic cerebral protection with Boston Sentinel cerebral embolic protection device (CEPD). The device deployment was successful in 333 cases (98.5%). In 15 cases (4.6%) the delivery system was damaged by sustained manipulation and a second device was needed and successfully deployed due to severe tortuosity and calcification of brachiocephalic trunk; 11 aborted cases happened during first learning curve. Two patients received 2 devices from both radial arteries, having an arteria lusoria. No additional contrast dye was needed to guide protection device implantation. Mean added procedural time (time from right radial artery puncture to dual filter removal) and filter implantation time were 5.37 minutes and 4.07 minutes, respectively. In 95 patients (26%) CEPD implantation required more than 2 minutes. A prosthesis was implanted in all patients: 123 Evolut R/Pro, 149 Sapien 3/Ultra, 66 Accurate Neo. Macroscopic and discernible debris were harvested in 319/333 cases (95.8%). Patients receiving Evolute R/Pro presented with a greater number and size (>2000 micron) of particles captured (49 vs 22 Sapien 3 vs 10 Accurate Neo, p=0.01). There were 3 periprocedural overt CNS injury (0.9%). One non-disabling stroke occurred in the unprotected left parieto-occipital brain region and another one in the protected left fronto-insular region. The third CNS injury happened because of severe haemodynamic turbulence at the end of procedure. We didn't observe device-related complications.

**Conclusions.** Systematic cerebral protection during TAVI is safe, does not affect dramatically procedural times nor requires additional contrast dye injection, and is effective in preventing cerebral embolization.

## P14

### CLINICAL COMPARISON OF A NOVEL BALLOON-EXPANDABLE VERSUS A SELF-EXPANDABLE TRANS-CATHETER HEART VALVE FOR THE TREATMENT OF PATIENTS WITH NATIVE SEVERE AORTIC STENOSIS

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**Background.** Trans-catheter aortic valve implantation (TAVI) has emerged as established treatment option in patients with symptomatic severe aortic stenosis (AS). Technical developments in valve design have addressed previous limitations such as suboptimal deployment, conduction disturbances, and paravalvular leakage (PVL). However, there are only limited data available for the comparison of newer generation self-expandable valve (SEV) versus balloon-expandable valve (BEV).

**Purpose.** To compare clinical outcomes and the rate of paravalvular leak (PVL) and permanent pacemaker implantation (PPI) in patients undergoing TAVI respectively with SEV versus a novel BEV (MyVal, Meril Life Sciences Pvt. Ltd., India) in a single center.

**Methods.** A single center, prospective, cohort analysis was performed in 146 consecutive patients undergoing TAVI from September 2019 to October 2020 for severe symptomatic AS treated with either the novel BEV MyVal (n=38) or the SEV CoreValve Evolut R (ER) bioprosthesis (n=108). The primary endpoint of this analysis was the presence of PVL, stroke rate and PPI at 30 days from discharge, including the periprocedural phase.

**Results.** Among 146 included patients (mean age 82±5.1 years, 49% male; mean STS predicted risk of mortality score, 4.2±2.6%), clinical follow-up information was available for 144 (98.6%) patients. Within 30 days, moderate-severe PVL was significantly higher in patients treated with ER SEV vs the MyVal BEV (ER 35% vs MyVal 14% respectively, 95% CI, 4.4233% to 33.1380%; p=0.01), while stroke rate was significantly lower in the MyVal arm (ER 15% vs MyVal 3%, 95% CI, -0.3522% to 20.2887%; p=0.05). However, no significant difference was observed when comparing post-procedural vascular complications (ER 21% vs MyVal 22%, 95% CI, -15.7221% to 14.2262%; p=0.89) and in terms of 30-day rates new PPI (ER 11% vs. 13% MyVal BEV, CI 95% -8.3489% to 16.8715%; p = 0.7).

**Conclusion.** In patients with severe symptomatic AS undergoing TAVI the novel MyVal BEV provided a comparable performance compared to the well-known ER SEV and it was associated with a lower rate of stroke and moderate-to-severe PVL within 30 days after the procedure. However, no significance difference was observed in terms of PPI in the two arms. These findings, although preliminary, may provide clinical evidence that could guide appropriate clinical management and proper patient selection for patients with severe symptomatic AS.



**P15****TEMPORAL TRENDS DIFFERENCES IN TREATMENT AND OUTCOMES FOLLOWING TAVI IN A HIGH-VOLUME ITALIAN CENTER**

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**Introduction.** In the last decade, the rapid spread of transcatheter aortic valve implantation (TAVI) for the treatment of severe aortic stenosis (AS) has led to a gradually increasing use of TAVI procedures also in patients potentially eligible for aortic valve replacement (AVR). This study aims to determine the temporal trends differences in treatment and outcomes following TAVI in a high-volume Italian center.

**Methods.** A total of 1993 patients who underwent TAVI enrolled in REPLACE registry between June 2007 and April 2021 were compared. The REPLACE (Registry of Percutaneous Aortic Valve Replacement) is a spontaneous registry created to monitor the institutional procedural, acute, and long-term outcomes of TAVI.

**Results.** The mean age was  $80.9 \pm 5.5$  years and STS-mortality score was  $4.5\% \pm 3.2\%$ . Most of the patients were on NYHA class III or IV before the procedure (73.7%) and trans femoral access was realized in the 96.5% of the patients. With the time trends analysis estimated by the Mann-Kendall test, the rate of device success, paravalvular regurgitation more-than-mild, all-cause death, cardiovascular death, major stroke, definitive pacemaker implantation, major and life-threatening bleeding, and hospital length of stay are improved in patients treated more recently.

**Conclusion.** The time trend analysis of this Italian TAVI registry showed an increased volume of the TAVI procedure, a change in the patients' clinical profile, and a significant improvement in in-hospital and mid-term clinical outcomes during the last 13 years.

### Cardiac/coronary physiology, hemodynamics and circulation

**P16****IMPACT OF GENDER IN THE FUNCTIONAL ASSESSMENT OF INTERMEDIATE CORONARY LESIONS BY INSTANTANEOUS WAVE-FREE RATIO**

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Gender differences in coronary physiology and in the pathogenesis of coronary artery disease (CAD) have been previously described. Contrasting data have been reported, so far, on the impact of gender in the assessment of the functional significance of intermediate coronary stenoses by fractional flow reserve (FFR) or instantaneous wave-free ratio (iFR). The present study aimed at assessing the gender differences in the results of iFR in a cohort of patients undergoing coronary angiography.

**Methods.** We included patients undergoing coronary angiography and functional assessment of intermediate (40 to 70%) coronary lesions in 2 centers. iFR measurement was performed by pressure-recording guidewire and automatically calculated at the core laboratory using the manufacturers' dedicated software. Quantitative parameters of the coronary lesions were calculated by an automatic edge-detection system. Minimal luminal diameter (MLD), reference diameter (RD), percent diameter stenosis, and length of the lesion were measured. Positive iFR was considered for values  $<0.90$ .

**Results.** We included 325 patients undergoing coronary angiography and iFR evaluation of 371 intermediate coronary stenoses, of whom 20.6% were women. Females were older, displayed lower body weight and hemoglobin, lower rate of active smoking ( $p<0.001$ ) and previous PCI ( $p=0.04$ ), lower platelet count ( $p=0.001$ ) and creatinine ( $p=0.02$ ). Systolic blood pressure and heart rate at admission were more elevated in women ( $p=0.001$  and  $p=0.05$ , respectively). At angiography, multivessel coronary artery disease was more uncommon ( $p=0.001$ ) and proximal lesions were more frequently assessed by iFR ( $p=0.04$ ). Mean values of iFR did not differ with to gender and neither the percentage of positive iFR ( $19.1\%$  vs  $18.8\%$ ,  $p=0.99$ , adjusted OR [95%CI] =  $0.51$  [ $0.18$ - $1.48$ ],  $p=0.22$ ).

**Conclusion.** Among patients undergoing functional assessment of intermediate coronary lesions by instantaneous wave-free ratio, no impact of gender was observed on the absolute values or the rate of positivity of iFR.

**P17****10-YEAR FOLLOW-UP OUTCOMES IN DIABETIC PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION: INSIGHTS FROM THE EXAMINATION EXTENDED TRIAL**

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**Introduction.** Long-term outcomes of diabetic patients suffering from ST-segment elevation myocardial infarction (STEMI) have been barely investigated. The aim of this post-hoc subanalysis of the EXAMINATION-EXTEND trial was to compare 10-year outcomes between diabetic and nondiabetic patients at the time of the index procedure.

**Methods.** The EXAMINATION-EXTEND study is a 10-year follow-up of the EXAMINATION trial, which randomly assigned 1498 patients with STEMI in a 1:1 ratio to receive either everolimus-eluting stent or bare metal stent. From the study population, 258 patients were diabetics and 1239 were nondiabetic. The primary endpoint was a patient-oriented composite endpoint (POCE) of all-cause death, any myocardial infarction (MI), or any revascularization. Secondary endpoints were a device-oriented composite endpoint (DOCE) of cardiac death, target vessel MI, or target lesion revascularization; the individual components of the combined endpoints and stent thrombosis. All results were adjusted for various potential confounders.

**Results.** At 10 years, diabetic patients showed a higher rate of POCE compared with nondiabetics ( $46.5\%$  vs  $33.0\%$ ; HR  $1.57$  [ $1.28$ - $1.93$ ];  $p=0.009$ ) mainly driven by a higher rate of MI ( $7.8\%$  vs  $5.3\%$ ; HR [ $1.48$  ( $0.89$ - $2.44$ );  $p=0.038$ ) and any revascularization ( $24.4\%$  vs  $16.6\%$ ; HR  $1.57$  [ $1.18$ - $2.08$ ];  $p=0.001$ ). No statistically significant differences were found with respect to all-cause death, DOCE and its individual components, and stent thrombosis. The landmark analysis showed a trend towards a higher rate of POCE from 0 to 5 years in diabetic patients ( $p=0.081$ ), that was significant from 5 to 10 years ( $p=0.046$ ).

**Conclusion.** Diabetic patients had worse clinical outcomes 10 years after STEMI compared with nondiabetics, mainly due to more comorbidities. From 0 to 5 years, diabetics trended toward a higher rate of POCE that was significant from 5 to 10 years.

**P18****COMPARISON OF ECMO VS ECPPELLA IN PATIENTS WITH NON POST-PERICARDIOTOMY CARDIOGENIC SHOCK: AN UPDATED META-ANALYSIS**

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**Introduction.** The impact of Impella and ECMO (ECPPELLA) in cardiogenic shock (CS) remains to be defined. The aim of this meta-analysis is to evaluate the benefit of ECPPELLA compared to VA-ECMO in patients with non post-pericardiotomy CS.

**Methods.** All studies reporting short term outcomes of ECPPELLA or VA ECMO in non post-pericardiotomy CS were included. The primary endpoint was 30-day mortality. Vascular and bleeding complications and LVAD implantation/heart transplant within 30-days were assessed as secondary outcomes.

**Results.** Of 407 studies identified, 13 observational studies (13682 patients, 13270 with ECMO and 412 with ECPPELLA) were included in this analysis. 30-day mortality was  $55.8\%$  ( $51.6$ - $59.9$ ) in the VA-ECMO group and  $58.3\%$  ( $53.5$ - $63.0$ ) in the ECPPELLA group. At meta-regression analysis

the implantation of IABP did not affect mortality in the ECMO group. The rate of major bleeding in patients on VA-ECMO and ECPella support were 21.3% (16.9-26.5) and 33.1% (25.9-41.2) respectively, while the rates of the composite outcome of LVAD implantation and heart transplantation within 30-days in patients on VA-ECMO and ECPella support were 14.4% (9.0-22.2) and 10.8%. When directly compared in 3 studies, ECPella showed a positive effect on 30-day mortality compared to ECMO (OR: 1.81: 1.039-3.159).

**Conclusions.** Our data suggest that ECPella may reduce 30-day mortality and increase left ventricle recovery, despite increased of bleeding rates.

## P19

### MINOCA: MULTICENTRIC REGISTRY OF LIGURIA REGION (MINOCA-CURE)

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**Introduzione.** Le forme di MINOCA (Myocardial Infarction with Non Obstructive Coronary Arteries) configurano circa il 5-8% degli infarti miocardici acuti e rappresentano una rilevante sfida diagnostica e terapeutica. Le evidenze sui fattori di rischio e predisponenti, e ancora sull'ottimale trattamento, sono tuttora ampiamente insufficienti. Infine, il percorso diagnostico, sebbene decisivo per guidare il corretto trattamento, risulta spesso incompleto.

**Metodi.** Abbiamo disegnato un studio osservazionale prospettivo multicentrico coinvolgente tutte le strutture di Cardiologia Ospedaliera Liguri. Obiettivi primari: 1. Studiare gli aspetti epidemiologici di MINOCA in Liguria; 2. Analizzare i percorsi diagnostici nelle varie strutture per identificare criticità strutturali od organizzative correnti. Obiettivi secondari: 1. Individuare fattori predisponenti e fattori di rischio per le varie forme di MINOCA; 2. Valutare la prognosi a breve e lungo termine delle varie forme di MINOCA; 3. Valutare l'outcome in relazione alla terapia medica. Lo studio è stato approvato dal Comitato Etico Regionale (CER Liguria) con inizio arruolamento a partire da Maggio 2021.

## P20

### SAFETY AND EFFICACY OF THE DISTAL RADIAL ARTERY APPROACH IN THE EARLY PHASE OF TRAINING: A LESSON FOR FELLOWS

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**Background.** Over the last couple of years the radial approach has become the gold standard access for coronary procedures in almost every cathlab in the world due to its well-established safety and efficacy compared to the femoral access. Recently, a new access site from the distal radial artery has gained popularity and is being increasingly used given its potential advantages. Although similar to the standard radial access, the distal radial access seems to be more technically challenging and time consuming. Further, given its novelty, randomized and/or prospective data on its safety and efficacy are still scarce. The purpose of this study is to demonstrate the efficacy of the distal radial approach by analyzing puncture success and safety in terms of radial artery patency within the first 24 hours in procedures performed by an interventional cardiology fellow in the early phases of training.

**Methods.** Fifty-seven consecutive patients (42 men, 15 women) with palpable distal radial arteries that underwent diagnostic or therapeutic coronary interventions (angiography, ventriculography, aortography or PCI) were included in our analysis. All procedures were performed using the standard puncture technique by a single interventional cardiology fellow at the beginning of his/her training. The fellow had two puncture attempts after which a trained operator would take over the procedure. The first 10 procedures were not included in the analysis as they were considered the run-in phase. Distal radial artery patency was evaluated using flow velocity measured with doppler ultrasound. Functional capacity and symptoms were evaluated through a physical exam before discharge.

**Results.** Forty-seven procedures were successfully completed using the right distal radial approach and five using the left distal radial approach, with a puncture success rate of 89.7%. Operator shift was necessary in five cases. Access site shift was necessary in five cases, three due to technical failure, and two due to severe calcifications, where puncture and guide advancement into the artery were successful but sheath insertion

was not. The alternate accesses employed were ipsilateral proximal radial artery in four cases, and the femoral artery in one case. Additionally, two cases of radial artery spasm with difficult sheath extraction were observed with no further complications. Twenty-four hours after the procedure the distal radial artery was patent in all patients, with two cases of flow demodulation. All patients were asymptomatic.

**Conclusion.** In this small prospective study the distal radial access proved to be a safe and effective alternative to the standard radial access when performed by operators without previous experience. Our findings support the incorporation of this access site in the early phases of interventional cardiology training, with the appropriate supervision.

## P21

### CORONARY ARTERY FISTULAE: ANATOMY, DIAGNOSIS AND MANAGEMENT STRATEGIES

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Coronary artery fistula (CAF) is a relatively rare anatomic abnormality of the coronary arteries representing 14% of all the anomalies of coronary arteries. Its clinical relevance focuses mainly on the mechanism of "coronary steal phenomenon", causing myocardial functional ischaemia even in the absence of stenosis, hence common symptoms are angina or effort dyspnoea. The suggested diagnostic approach is guided by the patient's symptoms and consists of a number of instrumental examinations like ECG, treadmill test, echocardiography, computed tomography scan, cardiac magnetic resonance and coronary angiography. If it is not an incidental finding, coronary angiography is required in view of the optimal therapeutic planning. Small-sized fistulae are usually asymptomatic and have an excellent prognosis if managed medically with clinical follow-up with echocardiography every 2 to 5 years. In the case of symptomatic, large-sized or giant fistulae an invasive treatment, by transcatheter approach or surgical ligation, is usually a reasonable choice, and both strategies show equivalent results at long-term follow-up. Antibiotic prophylaxis for the prevention of bacterial endocarditis is recommended in all patients with coronary artery fistulae who undergo dental, gastrointestinal or urological procedures. A life-long follow-up is always essential to ensure that the patient is not undergoing progression of disease or further cardiac complications.

## P22

### NUOVE PROSPETTIVE DELLA VALUTAZIONE FUNZIONALE CON ACIST NAVVUS

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**Introduzione.** La valutazione funzionale con guida di pressione delle stenosi coronariche angiograficamente intermedie ricopre un ruolo fondamentale nella selezione delle lesioni meritevoli di rivascularizzazione percutanea nei pazienti con sindrome coronarica cronica. Nonostante crescenti evidenze riguardo un possibile ruolo della valutazione funzionale post-PCI nel predire outcome clinici a distanza nei pazienti sottoposti ad angioplastica coronarica, questa metodica rimane ancora poco utilizzata. Possibili spiegazioni potrebbero essere la necessità di rewiring del vaso trattato, l'aumento dei tempi procedurali e della dose di mezzo di contrasto utilizzata ed il rischio di possibili complicanze durante la manipolazione delle guide coronariche. Il catetere monorail con sensore di pressione Acist Navvus, rappresenta una valida alternativa a queste problematiche in quanto non necessita di rewiring del vaso trattato utilizzando la guida workhorse utilizzata per l'esecuzione della PCI.

**Metodi.** All'interno del registro ambispettrico monocentrico PROPHET-FFR, siamo andati a valutare tutti i pazienti con sindrome coronarica cronica o acuta stabilizzata riferiti per studio coronarografico invasivo tra Gennaio 2018 e Giugno 2020, per i quali si sia resa necessaria una valutazione funzionale pre-procedurale con FFR con il catetere a pressione Acist Navvus.

**Risultati.** Ad oggi sono stati arruolati 56 pazienti, per un totale di 68 lesioni. In 40 pazienti (71%) si è ottenuto un valore funzionale significativo su almeno una lesione che ha condotto all'esecuzione di una PCI. La valutazione funzionale post-PCI è stata eseguita in 36 pazienti (66.1% del totale, 90% delle FFR positive). In 16 pazienti (29% del totale) l'FFR è risultava negativa. Per ciò che riguardava le lesioni i valori basali medi osservati sono stati: Pd/Pa 0.91 ± 0.056 (n=56), FFR 0.81 ± 0.057 (n=40), cFFR 0.84 ± 0.069 (n=49). I valori post-PCI erano: Pd/Pa 0.95 ± 0.038 (n=36), FFR 0.89 ± 0.041 (n=25), cFFR 0.90 ± 0.042 (n=28). La media del tempo di scopia utilizzato durante la singola procedura è stata di 25 minuti, mentre la dose di contrasto media usata è stata di 240 mL. Confrontando questi dati con quelli ottenuti da pazienti sottoposti a valutazione funzionale con guide di pressione tradizionali, si nota come la percentuale di pazienti sottoposti a PCI (71% vs 32%) e a FFR post-PCI sia molto superiore (66.1% vs 12%). Inoltre, la dose media di contrasto usata nei pazienti sottoposti a valutazione funzionale post-PCI con catetere Acist Navvus è risultata inferiore rispetto alle guide di pressione

tradizionali (237.8 mL vs 275.5 mL). Non ci sono invece grosse differenze per quanto riguarda il tempo di scopia (21.2 vs 24.2 minuti).

**Conclusioni.** L'utilizzo del catetere con sensore di pressione Acist Navvus appare ottimale per un utilizzo come guida funzionale alla PCI. Non solo la sua semplicità d'uso lo fanno preferire alle guide di pressione standard quando la probabilità di esecuzione di PCI appare più elevata ma la possibilità di utilizzare la guida workhorse in sede, senza perdere l'accesso al vaso o eseguire nuovamente un rewiring lo rendono particolarmente idoneo alla rivalutazione funzionale post-PCI con le conseguenti ricadute prognostiche e procedurali.

## P23

### MODELLO 3D CUORE-CORONARIE PER TEST TECNICI STENT CORONARICI

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**Introduzione.** Attualmente la valutazione degli stent viene eseguita conducendo o test su animali o utilizzando gli stent durante la normale procedura clinica su paziente. Entrambe queste metodiche presentano però delle criticità. In particolare, il punto critico è l'impossibilità di definire ed estrarre delle informazioni univoche, data la variabilità che presentano intrinsecamente sia il modello animale sia il soggetto paziente. Un approccio alternativo è dato dall'utilizzo di banchi prova, basati su phantom cardiovascolari realizzati mediante stampa 3D. Oggetto di questo lavoro è stato dunque la realizzazione di un dedicato di uno specifico banco prova per una valutazione oggettiva di una serie di stent per procedure di angioplastica coronarica.

**Metodi.** Nello studio presentato in questo abstract sono stati testati un totale di 32 dispositivi commerciali con diametri da 4 e 2.25 mm, realizzati da aziende diverse. I device sono stati testati da quattro clinici esperti. Il banco prova è stato realizzato a partire da immagini anatomiche presa da tac relative a un paziente con patologia coronarica. In particolare, le geometrie sono state segmentate con un algoritmo automatico e realizzate attraverso la tecnica di stampa 3D laser sintering per ottenere dei phantom utilizzabili nel banco prova. Il modello stampato è costituito da un ventricolo sinistro, un arco aortico e un tratto di aorta discendente con una sezione di tubo in silicone per permettere l'inserimento del catetere guida. Il piano di lavoro è stato ripreso con una telecamera. Il segnale video è stato riprodotto in real time su uno schermo posto di fronte all'operatore le immagini delle coronarie in modo da simulare il setting di una reale sala di emodinamica. Le coronarie destra e sinistra sono state realizzate in materiale deformabile trasparente in modo da riprodurre la compliance vascolare. Per permettere la visualizzazione del dispositivo durante la fase di posizionamento e deployment, il phantom è stato immerso in una miscela di acqua e glicerina. In fase di testing dei dispositivi, i seguenti parametri sono stati valutati dai clinici con un punteggio da 1 a 3: crossability, pushability, trackability, conformabilità al vaso e accesso al side branch.

**Risultati.** Il banco prova realizzato ha permesso la valutazione attiva dei parametri prestabiliti e la valutazione delle performance degli impianti. Tali punteggi sono stati poi utilizzati per la valutazione delle proprietà tecniche degli stent all'interno di una gara Regionale.

**Conclusioni.** L'evoluzione dei modelli di simulazione ha fatto un balzo in avanti trasformando modelli digitali in modelli "materiali" con l'ausilio delle stampanti 3D. Questa evoluzione ingegneristica associata all'esperienza di cardiologi interventisti renderà possibile ottimizzare le curve di apprendimento e sperimentare in anticipo le varie tecniche coronariche e di interventistica strutturale.

## DES-based PCI: devices and techniques

## P24

### EFFICACY AND SAFETY OF SHOCKWAVE INTRAVASCULAR LITHOTRIPSY IN DAILY PRACTICE: A SINGLE CENTER EXPERIENCE

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**Introduzione.** Calcified coronary lesions often cause suboptimal stent expansion, which is one of the most important predictors of adverse outcomes, such as stent thrombosis and restenosis. Traditional debulking devices prolong procedural time and require a long learning curve for operators. Shockwave intravascular lithotripsy (S-IVL; Shockwave Medical, Inc) is a recently approved technique that can be used in the treatment of heavily calcified coronary lesions. We present the real-world experience of our center with the S-IVL device.

**Methods.** Consecutive patients treated with S-IVL between February 1,

2019 and February 29, 2020 at our center were included. During this period, a total of 27 patients undergoing percutaneous coronary intervention PCI were treated with S-IVL even prior to than after stent deployment to optimize stent expansion. Indications for PCI were acute coronary syndromes (ACS) in 11 patients (40.7%) and stable angina in 16 patients (63%). We retrospectively performed quantitative coronary angiography (QCA)-based analysis for every procedure measuring basal MLD, MLD after post-dilation with NC balloon alone, MLD after S-IVL and final MLD after stent deployment and we calculated the lumen gain and the reduction of stenosis as percentage.

**Results.** We found that using S-IVL in addition to NC balloon resulted in a reduction of mean stenosis from 46.4% to 21.5% and a lumen gain from 18.5% to 24.9%. Angiographic success, defined as a residual stenosis <30% at the QCA, occurred in 88.9% of patients, and only 2 asymptomatic peri-procedural MIs, defined as increase of 5 fold in troponin level after procedure, occurred as complications.

**Conclusions.** S-IVL appears to be effective in addition to NC balloon dilation in coronary calcium cracking to optimize stent expansion and is easy to use with only few complications in relation to the complexity of PCI in this setting.

## P25

### FIRST VERSUS SECOND GENERATION DRUG-ELUTING STENT IN HEART TRANSPLANT PATIENTS WITH CARDIAC ALLOGRAFT VASCULOPATHY: A SINGLE-CENTER EXPERIENCE

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**Introduction.** Cardiac allograft vasculopathy (CAV) remains the "Achilles' heel" of successful long-term outcome after heart transplantation (HTx), and one of the leading causes of late mortality and allograft dysfunction. Percutaneous coronary intervention (PCI) has been previously considered as a palliative treatment option in this setting, for the higher rate of restenosis and the lack of a survival benefit over medical therapy. Although the use of first (I) generation drug-eluting stents (DES) was associated with a significant reduction of in-stent restenosis compared to bare-metal stents (BMS) at long-term follow-up, few data on second (II) generation DES are currently available. Our study aims to compare the efficacy and safety of PCI with I and II generation DES in patients with CAV.

**Methods.** All consecutive heart transplant patients who underwent urgent or elective PCI with I or II generation DES between 2003 and 2020 at Foundation IRCCS Policlinic San Matteo (Pavia) were enrolled. Data on timing of HTx, baseline clinical and procedural information were collected and compared between the two study groups (I and II generation DES groups). The extent of revascularization for each patient was assessed calculating the post-procedural residual SYNTAX score. The primary endpoint was a composite of MACE [any myocardial infarction, cardiovascular death and target vessel revascularization (TVR)] at 3 years. The secondary endpoint was target lesion failure (TLF) at 3 years - composite of cardiovascular death, target vessel myocardial infarction (TV-MI) and target lesion revascularization (TLR).

**Results.** A total of 90 transplant patients (113 coronary lesions) were included: 28 patients (32 lesions) were treated with I generation DES and 62 patients (81 lesions) with II generation DES. No differences between the two study groups were identified in term of number of stents per patient implanted (1.63±0.87, p=0.628), total stent length per patient (26 [25th-75th:18-44] mm, p=0.486), pre-PCI (8 [25th-75th: 5-15], p=0.286) and post-PCI residual (1.5 [25th-75th: 0-4], p=0.187) SYNTAX score. Clinical follow-up was available in 85 (94.5%) patients, with a mean follow-up time of 934.1±301.8 days (I generation DES 997.3 ± 252.5 days vs II generation DES 907.8 ± 318.3 days, p=0.111). In the whole study population, the primary and secondary endpoints occurred in 28 (33%) and 23 (27%) cases respectively, with a 3-year Kaplan-Meier estimate of freedom from MACE of 64%, and from TLF of 71%. No statistical differences between the two study arms were found (MACE log-rank test p=0.269, TLF log-rank test p=0.260). At multivariate Cox regression analysis, while treatment with II generation DES was confirmed to not predict the risk of MACE (HR 0.70, CI 0.32-1.5, p=0.368), a borderline significant higher rate of events was found in patients with a post-PCI residual SYNTAX score >8 (HR 2.37, CI 0.98-5.73, p=0.054). However, patients treated with II generation DES experienced a lower rate of TVR (3-year Kaplan-Meier estimate of freedom from TVR I generation DES 69% vs II generation DES 85%, log-rank test p=0.058, univariate Cox regression analysis HR 0.4, CI 0.13-1.07, p=0.069).

**Conclusion.** In heart transplant patients with CAV, compared with I generation DES, PCI with II generation DES did not show to reduce the risk of MACE and TLF, guaranteeing however a lower rate of TVR. In this complex clinical scenario, incomplete revascularization (defined as a residual post-PCI SYNTAX score >8) was associated with worse outcome at 3-year follow-up.



## Invasive coronary imaging

## P26

**PERCUTANEOUS CORONARY INTERVENTION FOR VULNERABLE CORONARY ATHEROSCLEROTIC PLAQUE: TWO CASE REPORTS**

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The treatment of intermediate coronary lesions (ICL) defined as angiographic stenosis between 30 and 70% represent a diagnostic and therapeutic challenge. Although revascularization based on FFR use as recommended by the guidelines is associated with reduction of major cardiovascular events, there is ever increasing evidence of revascularization based on intracoronary imaging of vulnerable coronary atherosclerotic plaque is associated with an even greater reduction in events. We present two clinical cases of percutaneous revascularization of ICL vulnerable plaques OCT-guided. The first case is a 61-year-old male, smoker, with family history of myocardial infarction, hypertensive and dyslipidemic, asymptomatic for rest and stress angina, with normal ECG and normal ejection fraction who performed a cardio CT scan for suspected CAD. At the level of the middle right coronary artery there was evidence of a long, predominantly non-calcified, eccentric hypodense mixed plaque associated with remodeling of the vessel inducing a stenosis greater than 50% (Fig. 1). The subsequent coronary angiography confirmed the presence of this plaque inducing an intermediate angiographic stenosis of 60% (Fig. 2). The subsequent OCT study showed plaque vulnerability criteria as 50  $\mu$  fibrous cap of and signs of intimal neoangiogenesis with MLA of 2.54 cm<sup>2</sup> and LAS of 67.5% (Fig. 3). It was decided to perform a PCI with an 3.0 x 28 mm ultrathin sirolimus medicated stent implantation with resorbable polymer and post-dilation to 3.5 mm successfully and without complications (Fig. 4). At six-month follow-up the patient is asymptomatic on OMT with DAPT, high-dose statin and ezetimibe.

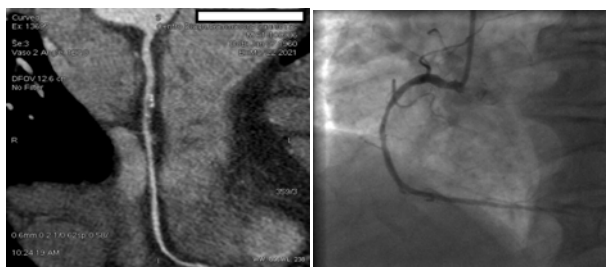


Figure 1

Figure 2

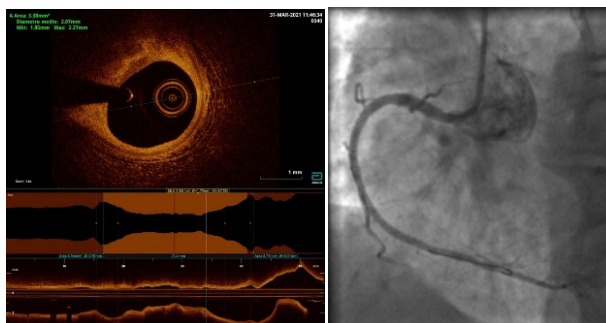


Figure 3

Figure 4

The second case is a 70-year-old male, dyslipidemic, with history of previous PCI on proximal left anterior descending artery for unstable angina 9 years ago, further procedure for very late stent thrombosis 4 years ago treated with only DEB, hospitalized for angiography control due to reappearance of exertional angina similar to previous episodes. Coronary angiography shows a good result of the previous PCI with the presence before the proximal edge of a plaque inducing an intermediate stenosis (Fig. 5). OCT study performed before and after injection of 20 micrograms of intracoronary NTG, showed a good result of the previous PCI with non-critical restenosis with MSA of 5.63 mm<sup>2</sup>. Proximal to the stent is a predominantly lipid plaque with micro-calcification in its context associated with positive vessel remodeling, a 60  $\mu$  fibrous cap, and evidence of multiple minute sub-intimal hemorrhages with LAS 50.5% and MLA 5.23 mm<sup>2</sup> associated with endothelial dysfunction (Figs. 6 and 7). It was decided to perform a PCI with an 3.0x18 mm sirolimus medicated stent implantation with resorbable polymer post-dilated to 3.5 mm. OCT control showed significant malapposition treated with further post-dilation

to 4.0 mm (Fig. 8). At one-month follow-up the patient is asymptomatic on OMT with DAPT, high-dose statin and ezetimibe.

**Conclusions.** The reported cases show how the use of intracoronary imaging, especially OCT, is needful for the study of vulnerable coronary atherosclerotic plaque and for decision of revascularization.



Figure 5

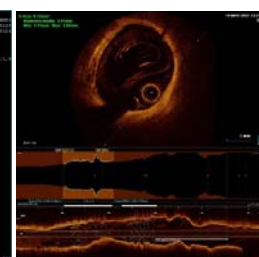


Figure 6

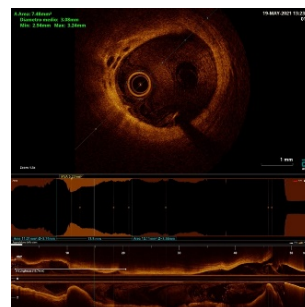


Figure 7

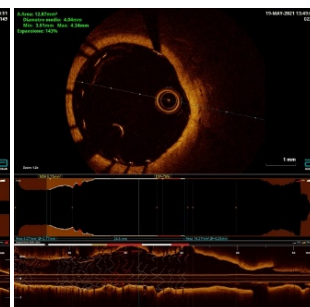


Figure 8

## P27

**TELEHEALTH EMPOWERED-MANAGEMENT OF CHRONIC CORONARY SYNDROME PATIENTS: THE SILVER LINING IN COVID-19 CLOUD?**

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**Introduction.** The COVID-19 pandemic affected the lives of millions of patients worldwide, both directly, with its insidious infection, and by means of collateral damages that severely hindered the health system. However, COVID-19 era has also become the testing ground for alternative ways to deliver healthcare avoiding in-hospital contacts, thus affirming the validity of telemedicine as a key tool to improve the patient journey. In our center, video consults have been integrated to follow chronic coronary syndrome (CCS) patients, not only preventing the risk of contagion but laying the groundwork for a shift in clinical care course.

**Methods.** Since July 2020, the Lazio Region offered to its inhabitants free of charge teleconsulting for both primary care and specialist referral. At the cardiovascular department of Fondazione Policlinico A. Gemelli IRCCS, this opportunity has been applied to optimize the CCS patient's care pathway, both replacing the in-person first visit to the clinic and to assess follow-up consult after percutaneous myocardial revascularization.

**Results.** In our experience, 110 patients have been examined with virtual visits. 37 patients (33.6%) have been referred to coronary angiography. Being CCS a context in which the transition to higher level-tests is mainly led by symptoms, these video consultations worked as well as in-hospital visits in ruling out which patients needed ischaemia testing or coronary angiography, and to probe the relative urgency criteria. Moreover, the implementation of this parallel virtual pathway for these patients allowed us to decrease the waiting times for in-person visits at our CCS clinic, with an estimated time reduction of almost 3 months.

**Conclusion.** COVID-19 accelerated the rise of telehealth to empower primary and specialty health care. The adoption of a remote pathway for chronic illness patients may also provide more opportunities for treatment of severe cases at in-person clinic that is often overcrowded. CCS seems the perfect setting for an integrated physical and virtual health system.

## P28

**SUDDEN CARDIAC ARREST IN A YOUNG FOOTBALL PLAYER DUE TO DOCUMENTED SPONTANEOUS CORONARY ARTERY DISSECTION**

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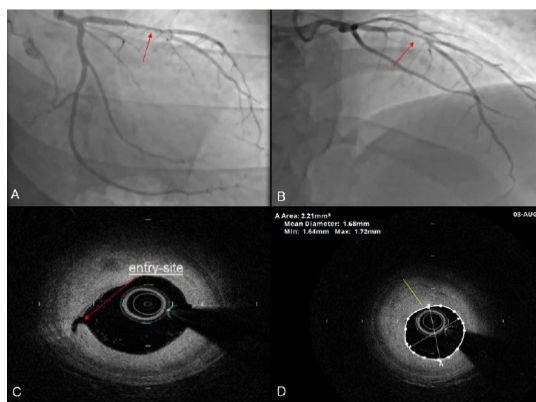
A 28-year-old male presented with sudden cardiac arrest while playing soccer. He was quickly resuscitated and transported to the closest cardiology department. He had no ECG or echocardiographic alterations. Coronary angiography (CA) showed a spontaneous coronary artery

dissection (SCAD)<sup>1</sup>, confirmed by optical coherence tomography (OCT)<sup>2,3</sup>, in the mid portion of left anterior descending artery (LAD). In light of his young age, and the lack of evidence of stenosis on angiography confirmed by an instant wave-free ratio (iFR) analysis that confirmed the absence of myocardial ischemia (value obtained 0.97), the patient was treated conservatively with aspirin, clopidogrel, a statin and a beta-blockers<sup>4</sup>.

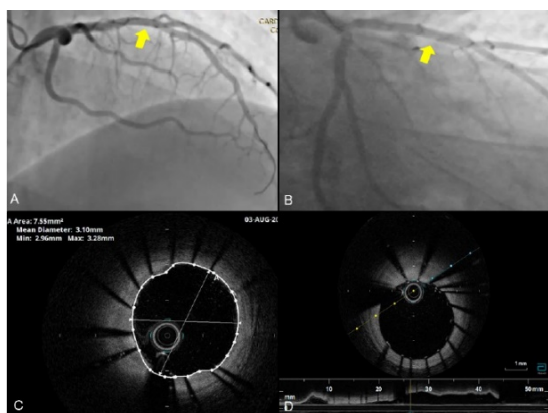
The patient refused implantation of a cardioverter-defibrillator (ICD) repeatedly. A repeat CA was performed 6-months later showing the same images of the previously documented lesion involving LAD. Therefore, the patient was indicated as unsuitable to play soccer.

At one-year from the index event, the patient had an episode of angina pectoris associated with intensive effort and, because of this, another CA with OCT analysis were performed. The LAD showed significant stenosis on angiography in the region correspondent to the previous by documented SCAD (Figure 1A and 1B). This was felt to be due to fibrosis of the vessel wall, as evidenced by the finding of hyperreflectivity on OCT (Figure 1C) probably caused by anomalous immunity reaction mimicking an autoimmune disease. Residual intimal-tear representing the entry-site of the dissection (Figure 1D) was also detected, and a minimal lumen area (MLA) of 2.21 mm<sup>2</sup> was calculated consistent with angiographic stenosis. A 3.0/18 mm zotarolimus-eluting stent (DES) was implanted in the mid portion of the LAD and optimized with a 3.25/15 mm non-compliant balloon (Figure 2A and 2B). The angiographic result was good, as shown by a final OCT analysis confirming perfect device expansion, without malapposition or dissection residual and a minimal scaffold area of 7.55 mm<sup>2</sup> (Figure 2C and D). At 2-month post-PCI the patient had returned to playing football without limitation of physical activities. One-year post-PCI follow-up the patient is still asymptomatic and healthy.

In summary, we present here a case of SCAD causing an acute coronary syndrome (ACS) and presenting with a sudden cardiac arrest, which limited subsequent physical activity. In young patients, mostly women, SCAD episode should be strongly considered in the setting of an ACS. With this in mind, we developed and previously reported an experience-based clinical-angiographic score as a tool to guide interventionists<sup>5-8</sup>. Several articles had reported that medical therapy should be oriented on the physiopathology of SCAD due to the absence of atherosclerotic burst<sup>9</sup>.



**Figure 1.** (A, B) Coronary angiogram showing significant LAD stenosis in the same region as the previous by documented SCAD (red arrow). (C) The OCT analysis showed the residual intimal-tear representing the entry site of the dissection and a hyper-reflective image consistent with vessel wall fibrosis causing stenosis with a minimal lumen area (MLA) of 2.21 mm<sup>2</sup> being calculated (D).



**Figure 2.** (A, B) Final angiographic result after PCI with a drug-eluting stent implanted into the middle portion of LAD (yellow arrow) with a perfect device expansion without malapposition or dissection. A minimal scaffold area of 7.55 mm<sup>2</sup> was determined by OCT analysis (C, D).

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## P29

### A "PARACHUTE EFFECT" MOCKINGLY SEALING SPONTANEOUS CORONARY ARTERY DISSECTION

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**Setting and patient details.** Spontaneous coronary artery dissection (SCAD) is still an intriguing entity representing 1-4% of all acute coronary syndromes (ACS). It occurs mostly in young women (<50 years old), frequently without coronary risk factors<sup>1,4</sup> and is often associated with pregnancy, entailing a worse prognosis. SCAD occurs in 0.1–1.1% of the major angiographic series<sup>1-3</sup>, but it is still underdiagnosed<sup>1,4</sup>. This is mainly due to the absence of angiographic hallmarks in more than 70% of cases<sup>4</sup>. Optical coherence tomography (OCT) or intravascular ultrasound (IVUS) is frequently useful to clarify a dissection in the majority of SCAD type 3 and sometimes in type 2 (A or B), of the Saw classification<sup>1,4</sup>, although this is a not free-of-risk maneuver for the propagation of the dissection by wiring or by advancement of OCT or IVUS catheters, as well as for the insertion of other devices during percutaneous coronary interventions<sup>5</sup>. Of note, almost two-thirds of SCAD patients presents with a type 2 angiographic pattern<sup>2</sup>. The primum movens causing SCAD is still unknown, but a multifactorial mechanism could be responsible<sup>3</sup>. In most series there is a predominant involvement of the left anterior descending artery, followed by the right coronary artery (RCA)<sup>1,4,6</sup>, even though a multi-vessel dissection has been frequently reported<sup>6,7</sup>. In 2018, the American Heart Association and European Society of Cardiology published, simultaneously, their consensus documents<sup>1,3</sup>. In this perspective, an experts' survey was published by Buccheri *et al.* in 2017 whose results are not far from the subsequently published experts' consensus documents<sup>8</sup>. Although these two consensus documents represent a step forward compared with the previous scientific papers, they do not definitively clarify how to manage SCAD. In fact, in both documents' recommendations are mostly based on experts' opinions<sup>1,3</sup>. In patients, presenting with ACS and high-risk anatomy (proximal/middle vessel segments, left main coronary artery or >3.0 mm vessel diameter), hemodynamically unstable and/or with ongoing ischemia, an early invasive strategy with myocardial revascularization should be considered<sup>9-12</sup>. On the other hand, low-risk patients (distal or <3.0 mm vessel diameter involved and/or hemodynamically stable) should be managed conservatively, above all with  $\beta$ -blockers and aspirin<sup>8-13</sup>. We present an exemplary case of a 38-year-old female admitted for non-ST-elevation myocardial infarction. The patient sailed the Mediterranean sea with other refugees from Tunisia to Trapani. When she arrived at the local refugee center, her husband and children were transferred elsewhere provoking a great emotional and mental stress, resulting in chest pain, weakness, dizziness and syncope. Fifteen days before her arrival in Sicily-Trapani, the patient experienced an inferior ST-elevation myocardial infarction. She underwent primary angioplasty and two drug-eluting stents were inserted, (edge-to-edge overlapping) in the middle segment of the RCA.

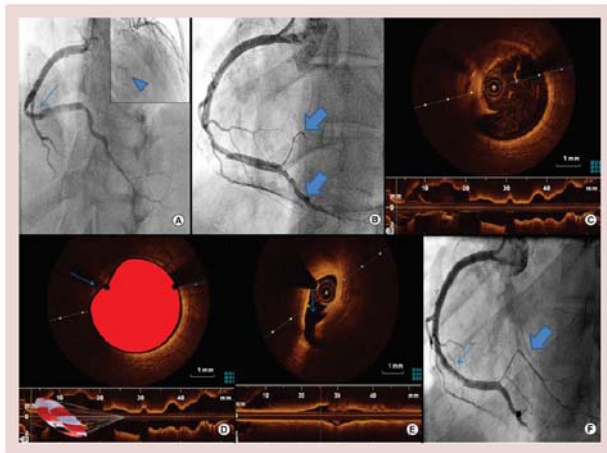
**Initial diagnosis.** At presentation the ECG and echocardiogram did not show any abnormality consistent with myocardial ischemia. For the typical chest pain, an urgent coronary angiography (CA) was performed. The previously stented RCA did not show any significant stenosis but a posterolateral branch appeared occluded at the ostium (Figure 1A), with a retrograde flow from the left anterior descending artery (Figure 1A, in the box). However, another interventional cardiologist expert on SCAD promptly suspected a dissection distally to the stents previously implanted. Thus, according to the experience-based score system published by Buccheri *et al.* (Figure 2)<sup>8-12</sup>, an OCT was performed after two guidewires placement (Figure 1B and 1C). The presence of two guidewires and the contrast medium pushing from inside-out caused a 'sealing effect' of the intima to the



media, hence hiding the presence of SCAD (Figure 1D). The day after, a new chest pain episode associated with transient ST-segment elevation in the inferior leads warranted a new CA. Another OCT of the RCA was performed, this time using a single guidewire. A clear imaging confirmed the SCAD presence (Figure 1E). To have a better understanding of the vessel morphology an IVUS analysis was carried out and even this imaging modality confirmed the presence of a true and false lumen.

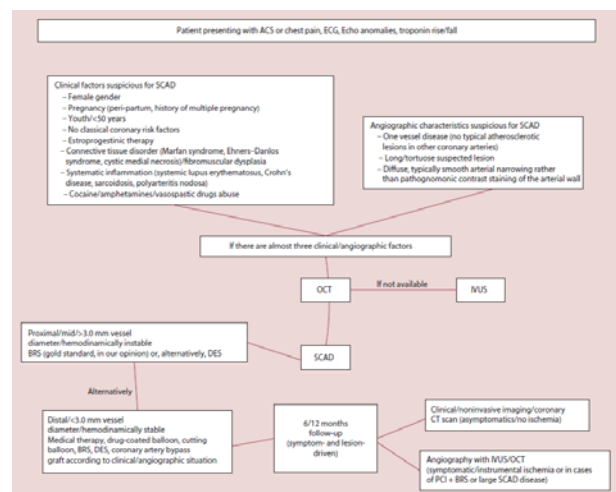
**Management.** Following a previously published algorithm<sup>11</sup>, the interventional cardiologist decided to treat the dissection with two overlapping drug-eluting stents and a TIMI-3 (thrombolysis in myocardial infarction) flow was restored, with the complete resolution of the symptoms (Figure 1F).

**Outcome and implications.** The patient was discharged after 5 days with dual antiplatelet therapy and statin. At the 24-month follow-up she was still asymptomatic.



**Figure 1.** Coronary angiography and optical coherence tomography analysis. (A) CA showed a good result of a previous PCI with two stents in the middle segment of the RCA, but the PL branch appeared occluded at ostium. Blue arrow highlighted what a SCAD expert operator suspected for a SCAD distal to the previously implanted stents. Arrowhead (in the box) shows PL seen by collateral flow from LAD. (B) After two guidewires placement, one into the posterior descending artery and the second into native PL branch (big blue arrows), an OCT showed (C) contrast-induced artifacts with a clear dissection image or anterograde flow impairment. This was due to a "sealing" effect in which the two guidewires and the contrast medium kept the artery "open" as a parachute, as is well represented in image (D) mimicking a healthy coronary artery (blue arrow) or causing artifacts without a clear interpretation. (E) Single guidewire OCT analysis revealed the dissection with a well evident entry door corresponding to a pathognomonic intimal tear (blue arrow). (F) DES implantation at mid-RCA between the two previous implanted stents (arrow), with a good final result and a patent PL branch (big blue arrow).

CA, coronary angiography; DES, drug-eluting stent; LAD, left anterior descending artery; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; PL, posterolateral; RCA, right coronary artery; SCAD, spontaneous coronary artery dissection.



**Figure 2.** Our proposal of an algorithm to manage spontaneous coronary artery dissection. Reproduced with permission from<sup>9</sup>.

**Conclusion.** SCAD expertise is of utmost importance in recognizing this entity and, perhaps, this is the reason why it is still underdiagnosed, also in view of the frequent absence of hallmarks at CA<sup>14-16</sup>. Physical and mental stress play a determinant role in SCAD, as well as in takotsubo cardiomyopathy and this is why the two entities may share a common

link<sup>14-18</sup>. In dubious cases a clinical-angiographic score system<sup>9-12</sup> could justify an endovascular imaging and help to reveal the presence of SCAD. Intravascular imaging techniques, above all OCT, are powerful tools to detect SCAD, but operators should avoid performing the analysis with two or more guidewires that may be responsible of a false 'sealing effect' and hiding the presence of a SCAD. We cannot be sure if the hospitalization in Tunisia was due to a SCAD, but it is possible that this is a case of relapse. It is useful to keep in mind that spontaneous dissection is frequently recurrent. Although the management and therapy of SCAD is still strongly disputed, during ACS or clinical instability and the vessel involved is in a proximal segment or has a diameter >3 mm we suggest to treat the lesion invasively, otherwise, medical therapy could be safe and efficacious. This is a case in which a complete imaging evaluation (CA + OCT + IVUS) has discovered and documented a SCAD after a recent stent implantation and in which the exclusive acquisition of angiograms by inexperienced operators could have missed the dissection.

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## Mitral repair

### P30

#### A NEW HEMODYNAMIC INDEX CHARACTERIZING MITRAL REGURGITATION UNDERGOING PERCUTANEOUS EDGE-TO-EDGE MITRAL VALVE REPAIR: THE VXC INDEX

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**Introduction.** Percutaneous edge-to-edge mitral valve (MV) repair is widely adopted in different pathological conditions affecting the MV. Randomized controlled trials have evaluated the role of this technique in both primary (organic) and secondary (functional) mitral regurgitation (MR). Moreover, recent analyses of these studies have shown the

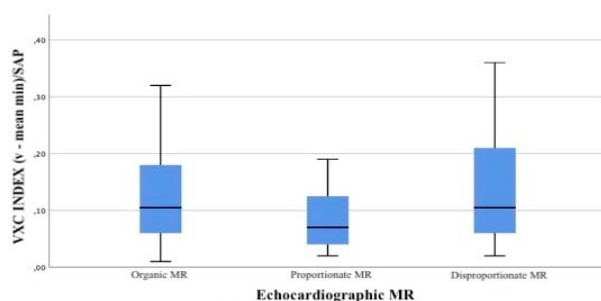


relevance of echocardiographic patient selection in the functional setting of MR, differentiating proportionate MR from disproportionate MR according to the degree of the effective regurgitant orifice area (EROA) when related to the left ventricular volume. The hemodynamic impact of MR cannot be univocally measured by echocardiography alone and the aim of this study was to determine how invasive left atrial pressure (LAP) monitoring could provide additional information on top of the echocardiographic assessment introducing the VXC INDEX determined by hemodynamic variables with direct influence on filling pressures.

**Methods.** The VXC INDEX is calculated by dividing the difference between v wave (ventricular systole in the LAP waveform) and the mean minimum LAP (mean between minimum LAP, x wave, and a/c wave) by systolic arterial pressure:  $(v \text{ wave} - \text{mean minimum LAP})/SAP$ .

**Results.** 57 out of 58 patients underwent MitraClip procedure with continuous invasive intraprocedural LAP measurement and were analyzed. According to the VXC INDEX in the study population (median 0.1; Q1-Q3 0.057-0.19) patients were divided into two groups: low or high VXC INDEX considering the cut-off value of 0.19. Patients with organic or disproportionate functional echocardiographic MR diagnosis (echoMR) were found to be evenly distributed in the low or high VXC INDEX groups. In the high VXC INDEX group only 1 out of 14 (7%) patients had a proportionate functional echoMR while in the low VXC INDEX group 6 out of 43 (14%) patients were characterized by proportionate functional echoMR.

**Conclusions.** The resulting discordance when comparing invasive LAP monitoring and echocardiography in the proportionate echoMR setting provides an insight of how hemodynamic assessment could be used as an independent tool during the procedure. Further studies are needed to confirm the VXC INDEX – echoMR discordance as well as to explore the prognostic value of the VXC INDEX and its post procedural variation.



## Multivessel coronary disease

### P31

#### CORONARY ECTASIA EXPRESSION IN DIFFERENT CLINICAL SUBSETS: STABLE AND ACUTE CORONARY SYNDROMES AND AORTIC ANEURYSMS

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**Introduction.** Coronary artery ectasia (CAE) is not a rare finding in coronary angiography, with a prevalence ranging from 1 to 20% according to clinical setting. The aim of this study was to analyze the angiographic differences of coronary ectasia based on admitting diagnosis.

**Methods.** A cohort study was conducted including patients with angiographic evidence of CAE between January 2016 and December 2020. The study population was divided into three groups according to the clinical presentation: stable coronary artery disease (SCAD), acute coronary syndrome (ACS), aortic disease (AD). Markis classification, basal thrombolysis in myocardial infarction (TIMI) flow of each coronary artery, associated coronary artery obstruction (CAO) and respective Gensini score were reported.

**Results.** A total of 342 patients were included in this study. Compared to general population, in ACS group a higher rate of myocardial infarction with non-obstructive coronary arteries (MINOCA) and ischemia with non-obstructive coronary arteries (INOCA) (31% of myocardial infarction and 42% of unstable angina, respectively) was observed. Furthermore, irrespective of lower Gensini score values, MINOCA patients showed significantly more widespread CAE and a more severe impairment of coronary flow compared to SCAD, AD and obstructive ACS patients (Markis class 1: MINOCA vs SCAD 48 - 21%,  $p=0.02$ ; MINOCA vs AD 48 - 21%,  $p<0.01$ ; MINOCA vs obstructive ACS 48 - 24%,  $p=0.05$ ; TIMI flow

$<3$  in at least one coronary artery: MINOCA vs obstructive ACS 48 - 24%,  $p=0.05$ ; MINOCA 48% vs AD 17%,  $p<0.01$ ).

**Conclusions.** CAE patients show a surprisingly high rate of acute coronary syndromes with non-obstructive coronary arteries. The extent of the ectatic involvement and its consequences on coronary blood flow could be the base of the higher rate of ACS events observed in this population, recognizing mechanisms other than plaque rupture.

### P32

#### CHRONIC TOTAL OCCLUSION ANGIOPLASTY AND VASCULAR ACCESS: A SINGLE CENTER EXPERIENCE

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**Introduction.** In the last years the improvement of interventional techniques for percutaneous coronary interventions (PCI) in the treatment of chronic total occlusions (CTO) contributed to the increase in the number of procedures performed and in the success rate. At the same time, transradial access is increasingly being used for CTO-PCI with encouraging even though there are concerns about its efficacy in this setting because of the higher procedural complexity and the need for strong guide catheter support. Aim of our study was to review the procedural success of all the CTO-PCI performed in our Center according to the vascular access utilized.

**Methods.** We retrospectively evaluated all the CTO-PCI performed in our Center from January 2018 to December 2019. These procedures were divided in two groups according to the vascular access employed: all femoral access procedures (Group 1) or procedures with at least one radial access (Group 2). The primary end-point of the study was the procedural success. Major procedural and in-hospital complications were also evaluated.

**Results.** A total of 52 CTO procedures have been performed: 13 procedures in Group 1 (85% males) and 39 (87% males) in Group 2. In Group 2, 12 procedures were performed using only radial access whereas in 27 procedures a combination of radial and femoral access have been utilized. There were no significant differences in age, sex, height or weight between the two groups. No differences in the vessel target has been observed with PCI of left anterior descending performed in 46% of cases in Group 1 and 33% in Group 2 ( $p=0.89$ ). Procedural success was similar in the two groups: 77% in Group 1 and 82% in Group 2. Major clinical complications were low with 2 post procedural myocardial infarction and 1 stroke in Group 1 and no complications in Group 2.

**Conclusion.** In our experience, the use of radial access alone or in combination with a single femoral access is safe and effective to perform CTO-PCI compared to a "all femoral" strategy.

### P33

#### A RARE CASE OF ACUTE RIGHT VENTRICULAR FAILURE

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**Background.** Heart failure with preserved ejection fraction (HFpEF) is a clinical entity which appears to be present roughly in 50% of all heart failure patients. Most of the studies on HFpEF focus on the left ventricle as the main prognostic determinant of this syndrome, but novel insights on right ventricle dysfunction (RVD) and its prognostic impact in patients with HFpEF are rising.

**Case summary.** A 62-year-old male with multiple cardiovascular risk factors, presented at the ED with signs and symptoms of right heart failure and decompensated HFpEF. After initial stabilization with diuretics and inotropes, the patient performed a coronary angiogram with evidence of critical disease of the left main, the left anterior descending artery and of the left circumflex artery in the context of combined post- and pre-capillary pulmonary hypertension as shown by the right heart catheterization. After complete revascularization, the diastolic function of the left ventricle improved dramatically, and the right ventricle recovered completely.

**Discussion.** We presented a paradigmatic case of acute right heart failure secondary to left ventricular diastolic impairment in a patient affected by severe ischemic coronary artery disease. Several risk factors are associated with RVD in HFpEF: atrial fibrillation, male sex, chronic obstructive pulmonary disease. Diastolic performance of the LV is one of the main determinants of the right ventricular function, which, in turn, is proven to have prognostic implication in HFpEF. Nowadays, there is no evidence-based treatment for right heart failure secondary to decompensated HFpEF and therapy should be tailored to the individual patient's response.

## Non-invasive imaging

### P34

#### MODERATE SEDATION FOR TRANSESOPHAGEAL ECHOCARDIOGRAPHY GUIDANCE OF PERCUTANEOUS LEFT ATRIAL APPENDAGE CLOSURE: THE MID-DEX PROTOCOL

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**Introduction.** Left atrial appendage closure (LAAC) is usually performed under general anesthesia (GA) with oral intubation to allow a prolonged transesophageal echocardiography (TEE) guidance. There is scarce knowledge about the feasibility and safety of MCS in LAAC procedures. Benzodiazepines are the most commonly used medications; however, these drugs can lead to cardiovascular and respiratory depressant effects. In alternative, dexmedetomidine (Dex), a 2-adrenoreceptor agonist, has showed to provide excellent "conscious sedation", without respiratory depression. We aimed to assess the feasibility, effectiveness and safety of an innovative MCS protocol of Dex plus Midazolam (MID-DEX), in a retrospective population of LAAC patients.

**Methods.** A total of 100 patients with AF underwent LAAC with MCS using the MID-DEX protocol between May 2019 and January 2021 in a single center. Clinical and procedural outcomes of these patients have been collected in the context of a retrospective registry about periprocedural performance of the new generation Watchman FLX device. All patients were treated preoperative with first generation antihistamine Chlorphenamine (10 mg i.v.). Dex was administered with initial bolus infusion (1.0 mcg/kg) in 10 minutes, then intravenous infusion was maintained throughout the LAAC procedure (0.2–1.0 µg/kg/h), tailored on patient's frailty (advanced age, low body mass index) and hemodynamic status (blood pressure, heart rate). Midazolam was administered to patients after Dex bolus, to induce sedation and to ease probe insertion, according to patient age and respiratory status (from 2.5 to max 10 mg). The ease of insertion of the TEE probe (1 very easy – 5 impossible), and the duration of the TEE (m') were recorded. Additional variables were: total amount of each drug given, total time to recovery from sedation. After procedure a verbal survey about the quality of sedation, level of comfort, recall of the procedure and acceptance of this type of sedation again in the future was administered. The operators also rated the procedural conditions on a scale of 1-5 (5 = excellent).

**Results.** Mean patient age was 78.5 ± 6.96 years and 34% were women. The mean left ventricular ejection fraction was 62.9 ± 8.9%. All patients underwent LAAC under MID-DEX MCS protocol with an acute procedural success rate of 100%. 90 patients (90%) successfully underwent TEE guidance under MCS for LAAC; in 10 patients ICE guidance was required. Fluoroscopic time was 31 ± 21.7 minutes. The median required dosage of Dex infusion was 0.08-0.09 µg/kg/h and Midazolam was 6.2 ± 2.4 mg. No complications were observed from MCS. There was no need for conversion from MCS to GA in any of the patients during the procedure. We observed 5 cases of bradycardia (solved by reducing to half Dex infusion) and 3 of hypotension, of which only 2 required Ringer's solution infusion. Echocardiographist rated procedural conditions as perfect (5) in 85% of cases and good (4) in 6%. Interventionalist rated procedural comfort with 5 (excellent) in 90% of cases and 4 (good) in 3%. Patients satisfaction was high with maximum rate (5) in 80% with 5% of 4 (good); however 12% of patients described procedural conditions as fair, without memory of discomfort.

**Conclusion.** LAAC is safe and effective when performed under MCS. Thus, applying MCS may simplify the LAAC procedure, as well as reduce procedural time and procedural costs, while increasing overall patient and physician satisfaction.

## Non-coronary cardiac interventions

### P35

#### LONG-TERM CLINICAL IMPACT OF PERMANENT PACEMAKER IMPLANTATION IN PATIENTS UNDERGOING TRANSCATHETER AORTIC VALVE INTERVENTION: A SYSTEMATIC REVIEW AND META-ANALYSIS

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<sup>1</sup>Department of Cardiovascular and Thoracic Sciences, Catholic University of the Sacred Heart, Roma, <sup>2</sup>Department of Cardiovascular Medicine, Roma, Fondazione Policlinico Universitario A. Gemelli IRCCS, **Introduction.** The clinical impact of permanent pacemaker implantation (PPMI) after transcatheter aortic valve intervention (TAVI) has not been fully established since available data are conflicting. We performed an

updated meta-analysis to assess the clinical outcomes related to PPMI post-TAVI at long-term (≥12 months) follow-up (LTF).

**Methods.** A systematic and comprehensive literature research was performed on PubMed and EMBASE databases. The primary endpoint was all-cause death at LTF. Secondary endpoints were rehospitalization for heart failure, stroke, and myocardial infarction. A subgroup analysis was performed according to Society of Thoracic Surgeon - Predicted Risk of mortality (STS-PROM) score. This study is registered with PROSPERO (CRD42021243301).

**Results.** A total of 30 studies were identified, providing data on 47649 patients. The mean duration of follow-up was 22 months. At LTF, PPMI post-TAVI was associated with a higher risk of all-cause death [risk ratio (RR), 1.16, 95% confidence interval (CI), 1.09-1.24] and rehospitalization for heart failure (RR, 1.25; 95% CI, 1.08-1.44). In contrast, risks of stroke and myocardial infarction were not significantly affected. Among the 20 studies that reported surgical risk, the association between PPMI and LTF all-cause death risk was statistically significant only in studies enrolling patients with high STS-PROM score (RR, 1.25; 95% CI, 1.12-1.40).

**Conclusion.** Patients necessitating PPMI after TAVI have a higher long-term risk of all-cause death and rehospitalization for heart failure as compared to those who do not receive PPMI. Thus, strategies aimed at reducing need for PPMI might improve survival after TAVI.

### P36

#### A 2-YEAR SINGLE-CENTER EXPERIENCE WITH V-LAP IMPLANTABLE REMOTE MONITORING SYSTEM IN ADVANCED HEART FAILURE PATIENTS

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**Introduction.** Heart failure (HF) is a complex syndrome affecting millions of people worldwide. Despite current therapies and disease management approaches, heart failure-related hospitalizations remain an unsolved issue. Worsening signs and symptoms are late manifestations of heart failure exacerbations leading to hospital admission. The increase of ventricular filling pressures anticipates clinical manifestations. Thus, remote intracardiac-pressure monitoring by using implantable devices may represent a key tool to personalize treatment and prevent hemodynamic destabilization.

**Methods.** In our Institution, four patients with chronic HF were enrolled in the VECTOR-HF trial (NCT03775161), a prospective, international, multicenter, clinical trial designed to assess the safety, performance and usability of the V-LAP System. V-LAP system is a remote monitoring system, fully digital and battery-less, that measures left atrial pressure (LAP) directly. The device was implanted percutaneously across the interatrial septum. After 3 months, the right heart catheterization was performed and, through comparison to pulmonary capillary wedge pressure (PCWP), the accuracy of LAP measurements has been validated. Since then, LAP trends have been monitored to optimize medical therapy. Patients were also evaluated through scheduled medical examinations at 3, 6, 12, and 24 months from implantation.

**Results.** According to our experience, the implantation of the V-LAP™ is feasible and safe, providing accurate LAP data remotely. Global patients' compliance to daily LAP measurements was really high (up to 92% in our center), and in over 58 months of cumulative follow up no HF-related readmission occurred. Besides, we observed improvements in New York Heart Association (NYHA) functional class (from III to II in 75% of patients), in 6 minute walking test results (from 395,5 ± 94,94 m at baseline to 483,33 ± 50,33 m at 6 months follow up, p=0,074) and in Kansas City Cardiomyopathy Questionnaire scores (overall summary score from 63,84 ± 16,35 at baseline to 82,26 ± 4,15 at 6 months follow up, p=0,121).

**Conclusion.** V-LAP system is displaying promising results, both in terms of safety and performance. Furthermore, patients felt directly more involved and confident in the management of their disease, becoming an active part of their own treatment. While further studies are needed, heart failure patient management guided by the V-LAP system has the potential to significantly improve patient outcomes and also decrease direct and indirect costs.

## PCI in STEMI – network and logistics

### P37

#### INFLUENCE OF DIFFERENT COVID-19 PANDEMIC PHASES ON STEMI: EXPERIENCE FROM AN ITALIAN HUB CENTRE

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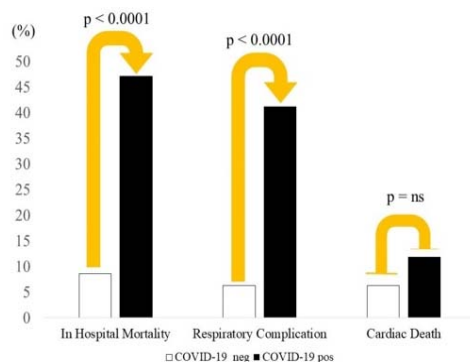
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**Introduction.** During the coronavirus disease 2019 (COVID-19) pandemic a reduction in ST-elevation acute myocardial infarction with an increase in in-hospital mortality has been observed. In our region the pandemic temporal trend was sinusoidal with peaks and valleys. A first outbreak was in March 2020 (248.12 cases for 100000 inhabitants), a reduction in May 2020 (16.68 cases for 100000 inhabitants) and a second outbreak in November 2020 (540.17 cases for 100000 inhabitants; data from Italian Health Ministry).

**Methods.** Our hospital was reorganized as one of the 13 Macro-Hubs identified in Lombardy and we retrospectively analysed consecutive STEMI patients hospitalized in the three different phases of COVID-19 pandemic.

**Results.** Despite no presence of COVID patients in the second phase we did not registered any difference in the number of STEMI hospitalized in the three phases (38 vs 34 vs 27; incidence STEMI/die: 1.19 vs 1.06 vs 0.90; p=ns). At multivariate analysis for the entire population COVID-19 infection was the strongest independent predictor of in-hospital mortality (OR 12.6 [95% CI] 2.18 – 72.77; p = 0.005). Focusing on COVID-19 patients they experienced a 5-time increased incidence of in-hospital mortality (COVID-19<sup>pos</sup> vs COVID-19<sup>neg</sup>, 47.1% vs 8.6%; p < 0.0001) mainly driven by a higher incidence of respiratory complications (COVID-19<sup>pos</sup> vs COVID-19<sup>neg</sup>, 41.2% vs 6.2%; p < 0.0001) with a similar incidence of cardiac death (COVID-19<sup>pos</sup> vs COVID-19<sup>neg</sup>, 11.8% vs 6.2%; p=ns) (Fig. 1). Among STEMI admitted during different phases of pandemic, this study found an increased mortality in patients affected by COVID-19; the co-presence of COVID-19 infection leads to an increase of mortality mostly related to respiratory complications. Interestingly the different incidence in the general population of COVID-19 did not influenced the incidence of STEMI.

**Conclusion.** In conclusion our data suggest the crucial need for an early and precise diagnosis of COVID-19 infection in STEMI to establish a correct management of this very high-risk patients.



### P38

#### THE MULTISTARS AMI TRIAL DESIGN: IMMEDIATE VERSUS STAGED COMPLETE REVASCUARIZATION IN PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION AND MULTIVESSEL DISEASE

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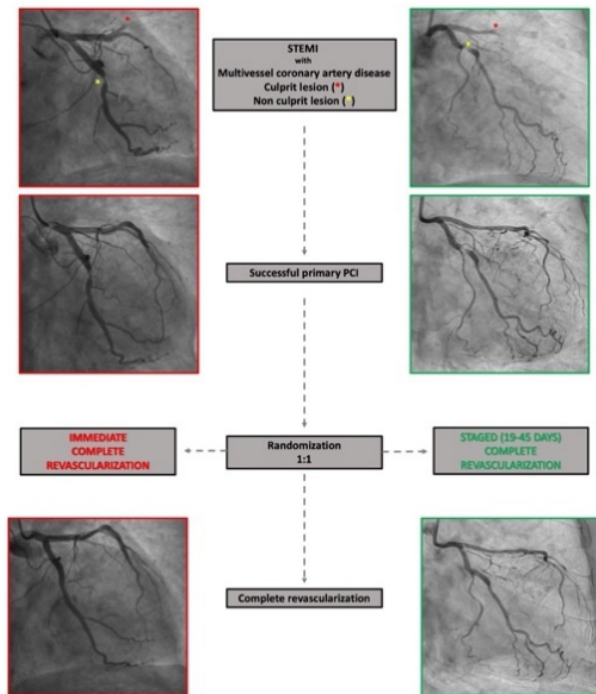
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**Background.** Patients presenting with acute ST-elevation myocardial infarction (STEMI) often present multivessel coronary artery disease (MVD). In this setting, primary percutaneous coronary intervention (PCI) of the culprit lesion represents the treatment of choice, followed by complete revascularization of non-culprit lesion. There is, however, uncertainty regarding the optimal timing of non-culprit lesion PCI.

**Study design.** MULTISTARS AMI is a randomized, international, multicenter, two-arm, open-label non-inferiority trial, planning to enroll at

least 840 consecutive patients in stable hemodynamic conditions presenting with STEMI and MVD. After successful PCI of the culprit vessel, patients are randomized in a 1:1 ratio to immediate versus staged (within 19-45 days) complete revascularization (Figure 1). The primary endpoint is a composite of all-cause death, non-fatal myocardial infarction, ischemia-driven revascularization, hospitalization for heart failure, and stroke at 1 year.

**Conclusions.** The MULTISTARS AMI trial is testing the non-inferiority of immediate compared to staged complete revascularization in hemodynamically stable patients with STEMI and MVD and will help to define the optimal revascularization strategy in this setting.



**Figure 1.** The MULTISTARS AMI trial design. PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction.

### P39

#### PREHOSPITAL ECG IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION DURING THE COVID-19 PANDEMIC

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**Introduction.** Primary percutaneous coronary intervention (PCI) represents the preferred revascularization strategy among patients with acute ST-segment elevation myocardial infarction (STEMI). A decline in the rates of primary PCI has been observed globally during the outbreak of coronavirus disease-19 (COVID-19). Fear of exposure to in-hospital infection has been hypothesized as the main mechanism of this phenomenon, also contributing to a delayed presentation of patients with STEMI. However, a formal assessment of initial electrocardiograms (ECGs) among STEMI patients during the COVID-19 pandemic is still lacking. We therefore compared pre-hospital ECGs of STEMI patients hospitalized in Italy after the first reported case of COVID-19 on February 21, 2020 with data from the same period in 2019 to identifying potential changes between the two periods.

**Methods.** Prehospital ECGs were obtained from the STEMI care network in the Campania region covering an area of about 5.8 million residents. STEMI patients were identified in the field through the emergency medical service (EMS) using a 12-lead ECG equipment available in the ambulance systems. A wireless transmission of prehospital ECGs for physician interpretation was performed by the EMS at the scene. Deidentified ECGs were analyzed by two expert reviewers who were blinded to date of recording. Pathological Q-waves were defined as a Q-wave with a duration ≥40 ms and/or depth ≥25% of the R-wave in the same lead or the presence of a Q-wave equivalent. These criteria have been shown to be associated with final infarct size at cardiac magnetic resonance. For all conventional STEMI, the timing of STEMI onset was estimated with the Anderson-Wilkins (AW) acuteness score, ranging from 1 (least acute) to 4 (most acute). Continuous data are reported as mean ± standard deviation and compared using Student's t-test. Categorical data



are reported as frequencies and percentages and compared using the chi-square test or Fisher exact test as appropriate. Statistical analysis was performed with Stata 14.2 (StataCorp, College Station, Texas).

**Results.** From February 21, 2020, to April 16, 2020, a total of 3,239 pre-hospital ECGs were recorded by the emergency medical system and 167 (5.15%) were classified as STEMI. During the same period in 2019, 3,505 pre-hospital ECGs were recorded and 196 (5.59%) were classified as STEMI. There was no difference between the two study periods in terms of age, gender, type (conventional vs. non-conventional) and location of STEMI. Pathological Q-waves were present in 54.5% of ECGs recorded during the COVID-19 period compared with 22.1% of ECGs recorded in the same period in 2019 (risk difference 32.3, 95% confidence intervals [CI], 21.2 to 43.5 percentage points). There was also an increase in the mean number of Q-waves during the COVID-19 compared with the control period (1.4 vs. 0.9;  $p < 0.001$ ). These findings remained similar when QS- and qR complexes were analyzed separately. Consistently, the AW score was significantly lower during the COVID-19 period (2.4 vs. 2.8;  $p < 0.001$ ).

**Conclusions.** Our data indicate that prehospital ECGs of STEMI patients during the COVID-19 pandemic presented more frequently with signs of late ischemia compared with the equivalent period in 2019. Approximately, 1 out of 2 patients had already pathological Q-waves in the initial ECG. The AW acuteness score is superior to patient history (historical timing) in predicting myocardial salvage and mortality after reperfusion in STEMI patients, thus explaining the higher mortality rate and the increased risk of infarct-related complications observed during the COVID-19 pandemic. Our findings support the hypothesis that COVID-19 outbreak was associated with a deferral of first medical contact among STEMI patients, prompting the continuous need for public campaigns to increase awareness of ischemic symptoms and confidence in the hospitals organization to preserve their safety.

## P40

### DEALING WITH ST-ELEVATION MYOCARDIAL INFARCTION DURING THE COVID-19 PANDEMIC

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**Introduction.** The deleterious side effects of coronavirus disease 2019 (COVID-19) pandemic on the care of patients with ST-elevation myocardial infarction (STEMI) have been reported worldwide, with most data about the period between March-April 2020. In the Lombardy region we dramatically faced with COVID-19 both in the first (February 22th-June 11th) and in the second (September 14th-December 31th) outbreaks of 2020: our center served as hub for STEMI patients with the network of care that was not modified by the decree of the healthcare Authorities, leading to an unbiased comparison with previous years. We aimed to compare admission, time of assistance and outcomes of STEMI patients undergoing primary PCI (pPCI) during the first-outbreak, the second-outbreak, and the inter-outbreak period of COVID-19 pandemic.

**Methods.** All consecutive patients who were referred to Foundation IRCCS Policlinico San Matteo (Pavia) for STEMI and underwent pPCI during the first COVID-19 outbreak, the second COVID-19 outbreak, and from June 12th to September 13th (inter-outbreak period) of 2020 were included. Data regarding baseline characteristics, clinical presentation, index procedure and hospitalization were collected and compared between the three study periods. The primary-outcome was in-hospital death. Incidence rate of STEMI admission and of primary-outcome were compared between the three study phases calculating the incidence rate ratios (IRR).

**Results.** A total of 231 STEMI patients were included: 86 underwent pPCI during the first COVID-19 outbreak, 71 during the second COVID-19 outbreak, and 74 during the inter-outbreak period. Regarding the rate of STEMI admission, no differences were found between the three periods (IRR = 1.2,  $p = 0.280$  for first-outbreak vs second-outbreak; IRR = 0.98,  $p = 0.918$  for first-outbreak vs inter-outbreak; IRR = 0.83,  $p = 0.255$  for second-outbreak vs inter-outbreak). Cardiac arrest as clinical presentation occurred in 24 patients, with a higher rate during the first outbreak (first-outbreak 16.3% vs second-outbreak 8.7% vs inter-outbreak 5.4%,  $p = 0.069$ ); 14 patients presented with cardiogenic shock (first-outbreak 9.3% vs second-outbreak 4.3% vs inter-outbreak 4%,  $p = 0.294$ ), needing circulatory support with intra-aortic-balloon-pump in 9 cases (first-outbreak 3.5% vs second-outbreak 4.3% vs inter-outbreak 4%,  $p = 0.702$ ). While the time interval "first medical contact-first ECG" was similar between the three periods, the time interval "first ECG-balloon" was lower during the first-outbreak: respectively, first-outbreak 96.5 (56.5-226) min vs second outbreak 115.5 (60-240.5) min vs inter-outbreak 125 (49-197) min,  $p = 0.920$ , and first-outbreak 98 (83-137) min vs second-outbreak 112.5 (88-160) min vs inter-outbreak 126 (86-176) min,  $p = 0.059$ . Overall, a total of 19 in-hospital deaths were reported, with 12 of them occurring during the first outbreak (first-outbreak vs second-outbreak IRR 1.6,

$p = 0.343$ ; first-outbreak vs inter-outbreak IRR 8.7,  $p = 0.009$ ; second-outbreak vs inter-outbreak IRR 5.4,  $p = 0.09$ ).

**Conclusion.** For patients with STEMI undergoing pPCI in the COVID-19 pandemic, despite a shorter time to treatment in the first outbreak, we found a higher rate of in-hospital death during the first-outbreak compared to the inter-outbreak period and no significant differences comparing the first-outbreak with second-outbreak and second-outbreak with the inter-outbreak period.

## P41

### ACUTE AND MID-TERM OUTCOMES OF PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION DURING THE COVID-19 PANDEMIC

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**Introduction.** A reduction of admissions for ST-elevation myocardial infarction (STEMI) has been reported worldwide during the coronavirus disease 2019 (COVID-19) pandemic. However, most available data refer to March-April 2020. Lombardy region dramatically faced with COVID-19 both in the first (February 22th-June 11th) and in the second (September 14th-December 31th) outbreaks of 2020, and our center served as hub for STEMI with the network of care that was not modified by the decree of the healthcare Authorities, leading to an unbiased comparison with previous years. We aimed to compare admission, time of assistance, and outcomes of STEMI patients undergoing primary PCI (pPCI) during the first-outbreak, the second-outbreak, and the inter-outbreak phase of the COVID-19 pandemic, with the same corresponding periods of the previous year (2019).

**Methods.** All consecutive patients who were hospitalized at Foundation IRCCS Policlinico San Matteo (Pavia) for STEMI and underwent pPCI from February 22th to June 11th (first COVID-19 outbreak), from September 14th to December 31th (second COVID-19 outbreak), and from June 12th to September 13th (inter-outbreak period) 2020 were included. Rates of admission and mortality at six months of the three study periods were compared with the corresponding periods of 2019. Survival analysis was made by applying the Kaplan-Meier method. The number of daily admission (NoDA) was calculated dividing the number of cumulative admissions by the number of days for each study period.

**Results.** A total of 231 STEMI patients underwent pPCI from February 22 to December 31, 2020: 86 during the first-outbreak, 71 during the second-outbreak and 74 during the inter-outbreak period. Although NoDA was reduced during both outbreaks, the difference with the previous year was greater during the second-outbreak: first-outbreak 0.77 (95% CI, 0.60-0.95) vs 0.88 (95% CI, 0.72-1.04)  $p = 0.36$ ; second-outbreak 0.64 (95% CI, 0.51-0.78) vs 0.87 (95% CI, 0.70-1.04)  $p = 0.035$ . On the contrary, in the inter-outbreak period, we found a significant increase in NoDA compared to 2019, 0.78 (95% CI, 0.60-0.98) vs 0.51 (95% CI, 0.39-0.63)  $p = 0.016$ . During the year 2020, a total of 19 in-hospital deaths was reported, with 12 of them occurring during the first outbreak (first outbreak 14% vs second outbreak 8.5% vs inter-outbreak 1.3%,  $p = 0.015$ ). Freedom from all-cause of death at 6-month was not different between 2020 and 2019 during all the three study periods: first-outbreak (95.9% vs 96.7, log-rank test  $p = 0.78$ ), second-outbreak (95.3% vs 95.4%, log-rank test  $p = 0.97$ ), inter-outbreak (94.2% vs 97.5%, log-rank test  $p = 0.42$ ).

**Conclusion.** The reduction of admissions for STEMI was greater during the second rather than the first COVID-19 outbreak compared to the corresponding periods of 2019. Although high rates of in-hospital death, especially during the first-outbreak, were reported, survival at 6 months was not different compared to the previous year within all the three study periods.

## P42

### COVID-19 AND STEMI: THE ROLE OF TELECARDIOLOGY IN THE MANAGEMENT OF STEMI DIAGNOSIS DURING THE COVID-19 PANDEMIC

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**Background.** Telecardiology has the advantage of reducing patient's access time to the hemodynamics units. Data from literature show a

reduction in ST-elevation myocardial infarction (STEMI) during the COVID-19 pandemic. However, there is a low number of studies on the impact of telecardiology during the pandemic.

**Methods.** Our telecardiology system is composed of a Hub-and-Spoke network of hospitals and ambulances that ensures a rapid exchange of information allowing STEMI patients to be treated in the shortest time possible. We compared data from electrocardiogram (ECG) transmissions and STEMI diagnosis collected between February and April 2020 with the data from the same period of 2019.

**Results.** Despite a significant reduction of ECG transmissions from the telecardiology network was observed, the number of diagnosed STEMI during 2020 was stable and did not show any significant difference compared to 2019. The total number of STEMI diagnosis in the months under examination during 2019 were 47 out of 7463 ECGs (0.63%), while in 2020 were 48 out of 5797 ECGs (0.83%).

**Conclusions.** The efficiency of our telecardiology system along with the low spread of the infection in our region contributed to maintaining the number of STEMI diagnosis and patient's care in line with the past even during the pandemic.

## P43

### SEPARAZIONE DEI PERCORSI PER PAZIENTI DURANTE LA PANDEMIA COVID-19 IN UN CENTRO HUB: 12 MESI DI WORKING PROCESS

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**Introduzione.** Nel periodo di lockdown durante la pandemia dovuta al SARS-CoV-2, tutti gli accessi totali in pronto soccorso sono drasticamente diminuiti, principalmente per la paura del contagio. Per evitare la commistione tra soggetti positivi/sospetti e soggetti normali la nostra azienda ha deciso di separare fin dai primi giorni i percorsi per pazienti, in particolare modo per i soggetti con patologie tempo-dipendenti (STEMI, stroke).

**Metodi.** Durante i primi mesi della pandemia, la separazione dei percorsi per pazienti COVID positivi risultava difficile, in primis per l'assenza di strumenti laboratoristici specifici atti ad identificare gli infetti. Per questo durante i primi mesi, tutti i pazienti venivano accolti in tende di pre-triage messe a disposizione dalla protezione civile fuori i principali ospedali, dove venivano rilevati i parametri vitali, la temperatura e sottoposto un questionario volto ad identificare soggetti a rischio di contatto con il virus. La separazione dei pazienti in sospetti/positivi e negativi veniva fatta sulla base di test sierologico (10 minuti) rapido con test punteggiato (bassa specificità e sensibilità alla malattia COVID-19). Ciò ha comportato, quindi, un'alta probabilità di falsi negativi favorendo il contagio di operatori sanitari, altri pazienti e contaminazione di sale operatorie, angiografiche e di emodinamica. Per questo motivo e per venire incontro alle esigenze dell'utenza garantendo la miglior assistenza possibile per le patologie urgenti, l'Azienda ha dotato la struttura COVID delle necessarie metodiche diagnostiche comprese TC e angiografo dedicato all'attività interventistica della neuroradiologia e della radiologia vascolare e della cardiologia. Un'equipe dedicata alla sala COVID composta da medico, 2 infermieri e un tecnico era disponibile 24/24 ore per eventuali urgenze cardiologiche (STEMI, NSTEMI, impianto di PMK temporaneo e/o definitivo). Solo nei mesi a seguire si è provveduto al miglioramento della definizione del percorso, sottoponendo tutti i pazienti con patologie tempo dipendenti a tampone antigenico oro-faringeo il cui risultato era disponibile in circa 20 minuti, con sensibilità e specificità più alta. I pazienti risultati negativi venivano inviati al percorso standard COVID-free, in emodinamica per studio coronarografico urgente e successivamente ricoverati presso la nostra UTIC in una stanza in isolamento (area grigia) dove veniva effettuato tampone molecolare SARS-CoV-2, al risultato del quale veniva poi deciso il definitivo ricovero. Al contrario se i pazienti risultavano positivi al tampone antigenico rapido oppure erano trasportati dal 118 come pazienti contagiati da SARS-CoV-2 e concomitante IMA, veniva effettuata la consulenza cardiologica in una stanza del PS dedicata e successivamente inviati al padiglione interamente dedicato ai pazienti e alle patologie COVID-19 correlate.

**Risultati.** Dal 4 marzo 2020 ad oggi la sala è stata utilizzata per un impianto di pace-maker definitivo per blocco A-V completo, 20 pazienti giunti per STEMI dalla rete IMA-COVID (per cui il nostro centro è HUB provinciale), in PS con mezzi propri o trasportati dal 118, ed una paziente con diagnosi di NSTEMI. Solo 2 (9,5%) pazienti erano di sesso femminile, mentre gli altri 19 (90,5%) di sesso maschile. Fattori di rischio: 6 fumatori (28,6%), 13 ipertesi (61,9%), 8 (38,1%) affetti da diabete mellito di tipo II. 3 di questi pazienti (14,3%) presentavano un quadro di STEMI subacuto con insorgenza dei sintomi da 3 a 6 h. 6 pazienti (28,6%) avevano una FE <35% mentre in 7 pazienti (33,3%) era compresa tra il 36% ed il 49%. 10 pazienti (47,6%) si sono presentati con diagnosi di STEMI anteriore. 10 pazienti (47,6%) avevano malattia coronarica monovasale. La mortalità intraospedaliera è stata del 47,6% con 10 decessi, con 4 decessi avvenuti nel 2020 e 6 nel 2021.

**Conclusioni.** Dal mese di marzo 2020 questa organizzazione ha garantito sempre all'utenza ospedaliera il miglior trattamento indicato per

le varie patologie in emergenza/urgenza. La riduzione del numero di SCA si è attestata intorno al 30% (maggiore la riduzione per angina instabile e NSTEMI), ma la complessità dei casi è aumentata, avendo riscontrato un incremento di infarti con complicanze (shock cardiogeno, rotture). Verosimilmente la presentazione tardiva, talvolta anche di alcuni giorni dall'inizio dei sintomi, ha reso questi pazienti particolarmente a rischio di complicanze, pre e post-procedurali.

## PCI in STEMI – pharmacologic strategies

## P44

### VITAMIN D DEFICIENCY IS ASSOCIATED WITH IMPAIRED REPERFUSION IN STEMI PATIENTS UNDERGOING PRIMARY PERCUTANEOUS CORONARY INTERVENTION

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**Background and Aims.** Vitamin D displays a broad spectrum of cardioprotective effects, preventing oxidative stress, inflammation and thrombosis and improving endothelial function. Previous studies have associated vitamin D deficiency with more extended and severe coronary artery disease (CAD) and worse outcome, and especially among patients with ST-segment elevation myocardial infarction (STEMI). However, few data have been reported on the association of vitamin D levels with the angiographic findings and the procedural results of primary percutaneous coronary intervention (pPCI) in STEMI, that was therefore the aim of the present study.

**Methods.** A consecutive cohort of patients admitted for STEMI treated with pPCI were included. The levels of 25(OH)D were assessed at admission by chemiluminescence immunoassay kit LIAISON® Vitamin D assay (Diasorin Inc). Hypovitaminosis D was defined for 25(OH)D <10 ng/ml.

**Results.** We included in our study 450 patients, divided according to tertiles values of 25(OH)D. Lower vitamin D was associated to higher use of diuretics (p=0.02), higher levels of white blood cells and glycemia (p<0.001), lower prevalence of lesions on bifurcations (p=0.03) and smaller diameter of the target coronary vessel (p=0.03). Procedural characteristics and pre-procedural TIMI flow were not different according to vitamin D levels, but for a higher rate of impaired epicardial reperfusion (12.8% vs 8.1% vs 5.3%, p=0.03, adjusted OR[95%CI]=2.6[1.05-6.6], p=0.04 for I vs III tertile, requiring higher use of adenosine (p=0.006) and glycoprotein IIb/IIIa inhibitors (p=0.01).

**Conclusion.** The present study shows that among patients with STEMI undergoing pPCI, lower levels of vitamin D are independently associated with impaired reperfusion. Future dedicated studies will shed light on the prognostic implications of hypovitaminosis D in these patients and the potential therapeutic perspectives.

## P45

### NEW ONSET ATRIAL FIBRILLATION IN STEMI PATIENTS: MAIN PROGNOSTIC FACTORS AND CLINICAL OUTCOME

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**Background.** New onset atrial fibrillation (NOAF) is not a so rare condition among patients hospitalized for ST-segment elevation myocardial infarction (STEMI). Several studies showed that NOAF during an acute coronary syndrome (ACS) leads to increased mortality, both at short and long term. The indications for the treatment of patients with known AF undergoing percutaneous coronary interventions (PCI) are clear, while less is available about the management of NOAF during ACS and in particular during STEMI. The purpose of this study is therefore to evaluate mortality and clinical outcome of this high risk subgroup of patients.

**Methods.** We analysed 1455 consecutive patients undergoing coronary angiography and/or PCI for STEMI. CHA<sub>2</sub>DS<sub>2</sub>-VASC and HAS-BLED scores were calculated for all patients. In-hospital, 1-year and long-term follow up mortality was the primary outcome. Cerebral ischemic and hemorrhagic events were also evaluated as clinical endpoints at 1 year.

**Results.** NOAF was detected in 102 subjects, 62.7% males, with a mean age of 74.8±10.6 years. We found a high prevalence of main cardiovascular risk factors such as hypertension, dyslipidemia, smoke and renal failure. Mean ejection fraction (EF) was 43.5±12.1% and the mean atrial volume was increased (58±20.9 ml). The most represented type of MI at admission was anterior STEMI (46%). NOAF occurred mainly in the peri-acute phase and had a variable duration (8.1±12.5 h). During hospitalization all patients were treated with enoxaparin, but only 21.6% of them were discharged with long term oral anticoagulation. The majority of

patients had a CHA<sub>2</sub>DS<sub>2</sub>-VASC score >2 and a HAS-BLED score of 2 or 3. In-hospital mortality was 14.2%, while 1-year mortality was 17.2% and long term mortality 32.1% (median follow-up time 1820 days, range 341 to 3985). Through a logistic regression analysis we identified age as an independent predictor of mortality both at short and long term follow up, while EF was the only independent predictor for in-hospital mortality and arrhythmia duration for 1-year mortality. At 1-year follow-up we recorded three ischemic strokes, while no bleeding complications.

**Conclusions.** STEMI patients who develop NOAF are a very high-risk population and are characterized by increased short and long term mortality. Even in patients with a single acute episode of NOAF cardioverted, our data suggest that the use of adequate risk scores, in particular CHA<sub>2</sub>DS<sub>2</sub>-VASC and HAS-BLED Score, must guide the indication for OAC therapy.

## P46

### LONG-TERM OUTCOMES WITH DRUG-COATED BALLOONS FOR THE TREATMENT OF IN-STENT RESTENOSIS AND DE NOVO LESIONS: THE NOBITRE REGISTRY

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Drug-coated balloons (DCB) have emerged for percutaneous coronary interventions (PCI) and mainly for in-stent restenosis or particular anatomies. However, the indications and the predictors of long-term failure of DCB have been poorly evaluated besides small-sized randomized clinical trials. Therefore, the aim of the present study was to provide a real-world analysis of the prognostic determinants and long-term outcomes among patients treated with DCB for any type of lesion and included in a comprehensive multicenter registry.

**Methods.** We included patients undergoing coronary angiography and PCI with DCB for in-stent restenosis or de novo lesions in 3 centers. Quantitative parameters for coronary lesions were calculated by an automatic edge-detection system. The primary study endpoint was the occurrence of major cardiovascular events (a composite of death, MI and target vessel revascularization) at the longest available follow-up. Secondary endpoints were the individual components of the primary endpoint, target lesion failure (TLF) or any acute coronary syndrome.

**Results.** Out of 281 patients treated with DCB, the 267 displaying a follow-up >12 months were included, of whom 196 treated for in-stent restenosis and 71 with de novo lesions. At a median follow-up of 616 [368-1025] days, MACE occurred in 70 (26.2%) of the patients. No difference in clinical, demographic or angiographic features was observed between patients with or without an event, with the exception of a higher rate of in-stent restenosis ( $p=0.04$ ), longer and more type C lesions ( $p=0.05$  and  $p=0.04$ ) related with MACE. At multivariate Cox-regression, type C lesions emerged as the only independent predictor of MACE (adjusted OR [95%CI] 1.83 [1.13-2.97],  $p=0.014$ ), mainly driven by target vessel revascularization (adjusted OR [95%CI] 1.78 [1.05-2.95],  $p=0.03$ ) although not conditioning survival. However, in-stent restenosis emerged as a major determinant of TLF (adjusted OR [95%CI] 2.59 [1.17-5.75],  $p=0.02$ ).

**Conclusion.** The present registry shows that drug-coated balloons represent a potential strategy even for de-novo lesions, especially in less complex cases. In fact, we observed an increased risk of MACE and target lesion failure in case of type C and restenotic lesions.

## P47

### PRIMARY PCI WITH HIGH-BOLUS DOSE TIROFIBAN: THE FAVORITE APPROACH TO SAFE AND EFFECTIVE TREATMENT FOR EARLY REPERFUSION: THE FASTER REGISTRY

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**Introduction.** By guidelines, GP IIb/IIIa inhibitors during primary PCI should only be considered for bail-out in case of no-reflow or thrombotic complications, although their use may be considered for high-risk PCI in P2Y<sub>12</sub> inhibitor-naïve patients. These recommendations are mainly based on the availability of oral antiplatelet agent with a fast onset of action, such as prasugrel and ticagrelor, and on the high risk of bleeding associated with GP IIb/IIIa inhibitors administration. However, several studies showed incomplete platelet inhibition with prasugrel and ticagrelor

during primary PCI, and high-bolus dose tirofiban was associated with better myocardial reperfusion and no increase in major bleeding as compared to placebo in the On-TIME 2 trial. The present study was designed under the auspices of the Italian Society of Interventional Cardiology (SICI-GISE) with the aim of investigating the safety and clinical efficacy of high-bolus dose tirofiban during primary PCI.

**Methods.** Patients with STEMI undergoing PCI within 12 hours from symptoms onset were prospectively enrolled in a multicenter registry conducted in high-volume centers in Italy. Left bundle branch block and cardiogenic shock refractory to drugs were exclusion criteria. All patients received intraprocedural high-bolus dose tirofiban followed by up to 18 hours infusion. Oral antiplatelet and parenteral anticoagulant therapy was left to local practice. The primary safety end-point was the occurrence of in-hospital bleedings according to the Bleeding Academic Research Consortium definition. In-hospital MACE (death, myocardial infarction, urgent TVR and stent thrombosis), final TIMI flow, myocardial blush grade and ST-segment resolution were also evaluated. The study was supported by an unrestricted educational grant issued by Corveio International. An external Clinical Research Organization (CliRest srl) was responsible for data capture and management.

**Results.** A total of 472 patients (mean age  $61 \pm 11$  years, 83% males) were enrolled in 16 Italian centers from October 2015 to June 2018. STEMI was anterior in 46%; time to PCI was less than 3 hours in 65% of patients; 73% of patients were pretreated with prasugrel or ticagrelor; mean basal thrombus grade score was  $3.47 \pm 1.25$ . Primary PCI was performed by transradial approach in 88% of the patients. Post-procedural infusion of tirofiban was administered to 65% of patients. We observed a very low rate of in-hospital BARC bleedings (1.7%) and MACE (1.0%). Complete (>70%) ST-segment resolution was observed in 67% of patients. At univariate analysis, pretreatment with prasugrel or ticagrelor and coronary thrombectomy were not associated to improved ST-segment resolution post-PCI.

**Conclusions.** Tirofiban administration during primary PCI in patients with high thrombus burden but low risk of bleeding (both because clinical characteristics and widespread use of transradial approach) is associated with high rates of complete ST-segment resolution and low rates of in-hospital bleeding and MACE.

## PCI pharmacology

## P48

### IMPIEGO DEL CANGRELOR IN SALA DI EMODINAMICA: ESPERIENZA DI UN SINGOLO CENTRO

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**Introduzione.** Il cangrelor è un inibitore parenterale del recettore piastirico P2Y<sub>12</sub> caratterizzato da una rapida insorgenza e offset dell'azione antiplateletica. Nel programma CHAMPION, in pazienti sottoposti a PCI, l'incidenza dell'end-point composto di morte, infarto, rivascolarizzazione e trombosi di stent a 48 ore è risultata significativamente inferiore nel gruppo cangrelor rispetto al gruppo clopidogrel. Tuttavia, la disponibilità di inibitori del P2Y<sub>12</sub> orali caratterizzati da maggior potenza e rapidità di azione rispetto al clopidogrel, unitamente alla carenza di evidenze a favore del pretrattamento sia nelle sindromi coronariche croniche (SCC) che acute (SCA), rendono ancora poco chiaro il ruolo del cangrelor ed il setting clinico ideale di impiego. Il nostro obiettivo è stato quello di valutare retrospettivamente l'impiego del cangrelor nel nostro laboratorio di emodinamica.

**Metodi.** Abbiamo valutato le caratteristiche cliniche, procedurali e gli outcome intraospedalieri (morte, re-infarto, ictus, TVR, e sanguinamenti maggiori) nei pazienti trattati con cangrelor durante PCI dall'inizio della disponibilità del farmaco nel nostro Ospedale.

**Risultati.** Nel periodo in esame (ottobre 2019 – maggio 2021) sono state effettuate complessivamente 712 PCI; il cangrelor è stato utilizzato in 25 procedure in altrettanti pazienti (3,5%) mediante somministrazione di bolo endovenoso ed infusione secondo peso corporeo iniziati subito prima della PCI e condotti sino al termine della stessa o sino a 2 ore dopo. L'età media era  $68,6 \pm 9,1$  anni, il 76% dei pazienti erano di genere maschile, il 64% ipertesi, il 40% diabetici, il 40% dislipidemic, il 32% fumatori, il 32% aveva storia di cardiopatia ischemica. La maggior parte dei pazienti presentava una SCA (68%), mentre i rimanenti presentavano una SCC. Le SCA erano prevalentemente rappresentate da NSTEMI-ACS (76%). Lo switch ad un inibitore orale del recettore piastirico P2Y<sub>12</sub> (52% dei casi clopidogrel, 48% ticagrelor) è stato effettuato subito dopo l'interruzione dell'infusione di cangrelor. L'anticoagulazione peri-procedurale è stata effettuata in tutti i pazienti con eparina sodica. L'accesso radiale è stato utilizzato nell'80% dei casi. Il numero medio di vasi malati è stato  $2,4 \pm 1,4$ ; il numero medio di vasi trattati è stato  $1,6 \pm 0,6$ ; il numero medio di DES impiantati è stato  $2,4 \pm 1,3$  e la lunghezza totale media degli stent



impiantati è stata 46,8±25,8 mm. Il cangrelor, su 6 primi operatori attivi nel laboratorio, è stato utilizzato da 4 ed in modo eterogeneo; nel dettaglio: operatore 1: 80% (n=20), operatore 2: 12% (n=3); operatore 3: 4% (n=1), operatore 4: 4% (n=1). Per quanto riguarda gli outcome intraospedalieri, abbiamo registrato un decesso per causa non cardiaca.

**Conclusioni.** Nel nostro laboratorio l'impiego del cangrelor è risultato sensibilmente operatore-dipendente e, a differenza del registro svedese SCAAR, più frequente in pazienti affetti da NSTEMI-ACS o SCC rispetto ai pazienti con STEMI. Tale dato può ricondursi ad un impiego decrescente del pretrattamento nei pazienti con NSTEMI-ACS rispetto ai pazienti con STEMI, nei quali il carico orale di inibitori del P2Y12 in Pronto Soccorso rappresenta ancora la routine nel nostro centro. Ulteriori fattori associati all'utilizzo di cangrelor sono stati la coronaropatia multivasale, la PCI multivasale e l'impianto di stent multipli, verosimilmente a causa della percezione, da parte degli operatori, della necessità di un'azione antiaggregante rapida in tali contesti.

## PCI: complications

### P49

#### RADIAL ARTERY OCCLUSION AS A POSSIBLE MARKER OF INCREASED RISK AFTER TRANSRADIAL PROCEDURES

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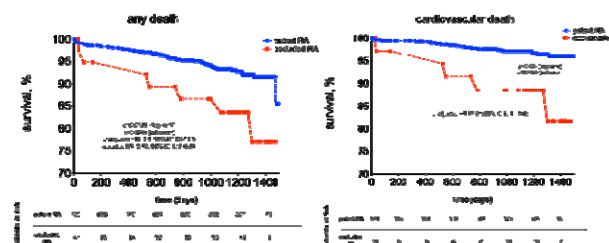
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**Background.** Radial artery occlusion (RAO) after catheterization occurs in up to 10% of cases. Although RAO is a well-known iatrogenic thrombotic process, the association of RAO with long-term cardiovascular events has so far never been investigated. The aim of this study is to investigate the relationship among RAO and mortality at 3 years.

**Methods.** The study analyzed the 3-years follow-up of a previously published prospective, multicenter observational cohort registry reporting the incidence of RAO according to ACT values. Endpoints were the incidence of all-cause and cardiovascular death.

**Results.** RAO occurred in 41 of 837 patients (4.8%). 764 patients (91.2%) were available for follow-up (median 1158 days, IQR 980-1317). All-cause death occurred in 7.4% of patients (n=57), cardiovascular death in 3.5% (n=26). At survival analysis all-cause death and cardiovascular death were significantly higher in patients with RAO (log-rank p=0.0133 and p=0.012 respectively). After stratification for patency at 30-day follow-up, patients with persistent RAO (n=14) had the worst prognosis compared to those with recanalized occlusion (n=27) and with patent radial artery (n=723) (log-rank p=0.0443). After adjustment for age, female gender, left ventricular ejection fraction, acute coronary syndrome and extension of coronary artery disease RAO was independently related to all-cause death (adjusted HR 2.76; 95% IC 1.17-6.54, p=0.02). In a sensitivity analysis this result was consistent even in multiple models with stepwise backward covariate selection.

**Conclusions.** Patients in whom RAO occurred showed an increased risk of all-cause and cardiovascular death. RAO emerged as an independent marker of subsequent cardiovascular risk, underscoring the importance of evaluating radial artery patency after transradial coronary procedures.



**Figure.** Survival from all-cause death and cardiovascular death according to radial artery patency status at 24 hours after index procedure. Kaplan-Meier survival curves with log-rank and Wilcoxon estimates for all cause-death and cardiovascular death. Patients with radial artery occlusion had a higher incidence of both hard endpoints. RA, radial artery.

## PCI: lesion/patient subsets

### P50

#### CLINICAL EXPERIENCE OF 31 CONSECUTIVE CORONARY INTRAVASCULAR LITHOTRIPSY PROCEDURES IN SEVERELY CALCIFIED CORONARY LESIONS AND IN-STENT RESTENOSIS IN AN ITALIAN CATH-LAB

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**Introduction.** Stent under expansion is one of the main predictors of percutaneous coronary intervention (PCI) failure, being a trigger for both in-stent restenosis and stent thrombosis, with their obvious clinical impact. Among the main causes of stent failure, the presence of a severely calcified lesion is the most frequent and dangerous. Correct recognition and preparation of target lesion are therefore mandatory before stenting. Recently, the introduction into clinical practice of intravascular lithotripsy (IVL) has enriched the interventional cardiologist's tool-box for calcium treatment.

**Methods.** We enrolled all the patients treated with angioplasty and IVL (Shockwave Medical Inc, Santa Clara, USA) from October 2020 to May 2021 in our cath lab. Clinical and procedural characteristics were retrospectively collected during index admission after PCI. Each patient signed informed consent.

**Results.** We enrolled 29 patients (with 31 lesions treated with IVL). Mean age was 73 years old, 24 were males (83%). Clinical characteristics are shown in the table. Seventeen lesions (58%) were treated up-stream before stenting, 6 (19%) were bail-out IVL for inadequate stent expansion after post-dilation and 7 (23%) were in-stent restenosis with evidence of stent under-expansion because of the high burden of calcium. Forty-eight per cent of patients were treated in the context of Acute Coronary Syndrome (ACS). Eighty per cent of patient had three-vessel disease. The majority of patients were treated by radial access (23 pts, 78%) and 77% of the stenosis was prepared with NC balloons (at least 2.5 mm diameter) before deployment of the IVL balloon; in 1 case IVL was done after rotational atherectomy. Intravascular ultrasound (IVUS) guidance was used in 11 pts (36%). In just one patient the lesion was so long that 2 different IVL balloons were requested; for the others application of IVL cycles in different section of the lesion was sufficient to obtain adequate result. Only 1 balloon was broken. In 24 out of 31 stenosis (77%) IVL delivery was obtained on a single wire, while 7 required buddy-wire (of whom 5 required child-in-mother technique to obtain adequate support for delivery). We had two major complications: 1 case of ventricular fibrillation (in a patients with recent myocardial infarction and severe reduction of ejection fraction and 1 case of perforation at the time of inflation of the NC balloon after IVL).

**Conclusion.** Intravascular lithotripsy is a safe and all-around technique for treatment of severely calcified lesion in different clinical contexts from stable coronary artery disease to ACS, useful for upstream calcium treatment as well as bail-out stent optimization and correction of under expansion in calcified in-stent restenosis.

Clinical characteristics	
Hypertension	26 (90%)
Dyslipidaemia	17 (59%)
Smokers	7 (24%)
Diabetes mellitus	12 (41%)
Prior PCI	14 (48%)
Prior CABG	1 (3.4%)
Chronic kidney failure	16 (55%)
eGFR <60	9 (31%)
Dialysis	1 (3.4%)
Atrial fibrillation	10 (34%)
Peripheral arterial disease	13 (45%)
Clinical presentation	
Stable angina	12 (41%)
Unstable angina	4 (13%)
NSTEMI	6 (22%)
STEMI	4 (13%)
Heart failure	3 (11%)
Vessel treated with IVL	
Left main	3 (11%)
LAD	9 (31%)
Circumflex	3 (11%)
RCA	14 (48%)
IVL balloon sizes used	
2.5 mm	4
3.0 mm	11
3.5 mm	10
4.0 mm	6

**P51****TAILORED MANAGEMENT OF A SACCULAR ANEURYSM OF LEFT DESCENDING ARTERY FOLLOWED BY SUB-OCCCLUSIVE STENOSIS IN BIFURCATION**

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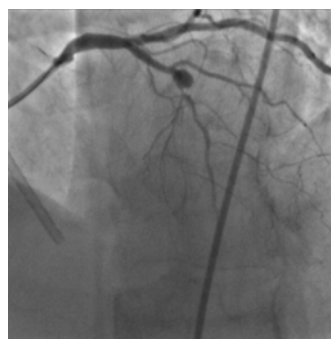
**Introduction.** Coronary artery aneurysm (CAA) is defined as a focal dilatation of at least 1.5 times the reference vessel. CAAs are morphologically divided in saccular, if transverse diameter is greater than longitudinal diameter, or fusiform, if longitudinal diameter is greater than transverse diameter<sup>1</sup>. The incidence of CAA ranges from 0.3% to 5% of invasive coronary angiography; CAA are more frequent in woman and in proximal coronary segment and the right coronary artery is the most affected artery<sup>2</sup>. There is no consensus about the best treatment strategy; CAA should be managed with conservative method by optimal medical therapy, percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG), according to each case.

**Case presentation.** We described the case of a 67-years old Caucasian male patient who was admitted to the Cardiology department of our hospital for an elective indication to invasive coronary angiography. The patient was a former smoker; he was affected by hypertension, end-stage renal disease (ESRD) in renal replacement therapy (RRT) and carried factor V Leiden. In therapy with vitamin-K-antagonist (VKA). His medical history reported a kidney transplantation for ESRD due to IgA-nephropathy in 2011 progressed to a graft failure requiring replacement therapy. For a renewed indication to kidney transplantation, the patient underwent myocardial perfusion scanning which documented reversible ischemia of anterior septal segment and mid-basal inferior segment. Therefore, invasive coronary angiography was suggested. On admission his vital signs were: blood pressure 116/65 mmHg, heart rate 78 bpm, respiratory rate 98% per minute, body temperature 36,4°C. Basal electrocardiogram showed sinus bradycardia, first-degree atrio-ventricular block and signs of left ventricular hypertrophy. On blood test macrocytic anemia (haemoglobin 12.9 g/dL, MCV 115 fl, MCH 37 pg), thrombocytopenia (platelet count 96.000/mm<sup>3</sup>) and normal liver function were detected. Transthoracic echocardiography was performed showing hypertensive cardiomyopathy, normal biventricular systolic function, second-degree diastolic dysfunction and calcification of posterior mitral leaflet resulting in mild regurgitation. Invasive coronary angiography was performed through 6-Fr right femoral artery access. The angiography showed a saccular aneurysm of 7 mm of diameter in the middle segment of left anterior descending artery (LAD) followed by sub-occlusive stenosis in bifurcation with a large septal branch and diagonal branch – Medina 1,0,0 (Figure 1). Due to the high risk of flow limitation of the side branches of the LAD pathological segment and the risk of peri-procedural myocardial infarction using a covered stent, we decided to perform percutaneous coronary intervention using conventional drug-eluting stent (DES). Using Adroit™ XB 3.5 6-Fr guiding catheter (Cordis, Santa Clara, California), the diagonal branch was wired with Hi-Torque Balance Middleweight Universal II guidewire (Abbott, Chicago, Illinois). To avoid wiring the aneurysm and to minimize the risk of aneurysmal rupture, we crossed the proximal neck of the saccular aneurysm using the SuperCross™ 45°-angled microcatheter (Teleflex, Wayne, Pennsylvania) and directed Hi-Torque Pilot 50 guidewire (Abbott, Chicago, Illinois) across the sub-occlusive stenosis to prevent inadvertent wiring of septal branch (Figure 2). Then, we advanced the microcatheter to LAD distal segment and exchanged the Hi-Torque Pilot 50 guidewire with an Hi-Torque Balance Middleweight Universal II guidewire (Figure 3). After withdrawal of microcatheter, the LAD critical stenosis was predilated using Emerge™ PTCA Dilatation Catheter (Boston Scientific, Marlborough, Massachusetts) 1.5x20 mm first and 2.0x20 mm then, both expanded up to 10 atmospheres. Then, Resolute Onyx zotarolimus-eluting stent (Medtronic, Dublin, Ireland) was deployed at its nominal pressure. Final DES optimization using NC Quantum Apex PTCA Dilatation Catheter (Boston Scientific, Marlborough, Massachusetts) 3.0x12 mm expanded up to 16 atmosphere was performed. On angiographic control we observed a reduction of contrast-medium flow through the aneurysm with a TIMI III flow in the downstream vessel; for this reason, we decided to not perform a coil embolization of CAA. The procedure ended without major complication. The patient was discharged the next day on anti-thrombotic therapy with aspirin 100 mg/day, clopidogrel 75 mg/day and VKA.

**Discussion.** There is controversy regarding coronary aneurysm pathophysiology; however, up to 50% of the cases are related to atherosclerosis. Atherosclerosis is the main risk factor for development of coronary artery aneurysm; the blood flow through a critical stenosis becomes turbulent and increases wall shear stress inducing endothelial dysfunction: in susceptible individual these flow abnormalities usually lead to post-stenotic aneurysm formation<sup>1,3</sup>. In our clinical case, the location of LAD aneurysm was just before a critical stenosis suggesting that the augmented pressure before the stenosis may induce a degeneration of vascular wall structure that finally ends in aneurismatic dilatation of the vessel. Based on this theory, we decided to perform percutaneous coronary intervention of the critical stenosis to restore a linear blood flow

and to reduce vascular resistance in the diseased segment aiming to make the flow through aneurysm neck smaller and, thus, achieving functional aneurysm exclusion. The optimal management of CAAs still needs to be clarified. The available options are medical, surgical, or percutaneous treatment. For percutaneous approach miscellaneous techniques are described; they could be divided in balloon-assisted/stent-assisted coil embolization of aneurysm or implantation of covered stent for aneurysm exclusion<sup>2</sup>. Regardless of technical issues about using specific interventional device, a careful evaluation of the coronary anatomy is mandatory: tortuosity may compromise the deployment of such devices and raising of significant side branch close to the aneurysm neck may prevent the use of covered stent. There are no covered stents that are specifically designed for the treatment of CAAs. Nevertheless, several covered stent are often used off-label to exclude CAAs. Furthermore, in a report of SCAAR registry covered stents are associated to high risk of in-stent restenosis, stent thrombosis, target lesion revascularization, re-infarction, re-PCI and mortality compared to conventional stent<sup>4</sup>. The limitation of this case is the lack of intra-coronary imaging analysis before performing PCI to obtain adjunctive information about vessel wall structure and important insights into the mechanisms of vessel wall injury. Further evaluation with invasive or non-invasive imaging (i.e. coronary CT angiography) is deemed useful to ascertain the hemodynamic aneurysm exclusion achieved by this interventional strategy.

**Conclusion.** Atherosclerosis is the most common cause of coronary artery aneurysm. The evaluation of the anatomy of coronary artery segment affected by aneurysm is crucial for the management. A tailored approach based on anatomical and functional characteristics of the affected coronary artery is the best choice in challenging scenario such as exclusion of coronary artery aneurysm.



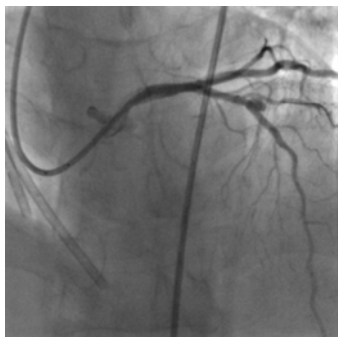
**Figure 1.** Saccular aneurysm of left anterior descending artery followed by sub-occlusive stenosis in bifurcation with large septal branch and diagonal branch.



**Figure 2.** Coronary angiography shows wiring of diagonal branch and attempt of crossing the critical stenosis of LAD using a microcatheter to direct the guidewire over the stenosis.



**Figure 3.** The microcatheter was advanced through the stenosis reaching the LAD distal segment.



**Figure 4.** LAD appearance after drug-eluting stent deployment, showing flow reduction to the coronary artery aneurysm.

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#### P52

##### GENDER-RELATED OUTCOMES FOLLOWING TREATMENT OF CORONARY ARTERY DISEASE WITH THIRD-GENERATION ULTRATHIN BIORESORBABLE-POLYMER SIROLIMUS-ELUTING STENTS

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**Introduction.** In recent years the new third-generation, ultrathin bioresorbable-polymer sirolimus-eluting stent (BP-SES), characterized by some of the thinnest struts among commercially available devices (60-80 µm) and an amorphous silicon carbide coating, has been introduced for the treatment of coronary artery disease (CAD). Aim of the present study was to assess the differential clinical outcomes and safety of this drug-eluting stent in male and female patients in a real-world setting.

**Methods.** The present study is a retrospective analysis including all patients treated with BP-SES between January 2017 and December 2019 at a single, high-volume center. Follow-up was performed by outpatient visit or by telephone contact. Main study outcome was target lesion failure (TLF), defined as a composite of cardiovascular death, target vessel myocardial infarction or target lesion revascularization.

**Results.** Overall, 66 (15.9%) female and 349 (84.1%) male patients were included; women were older (median age 70 vs. 66,  $P=0.003$ ) and with lower BMI (25.0 vs. 26.1,  $P=0.010$ ) compared to men, with no other relevant differences in baseline variables. Indication for percutaneous coronary intervention (PCI) was an acute coronary syndrome in 86 (20.7%) of the cases, with no significant differences between male and female patients. A total of 558 lesions were treated with BP-SES stents, 90 in women and 468 in men (1.36 vs. 1.34 lesions per patient,  $P=0.83$ ); cumulative stent length (33.6 mm vs. 38.4,  $P=0.078$ ) and mean stent diameter (2.92 vs. 3.0 mm,  $P=0.39$ ) did not differ between men and women. Technical and clinical success were achieved in all patients. Stent thrombosis (ST) occurred in 2 (0.5%) patients, both males. TLF occurred in 10 (2.9%) men and 2 (3.0%) women after a median follow-up of 402 days, with no significant differences at log-rank analysis (2.34 events per 100 patient-years in males, 2.53 in females;  $P=0.80$ ).

**Conclusions.** Ultrathin struts BP-SES showed a safe and effective option for the treatment of CAD in both female and male patients, with very low ST rate and favorable long-term outcomes.

#### P53

##### STUDIO RETROSPETTIVO CON FOLLOW-UP AD UN ANNO DI PAZIENTI CON SINDROME CORONARICA ACUTA TRATTATI CON LITOTRISSIA INTRAVASCOLARE CORONARICA

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In letteratura è noto che la presenza di calcificazioni coronariche severe condizioni il risultato immediato e a distanza della rivascolarizzazione. Le

calcificazioni coronariche possono impedire l'angioplastica mediante multipli meccanismi: impossibilità a superare la lesione con lo stent, alterazione della cinetica del rilascio del farmaco dallo stent, malapposizione dello stent per sottoespansione. Nel corso degli anni sono state sviluppate diverse tecniche per cercare di ridurre la componente calcifica della placca con l'utilizzo di palloni non compliant gonfiati ad alte atmosfere, con il cutting balloon, il laser, l'aterectomia rotazionale e orbitale. Tali metodiche possono complicarsi con la dissezione della parete vasale, l'embolizzazione periferica con no reflow o slow flow e con la perforazione del vaso. Recentemente è stata introdotta in ambito coronarico la litotriassia già utilizzata sul distretto vascolare periferico. Gli studi presenti in letteratura mostrano i vantaggi procedurali e a distanza della litotriassia intracoronarica, confermando la sicurezza e l'efficacia della metodica. La litotriassia intravascolare consiste di un generatore, un cavo di connessione e un catetere disponibile in diversi diametri, tutti compatibili con fili guida 0.014" e con introduttori 6 o 7 Fr. Sul catetere è montato un pallone semi-compiante su cui sono integrati molteplici emettitori i quali producono delle onde sonore pulsati. Le onde inducono delle alterazioni circonferenziali della placca calcifica riducendo al minimo il rischio di complicanze vascolari quali dissezioni o perforazioni al momento della dilatazione con i palloni e dell'impianto dello stent e frantumano il calcio in frammenti che rimangono in situ eliminando così il rischio di embolizzazione distale. Nel nostro laboratorio sono stati valutati in modo retrospettivo con follow-up ad un anno sei pazienti ricoverati dal 2019 al 2020 per sindrome coronarica acuta e trattati con litotriassia. I pazienti erano tutti di sesso maschile, con un'età media di 64 anni, in anamnesi erano presenti tabagismo ed ipertensione arteriosa nel 100% dei casi, diabete mellito non insulino-dipendente nel 66%, insufficienza renale cronica nel 16%. In tutti i pazienti la malattia coronaria era monovasale con stenosi critiche dal 70 al 90% e con calcificazioni di grado severo visibili già prima dell'iniezione del mezzo di contrasto. Nel 50% dei casi la calcificazione interessava in modo concentrico il vaso, la lunghezza era inferiore a 20 mm e il diametro del vaso sempre maggiore di 2 mm. Prima del passaggio del pallone per la litotriassia, tutte le lesioni sono state trattate mediante dilatazioni a basse atmosfere con palloni non compliant, quindi sono stati somministrati massimo 8 cicli di impulsi a lesione. Sono stati utilizzati due tipi di stent a rilascio di farmaco, 50% polimero free a rilascio di sirolimus e 50% a rilascio di everolimus, in tutti i casi gli stent sono stati post dilatati con palloni non compliant. Le procedure si sono svolte in due tempi data l'assenza del device nel laboratorio e i pazienti sono arrivati alla litotriassia pretrattati con un secondo antiaggregante. La rivascolarizzazione è stata priva di complicanze in fase acuta, si è ottenuto nel 100% dei casi un flusso TIMI 3 con stenosi residua tra 0% e <20%. Il decorso intraospedaliero è stato regolare e non sono stati registrati eventi avversi. Il follow-up clinico ad un anno è stato privo di complicanze e i MACE (morte cardiaca, infarto miocardico, rivascolarizzazione del vaso colpevole, ictus) sono risultati assenti. Nonostante la scarsa numerosità del campione, la nostra esperienza risulta in linea con i dati presenti in letteratura. In particolare riportiamo alcuni dati a scopo esclusivamente descrittivo, che potrebbero essere spunto per ulteriori studi: 1) a dispetto dei noti fattori di rischio cardiovascolare maggiormente correlati alla presenza di calcificazioni endovasali, nel nostro studio sono rappresentati in modo preminente il tabagismo ed il sesso maschile; 2) il follow-up ad un anno è stato privo di eventi e non influenzato dal tipo di stent utilizzato. Infine confermiamo la relativa semplicità della metodica che la rende utilizzabile in tutti i laboratori e con una breve curva di apprendimento.

#### P54

##### CLINICAL OUTCOME OF PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION AND ANGIOGRAPHIC EVIDENCE OF CORONARY ARTERY ECTASIA

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**Introduction.** The prognostic impact of CAE in STEMI patients has been poorly investigated. The aim of this study was to describe the prevalence of coronary artery ectasia (CAE) in patients with ST-elevation myocardial infarction (STEMI) and to compare the long-term outcome of subjects with and without CAE undergoing emergent coronary angiography.

**Methods.** This retrospective, single-center, study included consecutive patients with STEMI undergoing emergent coronary angiography from January 2012 to December 2017. The primary endpoint was the assessment of recurrent myocardial infarction (MI) in patients with versus those without CAE at the longest available follow-up. The propensity score weighting technique was employed to account for potential selection bias between groups.

**Results.** From 1,674 patients with STEMI, 154 (9.2%) had an angiographic evidence of CAE; 380 patients were included in the no CAE group. CAE patients were more often males and smokers, and showed a



lower prevalence of diabetes than no CAE patients. After percutaneous coronary intervention, the corrected thrombolysis in MI frame count ( $p < 0.001$ ) and the myocardial blush grade ( $p < 0.001$ ) were significantly lower in CAE than in no CAE patients. The mean follow-up was  $1,218.3 \pm 574.8$  days. The adjusted risk for the primary outcome resulted significantly higher in patients with CAE compared to those without (adjusted HR: 1.84;  $p = 0.017$ ). No differences in terms of all-cause and cardiac death were found between groups.

**Conclusions.** In this study, STEMI patients with CAE had a distinct clinical and angiographic profile, and showed a significantly higher risk of recurrent MI than those without CAE.9

## P55

### DRUG-COATED BALLOONS FOR CORONARY ARTERY DISEASE: CURRENT CONCEPTS AND CONTROVERSIES

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**Introduzione.** Drug-coated balloons (DCBs) are a novel development for percutaneous coronary intervention. The first successful application was in-stent restenosis but in recent years, strong evidence has been released for its use in native small-vessels disease. Additional applications such as acute myocardial infarction, chronic total occlusion and bifurcation lesions are still under investigation.

**Methods and Results.** A literature review was made including the keywords bioresorbable vascular scaffold, coronary artery disease, drug-coated balloon, in-stent restenosis, percutaneous coronary intervention. Several key studies were identified evaluating the role of DCBs in several settings and reports on interesting cases.

**Conclusions.** The current use of DCBs is diffused in several settings, DCBs show positive results especially for high-risk patients with neoplasm, as well as with high bleeding risk, planned surgery or renal injury. We also highlight a new biodegradable therapy for coronary bifurcation treatment, in which a bioresorbable vascular scaffold is implanted in the main branch, completed with a DCB angioplasty in the side branch when a treatment is deemed necessary.

## P56

### REDUCTION OF RADIATION EXPOSURE USING LEFT DISTAL RADIAL ACCESS FOR CORONARY PROCEDURES. THE RADIANT II STUDY

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**Introduzione.** Left distal radial approach (dLRA) with left hand dorsum positioned over the left groin could reduce operator radiation exposure compared to right radial approach (RRA) without increasing operators' discomfort.

**Methods.** Patients admitted for diagnostic coronary angiography (DCA) or percutaneous coronary interventions (PCI) were enrolled; choice of vascular approach (right radial at wrist or at snuffbox level vs left distal) was left to operators' choice. Demographic, clinical and procedural characteristics were recorded. End-point was operator radiation dose at the thorax (TD), as measured by electronic dosimeter worn above the lead apron. Kernel-algorithm based propensity score matching were performed to adjust for potential confounder (age, sex, patients BMI, acute coronary syndrome as admission diagnosis, DCA vs PCI, operator BMI, operator experience, angio suite, fluoroscopy at 7.5 vs 15 fps). Average treatment effect (ATE) and average treatment effect on the treated (ATT) were estimated. After logarithmic transformation, double robust multivariate linear regression analysis was performed.

**Results.** 371 patients were enrolled by 4 operators, with overall 546 procedures, 325 in RRA group and 221 in dLRA. TD was significantly lower in dLRA compared to RRA (6.9  $\mu$ S, IQR 3-18 vs 17  $\mu$ S, IQR 7-31,  $p < 0.0001$ ). After matching, standardized differences of the mean were within range of +0.1 around 0. dLRA reduced effectively TD (12  $\mu$ S, 95% IC 9-14 vs 20  $\mu$ S, 95% IC 15-26, ATE -8.23, 95% IC -15/-0.86,  $p = 0.029$ , ATT -9.37, 95% IC -18/-0.56,  $p = 0.037$ ). At regression analysis dLRA was still an independent predictor of radiation exposure (OR -0.5, 95% IC -0.7/-0.3,  $p < 0.0001$ ).

**Conclusions.** dLRA could reduce the operator radiation exposure during diagnostic coronary angiography and percutaneous coronary intervention compared to right radial approach.

## PCI: long-term outcome

## P57

### TROPPO VECCHI PER ESSERE SOTTOPOSTI A RIVASCULARIZZAZIONE DELLE OCCLUSIONI CRONICHE TOTALI: EFFICACIA E SICUREZZA DELLA PROCEDURA NELLA POPOLAZIONE ANZIANA

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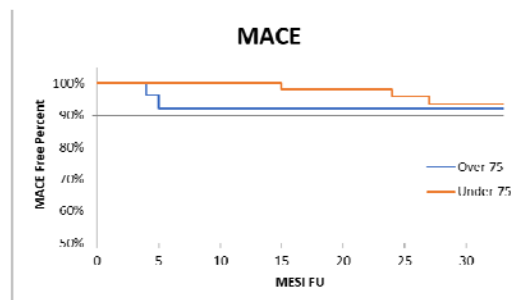
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**Introduzione.** La rivascularizzazione percutanea (PCI) delle occlusioni croniche totali (CTO) è un efficace trattamento dell'angina refrattaria. Sebbene la rivascularizzazione di una CTO migliori i sintomi e la qualità di vita, quest'ultima risulta una procedura a rischio più elevato rispetto ad un'angioplastica di routine. Per questo motivo la CTO PCI troppo spesso non è considerata una valida opzione per i pazienti più anziani. Lo scopo di tale lavoro è pertanto valutare l'efficacia e la sicurezza della CTO PCI in una popolazione di età superiore ai 75 anni.

**Metodi.** Sono stati considerati tutti i pazienti sottoposti a CTO PCI dal 01/01/2013 al 01/03/2021 suddivisi in due gruppi in base all'età (superiore e inferiore ai 75 anni). L'endpoint primario di efficacia è l'incidenza di eventi cardiovascolari avversi maggiori (MACE) durante il follow-up (22 mesi). All'interno di questo endpoint composito sono inclusi la rivascularizzazione del vaso target (TVR), la rivascularizzazione di vaso non target e la morte cardiovascolare. Come endpoint di sicurezza si sono valutate le complicanze legate alla procedura durante il periodo di ospedalizzazione e nei 15 giorni successivi. Per valutare i tassi di sopravvivenza libera da MACE tra i due gruppi si è usata l'analisi Kaplan-Meier.

**Risultati.** Abbiamo incluso 127 pazienti, 30 dei quali di età  $>75$  anni (24%). L'età media del sottogruppo più giovane era 69 anni contro 79 anni nel sottogruppo degli over 75. Le caratteristiche della popolazione erano le seguenti: sesso maschile 86%, diabete 32%, insufficienza renale 8%, ipertensione arteriosa 76%, familiarità per cardiopatia ischemica 40%. I fattori di rischio erano egualmente distribuiti tra i due gruppi. Durante il follow-up sono stati riscontrati 16 eventi MACE (1 morte per arresto cardiaco, 14 TVR, 1 rivascularizzazione di vaso non target). La rivascularizzazione del vaso target è stato l'endpoint più comune, nel 90% dei casi tale rivascularizzazione è però avvenuta in regime elettivo. Degli eventi totali, 4 (13%) si sono verificati nel gruppo con più di 75 anni d'età e i restanti 12 casi (12%) nell'altro gruppo. Tale minima differenza non è risultata statisticamente significativa. L'analisi di Kaplan-Meier dei tassi di sopravvivenza liberi da MACE non differisce significativamente tra i due sottogruppi. Sono state riportate solo 3 complicanze relative alla procedura (2,5%) e si tratta in tutti i casi di perforazione coronarica. Il tasso di successo della procedura di rivascularizzazione tra i due gruppi è stato analogo (80% per quelli sopra i 75 anni contro 82% del gruppo più giovane).

**Conclusioni.** L'efficacia e la sicurezza della CTO PCI non è influenzata dall'età. La CTO PCI è pertanto una valida opzione per l'angina refrattaria anche nei pazienti anziani. Il progresso della tecnica e dei materiali usati nelle CTO PCI insieme con l'aumentata aspettativa di vita suggerisce la necessità di un registro prospettico multicentrico capace supportare tale evidenza.



## P58

### FIRST GENERATION BIORESORBABLE VASCULAR SCAFFOLD VS NEXT GENERATION BIORESORBABLE VASCULAR SCAFFOLD: SINGLE CENTER, LONG-TERM FOLLOW-UP EXPERIENCE

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**Background.** Previous randomized controlled trials demonstrated a higher rate of stent thrombosis with first generation (Absorb; Abbott Vascular, USA) bioresorbable vascular scaffold (BVS) implantation as compared with second-generation drug-eluting stent. Currently, with

limited indications, others next generation BVS (NGB) are available (Magmaris; Biotronik AG, Switzerland and DESolve; Elixir Medical Corporation, USA). Real world long-term outcomes of such devices are limited.

**Methods and Results.** In our center from 27/09/2012 to 28/08/2018 in a cohort of 277 patients, a total of 259 BVS and 191 NGB (120 Magmaris and 71 DESolve) devices were implanted. The primary efficacy endpoint was a combined end point of target-lesion revascularization (TLR) and target lesion myocardial infarction (TLMI) the primary safety endpoint was scaffold thrombosis (ScT). At a median follow-up, of 83 months (interquartile range-IQR, 61-91 months) for BVS, and 48 months (IQR, 41-53.5 months) and 64.5 months (IQR, 58.5-69 months) for Magmaris and DESolve respectively, TLR/TLMI occurred in 17 patients (10.5%) in the BVS group and 4 patients (3.5%) in the NGB group ( $p$  value= 0.03), ScT occurred in 5 patient (3.1%) and 1 patient (0.9%),  $p$ -value=0.23, respectively. Median time of ScT occurrence in the BVS group was 12.5 months (IQR 9.75-16.75), ScT in the NGB group occurred after patient's suspension of dual antiplatelet therapy 3 month later from the implantation date.

**Conclusion.** In a single center real world setting, the use of NGB appear safer compared to BVS at long-term follow-up.

## PCI: pre-clinical studies

### P59

#### RADIOPROTEZIONE DELLO STAFF DI EMOdinamica: VALUTAZIONE SU FANTOCIO E SUL CAMPO DI UN NUOVO DISPOSITIVO PASSIVO

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**Introduzione.** Lo staff del laboratorio di cardiologia interventistica è tra le categorie con la più alta esposizione professionale a radiazioni ionizzanti. La radioprotezione degli operatori e del paziente è un argomento di estrema attualità anche in considerazione della recente Direttiva Europea recepita dal DL 101/2020. Diverse sono le strategie di radioprotezione degli operatori. Il sistema EggNest-XR (Egg Medical Inc) è un sistema di protezione "collettiva" dello staff che agisce direttamente attenuando alla sorgente le radiazioni indesiderate. Scopo del presente lavoro è valutare il livello di efficacia e la compatibilità con l'attività dell'equipe di EggNest-XR.

**Metodi.** EggNest-XR è costituito da un tavolo in fibra di carbonio a cui sono agganciate paratie rimovibili attenuanti che circondano la parte superiore del paziente e delle protezioni anti-X sotto il tavolo che avvolgono il tubo radiogeno. Tali protezioni non impediscono i movimenti standard dell'angiografo. Il dispositivo è stato testato mediante misure con fantoccio in una configurazione realistica in 5 posizioni corrispondenti a quelle degli operatori più rappresentativi (primo operatore, secondo operatore, anestesista, infermiere, ecografista). È stata misurata l'intensità del campo di radiazioni (uSv/h) a tre altezze di riferimento (150-100-50 cm da terra) e per le tre proiezioni più utilizzate (0°/0°, LAO 25°/CAU 20°, RAO 20°/CAU 20°), sia con il dispositivo sia senza. In una seconda fase il dispositivo è stato testato durante la normale attività di emodinamica. Per ogni procedura sono stati posizionati dei dosimetri elettronici all'altezza del torace, fuori dal camice di piombo, sul primo operatore, sul secondo operatore, sull'infermiere circolante, anestesista e ecografista quando presenti. Il campionamento è stato effettuato in 50 procedure (coronarografia, PCI, TAVI) sia in presenza del dispositivo sia senza. Il valore di dose in mSv ai differenti operatori è stato normalizzato per il valore di KAP (prodotto del kerma in aria e area) in mGycm<sup>2</sup>, in modo da tenere conto della differenza di durata e complessità delle procedure.

**Risultati.** Le misure con il fantoccio hanno dimostrato una riduzione delle dosi agli operatori con EggNest-XR. In particolare per il primo operatore e l'anestesista si è osservata una riduzione della dose del 20% nella posizione a 150 cm dal pavimento, mentre per le altre altezze di riferimento (100 e 50 cm da terra) e per gli altri operatori si è osservata una riduzione variabile fra il 60% e il 98%. Non è stata rilevata un aumento della dose al paziente. Le misurazioni durante l'attività di emodinamica hanno presentato una notevole variabilità dovuta al tipo di procedure eseguite, alle diverse modalità di lavoro dei singoli operatori. Tuttavia i risultati preliminari dimostrano una riduzione pari a circa il 30% per il primo operatore del 45% del secondo operatore e del 99% per l'infermiere circolante. Il dispositivo non ostacola l'attività clinica e anche in condizioni di criticità risulta facilmente rimovibile e scomponibile.

**Conclusioni.** I dati preliminari di questo studio sembrano indicare l'efficacia del sistema EggNest-XR nel ridurre la dose ai diversi componenti dello staff di emodinamica senza aumentare la dose al paziente e senza interferire con i movimenti dell'angiografo necessari nelle diverse procedure.

## Peripheral interventions

### P60

#### GLOBAL LONGITUDINAL STRAIN PREDICTS SIGNIFICANT CORONARY ARTERY STENOSIS IN PATIENTS UNDERGOING CAROTID ARTERY REVASCLARIZATION

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**Background.** Carotid artery stenosis is expression of systemic chronic atherosclerosis and the concomitant presence of coronary artery disease (CAD) can be related to the occurrence of cardiovascular events after carotid revascularization. The identification of non-invasive parameter able to detect significant CAD in patients without overt symptoms is deemed attractive. Left ventricular (LV) global longitudinal strain (GLS) has demonstrated to be a sensitive echocardiographic tool in the discrimination of significant CAD, providing incremental diagnostic value over LV ejection fraction (LVEF), even in absence of wall motion abnormalities.

**Purpose.** The assessment of global longitudinal strain (GLS) at rest could be useful to unmask CAD in patients undergoing endovascular carotid artery revascularization.

**Methods.** Of 115 patients scheduled for CAS in our institution between November 2018 and November 2020, 87 were excluded because history of CAD, LVEF <50%, resting wall motion abnormalities, cardiomyopathies, moderate-to-severe valvular heart disease, left bundle-branch block and suboptimal quality of speckle-tracking analysis. A total of 28 patients (mean age 69.5 ± 9.6 years, 53.6% males) were enrolled. The indication for endovascular carotid revascularization was based on current guideline recommendations. All patients underwent a complete echocardiographic assessment before angiography, including GLS analysis. Subclinical LV systolic dysfunction was defined by a GLS <20%. Before revascularization, all patients underwent coronary angiography (CA). Significant CAD was defined as ≥50% for left main coronary artery, ≥70% for the others epicardial arteries.

**Results.** After CA, CAD was detected in 13 (46%) patients (61.5% one-vessel, 23.1% two-vessels, 15.4% three-vessels disease). Patients with and without CAD didn't differ significantly in terms of risk factors, comorbidities and baseline echocardiographic parameters. Despite similar values of LVEF (60.8±4.0% vs 61.3±3.3%,  $p=0.690$ ), a trend of lower GLS was observed in CAD patients, compared to those without CAD (20.5±4.0% vs 22.7±2.4%,  $p=0.09$ ). Interestingly, all patients (100%) with impaired GLS (<20%) showed significant CAD at CA ( $p=0.02$ ). Moreover, GLS reduction in CAD patients was progressive with increasing vessels affected ( $p=0.005$ ).

**Conclusion.** This study suggests that in patients undergoing carotid revascularization, GLS shoes the capability in identifying patients at higher probability of significant CAD. Further and larger studies are needed to definitely attest the role of GLS in the selection of patients candidate with significant CAD before carotid revascularization.

### P61

#### SAFETY AND EFFICACY OF RENAL ARTERY DENERVATION FOR UNCONTROLLED RESISTANT HYPERTENSION IN A HIGH RISK POPULATION WITH CHRONIC KIDNEY DISEASE: THE VERONA REAL-WORLD EXPERIENCE

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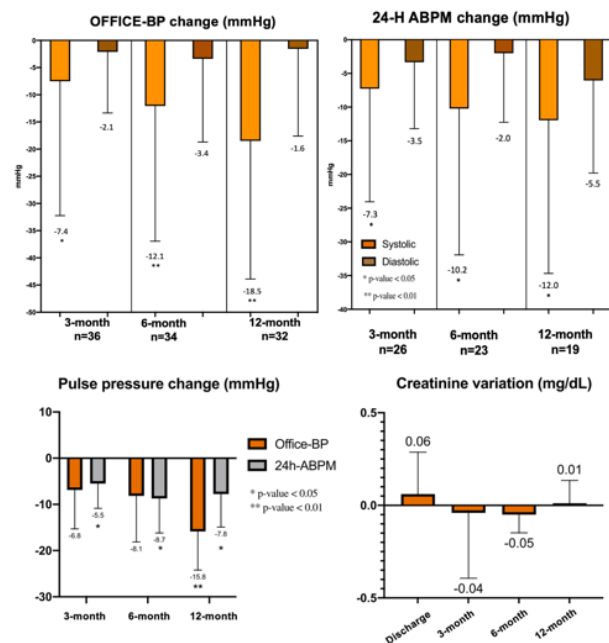
**Aims.** To evaluate the safety and the efficacy of catheter-based radiofrequency renal sympathetic denervation (RSD) in a daily practice population of patients with uncontrolled resistant hypertension (URH) on top of medical therapy.

**Methods.** Consecutive unselected patients with uncontrolled resistant hypertension undergoing RSD were enrolled. Office and ambulatory blood pressure (BP) monitoring were collected at baseline and 3, 6 and 12 months after RSD. Efficacy was assessed also in patients with an estimated glomerular filtration rate below 45 ml/min/1.73m<sup>2</sup>. Patients were defined responders to RSD if systolic BP decreased by at least 5mmHg at ambulatory BP or by 10 mmHg at office BP at the last follow-up available.

**Results.** Among an overall population of sixty patients that underwent RSD from 2012 to 2021, a subgroup of 54 patients with URH and multiple comorbidities was selected. Baseline office and ambulatory BP was 161.0/87.2±24.1/15.6mmHg and 155.4/87.5±19.3/14.6 mmHg respectively. At 12-month follow up a significant reduction of office and ambulatory systolic BP, respectively by -18.5±26.7 mmHg ( $P<0.01$ ) and by -12±23.1mmHg ( $P<0.05$ ), was noticed. BP reduction at 12-month follow-up among patients with eGFR <45 ml/min was similar to that obtained in patients with higher eGFR. Among patients treated before July 2020 with available follow-up (45/54) thirty-six patients (80%) were

classified as responders. Combined hypertension, higher ambulatory systolic BP and lower E/E' at baseline emerged as predictors of success of RSD at univariate analysis. Among responders and non-responders, the average medication number showed no significant difference at baseline and during follow-up. No major complications were observed and renal function was stable up to 12 months, even in patients with lowest eGFR at baseline.

**Conclusion.** RSD is safe and feasible in patients with uncontrolled resistant hypertension on top of medical therapy, even in a high-risk CKD population with multiple comorbidities, with a significant reduction of systolic BP and a trend of reduction of the diastolic BP up to 12 months.



## P62

### TRATTAMENTO DELLE OCCLUSIONI DELL'ARTERIA RENALE MEDIANTE ANGIOPLASTICA IN PAZIENTI PEDIATRICI CON IPERTENSIONE NEFROVASCOLARE: IL RUOLO DEL CARDIOLOGO INTERVENTISTA DELL'ADULTO IN UN CENTRO DI RIFERIMENTO

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**Introduzione.** L'indicazione al trattamento percutaneo mediante angioplastica (PTA) delle occlusioni croniche dell'arteria renale (RA) è controversa: negli ipertesi adulti con occlusione aterosclerotica di RA è quasi sempre presente una contestuale patologia dei vasi arteriosi intraparenchimali ed il rene presenta danno ischemico spesso irreversibile che rende clinicamente inefficace la rivascolarizzazione. È diverso invece il caso nei pazienti pediatrici in cui la patologia principale è la displasia fibromuscolare ed il rene rimane spesso perfuso grazie alla presenza di circoli collaterali capsulari e/o ilari che originano da rami polari o surrenalici. Questi soggetti presentano severa ipertensione su base nefrovaskolare tipicamente resistente a terapia farmacologica. Lo scopo di tale lavoro è pertanto valutare l'efficacia, la sicurezza ed i benefici clinici del trattamento di occlusione di RA mediante PTA eseguita da cardiologi interventisti in una popolazione pediatrica.

**Metodi.** Dal 01/01/2015 al 31/12/2020 abbiamo trattato con PTA 25 pazienti pediatrici affetti da ipertensione arteriosa nefrovaskolare. 4 pazienti (3 femmine, 1 maschio) presentavano una occlusione completa di RA. L'indicazione veniva posta da un team multidisciplinare guidato da nefrologo pediatra, le procedure sono state eseguite da un cardiologo interventista dell'adulto esperto in trattamento di occlusioni coronariche. Le età dei pazienti erano 7, 9, 15 e 17 anni. Tre casi erano di displasia fibromuscolare, uno (17 aa) di arterite di Takayasu. In tutti i casi era presente una circolazione collaterale sufficiente a garantire una perfusione renale buona valutata con indagine scintigrafica. In tutti i casi è stata utilizzata la tecnica anterograda analoga a quella coronarica. In un caso la periferia dell'arteria renale è stata visualizzata grazie ad iniezione selettiva di contrasto in vaso surrenalico da cui derivava il circolo collaterale, in un caso è stato utilizzato un catetere ecografico tipo ICE per identificare il punto di accesso della guida.

**Risultati.** I valori pre-procedurali di pressione arteriosa (PA) sistolica (S) e diastolica (D) erano 138.2±12.4 e 86.0±6.6 rispettivamente (mmHg, media ± DS). Il numero di farmaci antiipertensivi era di 3.5 per paziente.

Tutte le procedure sono state efficaci e non si sono verificate complicanze. Solo in due casi sono stati posizionati stent. La riduzione dei valori di PAS e PAD dopo 6 mesi è stata di -21.5±3.5 (-15.5%) per la sistolica e -10.6±2.2 (-12.3%) rispettivamente ed il numero di farmaci antiipertensivi era di 0,5 per paziente (-85%). Durante il follow-up medio di 25 mesi, eseguito con eco-Doppler, non si sono evidenziate ristrenosi.

**Conclusioni** Il trattamento di occlusione di RA mediante PTA in età pediatrica, eseguito da un cardiologo interventista con esperienza di occlusioni coronariche, ha una elevata probabilità di successo e bassa probabilità di complicanze. L'indicazione deve essere posta da un team multidisciplinare. I benefici clinici sono molto rilevanti sia sulla riduzione dei valori di pressione arteriosa che sul numero di farmaci necessari per ottenerla.

## P63

### PERCUTANEOUS CLOSURE OF A RIGHT AXILLARY ARTERY PSEUDOANEURYSM

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Pseudoaneurysms, or false aneurysms, occur as a result of arterial injury or anastomotic disruption. Many causes of pseudoaneurysms have been described including atherosclerosis, thoracic outlet syndrome, infection and iatrogenic trauma.

We present a case of right axillary pseudoaneurysm in a 62-year-old male resulting in a large pulsatile mass in the right pectoral region, evoking severe pain. He has undergone multiple vascular surgeries in the past months for critical aorto-iliac bifurcation disease. Firstly aorto-bifemoral bypass grafting was performed, after thrombosis the graft to the right femoral artery failed and right axillary-femoral bypass grafting was performed. After the graft failed (due to thrombosis), patient underwent above the knee amputation and the graft was removed. A large pulsatile mass appeared in the site of anastomosis to the axillary artery. A large pseudoaneurysm was diagnosed by contrast computed tomography (Figure 1). A surgical repair of the pseudoaneurysm was unsuccessful, hence leaving the percutaneous approach as the remaining option.

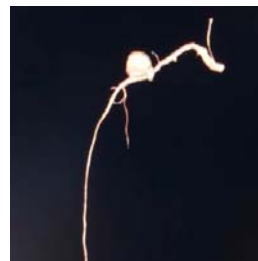


Figure 1. Contrast computed tomography identifying the pseudoaneurysm.



Figure 2. Angiography of the axillary artery before and after closure of the pseudoaneurysm.

Left femoral access was mandatory. Ultrasound guided micro-puncture was performed distally to the graft insertion and then exchanged to 8F sheath. Also, right radial access was obtained with a 6F sheath (Terumo®). Using a standard J-type 0.035" guidewire and a JR4 6F (Terumo®) diagnostic catheter we advanced toward the right subclavian artery and in to the brachial artery. We exchanged to a Supra Core 35 (Abbott vascular) guidewire and 10F guide sheath that was placed in the brachiocephalic trunk. The pseudoaneurysm was identified with contrast injection measuring 6 cm in diameter. We used a vascular stent graft Fluency Plus (Fluency®) 60x10 mm. After careful positioning it was released sealing the pseudoaneurysm. The following angiographies showed no extravasation of the dye, no endo-leak. Femoral hemostasis was achieved using a ProGlide® (Abbott Vascular) and manual compression and confirmed using echography. The patient was stable



during the procedure and hospital stay and had an uneventful recovery. On follow-up the pulsatile mass withdrawn and patient had no symptoms. Axillary artery pseudoaneurysms are a rare occurrence. The repair depends from the size of the pseudoaneurysm and its neck. Surgical repair was the preferred method for large pseudoaneurysms. Endovascular treatment is becoming the preferred way of closure in most cases in different anatomical sites, especially when surgery has more technical challenges and higher risks. As shown in this case it is feasible and associated with fewer risks than surgery.

## Renal dysfunction

### P64

#### PRELIMINARY FINDINGS OF THE DAVIDS REGISTRY (DYEVERT TO AVOID UNNECESSARY CONTRAST MEDIA DELIVERY DURING PCI SANREMO REGISTRY)

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**Introduction.** Contrast-induced acute kidney injury (CI-AKI) is a percutaneous coronary intervention's (PCI) feared complication, linked to increased morbidity and mortality. Many risk factors have been identified and several risk scoring systems were developed and validated. Amongst procedural variables contrast media (CM) volume is one of the most predictive. An easy-to-use and effective CM sparing device would represent a valuable tool in the cath-lab armamentarium, thus we evaluated the effectiveness of the DyeVert Power XT system in reducing CM delivery during PCI in patients at high risk of CI-AKI and consequently in reducing the risk itself.

**Methods.** Observational, prospective, monocentric, single-arm registry collecting procedural and outcome data of all consecutive patients (pts) who underwent interventional procedures with the use of the DyeVert system between September 2020 and June 2021. Inclusion criteria were reduced estimated glomerular filtration rate (eGFR) - defined as creatinine clearance (CrCl) <60 mL/min/m<sup>2</sup> - or need for a complex PCI - chronic total occlusion (CTO), previous coronary artery bypass graft (CABG) or diffuse multivessel disease (MVD) - with the likelihood to receive a high amount of CM.

**Results.** Patients median age was 73 (IQR 77-64) years old, with a large percentage of diabetic patients (n=24; 50%). Basal creatinine value and eGFR were 1.31 (SD ± 0.41) mg/dl and 52 (IQR 75-38) mL/min/m<sup>2</sup> respectively. Around 30% of clinical presentations were acute coronary syndromes (ACS), whilst looking at procedural aspects 20.8% of our pts had undergone a previous CABG and 22.9% of patients underwent CTO recanalization during the index procedure. The prevalence of MVD was significant with around 70% of pts undergoing PCI in 2 or 3 lesions. Median dose of CM delivered was 260 mL (IQR 304-218) while CM spared with DyeVert was 110 mL (IQR 150-95) (around 40% volume reduction, mean 2 point reduction in Mehran score). Turning to outcomes 6 pts (12.5%) experienced AKI stage I according to Kidney Disease – Improving Global Outcomes (KDIGO) definition, whilst only 2 pts (4%) and 1 pts (2%) experienced stage 2 and 3 AKI. At follow-up there were 3 in-hospital deaths, none linked to deteriorating renal function. DyeVert use was simple and effective in all cases, with preserved image quality according to the operators judgement.

**Conclusions.** In our registry DyeVert use was effective allowing about 40% of CM sparing without impairing angiographic image quality. Adequately powered clinical trials, targeting pts at higher risk for CI-AKI from a clinical and procedural point of view, are needed to assess if, as expected, such a significant CM saving can translate in meaningful clinical outcomes.

### P65

#### EXTRAVALVULAR CARDIAC DAMAGE AND RENAL FUNCTION FOLLOWING TRANSCATHETER AORTIC VALVE IMPLANTATION FOR SEVERE AORTIC STENOSIS

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**Aims.** Acute kidney injury (AKI) represents a common complication following both surgical (SAVR) and percutaneous aortic valve implantation (TAVI), with an incidence ranging between 12% and 28%. AKI correlates strictly with in-hospital, short, and long-term mortality. Extra-valvular cardiac damage (EVCD), firstly proposed by G  n  reux et al., has been described in patients with severe AS, as it is expected to affect long-term outcomes.

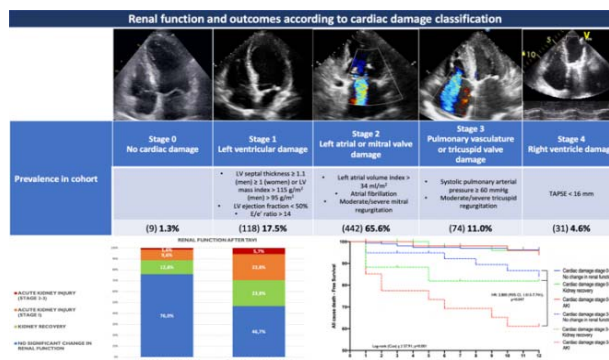
We sought to determine the differences in the incidence of AKI and acute kidney recovery (AKR) among patients undergoing transcatheter aortic valve implantation (TAVI), according to the degree of extravalvular cardiac damage (EVCD). No previous study investigated the incidence of AKI and

AKR and their impact on clinical outcomes according to pre-existing EVCD.

**Methods.** From the Verona Valvular Heart Disease Registry, 674 symptomatic severe AS patients were selected and retrospectively analyzed. Based on echocardiography findings, patients were classified based on the degree of EVCD. AKI was defined as a relative increase in sCr concentration of at least 0.3mg/dL as measured 24 hours and 72 hours, and was classified according to AKIN stages. AKR was defined as an increase of GFR of 25% at discharge compared to baseline GFR.

**Results.** After dichotomized analysis, patients in EVCD stage 3-4 reported a significantly higher rate of AKI (29.5% vs. 11.2%; p<0.001), significant AKI (5.7% vs. 1.6%; p<0.01) and the need for continuous renal replacement therapy (CRRT) after TAVI (2.9% vs. 0.7%; p<0.05). At the multivariate model higher EVCD stage, lower glomerular filtrate rate (GFR) at admission and the amount of contrast used were found to be independent predictors of AKI, while the stage of cardiac damage and GFR were found to be independent predictors of AKR. In the overall population after multivariate analysis AKI was associated with a higher incidence of all-cause mortality (HR 2.388; CI 95% [1.237-4.610]; p=0.010) and MACEs (HR 2.219; CI 95% [1.209-4.074]; p=0.010). Notably, at the multivariate analysis, AKI significantly impacted on survival in patients in stages 3-4 (HR 2.484; CI 95% [1.017-6.067]; p=0.046), but not in patients in stages 0-2 (HR 1.301; CI 95% [0.380-4.457; p=0.675]), with an interaction that achieved statistical significance (p for interaction 0.006). AKR did not reduce adverse clinical outcomes but was associated with an improvement of renal function at 12-months.

**Conclusions.** Advanced EVCD is associated with a higher incidence of AKI, all-cause mortality, and adverse clinical events at 12-months. AKI demonstrated to negatively impact mid-term prognosis only when occurring in advanced stages of EVCD, but not in early stages. AKR did not reduce adverse clinical outcomes but was associated with an improvement of renal function at 12-months. The application of this staging system may provide an additional tool for the decision-making process in patients with severe AS.



## Structural interventions

### P66

#### CORONARY ANGIOGRAM AT THE TIME OF TAVI IN LOW-RISK PATIENTS

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**Introduction.** Transcatheter aortic valve replacement (TAVR) is nowadays offered as an alternative to surgical aortic valve replacement (SAVR) in patients at 'low-risk' for surgery in high-volume centers. Pre-TAVR assessment includes pre-procedural coronary angiogram and the evidence of significant coronary artery stenosis (i.e., left main/multiple vessels disease) may sometime shift the indication over SAVR. Nevertheless the role of coronary angiogram and its specific timing in 'low-risk' candidates for TAVR needs further clarification. We hypothesized that in such group of patients, coronary angiogram could be safely performed at the time of TAVR with minimal cross over to surgery and little impact on post-operative outcomes. Thereby, the study was to investigate the role and feasibility of intra-procedural coronary angiogram in patients at low-risk.

**Methods.** This was an observational single center study (GVM Care&Research, Anthea Hospital, Bari, IT). Patients with EuroSCORE II ≤4% candidates for TAVR were included. Relevant peri and post-procedural details were recorded.

**Results.** From January 2020 till April 2021, 46 patients defined as low-risk underwent trans-femoral TAVR after Heart Team evaluation (mean age ± SD was 79±6.3 years old, ESII 2.4± 0.8; Table 1). Coronary angiogram was carried out during the index procedure in all patients and

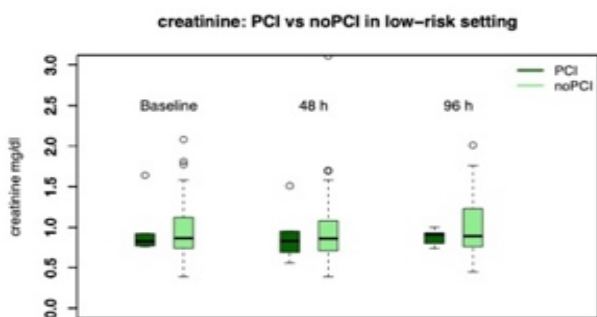
percutaneous coronary intervention (PCI) was performed in 6 individuals (13%) for significant coronary artery stenosis (PCIs details reported in Table 1). Valve success was achieved in all patients but 1 who died due to stiff wire perforation of the left ventricle in a context of undiagnosed non-compaction disease of the left ventricle. There were no major vascular complications; notably, the PCIs did not influence the post-operative outcomes and renal function (mean creatinine mg/dl at discharge  $0.88 \pm 0.09$  vs.  $1 \pm 0.6$ , PCI vs no PCI respectively,  $p=0.06$ ; Figure 1). Neither ischemic events nor bleeding were observed during the post-operative period.

**Conclusion.** In patients at low-risk for surgery, coronary angiogram at the time of TAVR procedure was safe and feasible; coronary angioplasty, if performed, did not influence the valve success and the early post-operative outcomes. There was no crossover to surgery.

**Table 1.** Baseline patient characteristics - peri and post-operative details (n=46).

Age, years, mean (SD)	79 (6.3)
Female sex, n (%)	23 (50)
BMI, kg/m <sup>2</sup> , mean (SD)	27.9 (4)
Diabetes mellitus, n (%)	13 (28.2)
LVEF, % (SD)	50.8 (6.6)
Creatinine, mg/dl, mean (SD)	0.96 (0.3)
ES II, mean (SD)	2.4 (0.8)
Coronary angiogram findings	
No significant (>70%) coronary artery stenosis, n (%)	40 (86.9)
PCI LMS, n (%)	1 (2.1)
PCI LAD, n (%)	1 (2.1)
PCI LAD and diagonal, n (%)	1 (2.1)
PCI OMB, n (%)	1 (2.1)
PCI intermediate branch, n (%)	1 (2.1)
PCI RCA and OMB, n (%)	1 (2.1)
Valve implanted	
Evolut R, n (%)	22 (47.8)
Evolut PRO	12 (26)
Portico, n (%)	12 (26)
Valve success (VARC criteria), n (%)	45 (97.8)
48 h Creatinine, mg/dl, mean (SD)	0.97 (0.45)
96 h Creatinine, mg/dl, mean (SD)	1 (0.5)
Length of stay, days, mean (SD)	6.2 (3.1)
De novo pacemaker, n (%)	12 (26)
Minor vascular complications, n (%)	4 (8.6)
In hospital death, n (%)	1 (2.1)

BMI, body mass index; ESII, EuroSCORE II; LAD, left anterior descending artery; LMS, left main stem; LVEF, left ventricular ejection fraction; OMB, obtuse marginal branch; RCA, right coronary artery.



## P67

### IMPIANTO DI VALVOLA MITRALICA PERCUTANEA CON ACCESSO TRANSCAPALE: L'ESPERIENZA DI PISA

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**Introduzione.** L'insufficienza mitralica è una patologia ad elevata incidenza e prevalenza che ha un importante impatto sulla mortalità e morbilità dei pazienti che ne sono affetti. In pazienti con elevato rischio chirurgico e non eligibili a riparazione percutanea del vizio valvolare, l'unica alternativa alla terapia medica ad oggi è rappresentata dai sistemi di impianto transcateretere di valvola mitralica (Transcatheter Mitral Valve Implantation, TMVI).

Questo studio si propone di descrivere e riportare la casistica dei pazienti con insufficienza mitralica funzionale moderato-severa e severa, trattati presso la SD di Emodinamica dell'Ospedale di Cisanello con impianto transcateretere di valvola mitralica biologica con accesso transcapale.

**Metodi.** Sono stati arruolati 14 pazienti, 7 uomini (50% del campione) e 7 donne (50% del campione). Di questi, 12 (85,7%) erano affetti da MR solo funzionale mentre 2 (14,3%) da IM mista. Il 64,3% dei pazienti (9) avevano una MR funzionale legata a pregressa patologia ischemica coronarica, mentre il 35,7% (5) aveva una forma funzionale dovuta a

cardiomiopatia dilatativa a coronarie indenni. L'età media della popolazione era di  $75 \pm 8$  anni, con elevato rischio chirurgico (Logistic EuroSCORE medio: 26,54; EuroSCORE 2 medio: 9,5; mortalità STS media: 11,3%; Mortalità e morbilità STS media: 25,1%). Il 35,7% (5) pazienti era in classe NYHA IIb, il 64,3% (9) dei pazienti in classe NYHA III. Il 71,4% (10) dei pazienti presentava un'insufficienza mitralica severa, la restante parte, il 28,6% (4) invece un'insufficienza moderato-severa. Le caratteristiche ecocardiografiche basali del campione analizzato evidenziano la presenza di funzione cardiaca compromessa: FE media  $34,34 \pm 4,50\%$ ; ipertensione polmonare moderata-severa, PAPs  $43,71 \pm 5,94$  mmHg, camere cardiache sinistre dilatate LVEDV  $181,57 \pm 58,52$  ml, LVEDD  $62,71 \pm 5,35$  mm, LAD  $47,86 \pm 4,95$  mm. Tutti i pazienti sono stati sottoposti alla procedura in anestesia generale, con successo procedurale del 100%.

**Risultati.** La percentuale di sopravvivenza a due anni è stata del 85,7% (12), con due decessi per cause non cardiache. Sono stati eseguiti follow-up ad 1, 6 e 12 mesi dall'intervento, che hanno evidenziato notevoli miglioramenti nella classe NYHA, già al controllo ad un mese, con la maggior parte dei pazienti (71,4%) che si porta in classe NYHA IIa e con i restanti (28,6%) in classe NYHA I; nessun paziente dopo l'intervento presenta una classe superiore a NYHA IIa. Il miglioramento rimane costante anche ai successivi follow-up: a 6 e 12 mesi sempre il 71,4% dei pazienti è in classe NYHA IIa, mentre il restante 28,6% in classe NYHA I. Il controllo ecocardiografico evidenziava la completa scomparsa dell'insufficienza mitralica in tutti i pazienti; la FE media migliorata fino ad un valore di  $40,33 \pm 13,49$  al follow-up a 6 e 12 mesi; LVEDV e LVESV si riducono rispettivamente ad un valore medio di  $162,50 \pm 68,54$  ml e di  $105,33 \pm 61,58$  ml già al follow up a 6 mesi. La PAPs ha un netto miglioramento soprattutto per quanto riguarda il follow-up ad un mese, con un valore medio di  $34,33 \pm 6,41$  mmHg.

**Conclusioni.** Il trattamento dell'insufficienza mitralica tramite l'utilizzo di sistemi percutanei TMVI risulta un'opzione fattibile ed efficace. In particolare si sottolineano i risultati osservati dal punto di vista clinico, con importanti miglioramenti nella classe funzionale NYHA dei pazienti trattati, e di quelli dal punto di vista ecocardiografico, che evidenziano una completa scomparsa del rigurgito, una tendenza al rimodellamento inverso delle camere cardiache sinistre ed un miglioramento dei parametri di funzionalità ventricolare sinistra e delle pressioni polmonari.

## P68

### TAVI IN MODALITÀ SERVICE: I PRIMI 100 CASI DEL PROGRAMMA ROMAGNA TAVI

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**Introduzione.** Le procedure d'impianto transcateretere di protesi valvolare aortica (TAVI) per il trattamento della stenosi aortica dell'anziano sono in forte incremento, considerate le indicazioni delle più recenti linee guida. In Romagna, con una popolazione di 95.000 ultraottantenni, il trattamento con TAVI della stenosi valvolare aortica è una priorità.

**Metodi.** Nell'anno 2019 è stato promosso un programma di sviluppo del percorso TAVI con il coinvolgimento di tutte le Cardiologie della Romagna appartenenti all'unica Azienda Sanitaria del territorio (AUSL Romagna). Le procedure vengono effettuate presso le sale ibride di Maria Cecilia Hospital (Cotignola, RA), riferimento territoriale per la cardiocirurgia, da un team di operatori (cardiologi interventisti e anestesisti) dell'AUSL Romagna. I pazienti afferiscono dalle varie U.O. di Cardiologia della Romagna e sottoposti ad intervento di TAVI in modalità service con rientro al reparto di provenienza il giorno successivo la procedura.

**Risultati.** Dal 9 luglio 2019 al 20 ottobre 2020, con una sospensione delle attività causa COVID dal 11 marzo al 6 luglio 2020, sono state effettuate 100 procedure di TAVI, circa 8/mese. L'età mediana dei pazienti è stata di 85 anni (range 68-93), con un rapporto maschi:femmine di 1:1. Nel 30% dei casi era stata precedentemente effettuata una valvuloplastica aortica presso le varie U.O. di Cardiologia della Romagna. Le procedure di TAVI sono state effettuate, nel 90% dei casi, per via percutanea (arteria femorale). Gli accessi chirurgici sono stati trans-succlavio (6 casi), trans-femorale (2 casi) e trans-aortico (2 casi). Il 10% delle procedure sono stati interventi di valve-in-valve. Il successo procedurale è stato del 98% con impianto di 52 valvole balloon-expandable e di 46 valvole self-expandable. Nessuna procedura è stata convertita in intervento cardiocirurgico. Nel 3% dei casi si è reso necessario un intervento di chirurgia vascolare. Il 3% dei pazienti è stato sottoposto ad emotrapifusioni. Nel 13% dei casi è stato impiantato un pace maker definitivo. Un solo paziente ha avuto un evento ischemico cerebrale minore. La mortalità a 30 giorni è stata del 1%. La mediana della degenza post TAVI

è stata di 4 giorni. Solo 2 pazienti hanno avuto necessità di prolungare la degenza presso il centro cardiocirurgico oltre la prima notte.

**Conclusioni.** La nostra iniziale esperienza dimostra che le procedure di TAVI possono essere effettuate con un programma di service in modo sicuro ed efficace, rappresentando un possibile modello per i centri sprovvisti di cardiocirurgia on-site.

## P69

### PATIENTS WITH ATRIAL FIBRILLATION UNDERGOING PERCUTANEOUS CORONARY INTERVENTION: A COMPARISON BETWEEN LEFT ATRIAL APPENDAGE CLOSURE AND TRIPLE ANTI-THROMBOTIC THERAPY

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**Introduction.** Recent guidelines suggests a limited duration of triple antithrombotic therapy (TAT) in patients with atrial fibrillation (AF) undergoing percutaneous coronary intervention (PCI) at an elevated bleeding risk. Indeed, in patients who are also at an elevated thrombotic risk, percutaneous left atrial appendage closure (LAAC) could be a possible safe and effective option to prevent both bleeding and thrombotic episodes.

**Methods.** Retrospective single-center study comparing patients who received LAA percutaneous closure to avoid TAT before or after PCI, deemed at increased thrombotic and bleeding risk, with respect to patients who received TAT between September 2012 and February 2020. The aim of the study was to establish the safety of percutaneous LAAC and its efficacy through the incidence of bleeding episodes, both major and minor, and the incidence of stroke or transient ischemic attacks with respect to the TAT regimen.

**Results.** A total of 168 patients were included in the study of which 56 underwent percutaneous LAAC while 112 were discharged in TAT. Overall, patient age was 75 years old (69-79) with a predominant male sex distribution (n = 136; 81.0%). A mean CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 4 (3-5) and a mean HAS-BLED score of 3 (2-3) were calculated in the population who was dismissed in TAT whereas a mean CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 5 (4-6) and a mean HAS-BLED score of 4 (3-4) were observed in the population who underwent percutaneous LAAC, varying significantly between the populations (p=0.001). The population who underwent LAAC was characterized by a remarkable procedural PCI complexity with a mean DAPT score of 2 (0.25-2) with respect to the population discharged in TAT which was 0 (-1-2). At follow-up (mean follow-up period in days: 727 (489-1000)), four bleeding episodes were recorded in the population who underwent LAAC with respect to 16 bleeding episodes in the population discharged in TAT (12.6% vs. 15.4%; p-value=0.142), of which two major bleeding episodes and five major bleeding episodes respectively (3.6% vs. 4.8%; p-value=1). One case of stroke (1.8%) occurred in the population who closed the left atrial appendage with respect to two cases of stroke (1.9%) which occurred in the population who was discharged in TAT, not varying significantly (p=1.000).

**Conclusions.** Despite our single-centre retrospective study showed no significant difference in terms of bleeding and thrombotic events between the two populations, the percentage of bleeding events which occurred in the population under TAT may show a trend towards a potential benefit of LAAC with respect to the TAT regimen. Indeed, a larger study population would be needed in order to confirm the efficacy of percutaneous LAAC with respect to TAT in patients with AF undergoing PCI.

## P70

### PERCUTANEOUS MITRAL PARAVULVULAR LEAK CLOSURE USING COMPUTED TOMOGRAPHY: A SINGLE CENTER EXPERIENCE

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**Objectives.** The aim of this study was to assess whether a routine cardiac computed tomography (CT) planning could improve procedural outcomes in patients undergoing percutaneous mitral paravalvular leak (PVL) closure.

**Background.** Percutaneous mitral PVL closure is a technically demanding intervention, requiring careful procedural planning and monitoring. Cardiac CT provides accurate PVL localization and identifies optimal fluoroscopic viewing angle to guide the procedure. Despite its growing utilization, the role of procedural CT planning in percutaneous mitral PVL closure has not been systematically evaluated.

**Methods.** Between November 2008 and November 2020, 47 PVL closure procedures were attempted in 38 consecutive patients at our Institution and were retrospectively included in this study. Procedural planning was performed using transesophageal echocardiography alone in 16 (42%) patients for 16 procedures and using cardiac CT in 22 (58%) patients for

31 procedures. Procedural outcomes were compared between these groups.

**Results.** Overall, patient age was 69±9 years and 44.7% were male with high surgical risk profile. The main indication for PVL closure was heart failure (89.4%). Patients undergoing procedural CT planning presented >1 target PVL in a significantly higher proportion of cases (31.8% vs. 0%, p=0.014). Compared to baseline, PVL regurgitation improved after the procedure (p<0.001). Successful PVL closure occurred in 91.4% of cases, similarly between the two groups (93.5% vs. 87.5%, p=0.597). Patients undergoing procedural CT planning presented a significantly lower procedural time (62.4±34 vs. 104.1±35 minutes, p=0.001).

**Conclusions.** Procedural cardiac CT planning significantly reduced procedural time in patients undergoing percutaneous mitral PVL closure.

## P71

### SAFETY AND EFFICACY TAVR WITH AND WITHOUT THE PRESENCE OF AN ANESTHETIST IN CATH LAB

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**Background.** Transcatheter aortic valve replacement (TAVR) were for many years performed under general anesthesia. In the last years, physician moves on a minimal approach with local anesthesia. In our center, since January 2019, majority of TAVR are being performed under local anesthesia without the presence of anesthetist in the cath lab. In this study we aim to compare procedural outcome and complications of patients undergoing transfemoral TAVR with and without the presence of an anesthetist in the cath lab.

**Methods.** From January 2020 to December 2020, 166 patients undergoing transfemoral TAVR with anesthetist in site (AIS) or anesthetist on call (AOC). In all patients, the initial anesthetic approach was local anesthesia. The presence or absence of an anesthetist in the cath lab depended on the day of the week (an anesthetist was present only one day a week). In AOC, conscious sedation was guided by the interventional cardiologists performing the procedure. Lidocaine 2% (10 to 20 ml) was used for local anesthesia. Morphine or other major sedative and painkillers could be administered at the discretion of the operator and/or anesthetist. In case of emergency during the procedure an anesthetist is available for calls and could arrive to the cath lab within 2 min, considering that anesthesiology unit is located in the same department of cath lab.

**Results.** The study included 166 patients (42.8% males) at a mean age of 82.4 ± 5.5. 48 patients in AIS group and 118 patients in AOC group. The clinical characteristics of patients according to the AIS and AOC groups are presented in Table 1. As shown, the baseline characteristics are similar among the groups. Procedure data are presented in Table 2. Uses of self-expandable or balloon expandable prosthesis were balanced in the groups. In AOC group temporary pacemaker was used less than AIS group (41.5% vs 77.1%, p <0.001), probably due to the availability of jugular venous access placed by anesthetist in AIS group. A high prevalence of radial as secondary access was observed in AOC group

Table 1. Baseline characteristics.

	Total (n=166)	AIS (n=48)	AOC (n=118)	p- value
Age at procedure (yrs)	82.4 ± 5.5	82.8 ± 7	82.1 ± 4	0.67
Male	42.8% (71)	43.8% (21)	42.4% (50)	0.87
Weight (kg)	71.5 ± 14.0	72.9 ± 14	70.7 ± 14	0.43
Height (cm)	165.1 ± 8.8	165.5 ± 8.7	164.8 ± 8.7	0.68
Body mass index, kg/m <sup>2</sup>	26.2 ± 4.8	26.6 ± 5.2	25.9 ± 4.7	0.47
EuroSCORE II	5.3 ± 3.8	6.0 ± 5.8	5.2 ± 3.0	0.40
STS Score	4.0 ± 2.1	4.2 ± 2.0	4.0 ± 2.1	0.48
GFR (ml/min/m <sup>2</sup> )	58.7 ± 19.1	61.7 ± 22.4	56.9 ± 16.8	0.31
NYHA III-IV	35.6% (58)	36.2% (17)	35.3% (41)	0.96
Hypertension	82.5% (137)	81.2% (39)	83.1% (98)	0.78
Diabetes	28.9% (48)	29.1% (14)	28.8% (34)	0.07
Prior stroke/TIA	10.8% (18)	6.2% (3)	12.7% (15)	0.72
CAD	23.5% (39)	25.0% (12)	22.9% (27)	0.77
Prior MI	11.5% (19)	10.4% (5)	12% (14)	0.77
Prior PCI	12.6% (20)	14.9% (7)	11.6% (13)	0.57
Prior CCH	12.7% (21)	20.8% (10)	9.3% (11)	0.04
Peripheral vascular disease	15% (25)	10.4% (5)	16.9% (20)	0.51
Chronic obstructive pulmonary disease*	11.4% (19)	16.7% (8)	9.3% (11)	0.18
Mean aortic gradient (mmHg)	47.6 ± 14.8	44.8 ± 14.8	48.3 ± 15.1	0.07
Aortic regurgitation 2+	29.5% (49)	25% (12)	31.8% (37)	0.70
Mitral regurgitation 2+	31.9% (53)	25% (12)	34.7% (41)	0.23
LVEDV (ml)	99.0 ± 36.7	93.8 ± 32.1	100.7 ± 38.3	0.25
LVEF (%)	56.4 ± 9.5	55.4 ± 10.0	56.9 ± 9.2	0.26
Any ECG alteration	48.4% (81)	44.7% (21)	52.6% (60)	0.35

Data are shown as % (n), means ± (SD), or median and interquartile range.

AIS, anesthetist in site; AOC, anesthetist on call; STS PROM, STS Predicted Risk of Operative Mortality; PCI, percutaneous coronary intervention; TIA, transient ischemic attack; GFR, glomerular filtration rate; LVEF, left ventricular ejection fraction; LAHB, left anterior hemi block.

\*Referred to severe stage with FEV1/FVC 30-49%.



Table 2. Procedural data.

	Total (n=166)	AIS (n=48)	AOC (n=118)	p-value
Temporary pacemaker	51.8% (86)	77.1% (37)	41.5% (49)	<0.001
Radial as secondary access	65.9% (111)	47.9% (23)	74.6% (88)	<0.001
Prosthesis type				0.12
Self-expandable	72.9% (121)	64.6% (31)	76.3% (90)	
Balloon expandable	27.1% (45)	35.4% (17)	23.7% (28)	
Post-dilatation	24.1% (40)	22.9% (11)	24.6% (29)	0.82
Device success	98.2% (163)	97.9% (47)	98.3% (116)	0.86
Procedural success	98.2% (163)	97.9% (47)	98.3% (116)	0.86
Paravalvular leak >2+	3.1% (5)	0% (0)	4.3% (4)	0.33
Procedural time (min)	105.6 ± 34.5	103 ± 30.6	106 ± 35.5	0.31
Implant deep				
<3 mm	55.8% (92)	39.6% (19)	62.4% (73)	0.007
3-6 mm	42.2% (68)	58.3% (28)	34.2% (40)	0.004
> 6 mm	3.0% (5)	2.1% (1)	3.4% (4)	0.65
Fluoroscopy time (min)	25.7 ± 11.3	24.3 ± 11.3	26.2 ± 11.4	0.46
Contrast media (ml)	110.4 ± 45.4	107.2 ± 46.2	112.9 ± 45.2	0.60

AIS, anesthetist in site; AOC, anesthetist on call.

Table 3. Procedural complications.

	Total (n=166)	AIS (n=48)	AOC (n=118)	p-value
Cardiac tamponade	0%	0%	0%	-
Conversion to open-chest surgery	0%	0%	0%	-
Cardiogenic shock	0%	0%	0%	-
AMI	0%	0%	0%	-
Coronary occlusion	0%	0%	0%	-
PCI	0%	0%	0%	-
CABG	0%	0%	0%	-
Aortic dissection	0%	0%	0%	-
Major vascular complications	3.6% (6)	4.2% (2)	3.4% (4)	0.80
Transfusion ≥2 units of blood	0.6% (1)	0%	0.8% (1)	0.65
Stroke/TIA	0%	0%	0%	-
Acute MR	0%	0%	0%	-
Procedural death	0%	0%	0%	-

Data shown as % (n) and as means ± (SD) or median and interquartile range.

AIS, anesthetist in site; AOC, anesthetist on call; AMI, acute myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; TIA, transient ischemic attack; MR, mitral regurgitation.

Table 4. Anesthetic management.

	Total (n=166)	AIS (n=48)	AOC (n=118)	p-value
Morphine use	49.4% (82)	33.3% (16)	55.9% (66)	0.008
Morphine (mg)	2.2 ± 1.0	2.8 ± 1.1	2.0 ± 0.9	0.006
Propofol use	0% (0)	0% (0)	0% (0)	-
Other major sedative	1.2% (2)	2.1% (1)	0.8% (1)	0.5
Painkillers use	8.4% (14)	20.8% (10)	3.4% (4)	<0.001
Inotropic drugs use	16.9% (28)	8.3% (4)	20.3% (24)	0.06

AIS, anesthetist in site; AOC, anesthetist on call.

(74.6% vs 47.9%;  $p < 0.001$ ). Fluoroscopy and procedural time and contrast media did not differ significantly among the 2 groups. Device and procedural success are high and similar between the 2 groups ( $p = 0.86$ ). Procedural complications were rarely and there were no significant differences among the 2 groups (Table 3). In AIS group, operators were less prone to use morphine respect AOC ( $p=0.008$ ) but with a higher dosage ( $2.8 \pm 1.1$  vs  $2.0 \pm 0.9$ ;  $p=0.006$  for the AIS and AOC, respectively). Otherwise, in AIS, anesthetist were more prone to use painkillers respect morphine (20.8% vs 3.4%;  $p < 0.001$  for the AIS and AOC, respectively) (Table 4).

**Conclusions.** Transfemoral TAVR procedures without presence an anesthetist in the cath lab are safety and efficacy.

## P72

### LOGISTICS AND OUTCOMES OF TRANSCATHETER AORTIC VALVE IMPLANTATION DURING THE COVID-19 PANDEMIC: EXPERIENCE FROM A LARGE VOLUME CENTER

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**Introduction.** The coronavirus disease 2019 (COVID-19) has caused a global pandemic, resulting in millions of deaths and in a dramatic burden

on health assistance. Hospitals worldwide had to apply remarkable modifications in their logistics to face such a tough challenge. Aortic stenosis (AS) is common and it affects patient groups particularly vulnerable to a poor outcome with COVID-19 infection. The purpose of this current study was to assess whether the logistics changes of our local transcatheter aortic valve implantation (TAVI) program during the COVID-19 pandemic affected procedural safety and effectiveness.

**Methods.** This is a retrospective, single-center analysis performed in a large volume TAVI center. During the COVID-19 pandemic our local TAVI program was not interrupted, but its logistics underwent several changes aimed at enhancing a more rapid patient discharge, minimizing hospital stay and reducing potential staff and patient exposure. Baseline characteristics, procedural and mid-term outcomes of patients undergoing TAVI with the implementation of the new logistics from March 15<sup>th</sup>, 2020 to July 2021 (COVID-19 period group) were compared with a control group of TAVI patients who underwent the procedure between February 2019 to March 14<sup>th</sup> 2020 (pre-COVID period group). TAVI device success, postprocedural complications and 30-day outcomes were defined according to the Valve Academic Research Consortium-2 (VARC-2).

**Results.** Data are presented up to April 2021. Of the 536 included patients, 227 (42.35%) underwent TAVI during the COVID-19 pandemic between March 15<sup>th</sup> 2020 and April 2021. This group was compared with the TAVI patients performed from February 2019 to March 14<sup>th</sup> 2020 ( $n=309$ , 57.65%). Patients had a median age and a STS Mortality of 81 (77- 85) years and 3.4 (2.2-5.6)%, respectively. During the COVID-19 pandemic, patients underwent pre-procedural CTA assessment in a higher percentage of cases compared to pre-pandemic period (97.4% vs. 92.6% for pandemic and pre-pandemic periods respectively,  $p<0.01$ ). As a corollary, times between pre-procedural CTA and TAVI [2 (1-4) vs. 7 (2-28),  $p<0.01$ ], and between admission day and TAVI [2 (1-3) vs 2 (1-4),  $p<0.01$ ] were shorter during the pandemic. The transfemoral approach was the preferred TAVI route during both periods taken into account ( $n=532$ , 99.3%). During hospitalization, no differences in all-cause death (3.1 vs. 3.2,  $p=0.92$ ), cardiovascular death (2.6 vs. 2.6,  $p=0.97$ ), any stroke (0.9 vs. 2.9,  $p=0.10$ ), myocardial infarction (MI) (0.0 vs. 0.6,  $p=0.23$ ), permanent pacemaker implantation (PPI) (7.5 vs. 10.4,  $p=0.26$ ), acute kidney injury (AKI) of grade 1 or 3 (2.6 vs. 3.9,  $p=0.43$ ; 4.4 vs 3.6,  $p=0.62$ ) were reported between pandemic and pre-pandemic periods. During COVID-19 pandemic, shorter postprocedural and total length of stay [2 (1-3) vs 2 (2-4) days,  $p<0.01$  and 4 (3-7) vs 5 (4-8) days respectively,  $p<0.01$ ] were reported. Thirty-day rates of overall mortality (4 vs. 4.5,  $p=0.75$ ) and major adverse cardiovascular events (4 vs. 6.1,  $p=0.26$ ) were similar between COVID-10 pandemic and pre-pandemic periods, respectively.

**Conclusion.** We want to include patients up to July 2021 when Italian government put the end of the COVID-19 emergency. So the results are partially presented and no conclusion are done.

## P73

### LEFT ATRIAL APPENDAGE CLOSURE DEVICE COMPLICATED BY LATE ONSET PERICARDIAL EFFUSION

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**Background.** Late-onset complications of left atrial appendage occlusion (LAAO) device procedure are anecdotal and there are no such complications reported in literature using Cardia Ultraseal (Cardia, Inc., Eagan, MN, USA).

**Case summary.** We report the case of a 74-year-old Caucasian man affected by paroxysmal atrial fibrillation with significant bleeding risk (familiar thrombocytopenia, macroscopic haematuria episodes during therapy with direct oral anticoagulants, HAS-BLED risk score: 4) and ischaemic risk as well (CHA<sub>2</sub>DS<sub>2</sub>-VASC score: 3). The patient was treated with LAAO device implantation for high bleeding risk. Subsequently, after 26 days from LAAO procedure, he was admitted to the emergency department for haematic cardiac tamponade. The patient was successfully treated with subxiphoid pericardiocentesis in the acute phase, unfortunately cardiac arrest occurred during the transfer to the referral hospital for urgent cardiac surgery. Permanent neurological damage was reported and the patient died on day 28.

**Discussion.** LAAO late-onset complications are very rare and the case presented is the first case described of late-onset pericardial effusion and tamponade secondary to the Cardia Ultraseal LAAO device implantation. We present a revision of the literature regarding the occurrence of similar adverse events and discuss the hypothetical mechanism of this major complication.