

Comunicazioni orali

ALL ABOUT ACUTE CORONARY SYNDROMES

C1

BIOMARKERS OF RESIDUAL RISK AND LONG-TERM PROGNOSIS IN MINOCA PATIENTS

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Background. Whether patients with myocardial infarction with non-obstructive coronary arteries (MINOCA) have better outcomes than patients with obstructive coronary artery (MICAD) disease remains controversial. The current study focuses on the cardiovascular residual risk at 1 month after acute coronary syndrome (ACS) and long-term prognosis of MINOCA patients.

Methods. We analyzed data of 1068 patients (74 MINOCA and 994 MICAD) admitted to our center for ACS who were enrolled in the PRATO-ACS Registry (ClinicalTrials.gov ID: NCT04087200) and underwent routine laboratory analyses 1 month after the index event. All patients had undergone early invasive strategy and received high intensity statins during hospitalization and at discharge. All-cause death and major adverse clinical events (MACE; including all cause death, myocardial infarction, stroke or congestive heart failure) within 3 years follow-up were registered. The association between 1 month biomarkers and outcome measures was evaluated with Cox proportional analysis expressed by hazard ratio (HR) and 95% confidence intervals (CI).

Results. MINOCA patients presented a better clinical risk profile (younger, more females, fewer prior vascular events and less myocardial damage) than MICAD. Lipid values show higher HDL cholesterol and lower triglycerides at baseline and 1-month evaluation (Table). There were no statistically significant differences between MINOCA and MICAD in the incidence of all-cause death (6.8% vs. 8.6%) and MACE (12.2% vs. 16.3%) at 3 years. However, there were different patterns of residual risk at 1 month associated with 3 year outcome for the two groups: triglycerides (HR 1.02; 95% CI 1.005-1.04, p=0.012) and hemoglobin (HR 0.29; 95% CI 0.1-0.78, p=0.014) for MINOCA and hs-CRP (HR 1.1; 95% CI 1.03-1.17, p=0.003), creatinine (HR 1.39; 95% CI 1.25-1.54, p=0.0001) and hemoglobin (HR 0.59; 95% CI 0.52-0.67, p=0.0001) for MICAD.

Conclusion. MINOCA and MICAD patients presented different residual risk profiles at 1 month follow up. Long-term prognosis is overall no better for MINOCA than MICAD patients. MINOCA patients appear to be a heterogeneous group that probably needs secondary prevention therapy that targets different parameters from routine cardiovascular risk reduction treatment.

	Laboratory variables at baseline			Laboratory variables at 1 month		
	MINOCA (n=74)	MICAD (n=994)	p-value	MINOCA (n=74)	MICAD (n=994)	p-value
Hemoglobin (mg/dl)	13.7 (12.7-14.7)	14.2 (13.2-15.3)	0.009	13.2 (12.3-14.1)	13.3 (12.2-14.4)	0.64
Creatinine (mg/dl)	0.89 (0.7-1.0)	0.99 (0.8-1.1)	0.01	0.8 (0.7-0.9)	0.9 (0.8-1.07)	0.0001
Creatinine clearance (ml/min)	68 (51-79)	66 (50-85)	0.97	69 (53-87)	67 (50-88)	0.51
Glycated hemoglobin (%)	5.8 (5.5-6.1)	5.9 (5.6-6.6)	0.05	6 (5.6-6.1)	6.2 (5.6-6.5)	0.13
hs-CRP (mg/l)	8 (1.6-9.1)	9.9 (1.9-9)	0.57	1.9 (0.8-4.0)	2.7 (1.3-6.1)	0.008
Total cholesterol (mg/dl)	197 (167-220)	188 (160-219)	0.35	154 (129-174)	140 (120-162)	0.001
LDL (mg/dl)	129 (103-154)	114 (97-141)	0.11	91.5 (73-108)	86 (69-102)	0.09
HDL (mg/dl)	49 (42-60)	43 (37-51)	0.0001	52 (43-59.5)	42 (36-49)	0.0001
Triglycerides (mg/dl)	104 (73-142)	117 (87-161)	0.06	95 (73-115)	108 (85-146)	0.0013

C2

PROGNOSTIC ROLE OF CORONARY ARTERY ECTASIA IN PATIENTS WITH NON-OBSTRUCTIVE CORONARY ARTERY DISEASE

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Introduction. Coronary artery ectasia (CAE) is not an innocent angiographic finding, being associated with the occurrence of adverse events in patients with non-obstructive coronary artery disease (NOCAD). However, previous studies focused on patients with CAE and ischemia or angina and no-obstructive coronary arteries (INOCA/ANOCA) and the relationship between CAE and myocardial infarction with NOCAD (MINOCA) has been poorly investigated. In our study we aimed at assessing differences in clinical, angiographic and prognostic features among patients with CAE and MINOCA vs INOCA/ANOCA presentation.

Methods. Patients with angiographic evidence of CAE and NOCAD were enrolled at the University Hospital of Parma between January 2013 and December 2022 and divided into two study groups according to MINOCA vs INOCA/ANOCA presentation. Clinical and quantitative coronary angiography information was recorded in each patient and the incidence of major adverse cardiovascular events (MACE) was assessed at follow-up.

Results. We enrolled a total of 97 patients, 49 (50.5%) with MINOCA and 48 (49.5%) with INOCA/ANOCA presentation. Patients with CAE and MINOCA had a higher frequency of inflammatory diseases (10 [20.4%] vs 3 [6.2%], p=0.041) and multivessel CAE (26 [53.1%] vs 15 [31.2%], p=0.030) along with a higher prevalence of TIMI flow <3 (23 [46.9%] vs 11 [22.9%], p=0.013) and thrombus in the dilated segment (11 [22.4%] vs 3 [6.2%], p=0.023) as compared to patients with CAE and INOCA/ANOCA. At a median follow-up of 38 [23; 65] months, patients with CAE and MINOCA had a significantly higher incidence of MACE compared to those with CAE and INOCA/ANOCA (8 [16.3%] vs 2 [4.2%], p=0.045), mainly driven by a higher rate of non-fatal MI (5 [10.2%] vs 0 [0.0%], p = 0.023) (Figure 1). Finally, comparison of the Kaplan-Meier curves by log-rank test showed that patients with CAE and MINOCA had also a lower MACE-free survival (p=0.026) compared to those with CAE and INOCA/ANOCA.

Conclusions. Among a cohort of patients with CAE and NOCAD, the presentation with MINOCA pinpoints a subgroup of patients with a worse outcome, maybe attributable to the higher inflammatory status and the more extensive CAE along with pro-coagulative features as compared to those with CAE and INOCA/ANOCA.

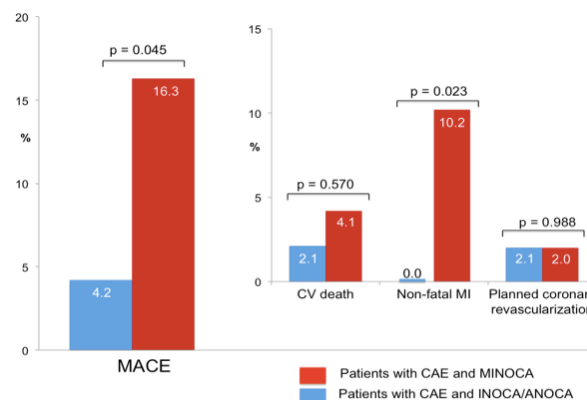


Figure 1. Clinical outcomes in the overall population according to ACS vs CCS presentation.

ANOCA, angina with no obstructive coronary atherosclerosis; CV, cardiovascular; INOCA, ischemia with no obstructive coronary atherosclerosis; MACE, major adverse cardiovascular events; MI, myocardial infarction; MINOCA, myocardial infarction with no obstructive coronary atherosclerosis.

C3

PROGNOSTIC SIGNIFICANCE OF THE SYNTAX SCORE AND SYNTAX SCORE II IN PATIENTS WITH MYOCARDIAL INFARCTION TREATED WITH PERCUTANEOUS CORONARY INTERVENTION

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Introduction. The role of SYNTAX score (SS) and SYNTAX score II (SS-II) in the prognostic stratification of patients presenting with myocardial infarction (MI) and undergoing percutaneous coronary intervention (PCI) has been poorly investigated. The aim of this study is to evaluate the prognostic significance of the SS and SS-II in a contemporary real-world cohort of MI patients treated with PCI.

Methods. This study included MI patients treated with PCI from January 2015 to April 2020 at the University Hospital of Salerno. Patients were divided into tertiles according to the baseline SS and SS-II values. The primary outcome measure was all-cause mortality at long-term follow-up; secondary outcome measures were cardiovascular (CV) death and MI.

Results. Overall, 915 patients were included in this study. Mean SS and SS-II were 16.1±10.0 and 31.6±11.5, respectively. At propensity weighting adjusted Cox regression analysis, both SS (HR 1.02; 95% CI 1.02-1.06) and SS-II (HR 1.08; 95% CI 1.07-1.10) were significantly associated with the risk of all-cause mortality at long-term follow-up; both SS and SS-II were significantly associated with the risk of CV death, but only SS-II showed a significant association with the risk of MI (Table 1). At 5 years, SS-II showed a significantly higher discriminative ability for all-cause mortality than SS (area under the curve: 0.82 vs 0.64; p<0.001) (Figure 1). SS-II was able to reclassify the risk of long-term mortality beyond the SS (net reclassification index 0.88; 95% CI 0.38-1.54; p=0.033).

Conclusions. In a real-world cohort of MI patients treated with PCI, SS-II was a stronger prognostic predictor of long-term mortality than SS.

Table 1. Unadjusted and adjusted Cox regression analysis for the primary and secondary outcome measures.

Adverse events	Score	HR	95% CI	p-value	p-value for interaction
Unadjusted					
All-cause death	SS	1.04	1.02-1.06	<0.001	<0.001
	SS-II	1.08	1.07-1.10	<0.001	<0.001
CV death	SS	1.06	1.04-1.08	<0.001	<0.001
	SS-II	1.09	1.07-1.11	<0.001	<0.001
MI	SS	1.03	1.01-1.05	0.011	0.033
	SS-II	1.04	1.02-1.06	<0.001	<0.001
Adjusted					
All-cause death	SS	1.02	1.00-1.04	0.017	<0.001
	SS-II	1.08	1.06-1.10	<0.001	<0.001
CV death	SS	1.04	1.02-1.06	<0.001	<0.001
	SS-II	1.08	1.06-1.10	<0.001	<0.001
MI	SS	1.01	0.99-1.03	0.297	<0.001
	SS-II	1.03	1.02-1.05	<0.001	0.014

CI, confidence interval; CV, cardiovascular; HR, hazard ratio; MI, myocardial infarction; SS, SYNTAX score; SS-II, SYNTAX score II.

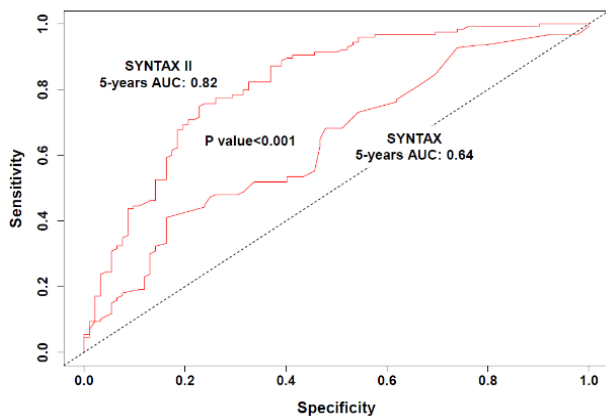


Figure 1. Receiving operator characteristic analysis with AUC values of the SYNTAX score; SS-II and SYNTAX score II for all-cause mortality at 5-year follow-up. AUC, area under the curve; SS, SYNTAX score; SS-II, SYNTAX score II.

C4

THE SALINE TECHNIQUE FOR THE TREATMENT OF NO-REFLOW PHENOMENON DURING PERCUTANEOUS CORONARY INTERVENTION IN STEMI

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Introduction. Primary percutaneous coronary intervention (pPCI) performed for STEMI may be complicated by the "no-reflow" phenomenon. A super-selective intracoronary injection of saline solution through a thrombus aspiration catheter (SALINE technique), was investigated for the treatment of no-reflow as compared with the standard care of therapy (SCT).

Methods. Among 1471 patients with STEMI undergoing pPCI, between May 2015 and June 2020, 168 patients developed no-reflow. Primary endpoints were incidence of ST-segment resolution (STR) >70% at 90 min after PCI and rate of flow restoration (TIMI flow grade 3 with a MBG >1). Secondary end point was the incidence of major adverse cardiac and cerebrovascular events at 3 years follow up.

Results. After propensity score matching analysis, patients treated with SALINE showed STR >70% in 12 out of the 16 patients (75.0%), while in only 3 patients out of the 16 of the SCT control group (19.0%) (p<0.004). SALINE was associated with a higher probability of final TIMI flow grade 3 with a MBG >1, as shown in 14 out of 16 patients (87.5%), as compared to only 7 out of 16 patients of SCT group (43.8%) (p<0.03). MACCE at 3-year follow-up occurred in only 1 patient (6.3%) in the SALINE group, as compared to 8 patients (50%) in the SCT group (p=0.047).

Conclusions. SALINE technique showed to be safe and effective strategy to reduce "no-reflow" in STEMI patients as assessed by significant STR, improvement of TIMI flow grade, and better 3-year outcomes.

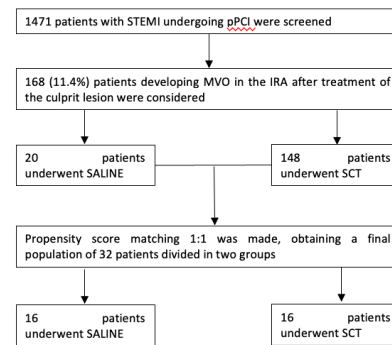


Figure 1. Population selection flow-chart.

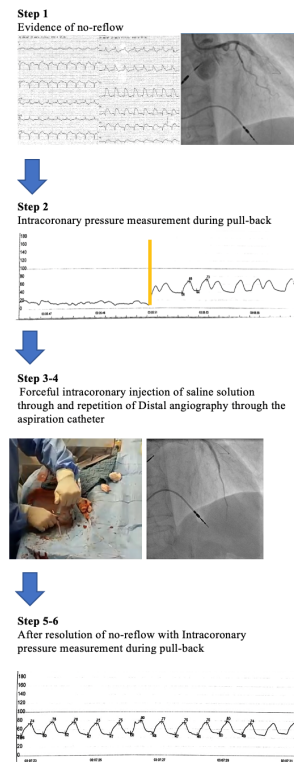


Figure 2. Stepwise flow-chart of a successful patient treated using SALINE.

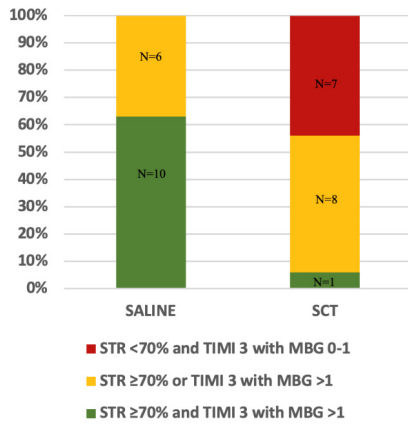


Figure 3. Myocardial reperfusion data as assessed by TIMI flow and STR according to the treatment group.

Table 1. Primary and secondary endpoints and clinical outcomes.

	(n=16)	(n=16)	value
STR ≥ 70%	12 (75.0%)	3 (18.8%)	0.004
Final TIMI flow 3 with MBG >1	14 (87.5%)	7 (43.8%)	0.023
Final TIMI flow 3 with MBG ≤1 or TIMI <3	2 (12.6%)	9 (56.3%)	-
Combined STR and angiographic MVO resolution	10 (62.5%)	1 (6.3%)	<0.001
LVEF at discharge, %	52.9 ± 8.8	55.8 ± 11.4	0.478
Hs-TnI (ng/L) peak	76.821±69.402 [IQR 29544, 86250]	79.989±78.261 [IQR 29932, 133549]	0.720
MACCE at 3 years	1 (6.3%)	8 (50.0%)	0.047
Cardiovascular Death	0	0	
MI	0	1 (6.3%)	
TLR	0	2 (12.5%)	
HF Hospitalization	1 (6.3%)	3 (18.8%)	
CVE	0	2 (12.5%)	
LVEF Δ* at 1 year	+6.8±8.5	+5.6±11.4	0.728
Any Bleeding	0	1 (6.3%)	-

*=considering difference between values at baseline and at 1-year follow-up.

C5 CLINICAL EFFECTIVENESS OF TICAGRELOR AND PRASUGREL COMPARED TO CLOPIDOGREL IN A REAL-WORLD COHORT OF ACS PATIENTS: INSIGHTS FROM THE PROSPECTIVE SPUM-ACS REGISTRY

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Introduction. While clearly demonstrated within randomized controlled trials, the real-life clinical efficacy of potent P2Y12 inhibitors (ticagrelor and prasugrel) over clopidogrel on top of aspirin in all-comer patients presenting with acute coronary syndrome (ACS) is still debated. The aim of this study was to evaluate cardiovascular as well as bleeding events stratified according to P2Y12 inhibitor treatment in a real-world cohort of ACS patients.

Methods. ACS patients admitted to four Swiss university hospitals and enrolled in the multicenter SPUM registry (NCT 01000701) between 2009 and 2017 were prospectively followed at 1 year. We compared the outcomes of patients treated with ticagrelor or prasugrel to those receiving clopidogrel, while all were on aspirin. The primary efficacy outcome observation was major adverse cardiac and cerebrovascular events (MACCE: stroke, myocardial infarction, cardiovascular (CV) death) at 1-

year, while the primary safety outcome observation was major bleeding, defined as BARC 3 to 5.

Results. Out of 4787 patients enrolled, 4488 patients (93.8%) were treated with a P2Y12 inhibitor and were included in the present analysis; among these 3047, (67.9%) received ticagrelor or prasugrel while the remaining 1441 (32.1%) were on clopidogrel. Patients receiving ticagrelor or prasugrel were more frequently younger and men (61.1±11.7 vs 68.2±12.4 and 83.1% vs 73.0%, p<0.001), had less traditional cardiovascular risk factors, except for smoking (42.2% vs 30.6%, p<0.001) and had an overall lower rate of comorbidities (all p<0.001) than those receiving clopidogrel. Among patients treated with potent P2Y12 inhibitors, ST-elevation myocardial infarction was a more frequent presentation (61.4% vs 40.2%, p<0.001) while high sensitivity-TnT as well as high sensitivity-CRP were lower in this group of patients (all p<0.001). At 1-year patients on ticagrelor or prasugrel had lower rate of MACCE (4.7% vs 12.3%, p<0.001), as well as CV-death (0.8% vs 6.4%, p<0.001) and cerebrovascular events (3.0% vs 1.0%, p<0.001) while the rate of non-fatal myocardial infarction (3.1% vs 3.9%) did not differ compared to those on clopidogrel. With respect to safety, a significant reduction in major bleeding (3.2% vs 7.0%, p<0.001). After adjustment for baseline confounding factors, patients on ticagrelor or prasugrel still presented a lower risk of MACCE (adjusted HR 0.60, 95% CI 0.45-0.79, p<0.001) and major bleeding (adjusted HR 0.67, 95%CI 0.52-0.67, p=0.002). In multivariate analysis, no difference in MACCE as well as major bleeding was observed between prasugrel and ticagrelor.

Conclusions. While statistical methods may not fully compensate for differences among treatment groups, this analysis support the concept of administering potent P2Y12 inhibitors over clopidogrel in at least 2/3 of all-comer patients presenting with ACS.

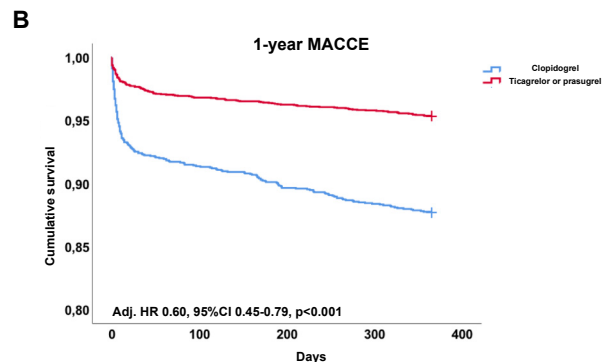
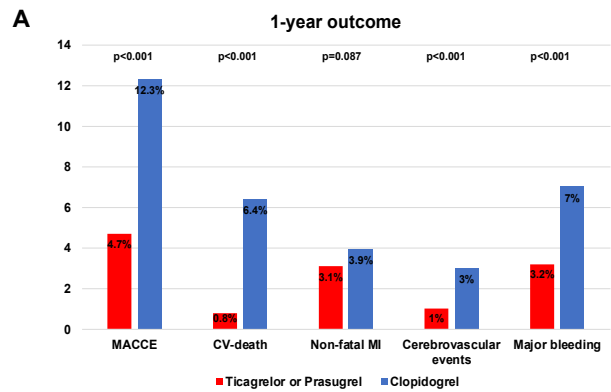


Figure. (A) The bar graph shows 1-year incidence of MACCE, each component of the composite endpoint and major bleeding BARC 3 to 5 in patients treated with ticagrelor or prasugrel compared with clopidogrel. (B) Cumulative survival between ACS patients treated with ticagrelor or prasugrel compared with clopidogrel.

C6 FAST-TRACK PCSK9I IN ACS: DATI A 6 MESI DELL'ESPERIENZA DI UN CENTRO AD ALTO VOLUME

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Introduction. The 2021 ESC guidelines for cardiovascular disease prevention in clinical practice recommend an LDL cholesterol treatment goal of a 50% reduction or <50 mg/dl for patients with ACS (and <40 mg/dl in those with recurrent events). The addition of more potent LDL-lowering therapy with proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9i) has shown a clinical benefit in patients with prior ACS

or atherosclerotic cardiovascular disease who have persistently high LDL cholesterol despite the use of statins. In these landmark trials, a PCSK9i was initiated after several months to years from the ACS event presentation and only in those patients with persistently elevated LDL despite high-dose statin therapy

Methods. To determine if strategy of PCSK9i administration as soon as possible (fast-track) followed by long-term therapy is translated into a reduction in major cardiovascular events we have considered many indicators, both clinical and procedural as age, familiarity, previous AMI, previous PCI, previous CABG, clinical presentation, BMI, smoke, hypertension, dyslipidemia, IDDM, EF, PCI-related culprit vessel, stent length and diameter. We analyzed results in 75 consecutive patients where PCSK9i were given less than 24 h from cardiac event on top of LLT with high intensity statins plus ezetimibe; patients were treated when basal LDL >140 mg/dl or multiple events regardless of LDL levels or in lipid-lowering therapy (LLT) not at target. Follow-up and data have been collected at 30 and 180 days.

Results. Results showed that in a population of 80% males, 57.4 years (range 27-79), with BMI 27.9 kg/m² (range 22.16-42.45) over 90% of patients were adherent to therapy; more than 90% had LDL levels at target, going down from 138.4 mg/dl pre- to 30.3 mg/dl at 30 days post-cardiac event, with 60% of patients discharged with EF improved (median from 43.9% pre- to 47.6% post PCI). Most remarkable finding was only one re-hospitalization for unstable angina in a in stent restenosis of an ostial circumflex in a double stent-treated distal left main PCI of 5 months before.

Conclusions. Sooner (in-hospital) and faster (less than 24 h from cardiac event) PCSK9i use resulted in a totally safe and effective (>90% LDL targets level reached) immediate reduction of more than 75% of LDL levels, with only one symptom-driven rehospitalization in a 6-month follow-up with very high adherence.

COMPLEXITY IN PCI: CALCIFIED LESIONS AND BIFURCATIONS

C7

ORBITAL ATHERECTOMY FOR THE TREATMENT OF SEVERELY CALCIFIED CORONARY LESIONS: A SINGLE-CENTER EXPERIENCE

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Introduction. The presence of heavy coronary artery calcification (CAC) represents a major challenge during percutaneous coronary intervention (PCI) and are associated with increased risk of angiographic complications and stent under-expansion. The use of orbital atherectomy (OAS) for adequate lesion preparation can help optimize the result of PCI in these complex lesions.

Methods. This is a prospective, single-center study. All consecutive patients treated with orbital atherectomy system were included.

Results. From April 2021 to May 2023, a total of 22 patients and a total of 23 lesions were treated. Median age was 72.2 ± 8.7 years and 36.4% of patients has diabetes. Lesion treated involved mainly LAD (81.8%) and medium length of the treated segment was 48.5 ± 17.8. Complex lesions involving left main (LM) and chronic total occlusions (CTOs) were treated in 9.1% and 13.6% of patients, respectively. The approach was 90.9% transradial and procedural success was obtained in all patients. No major procedural events occurred.

Conclusions. In this prospective, single-center study, the use of an orbital atherectomy device for the treatment of severely calcified coronary lesions was safe and associated with high procedural success rate and low early complications rates.

C8

PROGNOSTIC IMPACT OF HIGH BLEEDING RISK IN PATIENTS WITH CALCIFIED CORONARY ARTERY DISEASE UNDERGOING ROTATIONAL ATHERECTOMY PCI

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Introduction. Percutaneous coronary intervention (PCI) in calcified coronary artery lesions is associated with higher rate of cardiovascular adverse events and mortality. The aim of our study was to evaluate the prognostic impact of high bleeding risk (HBR) condition, as defined by the Academic Research Consortium (ARC) HBR criteria, on clinical outcomes in patients with complex calcified coronary artery disease undergoing PCI after lesion preparation using rotational atherectomy (RA).

Methods. In this observational retrospective study, all patients with calcified coronary artery disease undergoing RA-assisted PCI between 2011 and 2021 were included. According to ARC-HBR criteria, patients were considered at HBR if at least one major criterion or two minor criteria were met. The primary endpoint was the occurrence of major adverse cardiac and cerebrovascular events (MACCE) at 4 years defined as the composite of cardiovascular death, myocardial infarction, stroke and target vessel revascularization (TVR). Secondary endpoints were cardiovascular death, bleeding events and TVR.

Results. The final population consisted of 343 patients. Median follow-up was 39 months. Among patients, 198 (57.7%) met the HBR criteria while 145 (42.7%) did not. Patients with HBR criteria were older (78.21 vs 71.68; p<0.001), with lower GFR (ml/min/1.73 m²) (53.67 vs 77.51; p<0.001) and lower hemoglobin levels (Hb: g/dl; 11.93 vs 13.74; p<0.001) compared with patients without HBR. The rate of MACCE was significantly higher in patients at HBR compare with patients not at HBR (HR 1.86 [1.08-3.26]; p=0.026) mainly driven by an increased risk of cardiovascular death. No significant differences were found concerning the rates of TVR (HR 0.48 [0.21-1.04]; p=0.057), stroke (HR 7.7 [0.98-61.09], p=0.05) and MI (HR 2.2 [0.58-8.35], p=0.241) between the two groups. Bleedings were more frequent in patients at HBR (HR 12.31 [2.93-51.64]; p<0.001) compared to patients without HBR.

Conclusions. In patients with calcified coronary artery disease PCI, despite the use of dedicated tools for optimal lesion preparation such as RA, those at HBR still present higher risk of MACCE and cardiovascular death. Conversely, rates of TVR and MI were comparable, suggesting frailty and comorbidities as primary causes of worse outcomes in patients at HBR.

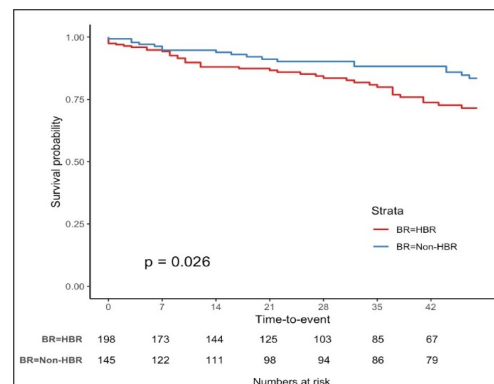


Figure 1. Incidence of the primary endpoint (all cause-death, cardiovascular death, myocardial infarction, stroke, target lesion failure (TLF) and target vessel revascularization (TVR), through 3.5 years of follow-up.

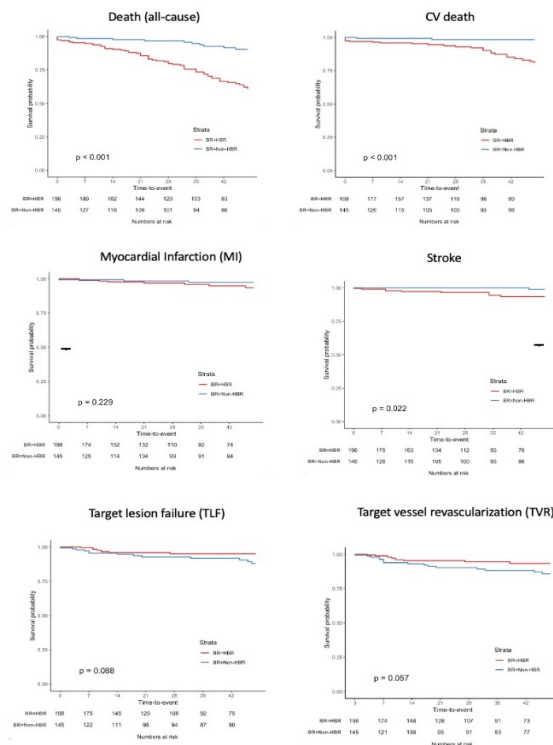


Figure 2. Rates of the components of the primary endpoint.

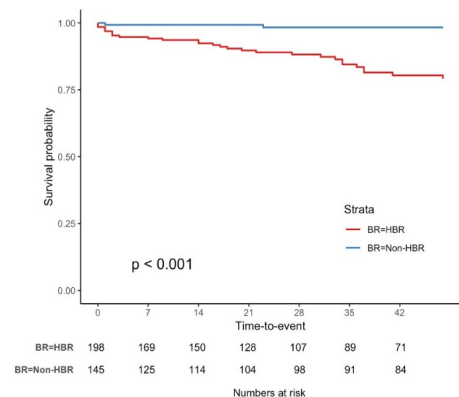


Figure 3. Incidence of bleeding among HBR and No-HBR patients.

C9

SHOULD WE BE CONCERNED ABOUT USING INTRAVASCULAR LITHOTRIPSY ON THE LEFT MAIN? INSIGHT FROM ROLLING STONE RETROSPECTIVE REGISTRY

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Introduction. Intravascular lithotripsy (IVL) is a promising, user-friendly and increasingly employed technique for calcific plaque modification before percutaneous coronary intervention. Although in many cath labs it is now routinely used to treat lesions of the three main coronary arteries, there are still concerns about its use in the left main (LM) due to prolonged inflations required for its efficacy.

Methods. We conducted a retrospective analysis using data from the multicenter Rolling Stone registry. Data from 474 patients were analyzed, stratifying for IVL procedures involving left main (46 patients) or not (428 patients). The primary effectiveness endpoints were procedural success (defined by residual stenosis <30% without angiographic or clinically relevant complications) and adverse in hospital outcomes (death, periprocedural myocardial infarction, stroke, contrast induced – acute kidney injury, pericardial drainage, stent thrombosis and ischemia target revascularization). The primary safety endpoints were death, ischemia-driven target lesion revascularization and stent thrombosis at one and six months from the index procedure.

Results. From April 2018 to January 2023 474 patients were treated by IVL. Most patients presented with calcific lesion requiring lithotripsy in non-left main segments, while IVL was performed on the left main artery in 46 patients. No significant differences were found on baseline characteristics between LM and non-LM group. IVL-LM lesion treatment was characterized by the use of larger IVL balloons (mean diameter 3.40 vs. 3.21, p=0.022) and by a more extensive use of IVUS to guide the procedure (63% vs 23.9%, p<0.001). There was a higher usage of hemodynamic support devices in procedures involving the left main artery (15.6% vs 3.2%, p=0.003). No significant differences were found in procedural success, in-hospital outcomes and 6 months outcomes.

Conclusions. The use of intravascular lithotripsy in the left main coronary artery is safe and leads to excellent outcomes, comparable to its use in other coronary branches.

C10

IMPACTUS LM-PCI (LONG TERM IMPACT OF IVUS GUIDED LM-PCI): STUDIO OSSERVAZIONALE, MULTICENTRICO

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Introduzione. La malattia coronarica che coinvolge il tronco comune si configura come un setting di patologia ad alto rischio in considerazione della grande quota parte di tessuto miocardico che è sotteso dalla vascolarizzazione di questo vaso. Recenti trial hanno dimostrato il ruolo, a medio termine, della rivascularizzazione percutanea del tronco comune, specialmente in pazienti con bassa ed intermedia complessità anatomica. In tal senso l'utilizzo dell'IVUS permette una maggiore accuratezza tecnica nell'angioplastica del tronco comune. I dati presenti in letteratura relativamente all'utilizzo dell'IVUS nell'angioplastica del tronco comune sono provenienti da piccoli trial randomizzati, sotto-analisi di trial randomizzati e per lo più studi osservazionali e metanalisi. Nonostante la presenza di una cospicua quota di dati in letteratura relativamente al ruolo dell'IVUS-guided PCI nel tronco comune, resta ancora incerto l'impatto a

lungo termine (>10 anni) di tale metodica. Il nostro studio, osservazionale, retrospettivo, multicentrico, internazionale, vuole valutare l'impatto a lungo termine su endpoint clinici maggiori dell'angioplastica del tronco comune guidata da IVUS, confrontata con angioplastica del tronco comune guidata dalla sola angiografia.

Metodi. Sono stati arruolati dal 1° Gennaio 2002 al 31 Dicembre 2015 un totale di 699 pazienti con malattia del tronco comune non protetto di cui: 214 pazienti (31%) sono stati sottoposti ad angioplastica IVUS-guidata e 485 pazienti (69%) sono stati sottoposti ad angioplastica angio-guidata. Le caratteristiche basali cliniche, angiografiche e procedurali dei pazienti sono riportate nella Tabella 1. L'endpoint primario dello studio era rappresentato dagli eventi cardiovascolari maggiori (MACE) ovvero un composito di morte cardiovascolare (CVD), target vessel myocardial infarction (TVMI) e target vessel revascularization (TVR). L'endpoint secondario era rappresentato invece da morte per tutte le cause.

Risultati. La durata media del follow-up è stata di 8.4 anni ed il follow-up massimo è stato di 19 anni. Durante l'intero periodo preso in esame si sono verificate 213 morti (38 nel gruppo IVUS, 175 nel gruppo angio-guidato), 256 MACE (49 nel gruppo IVUS, 207 nel gruppo angio) e 124 TVR (22 nel gruppo IVUS, 102 nel gruppo angio). Il tasso osservato di outcome clinici (non corretto) tra il gruppo IVUS-guidato ed il gruppo angio-guidato sono mostrati nelle Figure 1 e 2 e nella Tabella 2. Se confrontato con il gruppo angio-guidato, il gruppo IVUS-guidato è associato ad una mortalità per tutte le cause significativamente più bassa a 15 anni (HR 0.43 [0.30-0.62], p < 0.001) e ad un più basso tasso di MACE (HR 0.42 [0.30-0.58], p < 0.001). Tale dato risulta consistente anche valutando separatamente le procedure eseguite prima del 2010 e dopo il 2010 (Figura 3). Il tasso di eventi e le curve di sopravvivenza dopo la correzione con l'inverse-probability-treatment-weighting (IPTW) sono riportate nelle Figure 4 e 5 e nella Tabella 3. Da tale analisi è possibile notare come il gruppo IVUS-guidato è associato ad una mortalità più bassa a 15 anni (HR 0.34 [0.22-0.60], p < 0.001) e ad un più basso tasso di MACE (HR 0.44 [0.28-0.69], p < 0.001). Risulta inoltre più basso il tasso di TVR (HR 0.36 [0.19-0.71], p < 0.003) ma non sono presenti tra i due gruppi differenze statisticamente significative in termini di TVMI (HR 0.70 [0.23-2.12], p=0.53).

Conclusioni. IMPACTUS LM-PCI è lo studio con il follow up più lungo al mondo che vuole valutare l'impatto a lungo termine dell'angioplastica del tronco comune non protetto eseguita con guida IVUS, confrontata alla sola guida angiografica. È emerso che l'utilizzo dell'imaging intracoronarico è associato ad una riduzione significativa della morte per tutte le cause e degli eventi cardiovascolari maggiori.

Tabella 1. Caratteristiche basali dei due gruppi di pazienti.

Characteristics	IVUS (n = 214)	ANGIOGRAPHY (n = 485)	p value
Age	68	69.5	0.97
Male sex	154 (71.96)	350 (72.16)	0.956
Hypertension	136(63.2)	300 (62.25)	0.096
Hyperlipidemia	152(71.03)	285(61.69)	0.018
Diabetes mellitus	55(25.70)	108(23.38)	0.183
Smoker	104(48.60)	151(33.04)	< 0.001
Previous CABG	5(2.34)	38(7.93)	0.005
Admission Diagnosis			0.065
STEMI	44(20.56)	85(17.56)	
NSTEMI	54(25.23)	94(19.42)	
Unstable angina	44(20.56)	149(30.79)	
Stable angina	46(21.50)	102(21.07)	
Other	26(12.15)	54(11.16)	
ACS	141(66.51)	302(70.73)	0.276
Vessel disease			
Left main	209(98.58)	291(70.29)	< 0.001
LAD	184(86.79)	306(73.91)	< 0.001
Lcx	102(48.11)	234(56.52)	0.046
RCA	84(39.62)	127(30.68)	0.025
SYNTAX score			< 0.001
<18	31(14.90)	48(24.24)	
18-27	126(60.58)	74(37.37)	
>27	51(24.52)	76(38.38)	
Site of LM disease			< 0.001
Distal	18(8.41)	106(23.25)	
Mid	18(8.41)	68(14.91)	
Distal	176(82.24)	282(61.84)	
Medina class			< 0.001
1,1,1	38(19.39)	58(31.69)	
1,1,0	133(67.86)	66(36.07)	
1,0,0	1(0.51)	37(20.22)	
1,0,1	13(6.63)	14(7.65)	
0,1,1	1(0.51)	4(2.19)	
0,1,0	1(0.51)	0	
1,0,0	9(4.59)	4(2.19)	
Moderate or severe calcification	23(10.75)	56(17.50)	0.011
Side branch stenosis >70 %	52(25.37)	149(53.60)	< 0.001
LAD-Lcx angle > 70°	54(27.41)	24(42.11)	0.034
Kind of stent			< 0.001
BMS	5(2.34)	124(26.50)	
DES	208(97.20)	321(68.59)	
Bifurcation with LM	190(89.62)	274(63.28)	< 0.001
Bifurcation strategy			0.560
Provisional	159(78.33)	221(75.43)	
2-stent technique	39(19.21)	60(20.48)	
Kind of technique			< 0.001
T-stent	4(11.11)	16(69.57)	
Culotte	29(80.56)	6(26.09)	
Crush	3(8.33)	1(4.35)	
POT	202(95.28)	125(37.65)	< 0.001
FKT	187(89.90)	148(33.94)	< 0.001
FE < 35%	19(9.05)	52(17.16)	0.009
Kind of 1° stent on other vessel			< 0.001
BMS	3(2.16)	55(26.57)	
DES	127(91.37)	111(53.52)	
BVS	6(4.32)	10(4.83)	
Kind of 2° stent on other vessel			< 0.001
BMS	1(1.37)	30(50.85)	
DES	69(94.52)	24(40.68)	
BVS	2(2.74)	5(8.47)	

Tabella 2. Tasso di eventi osservato a 15 anni e HR relativamente ad outcome clinici tra gruppo IVUS e gruppo angio-guidato.

	TASSO EVENTI A 15 ANNI, n (%)		Unadjusted risk	
	IVUS (214)	ANGIOGRAFIA (485)	HR (95% CI)	P value
Morte per tutte le cause	38 (15.7%)	175 (31%)	0.43 [0.30-0.62]	<0.001
MACE (CVD, MI e TVR)	49 (22.8%)	207 (42.6%)	0.42 [0.30-0.58]	<0.001
CVD	19 (8.8%)	66 (13.6%)	0.55 [0.33-0.92]	0.025
MI	8 (3.7%)	39 (8%)	0.41 [0.19-0.89]	0.025
TVR	22 (10.2%)	102 (21%)	0.40 [0.25-0.64]	<0.001

Tabella 3. Adjusted HR a 15 anni relativamente ad outcomes clinici tra gruppo IVUS e gruppo angio-guidato.

Adjusted risk with the inverse probability weighting		
	HR (95% CI)	P value
Morte per tutte le cause	0.34 (0.22-0.60)	< 0.001
MACE (CVD, MI e TVR)	0.44 (0.28 - 0.69)	< 0.001
CVD	0.39 (0.18 - 0.83)	0.015
MI	0.70 (0.23 - 2.12)	0.532
TVR	0.36 (0.19 - 0.71)	0.003

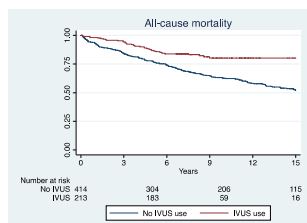


Figura 1. Curve Kaplan-Meier dell'evento morte per tutte le cause a 15 anni.

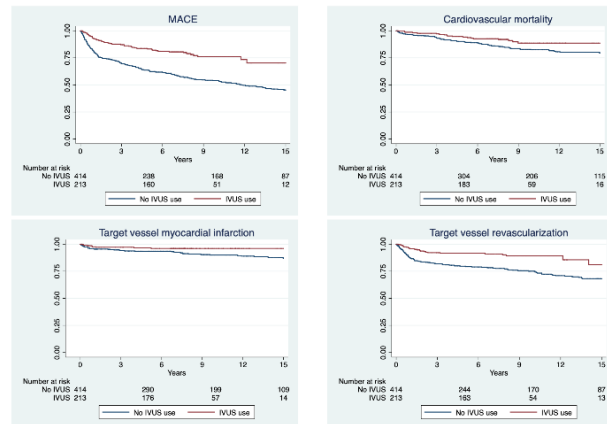


Figura 2. Curve Kaplan-Meier dei MACE e di CVD, TVMI e TVR a 15 anni.

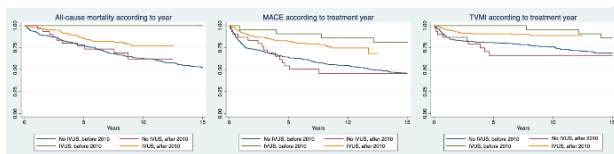


Figura 3. Curve Kaplan-Meier con stratificazione delle procedura eseguite prima e dopo il 2010.

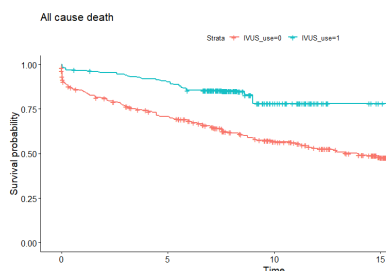


Figura 4. Curve Kaplan-Meier dell'evento morte per tutte le cause a 15 anni dopo IPTW.

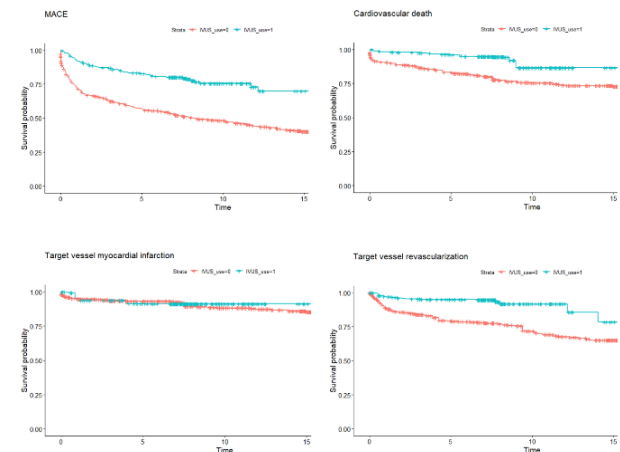


Figura 5. Curve Kaplan-Meier dei MACE e di CVD, TVMI e TVR a 15 anni dopo IPTW.

C11

LEFT MAIN BIFURCATION B ANGLE AND DEVELOPMENT OF SIGNIFICANT STENOSIS IN THE PROXIMAL LEFT ANTERIOR DESCENDING ARTERY: A MULTI-IMAGING MODALITY EVALUATION

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Introduction. A wider left main coronary bifurcation B angle (LMBA) is a predictor of severe plaque development in the proximal left anterior descending artery (LAD). Limited data are available comparing mean LMBA obtained from invasive coronary angiography (ICA) and coronary computed tomography angiography (CCTA). Yet diagnostic accuracy of CCTA in bifurcation angle analysis has not been compared with novel specialized bifurcation software, such as the three dimensional quantitative coronary angiography (3D-QCA).

Methods. Between March 2021 and March 2023, consecutive patients referred to CCTA underwent LMBA analysis, using 2D and 3D volume reconstructions. The type of plaque, its localization and the degree of lumen stenosis was assessed to determine the disease severity. In a subgroup of patients who underwent ICA, the LMBA was also analyzed using 3D-QCA software.

Results. Out of the 499 CCTA examined, mean LMBA was 84.7±31.9° (from 40° to 200°). In 160 (32%) patients, a severe proximal LAD stenosis was diagnosed. Plaque composition was soft in 113 (70%) cases and calcific in 47 (30%) cases. ICA was performed in 288 of the 499 (57.7%) patients. Severe proximal LAD stenosis was confirmed in 124 (43%) pts. PCI was performed in 110 (28%) cases, while 14 patients were referred to surgery due to significant distal LM disease. The mean LMBA, evaluated by 3D-QCA analysis, was 86.6±31.7 (from 43° to 205°). A strong and significant positive linear correlation (r=0.92, p<0.0001) was observed between the LMBA measurements obtained both from CCTA and 3D-QCA. The area under the curve (AUC) to predict significant proximal LAD disease was 0.835 (standard error: 0.024, 95% CI 0.788-0.882) for CCTA and 0.863 (standard error: 0.022, 95% CI 0.819-0.907) for 3D-QCA. The difference in the AUC values was -0.02817 (standard error: 0.00752, 95% CI -0.04291 to -0.01343, p=0.00018), suggesting a slightly higher predictive capability for 3D-QCA analysis in identifying proximal severe LAD disease compared to CCTA. In logistic regression analysis, LMBA (β= 0.02396, p=0.00569), diabetes mellitus (β= 1.21241, p=0.01524), and MLD (β= -2.49380, p<0.00001) were identified as independent predictors of significant stenosis of proximal LAD.

Conclusions. Our study found a strong positive correlation between LMBA measurements obtained by CCTA and 3D-QCA. However, 3DQCA had a slightly higher predictive ability for significant proximal LAD disease compared to CCTA. Routine assessment of the LMBA at CCTA could be useful for risk stratification and to optimize interventions in patients undergoing ICA.

C12**A RANDOMIZED CLINICAL STUDY COMPARING REVERSE T-STENTING AND MINIMAL PROTRUSION WITH EXTERNAL MINICRUSH FOR TREATMENT OF COMPLEX CORONARY BIFURCATION: STUDY DESIGN OF THE T-REX RANDOMIZED TRIAL**

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Background. Nowadays, no studies compare the Reverse-TAP and the External Minicrush in treating complex coronary bifurcation, so eventually procedural, clinical and safety differences remain unknown.

Methods. This study is a randomized, prospective, multicenter trial comparing long-term clinical outcomes of 361 consecutive patients with complex coronary bifurcation lesions according to DEFINITION criteria involving both left and non-left main coronary artery and randomized in a 1:1 ratio to Reverse-TAP and External Minicrush. Control coronary angiography at 12 months is planned, and clinical follow-up will be extended to 5 years. The primary endpoint is a composite of target lesion failure (TLF) (composite of all-cause death, non-fatal target-vessel myocardial infarction [TVMI], ischemia-driven target lesion revascularization [TLR] + definite or probable stent thrombosis [ST] + in-stent restenosis [ISR] >50% at coronary angiography at 12 months). Secondary endpoints are 1) a composite of cardiac death + TVMI + ST, and 2) a composite of cardiac death + TVMI + ST + TLR at 3 and 5 years.

Ethics and dissemination. The institutional review board will approve the study protocol at each participating institution, and written informed consent will be obtained from all patients. This study will be conducted according to the provisions of the Declaration of Helsinki and the International Conference on Harmonization of Good Clinical Practice.

Trial registration number. ClinicalTrials.gov NCT05782738.

THE DARK SIDE OF PCI**C13****DRUG-COATED BALLOON VERSUS DRUG-ELUTING STENT FOR TREATING DE NOVO LESIONS IN NON-SMALL VESSELS: A SYSTEMATIC REVIEW AND META-ANALYSIS OF 10 STUDIES INVOLVING 1504 PATIENTS**Rodolfo Caminiti¹, Giampaolo Vetta¹, Antonio Parlavacchio¹, Giampiero Vizzari¹, Alfonso Ielasi², Gianluca Di Bella¹, Scipione Careri¹, Antonio Micari¹

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Introduction. Drug-coated balloon (DCB) has been an attractive option in de novo vessels. A systematic review and meta-analysis were conducted to evaluate the efficacy and safety of DCB vs. drug-eluting stent (DES) for treating de novo lesions in non-small vessels.

Methods. We systematically searched Medline, Embase and Cochrane electronic databases up to February 7th, 2023, for studies that compared the efficacy and safety of DCB and DES for treating de novo lesions in non-small vessels (≥ 2.5 mm) reporting at least one clinical outcome of interest. The outcomes analysed were cardiovascular death (CVD), myocardial infarction (MI), target lesion revascularization (TLR) and late lumen loss (LLL) at follow-up. The effect size was estimated using a random-effect model as risk ratio (RR) and mean difference (MD) and relative 95% confidence interval (CI).

Results. A total of 10 studies (5 RCTs and 5 observational studies) with 1504 patients (DCB: 623; DES:881) were included in this meta-analysis following our inclusion criteria. DCB did not prove inferior to DES for CVD (RR 1.11; 95% CI [0.35-3.53]; $p = 0.86$), MI (RR 0.67; 95% CI [0.19-2.37]; $p=0.53$), TLR (RR 0.99; 95% CI [0.59-1.65]; $p=0.97$) and LLL (MD -0.15; 95% CI [-0.30-0.01]; $p = 0.07$) for de novo non-small coronary artery disease treatment.

Conclusions. Our metanalysis showed that DCB might provide a promising way on de novo non-small coronary artery disease compared to DES. However, more RCTs are still needed to further prove the benefits of the DCB strategy.

C14**TREATMENT OF IN-STENT RESTENOSIS WITH ULTRATHIN-STRUTS VERSUS THIN STRUTS DRUG-ELUTING STENTS OR DRUG-ELUTING BALLOON: A PROPENSITY MATCHED ANALYSIS (DRAGON-ULTRA REGISTRY)**Ovidio De Filippo¹, Wojciech Wantha², Federico Giacobbe³, Gianluca Campo⁴, Tineke Pinxterhuis⁵, Davide Francesco Capodanno⁶, Mario Iannaccone⁷, Attilio Leone⁸, Francesco Bruno⁹, Giuseppe Patti¹⁰, Giuseppe Musumeci¹¹, Roberto Verardi¹², Gaetano Liccardo¹³, Sergio Raposeiras Rubin¹⁴, Giuseppe Tarantini¹⁵, Leor Peri¹⁶, Andrea Gagnor¹⁷, Domenico Tuttolomondo¹⁸, Eline Ploumen¹⁹, Serena Caglioni²⁰, Antonio Greco⁶, Raffaele Piccolo⁸, Arianna Morena¹, Mauro Pennone¹, Federico Conrotto¹, Clemens Von Birgelen¹⁹, Mariusz Gasior²¹, Wojciech Wojakowski²², Gaetano Maria De Ferrari¹, Fabrizio D'Ascenzo¹

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Introduction. Data regarding the performance of ultrathin-struts drug-eluting stents (DES) in DES in-stent restenosis (ISR) are scant. We aimed to evaluate the efficacy and safety profile of ultrathin DES vs thin-strut DES or DEB in DES-ISR.

Methods. Patients treated for DES-ISR from the DEB-Dragon (NCT04415216) and ULTRA registries (NCT05205148) were allocated into three groups according to the device used for ISR treatment (ultrathin DES, thin-strut DES or DEB). Target-lesion revascularization (TLR) was the primary endpoint. Secondary endpoints included device-oriented composite endpoint (DOCE) a composite of cardiac death, TLR, and target vessel myocardial infarction (MI) (Incidences of the primary and secondary outcomes were appraised according to the kind of ISR (focal vs non-focal ISR) with cox multivariate analysis and with propensity score matching (PSM).

Results. 280, 530 and 557 patients treated with ultrathin DES, thin-strut DES or DEB were respectively included. After PSM, a non-significant different risk of TLR (4.1% vs 7.8%, $p=0.11$) was observed when comparing ultrathin-DES and thin-strut DES. Ultrathin DES were associated with a lower risk of TLR compared to matched patients treated with DEB (4.9% vs 13.2%, $p=0.003$). The three platforms were associated with similar outcomes among matched patients treated for focal ISR. Among patients with non-focal ISR, ultrathin DES were associated with a lower incidence of TLR (3.9% vs 9%, $p=0.04$), DOCE (7.9% vs 15.6%, $p=0.02$) and TVR (4.4% vs 12%, $p=0.007$) compared with the matched cohort of patients treated with thin-strut DES. Similarly, a lower incidence of TLR (4.8% vs 11.6%, $p=0.023$), TVR (5.3% vs 12.4%, $p=0.023$) and a trend towards lower incidence of DOCE (8.5% vs 14%, $p=0.07$) among those receiving ultrathin DES vs DEB for non-focal ISR was observed. These results were confirmed at Cox multivariate analysis.

Conclusions. The present analysis revealed similar long-term outcomes between ultrathin DES, thin-strut DES and DEB for focal in-stent restenosis. For non-focal ISR, ultrathin DES were associated with reduced risk of TLR either compared to thin-strut DES or to DEB.

Conclusions. The present analysis revealed similar long-term outcomes between ultrathin DES, thin-strut DES and DEB for focal in-stent restenosis. For non-focal ISR, ultrathin DES were associated with reduced risk of TLR either compared to thin-strut DES or to DEB.

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C15**RISK OF FULL METAL STENTING IN PATIENTS WITH MULTIVESSEL DISEASE UNDERGOING PERCUTANEOUS CORONARY REVASCULARIZATION (METALLICA)**

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Introduction. The optimal revascularization strategy for patients with multivessel disease and complex clinical conditions requires a multidisciplinary approach. The Heart Team is recommended as a valuable tool for improved patient management in this scenario. The aim of this study was to investigate the safety and efficacy of multivessel percutaneous coronary intervention (PCI) using current drug-eluting stents (DES) generation in patients scheduled for percutaneous revascularization after being turned down for surgery.

Methods. From 2020 to 2021, a total of 186 out of 447 patients with three-vessel disease, scheduled for a complex high-risk indicated procedure (CHIP) following formal discussions within our Heart Team,

were retrospectively collected. The primary endpoint was to assess the impact of such an extensive stent implantation on clinical outcomes in patients with high risk profile. Assessment of long-term outcome predictors, including revascularization completeness, constituted the secondary endpoint of this registry

Results. Among the study population, with a median follow-up of 757 days, 47 (25.3%) major adverse cardiac and cerebrovascular events (MACCE) occurred. The overall mortality was 16.1%, with 36 deaths (30 cardiac deaths and 6 non-cardiac deaths). The rate of peri-procedural myocardial infarction (PPMI) was 22.6%, and the rate of contrast-induced nephropathy (CIN) was 11.3%. The total stent length implanted did not significantly impact on the occurrence of MACCE (102 [52-138] mm vs. 101 [71-142] mm, $p=0.70$) and PPMI (114 [67-142] vs. 99 [66-142], $p=0.66$), but was associated with the occurrence of CIN (135 [97-190] mm vs. 99 [66-139] mm, $p=0.05$). In the multivariate analysis, the British Cardiovascular Intervention Society (BCIS) Jeopardy Score revascularization index $<70\%$ (HR 1.951 [95% CI 1.1-3.8], $p=0.046$), the presence of chronic obstructive pulmonary disease (HR 2.924 [95% CI 1.3-6.5], $p=0.008$), anemic status or bleeding history (HR 3.101 [95% CI 1.4-6.8], $p=0.005$), the use of left ventricular mechanical support (HR 3.376 [95% CI 1.6-7.3], $p=0.002$), and presentation as acute coronary syndrome (HR 2.192 [95% CI 1.1-4.6], $p=0.037$) were independent predictors of MACCE at follow-up.

Conclusions. In patients with three-vessel disease undergoing CHIP-PCI after being turned down for surgery, the revascularization incompleteness but not an extensive stent implantation was independently associated with the risk of MACCE at long-term follow-up. Further specific therapeutic strategies are warranted to improve outcome in patients undergoing CHIP-PCI and not receiving complete revascularization.

C16

MANAGEMENT OF SEPTAL HEMATOMA

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Rationale. Percutaneous coronary intervention (PCI) has undergone rapid evolution over the last years. PCI could be considered a safe and effective treatment for the majority of patients with coronary artery disease. Currently, approximately 30% of PCIs are considered complex PCIs. Complex PCIs are commonly associated with higher rate of complications, such as coronary perforation. Interventricular septal hematoma (IVSH) is a rare and potentially dangerous complication due to rupture of a septal perforator, generally occurring in retrograde chronic total occlusion PCI. We present an uncommon and life-threatening case of a large IVSH occurred as a result of perforation of septal collateral during a complex PCI on left descending coronary artery, managed by coils delivery.

Technical resolution. Urgent embolization with detachable coils has been performed using the block and deliver technique. The culprit vessel, which was the distal septal perforator, was successfully sealed with coils. However, contrast injection showed that another proximal collateral septal was still spilling into the cavity; it was probably due to rapid hematoma expansion involving proximal collateral septal. A prompt second coil embolization was repeated on proximal collateral septal arresting the growth of septal hematoma.

Clinical implications. IVSH is a rare and potentially life-threatening complication that can have a fatal outcome if not correctly managed. Most cases can be treated conservatively, but it can progress at any time to life-threatening consequences and need prompt sealing. In our case management using coils represented a very fast, safe and effective way to treat septal rupture avoiding significant complications due to hematoma expansion, such as obstructive cardiogenic shock or rupture of the ventricular septum. Sometimes, additional branches can feed the hematoma and need treatment to completely isolate the bleeding site, as in our case. Furthermore, the potential need of triple antithrombotic therapy in patients with IVSH, a recent stent implantation and strict indication for anticoagulation for atrial fibrillation poses a bigger challenge in the postprocedure management. Caution needs to be taken by close coronary care unit observation and serial imaging to detect its progression and the need for re-intervention.

Perspectives. The spread of complex PCI could lead to an increasing number of complications related to index procedure. Young interventional cardiologists have to be trained and have to be familiar with certain materials, such as coils: how they work, how to deliver them and their MC compatibility in order to successfully facing the unexpected, related to complex procedures.

C17

AGE AND VASODILATOR RESPONSE TO DIFFERENT HYPEREMIC AGENTS: ADENOSINE VERSUS CONTRAST MEDIUM

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Background. The influence of age on the vasodilatory response to different hyperaemic agents as well its influence on FFR and cFFR has not been previously explored.

Aims. To investigate the impact of age on these indices.

Methods. We extrapolated data from the PROPHET-FFR and MEMENTO studies. Only lesions with a relevant vasodilatory response to adenosine and contrast medium were considered of interest. A total of 2080 patients, accounting for 2294 pressure recordings were available for analysis. The cohort was stratified into three age terciles. Age-dependent correlations with FFR, cFFR, Pd/Pa and iFR were calculated. The vasodilatory response was calculated in 1619 lesions (with both FFR and cFFR) as the difference between resting and hyperaemic pressure ratios and correlated with ageing. The prevalence of FFR-cFFR discordance was assessed.

Results. Age correlated positively to FFR ($r=0.062$, $p=0.006$), but not with cFFR ($r=0.024$, $p=0.298$), Pd/Pa ($r=-0.015$, $p=0.481$) and iFR ($r=-0.026$, $p=0.648$). The hyperaemic response to adenosine ($r=-0.102$, $p<0.0001$) and to contrast medium ($r=-0.076$, $p=0.0023$) showed a negative correlation with age. When adjusted for potential confounders, adenosine induced hyperaemia was negatively associated with age ($p=0.04$ vs $p=0.08$ for cFFR). Discordance decreased across age terciles (14.64% vs 12.72% vs 10.12%, $p=0.032$).

Conclusions. As compared to adenosine, contrast induced hyperaemia appeared to be less affected by age. cFFR may be considered a more stable and reproducible tool to assess epicardial stenosis in elderly patients.

C18

PROGNOSTIC VALUE OF COMBINED FRACTIONAL FLOW RESERVE AND PRESSURE-BOUNDED CORONARY FLOW RESERVE

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Background. Coronary flow reserve (CFR) has an emerging role to predict outcome in patients with and without flow-limiting stenoses. However, the role of its surrogate pressure bounded-CFR (Pb-CFR) is controversial. We investigated the usefulness of combined use of fractional flow reserve (FFR) and Pb-CFR to predict outcomes.

Methods. This is a sub-study of the PROPHET-FFR trial, including patients with chronic coronary syndrome and functionally tested coronary lesions. Patients were divided into four groups based on positive or negative FFR (cut-off 0.80) and preserved (lower boundary ≥ 2) or reduced (upper boundary < 2) Pb-CFR: Group 1 FFR ≤ 0.80 / Pb-CFR < 2 ; Group 2 FFR ≤ 0.80 /Pb-CFR ≥ 2 ; Group 3 FFR > 0.80 /Pb-CFR < 2 ; Group 4 FFR > 0.80 /Pb-CFR ≥ 2 . Lesions with positive FFR were treated with PCI. Primary endpoint was the rate of major adverse cardiac events (MACEs), defined as a composite of death from any cause, myocardial infarction, target vessel revascularization, unplanned cardiac hospitalization at 36 months.

Results. A total of 609 patients and 816 lesions were available for the analysis. At Kaplan-Meier analysis MACEs rate was significantly different between groups (36.7% Group 1, 27.4% Group 2, 19.2% Group 3, 22.6% Group 4, $p=0.019$) and more prevalent in groups with FFR ≤ 0.80 irrespective of Pb-CFR. In case of discrepancy, no difference in MACE were observed between groups stratified by Pb-CFR. FFR ≤ 0.80 was associated with an increased MACE rate (30.2% vs 21.5%, $p<0.01$) while Pb-CFR < 2 was not (24.5% vs 24.2% Pb-CFR ≥ 2 $p=0.67$).

Conclusions. FFR confirms its ability to predict outcomes in patients with intermediate coronary stenoses. Pb-CFR does not add any relevant prognostic information.

MISCELLANEOUS

C19

IMPORTANCE OF MEHRAN SCORE IN PREDICTING ACUTE KIDNEY INJURY IN TAVI PATIENTS: A MULTICENTER COHORT STUDY

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Introduction. Transcatheter aortic valve implantation (TAVI) is an alternative to surgery for symptomatic patients with aortic stenosis (AS). An important complication of TAVI is acute kidney injury, which can develop after the procedure due to a variety of factors such as contrast agent administration, concomitant drugs, hypotension and renal hypoperfusion, blood loss, patient age, and postoperative severe inflammatory response syndrome, unlike in coronary intervention. The study aims to investigate if the Mehran score (MS) could be used to predict acute kidney injury (AKI) in TAVI patients.

Methods. This multicenter, retrospective, observational study included 1180 patients with severe AS. The MS is made of eight clinical and procedural variables: hypotension, congestive heart failure class, glomerular filtration rate, diabetes, age >75 years, anemia, need for intra-aortic balloon pump, and contrast agent volume use. We assessed the sensitivity and specificity of the MS in predicting AKI following TAVI, as well as the predictive value of MS with each AKI-related characteristic, with a particular focus on eGFR (Figure B e C).

Results. Based on their MS, patients were divided into four risk groups: low (5), moderate (6-10), high (11-15), and extremely high (16). In 139 patients (11.8%), post-procedural AKI was detected. In the multivariate analysis, MS classes had a greater risk of AKI (HR 1.38, 95% CI, 1.43-1.63, p 0.01). MS had the best cutoff for predicting the onset of AKI at 13.0 (AUC, 0.62; 95% CI, 0.57-0.67), whereas eGFR had the best cutoff at 42.0 mL/min/1.73 m² (AUC, 0.61; 95% CI, 0.56-0.67). MS was found to be a predictor of AKI development in TAVI patients.

Conclusions. MS has been demonstrated as a predictor of AKI development in the TAVI setting, and its use should be diffused in clinical practice in order to decrease the renal complications of TAVI or, at least, better manage their occurrence.

Table. Cox regression for AKI prediction in the univariate and multivariate analysis.

	AKI (Univariate Analysis)			AKI (Multivariate Analysis)		
	HR	95% CI	p value	HR	95% CI	p value
MEHRAN Classes	1.64	1.31-2.06	<0.01	1.36	1.23-1.63	<0.01
Age	1.02	0.99-1.05	0.15			
Diabetes	1.26	0.88-1.81	0.20			
NYHA	1.59	1.12-2.25	<0.01	1.27	0.86-1.88	0.23
eGFR CKD-EPI	1.48	1.27-1.74	<0.01	1.21	0.91-1.62	0.17
Hematocrit	0.96	0.94-1.01	0.06			
Contrast	1.00	0.99-1.01	0.37			

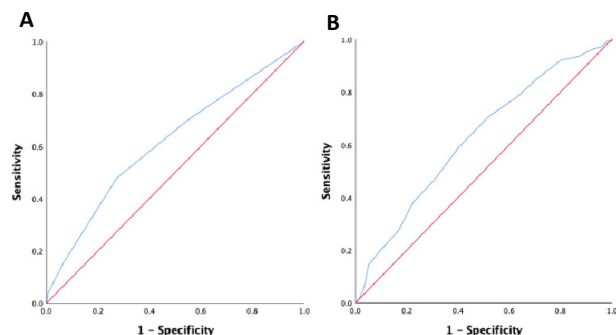


Figure. (A) ROC curve for the prediction of AKI using Mehran score. (B) ROC curves for the prediction of AKI using eGFR.

C20

SURGICAL MORTALITY RISK SCORES IN TAVI: IS THEIR EARLY PREDICTIVE VALUE STILL STRONG?

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Introduction. Transcatheter aortic valve implantation (TAVI) has recently spread as an attractive, less-invasive option than surgical replacement for high surgical risk patients with symptomatic aortic stenosis. According to the European Society of Cardiology, the calculation of some mortality risk scores should guide the heart team in the correct management of these patients; anyhow, such scores had been developed to assess the surgical operative risk and their predictive performance in interventional cardiology has been rarely tested in small groups. The aim of our study is to evaluate for the first time, if these surgical scores could realistically predict the composite endpoint early safety (ES), defined both with Valve Academic Research Consortium (VARC)-2 and VARC-3 criteria.

Methods. We enrolled 1763 consecutive patients (982 female, mean age 80.94±5.73 years) admitted for TAVI, all of them included in the multicentric "Magna Graecia" TAVI registry. Of the study population, 248 (14.07%) and 713 (40.44%) did not present VARC-2 and VARC-3 ES, respectively. Patients' population was retrospectively split according to the mortality risk thresholds of last European Society of Cardiology guidelines: low if logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE), EuroSCORE II and Society of Thoracic Surgeons predictive risk of mortality (STS-PROM) were <10%, <4% and <4% respectively, intermediate when between 10-20%, 4-8% and 4-8% respectively, and high if they were ≥20%, ≥8% and ≥8% respectively. All the adverse events and the ES were also re-adjudicated retrospectively, by an external committee, according to both VARC-2 and VARC-3 criteria.

Results. The patients who present VARC-2 ES had significantly lower absolute values of all the three surgical mortality risk scores (p<0.001) than those who did not; conversely, higher values of logistic EuroSCORE, EuroSCORE II and STS-PROM were not significantly correlated to the absence of VARC-3 ES (p=0.334, p=0.097 and p=0.177, respectively). Particularly, after splitting the population according to its surgical mortality risk profile, such significant correlation with the absence of VARC-2 ES was maintained only in low and high risk patients, rather than in intermediate risk ones (p=0.445 if logistic EuroSCORE 10-20%, p=0.130 if EuroSCORE II 4-8%, and p=0.276 if STS-PROM 4-8%). The receiver-operating characteristic (ROC) analysis also showed a significant correlation between these three scores and VARC-2 ES but, based on their area under the curve (AUC) values (≤0.595 for all), none had adequate diagnostic accuracy in predicting it. Importantly, ROC analysis was also performed to evaluate the correlations between the number of complications and 1-year mortality too: according to its new established cut-off value (1±0.062), even a single complication included in the composite endpoint ES could significantly affect 1-year mortality, with a sufficient predictive performance (AUC 0.646, 95% CI 0.624-0.669, sensitivity 53%, specificity 86%, asymptotic significance <0.001). Moreover, several baseline and procedural features were found to be associated with the absence of VARC-2 and VARC-3 ES at univariate logistic regression model: in spite of that, only postdilatation (OR 1.962; 95% CI 1.042 to 3.695, p=0.037) of any prosthesis implanted and new-onset atrial fibrillation/flutter (OR 3.220; 95% CI 1.536 to 6.750, p=0.002) have been identified as independent predictors of VARC-2 ES, whereas administration of low-osmolar contrast medium (OR 2.876; 95% CI 1.582 to 5.228, p=0.001) was identified as the only independent predictor of VARC-3 ES. In the end, among 1-year mortality predictors, the EuroSCORE II (OR 1.060; 95% CI 1.013 to 1.108, p=0.011), the use of self-expanding valves (OR 0.270; 95% CI 0.143 to 0.509, p<0.001), a new-onset atrial fibrillation/flutter (OR 2.558; 95% CI 1.213 to 5.392; p=0.014) and the absence of VARC-2 ES (OR 2.263; 95% CI 1.021 to 5.018, p=0.044) remained independently associated to this adverse event.

Conclusions. The worldwide extension of the indication for TAVI to patients with increasingly lower surgical risk makes risk stratification of paramount importance; unfortunately, currently available mortality risk scores are not properly designed for transcatheter interventions, in fact they have not demonstrated sufficient predictive performance in this setting. Our analysis confirms the inadequate diagnostic accuracy of these scores to predict VARC-2 ES, but also detect an even poorer diagnostic accuracy to predict VARC-3 ES. Interestingly, the several complications included in the composite endpoint ES have not additive effect to influence 1-year mortality, in fact only one of these complications is sufficient to determine TAVI patients' 1-year prognosis.

C21

RENAL DENERVATION IN PATIENTS WITH UNCONTROLLED HYPERTENSION AND MODERATE-TO-SEVERE CHRONIC KIDNEY DISEASE: IS IT A SAFE OPTION?

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Introduction. Hypertension is highly prevalent in patients with chronic kidney disease (CKD) and it is both a cause and a consequence of CKD. Reaching an optimal blood pressure (BP) control is particularly challenging in these patients, who have an estimated prevalence of uncontrolled hypertension of about 40% and might present contraindications to the administration of some antihypertensive classes. Catheter-based renal denervation (RDN) has been proposed as a safe and valid adjunctive therapeutic strategy for the treatment of hypertensive states not adequately controlled by lifestyle modifications and antihypertensive medications, but its safety in hypertensive patients with moderate-to-severe renal impairment is to date still under evaluation. Given the lack of large randomized controlled trials (RCTs) data, what is available comes mostly from small studies, although there is a growing body of clinical evidence which supports the safety and efficacy of RDN in this setting. Moreover, some preclinical and clinical research works suggest potential nephroprotective effects of RDN which go beyond the BP control. Our study aims to assess the safety of RDN in a population with uncontrolled, resistant essential hypertension (URH) and moderate-to-severe CKD (eGFR<45 ml/min/1.73m²), which is usually excluded from RCTs, in terms of eGFR variations at 36 months, compared with the expected eGFR trend according to the natural progression of CKD.

Methods. The study recruited patients with URH and stages IIIB-IV CKD (eGFR between 45 and 15 ml/min/1.73 m²), whose data were collected from the single center RDN registry of Verona University. Proposal for RDN was assessed in a multidisciplinary team involving cardiologists, nephrologists and hypertension specialists, after secondary forms of hypertension had been excluded and optimal medical therapy (OMT) had been administered. Serum creatinine levels were assessed at 24 and 48 hours after the procedure and then regularly monitored up to 36 months after RDN, as per internal protocols. Estimated GFR was calculated with CKD-EPI formula. The results were compared to the eGFR value that would have been expected in a population suffering from hypertension and CKD, which did not undergo RDN.

Results. From November 2012 to April 2023 23 patients with moderate-to-severe renal impairment (stages IIIB-IV CKD) and URH underwent RDN. Mean age at the time of the procedure was 63,43±13,69 years; 78,26% (n=18) were male. Average serum creatinine and CKD-EPI eGFR at baseline were 2,15±0,52 mg/dL and 31,61±7,73 ml/min/1,73 m², respectively. Average BP were 153,50±17,66/83,58±13,87 mmHg at the 24-hours monitoring (ABPM) and 154,36±16,99/84,32±15,52 mmHg at the office measurement (OBP). The study population showed a high prevalence of cardiovascular risk factors, in addition to hypertension: almost all were overweight (95,65%, n=22), with an average BMI of 31,32±5,35 kg/m², 60,87% (n=14) were diabetics, 47,83% (n=11) were smokers or former, 69,57% (n=16) had dyslipidemia. Average number of antihypertensive medications at baseline was 4,00±1,77. Renal denervation was performed with the Spyrax tetrapolar-radiofrequency ablation catheter in 82,61% (n=19); the first 4 patients were treated with the Flex catheter. The procedure was performed with deep conscious sedation to manage the pain and avoid excessive patient movement, using an average amount of contrast medium of 70,13±34,00 mL and with an average of 35,35±15,46 ablations delivered on the main renal arteries and on the main secondary branches with a minimum diameter of 3 mm. After the procedure adequate intravenous hydration was administered. During the hospital stay three patients experienced acute kidney injury, with subsequent full recovery. At three months follow-up we found an increase in eGFR of 4,47±7,44 ml/min/1,73 m² (p=0,03; n=13). At 6, 12, 24 and 36 months minimal and not statistically significant (p>0,05) eGFR variations were reported, of respectively +2,84±7,10 ml/min/1,73 m² (n=15), +2,46±12,06 ml/min/1,73 m² (n=14), -1,78±10,16 ml/min/1,73 m² (n=9), -1,36±19,09 ml/min/1,73 m² (n=5). Considering a reported age-related decline of between 1 and 2 ml/min/1,73 m² per year in hypertensive patients, the variations we reported are largely consistent with them and indeed they could suggest a slowdown in the eGFR decline.

Conclusions. Patients with moderate-to-severe CKD are at high cardiovascular risk and hypertension is often difficult to treat despite OMT, whereas some antihypertensive drugs are contraindicated in this population. In this setting, URH is particularly dangerous and accelerates the decline of renal function. Although renal denervation could be an adjunctive therapeutic weapon for these patients, they are usually excluded from trials because the safety has not been proven yet. Our single center experience showed that RDN is safe, and it does not cause renal function decline. In comparison to the expected loss of renal function, no significant changes in eGFR occurred during a 36-month follow-up. This study suggests that RDN can be safely and effectively performed also in CKD patients. Larger studies are needed to confirm those data and potentially extend indications for RDN.

C22

FATTIBILITÀ ED EFFICACIA DELLA DENERVAZIONE RENALE DOPO VALUTAZIONE FUNZIONALE E/O IVUS NEL PAZIENTE CON IPERTENSIONE ARTERIOSA NON CONTROLLATA E STENOSI DELLE ARTERIE RENALI

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Introduzione. L'ipertensione nefrovascolare è una delle più frequenti cause di ipertensione secondaria e ha una prevalenza del 5-10% nella popolazione ipertesa; la principale eziologia è l'aterosclerosi nefrovascolare ARVD (6.8%), potenzialmente responsabile di nefropatia cronica progressiva e conseguente aumento del rischio cardiovascolare. L'ecografia doppler con la valutazione della velocità di picco sistolico e dell'indice di resistività rappresentano l'esame diagnostico di primo livello nel caso di sospetto di ARVD, mentre l'angiografia renale ne rimane il gold standard. Le stenosi >70% sono definite di grado severo e con impatto emodinamico (per cui suscettibili di angioplastica ed impianto di stent), mentre per le stenosi moderate (50-70%), nelle quali l'impatto è ancora incerto, l'ecografia intravascolare (IVUS) e lo studio funzionale della lesione possono aiutare nella scelta dell'iter terapeutico tra denervazione delle arterie renali (RDN) ed angioplastica con impianto di stent (PTA).

Metodi. Dal 2015 ad ora presso il nostro centro sono stati valutati con tecnica IVUS e/o valutazione funzionale mediante rapporto Pd/Pa (parametro esprime il rapporto tra pressione media distalmente rispetto alla lesione e pressione aortica media) 17 pazienti con stenosi uni o bilaterale delle arterie renali di grado moderato all'angiografia. Pd/Pa. Un valore >0.9 di Pd/Pa escludeva la significatività emodinamica e consentiva di procedere a RDN dell'arteria renale in esame. Globalmente sono stati sottoposti a RDN bilateralmente 7 pazienti (41%), a RDN su un'arteria renale e PTA sulla controlaterale 1 paziente (6%), i restanti 9 pazienti (53%) a PTA. L'indicazione ad una o all'altra procedura era stata precedentemente discussa con il gruppo multidisciplinare (GITIAR) del nostro centro, comprendente anche colleghi specialisti della Nefrologia e della Medicina Interna specializzati nello studio e nel trattamento dell'ipertensione arteriosa.

Risultati. L'età media del campione sottoposto a RDN di almeno un'arteria renale era di 64 anni (48-81), il 75% (n=6) di sesso maschile. Il 100% dei pazienti era affetto da ipertensione arteriosa non controllata (numero medio di farmaci assunti= 5). La totalità dei pazienti era affetto da IRC, di cui il 25% (n=2) in trattamento dialitico, il rimanente 75% (n=6) presentavano IRC di stadio IIIB (CKD-EPI eGFR medio 42 ml/min/1.73 m²). Nel 37.5% dei casi (n=3) è stato eseguito uno studio IVUS, nel 37.5% (n=3) la valutazione con Pd/Pa e nel 25% (n=2) entrambe le metodiche. La procedura di RDN è stata praticata durante la stessa seduta, efficace nel 100% dei casi. Al ricontrollo ematochimico a 3 mesi, la funzionalità renale ha mostrato un trend in miglioramento, escludendo i pazienti in dialisi (eGFR CKD-EPI medio 49 ml/min/1.73 m²) con peggioramento del filtrato renale soltanto nel 12,5% dei casi (n=1). Al ricontrollo pressorio delle 24 h, sempre a tre mesi dalla procedura, sono stati riscontrati miglioramenti dei valori pressori sistolici e/o diastolici nel 87.5% dei casi (n=7), inoltre il 50% (n=4) sono rientrati nei limiti di norma. Il carico farmacologico è rimasto uguale in tutti i pazienti in esame.

Conclusioni. Nel paziente con ipertensione arteriosa non controllata ed ARVD angiograficamente moderata, senza severo impatto emodinamico alla valutazione IVUS e/o studio funzionale, la procedura di RDN nella maggioranza dei casi non determina a breve termine peggioramento della funzionalità renale e migliora il controllo dei valori pressori, determinandone il rientro entro i limiti di norma nella metà dei pazienti in esame.

C23

IMPACT OF RENAL DENERVATION ON BLOOD PRESSURE CONTROL IN A REAL POPULATION WITH MODERATE-TO-SEVERE CHRONIC KIDNEY DISEASE

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Introduction. Hypertension and chronic kidney disease (CKD) represent serious global health issues. They share pathophysiological mechanisms which lead to a vicious feedback loop in which they reinforce each other, leading to difficult-to-treat hypertension and accelerated renal function decline. Hypertension is present in about 80% of CKD patients, and its prevalence increases as estimated glomerular filtration rate (eGFR) declines. Blood pressure (BP) lowering has proven to drastically reduce the risk of cardiac events and death. Patients with CKD are typically characterized by sympathetic hyperactivity and renal denervation (RDN) has been proposed as an effective therapeutic option in addition to optimal medical therapy (OMT) in this population, in which it is often difficult to obtain an effective BP control. Only few studies investigated the

effects of RDN specifically in a CKD population and most of them were limited by a small sample size. Our study aims to evaluate the efficacy of catheter-based radiofrequency RDN on BP in patients with uncontrolled resistant hypertension (URH) and moderate-to-severe CKD, including dialysis patients.

Methods. Data on patients with moderate-to-severe CKD and URH were collected from our spontaneous, independent, single center registry of Verona University. Patient selection and proposal for RDN were assessed in multidisciplinary team meetings, involving cardiologists, nephrologists, and hypertension specialists, after secondary forms of hypertension had been excluded and OMT had been administered. Patients with eGFR below 45 mL/min/1.73m² (stages IIIB-V CKD) were selected for this analysis. Dialysis patients were included. Efficacy of RDN was assessed with ambulatory blood pressure measurements (ABPM) and office BP (OBP) at 3, 6, 12 months and then annually, as per internal protocols.

Results. From November 2012 to April 2023 34 patients with stages IIIB-V CKD and URH underwent RDN. Among them, 11 (32,35%) were dialysis patients. Mean age was 58,54±16,78 years; 79,41% (n=27) were male. Average BP were 154,91±17,66/85,55±13,87 mmHg and 154,50±20,04/86,83±14,19 mmHg at ABPM and OBP, respectively, for patients with stages IIIB-IV CKD, and 167,63±18,50/105,50±14,90 mmHg and 162,00±18,89/97,33±17,88 mmHg for dialysis patients. In the first group, average serum creatinine at the baseline was 2,15±0,52 mg/dL (average eGFR 31,61±7,63 mL/min/1,73m²). Three patients were possible transplant candidates, but the poor BP control contraindicated their proposal. The study population had a high prevalence of cardiovascular risk factors in addition to hypertension: 73,53% (n=25) were overweight (average BMI 28,23±7,54 kg/m²), 47,06% (n=16) had diabetes mellitus, 32,35% (n=11) were smokers (or formers), 61,76% (n=21) had dyslipidemia. 20,59% (n=7) suffered from coronary artery disease, 5,88% (n=2) experienced previous ictus or minor stroke, 44,12% (n=15) had peripheral arterial disease; 8,82% (n=3) had a diagnosis of obstructive sleep apnea syndrome. Average number of antihypertensive medications at baseline was 4,42±1,98. Renal denervation was performed with the Spyral tetrapolar-radiofrequency ablation catheter in 88,24% (n=30); the first 4 patients were treated with the Flex catheter. The procedure was performed with deep conscious sedation to manage the pain and avoid excessive patient movements. The average amount of contrast medium was of 71,71±32,86 ml; an average of 34,62±13,33 ablations were delivered on the main renal arteries and on the main secondary branches with a minimum diameter of 3 mm. After the procedure three patients experienced acute kidney injury, with subsequent full recovery. Follow-up data were available for 30/34 patients (two were lost at follow-up, two are on-going). In subjects with stages IIIB-IV CKD we found a significant systolic ABPM reduction at 12 months of -10,78±17,63 mmHg (p=0,05; n=9) which was maintained up to 36 months, with a reported systolic BP reduction of -12,20±11,17 mmHg (p=0,03; n=5). Diastolic BP values showed a trend towards a reduction, with a significant reduction of 5,00±4,89 mmHg (p=0,04; n=5) at 36 months. Dialysis patients reported similar results. At 24-months OBP a significant reduction in SBP was reported in both groups, respectively of -16,21±30,38 mmHg (p=0,03; n=14) for the first one and -52,3±10,96 mmHg for the dialysis subgroup (p=0,007; n=3). This trend was confirmed at 36 months, with a decrease in systolic OBP of -27,50±9,86 mmHg in IIIB-IV CKD patients (p=0,002; n=8). Three dialysis patients initially not eligible for kidney transplantation successfully underwent it after an acceptable BP control was obtained.

Conclusions. Hypertension and renal failure are strictly linked and reinforce each other. The increased sympathetic tone in CKD patients has been suggested as a rationale for expecting a good response to RDN, with benefits which might go beyond the BP control. However, moderate-to-severe renal failure is usually an exclusion criterion for the majority of randomized controlled trials (RCTs), so data on large populations are lacking. Our experience showed that RDN is safe and effective in moderate-to-severe CKD population in improving BP control. Larger studies are needed to confirm these findings.

C24

THE ROLE OF NEW ANTIDIABETIC DRUGS SUCH AS SODIUM-GLUCOSE COTRANSPORTER-2 INHIBITORS, GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS AND DIPEPTIDYL-PEPTIDASE-4 INHIBITORS, IN THE PREVENTION OF RENAL FAILURE AFTER PROGRAMMED PERCUTANEOUS CORONARY INTERVENTION

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Introduction. Contrast-induced acute kidney injury (CI-AKI) is a complication associated with high morbidity and mortality in patients undergoing percutaneous coronary intervention (PCI), significantly increased in patients with type-2 diabetes mellitus (T2DM). Several

randomized studies have shown a clear benefit of new antidiabetic drugs (NADs) such as sodium-glucose cotransporter-2 inhibitors (SGLT-2i), glucagon-like peptide-1 receptor agonists (GLP-1RA) and dipeptidyl-peptidase-4 inhibitors (DPP-4i), in the prevention of major adverse cardiovascular events (MACE) and renal failure. Despite this, no study has evaluated their efficacy in containing CI-AKI in elective PCI. The purpose of this study is to evaluate whether long-term treatment with NADs was associated with a lower incidence of CI-AKI compared with standard antidiabetic therapy (SAT) in patients with T2DM undergoing PCI.

Methods. In this single-centre, prospective study, we enrolled patients with T2DM on NADs (n=257) and SATs (metformin, sulphonylureas, thiazolidinediones, insulin) (n=298); we also included a control group consisting of non-diabetic patients undergoing PCI (n=252). Blood samples were collected before and at 24 and 48 hours after PCI in order to evaluate the incidence of CI-AKI, defined as a post-intervention increase in serum creatinine ≥ 0.3 mg/dl or $>25\%$ from baseline.

Results. We enrolled 807 patients undergoing PCI (mean age 69.7 ± 9.3 years; males 78.6%). No specific difference was detected in demographic and clinical variables among the three groups, including contrast medium amount. Considering the absolute pre and post-PCI creatinine values, a significant increase in creatinine peak was reported in the SAT group (p=0.004); otherwise, no significant rise was reported in NAD and controls (in this last group, even a slight drop in renal function was reported). The incidence of CI-AKI, defined as a percentage increase in serum creatinine $\geq 25\%$, was lower in NAD patients compared to the SAT group (6.2% vs 11.1%, p=0.045; p for trend=0.001) but higher than non-diabetic group despite non-statistical significance (6.2% vs 3.1%, p=0.104). Similarly, considering CI-AKI as an absolute increase in creatinine ≥ 0.3 mg/dl, the incidence was 7.4% in the SAT group, 5.4% in the NAD group (p=0.356 vs SAT) and 2.4% in the non-diabetic group (p=0.075 vs SAT) (p for trend=0.031).

Conclusions. The results of this study suggest that diabetic patients treated with NADs may benefit from a meaningful reduction in the incidence of CI-AKI after PCI compared with patients taking SAT. These findings may be explained by NAD's positive effects on inflammation and oxidative stress, factors that have been demonstrated to be involved in the CI-AKI pathophysiology. A larger sample of patients will allow outcomes to be analyzed for each NAD molecule to establish any protective role on procedural complications in patients undergoing PCI.

HEART AND BRAIN

C25

CHIUSURA PERCUTANEA DI AURICOLA SINISTRA IN "COR TRIARIATUM" MISCONOSCIUTO

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Introduzione. Il Cor triariatum è una rara anomalia congenita che è più comunemente descritta nei bambini con cardiopatie congenite. Tuttavia, le forme non restrittive hanno spesso decorso subclinico e possono essere riscontrate, incidentalmente, specialmente nei pazienti sottoposti a procedure interventistiche strutturali cardiache del cuore sinistro, come infatti riportiamo nel nostro caso di chiusura percutanea di auricola sinistra.

Metodi. Paziente maschio di 80 anni, malattia renale IV stadio, iperteso, affetto da fibrillazione atriale (FA) permanente in anticoagulazione con apixaban 2,5 mg. Portatore di ICD (defibrillatore cardiaco). Ripetute emorragie gastrointestinali, severa anemia e emorragie ed emotrasfusioni, alla colonscopia diverticolosi del colon trasverso/discendente e angioplasia. Interrotto apixaban 2,5 e posta indicazione a chiusura percutanea di auricola sinistra (LAAC). Il paziente ha eseguito ecocardiogramma transtoracico e transesofageo (ETE) preintervento con riscontro di membrana iperocogena nella porzione laterale dell'atrio sinistro estesa, in senso anteroposteriore e craniocaudale, fino alla prossimità del piano valvolare mitralico, con apparente discontinuità inferiormente alla vena polmonare superiore sinistra (VPSS). La membrana risultava invece integra nella sua porzione antistante l'ostio auricolare sinistro, l'auricola sinistra mostrava anatomia complessa con reverse chicken wing. È stata indicata TC cardiaca per lo studio della struttura riscontrata all'ETE con parere negativo dei nefrologi per elevato rischio di progressione dell'insufficienza renale.

Risultati. Si è quindi deciso di procedere alla procedura percutanea sotto guida ETE ed Rx-scopica. La puntura transtetale è stata eseguita agevolmente con tecnica standard mediante introduttore transtetale di Mullins 8F. Difficoltoso posizionamento di catetere guida curva singola in VPSS su guida stiff 0.035, per cui è stato necessario l'ausilio di catetere pigtail angolato 6F. Al passaggio in auricola sinistra si riscontrava notevole tensione sul catetere, causata verosimilmente dalla consistenza elastica della membrana atriale accessoria per cui la manovra è stata

ripetuta ripetutamente, infine l'inserimento di guida stiff 0.035, per aumentare la rigidità del sistema, ha reso possibile la manovra. È stata eseguita angiografia con conferma della anatomia auricolare chicken wing e importante trabecolatura diffusa a tutta l'auricola sino al segmento paraostiale (Figura 1), la contrastografia ha messo in evidenza la reale presenza di una camera atriale separata (camera vestibolare) comunicante con l'auricola sinistra e aperta supero-posteriormente verso la VPSS (verosimilmente fenestrata) e infero-anteriormente verso la valvola mitralica, ponendo così diagnosi di Cor triatriatum (Figura 2). Misurato l'ostio auricolare si è scelto di impiantare WATCHMAN FLX 31 mm, procedura avvenuta agevolmente e con buon sealing auricolare finale (Figura 3).

Conclusioni. Il caso è stato portato a compimento con successo ma ci ha posto di fronte una serie di difficoltà: difficoltà di accesso all'auricola per presenza di setto aggiunti; manovre in atrio sin limitate dalla presenza della membrana della camera vestibolare; ausilio della sola guida angiografica per la pessima finestra eco all'ETE, assenza di guida TC ed elevato rischio di somministrazione di mezzo di contrasto iodato a causa della malattia renale avanzata. In ultimo la principale sfida è stata approssiarsi alla chiusura di auricola sinistra direttamente, nell'impossibilità di discernere, prima della procedura interventistica, l'anomalia anatomica che ci si poneva davanti.

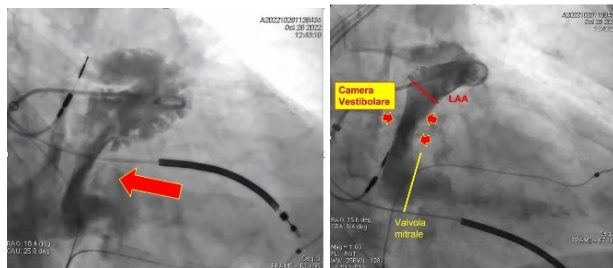


Figura 1.

Figura 2.

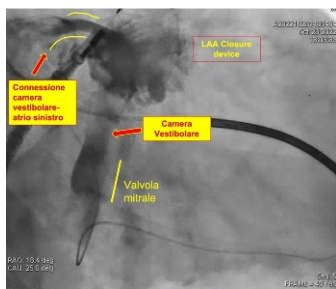


Figura 3.

C26

SAFETY AND EFFECTIVENESS OF CONCOMITANT MITRAL TRANSCATHETER EDGE-TO-EDGE REPAIR AND LEFT ATRIAL APPENDAGE CLOSURE

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Introduction. Concomitant mitral transcatheter edge to edge repair (M-TEER) and left atrial appendage closure (LAAC) showed to be a feasible approach to optimize the treatment of patients eligible to both the procedures, but mid-term outcomes are unclear.

Methods. We retrospectively analysed consecutive patients undergoing M-TEER and enrolled in the local prospective Getting Reduction of Mitral Insufficiency by Percutaneous Clip Implantation (GRASP) registry. We compared patients undergoing isolated M-TEER (n=58, 58.5%) with those undergoing concomitant M-TEER and LAAC (n=41, 41.5%) from January 2018 to December 2022. The primary endpoint was a composite of all cause death, stroke or systemic embolism, hospitalization for heart failure and bleeding at 1 year. The co-primary endpoint was procedural success.

Results. The primary endpoint was similar between patients undergoing concomitant M-TEER+LAAC or isolated M-TEER [Kaplan-Meier (KM) estimates 36.6% vs. 44.8%; p log-rank =0.75]. Procedural success was also similar (92.7% vs. 94.8%; p=0.69). At 1-year, minor bleeds were lower in patients undergoing concomitant M-TEER and LAAC (KM estimates 0.0% vs. 18.9%; p log-rank <0.01).

Conclusions. In patients with concomitant MR and AF and eligible for M-TEER and LAAC treatment, a combined approach of M-TEER and LAAC was as safe as a M-TEER alone strategy and associated with lower minor bleeding at 1 year.

C27

AN ITALIAN EXPERIENCE ON THE USE OF CEREBRAL EMBOLIC PROTECTION DURING TAVI – THE VERAN REGISTRY

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Introduction. Although in the context of transcatheter aortic valve implantation (TAVI) technological improvements, technique advances and increased operator experience have led to progressive reduction in most complications, periprocedural neurologic event (stroke and transient ischemic attack -TIA-) continues to occur in up to 2% of patients. Many of these derive from embolic events during the procedure and can lead to potentially devastating consequences. Cerebral Embolic Protection (CEP) devices have been developed to mitigate this risk. In particular, the Sentinel CEP (Boston Scientific), approved by the FDA, is indicated for use as an embolic protection device to capture and remove thrombus/debris while performing TAVI procedures, when the diameters of the arteries at the site of filter placement are adequate. Data regarding the clinical efficacy of this device in preventing neurologic events are conflicting. The aim of the present study is to investigate the impact of CEP on neurologic events in TAVI patients.

Methods. This is a multicentric retrospective observational case-control study performed to evaluate the rate of periprocedural neurologic event in patients undergoing transfemoral TAVI with or without using Sentinel CEP during the procedure. Patients were consecutively enrolled between January 2018 and December 2021 by two tertiary centers (Verona and Ancona). The primary endpoint was a composite of periprocedural all-cause death and neurologic events according to Valve Academic Research Consortium-3 (VARC-3) classification. The secondary endpoint was a composite of in-hospital major bleeding and major vascular complication according to VARC-3 classification. Considering the retrospective design of the study, a propensity score matching analysis was performed to account for differences in the baseline characteristics of patients in the two enrolling centers (variables: sex, age, hypertension, diabetes, atrial fibrillation, previous stroke, EuroSCORE II, glomerular filtration rate and left ventricular ejection fraction). The overall population (n=1042) included patients underwent TAVI without (No-CEP, n=581) and with CEP (CEP, n=461). After propensity score matching, the final cohort amounted at 794 patients (No-CEP= 397 patients vs. CEP= 397 patients). The 30-day follow-up was available for 781 patients overall (drop-out rate 1,4%).

Results. The primary endpoint occurred in 27 (3,4%) patients (No-CEP: 12 [3,0%] vs. CEP: 15 [3,8%], p=0,696). In particular: periprocedural death occurred in 13 (1,6%) patients (4 [1,0%] vs. 9 [2,3%], p=0,263), while periprocedural neurologic events occurred in 14 (1,8%) patients (8 [2,0%] vs. 6 [1,5%], p=0,789) (Figure 1). The secondary endpoint was observed in 36 (4,5%) patients (22 [5,5%] vs. 14 [3,5%], p=0,232). Among these, 12 (1,5%) patients suffered from major vascular complication (8 [2,0%] vs. 4 [1,0%], p=0,384). Multiple logistic regression analysis showed that previous stroke (OR, 3,349; 95% CI, 1,333–9,147; p=0,011) and the unsuccessful valve implantation (OR, 6,269; 95% CI, 1,339–29,358; p=0,020) were associated with the primary endpoint after TAVI, while CEP and valve type were not.

Conclusion. This is the first, multicentre, real-life experience on the use of CEP during transfemoral TAVI. The study suggests that using Sentinel CEP in this setting is safe and does not increase in-hospital major bleeding and vascular complications. However, its use does not reduce the rate of periprocedural death and neurologic events.

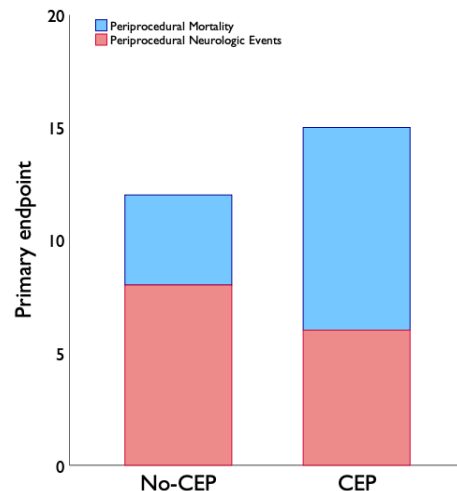


Figure 1. The primary endpoint in CEP and no-CEP patients (p=0,696).

C28

IMPACT AND TIMING OF ELECTIVE PERCUTANEOUS CORONARY INTERVENTION IN PATIENTS UNDERGOING TRANSCATHETER AORTIC VALVE INTERVENTION

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Introduction. Coronary artery disease (CAD) has been shown to coexist in up two-thirds of patients with aortic stenosis (AS), most likely because of overlapping risk factors. Percutaneous coronary intervention (PCI) in the presence of severe AS is not without risk and its potential benefits are far to be demonstrated. Consequently, there is currently insufficient evidence regarding the role of PCI in patients undergoing transcatheter aortic valve implantation (TAVI) to inform guideline recommendations and clinical practice. The optimal timing of PCI in relation to TAVI remains unclear too. Therefore, this study aimed to evaluate patient and procedural characteristics as well as clinical outcomes of patients who underwent elective PCI before or concomitant with TAVI.

Methods. We enrolled 350 patients who underwent TAVI at our center from 2018 to 2022 and were prospectively followed for one year after the procedure. Elective PCI of significant stenosis located at proximal segment of main epicardial vessels was performed before or concomitant with TAVI.

Results. Overall, 57 patients (16.3%) received PCI: 40 before and 17 concomitant with TAVI. PCI did not impact mortality but was associated with increased risk of bleeding, vascular complications and all-cause rehospitalization, irrespectively of timing. However, at linear regression analysis, concomitant but not staged PCI was a predictor of bleeding events (HR: 2.77, p=0.0047).

Conclusions. In our study, elective PCI in patients undergoing TAVI did not affect mortality at one-year but was associated with higher risk of bleeding and vascular complications. Specifically, concomitant PCI was a predictor of bleeding events with a two-fold increased risk. Conversely, staged PCI before TAVI did not predict bleedings. Our findings could help to define the optimal timing to perform PCI in TAVI patients with chronic coronary syndrome.

C29

ATRIAL FIBRILLATION IN TAVI PATIENTS: SHORT- AND LONG-TERM OUTCOMES

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Introduction. Patients with atrial fibrillation (AF) undergoing transcatheter aortic valve implantation (TAVI) have been associated with worse short-term outcomes compared to patients in sinus rhythm but data on long-term outcomes are limited. The aim of our study was to evaluate the association between AF and short- and long-term outcomes in patients undergoing TAVI.

Methods. We retrospectively evaluated patients undergoing TAVI between 2012 and 2022 in 4 tertiary centres. Two different analyses were conducted: (i) in-hospital and post-discharge analysis. First, we evaluated the association between pre-existing AF and short-term outcomes according to VARC-3 criteria. Second, we analyzed the association between AF at discharge (defined as both pre-existing and new-onset AF occurring after TAVI) and long-term outcomes (i.e. all-cause death, hospitalization and major adverse cardiovascular events).

Results. A total of 759 patients were initially categorized according to the presence of pre-existing AF (241 vs 518 patients). The pre-existing AF group had higher occurrence of acute kidney injury (OR 1.87; 95% CI 1.10-3.11) and major bleeding (OR 1.83, 95% CI 1.03-3.23). Subsequently, the population was categorized according to the presence of AF at discharge. At the adjusted Cox regression analysis, AF was independently associated with an increased risk of all-cause death and CV hospitalization (aHR 1.42, 95% CI 1.09-1.86), all-cause death and all-cause hospitalization (aHR 1.38, 95% CI 1.06-1.78) and all-cause hospitalization (aHR 1.59, 95% CI 1.14-2.22).

Conclusions. In a real-world cohort of patients undergoing TAVI, the presence of AF (pre-existing and new onset) was independently associated with both short- and long-term adverse outcomes.

Table 1. Primary and secondary in-hospital outcomes.

Primary in-hospital outcome	Unadjusted Analysis			Adjusted Analysis*		
	OR	95% CI	p	aOR	95% CI	p
Any VARC						
Pre-existing AF (vs. No AF history)	0.84	0.61-1.14	0.26	0.86	0.62-1.18	0.35
Secondary in-hospital outcomes						
AKI						
Pre-existing AF (vs. No AF history)	1.65	1.15-2.38	<0.01	1.65	1.13-2.41	<0.01
Major Bleeding						
Pre-existing AF (vs. No AF history)	1.86	1.06-3.27	0.03	1.77	0.99-1.13	0.05

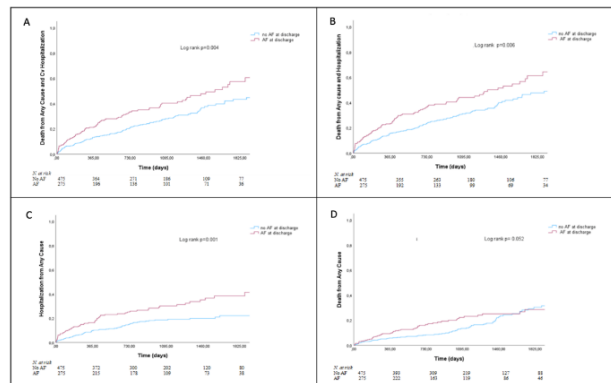


Figure 1. Kaplan-Meier curves for the primary and secondary long-term outcomes according to the presence of AF at discharge.

C30

HYPOATTENUATED THICKENING LESIONS FOLLOWING TRANSCATHETER AORTIC VALVE REPLACEMENT

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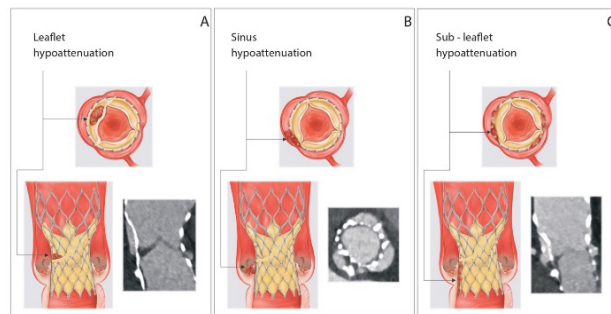
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Introduction. Subclinical leaflets thrombosis is a condition diagnosed with multi-detector computer tomography (MDCT) characterized by a meniscal-shaped hypoattenuated lesion of one or more leaflets. Transcatheter aortic self-expandable valves are commonly manufactured with pliable pericardium over a nitinol frame that forms the leaflets and the extra-leaflets components, such as the valve skirt. Little is known about extra-leaflets hypoattenuated lesions localization, including the anatomic sinus level.

Methods. This was an ambi-directional study. Fifty patients underwent MDCT at follow-up.

Results. At mean follow-up was of 12 months, hypoattenuated leaflet lesion with mild to severe restricted movement was detected in 8 individuals (16%); anatomic sinus lesion was identified in 9 patients (18%) with higher prevalence in the non-coronary sinus (16%); subvalvular lesion with a variable extension toward the valve inflow, was diagnosed in 8 patients (16%). In 4 patients (8%) the anatomic sinus thrombus was 'in overlap' with the leaflet thrombus; in 3 patients (6%) was in continuity with the subvalvular frame thrombus. Bicuspid valve was the only independent predictor associated with hypoattenuated lesions (adj OR 8.25 [95% CI: 1.38, 49.21], p=0.02).

Conclusions. This study demonstrated that hypoattenuated lesions could be identified not only at leaflet, but also at subvalvular and anatomic sinus level. The clinical relevance of such lesions remains uncertain.



TAVI TECHNICALITIES

C31

STENT FRAME DECOUPLING FOLLOWING SELF-EXPANDABLE TRANSCATHETER AORTIC VALVE REPLACEMENT

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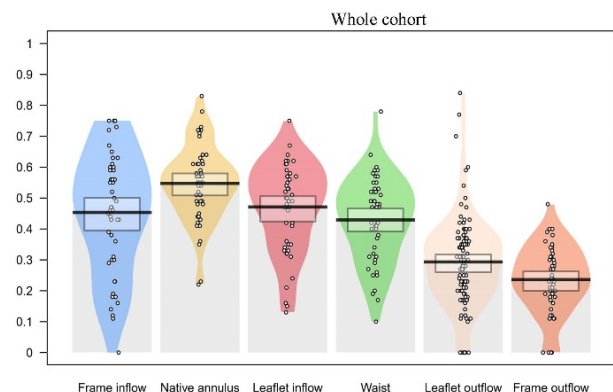
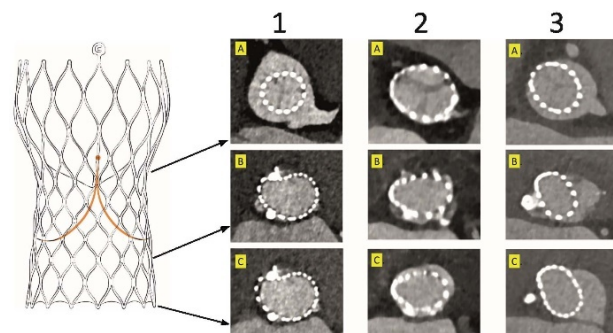
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Introduction. Transcatheter heart valve (THV) deformation may affect leaflet kinematics and coaptation, with potential formation of hypoattenuated leaflet thickening (HALT). The flexible nitinol frame of the self-expandable THV, conforms to the native annulus shape while maintaining the prosthesis in a higher position. This arrangement is called stent-frame 'decoupling' and should minimize the impact of ellipticity at the valve level post-deployment.

Methods. We analysed multi detector computer tomography scan and 2D transthoracic echocardiography from 50 patients. Prosthesis eccentricity was computed at 6 levels: i) frame inflow; ii) native annulus; iii) leaflets inflow; iv) prosthesis waist; v) leaflets outflow; vi) frame outflow. Implantation depth and canting, leaflets expansion and alignment and residual anatomic sinus area ratio were also calculated. Frame inflow and native annulus eccentricity were compared to the valvular eccentricity to assess 'decoupling'.

Results. Highest eccentricity was observed at the native annulus (0.54±0.12) and progressively decreases toward the outflow level (0.23±0.11). Subvalvular eccentricity was significantly higher as compared with valvular components (0.50±0.13 vs. 0.37±0.09, p<0.001). Similar results were observed in the subgroup analysis of 23, 26, 29 and 34 size. At 12-month follow-up, HALT with mild to severe restricted movement was detected in 8 individuals (16%). There was no correlation between implantation depth and prosthesis eccentricity (r= -0.08, p=0.128).

Conclusions. Stent frame decoupling can be frequently detected after (THV) replacement with Evolut R. The effect on valve performance and clinical implications remains uncertain.



C32

ONE-YEAR CLINICAL OUTCOMES OF TRANSCATHETER AORTIC VALVE IMPLANTATION WITH THE LATEST-ITERATION SELF-EXPANDING OR BALLOON-EXPANDABLE DEVICES: INSIGHTS FROM THE OPERA-TAVI REGISTRY

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Introduction. Despite have been entered the market since different years, mid-term comparative analyses of the latest iterations of Evolut and Sapien platforms for transcatheter aortic valve implantation (TAVI) are lacking. The aim of the study was to compare 1-year clinical outcomes of TAVI patients receiving Evolut PRO/PRO+ (PRO) or Sapien 3 ULTRA (ULTRA) devices in the current real-world practice.

Methods. Among patients enrolled in the OPERA-TAVI registry, a total of 1897 patients with complete 1-year follow-up were considered for the purpose of this analysis. One-to-one propensity score matching was used to compare TAVI patients receiving PRO or ULTRA devices. The primary endpoint was a composite of 1-year all-cause death, disabling stroke and re-hospitalization for heart failure. Five pre-specified subgroups of patients were considered according to leaflets and left ventricle outflow tract calcifications, annulus dimensions and angulation, and leaflets morphology.

Results. A total of 587 matched pairs of patients were compared. The primary composite endpoint did not differ between patients receiving PRO or ULTRA [Kaplan Meier (KM) estimates 10.2% vs 10.6%, $p_{log-rank}=0.86$]. Patients receiving PRO had higher rates of 1-year disabling stroke (KM estimates 2.6% vs 0.4%, $p_{log-rank}=0.001$), predominantly confined within 30 days after TAVI (1.4% vs. 0.0%, $p=0.004$). Outcomes were consistent across all the pre-specified subset of anatomical scenarios (all $p_{interaction}>0.10$).

Conclusions. One-year clinical outcomes of patients undergoing transfemoral TAVI and receiving PRO or ULTRA devices in the current clinical practice were similar, but PRO patients had higher rates of disabling stroke. Outcomes did not differ across different anatomical subsets of aortic root.

C33

MEMBRANOUS SEPTUM LENGTH ASSESSMENT AS A PREDICTOR OF PERMANENT PACEMAKER IMPLANTATION: INSIGHT FROM A TAVI REGISTRY INCLUDING SELF-EXPANDING AND BALLOON EXPANDABLE TRANSCATHETER AORTIC VALVES

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Introduction. Cardiac conduction disturbances (CD) and the subsequent need for permanent pacemaker implantation (PPMI) remain the most common complications of transcatheter aortic valve implantation (TAVI). The effectiveness and safety of TAVI have been demonstrated not only in inoperable and high-risk patients but also in the increasingly growing utilization of TAVI among intermediate- and low-risk populations, including younger patients. In these prospective cases, the risk of developing new-onset CD becomes progressively more significant in clinical management. Several factors, both nonmodifiable (e.g., right bundle branch block) and modifiable (such as valve type and implantation depth), have been linked to the occurrence of CD after TAVI. The aim of this study is to investigate the predictors of new PPMI in patients undergoing TAVI with new-generation valves, optimizing the implantation process using the cusp

overlap technique (COT), and to evaluate the disparity in PPM implantation rates between the two commonly used types of valves.

Methods. This retrospective real-world study included patients treated at a high-volume center with experienced operators who underwent a successful TAVI procedure using either a balloon-expandable or self-expanding valve between January 2019 and August 2021. The follow-up period for detecting new instances of permanent pacemaker implantation was 30 days. Valve selection was based on pre-procedural computed tomography (CT), and all valves were implanted following the manufacturer's guidelines.

Results. Patients underwent TAVI with balloon expandable valve in 52.4% (n=88) and with self-expanding valve in 47.6% (n= 80). A total of 11 patients (6.5%) received a PPMI within 30 days after TAVI and all of these within 1 week. At multivariate logistic regression only membranous septum length was identified as an independent predictor for new PPMI post-TAVI regardless of the type of valve used.

Conclusion. Preprocedural anatomic CT evaluation, implantation technique, and final device position represent an important and modifiable factor to further minimize the risk of PPMI following TAVI. The implementation of the cusp overlap technique has been associated with a significant and substantial decrease in PPI, thereby mitigating the occurrence of this complications between the two commonly utilized types of valves.

Table 1. Univariate binary logistic regression.

	HR	IC per HR (95%)	P value	
Self-expanding	0,497	0,140	1,76	0,279
LBBB	4,5	0,818	24,762	0,084
RBBB	6,45	1,569	26,517	0,010
LAHB	6,40	1,557	26,313	0,010
AVB	0,556	0,067	4,58	0,585
ID (NCC)	1,182	1,013	1,380	0,034
ID (AM)	1,219	1,028	1,446	0,023
ID (DE)	1,171	1,007	1,362	0,040

Table 2. Multivariate binary logistic regression.

	HR	IC per HR (95%)	P value	
ID (NCC)	1,183	0,906	1,546	0,217
RBBB	2,999	0,308	29,213	0,344
LAHB	5,955	0,665	53,301	0,111
Septum length	0,356	0,173	0,731	0,005

C34

CLINICAL IMPACT OF MULTIPLE RESHEATHING FOLLOWING TRANSCATHETER AORTIC VALVE IMPLANTATION ON MID-TERM FOLLOW-UP

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Introduction. Resheating during transcatheter aortic valve implantation (TAVI) of self-expandable prostheses allows for proper positioning of the device to avoid some complications such as paravalvular leaks and conduction disorders. Nevertheless, performing a recapture increases the interaction between the stent frame of the prosthesis and the calcium of the native valve, and some concerns exist about the potential risk of embolic cerebrovascular events and consequent worse clinical outcomes. Although there are some studies demonstrating the early safety of resheating, no data exist about its relationship with clinical outcomes at mid-term follow-up. In addition, there are few data in the literature reporting outcomes between different number of recaptures. In our study, we sought to assess the association between resheating and cardiovascular death at a mid-term follow-up.

Methods. Our retrospective observational study aimed to assess the impact of resheating at 3 years follow-up. The study population included patients with symptomatic severe aortic stenosis undergoing TAVI from December 2018 to December 2022. All procedures were performed using self-expanding valves of the Evolut family (Evolut R and Pro, Medtronic, Minneapolis, MN, USA). Procedures with recaptures were compared with procedures without recaptures and TAVI with ≥ 3 recaptures were compared to procedures with <3 recaptures. The primary endpoint was the rate of cardiovascular mortality at a 3-year follow-up.

Results. The study included 470 patients who underwent TAVI between

December 2018 and December 2022. Mean age was 81 ± 6.8 years. Female patients were 266 (56.7%). TAVI procedures were performed through a transfemoral access in 460 (98.1%) cases. In 253 cases (53.9%) at least 1 recapture was performed, while 3 or more recaptures were performed in 68 (15.4%) procedures. The mean follow-up time was 635 days. Kaplan-Meier curves estimated no significant differences in the cumulative incidence of cardiovascular death between 0 and ≥ 1 recaptures ($p = 0.158$) and between ≥ 3 recaptures and <3 recaptures ($p = 0.731$, Figure 1).

Conclusions. In our study, the re-sheathings during transcatheter aortic valve implantation did not significantly influence the cardiovascular mortality rate at a medium-term follow-up of 3 years. Furthermore, a high number of resheating is not associated to significant difference in clinical outcomes.

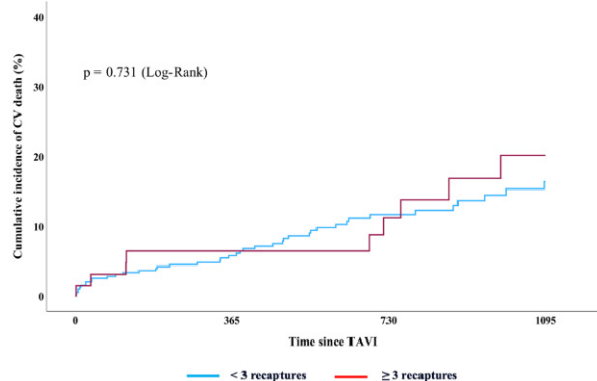


Figure 1. Kaplan-Meier curve for primary endpoint.

C35

BALLOON-EXPANDABLE PERFORMANCE IN INOPERABLE PATIENTS WITH PURE AORTIC REGURGITATION OF A NATIVE VALVE: A SUB-ANALYSIS FROM THE PANTHEON INTERNATIONAL PROJECT

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Introduction. The off-label utilization of transcatheter heart valve (THV) devices for the treatment of inoperable or high-surgical risk patients with pure native aortic valve regurgitation (NAVR) has been shown to be feasible with suboptimal outcomes. Nevertheless, only a few reports have reported the performance of balloon-expandable (BE) devices in this context. The study aimed to compare the use of different BE scaffolds in treating pure NAVR with a focus on cases with large annuli.

Methods. The data analyzed was from the PANTHEON registry and included patients with pure severe NAVR who were deemed to be at high or prohibitive surgical risk and were treated with last-generation THVs among sixteen Centers between Europe and US.

Results. Among 69 patients treated with BE platforms, 58% received a MyVal device and 42% were treated with a Sapien THV. The study showed that patients in the MyVal group had significantly larger diameters of the aortic structures compared to the Sapien group. Technical and device success rates were 90% and 72%, respectively. The rate of THV migration/embolization (MyVal 5% vs. Sapien 17%, $p=0.12$) and second valve needed (5% vs. 14%, $p=0.2$) were numerically lower in the MyVal group.

Conclusions. Off-label use of BE devices for pure NAVR represents a promising alternative in inoperable and high-surgical risk patients, with acceptable outcomes. Larger THV sizes, such as those available with the MyVal device, can provide a viable treatment option even for patients with extra-large annuli previously considered unsuitable for other THV devices.

C36

IVUS-GUIDANCE REDUCES CHIMNEY STENTING IN VIV-TAVI AT HIGH RISK FOR CORONARY OCCLUSION: LONG-TERM FOLLOW-UP OF NO-REVASULARIZED PATIENTS

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Aims. Coronary artery obstruction (CAO) is a life-threatening complication of valve-in-valve (VIV) TAVI, and occurs in 3-8% of VIV procedures, leading to high mortality rates. Upfront CHIMNEY stenting represents a preventive technique to minimize this risk, but leads to multiple drawbacks, such as difficulties in future coronary engagement and stent related complications (stent thrombosis, restenosis). However, CAO may

not occur even in many cases deemed at high-risk, therefore a method to identify the real need for intra-procedural CHIMNEY stent is needed. Past experiences showed angiography is unreliable for such a purpose. IVUS assessment of coronary ostia after TAVI and before CHIMNEY stenting may detect the presence of displaced leaflets in front of the coronaries, or the absence of such disquieting images, supporting the decision to stent or not to stent, before wire removal. The aim of this study is to assess the safety of IVUS assessment in this context, with a specific focus on patients deferred from CHIMNEY stenting on its basis.

Methods. This was an observational, prospective, single-arm study (ethic committee protocol CESC 3708). The primary endpoint was the feasibility and safety of IVUS assessment after valve deployment. Secondary endpoints included CHIMNEY stenting rate according to IVUS assessment; and MACE (cardiac death, myocardial infarction, target vessel revascularizations and stroke) at 1-year follow-up, occurring among patients treated with CHIMNEY stenting or with a deferred stent strategy.

Results. A total of 48 VIV patients were screened at University of Verona, of those 22 (29 vessels) were deemed at very high-risk for CAO on the basis of CT pre-TAVI analysis, and underwent IVUS assessment during VIV-TAVI procedures. IVUS was feasible and safe in 100% of cases, reporting no acute complications related to the technique. In 12 (40%) vessels (11 patients) IVUS detected the footprint of the displaced degenerated leaflet in front of the coronary ostium, or its compression, supporting the operators to perform CHIMNEY stenting. On the contrary, in the remaining cases IVUS showed a patent ostium and para-ostial space, excluding the need of stenting. Of note, angiography and IVUS disagreed on the evaluation of the ostia patency in 11 cases (38%). MACE occurred in 3 patients (3 cardiac deaths) at 1 year (15%) all in the stented group (3/11, 27%). None of the patients (11) deferred from CHIMNEY stenting, based on IVUS assessment, reported major adverse cardiac events neither during the hospital admission nor after 1 year of follow-up.

Conclusions. Initial findings, on the use of IVUS to assess the actual risk of CAO during VIV-TAVI, suggest this technique is feasible and safe. The absence of MACE in the deferred group, suggests IVUS guidance is a reliable toll to prevent both acute and delayed CAO.

STRUCTURAL HEART DISEASE: THERE IS MUCH MORE THAN A DEVICE

C37

CALCIFICAZIONE ANULARE MITRALICA NEI PAZIENTI SOTTOPOSTI A TAVI

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Introduzione. L'associazione tra valvulopatia aortica calcifica e calcificazione dell'anulus mitralico (MAC) è frequente; dati di registro riportano un'alta prevalenza (fino al 53% dei casi) nei pazienti candidati ad un impianto percutaneo di protesi valvolare aortica (TAVI). Tuttavia la valutazione della MAC nel percorso diagnostico pre-TAVI non rientra tra le procedure svolte di routine. In questo studio retrospettivo condotto su pazienti sottoposti a TAVI abbiamo valutato: 1) la presenza e l'estensione della MAC utilizzando un approccio di imaging multimodale; 2) i fattori clinici e strutturali che si associano ad essa; 3) il possibile ruolo prognostico della MAC.

Metodi. Tra il 2016 ed il 2022, 62 pazienti affetti da stenosi aortica severa sono stati sottoposti a TAVI presso il Dipartimento Cardiovascolare dell'A.O.U. Careggi (Firenze). I dati clinici ed ecocardiografici basali e post-TAVI sono stati raccolti presso l'Ospedale Santo Stefano (Prato). La valutazione della MAC è stata eseguita con analisi quantitativa sulle immagini ecocardiografiche e di tomografia computerizzata (TC), ottenendo uno score di severità della MAC. Un follow-up clinico è stato condotto a distanza di 30 giorni in tutti i pazienti.

Risultati. Una MAC è stata rilevata in 48 pazienti (77%), una MAC severa in 16 pazienti (26%). L'analisi TC è risultata più accurata per definire la presenza e l'estensione della MAC. I pazienti con MAC erano più femmine, di età più avanzata, con maggior profilo di rischio cardiovascolare e comorbilità; presentavano più frequentemente una valvulopatia mitralica ed aritmie. Queste differenze venivano amplificate stratificando la popolazione in base allo score di severità della MAC. I pazienti con MAC severa presentavano un pattern di rimodellamento ventricolare con prevalente ipertrofia concentrica. Post-TAVI, i pazienti con MAC severa hanno ottenuto un minor beneficio emodinamico ed una maggiore necessità di impianto di pacemaker. È stato rilevato un trend di incremento di mortalità per tutte le cause al crescere dello score MAC.

Conclusioni. La valutazione del calcio anulare mitralico e della sua estensione dovrebbero divenire parte integrante del processo di stratificazione del rischio nei pazienti candidati a TAVI. La presenza di una MAC severa identifica una categoria di pazienti con minor recupero post procedurale.

C38

UPDATED VALUES FOR PULMONARY HYPERTENSION AND OUTCOME AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION

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Introduction. The European Society of Cardiology guidelines have recently defined new cut-offs for pulmonary hypertension (PH) and pulmonary vascular resistance (PVR; mean pulmonary artery pressure [mPAP] >20 instead of 25 mmHg and PVR >2 instead of 3 WU). The prognostic value of this updated classification after transcatheter aortic valve implantation (TAVI) is unknown.

Methods. 579 consecutive TAVI patients with pre-procedural right heart catheterization (RHC) evaluation were included. Patients were grouped as: 1) No PH, 2) Isolated pre-capillary/Combined (I-PreC/Co) PH and 3) Isolated post-capillary PH (I-PoC). All cause death, cardiovascular (CV) death and hospitalizations for heart failure (HF) were evaluated at follow-up. We also analyzed the prognostic role of residual post-procedural PH.

Results. Out of 579 patients, 299 (52%) had PH according to the new criteria compared to 185 (32%) according to the previous ones. Overall median age was 82 years, while 55.3% patients were male. Patients with PH were more frequently diagnosed with chronic obstructive pulmonary disease and atrial fibrillation and were characterized by higher surgical risk as compared to patients without PH. At a median follow-up of 2.9 years, the presence of PH according to previous definition was associated with worse survival (p<0.001) and HF hospitalization (p=0.002) rates, irrespective of PVR values. With newer cut-offs, PH was associated with worse outcomes only in patients with increased PVR, while no differences were found between patients with PH and normal PVR values and those without PH. Post-procedural mPAP normalization was observed in 45% of the cases, but it was associated with improved long-term survival only in the I-PoC PH group.

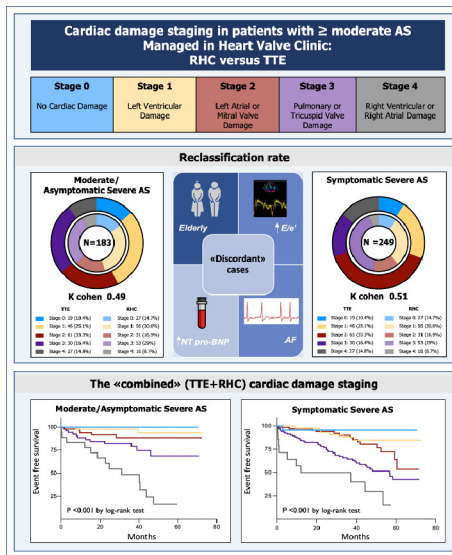
Conclusions. New ESC PH cut-offs increased the number of PH diagnoses. The presence of PH, particularly in the setting of increased PVR, identify patients at higher risk for post-procedural mortality and re-hospitalization. Normalization of PH was associated with better survival only in I-PoC group.

C39

CARDIAC DAMAGE STAGING IN PATIENTS WITH AORTIC STENOSIS: THE ROLE OF RIGHT HEART CATHETERIZATION

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Introduction. Cardiac damage staging enhances risk stratification in patients with clinically significant aortic stenosis (AS). We aimed to assess the prognostic value and reclassification rate of right heart catheterization (RHC) compared to transthoracic echocardiography (TTE) in characterizing cardiac damage at long-term follow-up in patients with clinically significant AS; to identify patients that would benefit of RHC for prognostic stratification. The prognostic value of "combined" cardiac damage staging was tested.



Results. In both cohorts, TTE- and RHC-derived staging system had prognostic value, although the agreement between them appeared moderate. A higher proportion of patients were assigned in Stage 2 by TTE, compared to RHC. Patients in TTE-derived Stage 2 had high reclassification rate with 40-50% presenting with right chambers involvement (stages 3-4) at RHC. "Discordant" cases were significantly older, with higher prevalence of AF, markedly elevated NT pro-BNP, higher LAVi, E/e' and SPAP versus "concordant" cases (p<0.05). The "combined" cardiac damage staging, integrating TTE and RHC, was more accurate in predicting mortality than TTE-derived system (p<0.05).

Conclusion. In patients with m/asAS and ssAS, TTE provided a good assessment of left ventricular impairment, whereas RHC was more accurate in assessing right ventricular involvement. Combining both staging systems, patients with m/asAS and ssAS could be better stratified.

C40

IMPROVEMENT IN PULMONARY FUNCTION FOLLOWING MITRAL TRANSCATHETER EDGE-TO-EDGE REPAIR: SHORT- AND LONG-TERM RESULTS FROM A SINGLE CENTRE

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Introduction. In patients with significant mitral regurgitation (MR), heart-lung interaction is decisive in defining symptoms, functional capacity, quality of life and prognosis. Several studies show the impact of mitral transcatheter edge-to-edge repair (M-TEER) on systolic pulmonary artery pressure (sPAP), but little is known about direct effects of this procedure on pulmonary circulation and changes in lung function. The aim of this study is to directly evaluate, through the execution of pulmonary function tests (PFTs), lung function and congestion before and after the M-TEER procedure.

Methods. This retrospective observational study includes all consecutive patients who underwent M-TEER using the MitraClip system from January 2019 to June 2022 at our Institution. At baseline, patients underwent full clinical, laboratory and cardiac ultrasound evaluation (both transthoracic [TTE] and transesophageal [TEE]) followed by PFTs, including spirometry and diffusing capacity of the lungs for carbon monoxide (DLCO). Clinical follow-up was performed after 1, 3 and 12 months; TTE and PFTs were performed after 3 and 12 months. In addition, at baseline and during the follow-up visits (3 and 12 months), patients were investigated about quality of life (through the Minnesota living with heart failure questionnaire) and exercise functional capacity (using the six minute walking test, 6MWT).

Results. From January 2019 to June 2022, 60 patients (18% with degenerative, 75% with functional and 7% with mixed MR) underwent elective and successful mitral-TEER and completed 1 year follow-up. Mean age was 77±6 years; most patients were male and presented with a NYHA functional class III or IV within two last weeks. M-TEER was mostly performed in patients with right ventricular function not severely impaired, despite the sometimes-severe impairment of left ventricular systolic function. In mid- and long-term follow-up, patients showed a significant and persistent reduction in sPAP and favourable cardiac remodelling. The table shows the improvement in pulmonary function following M-TEER as evidenced by the significant increase in DLCO, forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV1) values, together with noticeable improvement in the patients' quality of life and functional abilities.

Conclusions. The pulmonary benefit of the M-TEER procedure on the overall treated patient population is demonstrated for the first time in this study through the direct evaluation of lung function by PFTs. The increased recruitment of lung area for gas exchange after M-TEER is evident 3 months after the procedure and persists in long-term follow-up.

Table. Significant changes in the continuous variables examined after MitraClip procedure.

	Baseline (mean±SD)	3 months (mean±SD)	p vs baseline	12 months (mean±SD)	p vs baseline
DLCO (%)	66 ± 18	75 ± 17	<0.001	73 ± 19	0.005
CVF (%)	80 ± 19	93 ± 20	<0.001	93 ± 25	<0.001
FEV1	88 ± 23	97 ± 27	0.001	99 ± 30	0.040
6MWT (m)	206 ± 128	281 ± 128	<0.001	273 ± 130	<0.001
Minnesota QoL	47 ± 20	29 ± 35	<0.001	23 ± 18	<0.001

C41

EXTRA-MITRAL VALVE CARDIAC INVOLVEMENT IN PATIENTS WITH PRIMARY MITRAL REGURGITATION UNDERGOING TRANSCATHETER EDGE-TO-EDGE REPAIR

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Introduction. In the context of primary mitral regurgitation (PMR), selection of patients for transcatheter edge-to-edge repair (TEER) does not include a systematic evaluation PMR-associated cardiac remodelling, that may have a relevant prognostic impact. The aim of the study was to investigate epidemiology and prognostic significance of different phenotypes of extra-mitral valve (MV) cardiac involvement in a large series of patients with PMR referred for TEER, and to assess predictors of clinical outcome.

Methods. The study included 654 patients with severe PMR from the multicenter Italian Society of Interventional Cardiology (Glse) Registry Of Transcatheter Treatment of Mitral Valve Regurgitation (GIOTTO), stratified into groups according to extra-MV cardiac involvement: group 0, no cardiac involvement (9%, n=56); group 1, left ventricular involvement (18%, n=120); group 2, left atrium involvement (30%, n=199); group 3, pulmonary vasculature or tricuspid valve involvement (31%, n=202); group 4, right ventricular involvement (12%, n=77). Primary endpoint was a composite of all-cause death and re-hospitalization for heart failure over a 2-year follow-up period.

Results. Acute technical success was achieved in 98% of patients. Kaplan-Meier curve analysis revealed significantly worse survival in higher groups of extra-MV cardiac involvement (p = 0.039, generated by the Cox-Mantel analysis). On multivariate Cox regression analysis, group of extra-MV cardiac involvement, hemoglobin level and technical success were independent predictors of the primary endpoint. Compared to group 0, group 2 (HR 6.549, 95% CI: 1.529-28.051, p=0.011) and group 4 (HR 6.528, 95% CI: 1.499-28.434, p=0.012) showed the highest risk of primary endpoint occurrence.

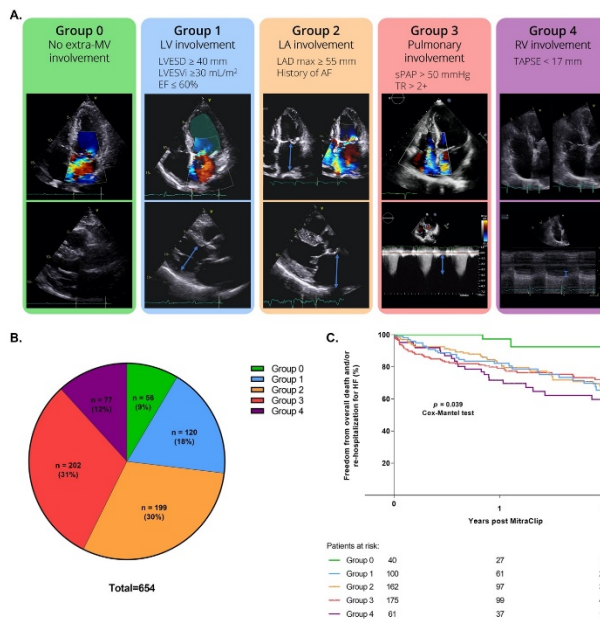


Figure. Definition and prognostic significance of extra-mitral valve cardiac involvement. (A) Patient classification on the basis of baseline transthoracic echocardiography characteristics mirroring the extent of extra-mitral valve cardiac involvement. (B) Distribution of the study cohort according to the extent of extra-mitral valve cardiac involvement. (C) Kaplan-Meier survival estimates for the occurrence of the primary endpoint.

Conclusions. Classification of patients with PMR undergoing TEER into groups according to extra-MV cardiac involvement provides prognostic value in terms of post-interventional outcome. Grading cardiac involvement may help refine risk stratification and timing of procedure, since ≥ 1 group of extra-MV cardiac involvement represents itself a negative predictor of mid-term outcome.

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LEFT VENTRICLE STRAIN PATTERN ASSESSMENT AND PROGRESSION IN TRANSCATHETER AORTIC VALVE REPLACEMENT-INDUCED LEFT BUNDLE BRANCH BLOCK

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Introduction. Transcatheter aortic valve replacement (TAVR) is associated with the potential occurrence of conduction abnormalities, including the development of left bundle branch block (LBBB). Recently a strain-based staging classification of LBBB-induced left ventricle (LV) remodeling and dysfunction has been proposed, identifying four distinct strain patterns in patients with LBBB and septal flash (SF). The aim of this study was to assess the LV strain patterns in patients with new onset TAVR-induced LBBB. We therefore aim to investigate the evolution of this strain patterns during follow-up and determine its correlation with the extent of LV remodeling and dysfunction.

Methods. All consecutive patients admitted to the Cardiovascular Center at OLV Hospital in Aalst, Belgium, between January 2018 and May 2022, who were diagnosed with severe aortic stenosis and developed new-onset LBBB following TAVR were included. Conventional echocardiographic parameters as well as the calculation of LV strain pattern at baseline echocardiography was performed in order to evaluate any changes following the development of TAVR-induced LBBB and during the follow-up period.

Results. To assess the progression of LBBB-strain patterns at FU, we included a total of 53 patients out of the initial 75 who had available strain analysis data at baseline, discharge, and FU. Patients were divided into two groups: those with non-changing or improving LBBB-pattern (LBBB-pattern =/+) [N=42], and those with worsening LBBB-pattern (LBBB-pattern -) [N=10]. Patients in the (LBBB-pattern -) group exhibited worse LVEDVi (76.52 \pm 29.50 vs 56.19 \pm 18.82; p=0.009), LVESVi (39.28 \pm 20.90 vs 26.18 \pm 15.40; p=0.029), higher E/e ratio (28.32 \pm 18.59 vs 19.0

Table 1. Baseline characteristics of patients with non-changing/improving LBBB-pattern and patients with worsening LBBB-pattern from discharge to follow-up.

	LBBB-pattern - (N=10)	LBBB-pattern =/+ (N=42)	p-value
LVEDVi	76.52 \pm 29.50	56.19 \pm 18.82	0.009
LVESVi	39.28 \pm 20.90	26.18 \pm 15.40	0.029
LV mass index	150.53 \pm 40.90	131.18 \pm 41.48	0.190
E/e'	28.32 \pm 18.59	19.0 \pm 8.76	0.027
NT-proBNP	6234.5 \pm 7043.62	2310.95 \pm 2009.12	0.009
LVEF	46.80 \pm 9.77	54.02 \pm 9.77	0.041
LVEF>50%	3 (30.0)	31 (73.8)	0.022
GLS	-13.08 \pm 4.50	-16.04 \pm 4.73	0.075

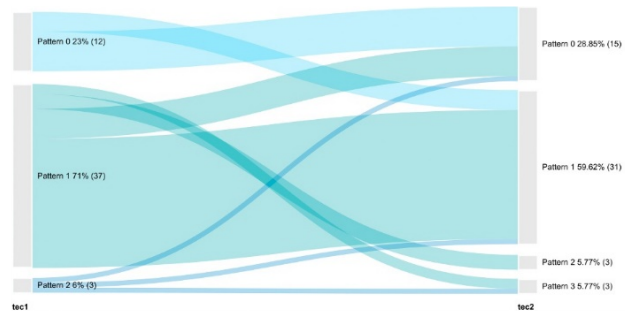


Figure 1. LBBB-pattern progression between discharge and follow-up.

\pm 8.76; p=0.027), higher baseline levels of NT-pro-BNP (6234.5 \pm 7043.62 vs 2310.95 \pm 2009.12; p=0.009), and lower LVEF (46.80 \pm 9.77 vs 54.02 \pm 9.77; p=0.041). When evaluating the echocardiographic characteristics at follow-up, no statistically significant differences were observed between the two groups in terms of LVEDVi, LVESVi, LV mass index, E/e ratio and LVEF. However, patients with (LBBB-pattern =/+) compare to patients with (LBBB-pattern -) had a significantly lower proportion of patients with LVEF >50% [4 (40.0) vs 34 (81.0); p=0.016] and exhibited reduced GLS (-13.2 \pm 2.90 vs -17.5 \pm 2.96; p=0.001).

Conclusions. In patients with severe AS that develop persistent LBBB after TAVR, those with impaired baseline echocardiographic characteristics, have higher likelihood to develop a worst LV strain pattern at follow-up. However, despite a worse LV strain pattern is associated with a higher probability of adverse remodeling and LV dysfunction, this did not occur in our population. Suggesting the effectiveness of TAVR and the relatively benign nature of TAVR-induced LBBB. Nonetheless, a relatively close echocardiographic follow-up is suggested in patients who develop a worse LV strain pattern, in order to early detect signs of adverse remodeling and progression of LV dysfunction.