Comunicazioni orali

Coronary physiology

C1

PROGNOSTIC ROLE OF INVASIVE INTRACORONARY ASSESSMENT IN PATIENTS WITH MYOCARDIAL BRIDGE: THE RIALTO REGISTRY

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Introduction. Myocardial bridge (MB) is the most common congenital coronary anomaly in which a segment of an epicardial artery takes a tunneled course under a bridge of myocardium. Although MB has long been considered an accidental finding, a growing body of evidence suggests its association with anginal symptoms and adverse cardiac events. It has been recently recognized as a cause of ischemia with non-obstructive coronary arteries disease (INOCA) and several mechanisms, such as the development of vasomotor disorders and microvascular dysfunction, have been described as possible pathophysiological substrates of MB-related ischemia. Our study has the aim to describe the impact of MB on anginal symptoms and major adverse cardiovascular events (MACE), and the role of invasive intracoronary assessment with provocative and functional tests in detecting specific endotypes which deserved a personalised therapy impacting on prognosis.

Methods. This is an ambispective and observational registry in which we included 405 patients with angiographic evidence of MB. In-hospital clinical-instrumental data was acquired after coronary angiography (CA), including cardiological symptoms and signs, cardiovascular risk profile, pharmacological anamnesis, comprehensive echocardiographic evaluation, coronary CT scan, angiographic data, provocative and functional tests performed during invasive CA. The data obtained in the follow-up visit (at 6, 12 and 24 months) is included in the study. In particular, we recorded MACE and Seattle Angina Questionnaire (SAQ). The primary endpoint of the study is the incidence of MACE, defined as the composite of cardiac death, myocardial infarction, cardiac hospitalization and target vessel revascularization. The secondary endpoints are the rate of patients with SAQ angina summary score <70 and the incidence of MACE in patients undergoing invasive intracoronary assessment.

Results. The most frequent location of MB was the left anterior descending coronary artery (96,8%). Chronic coronary syndrome (CCS) was the most frequent clinical presentation (62%). Interestingly, a big proportion (38%) of our patients were found to have MB during the occurrence of an ACS. Functional assessment with FFR/iFR/contrast-FFR was performed in 64 patients (15,8%) to assess the hemodynamic significance both of MB and plaques proximal to MB: these tests resulted positive in 27 procedures. Provocative test with intracoronary acetylcholine (IC ACH) was performed in 72 patients (17,8%) in order to search vasomotor disorders: 39 of them received diagnosis of vasospastic angina according to "COVADIS criteria". Among patients undergone follow-up visit, we recorded 31 MACE at 6 months (11,6%), 16 MACE at 12 months (6,5%) and 26 MACE at 24 months (13,5%). The rate of patients with SAQ <70 is 18,8% at 6 months, 20,6% at 12 months and 21,8% at 24 months. To evaluate the prognostic role of invasive intracoronary assessment, we compared MB patients with only angiographic evaluation (angio group) compared to those who underwent provocative test with IC ACH with indication of calcium-channel blockers at discharge (ACH group) and those who underwent functional assessment with FFR/iFR/cFFR with indication to beta blockers at discharge (FFR group). After two years of follow-up, the rate of MACE was significantly reduced in both the ACH group (6% vs 25%, p=0.029) and FFR group (3% vs 25%, p=0.005) compared to angio group.

Conclusions. The early results of the study confirmed that MB is a challenging cause of ischemia in patients referred for CA. A remarkable proportion of these patients were found to have MB during the occurrence of an ACS or CCS, highlighting that different mechanisms of ischemia may coexist. Moreover, invasive intracoronary assessment may unmask pathophysiological mechanisms, such as vasomotor disorders and microvascular dysfunction, which may underlie the ischemic burden related to MB, allowing to guide the treatment according to specific endotypes. In fact, stratified medical therapy, guided by invasive assessment, proved to have a significant impact on cardiovascular outcomes in patients with MB.

C2

CORONARY ATHEROSCLEROSIS PHENOTYPES IN FOCAL AND DIFFUSE DISEASE

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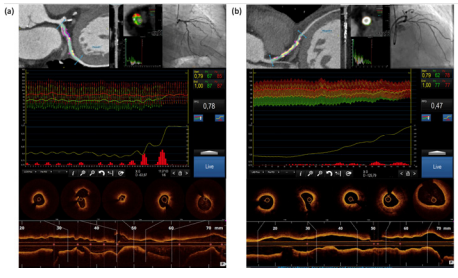
Introduction. The pathophysiological interplay between coronary physiology and plaque characteristics remains poorly understood. Pullback pressure gradient (PPG) is a novel physiological index that discriminates focal from diffuse coronary artery disease (CAD) based on coronary physiology. We aimed to compare plaque characteristics using between atherosclerotic patterns defined by coronary physiology.

Methods. Multicenter, prospective, controlled, single-arm study conducted in five countries (NCT03782688). Patients with functionally significant lesions based on invasive fractional flow reserve (FFR <0.80) were included. Subjects underwent coronary computed tomography angiography (CCTA) with quantitative plaque analysis followed by an invasive procedure with optical coherence tomography (OCT) and motorized intracoronary pressure recordings. Fractional flow reserve (FFR) pullback curves were processed to calculate the PPG. The PPG ranges from 0, indicating diffuse disease, to 1, pointing to focal CAD. Focal and diffuse CAD were defined according to the median PPG value.

Results. Overall, 117 patients (120 vessels) were included. The mean age was 64±9, 80% were male, and 22% had diabetes (no difference between focal vs. diffuse). Median PPG was 0.66 [0.54, 0.75]. In CCTA analysis, the plaque burden at minimum lumen area was higher in patients with focal CAD (87±8% focal vs. 82±10% diffuse, p=0.003). Calcifications were significantly more prevalent in patients with diffuse CAD (Agatston score per vessel 50 [9, 166] focal vs. 151 [46, 360] diffuse, p=0.019). In OCT plaque analysis, patients with focal CAD had a significantly higher prevalence of circumferential lipid-rich plaque (37% focal vs. 4% diffuse, p=0.001) and thin-cap fibroatheroma (TCFA 47% focal vs. 10% diffuse, p=0.002). High PPG predicted the presence of TCFA with an AUC of 0.73 (95% CI 0.58 to 0.87). PPG and fibrous cap thickness were negatively correlated (r=-0.55, 95% CI -0.74 to -0.28) independently of FFR.

Conclusions. Atherosclerotic plaque phenotypes associate with intracoronary hemodynamics. Vessels with focal disease (high PPG) had a higher plaque burden and predominantly lipid-rich plaque with a high prevalence of TCFA, whereas calcifications were the hallmark of vessels with diffuse pressure loss.



C3

DIFFERENTIAL IMPROVEMENT IN ANGINA AND HEALTH-RELATED QUALITY OF LIFE AFTER PERCUTANEOUS CORONARY INTERVENTIONS IN FOCAL AND DIFFUSE CORONARY ARTERY DISEASE

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Introduction. Increase in fractional flow reserve (FFR) following

percutaneous coronary interventions (PCI) is associated with improvement in angina. Coronary artery disease (CAD) patterns (focal vs. diffuse) influence the FFR change after stenting and may predict angina relief. The objective was to investigate the differential improvement in patient-reported outcomes after PCI in focal and diffuse CAD as defined by the pullback pressure gradient (PPG).

Methods. This is a sub-analysis of the TARGET-FFR randomized clinical trial (NCT03259815). The 7-item Seattle Angina Questionnaire (SAQ-7) was administered at baseline and three months after PCI. The PPG index was calculated from manual pre-PCI FFR pullbacks. The median PPG value was used to define focal and diffuse CAD. Residual angina was defined as an SAQ score less than 100.

Results. One hundred and three patients were analyzed. There were no differences in baseline characteristics between patients with focal and diffuse CAD. Focal disease had larger increases in FFR with PCI than diffuse disease (0.30±0.14 vs. 0.19±0.12, p<0.001). Patients who underwent PCI to focal CAD had significantly higher SAQ-7 summary scores at follow-up than those with diffuse CAD (87.1±20.3 vs. 75.6±24.4, mean difference 11.5 [95%CI 2.8 to 20.3], p=0.01). Following PCI, residual angina was present in 39.8% but was significantly lower among those with treated focal CAD (27.5% vs. 51.9%, p=0.020).

Conclusion. Residual angina after PCI was almost twice as common in patients with a low PPG, whereas patients with focal disease reported greater improvement in angina and quality of life. The baseline pattern of CAD can predict the likelihood of angina relief.

C4

RELIABILTY OF QUANTITATIVE FLOW RATIO ASSESSMENT IN PATIENTS WITH DIFFERENT CORONARY MICROVASCULAR FUNCTION UNDERGOING TRANSCATHTER AORTIC VALVE IMPLANTATION

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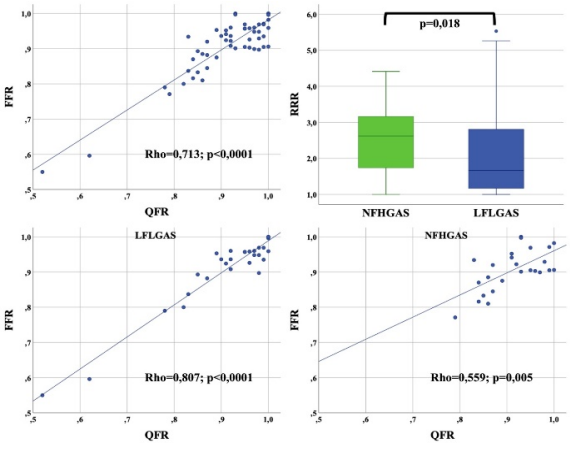
Introduction. Coronary artery disease (CAD) is a common finding in patients with symptomatic severe aortic stenosis (SAS) undergoing transcatheter aortic valve implantation (TAVI). CAD management in this setting remains controversial, in particular for intermediate stenosis. Invasive physiologic assessment with fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) have not been fully validated in a patient with SAS. SAS deeply affects the coronary microcirculation and therefore the hyperemic response and so the FFR values. Indeed, FFR assessed post-TAVI has been proposed for evaluating CAD in this setting. In the last years, computational methods to functional assess CAD based on resting coronary angiograms have developed. In particular, quantitative flow ratio (QFR) has already shown high accuracy in defining the physiological relevance of CAD in different clinical scenarios.

Recent studies underlined a good correspondence between QFR and FFR in TAVI setting but no data about QFR variations, its correspondence with FFR before and after TAVI and the influence of coronary microvascular status on QFR assessment are nowadays available.

Methods. This manuscript relays on a sub-analysis of another study that performed a systematic thermodilution-based physiological assessment of 42 consecutive patients with isolated SAS undergoing TAVI. In this population, FFR and other physiological parameters were assessed before and after TAVI on the left anterior descending artery without critical lesion at coronary angiograms. Subsequently, QFR assessment was performed by a certified analyst, excluding suboptimal coronary angiograms. QFR analysis was conducted blinded to both FFR values and clinical decisions on coronary revascularization.

Results. A total of 53 vessels with pre or post-TAVI FFR evaluation were eligible for QFR assessment. For 19 vessels QFR assessment was possible both before and after TAVI. The overall correlation between QFR and FFR was great (rho=0,713, p<0,0001). Pre-TAVI QFR was positively correlated with post-TAVI QFR (rho=0,716, p<0,001). Post-TAVI QFR correlated well with post-TAVI FFR (rho=0,714, p<0,0001), slightly better than pre-TAVI QFR and pre-TAVI FFR (rho=0,680, p<0,0001). Pre-TAVI QFR showed a good correlation even with post-TAVI FFR (rho=0,515, p=0,003). To note, the correlation between QFR and FFR assessed was greater in the 22 patients with low flow low gradient aortic stenosis (LFLGAS) (rho=0,807, p<0,0001) than in the 20 patients with normal flow high gradient aortic stenosis (NFHGAS) (rho=0,559, p=0,005). Importantly, the thermodilution-based physiological assessment performed in these patients underlined a low residual vasodilatory capacity in patients with LFLGAS with resistive reserve ratio (RRR) values significantly lower than patients with NFHGAS (1.4 [1.1-2.1] vs 2.6 [1.5-3.3] p=0,018).

Conclusion. In patients with SAS undergoing TAVI, QFR has an overall good correlation with FFR both in pre-TAVI and post-TAVI settings. To report, QFR differently correlated with FFR in patients with NFHGAS or LFLGAS, which were found to have a different coronary microvascular function with a different reply to hyperemic agent.



C5

UTILIZATION OF DRUG-COATED BALLOON GUIDED BY POST-PERCUTANEOUS CORONARY INTERVENTION PRESSURE GRADIENT: THE U-REDUCE STENT REGISTRY

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Introduction. Usage of drug-coated balloon (DCB) angioplasty in complex lesions is low due to the difficulties to evaluate the angiographic result frequently associated with a dissection. The approach to stent most of these residual dissections is justified by the need of a safe result without any risk for the patient. We propose utilization of distal coronary (Pd) to aortic (Pa) pressure gradient post lesion preparation, with the objective to safely avoid stenting when the result is considered angiographically problematic.

Methods. The approach included DCB treatment as intention-to-treat following optimal lesion preparation with any available device. Evaluation by angiography, with liberal use of intravascular imaging, was paralleled by utilization of pressure wire, establishing a threshold of 0.90 or more Pd/Pa ratio as proxy of optimal result. Of note, coronary dissections, unless > type B, were not systematically treated with stenting.

Results. Sixty-five patients (86% male) were enrolled between February 2020 and November 2021, for a total of 86 lesions. Target lesions were complex (ACC/AHA class B2 or C 90.7%), long (35.1 mm), mostly on LAD (80%) with vessel diameter of 2.96 ± 0.50 mm. Bifurcations were involved in 25.6% of cases. Lesion preparation included cutting balloon (25.6%), rotational atherectomy (5.8%) and intravascular lithotripsy (5.8%). Balloons were on average 2.86 mm in diameter and inflated at mean pressure of 19.9 atm. Intravascular imaging was liberally adopted (62.8%), and Pd/Pa gradient went from a baseline of 0.80, to 0.90 after lesion preparation (p<0.001) and 0.93 after DCB angioplasty (p =0.284 vs. after lesion preparation). Of note, dissection was visible in 67.4% (58) of lesions at final angiography. Finally, 60 lesions (69.7%) were treated with DCB alone, 10 lesions (11.6%) with a hybrid strategy and 11 lesions (12.8%) with final drug-eluting stent implantation covering the treated segments. No cases of acute vessel occlusion occurred, and at a median follow-up of 365 days (interquartile range 226-430 days) one only case of definite vessel occlusion occurred at a late stage, contributing to the single target vessel myocardial infarction event. Target lesion failure and revascularization Kaplan-Meier estimates were 13.2% and 8.7%, respectively.

Conclusion. This proof-of-concept study is the first to test a DCB intention-to-treat strategy guided by post-PCI pressure gradient in complex lesions located in medium and large size vessels. Results support safety and feasibility of such an approach.

C6

TAILORED RADIATION DOSE IN THE CATH LAB: AN "UNICUIQUE SUUM" APPROACH WITH A LAST GENERATION CARDIOLOGICAL-DEDICATED ANGIOGRAPHY SYSTEM

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Introduction. Radiation exposure (RE) optimization during coronary

artery interventions is of paramount importance to warrant both patients and operators' safety. Access site, patients feature, type of procedure as well interventional angiography system could influence radiation dose to patient and operator during coronary interventions. Our aim was to record and analyze RE using a new generation "cardiological" dedicated angiography system.

Methods. This retrospective study included patients underwent elective or emergence coronary angiography (CA) +/- PCI at our institution between September and November 2021. Procedures were performed using a cardiological Siemens Artis Zee floor angiography system (SAS) characterized by a small size flat detector (20x20 cm). The primary end point was patient's RE reported as dose-area product (DAP). We also recorded the access site (femoral Vs radial), patients Body Mass Index (BMI) and type and length of procedure. We compared our findings with an historical patient group submitted to CA +/- PCI with a previous generation multi-purpose Philips Allura Xper System (PAS) provided of a" standard-size" flat detector (30x40cm).

Results. We studied 100 consecutive patients (29% female) submitted to angiography for stable or unstable coronary syndromes. The mean age was 66. The mean BMI was 28 and PCI was performed in 53% of patients. Trans radial approach was chosen in 89/100 patients. The mean DAP recorded was 47601 mGy/cm^2 and the mean length of procedure was 10.3 min. We compared these results with an historical population of 100 patients submitted to CA in the same institution by the same cardiologists with a first generation multi-purpose angiography system. Mean RE was significant lower in SAS procedures compared to PAS (DAP 47691 mGy*cm^2 for SAS vs 77660 mGy*cm^2 for PAS; p=0,01). Patient's features (mean age 66 for SAS Vs 70 for PAS; BMI 28 for SAS vs 28 for PAS) and characteristics of procedures (mean length 11min [SAS] vs 14,3 [PAS]; radial access 89% [SAS] vs 86% [PAS]; PCI (53% SAS vs 55% PAS) were not statistically different between the two groups.

Conclusions. Radiation exposure for patients and operators was significant lower using a last generation cardiological-dedicated angiographic system as compared to a first generation multi-purpose technology. Our findings can be related to several factors. First, the smaller size of detector in the cardiological-dedicated system decreases radiation dose during CA. Second, "Radiation free position system" program is very useful in reducing the number of fluoroscopic images needed when changing projection angle is required. Finally, a real "tailored" x-ray dose adjustment according to both clinical/procedural features and operators' needs is feasible with SAS thanks to many different dose programs installed for radiographic image acquisition and fluoroscopy.

Transcatheter mitral edge-to-edge repair

C7

CHANGES IN RIGHT VENTRICULAR-TO-PULMONARY ARTERY COUPLING AFTER TRANSCATHETER EDGE-TO-EDGE REPAIR IN SECONDARY MITRAL REGURGITATION

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Introduction. Preprocedural right ventricular-to-pulmonary artery (RV-PA) coupling is a major predictor of outcome in patients with secondary mitral regurgitation (SMR) undergoing transcatheter edge-to-edge repair (TEER). However, clinical significance of its changes after TEER is unknown. The objective of this study is to evaluate changes in RV-PA coupling after TEER, their prognostic value and predictors of improvement.

Methods. Patients undergoing successful TEER (defined as residual MR <2+ at discharge) for SMR at 13 European centres and with complete echocardiographic data at baseline and short-term follow-up (30 to 180 days) were included. RV-PA coupling was assessed by transthoracic echocardiography as tricuspid annular plane systolic excursion-to-pulmonary artery systolic pressure ratio (TAPSE/PASP). All-cause death was assessed at the longest available follow-up starting from the time of the echocardiographic reassessment.

Results. Among 501 patients included, 331 (66%) improved their TAPSE/PASP after TEER (responders) at short-term follow-up (median of 89 days, interquartile range [IQR], 43 – 159 days), whereas 170 (34%) did not (non-responders). Lack of prior cardiac surgery, low post-procedural mitral gradient, low baseline TAPSE, high baseline PASP, and baseline tricuspid regurgitation 3/4+ were independently associated with TAPSE/PASP improvement after TEER. Compared to non-responders, responders had lower NYHA class and less heart failure hospitalizations at short-term follow-up. Improvement in TAPSE/PASP was independently associated with reduced risk of mortality at long-term follow-up (584 days, IQR 191 – 1243) (HR 0.65; 95% CI 0.42-0.92; p=0.017).

Conclusion. In patients with SMR, improvement in TAPSE/PASP after successful TEER is predicted by baseline variables and post-procedural mitral gradient and is associated better outcomes.

C8

PROGNOSTIC SIGNIFICANCE OF FLAIL LEAFLET ETIOLOGY IN TRANSCATHETER EDGE-TO-EDGE MITRAL VALVE REPAIR FOR PRIMARY MITRAL REGURGITATION: RESULTS FROM THE MULTICENTER GIOTTO REGISTRY

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Introduction. Despite the ongoing growing experience with MitraClip in broad spectrum of primary mitral regurgitation (PMR), only symptomatic improvement has been established. Limited data are available regarding the independent prognostic role of different mitral regurgitation (MR) etiologies. We sought to evaluate the real impact of flail leaflet-related etiology in a large series of patients with PMR undergoing MitraClip treatment.

Methods. The study included 588 patients with significant PMR from the multicenter Italian GIOTTO registry. Patients were stratified into two groups according to MR etiology: Flail+ (n=300) and Flail- (n=288). Primary endpoint was a composite of cardiac death and first re-hospitalization for HF, secondary endpoints were overall death, cardiac death and first re-hospitalization for HF considered singularly.

Results. Flail leaflet-related etiology was present in about a half of patients. At 2-year Kaplan Meier analysis, primary clinical endpoint occurred in 13% of Flail+ patients, compared to 23% cases in Flail- (p=0.009). Flail+ presented a lower rate of both cardiac death and re-hospitalization for HF, whereas similar overall death rate was observed between the two groups. Multivariate Cox-regression analysis identified flail leaflet etiology as an independent predictor of favorable outcome in terms of primary endpoint (HR 0.141, 95% CI 0.049-0.401; p<0.001).

Conclusion. Flail leaflet-related etiology was common in PMR, and it was an independent predictor of mid-term positive outcome.

C9

SAFETY AND EFFICACY OF TRANSCATHETER EDGE-TO-EDGE MITRAL VALVE REPAIR WITH THE PASCAL SYSTEM IN A REAL-WORLD SETTING

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Introduction. Mitral regurgitation (MR) is the second most frequent heart valve disease, and an important cause of morbidity and mortality. Transcatheter mitral valve edge-to-edge repair (TEER) has become a valuable treatment option for high-risk patients with degenerative or functional MR. The PASCAL Transcatheter Valve Repair System has unique features compared to the MitraClip system including a central spacer, broader paddles made of flexible nitinol and for the first time the possibility of the independent leaflet grasping and has emerged as an effective treatment in a dedicated clinical trial.

Our aim is to characterize the safety and efficacy of TEER with the PASCAL System in a real-world setting.

Methods. Patients with symptomatic moderate-to-severe or severe MR, receiving optimal medical therapy, and deemed candidates for transcatheter mitral repair by the local Heart Team were treated with the PASCAL system at our centre. Primary efficacy endpoints included procedural success and clinical success, defined as below. The primary safety endpoint was the rate of major adverse events at 30 days and 6 months.

Results. Between January 2020 and June 2021, 45 patients were enrolled. Mean age was 79 years. Patients were in New York Heart Association (NYHA) functional class III or IV, and had functional (78%) or degenerative (22%) MR. Mean preprocedural left ventricular ejection fraction was 42% ± 12% (degenerative 54% and functional 38%). Mitral repair was successful in all cases. The procedural success rate (expressed as significant acute MR reduction) was 93%, while the clinical success rate was 89% at 30 days follow-up and 93% at 6 months follow-up. In detail, patients with either degenerative or functional aetiologies

displayed reduction of MR grade ≤ 2+ at 30 days (both p<0.001 vs. baseline). This result was maintained at 6 months in both groups (p<0.001 for both). At 30 days, 25 patients (56%) were in NYHA class I and 18 patients (40%) were in NYHA class II, and the mean six-minute walking distance (6MWD) increased by 65 metres (p<0.001 vs. baseline). The improvement of symptoms and functional capacity was maintained at 6 months, with 95% patients in NYHA class I or II (p<0.001 vs baseline) and mean 6MWD increasing by 80 metres (p<0.001; Figure 1). The EQ-5D Health Questionnaire scores improved significantly from baseline to 6 months (p<0.0001). The primary safety endpoint was met by 4% of patients at 30 days and 5% at 6 months. The rate of all-cause mortality was 7%, cardiovascular mortality was 5% and heart failure hospitalizations rate was 2% at 6 months (Figure 2).

Conclusions. In a real-world population, severe MR can be successfully and safely treated with the PASCAL device regardless of MR aetiology. This intervention resulted in a sustained MR reduction, improved exercise capacity and quality of life at 1- and 6-month follow-up.

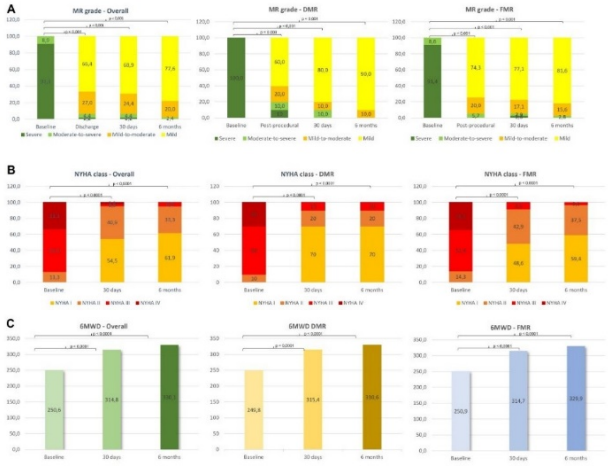
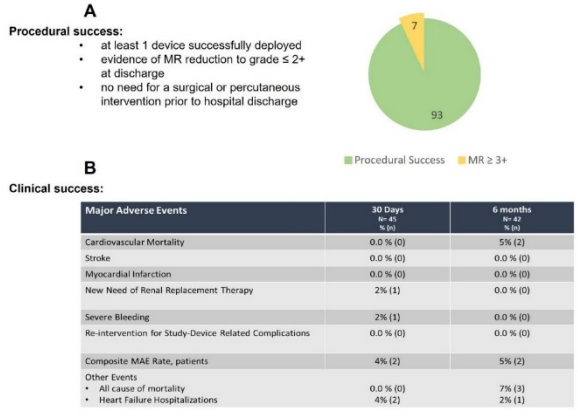


Figure 1. MR grade (*A*), NYHA functional class (*B*) and 6MWD (*C*) at baseline, 30 days, and 6 months of follow-up in patients undergoing TEER with the PASCAL system.
DMR, degenerative mitral regurgitation; FMR, functional mitral regurgitation.



Major Adverse Events	30 Days N= 45 % (n)	6 months N= 42 % (n)
Cardiovascular Mortality	0.0 % (0)	5% (2)
Stroke	0.0 % (0)	0.0 % (0)
Myocardial Infarction	0.0 % (0)	0.0 % (0)
New Need of Renal Replacement Therapy	2% (1)	0.0 % (0)
Severe Bleeding	2% (1)	0.0 % (0)
Re-intervention for Study-Device Related Complications	0.0 % (0)	0.0 % (0)
Composite MAE Rate, patients	4% (2)	5% (2)
Other Events • All cause of mortality • Heart Failure Hospitalizations	0.0 % (0) 4% (2)	7% (3) 2% (1)

Figure 2. Procedural success (*A*) and clinical success (*B*) in patients undergoing TEER with the PASCAL system.

C10

CLINICAL OUTCOMES IN PATIENTS WITH HIGH TRANSMITRAL GRADIENT FOLLOWING MITRAL VALVE TRANSCATHETER EDGE-TO-EDGE REPAIR FOR FUNCTIONAL MITRAL REGURGITATION

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Introduction. Despite highly effective in reducing residual mitral regurgitation (rMR) and improving outcomes, mitral valve transcatheter edge to edge repair (MV-TEER) may be associated with high post-procedural residual mitral gradient (rMG). Conflicting results have been reported regarding the relationship between rMG and adverse events. This study was aimed to evaluate the predictors and the impact of elevated rMG after MV-TEER on clinical events in patients with functional mitral regurgitation (FMR) at 2-year follow-up.

Methods. We selected a cohort of 864 patients with FMR who were treated with MV-TEER enrolled in the "Multicentre Italian Society of Interventional Cardiology (GISE) registry of transcatheter treatment of mitral valve regurgitation" (GIOTTO). Patients were stratified in tertiles according to rMG. Primary clinical endpoint was a composite of all-cause death and hospitalization due to HF at two-year follow-up.

Results. Overall, 269 (31.5%) patients with a rMG<3mmHg, 259 (30.3%) with a rMG >3/<4 mmHg and 326 (38.2%) with a rMG >4 mmHg were considered. At multi-variate logistic regression ischemic FMR etiology, baseline MG and the number of implanted clips were independent predictors of a rMG >4 mmHg. Clinical follow-up was available in 570 (63.2%) patients. Patients with a rMG >4 mmHg experienced higher rates of the composite endpoint in comparison with patients of the other tertiles (51.1%, vs 42.3% vs 40.8% log rank test: p=0.033). At multi-variate Cox's regression, both rMG >4 mmHg [HR 1.54, 95% CI (1.14-2.08)] and rMR >2+ [HR 1.36, 95% CI (1.01-1.83)] were independent predictors of adverse events at two-year follow-up.

Conclusions. In a real-world cohort of patients with FMR treated with MV-TEER, a rMG >4 mmHg was associated with a composite endpoint of all-cause death and hospitalization due to HF at two years. Patients with ischemic FMR, high pre-procedural MG and treated with multiple clips had a higher risk of elevated rMG.

C11

A NOVEL HEMODYNAMIC INDEX CHARACTERIZING MITRAL REGURGITATION UNDERGOING TRANSCATHETER EDGE-TO-EDGE MITRAL VALVE REPAIR: THE MITRAL PULSE PRESSURE FRACTION (MPF)

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Introduction. Mitral valve (MV) transcatheter edge-to-edge repair (TEER) is an established treatment for symptomatic mitral regurgitation (MR) associated with durable MR reduction at follow-up, improved functional status and amelioration of symptoms. The direct hemodynamic impact of residual MR after TEER is not always univocally measured by echocardiographic assessment alone which cannot estimate acute changes in filling pressures and left atrial compliance. Invasive continuous left atrial pressure (LAP) monitoring during TEER has been proven to be a feasible intraoperative tool although it showed equivocal correlation with functional outcomes, while other studies indicated that it can predict clinical outcomes independently from TEE guidance.

Methods. Mitral pulse pressure fraction (MPF) is extracted from continuous LAP monitoring during TEER, and it is calculated by dividing the difference between v wave (ventricular systole in the LAP waveform) and the mean minimum LAP (mean between minimum LAP, x/y wave, and a/c wave) by systolic arterial pressure (SAP): (v wave – mean minimum LAP)/SAP. We conducted a retrospective observational study on 73 patients with moderate-to-severe MR who underwent mitral valve TEER at our institutions between September 2017 and March 2022 with continuous invasive intraprocedural LAP measurement. LAP tracings along with systemic arterial pressure tracings were analyzed and MPF was calculated before and after the implantation procedure. For all 73 patients clinical data, echocardiographic assessment, and functional

status as classified by the New York Heart Association (NYHA) were collected at baseline and for 69 patients (94%) occurrence of major adverse events, such as death from any cause, cardiovascular hospitalization or TEER device-related complications was evaluated at follow-up (median 8.8 months, IR 4.7-18.8 months), while for 59 patients (81%) functional status was reassessed at follow-up. Moreover, we analyzed and extracted MPF from pulmonary capillary wedge pressure (PCWP) tracings of a control group of 23 patients with moderate-to-severe MR who underwent right heart catheterization and did not undergo TEER.

Results. Median MPF was 0.098 (IR 0.056-0.188) before TEER and 0.043 (IQR 0.02-0.067) after the procedure (p<0.001), consistent with an overall favorable hemodynamic effect of mitral valve TEER. Median MPF change (difference between MPF before implantation and MPF at the end of the procedure) was 0.043 (IQR 0.015-0.13). Median MPF in the control group was 0.067 (IR 0.05-0.149). The amplitude of reduction in MPF did not differ when comparing patients based on different echocardiographic etiologies of MR, namely organic, functional proportionate, or functional disproportionate MR (p=0.122). At follow-up there was no significant correlation between invasive hemodynamic parameters and major adverse events (death, cardiovascular hospitalization, TEER device-related hospitalization). Patients characterized by a greater reduction in MPF reported a higher improvement in functional status (Figure 1): median MPF reduction was 0.149 (IR 0.097-0.174) in patients reporting improvement of two or more classes in the NYHA classification, 0.045 (IR 0.021-0.099) for patients who gained 1 NYHA class and 0.024 (IR 0.003-0.043) for patients who remained in the same NYHA class as before TEER (p=0.009).

Conclusions. MPF can provide an immediate estimate of the real hemodynamic impact of MR, both in the preprocedural setting and during TEER procedure. We considered different echocardiographic MR etiologies, such as organic, functional proportionate, and functional disproportionate MR, and they were characterized by a comparable hemodynamic response to TEER based on MPF change. No other hemodynamic variable analyzed in our study other than MPF reduction amplitude correlates with improvement in functional class as assessed by the NYHA classification at follow-up. MPF is easy to calculate and to combine on top of the intraprocedural echocardiographic guidance offering a prompt prediction of clinical improvement in functional class.

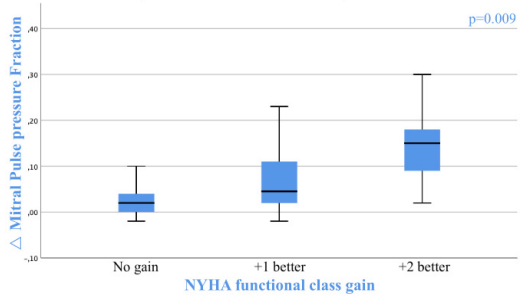

Figure 1. Improvement in NYHA functional class at follow-up and change in MPF after mitral valve TEER.
NYHA, New York Heart Association; MPF, mitral pulse pressure fraction; TEER, transcatheter edge-to-edge repair.

C12

EVOLUTION OF TRICUSPID REGURGITATION AFTER TRANSCATHETER EDGE-TO-EDGE MITRAL VALVE REPAIR FOR SECONDARY MITRAL REGURGITATION AND ITS IMPACT ON MORTALITY

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Aim. To evaluate short-term changes in tricuspid regurgitation (TR) after transcatheter edge-to-edge repair (TEER) in secondary mitral regurgitation (SMR), their predictors and impact on mortality.

Methods and results. This is a retrospective analysis of SMR patients undergoing successful TEER (post-procedural MR <2+) at 13 European centres. Among 503 patients evaluated 79 (IQR 40-152) days after TEER, 173 (35%) showed >1 degree improvement of TR, 97 (19%) had worsening of TR, and 233 (46%) remained unchanged. Smaller baseline left atrial diameter and residual MR 0/1+ were independent predictors of TR <2+after TEER. There was a significant association between TR changes and NYHA class and pulmonary artery systolic pressure decrease at echocardiographic reassessment. At a median follow-up of 590 (IQR 209 – 1103) days from the echocardiographic reassessment, all-cause mortality was lower in patients with improved compared to those with unchanged/worsened TR (29.6% versus 42.3% at 3 years; Log Rank p=0.038). Baseline TR severity was not associated with mortality, whereas TR 0/1+ and 2+ at follow-up was associated with lower all-cause mortality compared to TR 3/4+ (30.6% and 35.6% versus 55.6% at 3 years, p=0.001). A TR <2+ after TEER was independently associated with a 42% decreased risk of long-term mortality (p=0.011).

Conclusion: More than one third of patients with SMR undergoing successful TEER experienced an improvement in TR. Pre-procedural TR was not associated with outcome, but a TR <2+ at short-term follow-up was independently associated with long-term mortality. Optimal TEER result and small left atrial dimension were associated with a higher likelihood of TR <2+ after TEER.

TAVI

C13

TRANSCATHETER AORTIC VALVE IMPLANTATION WITH SELF-EXPANDING ACURATE NEO2: POST-PROCEDURAL HEMODYNAMIC AND SHORT-TERM CLINICAL OUTCOMES

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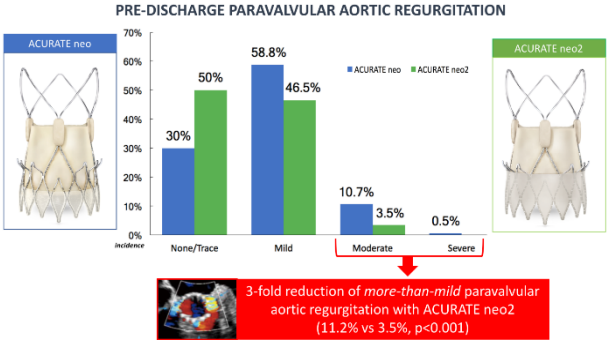
Introduction. To assess the efficacy and safety of ACURATE neo2 THV in patients with severe aortic valve stenosis. The first-generation ACURATE neo transcatheter heart valve (THV) was associated with a not negligible incidence of more-than-mild paravalvular aortic regurgitation (AR) following transcatheter aortic valve implantation (TAVI). To overcome this issue, the ACURATE neo2 iteration, featuring technological refinements aimed at reducing the incidence of paravalvular AR, has recently been developed.

Methods. The ITAL-neo was an observational, retrospective, multicenter registry enrolling consecutive patients with severe aortic valve stenosis, treated with first- and second-generation ACURATE neo THV, via transfemoral and transubclavian access, in 13 Italian centers. A 1:1 propensity score matching was applied to account for baseline characteristics unbalance. The primary endpoint was the incidence of more-than-mild paravalvular AR at pre-discharge echocardiographic assessment. Secondary endpoints included post-procedural technical success and 90-day device success and safety.

Results. Among 900 patients included in the registry, 220 received ACURATE neo2 THV whereas 680 were treated with first-generation device. The ACURATE neo2 THV was associated with a 3-fold reduction in post-procedural more-than-mild paravalvular AR (11.2% vs. 3.5%, p<0.001). No other hemodynamic differences were observed. Post-procedural technical success was similar between the two cohorts. A numerically higher rate of 90-day device success and safety endpoints were observed in patients treated with ACURATE neo2.

Conclusions. Transfemoral TAVI using the ACURATE neo2 was associated with a significant reduction of more-than-mild paravalvular AR compared to the earlier generation ACURATE neo device, with encouraging short-term safety and efficacy.

Primary endpoint



Baseline clinical characteristics

	Unmatched			Marched		
	ACURATE neo (n=680)	ACURATE neo2 (n=220)	p-value	ACURATE neo (n=205)	ACURATE neo2 (n=205)	p-value
Age (years), median[IQR]	83 [80-86]	83 [80.7,86.0]	0.624	84.00 [80.00, 86.00]	83.00 [81.00, 86.00]	0.746
BMI (kg/m²), median[IQR]	25.96 [23.21,29.18]	26.22 [23.00,29.71]	0.489	26.57 [24.00, 29.91]	26.14 [23.00, 29.38]	0.443
Male sex, n (%)	237 (34.9)	68 (30.9)	0.288	68 (33.2)	66 (32.2)	0.916
Arterial hypertension, n (%)	560 (82.4)	184 (83.6)	0.759	172 (83.9)	170 (82.9)	0.894
Diabetes mellitus, n (%)	179 (26.3)	50 (22.7)	0.327	50 (24.4)	48 (23.4)	0.908
Active malignancy, n (%)	33 (4.9)	15 (6.8)	0.299	16 (7.8)	14 (6.8)	0.850
Previous PM implantation, n (%)	66 (9.7)	21 (9.5)	1.000	19 (9.3)	20 (9.8)	1.000
History of CAD, n (%)	234 (34.4)	78 (35.5)	0.807	76 (37.1)	73 (35.6)	0.837
Previous MI, n (%)	76 (11.2)	28 (12.7)	0.545	30 (14.6)	27 (13.2)	0.775
Previous PCI, n (%)	152 (22.4)	51 (23.2)	0.782	50 (24.4)	49 (23.9)	1.000
Previous CABG, n (%)	42 (6.2)	7 (3.2)	0.122	7 (3.4)	7 (3.4)	1.000
Previous non-CABG cardiac surgery, n(%)	40 (5.8)	11 (5.0)	0.802	11 (5.4)	10 (4.9)	1.000
PAD, n(%)	64 (9.4)	29 (13.2)	0.126	20 (9.8)	25 (12.2)	0.528
Carotid artery disease, n(%)	81 (11.9)	27 (12.3)	0.905	20 (9.8)	24 (11.7)	0.633
History of AF, n (%)	161 (23.7)	75 (34.1)	0.003	64 (31.2)	63 (30.7)	1.000
History of TIA or cerebral stroke, n (%)	53 (7.8)	19 (8.6)	0.670	17 (8.3)	16 (7.8)	1.000
COPD, n(%)	86 (12.6)	32 (14.5)	0.491	26 (12.7)	28 (13.7)	0.884
Severe arterial pulmonary hypertension*, n (%)	29 (4.3)	16 (7.3)	0.107	14 (6.8)	12 (5.9)	0.840
eGFR (ml/min/1.73m²), median[IQR]	50.00 [38.06, 67.00]	58.50 [42.00, 73.00]	<0.001	56.00 [43.00, 73.20]	57.00 [41.00, 73.00]	0.963
NYHA class ≥3, n (%)	420 (61.8)	139 (63.2)	0.749	128 (62.4)	130 (63.4)	0.919
Presence of angina, n (%)	65 (9.6)	28 (12.7)	0.240	22 (10.7)	26 (12.7)	0.645
EuroSCORE II, median[IQR]	3.46 [2.30, 5.53]	2.98 [2.00, 5.67]	0.071	3.07 [2.29, 4.65]	3.01 [2.00, 5.81]	0.894
STS-PROM, median[IQR]	3.60 [2.50, 5.00]	3.38 [2.23, 5.10]	0.541	3.33 [2.40, 4.80]	3.40 [2.23, 5.10]	0.679

AF, atrial fibrillation; BMI, body mass index; CABG, coronary artery bypass graft; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate; IQR, interquartile range; MI, myocardial infarction; NYHA, New York Heart Association; PAD, peripheral artery disease; PM, pacemaker; PCI, percutaneous coronary intervention; STS-PROM, Society of thoracic surgeons predicted risk of mortality; TIA, transient ischemic attack.
*Defined as systolic pulmonary artery pressure ≥60 mmHg at echocardiography.

Procedural characteristics and antithrombotic regimens

	ACURATE neo (n=205)	ACURATE neo2 (n=205)	p-value
Anesthesia type, n (%):			0.114
- conscious sedation	203 (99)	197 (96.1)	
- general	2 (1)	8 (3.9)	
Trans-femoral access, n (%)	205 (100)	205 (100)	1.000
Concomitant PCI, n (%)	18 (8.8)	17 (8.3)	1.000
Cerebral embolic protection, n (%)	7 (3.4)	6 (2.9)	1.000
THV size, n (%):			0.491
- 23 mm (S)	61 (29.8)	50 (24.4)	
- 25 mm (M)	84 (41.0)	91 (44.4)	
- 27 mm (L)	60 (29.3)	64 (31.2)	
Valve predilatation, n (%)	140 (69.0)	189 (92.2)	<0.001
Valve postdilatation, n (%)	99 (48.3)	65 (31.7)	0.001
Need for second THV implantation	6 (2.9)	1 (0.5)	0.122
Procedure length (min), median[IRQ]	105.00 [80.00-121.00]	100.00 [76.75, 125.00]	0.310
Contrast dye amount (ml), median[IRQ]	150.00 [100.00, 200.00]	127.50 [80.00, 188.75]	0.057
LMCA protection, n (%)	0 (0.00)	1 (0.5)	1.000
RCA protection, n (%)	0 (0.00)	0 (0.00)	NA
Post-procedural antithrombotic therapy, n (%):			NA
- SAPT	75 (37.9)	86 (42.6)	
- DAPT	62 (31.3)	47 (23.3)	
- OAC	44 (22.2)	58 (26.2)	
- DAT*	11 (5.6)	10 (5.0)	
- TAT**	3 (1.5)	1 (0.5)	

DAT, dual antithrombotic therapy; DAPT, dual antiplatelet therapy; IQR, interquartile range; LMCA, left main coronary artery; OAC, oral anticoagulant; PCI, percutaneous coronary intervention; RCA, right coronary artery; SAPT, single antiplatelet therapy; TAT, triple antithrombotic therapy; THV, transcatheter heart valve.
*Single antiplatelet therapy plus oral anticoagulant.
**Dual antiplatelet therapy plus oral anticoagulant.

In-hospital outcomes

	ACURATE neo (n=205)	ACURATE neo2 (n=205)	p-value
All-cause mortality, n (%)	1 (0.5)	3 (1.5)	0.623
CV death, n (%)	1 (0.5)	3 (1.5)	0.623
Intra-procedural death, n (%)	1 (0.5)	0 (0.0)	1.000
Peri-procedural MI, n (%):	1 (0.5)	0 (0.0)	1.000
Development of new AAVB and/or BBB, n (%);	53 (25.9)	59 (28.8)	0.580
of those, spontaneous regression, n (%)	21 (39.6)	27 (39.1)	1.000
Need of PPM implantation, n (%)*	17 (9.1)	14 (7.6)	0.709
Cerebral ischemic event, n (%):			1.000
- TIA / non-disabling stroke	1 (0.5)	2 (1.0)	
- Disabling stroke	1 (0.5)	0 (0.0)	
VARC-3 bleeding, n (%):			0.947
- Type 1	23 (11.2)	20 (9.8)	
- Type 2	6 (2.9)	5 (2.4)	
- Type 3	3 (1.5)	3 (1.5)	
- Type 4	0 (0.0)	0 (0.0)	
VARC-3 vascular complication, n (%):			0.862
- Minor	9 (4.4)	12 (5.9)	
- Major	8 (3.9)	7 (3.4)	
Coronary occlusion, n (%)	1 (0.5)	1 (0.5)	0.842
Cardiac tamponade, n (%)	3 (1.5)	2 (1.0)	0.842
VARC-3 AKI, n (%):			0.546
- Type 1	1 (0.5)	4 (2.0)	
- Type 2	5 (2.5)	5 (2.5)	
- Type 3	1 (0.5)	0 (0.0)	
- Type 4	0 (0.0)	1 (0.5)	
VARC-3 technical success, n (%)	195 (95.1)	200 (97.6)	0.293
Intensive care unit stay (days), median[IRQ]	1.50 [1.00, 3.00]	1.00 [0.00, 3.00]	0.003
Hospital length (days), median[IRQ]	7.00 [5.00, 9.00]	6.00 [4.00, 9.00]	0.136

AAVB, advanced atrioventricular block; AKI, acute kidney injury; BBB, bundle branch block; CV, cardiovascular; IQR, interquartile range; MI, myocardial infarction; PPM, permanent pacemaker; TIA, transient ischemic attack; VARC-3, Valve Academy Research Consortium-3.
*Patient already carrying a permanent pacemaker at time procedure were excluded from denominator.

90-day outcomes

	ACURATE neo	ACURATE neo2	p-value
VARC-3 device success, n (%)	172 (83.9)	184 (89.8)	0.108
VARC-3 early safety, n (%)	151 (73.7)	164 (80.0)	0.160

	ACURATE neo (n=175)	ACURATE neo2 (n=200)	p<0.001
All-cause mortality, n (%)	7 (4.0)	9 (4.5)	1.000
CV death, n (%)	5 (3.2)	5 (3.2)	1.000
MI, n (%)	1 (0.6)	0 (0.0)	0.469
Cerebral ischemic event, n (%):			0.689
- TIA / non-disabling stroke	1 (0.6)	1 (0.5)	
- Disabling stroke	1 (0.6)	4 (2.0)	
Re-hospitalization, n (%)	9 (5.2)	11 (5.6)	1.000
VARC-3 bleeding, n (%):			0.909
- Type 1	23 (12.9)	23 (11.7)	
- Type 2	6 (3.4)	5 (2.5)	
- Type 3	3 (1.7)	4 (2.0)	
- Type 4	1 (0.6)	0 (0.0)	
New PPM implantation, n (%)	19 (10.9)	15 (7.7)	0.368

	ACURATE neo (n=175)	ACURATE neo2 (n=200)	p=0.192
LVEF, median[IQR]	58.00 [55.00, 62.00]	60.00 [55.00, 63.00]	0.236
Mean transvalvular gradient (mmHg), median[IRQ]	7.00 [5.00, 10.00]	7.00 [5.00, 10.00]	0.826
Max transvalvular gradient (mmHg), median[IRQ]	12.00 [9.75, 17.00]	13.00 [10.00, 19.00]	0.453
Max transvalvular velocity (m/s), median[IRQ]	1.73 [1.56, 2.06]	1.80 [1.58, 2.18]	0.453
AVA (cm²), median[IRQ]	1.83 [1.40, 2.10]	1.74 [1.42, 2.09]	0.621
Prosthesis-patient mismatch (cm²/m²), median[IRQ]	1.03 [0.75]	1.03 [0.89, 1.20]	0.355
Paravalvular AR, n (%)			0.002
- None/Trace	39 (31)	58 (50.9)	
- Mild	71 (56.3)	52 (45.6)	
- Moderate	15 (11.9)	4 (3.5)	
- Severe	1 (0.8)	0 (0.0)	

AVA, aortic valve area; AR, aortic regurgitation; CV, cardiovascular; IQR, interquartile range; LVEF, left ventricular ejection fraction; MI, myocardial infarction; PPM, permanent pacemaker implantation; TIA, transient ischemic attack; VARC-3, Valve Academy Research Consortium-3.

C14

LONG-TERM SURVIVAL AFTER TAVR IN PATIENTS WITH LOW FLOW-LOW GRADIENT VS HIGH GRADIENT AORTIC VALVE STENOSIS

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Introduction. Transcatheter aortic valve replacement (TAVR) has become the treatment of choice in elderly patients affected by severe aortic stenosis (AS). In patients with low-flow low-gradient (LFLG) AS, a clear benefit of TAVR over conservative treatment has been

demonstrated. Notwithstanding, patients with classical LFLG (cLFLG) AS have shown worse early post-procedural outcomes compared to those with high-gradient (HG) AS. Given the absence of data, we aimed to evaluate long-term survival (up to 10 years) after TAVR in patients with cLFLG and paradoxical LFLG (pLFLG) AS as compared to those with HG-AS.

Methods. Consecutive patients undergoing TAVR at our center with a minimum 5-year follow up (i.e. treated between June 2007 and December 2016) were considered for this analysis. According to baseline echocardiography, patients were divided in three groups: 1) HG-AS (MG > 40 mmHg); 2) cLFLG-AS (MG <40 mmHg, EF <50%); and 3) pLFLG-AS (MG <40 mmHg, EF >50%). The study endpoint was post-procedural all-cause mortality. To test differences in long-term outcomes among groups, survival curves using the Kaplan Meier estimator were plotted and compared with the log-rank test. To adjust for possible baseline confounders, a propensity score weighted survival analysis was then performed (standard mean deviation <0.1 for all the considered covariates).

Results. A total of 574 subjects were included in the analysis (419 [73%] HG-AS; 91 [15%] pLFLG-AS; and 64 [11%] cLFLG-AS). Median survival time was 4.8 years [IQR 2.3 – 6.2], with a maximum of 12.3 years. Patients with cLFLG-AS presented higher baseline cardiovascular risk compared to those with both HG-AS and pLFLG-AS. At unadjusted survival analysis, patients with cLFLG-AS showed the worst long-term prognosis after TAVR (overall log-rank test p=0.023). However, after propensity weighted adjustment, the long-term survival of patients with cLFLG-AS was similar to those with HG-AS (p=0.77). Patients with pLFLG and HG-AS presented similar survival rate. Unadjusted (Panels A and C) and adjusted (Panels B and D) survival curves are reported in Figure 1. Out of 64 patients with cLFLG-AS, 43 (67%) presented an improvement in LV-EF (>15% from the baseline value) within the first year after TAVR. LV-EF improvement, but not baseline LV-EF, was apparently related to longer post-TAVR survival (Figure 2).

Conclusions. In the current study, patients with cLFLG-AS had worse long-term survival after TARV as compared to either HG or pLFLG-AS subjects. This difference was not present after adjusting for possible baseline confounders. Thus, the low-flow state condition per se might have a lower impact on long term prognosis of TAVR patients than previously hypothesized. Post-TAVR LV-EF recovery was common among patients with cLFLG-AS and was associated with improved long-term survival.

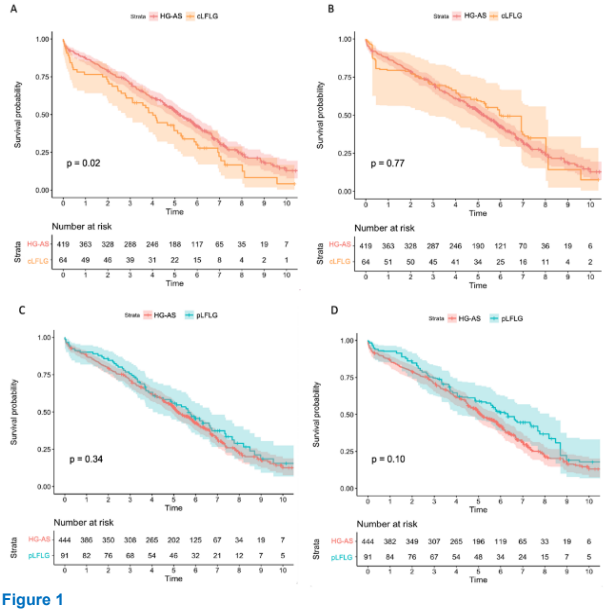

Figure 1

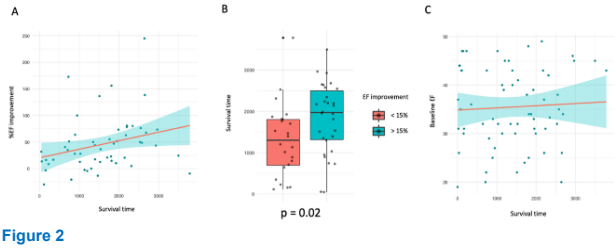

Figure 2

C15

FUNCTIONAL AND METABOLIC FRAILTY PREDICTS MORTALITY IN PATIENTS UNDERGOING TAVI: INSIGHTS FROM THE OBSERVANT II STUDY

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Background/Aim. Despite the prognostic role of frailty among elderly patients undergoing transcatheter aortic valve implantation (TAVI) is known, its assessment still represents a challenge due to the multitude of scales proposed in literature. The aim of this study was to define the prognostic impact of a simple combined frailty model including both functional and metabolic parameters in a large cohort of patients undergoing TAVI with new generation devices.

Methods. We examined 1-year survival of patients affected by aortic valve stenosis treated with new generation TAVI devices from the OBSERVANT II study. Frailty of patients undergoing TAVI was stratified in four groups according to a combination of functional (geriatric status scale - GSS) and metabolic (global nutritional risk index - GNRI) assessment. Among 1986 patients included in the analysis, 1008 (51%) had no significant frailty, 247 (12%) had only functional impairment, 522 (26%) had only metabolic impairment and 209 (11%) had both functional and metabolic impairment.

Results. The presence of combined functional and metabolic frailty was associated with a two-fold increased risk of 1-year all-cause mortality (HR 2.07 [95% CI 1.35-3.18]; p=0.001). GNRI as a single parameter had a lower impact on mortality (HR 1.47 [95% CI 1.04-2.08]; p=0.030), whereas GSS did not impact on mortality (HR 1.24 [95% CI 0.77-2.01]; p=0.37).

Conclusions. In a large real-world cohort of patients undergoing TAVI with new generation devices, combined functional and metabolic frailty had a significant and incremental impact on 1-year mortality.

C16

DEFINITION OF TRANSCATHETER HEART VALVE ORIENTATION IN BICUSPID AORTIC VALVE:2 THE DA VINCI PILOT STUDY

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Introduction. Transcatheter aortic valve replacement (TAVR) is approved for low-risk and younger patients with severe aortic stenosis. Given the longer life-expectancy of this population, the preservation of free coronary access (CA) for future coronary interventions is of utmost importance. Specific techniques to align the neo-commissures have been recently reported for supra-annular THVs, such as the Evolut R/Pro/Pro+ (Medtronic) and the Acurate Neo/Neo2 (Boston Scientific), but these have been explored only in the setting of tricuspid aortic (TAV). Less is known about the rate of successful commissural alignment with current implantation techniques in patients with bicuspid aortic valve (BAV) treated by TAVR.

Methods. The DA VINCI (Definition of trAnscatheter aortic Valve orIeNtation in biCuspId aortic 38 valve) study is a prospective registry enrolling consecutive patients with severe BAV stenosis undergoing TAVR with last generation supra-annular tall-frame THVs implanted with a cusp overlap view-based commissural alignment. Patients underwent pre- and post-TAVR computed tomography (CT) and coronary angiography. The study endpoint was the rate of favorable THV orientation, defined as an angle >40° between the THV commissural post and the coronary ostia. Other endpoints were the rates of successful THV alignment with respect to the raphe and of selective CA after TAVR. Moreover, different virtual THV alignment models were tested to identify which one would produce the lower degree of THV/coronary overlap.

Results. Thirty-four patient with type 1 BAV undergoing TAVR (23 with Evolut Pro/Pro+ and 11 with Acurate Neo2) were included. Moderate/severe cusp asymmetry was found in 50.0% of patients, 48 severe coronary ostia eccentricity was observed in 47.1% for the RCA vs. 8.8% for the LCA (P<0.007). At post-TAVR CT, optimal THV

alignment/mild misalignment to the raphe was observed in 86.2%, but a moderate/severe overlap with the coronaries was seen in 13.7% for the RCA and 44.8% for the LCA. After TAVR, selective RCA cannulation was possible in 82.8% vs. 75.9% for the LCA (P=0.74). Virtual THV alignment in the coronary overlap view assuming a hypothetical circular THV expansion produced an optimal THV/coronary overlap in 90% of cases.
Conclusions. Given cusp asymmetry and coronary ostia eccentricity of BAV, conventional commissural alignment techniques are associated with higher rates of THV misalignment and of moderate/severe neo-commissure overlap with the coronary ostia as compared to tricuspid aortic stenosis, resulting in lower rates of selective CA after TAVR. A modified THV orientation technique based on the coronary overlap view might be preferable in BAV patients.

C17

OUTCOMES OF TRANSCATHETER AORTIC VALVE IMPLANTATION WITH EVOLUT PRO/PRO+ OR SAPIEN 3 ULTRA DEVICES IN PATIENTS WITH SMALL AORTIC ANNULI: INSIGHTS FROM THE OPERA-TAVI REGISTRY

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Introduction. Latest iterations of devices for transcatheter aortic valve implantation (TAVI) have brought refinements to further improve patients' outcomes, but large comparisons of the most used self-expanding and balloon-expandable valves are lacking. The aim of this analysis was to compare early outcomes of TAVI patients with native aortic annulus diameter smaller than 23 mm, receiving Evolut PRO/PRO+ (PRO) or Sapien 3 ULTRA (ULTRA) devices.
Methods. The OPERA-TAVI registry collected data from 14 high-volume centers worldwide on patients undergoing TAVI with PRO or ULTRA devices. After excluding patients who could not receive both devices indifferently according to manufactures' instructions for use, 1063 patients with native aortic annulus diameter <23 mm were compared using 1:1 propensity score matching. The primary and co-primary outcomes were VARC-3-defined device success and early safety, respectively.
Results. A total of 323 pairs of patients were matched. The primary outcome (85.4% vs. 86.7%, p=0.73) did not differ between patients receiving PRO or ULTRA transcatheter aortic valve (TAVs), but ULTRA recipients showed significant higher rates of the co-primary outcome (71.8% vs. 84.8%, p<0.01). This finding was driven by a significantly higher rate of permanent pacemaker implantation (PPI) reported in PRO recipients (16.1% vs. 8.7%, p<0.01). At post TAVI echocardiographic assessment, similar rates of moderate-to-severe PVR (4.3% vs. 2.2%, p=0.18) were reported, but PRO showed lower mean transvalvular gradients (median 7 vs. 13 mmHg, p<0.01).
Conclusions. The OPERA-TAVI registry showed that PRO and ULTRA TAVs had comparable device success rates, but ULTRA had higher rates of early safety in patients with small aortic annuli. The higher rate of PPI was the main determinant of the lower safety for patients receiving PRO valves.

C18

TRANSCATHETER AORTIC VALVE REPLACEMENT IN PATIENTS WITH BICUSPID AORTIC VALVE: COMPARISON BETWEEN ANNULAR AND SUPRA-ANNULAR PROSTHESIS SIZING

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Introduction. Transcatheter Aortic Valve Replacement (TAVR) in patients with bicuspid aortic valve (BAV) still represents a challenge due to the peculiar anatomy and the lack of consensus for the optimal CT scan sizing method for prosthesis selection. Recent evidences have shown that transcatheter heart valve (THV) anchoring in BAV patients might occur at the raphe-level, known as the LIRA (Level of Implantation at the RAphe) plane. Furthermore, a novel supra-annular sizing method based on the measurement of the perimeter at the raphe-level (LIRA-method) was shown to be safe and effective in BAV patients. The aim of our study is to compare the LIRA method with the annular sizing method (the gold standard in patients with tricuspid aortic valve) for prosthesis selection in patients with raphe-type BAV.
Methods. We enrolled consecutive patients with raphe-type BAV that underwent TAVR for severe aortic stenosis in our center between January 2011 and January 2022. All patients underwent pre-operative MDCT assessment for procedural planning. The primary endpoint of the study was to compare the effectiveness of LIRA plane sizing in comparison to annular sizing in terms of device success as defined by VARC-3 criteria (technical success; freedom from procedural mortality; freedom for surgery or intervention related to the device or a major vascular complication; mean aortic valve gradient <20 mmHg or peak velocity <3 m/s, and less than moderate aortic regurgitation). The secondary endpoints were early safety endpoints as defined by VARC-3 criteria (freedom from all-cause mortality, stroke, VARC type 2-4 bleedings, major vascular complications, AKI 3-4, moderate-severe paravalvular leaks, stroke, permanent pacemaker implantation, surgery or intervention related to the device).
Results. During the study period a total of 117 patients with bicuspid aortic valve type 1 and 2 underwent TAVR at our institution. Of these 64 (54.7%) patients underwent TAVR with prosthesis sizing based on measurements performed at the virtual basal ring (VBR group), while 53 (45.3%) patients underwent TAVR with prosthesis sizing performed according to the LIRA method (LIRA group). Baseline clinical characteristics were similar between the two populations. According to the VARC-3 criteria, device success rate was significantly higher in the LIRA population compared to VBR population (88.7% vs 62.5%; p=0.001). Regarding the safety endpoints LIRA method resulted in higher rate of freedom from moderate-severe aortic regurgitation (86.8% vs 68.9%; p=0.023).
Conclusions. This study shows the superiority of LIRA method sizing in comparison to the traditional annular sizing in patients with raphe-type BAV type anatomy in terms of the primary efficacy endpoint of device success. As TAVR indication is expanding towards a younger and lower risk population, it is of the utmost importance to achieve optimal procedural results. Future randomized studies are needed to validate these results.

Structural heart interventions, various

C19

CLINICAL IMPACT OF VASCULAR COMPLICATIONS AFTER PERCUTANEOUS TRANSCATHETER AORTIC VALVE IMPLANTATION. VASC-OBSERVANT II SUB-STUDY

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Background. The trans-femoral (TF) access is the commonest approach for transcatheter aortic valve implantation (TAVI) and it is associated with better clinical outcomes compared to non-TF access. However vascular complications (VCs) after TF-TAVI are associated with worse outcomes. The aim of this study is to evaluate the clinical impact of access site VCs in patients undergoing TAVI with last generation transcatheter valve (THV) enrolled in the national observation prospective multicenter study OBSERVANT II.
Methods. All vascular events were defined according to the Valve Academic Research Consortium (VARC)-2 criteria (VARC-3 criteria are not so much different). The study population was divided into 3 groups: patients without vascular complications (No-VC), patients with minor vascular complications or percutaneous closure device failure (Minor-VC) and patients with major vascular complications (Major-VC). The primary endpoint was the 1 year MACCE (Major adverse cardio and cerebrovascular event, including all-cause mortality, stroke, myocardial infarction and coronary revascularization). A multivariate Cox regression model was used to investigate the differences in survival free from MACCE between the three analyzed groups, adjusting for the main available risk factors.
Results. 2.504 patients (pts) were considered in this analysis: 2.167 pts in No-VC group; 249 pts in Minor-VC and 88 pts in Major-VC 88 pts. At 1-year follow-up Major-VC group was associate to a worse clinical outcome, while outcome of Minor-VC group was similar to patients belonging to the No-VC group (p=0.003, Figure 1). This results was driven by a statistically-significant higher occurrence of death in Major-VC as compared to Minor-VC and No-VC groups (22% vs 7% vs 11%; p<0.0001). At Cox-regression analysis Major-VC was an independent predictors of MACCE (HR 1.89, 95%CI 1.18-3.03, p=0.008).
Conclusions. VCs continue to be associated with worse clinical outcomes (Figure 2) also with last generations THV. Further study are needed to assess the role of refined patient care pathways including, comprehensive imaging-based case planning, ultrasound guidance, prompt recognition and appropriate treatment of VCs.

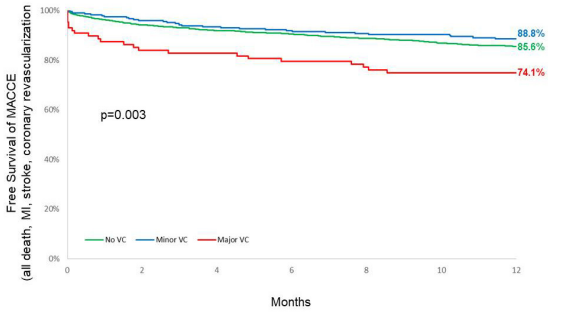

Figure 1. Kaplan-Meier MACCE (all death, non-fatal MI and non-fatal stroke) free survival curves in the study population stratified according to vascular complications (VC).

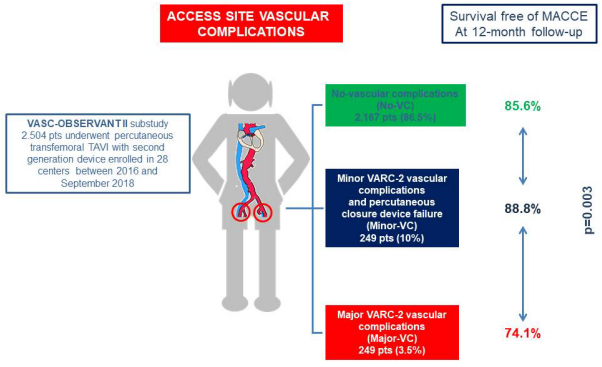

Figure 2. VASC-OBSERVANT II study design and main results.

C20

BALLOON FRACTURE DURING TAVR EFFECTIVE AND REPEATABLE TECHNIQUE NOT WRITTENIN THE TEXTBOOK

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Introduction. An 88-year-old man was referred to transcatheter aortic valve replacement for severe symptomatic aortic stenosis. Edwards 26-mm Sapien bioprosthetic valve (Sapien) implantation was planned after accurate computed tomography–based procedure planning. When the valve was released, the inflation pressure decreased rapidly due to the balloon bursting.

Methods. The procedure was performed using right femoral approach to advance the Edwards 14F eSheath Introducer. When the valve was released, the inflation pressure decreased rapidly due to the balloon burst. The aortic valve was already correctly released. The balloon catheter was immediately pulled back into the descending aorta. Its 2 edges had the shape of 2 facing parachutes (Figure 1). Although the proximal could be easily withdrawn into the sheath, the distal one prolapsed over the sheath edge and could not be further retracted back into the delivery system.

Results. The knowledge of the exact internal structure of the delivery balloon was crucial to provide the chance of a complete endovascular solution to this un wanted complication. The 0.038-inch wire slides with in an internal bar jointly integrated with the noscom, which is in turn attached to the distal edge of the balloon. Conversely, the internal bar is surrounded by a larger catheter–the one constituting the visible shaft of the catheter–which is distally connected with the proximal edge of the balloon. The concept of a complete endovascular solution to this complication is based on the separability of these 2 parts–the internal one linked to the distal edge of the balloon by the noscom, while the outer shaft to the proximal one. Having this in mind, left femoral artery percutaneous access was obtained and an18-Fsheathadvanced just above carrefour. The wire of the delivery system was then captured at the level of the descending thoracic aorta by a Goose-neck snare, previously advanced from left access. The 2 systems–the fractured balloon together with the delivery system and the snare entrapping the 0.038-inch wire–werethus gently pulled back in parallel just above the aortic carrefour. The delivery wire was then externalized, thus creating a right-to-left femoral loop. The snare was again readvanced from left femoral sheath over the wire up to the noscom, which was then easily captured at the level of aortic carrefour. At this stage, the shaft of the catheter was cut with a blade just distally to the Y valve to free the internal core. In this way, the system internal core-noscom-distal edge of the balloon was gently removed, simply tractioning the snare through the left femoral access. As the final step, the proximal part of the balloon adhering to the balloon catheter was easily pulled out from the right femoral sheath.

Conclusions. The patient was asymptomatic and consequently discharged home after 3 days. After a few weeks after the successful management of this complication, we had a similar balloon fracture during valve positioning, we repeated the same maneuver with effective resolution of the complication in approximately 30 minutes.

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C21

RITIRATO

C22

CARDIOBAND TRICUSPID SYSTEM FOR FUNCTIONAL TRICUSPID REGURGITATION: A SINGLE-CENTRE ITALIAN EXPERIENCE

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Introduction. Functional tricuspid regurgitation (TR) is the most frequent aetiology of tricuspid valve disease, and it is due to the tricuspid annulus dilatation and right ventricular enlargement and dysfunction. Functional TR is most often secondary to left-sided heart disease, especially in the setting of mitral valve pathology. Increasing severity of TR is associated with progressively higher morbidity and mortality; however, treatment options are limited. The Cardioband Valve Reconstruction System (Edwards Lifesciences, Irvine, California) is a novel transfemoral direct annular reduction therapy. We report 30 days-outcomes of a single centre Italian experience in the treatment of symptomatic functional tricuspid regurgitation with the Cardioband system.

Methods. 10 patients with severe or greater symptomatic functional TR were enrolled who were deemed candidates for transcatheter tricuspid repair with the Cardioband system by the local heart team and multidisciplinary screening committee.

Results. The mean patient age was 7 years, 90% were women, 100% had atrial fibrillation, 60% were in New York Heart Association functional class III to IV with mean left ventricular ejection fraction of 51%, and 20% had massive and 80% torrential TR**.** Device success was 100% and all patients were alive at 30 days**.** Between baseline and 30 days, septo-lateral tricuspid annular diameter was reduced by 23% (p<0.001), 100% of patients had ≥ 1 grade TR reduction and 60% had ≤ moderate TR, 75% were in New York Heart Association functional class I to II (p<0.001). The EQ-5D Health Questionnaire scores improved significantly from baseline to 6 months (p<0.0001).

Conclusions. In our real-world population, this early feasibility study demonstrates high procedural feasibility with no 30-day mortality. There is significant reduction of functional TR with clinically significant improvements in functional status and quality of life.

C23

NOVEL COMPUTED TOMOGRAPHY VARIABLES FOR ASSESSING TRICUSPID VALVE MORPHOLOGY: RESULTS FROM THE TRIMA (TRICUSPID REGURGITATION IMAGING) STUDY

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Background. Computed tomography (CT) is the recommended imaging technique for defining the anatomical suitability for current transcatheter technologies and planning tricuspid valve (TV) intervention. The aim of the TRIMA (Tricuspid Regurgitation IMAging) study was to assess the geometrical characteristics of the TV complex using novel CT parameters.

Methods. This prospective, single-center study enrolled 36 consecutive patients with severe tricuspid regurgitation, who underwent a cardiac CT study dedicated to the right-chambers. The following variables were obtained: annulus area and perimeter, septal-lateral and antero-posterior diameters, tenting height, anatomical regurgitant orifice area. Moreover, novel annular parameters were assessed: distance between commissures, distance between TV centroid and commissures, angles between centroid and commissures.

Results. A significant phasic variability during the cardiac cycle existed for all variables except for eccentricity, angles and distance between the postero-septal and antero-posterior commissure and distance between centroid and antero-posterior commissure. There was a significant relationship between TV annulus area and novel annular parameters, except for annular angles (Annulus perimeter Diastole r=0.92, p<0.001, Systole r=0.98, p<0.001; SL diameter Diastole r=0.93, p<0.001, Systole r=0.92, p<0.001; AP diameter Diastole r=0.87, p<0.001, Systole r=0.86, p<0.001; AS-PS Diastole r=0.72, p<0.001; Systole r=0.72, p<0.001; PS-AP Diastole r=0.80, p<0.001, Systole r=0.90, p<0.001; AP-AS Diastole r=0.71, p<0.001, Systole r=0.73, p<0.001; Ce-AS Diastole r=0.84, p<0.001, Systole

r=0.72, p<0.001; Ce-PS Diastole r=0.67, p<0.001, Systole r=0.81, p<0.001; Ce-AP Diastole r=0.75, p<0.001, Systole r=0.83, p<0.001. Additionally, novel annular variables were found to predict annulus area.
Conclusions. These novel additional variables may provide an initial platform from which the complexity of the TV annular morphology can continue to be better understood for further improving transcatheter therapies.

C24

MECHANISMS OF INEFFECTIVE PATENT FORAMEN OVALE CLOSURE USING THE PERCUTANEOUS SUTURE-MEDIATED NOBLESTITCH SYSTEM

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Introduction. Patent foramen ovale (PFO) is implicated in the pathogenesis of paradoxical embolism causing a number of medical conditions such as cryptogenic stroke. The NobleStitch EL (HeartStitch, Fountain Valley, CA) has emerged as a novel deviceless system based on a percutaneous suture-mediated PFO closure and it has been employed in clinical practice as an effective and safe alternative to device closure. In previous studies, recurrence of a residual atrial right-to-left shunt (RLS) during follow-up was estimated at almost 20%. Specific mechanisms of failure have not been systematically described and they still remain unknown. The aim of the study was to describe the mechanisms of failure after NobleStitch system.
Methods. 122 patients who had undergone percutaneous PFO closure with NobleStitch system, between June 2016 and September 2021 at the authors' institution, were prospectively included into the study. The overall population underwent a systematic echocardiographic evaluation (transthoracic echocardiography and/or transcranial colordoppler with bubble study) within 6 months after the procedure. Patients with RLS≥2 grade were then studied with transoesophageal echocardiography (TOE), in order to define specific mechanisms of ineffective closure. The data were analysed with SPSS statistics software (version 25, IBM Corp). A 2-sided p-value <0.05 was required for statistical significance.
Results. The baseline characteristics of both groups, with and without significant residual RLS, are summarized in Table 1.

Table 1. Baseline demographic, clinical and echocardiographic characteristics of the study population.

	Overall (n=122)	RLS ≤1 (n=99)	RLS ≥2 (n=23)	p-value
Baseline Characteristics				
Age, years	48±12	48±11	46±14	0.349
Female, n (%)	61 (50.0)	50 (53.8)	11 (37.9)	0.137
BMI, kg/m² (IQR)	21 (19-23)	21 (19-24)	21 (18-23)	0.702
RoPE Score, points (IQR)	6 (5-7)	6 (5-7)	6 (5-7)	0.478
RoPE≥6, n (%)	71 (61.2)	56 (60.2)	15 (65.2)	0.659
Medical History				
Hypertension, n (%)	29 (24.0)	23 (24.7)	6 (21.4)	0.720
Diabetes, n (%)	3 (2.5)	3 (3.2)	0 (0.0)	1.000
Smoking history, n (%)	26 (21)	20 (21.5)	6 (20.6)	0.993
Dyslipidemia, n (%)	31 (25.4)	24 (25.8)	14 (24)	0.932
Family history of CVD, n (%)	16 (13.1)	10 (10.7)	6 (20.7)	0.144
Prior deep vein thrombosis, n (%)	4 (3.3)	2 (2.2)	2 (7.1)	0.229
Thrombotic Diathesis, n (%)	13 (10.7)	8 (8.6)	5 (17.9)	0.166
Clinical Presentation				
Cryptogenic stroke, n (%)	47 (38.8)	32 (34.4)	15 (53.6)	0.068
TIA, n (%)	39 (32.2)	30 (32.3)	9 (32.1)	0.991
Intractable migraine, n (%)	26 (21.5)	19 (20.4)	7 (25.0)	0.606
Decompression sickness, n (%)	11 (9.0)	10 (10.8)	1 (3.4)	0.457
Neuroimaging ischemic lesion, n (%)	87 (71.9)	65 (69.9)	22 (78.6)	0.669
Anatomical Characteristics				
Atrial septal aneurysm, n (%)	19 (15.6)	10 (10.8)	9 (31.0)	**0.009**
Atrial septal hypermobility, n (%)	48 (39.3)	30 (32.3)	18 (62.1)	**0.004**
Septum cribrosus, n (%)	2 (1.7)	1 (1.1)	1 (3.4)	0.423
Chiari network, n (%)	84 (69.4)	58 (63.0)	26 (89.7)	**0.007**
Fossa ovalis diameter, mm (IQR)	20 (17-22)	20 (17-22)	19 (17-23)	0.941
PFO tunnel length, mm (IQR)	11 (9-13)	11 (9-12)	12 (9-15)	0.058
PFO width, mm (IQR)	2.6 (2-3.8)	2.5 (2.0-3.0)	3.0 (2.3-4.0)	**0.020**
Functional Characteristics				
Interatrial shunting at rest, n (%)	34 (28.1)	20 (21.7)	14 (48.3)	**0.006**
Atrial RLS after Valsalva, n (%)	122 (100)	93 (100)	29 (100)	-
Left-to-right shunt, n (%)	16 (13.2)	9 (9.8)	7 (24.1)	**0.047**
Spontaneous color Doppler shunt, n (%)	10 (8.3)	8 (8.7)	2 (7.1)	1.000
Grade of RLS after Valsalva at TTE/TEE	10 (8.2)	10 (10.8)	0 (0.0)	0.115
Mild, n (%)	68 (55.7)	53 (57.0)	15 (51.7)	0.618
Moderate, n (%)	44 (36.1)	30 (32.3)	14 (48.3)	0.117
Severe, n (%)				
Grade of RLS after Valsalva at TCD, n (%)	9 (9.9)	9 (13.4)	0 (0.0)	0.105
Mild, n (%)	40 (44.0)	32 (47.8)	8 (33.3)	0.222
Moderate, n (%)	42 (46.2)	26 (38.8)	16 (66.7)	**0.019**
Severe, n (%)				

Categorical variables are expressed as n (%). Continuous variables are expressed as median and interquartile range (IQR), as appropriate.
BMI, body mass index; RoPE score, Risk of Paradoxical Embolism; CVD, cardiovascular disease; TIA, transient ischemic attack; PFO, patent foramen ovale; RLS, right-left shunt; TTE, transthoracic echocardiography; TEE, transesophageal echocardiography; TCD, transcranial Doppler.

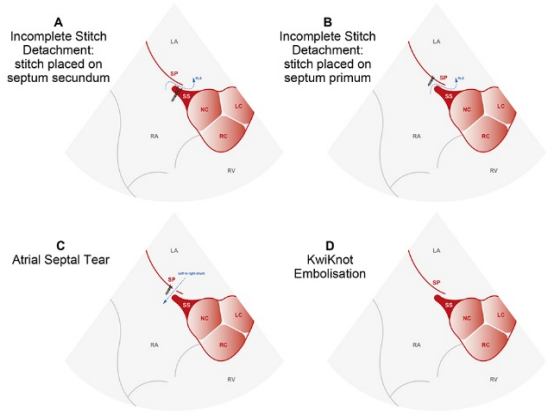

Figure 1. Representative transesophageal echocardiographic images of different mechanisms of ineffective PFO closure: (*A*) Stitch Incomplete Detachment: one of the most frequently identified mechanisms of ineffective PFO closure was partial stitch detachment with opening of the foramen ovale and right-to-left passage of microbubbles at bubble test. In this case the stitch is placed only on septum secundum. (*B*) Stitch Incomplete Detachment: the same mechanism of A but in this case the NobleStitch was found on septum primum resulting in recurrent atrial shunt. (*C*) Atrial Septal Tear: a new atrial septal tear can occurred really close to the stitch after NobleStitch procedure causing a left-to-right shunt. (*D*) KwiKnot embolization: complete detachment of the stitch and the KwiKnot into the pulmonary circulation resulting in a PFO reopening.

The NobleStitch procedure was successfully performed in 95.1% of cases (116 patients). No major procedure-related complications occurred. At a median follow-up of 1 year, atrial RLS ≥2 occurred in 19.8% of patients. Three different mechanisms of late failure (Figure 1) were identified by TOE: partial stitch detachment, atrial septal tear and KwiKnot embolisation. A partial stitch detachment was found as the main mechanism in 52.2% of cases: the KwiKnot was attached only on the septum primum or septum secundum, with the clear identification of 2 separated septal sheets, leading to an opening tunnel with consequent residual atrial RLS. A second mechanism found was an atrial septal tear (13%) occurring really close to the stitch, with consequent left-to right shunt. Finally, the third mechanism identified was a complete embolisation of the stitch and the knot into the pulmonary circulation (8.7%).
Conclusions. Percutaneous suture-mediated PFO with NobleStitch system is a safe and effective alternative to traditional device closure, although recurrence of atrial RLS during the follow-up is not rare. To the best of our knowledge, this is the first study in which three different mechanisms of late failure were identified. Hence, we want to highlight the importance of TEE as an essential tool to assess the anatomical and functional characteristics of PFO, in order to improve patients' selection for NobleStitch procedure and long term-outcomes.

Coronary CTO and complex lesions

C25

APPLICABILITY OF J-CTO CHANNEL SCORE TO PREDICT MICROCATHETER CROSSING DURING RETROGRADE PERCUTANEOUS INTERVENTION OF CHRONIC TOTAL OCCLUSIONS: INSIGHTS FROM THE SURFING MICRO REGISTRY

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Objective. To compare the applicability of J-CTO channel score to predict microcatheter tracking of collaterals channel in patients undergoing retrograde percutaneous coronary intervention (PCI) of chronic total occlusions (CTO).
Background. In patients undergoing retrograde CTO-PCI, implementation of J-CTO channel score can predict the difficulty of the guidewire to track collateral channel. However, the efficacy of J-CTO channel score to predict microcatheter tracking has never been tested in the setting of retrograde CTO-PCI.
Methods. A total of 189 patients undergoing retrograde CTO-PCI from October 2015 to August 2021 were screened. The primary outcome of interest was a correlation between J-CTO channel score and microcatheter tracking failure after successful collateral channel tracking by guidewire. The independent association between anatomical features of the J-CTO channel score and the primary outcome of interest was explored. A logistic regression model was properly designed to identify independent predictors of microcatheter tracking failure including

anatomical features of collateral channel (size, continuos bends, reverse bends) and procedural features (diameter of largest retrograde guiding catheter used during the procedure, double trans-radial vascular access and types of microcatheter used).
Results. At univariate analysis for septal collaterals, small size, reverse bends, continuous bends and double TRA access were associate with an increased risk of MTF. After adjustment, only small size (adjusted odds ratio [OR] 12.73, 95% confidence interval [CI] 2.36 to 68.63; p=0.003) and continuous bends (adjusted OR 7.93, 95% CI 1.97 to 31.88; p=0.004) remained significantly associated with an increased risk of MTF. Small size remains the only predictor of the MTF for epicardial collaterals (OR 6.39, 95% CI 1.13 to 35.96; p=0.020) at univariate analysis but not after adjustment (OR 14.43, 95% CI 0.58 to 360; p=0.104). Patients in MTF group had lower incidence of procedural success compared with patients in MTS group (40.0% vs 93.9%, p<0.001) and had higher incidence of procedural complications (24.0% vs 3.7%, p<0.001), driven by an increase risk of collateral perforations (20.0% vs 3.0%, p<0.001) and cardiac tamponade requiring pericardiocentesis (8% vs 1.8%, p=0.028).
Conclusion. J-CTO channel score > 3 is associated with an increases risk of microcatheter tracking failure and consequently with a lower incidence of procedural success. Patients in MTF group had higher risk of procedural complications, primarily driven by collateral perforations and cardiac tamponade requiring pericardiocentesis.
Abbreviations. Japanese-Chronic Total Occlusion (J-CTO); Percutaneous Coronary Intervention (PCI); Chronic Total Occlusion (CTO); Microcatheter tracking failure (MTF); Microcatheter tracking success (MTS).

C26

GUIDE EXTENSION CATHETER: INDICATION, USE AND RESULTS IN A LARGE SERIES OF COMPLEX PERCUTANEOUS CORONARY INTERVENTIONS

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Aims. The guide extension catheter (GEC) is a helpful tool to increase catheter support when facing complex percutaneous coronary intervention (PCI) in unfavorable coronary anatomies. The aim of this study was to describe indication, efficacy, and safety of the GEC in a high-volume center.
Methods and results. From 2014 to 2021, we retrospectively identified and analyzed 351 interventional cases in which GEC was used to complete the procedure. The endpoints of the study were PCI success, procedural success and device failure. GEC use increased over the years and was more frequently used by radial approach (92.1%) in elective setting (90.6%) and using the 6F size (95.3%). The GEC was mostly implemented as bail-out strategy (75.9%) with the aim to improve back-up (89.6%), less frequently to optimize catheter alignment or obtain selective coronary cannulation (10.4%). Intracoronary advancement was performed using the guidewire in 1.3% of cases, after positioning of a second "buddy" wire in 23.2%, with support of a deflated balloon at the distal tip in 12.2%, or with anchoring technique in 63.3%. Mean coronary deep intubation depth was 38.8±23.9 mm. Vessel and lesion characteristics are reported in Table I. Overall, PCI success rate was 92.5%, while procedural success (PCI success without in hospital adverse event) was 88.6%. GEC was successfully used in 92.7% of patients with no device-dependent severe adverse events; in particular, failures were related to inability to cross the target lesion in 4.5% or to device-related complication in 2.85% of cases (Table).
Conclusions. This large real-world registry on GEC use in complex PCI confirms the GEC as a valid and safe tool to increase backup support and overcome the limits of conventional technique during complex PCI.

Lesion characteristics		Target vessel	
Distal lesion	36.2%	LAD	30.2%
Moderate/heavy calcification	58.6%	RCA	47.7%
Proximal/ostial disease	62.4%	LCx	16.5%
Proximal stent	47.5%	Graft	5.6%
Tortuous vessel	82.38%		
Severe vessel angulation	69.2%		
In-stent restenosis	10.5%	**GEC related complication**	
Chronic total occlusion	7.0%	Pressure dumping	0.96%
Atherectomy	5.4%	Vessel dissection	1.29%
Intravascular imaging	4.7%	Catheter thrombosis	0.6%
Full metal jacket	18.7%	Stent loss or damage	0.6%
Number of stent implanted	1.63±1.03		
Total stent length, mm	51.04 ± 34.7		
Max stent diameter, mm	2.98 ± 1.46		

C27

COMPLETE OR INCOMPLETE REVASCULARIZATION AND INCIDENCE OF HEART FAILURE IN PATIENTS WITH ACUTE CORONARY SYNDROME AND MULTIVESSEL DISEASE. A SUB-ANALYSIS OF THE CORALYS REGISTRY

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Introduction. Protective role of complete revascularization towards development of HF after ACS remains to be elucidated. The main aim of this subanalysis of the CORALYS registry is to evaluate the impact of CR on adverse outcome at follow-up, including heart failure hospitalization in patients with ACS and multivessel coronary artery disease undergoing PCI.
Methods. Consecutive ACS patients with multivessel disease from the CORALYS registry were analyzed. Incidence of first hospitalization for HF or CV death was the primary endpoint, while the single component and all-cause death were the secondary ones. Patients were stratified according to completeness of coronary revascularization.
Results. Out of 14699 patients in the CORALYS registry, 5054 presented with multivessel disease. 1473 (29.2%) underwent CR, while 3581 (70.8%) did not. Over 5 years follow-up, CR was associated with a reduced incidence of the primary endpoint of HF hospitalization or CV death (adjusted HR 0.66, 95% CI 0.51-0.85), first HF hospitalization (adjusted HR 0.67, 95% CI 0.49-0.90) along with all-cause death and CV death alone (adjusted HR 0.74, 95% CI 0.56-0.97 for all-cause death; and adjusted HR 0.56, 95% CI 0.38-0.84 for CV death). The results were consistent also in the propensity-score matching population and in IPTW analysis. The benefit of CR was consistent across ACS presentations (HR 0.59, 95% CI 0.39-0.89 for STEMI and HR 0.71, 95% CI 0.50-0.99 for NSTE-ACS) and in patients with LVEF >40% (HR 0.52; 95% CI 0.37-0.72), while no benefit was observed in patients with LVEF ≤40% (HR 0.77; 95% CI 0.37-1.10, p for interaction 0.04).
Conclusions. In patients with ACS (both STEMI and NSTE-ACS) and multivessel disease, CR reduced the risk of the primary endpoint of first hospitalization for HF and CV death, as well as first HF hospitalization, CV and overall death. When feasible, CR should be performed in all patients with ACS to reduce the incidence of HF and death at follow-up.

C28

IMPACT OF SUCCESSFUL CHRONIC CORONARY TOTAL OCCLUSION RECANALIZATION ON RECURRENCE OF VENTRICULAR ARRHYTHMIAS IN IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR RECIPIENTS FOR ISCHEMIC CARDIOMYOPATHY (VACTO PCI STUDY)

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Introduzione. Le occlusione coronariche croniche totali (CTO) conferiscono un aumentato rischio di aritmie ventricolari maligne nei pazienti con cardiomiopatia dilatativa (CMD) post-ischemica, tuttavia appare controverso l'impatto della rivascolarizzazione delle CTO in questa popolazione. Lo scopo di questo studio è quello di valutare l'impatto della rivascolarizzazione percutanea delle CTO nei paziente con CMD post-ischemica (già portatori di ICD) in termini di eventi aritmici.

Metodi. La coorte di pazienti (n=622) reclutati in questo studio derivano da 3 differenti registri (Fig. 1): VACTO I ovvero registro spagnolo (n = 162) che comprendeva pazienti con CMD-post ischemica portatori di ICD in prevenzione primaria di cui 71 con CTO. VACTO II ovvero registro internazionale (n = 425) che comprendeva paziente con CMD post-ischemica portatori di ICD in prevenzione secondaria di cui 215 con CTO. Tutti i pazienti del VACTO I e II con CTO erano stati trattati con sola terapia medica ottimale (TMO). Pazienti (n = 113) con CMD-post ischemica con CTO e portatori di ICD sottoposti a disostruzione coronarica tra il 2012 ed il 2019 in 3 centri ad alto volume (San Giovanni Bosco di Torino, GVM Care & Research Maria Cecilia Hospital di Cotignola e University Heart Center Freiburg - Bad Krozingen, Germania). L'endpoint primario era rappresentato da appropriata ICD therapy mentre l'endpoint secondario era rappresentato da tutte le cause di morte.

Risultati. Un totale di 622 pazienti (età media di 67 ± 10 anni, frazione di eiezione media di 36 ± 11%) inclusi nell'analisi erano suddivisi in: gruppo CTO-PCI n=113, gruppo CTO-TMO n=286, gruppo no-CTO n=223. I pazienti del gruppo CTO-PCI se confrontati con i pazienti del gruppo CTO-TMO presentavano ad un follow-up di 5 anni una più bassa incidenza di ICD therapy (20.4% vs. 56.4%, IPW-adjusted HR: 0.45, 95% CI 0.29–0.71) ed una mortalità più bassa (8.8% vs. 23%, IPW-adjusted HR: 0.43, 95% CI 0.22–0.85) (Fig. 2). Un simile tasso di eventi si evidenziava invece se si confrontava il gruppo CTO-PCI con il gruppo no-CTO.

Conclusioni. Nella popolazione presa in esame in questo studio i pazienti con CMD-post ischemica portatori di ICD che sono stati sottoposti a disostruzione di CTO hanno avuto un tasso minore di eventi aritmici ed una più bassa mortalità rispetto ai pazienti con CMD-post ischemica portatori di ICD con CTO trattato con terapia medica.

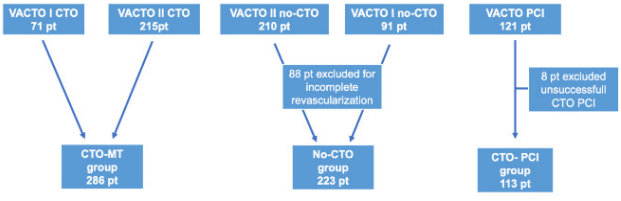

Figura 1

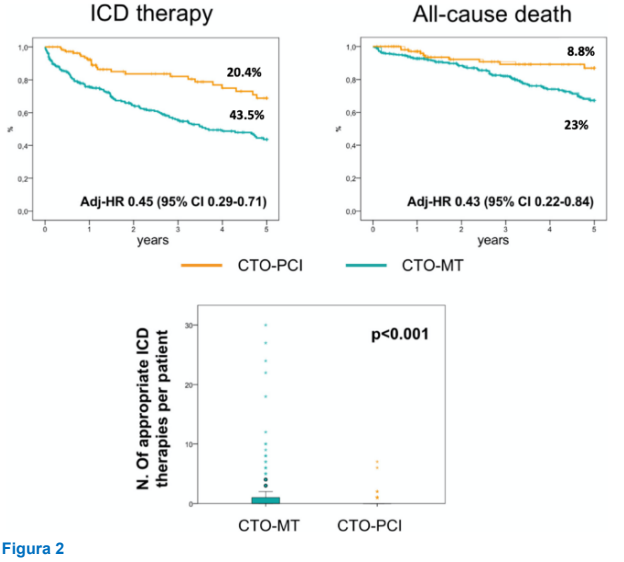

Figura 2

C29

MULTIMODALITY COMPARISON OF TWO-STENT CORONARY BIFURCATION TECHNIQUES IN A BEATING HEART MODEL: THE MOBBEM STUDY (MULTIMODALITY TWO-STENT BIFURCATION TECHNIQUE COMPARISON IN A BEATING HEART MODEL)

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Introduction. The improvement of percutaneous coronary interventions (PCI) on coronary bifurcation lesions is a hot topic of interventional cardiology. Two-stent techniques are preferred in case of complex bifurcation lesions and are practiced according to the individual operator's attitudes. The Visible Heart® Laboratory (VHL) provides an experimental environment where bifurcation stenting techniques might be practiced similarly to clinical activity and evaluated using unique multimodality imaging. The aim of the present study was to compare the results achieved by interventional cardiologists hosted in the VHL using different two-stent bifurcation stenting techniques.

Methods. PCI were performed in the Visible Heart Laboratories by visiting interventional cardiologists using ex vivo cardiac perfusion apparatus. The procedures were two-stent techniques were adopted entered the study. PCIs were conducted using Resolute Onyx drug-eluting stents according to the individual operator's yield. For each PCI, the adopted bifurcation PCI technique was classified according to MADS-2 (for both stent implantation and ballooning sequences). The technical sequences applied were divided into those following or not EBC best practice recommendations. After procedure, hearts were scanned using micro-CT in order to define post-PCI stent configuration (expansion, gaps, side-branch ostial area). Primary end-point of the study was "technical failure" defined as a composite endpoint of stent under-expansion (in the proximal or distal main vessel, side-branch), side-branch ostial area stenosis >50% and gaps between stents.

Results. A total of 82 two-stent bifurcation PCI were enrolled (comprising 28 T/TAP; 25 Culotte; 29 Crush) and micro-CT showed imperfections falling into the technical failure definition in as high as 53.7% of the cases. Procedures with technical failure had similar baseline characteristics (vessel size, stent size, and bifurcation angle). Moreover, the selected bifurcation stenting technique did not significantly influence the occurrence of technical failure. On the opposite, a lower number of proximal optimization technique (POT) (p=0.013), a lower number of kissing balloon inflations (KBI) (p=0.017) and no adherence to EBC best practices (p=0.004) were significantly associated with technical failures.

Conclusions. This study using the unique opportunities offered by VHL shows that different two-stent bifurcation techniques might commonly result in imperfect stent configurations. Higher number of POT/KBI and best practices recommendations might reduce the occurrence of suboptimal stent configurations.

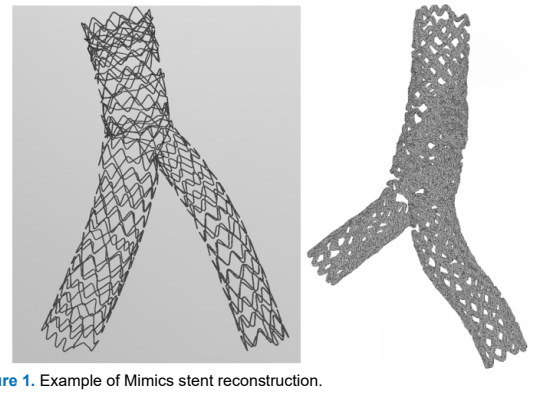

Figure 1. Example of Mimics stent reconstruction.

Miscellaneous

C30

RENAL DENERVATION: A NOVEL THERAPEUTIC OPTION IN THE ACUTE PHASE OF HEMORRHAGIC STROKE

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Introduction. Acute hemorrhagic stroke due to intracerebral hemorrhage (ICH) represents a dramatic event with high mortality rate. Acute hypertensive response is highly prevalent among patients with ICH and the rapid achievement of BP target value in these patients is however challenging and multiple drug therapy is not enough. Renal denervation (RDN) is an ongoing therapeutic option for the treatment of resistant arterial hypertension.

Methods. We designed a single-center all-comers registry including all patients admitted to our stroke unit with ICH and persistently high systolic BP (SPB) (≥150/90 mmHg), despite therapy with ≥4 anti-hypertensive drugs at maximum tolerated dose. The RDN procedure was performed according to a standard protocol with the Symplicity-Spyral device (Medtronic, Ireland). The primary endpoint was the effect of RDN treatment on established BP targets (<150/90 mmHg).

Results. From January 2021 to May 2022, 10 consecutive patients met inclusion criteria and were included in our analysis: 55% were male and most surprisingly young (50.8 ±11.1 years old). Almost all patients were previously already treated for arterial hypertension with a mean 2.22±1.3 anti-hypertensive drugs (AHD)/patient. At hospital admission, mean SBP was 197.7±15.1 mmHg, and mean diastolic BP (DBP) was 104.6±7.6 mmHg. During hospitalization, BP reduction was attempted with 5.0±0.5 AHD and deep sedation, failing to achieve normal values (mean SBP 185.0±11.2 mmHg, mean DBP 94.4±10.1 mmHg), despite a significant drop for DBP in comparison to admission BP (p=0.03). All patients were undergone RDN and ablations were completed 13.3±6 times on the right renal artery and 14.2±6.6 times on the left one. After the intervention, SBP decreased to 126.1±8.2 mmHg, and DBP to 74.6±9.6 mmHg, with a significant drop for both (respectively -71.6 mmHg and -30 mmHg, p<0.001 for both). All subjects were safely discharged, with a mean BP of 131.1±6/75.5±8.1 mmHg, and 2.8±1.1 AHD as home therapy.

Conclusions. Our study represents the first clinical evidence that RDN in the acute phase of ICH may lead to an immediate, significant and persistent BP reduction and possibly improve clinical outcomes.

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A CASE OF CARDIOGENIC SHOCK DUE TO MASSIVE PULMONARY EMBOLISM

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Introduction. Despite the trend in the reduction of mortality, Pulmonary Embolism (PE) represents a relevant medical problem because of its high incidence. Guidelines recommend medical therapy also in case of high-risk PE and consider percutaneous catheter-directed treatments for patients in whom thrombolysis is contraindicated or has failed. We present a case of a 55 years-old man, former smoker, affected by arterial hypertension, who arrived in our Emergency Department with great dyspnea. Electrocardiogram showed sinus tachycardia with right bundle block and laboratory tests high D-dimer level; the echocardiogram revealed right ventricular dilatation, with reduced contractility and severe tricuspid regurgitation; CT pulmonary angiogram showed massive PE.

Methods. Due to the hemodynamic instability, we decided to treat the patient with percutaneous mechanical thrombectomy. We used a Lunderquist Extra-Stiff guide wire (Cookmedical, Bloomington, USA) to advance a 24 F bore catheter in the pulmonary artery. The INARI FlowTriever 2 aspiration catheter (Inarimedical, Basel, SW) captured and removed a thrombus of about 15 cm in length (Figure 1). At the end of the intervention hemodynamic was stable; the patient had relief of symptoms and he started oral anticoagulation therapy with Rivaroxaban. Ten days after the procedure, CT pulmonary angiogram showed complete resolution of PE.

Results. The use of percutaneous catheter-directed treatment for PE allows reduction of thrombotic load responsible for hemodynamic instability exiting in improvement of vital signs and instant relief of symptoms, without complications.

Conclusions and perspectives. Nowadays several percutaneous catheter-directed PE treatments are available; it is necessary for the interventional cardiologist to become familiar with such devices. Many trials are ongoing to demonstrate the safety and efficacy and to change future recommendations in this field.

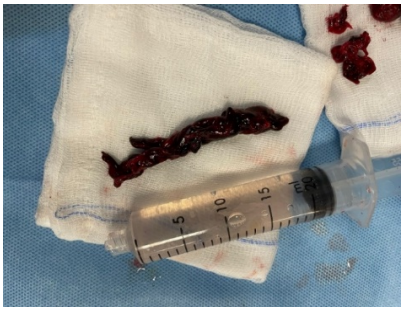

Figure 1. Pulmonary thrombus of about 15 cm in length.

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IMPACT OF ASPIRATION THROMBECTOMY ON LEFT VENTRICULAR REMODELING AND FUNCTION IN PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION: A META-ANALYSIS OF 27 RANDOMIZED CONTROLLED TRIALS

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Objectives. We aimed to perform a meta-analysis of randomized controlled trials (RCTs) to summarize the available data on the impact of aspiration thrombectomy (AT) on various surrogate endpoints assessing ventricular remodeling and function after primary percutaneous coronary intervention (PCI). We also aimed to perform different pre-specified sensitivity analysis to investigate the effect of AT on specific clinical and procedural settings.

Background. The impact of AT on hard clinical end-points in patients with ST-elevation myocardial infarction (STEMI) remains debated. Different soft endpoints, such as imaging parameters of left ventricular (LV) remodeling and function, have been assessed in multiple small RCTs, with conflicting results.

Methods. Available studies were identified through a systematic search of PubMed and CENTRAL. Primary outcome measures were: left ventricular ejection fraction (LVEF), left ventricular end diastolic volume (LVEDV), left ventricular end systolic volume (LVESV) and wall motion score index (WMSI). Sensitivity analysis regarding mean ischemic time, follow-up time and aspiration thrombectomy device type were performed.

Results. A total of 27 studies enrolling 4938 patients were included in the meta-analysis. On pooled analysis, WMSI was the only parameter to be significantly lower in AT group (effect size [ES] -0.38, 95% confidence interval [CI] -0.66 to -0.09). In the subgroup of studies where the mean total ischemic time was higher than 6 hours, a significant beneficial effect of AT was observed for most of primary outcomes: LVEF (ES 0.23, 95% CI 0.05 to 0.40), LVEDV (ES -0.40, 95% CI -0.79 to -0.02) and LVESV (ES -0.37, 95% CI -0.70 to -0.03). Manual AT devices provided improvement in LVEF (ES 0.21, 95% CI 0.07 to 0.35), and a significant reduction in LVESV (ES -0.31, 95% CI -0.62 to -0.01). Meta regression including patients with left anterior descending artery (LAD) involvement showed a significant association of AT use with a reduction in both LVEDV and LVESV (z=-2.33, p=0.02; z=-4.00, p<0.001).

Conclusion. This meta-analysis showed an association of AT use with favorable ventricular remodeling and function. Factors such as mean ischemic time, culprit lesion location and manual AT devices use seem to have an impact on these endpoints. The beneficial effect of AT on ventricular remodeling and function seems to be more pronounced in patients with a delayed time to reperfusion.

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EARLY OUTCOMES OF PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION WITH OR WITHOUT STANDARD MODIFIABLE CARDIOVASCULAR RISK FACTORS

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Introduction. Targeted strategies against the well-recognized standard modifiable cardiovascular risk factors (SMuRFs), such as diabetes mellitus, hypercholesterolaemia, hypertension, and smoking, have led to major improvements in prevention and treatment of coronary artery disease. However, a nonnegligible proportion of patients presenting with acute ST-segment myocardial infarction (STEMI) does not feature any

SMuRF. Some authors have coined the term SMuRF-less to raise awareness on this challenging population and encourage focused research efforts. SMuRF-less patients are often overlooked in clinical trials, which usually report only the proportion of patients with each of the known risk factors. In this study, we sought to compare in-hospital outcomes among patients with and without SMuRFs.

Methods. We included consecutive patients treated for ST-elevation myocardial infarction (STEMI) at Federico II University hospital, Naples. Patients with at least one modifiable risk factors, including current smoker status, hypercholesterolemia, diabetes, or hypertension, were defined as non-SMuRFLess subgroup. Conversely, patients without any of the previously reported risk factors were considered as SMurFLess. The primary outcome of interest was in hospital all-cause mortality and the secondary outcome was major adverse cardiovascular events (MACE), defined as the composite of cardiac death, reinfarction, stroke, heart failure, stent thrombosis, cardiogenic shock, or cardiac arrest at presentation. 94 clinical and procedural variables were compared between the two groups. Categorical variables were reported as frequencies and percentages and numerical variables were reported as mean ± standard deviation.

Results. We included 269 patients. Ten patients (3.7%) met the SMuRFLess criteria, whereas 259 (96.3%) were included in non-SMuRFLess group. Except for modifiable risk factors, there were no differences between groups as it relates to baseline characteristics. Non-SMuRFLess patients had a lower left ventricular ejection fraction (45.2 ± 7.4 vs 50.9 ± 5.6 percentage points; p=0.031) and were more frequently already on treatment with aspirin (0% SMuRFLess vs. 30.6%; p=0.037) and Angiotensin-converting enzyme (ACE) inhibitors/Angiotensin II receptor blockers (ARBs) (0% vs. 39.6% p=0.015). No differences were found in rates of primary (all cause death; 0% vs. 1.5% p=1) and secondary outcomes between the two study groups.

Conclusions. In-hospital outcomes of STEMI patients undergoing primary PCI did not differ between non-SMuRFLess and SMuRFLess groups. Despite limited by the low sample size, our study challenges the current concept supporting a higher risk of adverse events among SMuRFLess patients.

Table 1. Baseline (preadmission) characteristics

	All smurfless groups (n=271)	0 SMURFless (n=10)	1 SMURFless (n=259)	Difference and 95% CI	p-value
Sex	n=269, 58 (21.6%)	n=10, 0 (0.0%)	n=259, 58 (22.4%)	-22.4% (-48.4%; 3.7%)	0,125
Age	n=269, 62.8(11.9%)	n=10, 60.3(11.9%)	n=259, 62.9 (11.9)	-2.6% (-10.2; 4.9%)	0,492
Diabetes	n=267, 60 (22.5%)	n=10, 0 (0.0%)	n=257, 60 (23.3%)	-23.3% (-49.8%; 3.1%)	0,123
Hypertension	n=267, 168 (62.9%)	n=10, 0 (0.0%)	n=257, 168 (65.4%)	-65.4% (-95.1%; -35.6%)	<0.001
Hypercholesterolaemia	n=267, 115 (43.1%)	n=10, 0 (0.0%)	n=257, 115 (44.7%)	-44.7% (-75.8%; -13.7%)	0,006
Current smoker	n=267, 178 (66.7%)	n=10, 0 (0.0%)	n=257, 178 (69.3%)	-69.3% (-98.1%; -40.4%)	<0.001
Weight (kg)	n=261, 78.5(18.4%)	n=10, 82.5(8.1%)	n=251, 78.4 (18.6%)	-4.1% (-6.3; 14.5%)	0,435
History of CAD	n=267, 61 (22.8%)	n=10, 0 (0.0%)	n=257, 61 (23.7%)	-23.7% (-50.3%; 2.9%)	0,123
Prior stroke or TIA	n=267, 13 (4.9%)	n=10, 0 (0.0%)	n=257, 13 (5.1%)	-5.1% (-18.8%; 8.6%)	1
Peripheral artery disease	n=267, 17 (6.4%)	n=10, 0 (0.0%)	n=257, 17 (6.6%)	-6.6% (-22.7%; 8.9%)	1
Congestive HF	n=267, 18 (6.7%)	n=10, 0 (0.0%)	n=257, 18 (7.0%)	-7.0% (-23.0%; 8.9%)	1
COPD	n=267, 34(12.7%)	n=10, 0 (0.0%)	n=257, 34 (13.2%)	-13.2% (-34.4%; 7.9%)	0,371
CKD	n=267, 11 (4.1%)	n=10, 0 (0.0%)	n=257, 11 (4.3%)	-4.3% (-16.9%; 8.4%)	1
History of FA/Flutter	n=267, 6 (2.2%)	n=10, 0 (0.0%)	n=257, 6 (2.3%)	-2.3% (-11.8%; 7.1%)	1
Previous MI	n=267, 32(12.0%)	n=10, 0 (0.0%)	n=257, 32 (12.5%)	-12.5% (-33.1%; 8.2%)	0,614
Previous PCI	n=267, 34(12.7%)	n=10, 0 (0.0%)	n=257, 34 (13.2%)	-13.2% (-34.4%; 7.9%)	0,371
Previous CABG	n=267, 14 (5.2%)	n=10, 0 (0.0%)	n=257, 14 (5.4%)	-5.4% (-19.6%; 8.7%)	1
Active malignancy within past 12 mo	n=267, 14 (5.2%)	n=10, 0 (0.0%)	n=257, 14 (5.4%)	-5.4% (-19.6%; 8.7%)	1
Liver cirrhosis with portal hypertension	n=267, 6 (2.2%)	n=10, 0 (0.0%)	n=257, 6 (2.3%)	-2.3% (-11.8%; 7.1%)	1
Aspirin	n=265, 78 (29.4%)	n=10, 0 (0.0%)	n=255, 78 (30.6%)	-30.6% (-59.4%; -1.8%)	0,037
Any P2Y12	n=265, 19 (7.2%)	n=10, 0 (0.0%)	n=255, 19 (7.5%)	-7.5% (-23.9%; 9.0%)	1
Beta-blocker	n=265, 61 (23.0%)	n=10, 0 (0.0%)	n=255, 61 (23.9%)	-23.9% (-50.6%; 2.7%)	0,123
Statin	n=265, 71 (26.8%)	n=10, 0 (0.0%)	n=255, 71 (27.8%)	-27.8% (-55.9%; 0.2%)	0,067
Other lipid lowering drug	n=265, 9 (3.4%)	n=10, 0 (0.0%)	n=255, 9 (3.5%)	-3.5% (-15.1%; 8.0%)	1
Ca-antagonist (0)	224 (84.5%)	10 (100.0%)	214 (83.9%)	16.1% (-6.9%; 39.0%)	0,369
Ca-antagonist (1)	40 (15.1%)	0 (0.0%)	40 (15.7%)	-15.7% (-38.4%; 7.0%)	0,368
Ivabradine	n=265, 265 (100.0%)	n=10, 10 (100.0%)	n=255, 255 (100.0%)	0.0% (0.0%; 0.0%)	
ACEI/ARB	n=265, 101 (38.1%)	n=10, 0 (0.0%)	n=255, 101 (39.6%)	-39.6% (-70.2%; -9.0%)	0,015
Sacubitril/Valsartan	n=265, 3 (1.1%)	n=10, 0 (0.0%)	n=255, 3 (1.2%)	-1.2% (-7.9%; 5.6%)	1
Nitrates	n=265, 2 (0.8%)	n=10, 0 (0.0%)	n=255, 2 (0.8%)	-0.8% (-6.3%; 4.7%)	1
Diuretics	n=265, 31 (11.7%)	n=10, 0 (0.0%)	n=255, 31 (12.2%)	-12.2% (-32.6%; 8.3%)	0,612
Oral Anticoagulation	n=265, 5 (1.9%)	n=10, 0 (0.0%)	n=255, 5 (2.0%)	-2.0% (-10.6%; 6.7%)	1
Amiodarone	n=265, 2 (0.8%)	n=10, 0 (0.0%)	n=255, 2 (0.8%)	-0.8% (-6.3%; 4.7%)	1
Other antiarrhythmic	n=265, 2 (0.8%)	n=10, 0 (0.0%)	n=255, 2 (0.8%)	-0.8% (-6.3%; 4.7%)	1

TIA, transient ischemic attack; HF, heart failure; COPD, chronic obstructive pulmonary disease; CKD, chronic kidney disease; ACE, angiotensin-converting enzyme; ARB, angiotensin II receptor antagonist blocker; CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; SMuRFs, standard modifiable cardiovascular risk factors.

Table 2. First available laboratory values, patient characteristics on presentation and discharge.

	All smurfless groups (n=271)	0 SMURFless (n=10)	1 SMURFless (n=259)	Difference and 95% CI	p-value
CK-MB (ng/ml)	n=265, 16.0 (3.3; 60.6)	n=10, 26.1 (4.8; 66.5)	n=255, 14.8 (3.2; 60.3)	-9.7 (-70.9; 51.4)	0,443
hsTn	n=266, 1598.0 (155.2; 8698.0)	n=10, 2156.0 (234.5; 16042.5)	n=256, 1557.0 (144.8; 8575.2)	8662.9 (-21798.8; 39124.6)	0,503
Creatinine	n=266, 0.9 (0.8; 1.0)	n=10, 0.9 (0.9; 1.0)	n=256, 0.9 (0.8; 1.0)	-0.1 (-0.6; 0.3)	0,836
Hb	n=267, 13.9 (12.9; 15.0)	n=10, 14.7 (13.4; 15.3)	n=257, 13.9 (12.8; 15.0)	0.6 (-0.5; 1.7)	0,284
Platelets (x10^3/uL)	n=267, 219.0 (189.0; 266.0)	n=10, 198.0 (170.5; 234.8)	n=257, 221.0 (190.0; 266.5)	-33.8 (-77.6; 9.9)	0,066
SBP	n=267, 135.0 (120.0; 150.0)	n=10, 134.0 (130.2; 155.5)	n=257, 135.0 (120.0; 150.0)	3.0 (-12.5; 18.5)	0,734
DBP	n=267, 80.0 (70.0; 89.0)	n=10, 85.5 (77.0; 88.5)	n=257, 80.0 (70.0; 89.5)	5.1 (-4.7; 14.8)	0,295
HR	n=266, 78.0 (69.0; 89.2)	n=10, 80.0 (73.8; 87.2)	n=256, 78.0 (69.0; 89.8)	1.2 (-8.6; 10.9)	0,555
Cardiac arrest at presentation	n=269, 8 (3.0%)	n=10, 0 (0.0%)	n=259, 8 (3.1%)	-3.1% (-13.9%; 7.7%)	1
LVEF baseline	n=250, (45.6; 7.9)	n=8, 48.6 ± 9.3	n=242, (45.5± 7.9)	3.2 (-2.4; 8.7)	0,268
LVEF before discharge	n=192, 45.4; 7.4	n=8, 50.9 ± 5.6	n=184, (45.2±7.4)	5.7 (0.5; 10.9)	0,031
Killip Class	n=269,	n=10,	n=259,		0,344
Killip Class I	90 (33.5%)	5 (50.0%)	85 (32.8%)	17.2% (-12.8%; 47.2%)	0,31
Killip Class II	121 (45.0%)	2 (20.0%)	119 (45.9%)	-25.9% (-57.5%; 5.6%)	0,193
Killip Class III	50 (18.6%)	3 (30.0%)	47 (18.1%)	11.9% (-12.9%; 36.6%)	0,401
Killip Class IV	8 (3.0%)	0 (0.0%)	8 (3.1%)	-3.1% (-13.9%; 7.7%)	1
Peak CK-MB	n=265, 94.8 (30.2; 202.0)	n=10, 92.4 (18.9; 392.0)	n=255, 94.8 (30.5; 199.4)	174.4 (53.7; 295.1)	0,802
Peak HsTn	n=266, 31791.0 (12267.2; 89892.5)	n=10, 33124.5 (12481.5; 89656.5)	n=256, 31791.0 (12181.8; 90645.5)	-17419.8 (-1.5e+05; 119037.7)	0,984
Peak creatinine	n=266, 0.9 (0.9; 1.1)	n=10, 0.9 (0.9; 1.0)	n=256, 0.9 (0.9; 1.1)	-0.1 (-0.6; 0.3)	0,625
Lowest value Hb	n=267, 13.3 (12.0; 14.3)	n=10, 14.3 (12.9; 14.6)	n=257, 13.2 (12.0; 14.2)	0.8 (-0.3; 1.8)	0,107
Lowest value platelet	n=267, 200.0 (175.0; 238.0)	n=10, 186.5(163.0; 199.2)	n=257, 201.0 (175.5; 240.5)	-23.3 (-57.4; 10.9)	0,117
Aspirin	n=268, 265 (98.9%)	n=10, 10 (100.0%)	n=258, 255 (98.8%)	1.2% (-5.5%; 7.9%)	1
P2Y12 inhibitor	n=268, 267 (99.6%)	n=10, 10 (100.0%)	n=258, 257 (99.6%)	0.4% (-3.5%; 4.3%)	1
Beta- blocker	n=268, 261 (97.4%)	n=10, 10 (100.0%)	n=258, 251 (97.3%)	2.7% (-7.4%; 12.9%)	1
Statin	n=268, 265 (98.9%)	n=10 10 (100.0%)	n=258, 255 (98.8%)	1.2% (-5.5%; 7.9%)	1
Other lipid lowering drug	n=268, 34 (12.7%)	n=10, 1 (10.0%)	n=258, 33 (12.8%)	-2.8% (-24.0%; 18.4%)	1
Ca-antagonist	n=268,1 (0.4%)	n=10,0 (0.0%)	n=258, 1 (0.4%)	-0.4% (-4.3%; 3.5%)	1
Ivabradine	n=268, 268(100.0%)	n=10, 10 (100.0%)	n=258, 258 (100.0%)	0.0% (0.0%; 0.0%)	
ACEI/ARBB	n=268, 248 (92.5%)	n=10, 10 (100.0%)	n=258, 238 (92.2%)	7.8% (-9.0%; 24.5%)	1
Sacubitril/Valsartan	n=268, 17 (6.3%)	n=10, 0 (0.0%)	n=258, 17 (6.6%)	-6.6% (-22.1%; 8.9%)	1
Nitrates	n=268, 2 (0.7%)	n=10, 0 (0.0%)	n=258, 2 (0.8%)	-0.8% (-6.3%; 4.7%)	1
Diuretics	n=268, 17(6.3%)	n=10, 0 (0.0%)	n=258, 17 (6.6%)	-6.6% (-22.1%; 8.9%)	1
Oral anticoagulation	n=268, 268 (100.0%)	n=10, 10(100.0%)	n=258, 258 (100.0%)	0.0% (0.0%; 0.0%)	
Amiodarone	n =268, 1 (0.4%)	n=10, 0 (0.0%)	n=258, 1 (0.4%)	-0.4% (-4.3%; 3.5%)	1

SBP, systolic blood pressure; DBP, diastolic blood pressure; HR, heart rate; LVEF, left ventricular ejection fraction; ACE, angiotensin-converting enzyme; ARB, angiotensin II receptor antagonist blocker, SMuRFs, standard modifiable cardiovascular risk factors (hypertension, diabetes mellitus, hypercholesterolemia, and smoking).

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TREND TEMPORALE NEL MANAGEMENT FARMACO-INTERVENTISTICO DEI PAZIENTI CON SINDROME CORONARICA ACUTA: DATI DAL REGISTRO MULTICENTRICO START-ANTIPLATELET

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Introduzione. Negli ultimi anni, l'epidemiologia ed il trattamento farmaco-interventistico dei pazienti con sindrome coronarica acuta (SCA) si sono sostanzialmente modificati. Il registro italiano multicentrico START-ANTIPLATELET ha arruolato, dal 2014 ad oggi, oltre 2700 pazienti con SCA. L'obiettivo del nostro studio è quello di descrivere i cambiamenti nelle caratteristiche cliniche e nel management (in termini di prescrizione di farmaci e rivascolarizzazione) nella popolazione italiana con SCA.

Metodi. Il registro START-ANTIPLATELET è un registro multicentrico, prospettico, osservazionale. Nella presente sotto-analisi, i pazienti sono stati suddivisi in 4 gruppi in base all'anno di arruolamento: 2014-15, 2016-17, 2018-19 e 2020-21. Abbiamo confrontato le caratteristiche cliniche e le strategie di trattamento farmaco-invasive al fine di descrivere l'evoluzione negli ultimi anni dell'epidemiologia e della gestione terapeutica dei pazienti "real-world" con SCA.

Risultati. Il registro START-ANTIPLATELET ha incluso 2707 pazienti con SCA. La presentazione clinica si è modificata negli anni, con un aumento della percentuale di STEMI (48% nel 2014-15 e 2016-17; 56% nel 2018-19; 51% nel 2020-21). Nel tempo, abbiamo osservato un aumento della prevalenza di ipercolesterolemia (51% nel 2014-15; 63% nel 2020-21), una riduzione dell'abitudine al fumo (46% nel 2014-15; 52% nel 2016-17; 47% nel 2018-19; 44% nel 2020-21), mentre non si è modificata la prevalenza di ipertensione arteriosa sistemica e diabete mellito. Dal 2014 al 2021, l'utilizzo di rivascolarizzazione percutanea è aumentato progressivamente (81% nel 2014-15; 84% nel 2016-17; 88% nel 2018-19; 90% nel 2020-21), così come l'uso di stent coronarici, soprattutto medicati (72% nel 2014-15; 76% nel 2016-17; 84% nel 2018-19; 86% nel 2020-21). L'utilizzo di aspirina è rimasto stabilmente elevato nel tempo (>97% durante tutto il periodo di arruolamento). Abbiamo osservato una riduzione significativa della prescrizione di clopidogrel (34% nel 2014-15; 32% nel 2016-17; 19% nel 2018-19; 20% nel 2020-21; P<0.001) e prasugrel (14% nel 2014-15; 11% nel 2016-17; 5% nel 2018-19; 2% nel 2020-21; P<0.001) a favore di un aumento significativo dell'utilizzo di ticagrelor (44% nel 2014-15; 48% nel 2016-17; 72% nel 2018-19; 76% nel 2020-21; P<0.001).

Conclusioni. Nel registro START-ANTIPLATELET, dal 2014 al 2021, abbiamo osservato un aumento nell'uso delle strategie di trattamento raccomandate dalle linee guida, con un più alto utilizzo di strategie di rivascolarizzazione percutanea con stent medicati ed un significativo aumento della prescrizione di nuovi inibitori del $P2Y_{12}$. Ulteriori studi sono necessari per valutare se queste modifiche terapeutiche abbiano inciso sull'outcome dei pazienti con SCA.

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IMPACT OF SECONDARY PREVENTION MEDICAL THERAPIES ON OUTCOMES OF PATIENTS SUFFERING FROM MYOCARDIAL INFARCTION WITH NONOBSTRUCTIVE CORONARY ARTERY DISEASE: A META-ANALYSIS

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Introduction. The aim of this meta-analysis is to assess the impact of secondary prevention medical therapies (statins, ACE-inhibitors/angiotensin receptor blockers [ARB], beta-blockers [BB] and dual antiplatelet therapy [DAPT]) on outcomes of patients with myocardial infarction with nonobstructive coronary artery disease (MINOCA).

Methods. Five adjusted observational studies encompassing 10546 were included in this meta-analysis. All-cause death was the primary endpoint, while major adverse cardiovascular events (MACE) and acute myocardial infarction (AMI) were the secondary endpoints.

Results. After 24 months of follow up, statins (tested in 8093 patients) were associated with a reduced risk of all-cause death (HR 0.60:0.45-0.81, p<0,001), while ACE-inhibitors/ARB (on 9666 patients) were not. Aggregate data from two studies (n=9720, 7719 on BB, 6423 on DAPT) indicated that BB and DAPT (median follow-up 34.1 and 15.7 months, respectively) were both associated with a significant reduction of all-cause death (HR 0.81, 0.66-0.99, p=0.04, and HR 0.73, 0.55-0.98, p=0.03, for beta-blockers and DAPT, respectively). Among the investigated therapies, only ACE-inhibitors/ARBs entailed a reduced risk of MACE (HR 0.65, 0.44-0.94, p=0.02, all CI 95%) over 36.5 months (four studies, n=10150). None of the investigated therapies was associated with a reduced risk of AMI.

Conclusions. Data from adjusted observational studies suggest that BB, statins and DAPT are associated with a survival benefit among MINOCA patients. ACE-inhibitors/ARB entail a reduced risk of MACE while none of the investigated secondary prevention therapies is associated with a reduced risk of AMI. Randomized controlled trials are warranted to confirm these findings.